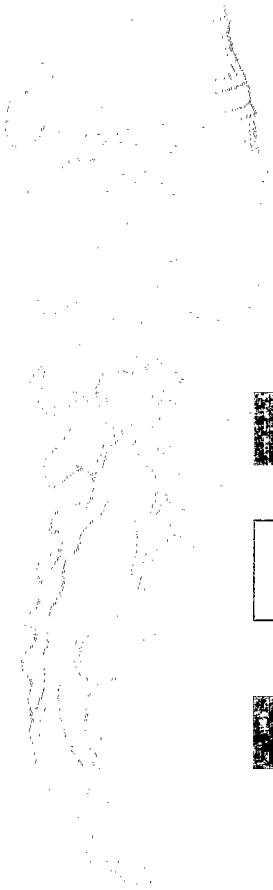
WHO/NCD/NCM/CRA/99.1
DISTR: GENERAL
ORIGINAL: ENGLISH

The World Health Organization

Department of
Noncommunicable Disease Management

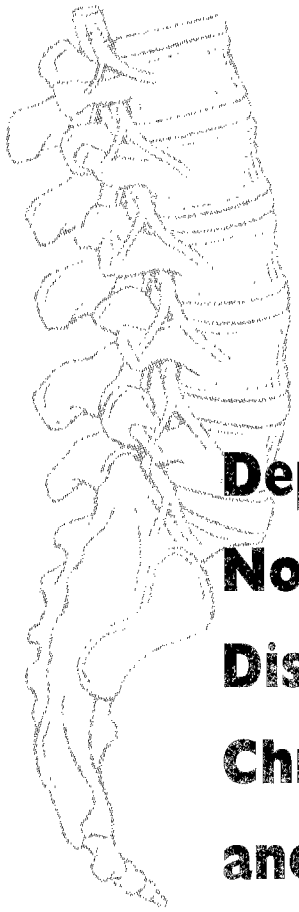
Low Back Pain Initiative



LOW BACK PAIN INITIATIVE

Editors:
Professor George E. Ehrlich
Professor N.G. Khaltaev

Department of Noncommunicable Disease Management
The World Health Organization



Department of Noncommunicable Disease Management Chronic Rheumatic Diseases and Asthma

TABLE OF CONTENTS

PREFACE

Professor N. G. Khaltaev
Responsible Officer
Chronic Rheumatic Diseases and Asthma
Department of Noncommunicable Diseases Management
World Health Organization, Geneva, Switzerland

Low Back Pain (LBP) with or without sciatica, has reached epidemic proportions being reported by about 80% of people at some time in their life. Seventy-five percent of these people with LBP are between 30 and 59 years of age, i.e. during their most productive years.

LBP is a symptom and not a diagnosis. Only a small proportion of patients suffer from identifiable organic diseases, such as disc herniation, spondylolisthesis, instability defined by flexion-extension X-ray, osteoporosis, fracture, tumour, infection, or rheumatic diseases (e.g. ankylosing spondylitis).

In several community-based studies in different countries, of the 50% of patients still unable to work one week after the onset of symptoms, only 2% had such valid organic diagnoses; while after six weeks, when 12% were still unable to work, only 15% had a definite diagnosis. Finally, after three months, when 5% of the patients were still not working, an anatomically definable diagnosis could be found in only 30%.

These findings indicate that the cause of back pain in most patients is unknown. It has been clearly demonstrated in many studies that X-ray examination does not reveal a cause. For example, degeneration of a single disc is found more often in people without pain than in people with pain.

In view of the above, the growing trend for more people to take more time off work because of back problems, and an increase in permanent disability caused by LBP, the World Health Organization has addressed the problem through the Low Back Pain Initiative, the first results of which are presented in this book.

The book summarises the extensive discussions in the general areas of LBP and in particular, development of outcome measures to allow comparability between different studies and which may be applied in different countries and cultures. It contains an introduction, seven chapters, and recommendations and conclusions.

The book also contains four appendices reflecting practical experience with application of WHO outcome measures in different countries, an introduction and explanation of chiropractic science and theory, and basic questionnaires which have been translated from English into various languages whose accuracy has been checked by back translation.

This book is the result of the collaborative efforts of medical professionals and doctors of chiropractic from different countries, which have been united by the World Health Organization in its endeavour to improve the quality of life of patients with LBP.

1. INTRODUCTION

Professor George E. Ehrlich
(Adjunct Professor of Medicine (Rheumatology), University of Pennsylvania;
Professor of Clinical Medicine, New York University)

Four WHO informal consultations on low back pain between 1993 and 1997 brought together a core group of experts[1] and a variable number of advisers[2] to address what has generally been identified as a – if not the – major cause of disability and absenteeism from the workplace, both in industrialized and in emerging nations. Despite a voluminous medical literature addressing different aspects of the problem – prevalence, causation, and treatment – few of the published studies reviewed were sound enough to invite comparison or meta-analysis. The same quandary was experienced by a task force constituted by the Agency for Health Care Policy and Research of the United States Department of Health and Human Services[3] , whose deliberations, aided by a large supporting staff, screened more than 10, 000 abstracts, concentrated on almost 4, 000 deemed useful, added additional information provided by panel members and consultants, and concluded that there was still a dearth of useful information about how best to approach the problem. And that held for acute back pain, which, in the vast majority of cases, is self-limited, rarely lasting more than 12 weeks. Subacute and chronic low back pain were only peripherally approached by this panel.

The WHO initiative also concerned itself with acute back pain, but labelled pain longer than 4 weeks in duration but shorter than 12 weeks as subacute for purposes of assessment for treatment. Both panels eschewed an analysis of back pain whose cause was known: trauma, infections, tumours, spondyloarthritis, metabolic abnormalities, osteoporosis, and congenital malformations were excluded, as their assessment and especially their treatment followed other paradigms. But even excluding these specific causes left the majority of low back pains to consider. Estimates suggest that nearly everyone will experience some non-specific back pain sometime during life, and in the United States, annual prevalence is between 15 and 20%, with 50% of the working age population experiencing it at least once a year! And the incidence and prevalence is not lower in pre-industrialized and developing nations, despite the prior lack of data, as recent COPCORD studies, performed in collaboration with WHO, have documented.

The WHO Low Back Pain Initiative obviously can not – and does not want to – duplicate the extensive work already done or in progress. The small group of experts and the limited resources alone countermand that, and the project would have been redundant. Rather, the Initiative took as its

---

[1] G.E. Ehrlich, USA, Chairman: M. Alattar, USA; W. H. Chahade, Brazil; J. Darmawan, Indonesia; M. Homma, Japan; M.I.V. Jayson, UK; V. Nassonova, Russian Federation; R. Arinoviche, Chile, ex-officio (ILAR); N. G. Khaltaev, WHO Division of Noncommunicable Diseases, Geneva, Switzerland.

[2] G. Auerbach, USA; Tran Ngoc An, Viet Nam; P. Brooks, Australia; A. Burdeiny, Russian Federation; RA Deyo, USA; NM Hadler, USA; Doan Minh Chau, Viet Nam; J. H. Gillies, Canada; J.-P. Giroud, France; C. H. Nachemson, Sweden; M. Reidenberg, USA; P. Tugwell, Canada; S. Van der Linden, The Netherlands; K. Verapeen, Malaysia; N. K. Williams, USA; S. E. Williams, USA.

[3] Bigos S, Bowyer O, Braen G. et al. Acute Low Back Problems in Adults. Clinical Practice Guideline No. 14. AHCPR Publication No. 95-0642. Rockville MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services. December 1994.

mission identification of core outcome measures that, if included in studies of any type of intervention, would permit reasonable comparisons of the efficacy and efficiency of different approaches. If validated, such measures would be able to assess the relative merits of commonly used medical treatments, such as drugs, physiotherapy, and a variety of other therapies. If studies contained these core elements, regardless of what else they measured, they could help define meritorious and cost-effective interventions.

To that end, a small number of outcome measures are needed, as too large a list would again impede appropriate comparisons. Moreover, they needed to be validated as reliable comparators, even if each had already been validated for itself. We recognize that no list will necessarily be permanent, engraved in stone, so to speak, but the current list reflects the state of the art in this last decade of the twentieth century. Also, the members of the panel were encouraged to incorporate these measures in studies they intended to do or that they encouraged colleagues to do. These would not require WHO to fund them, but would demonstrate, nevertheless, the applicability of the measures and the treatments they judged. These measures are not meant to limit the studies; they are proposed as core outcome measures that can – and should – by supplemented as appropriate in tests of various interventions. But if the core measures were to be included in all future studies, valid comparisons would be possible. Several such studies were undertaken by members of the Initiative or their colleagues, with data sent to the statistical monitor (initially the late Dr J. Grostic, succeeded upon his untimely death by Dr B. Pfleger). These included centers in Atlanta, GA, USA (Pfleger, McDuffie, Wilson); Bombay, India (Pispati, Darmawan); Cairo, Egypt (Handly, Awad, Etibi, Elsangak); Indonesia (Briliantono, Darmawan); Manila, Philippines (Navarra, Darmawan); Moscow, Russia (Nassonova); Santiago, Chile (Arinoviche); Sao Paulo, Brazil (Chahade); and Tokyo, Japan (Homma). The analyses addressed the core measures and the applicability of the (translated) instruments.

Fortuitously for the Initiative, some major studies began during the five years of the Panel's intermittent meetings, independent of but cognisant of the Initiative. An example is the Interregio study in southern Germany, northern Switzerland, and the Alsace in France; three different countries, three medical systems, three systems of reimbursement, all incorporating the outcome measures recommended by the Initiative's panel. This particular study also addressed the sources of payment, the contributions required of the patients, and some differences in approaching the problem[4]. A similar project was a comparison of chiropractic with standard medical care, in which physicians not involved in the treatments monitored outcomes, while patients were randomized to adjustment, medication or sham medication, sham adjustment. Studies of acupuncture, yoga[5] , herbal (south Asian) medicines and, other widely used interventions are still pending.

The members of the Low Back Pain Initiative devoted most of their deliberations to applying Occam's razor to the vexing problem of studying outcomes of interventions for low back pain. The outcome measures ultimately agreed to are, in addition to the obvious ones of history and physical examination to establish that non-specific back pain is indeed the malady and not the result of the enumerated identifiable organic causes, measurement of the degree of pain on a visual analogue pain scale, the Oswestry disability questionnaire, a modified Zung questionnaire, modified somatic perception questionnaire, and the modified Schober test of spinal mobility. Many other measures were proposed,

[4] Die Interregio-Studie. Hochrhein-Institut für Rehabilitation, Bad Säckingen, Germany, 1998.

[5] Controlled studies are currently underway at the University of Pennsylvania. Conducted by M. Garfinkel and R. Schumacher

but the afore-mentioned survived the discussions. Others recommended, in addition when appropriate, were the Waddell indices: chronic disability and physical impairment. A present pain index and pain drawing were recommended as useful by some of the participants. The accepted measures will be defined and addressed in subsequent chapters. As some of these require understanding by the patients, translation into a variety of languages, where not already at hand, was needed, and then back translation to determine if the same phenomenon was being assessed. Moreover, statistical analysis and support were needed, provided for much of the study by the statistical centre at Life College (Now University), a major chiropractic educational institution, Marietta, Georgia, in the USA. The Department of Noncommunicable Diseases Management at The World Health Organization in Geneva, Switzerland served as headquarters and compiled the contributions and guided the process.

Most of the recommended measures are not intended for use by practitioners treating sufferers, but will provide guidance to studies of what will likely bring about favourable outcomes. The problem is adumbrated in Professor Jayson's remarks, which posit a work in progress, recognizing that medicine itself continually undergoes change. The pharmacological and chiropractic interventions were put to the test in studies by members of the Initiative or co-opted colleagues. The results to date are reported in this publication. On the other hand, comments about physical therapy, spas, and psychosocial aspects were solicited, the latter two from noted advocates who were not members of the steering committee. The summaries to follow reflect the current thinking of the panel and its consultants. This is not the final work. Voluminous compendia on the subject are appearing. The final answers are not at hand. Much remains mysterious about "nonspecific" low back pain. But this technological booklet hopes to shed some light on this vexatious issue, to discourage over-treatment or hasty resort to a beleaguered compensation system, and to shift the emphasis to chronic back pain, whose causes and prolongation remain even more elusive.

Much of nonspecific low back pain bears resemblance to – and probably contains – fibromyalgia, currently discredited as a disease, though the amalgam of symptoms probably reflects a hypersensitive and over-dramatized response, encouraged by a beguiled compensation system in industrialized societies. Low back pain, on the other hand, has more validity as an entity, although the myriad causes likewise remain elusive. Popular understanding accepts this role for low back pain. In the vernacular, "oh, my aching back" is a common American response to unwanted job demands, as "pain in the neck" or other regions designates the source of these demands.

The purpose of this interim publication is to promulgate awareness of the world-wide nature of this affliction and its considerable cost to national economies and human suffering, and to motivate assessments and responsible reactions to these problems. With the cost of health care rising everywhere, it behoves us to understand a syndrome that has major economic and social consequences and to address its cost realistically by emphasizing what works and what doesn't and how best to husband ever scarcer resources in dealing with the challenge.

2. OUTCOME MEASURES FOR BACK PAIN: INTRODUCTION, JUSTIFICATION AND EPIDEMIOLOGY

Professor Malcolm I.V. Jayson
(Professor of Rheumatology, University of Manchester)

INTRODUCTION AND EPIDEMIOLOGY

Back pain is a major clinical and public health problem. It is the most common cause of disability among younger adults (Kelsey et al, 1992). In the United Kingdom it is estimated that over 100 million working days are lost per year because of back problems (Clinical Standards Advisory Group, 1994). Moreover the prevalence of back disability is increasing rapidly. Similar high prevalence and increases in the problem have been observed in other countries. For example, in Sweden with a total population of 4.5 million people the numbers of days of work loss related to back pain increased from 7 million in 1980 to 28 million in 1987 (Nachemson, 1992).

Our own studies (Papageorgiou et al, 1995) were performed in Manchester on a population of 4, 501 people. We found the prevalence of back pain experienced in the previous month was between 35 and 37 per cent with the peak prevalence in those between 49 and 59 years of age.

Although detailed epidemiological studies have not been performed in less developed countries it is clear that the prevalence of back problems is high and likely to provide similar figures. However the resulting disability may well reflect the local working environments and social and occupational support factors which cannot be elucidated without careful analysis.

The costs of back problems are huge. In part they are due to the direct costs of medical care but in addition many disabled workers receive disability benefits. A major element is the loss of production. These various factors will reflect the economies of different countries. The best estimates of the costs of back pain are over $ 25-85 billion per annum in the United States (Frymoyer, 1996) and over £ 6 billion per annum in the United Kingdom (Clinical Standards Advisory Group, 1994).

Epidemiological studies show little difference in prevalence of back problems between the sexes and if anything the one month prevalence and the lifetime prevalence are slightly greater in females than in males (Papageorgiou et al, 1995). There may however be a slightly greater amount of time off work in men than in women (Walsh et al, 1992). This probably relates to the heavier work tasks undertaken by males so they have greater difficulty in continuing in work. There is an increased risk of back pain associated with lower social class. Walsh, et al (1992) found that the one year prevalence of back pain increased in men from 23 to 42 per cent and the lifetime prevalence from 51 to 65 per cent between social classes I – II and IV – V. In a Dutch population (Valkenburg et al, 1982) found increased figures performing skilled work. Our own survey (McFarlane et al, 1997) found increased prevalence in those working with heavy weights or spending lengthy periods standing or walking. It is difficult from these analyses to determine whether the work caused the development of back pain or simply that the subject was unable to perform the job because of an underlying back problem.

Perhaps the most important risk factor the development of back pain is a previous history of pain problems. In an extensive study (Papageorgiou et al, 1996) we found that a previous history of back pain and in particular having seen one's doctor because of back pain greatly increased the risk of developing back problems in the future. Moreover the presence of neck pain or other musculoskeletal pain also acted as an important risk factor.

We increasingly recognize the prevalence of psychological distress. In the Boeing factory in North America (Bigos et al, 1991) dissatisfaction with work was a major predictor of later presentation to the medical services with low back pain. In our study (Croft et al, 1996) of 1,638 subjects who were free of low back pain at baseline the likelihood of developing a new episode of back pain was significantly higher in those who were distressed. Psychological tests have been used as a predictor of outcome of surgery for back problems (Wiltse and Rocchio, 1975).

Finally we have also found that the risk of low back pain was increased with marriage and with increasing numbers of children (Silman et al, 1995). Surprisingly this increase was similar or if anything greater in males than females. It therefore appears that the association of back pain is not with the actual pregnancy or any procedures associated with it but rather to child rearing and perhaps due to increased lifting or carrying or increased psychological stresses.

UTILIZATION OF HEALTH CARE SERVICES

The patterns of delivery of health care differ enormously throughout the world. In Britain there is a complete network of Primary Care Physicians. These general practitioners see and treat the vast majority of back pain patients. In a survey of two large Primary Care Practices (Croft PR et al, 1994) we found that 6.4 per cent of all adults consulted at least once about back pain in a twelve-month period. In the USA (National Center for Health Statistics, 1977) 14.3 per cent of new patients visits to physicians were because of low back symptoms. Clearly back pain makes an enormous demand on medical resources.

The treatments provided vary enormously amongst these countries. They include medication, ergonomic advice, the prescription of rest, deep heat, local cream and sprays and exercises. Notable however is the huge variation in the prevalence of spine surgery. There is a 10 to 15 fold difference between different countries (Deyo et al, 1992) and even within relatively small geographic areas (Volinn et al, 1983). Deyo's study showed that the greatest predictor of the risks of spine surgery was the number of spine surgeons in the population.

In less developed countries access to specialist surgeons is limited and good data are not available. Many back sufferers do not receive medical or physiotherapy advice.

THE IMPORTANCE OF OUTCOME MEASURES

It is clear that throughout the world back problems are major causes of morbidity. They cause enormous human suffering. The costs to society of medical care, benefits and loss of production can threaten the economies of many countries.

The World Health Organization is planning a global strategy of prevention and control of non-communicable disease including back problems. In the context standardized methods of assessment of the problem and using these methods to evaluate different treatment programmes appear paramount.

In order to make meaningful comparisons between the different countries, realistic measures which can be used on a universal basis must be developed. With this in mind back care experts from around the world met to discuss the problem and to agree a way forward. We hope to develop parameters for quantifying the severity of back pain and back disability; which will be applicable in different countries and different societies. We plan comparisons of the prevalence and severities of the back problem and the effects of treatment.

METHODS OF MEASURING OUTCOME

Most clinical outcome measures are based on quantification of hard data. For example evaluation of tuberculosis may be determined from microbiological data or x-rays, cardiac diseases may be related to ECG (electrocardiogram) changes or mortality rate.

Back pain is a symptom not a diagnosis. The symptoms of back pain and the resultant disability bear only a poor relation to objective data such as the imaging evidence of degenerative disease of the spine. Much thought has been given in trying to identify meaningful outcome measures. They broadly may be classified into several different types.

- Pain questionnaires such as the McGill Pain Questionnaire and the Million Back Pain Score (Million et al, 1982).

- Measurements of function questionnaires such as the Sickness Impact Profile and the Oswestry Disability Questionnaire.

- Psychosocial assessments such as the Distress Risk Assessment Method (DRAM) (Main et al, 1992) measure the psychosocial consequences such as depression, coping behaviours, illness behaviour and fear avoidance.

- Composite measures which are instruments designed to incorporate a cross section of all these aspects of the back pain problem.

- Quality of Life Assessment (Patrick et al, 1995).

Extensive experience has been obtained with these instruments in North America and Western Europe. However the applicability to other countries remains in doubt. Much has yet to be done to establish these methodologies on a universal basis. For example pain may not be the symptom of greatest concern to the patient. Sometimes the pain is replaced by numbness, weakness or paraesthesiae. Dysfunction may not reflect the severity of pain symptoms. The ability to work is likely to reflect the social and environmental support available for disabled people.

There is a conflict between the need to simplify questionnaires and the need to embrace all the clinical information. Many questionnaires are too long and complicated and sometimes difficult for patients to understand. They may not be relevant in less developed societies. The context of any study is also an essential component of outcome assessments. A minor degree of disability not of real significance for an elderly person may yet become a major problem for a young athlete. The requirement for heavy manual labour has decreased considerably in many Western societies so that the impact of a back problem will differ. The degrees of social and family support will also affect outcome and are relevant to the problem.

In developing these outcome measures the following issues must be considered:

- Ensure that the assessments are relevant to the patient problems.

- Reliable so similar scores will be obtained when the measurements are repeated by the same and different observers.

Valid which means the appropriateness, meaningfulness and usefulness of conclusions drawn from the scores. These include construct-related validity which determines whether the measure is an accurate indicator of the underlying variable of interest; content-related validity which demonstrates the degree to which any measures are representative of the problem; criterion-related validity which demonstrates which measures are systematically related to other independent outcome measures.

Conclusion

With this background the World Health Organization is seeking to develop outcome measures which may be universally applied. Preliminary experience of co-operation between different centres has been obtained with preliminary trials of the use of certain measures in different countries. These have served to indicate the way forward in the future and highlight the importance of applying universal assessments between different countries with different forms of health service and different cultural, social and economic backgrounds. It is clear that this work will be essential in developing back pain strategies on a global scale.

REFERENCES:

Bigos SJ, Battie MC, Spengler DM et al. A prospective study of work perceptions and psychosocial factors affecting the reporting of back injury. Spine, 1991, 16:1-6.

Clinical Standards Advisory Group, 1994. Epidemiology Review: The epidemiology and cost of back pain. HMSO, London.

Croft PR, Joseph F, Cosgrove S, Jordon L, Papageorgiou A, Pope A, Ferry S, Jayson MIV, Silman AJ. Back Pain in the Community and in Hospitals. A report to the Clinical Standards Advisory Group, Department of Health, 1994.

Croft PR, Papageorgiou AC, Ferry S, Thomas E, Jayson MIV, Silman AJ. Psychological distress and low back pain. Spine, 1996, 24, 2731-2737.

Deyo RA, Cherkin DC, Loeser JD et al. Morbidity and mortality in associations with operations on upper spine: the influence of age, diagnosis and procedure. Journal of Bone and Joint Surgery, 1992, 74 A:536-543.

Frymoyer JW. Magnitude of the problem. In the lumbar spine. Edtd Wiesel SW, Weinstein JN, Herkowitz H, Dvorak J, Bell GR. Saunders, Philadelphia, 1996, 8-16.

Kelsy JL, Mundt DJ, Golden AL. Epidemiology of Low Back Pain. In: Jayson MIV Ed. The Lumbar Spine and Back Pain – 4th Edition, Edinburgh: Churchill Livingstone, 1992, 537-549.

Main CJ, Wood PLR, Hollis S, Spanswick CC & Waddell G. The Distress Risk Assessment Method. Spine, 1992, 17:42-52.

MacFarlane GJ, Thomas E, Papageorgiou A, Croft PR, Jayson MIV, and Silman AJ. Employment and physical work activities as predictors of future low back pain. Spine, 1997, 22:1143-1149.

Million R, Hall W, Haavik Nilsen K, Baker RD, Jayson MIV. Assessment of the progress of the back pain patient. Spine, 1982, 7:204-212.

Nachemson A. Latest knowledge of low back pain: a critical look. Clinical orthopaedics and Related Research, 1992, 279:8-20.

National Center for Health Statistics: Prevalence of selected impairment. United States – 1977. Hyattsville DHHS publication (PHS) series 10, no. 134, 1981.

Papageorgiou A, Croft PR, Ferry S, Jayson MIV, and Silman AJ. Spine, 1995, 20:1889-1894.

Papageorgiou A, Croft PR, Thomas E, Ferry S, Jayson MIV, Silman AJ. Influence of previous pain experience on the episode incidence of low back pain: Results from the South Manchester Back Pain Study. Pain, 1996, 66:181-185.

Patrick DL, Deyo RA, Atlas SJ, Singer DE, Chapin A and Keller RB. Assessing health related quality of life in patients with sciatica. Spine, 1995, 20:1899-1909.

Silman AJ, Ferry S, Papageorgiou A, Jayson MIV, Croft PR. Number of children as a risk factor for low back pain in men and women. Arthritis and Rheumatism, 1995, 38:1232-1235.

Valkenburg HA and Haanen HCM (1982). The epidemiology of low back pain. In Symposium on Idiopathic Low Back Pain. Edtd. White AA, Gordon SL, Mosby, St. Louis, 9-22.

Volinn E, Mayer J, Diehr P and Koevering DV. Small area analysis of surgery for low back pain. Spine, 1983, 8:121-140.

Walsh A et al. Low Back Pain in 8 Areas of Britain. Journal of Epidemiology and Community Health, 1992, 46:227-230.

Wiltse LL, Rocchio PD. Preoperative psychological tests as predictions of success of chemonucleolysis in the treatment of the low back syndrome. Journal of Bone and Joint Surgery, 1975, 57A:478-483.

3. IMPLEMENTATION OF OUTCOME MEASURES IN A MULTI-SITE STUDY OF LOW BACK PAIN

Professor Bruce Pfleger; Professor Kathryn Hoiriis; Susan Brown, Ph.D., D.C.;
Omar Elsangak, M.B.B.Ch.
(Life University, Marietta, Georgia, USA)

PROTOCOL DEVELOPMENT

In November, 1993, a group of renowned healthcare professionals from around the world (The WHO Low Back Pain Initiative) met on the campus of Life University to discuss low back pain and its management. One of the principal decisions made was to promote clinical research in the area utilizing a number of diverse interventions. Further meetings took place in Manchester, England; Kuala Lumpur, Malaysia; Amsterdam, The Netherlands; and Melbourne, Australia. These meetings helped to specify aspects of the methodology to be employed. Essential elements of the research design include selection of outcome measures and defining a specific patient population.

Based on the recommendations of the WHO initiative on low back pain management, the following outcome measures were used:

- **Oswestry Disability Index** - This index is formed from answers to a 10-question survey called the Oswestry Low Back Pain Disability Questionnaire (Fairbanks et al, 1980). The test is self-administered and takes less than five minutes to fill out. The index shows the extent to which an individual's functional level is restricted by back or leg pain. Studies show that the survey is reliable and valid (Fairbanks et al, 1980; Baker et al, 1989; Stratford et al, 1994). The index is calculated by dividing five times the number of questions answered into the sum of the weighted, answered scores.

- **Modified Zung Index** - This index is formed from a survey originally called The Self-Rating Depression Scale, since modified (Main and Waddell, 1984). The test is self-administered and takes 10-15 minutes to fill out. The purpose of the instrument is to assess the severity of current depression in patients. Low back pain (LBP) often causes psychological distress, and relief from pain can result in improvement. The survey has been demonstrated to have good reliability (Toner et al, 1988; Tanaka-Matsumi and Kameoka, 1986; Jegede 1976, Yesavage et al, 1983; McKegney et al, 1988) and the validity has been extensively studied (Hedlund and Vieweg, 1979; Lambert et al, 1986). The index is formed from the sum of weighted answers to 23 questions.

- **Schober's Test** - Back flexibility is measured by marking two locations in relation to the second sacral tubercle (S2) with the patient standing erect: 0.5 cm below S2 and 10 cm above S2. The patient is asked to flex forward as far as comfortable. Change in the distance between the two points is observed and recorded (Dequeker et al, 1997). The Modified Schober's Test is measured using a similar procedure, except that a 15 cm distance is used instead of 10 cm.

- **Visual Analog Scale for Pain** - This scale provides a method to record the pain level reported by the patient. Written and verbal instructions are to place a cross on the line to indicate the intensity of present pain. The distance from the cross to the left end of the 10 cm line is used as the outcome measure. The left anchor is labeled "No Pain" and the right anchor is labeled "Worst Pain ." Visual Analog Scales for pain have been shown to be reliable (Scott and Huskisson, 1979; Ferraz et al, 1990) and valid (McCormack et al, 1988).

In order to determine if these four written instruments could be effective in other countries, original versions were compared to those that were translated into another language and then back-translated into English. Original versions compared well to back-translated versions. This battery of tests was used in a pilot study that suggested that the chosen instruments were reliable.

CROSS-SITE IMPLEMENTATION OF OUTCOME MEASURES

The core outcome measures were implemented at six sites world-wide on patients complaining of low back pain. Information about these sites is listed in Table 1. Some of the sites involved in this initiative administered the core instruments only one time upon entry into the clinical study. For these sites, analysis was limited to assessing the suitability of each instrument, as translated into the native language. Data from sites that utilized the instruments before and after the intervention could be analyzed to determine reported improvement (analysis presented in other chapters of this document).

Table 1. SITES USING CORE OUTCOME MEASURES

City	Site	Coordinator	N	Trials	Core Instruments
Atlanta	Life University	Pfleger	105	1 to 3	Oswestry, Zung, VAS, Schober
Bombay (Mumbai)	Consulting Rheumatologist	Pispati (Darmawan)	30	1	Oswestry, Zung, VAS, Schober
Cairo	El-Aguoza Military Rehabilitation Center and Ain Shams University	Handly	157	1 to 5 Zung, VAS, Schober	Oswestry,
Moscow	Moscow Institute of Rheumatology	Nassonova	27	2	Oswestry, Zung, VAS Schober
Tokyo	Keio and Kitasato Universities	Homma	60	2	Oswestry, Zung, VAS, Schober
São Paulo	Hospital do Servidor Publico Estadal	Chahade	67	1	Oswestry

Note: N refers to the number of subjects in the study (Atlanta is ongoing). Trials refers to the number of times the outcome measure was taken; sites with two or more trials represent clinical trials.

A chief concern for these studies is determining how sensitive the instruments are to clinical intervention. Essentially, to be an effective instrument, the initial application must exhibit a mean and variance that places the majority of the scores toward the middle of the range of values that the instrument is capable of reporting. If initial scores are consistently near the lower boundary of possible values, the test will be incapable of measuring a downward change as a result of clinical intervention. Similarly, one cannot assess upward change in scores if they are already near the highest possible value during initial application. The means and standard deviations for trial 1 of each test for the six sites are listed in Table 2 along with the range for each test.

Table 2. BASELINE CORE INSTRUMENT VALUES

	Oswestry	Zung	VAS	Schober
Range	[0 - 100]	[0 - 69]	[0 - 10]	[0 -¥_]*
Atlanta*	23.5 ± 11.8	18.0 ± 10.5	4.1 ± 2.0	3.1 ± 1.2
Bombay	34.7 ± 24.1	28.5 ± 9.4	5.7 ±2.7	5.7± 3.0
Cairo	41.6 ± 15.5	21.7 ± 9.7	5.7 ± 2.3	6.3 ±1.5
Moscow	53.0 ± 16.5	22.0 ± 9.1	6.0 ± 2.4	2.7 ± 1.0
Tokyo	23.1 ± 15.1	22.8 ± 9.3	3.7 ± 2.2	
São Paulo	31.2 ± 15.6			

* The Atlanta site used an upper limit on Schober of 5 cm.

Table 2 shows means for all measures to be centrally located within the instrument's range of measurements. In every case, two-thirds of the data (represented by the mean plus or minus the standard deviation for a normal distribution) fit well within the end points for the instrument. Although mean responses varied greatly across sites, the data suggests that the instruments are capable of measuring response, either positive or negative, to a subsequent intervention.

Table 2 also indicates that mean core instrument values varied substantially across sites. This could be due to a number of reasons as will be discussed following individual analyses of the four measurements.

Oswestry Low Back Pain Disability Questionnaire. Results from the trial 1 (baseline) administration of the Oswestry are listed in Table 3.

Table 3. CROSS-SITE OSWESTRY STATISTICS

Mean	Std	Dev	N	Max	Min
Atlanta	23.5	1.8	77	58.0	2.0
Bombay	4.7	24.1	30	94.0	4.0
Cairo	41.6	15.5	157	82.0	8.0
Moscow	53.0	16.5	37	90.0	17.1
São Paulo	31.2	15.6	67	71.1	0.0
Tokyo	23.1	15.1	60	78.0	2.0

The Oswestry test assesses physical disability due to the patient's low back pain. Baseline values varied greatly across sites, with patients from Tokyo appearing the least disabled and patients from Moscow appearing the most disabled. Analysis of Variance (ANOVA) revealed significant differences among the mean responses across the five sites ($F = 38.4519, p < 0.0001$). Significant differences across sites were also seen for the ten individual questions of the Oswestry, as shown in Table 4.

Table 4. MEAN SCORES FOR OSWESTRY QUESTIONS

Question	Atlanta	Bombay	Cairo	Moscow	São Paulo	Tokyo	F-VALUE	P-VALUE
Q1	1.55	1.86	3.03	2.97	1.82	1.70	20.8172	<0.0001
Q2	0.57	1.30	1.78	1.95	1.19	0.98	20.4798	<0.0001
Q3	1.64	2.20	3.09	3.05	1.76	1.55	14.5740	<0.0001
Q4	0.73	1.40	1.50	2.43	1.15	0.59	25.2802	<0.0001
Q5	1.57	2.03	2.13	3.22	2.09	1.28	22.7533	<0.0001
Q6	1.34	2.07	2.69	3.00	1.96	1.32	20.3148	<0.0001
Q7	1.04	1.33	1.53	1.76	1.27	0.57	14.0811	<0.0001
Q8	0.99	1.19	2.03	3.30	1.05	1.09	9.3317	
Q9	1.24	2.03	2.06	3.09	1.45	1.15	10.9854	<0.0001
Q10	1.19	1.70	2.13	3.09	1.56	1.24	9.9342	<0.0001

The extremely high F-values and low p-values indicate significant cross-site difference for each of the ten questions. As some of the questions could be considered personal in nature, it is also worth looking at the percent of subjects who chose not to respond to a particular question (Table 5):

Table 5. PERCENT OF SUBJECTS NOT RESPONDING TO OSWESTRY QUESTIONS

Question	Atlanta	Bombay	Cairo	Moscow	São Paulo	Tokyo
Q1	0%	3%	0%	0%	0%	0%
Q2	0%	0%	0%	0%	0%	0%
Q3	0%	0%	0%	0%	0%	0%
Q4	0%	0%	6%	0%	0%	2%
Q5	0%	0%	3%	0%	0%	0%
Q6	0%	0%	0%	0%	0%	0%
Q7	0%	0%	0%	0%	0%	0%
Q8	8%	13%	3%	3%	45%	43%
Q9	0%	0%	3%	0%	1%	0%
Q10	0%	0%	0%	0%	1%	8%

Good compliance was noted in filling out the self-rated form, with the exception of question number 8 which asks the patient how their back or leg pain affects their sex life. Nearly half of the patients in São Paulo and Tokyo were reluctant to provide such information. With some surveys, omissions will result in lower index scores, making the patient's condition appear less severe. However, with the Oswestry survey, the overall index is computed by dividing the total score by the number of questions answered. Therefore, omissions have a lesser effect.

Modified Zung. Results from the trial 1 (baseline) administration of the Modified Zung are listed in Table 6.

Table 6. CROSS-SITE ZUNG STATISTICS

	Mean	Std Dev	N	Max	Min
Atlanta	18.0	10.5	76	50	3
Bombay	28.5	9.4	29	47	12
Cairo	21.7	9.7	200	47	1
Moscow	22.0	9.1	11	37	10
Tokyo	22.8	9.3	57	48	0

ANOVA revealed that this data represents a significant difference among means as well ($F = 5.1949$, $p = 0.0004$). Mean scores for some individual questions were statistically different across sites as can be seen in Table 7.

Table 7. MEAN SCORES FOR ZUNG QUESTIONS

Question	Atlanta	Bombay	Cairo	Moscow	Tokyo	F-VALUE	P-VALUE
Q1	0.51	1.34	0.77	1.45	0.68	8.2017	<0.0001
Q2	1.53	1.64	1.18	1.64	1.85	1.0114	0.3890
Q3	0.15	1.10	0.53	0.45	0.27	12.6448	<0.0001
Q4	1.22	1.41	0.90	0.91	0.88	2.0657	0.1067
Q5	0.31	1.21	0.43	0.09	0.28	10.9720	<0.0001
Q6	1.06	1.55	0.97	0.55	1.16	1.6405	0.1820
Q7	1.17	1.88	2.13	1.45	2.24	8.7781	<0.0001
Q8	0.24	0.48	0.48	0.00	0.33	1.7861	0.1519
Q9	0.38	0.83	0.93	1.73	0.65	7.6635	<0.0001
Q10	0.40	0.86	0.77	0.91	0.20	6.9231	0.0002
Q11	0.99	0.97	1.19	1.73	0.79	2.9627	0.0338
Q12	0.97	1.46	1.47	0.36	1.48	4.0113	0.0087
Q13	0.92	1.14	1.07	1.91	1.02	2.4331	0.0668
Q14	1.55	1.93	1.60	1.45	2.04	2.9033	0.0365
Q15	1.23	1.07	1.03	1.09	0.57	4.7852	0.0032
Q16	0.70	1.66	1.00	0.64	1.64	10.1353	<0.0001
Q17	1.03	1.00	0.97	1.64	0.87	1.9525	0.1232
Q18	0.93	1.41	1.07	1.09	1.93	10.0785	<0.0001
Q19	0.39	0.86	0.64	0.27	0.30	3.5526	0.0158
Q20	0.80	1.52	1.03	0.82	1.53	5.5781	0.0011
Q21	0.71	1.52	0.77	1.27	1.44	7.0370	0.0002
Q22	0.14	0.55	0.14	0.18	0.11	2.9619	0.0339
Q23	1.00	1.55	0.97	0.36	1.50	5.7196	0.0009

Owing to the large number of comparisons, it is difficult to say exactly what value of p represents a significant difference across sites. Still, Table 7 reveals that there was a significant difference in the way various sites answered most of the Zung questions. The percent not responding to individual questions was is listed in Table 8.

Table 8. PERCENT NOT RESPONDING TO ZUNG QUESTIONS

Question	Atlanta	Bombay	Cairo	Moscow	Tokyo
Q1	0%	0%	3%	0%	7%
Q2	3%	3%	10%	0%	12%
Q3	1%	0%	3%	0%	8%
Q4	0%	0%	0%	0%	5%
Q5	0%	0%	3%	0%	10%
Q6	1%	0%	0%	0%	5%
Q7	7%	14%	3%	0%	23%
Q8	4%	0%	6%	0%	10%
Q9	0%	0%	6%	0%	8%
Q10	1%	0%	3%	0%	7%
Q11	0%	0%	0%	0%	5%
Q12	0%	3%	3%	0%	7%
Q13	0%	0%	3%	0%	8%
Q14	0%	0%	3%	0%	10%
Q15	0%	0%	0%	0%	7%
Q16	0%	0%	0%	0%	7%
Q17	0%	3%	3%	0%	8%
Q18	0%	0%	3%	0%	7%
Q19	0%	3%	10%	0%	7%
Q20	0%	0%	0%	0%	5%
Q21	3%	0%	3%	0%	5%
Q22	7%	0%	6%	0%	10%
Q23	0%	0%	0%	0%	7%

Here, the percent not responding is not as high as for the Oswestry, but is still significant for some of the questions. Subjects in the Tokyo study were the most reluctant to complete the survey. It is worth noting that the mechanism for calculating the index for the Oswestry takes into account the number of questions that were answered while the Zung does not. This means that subjects who choose not to answer one or more questions for the Zung might appear healthier than they are.

Visual Analog Scale for Pain (VAS). Responses for the five sites that did baseline assessment using the VAS are listed in Table 9.

Table 9. CROSS-SITE VAS STATISTICS

	Mean	Std Dev	N	Max	Min
Atlanta	4.1	2.0	75	8	0.5
Bombay	5.7	2.7	29	10	1.3
Cairo	5.7	2.3	385	10	0.0
Moscow	6.0	2.4	11	10	2.2
Tokyo	3.7	2.2	56	8.4	0.2

Examination of the raw data revealed that the Atlanta, Bombay, Moscow, and Tokyo sites measured the VAS with greater precision in that one decimal place was used while Cairo used the closest whole number. A significant difference was seen among the means for VAS as well ($F = 16.1035$, $p < 0.0001$). Patients from Atlanta and especially Tokyo reported lower initial pain levels.

Schober's Test. Five sites also reported baseline measures for Schober's test (Table 10):

Table 10. CROSS-SITE STATISTICS FOR SCHOBER'S TEST

	Mean	Stds	N	Max	Min
Atlanta	3.1	1.2	77	5	0
Bombay	5.7	3.0	14	10	2
Cairo	6.3	1.5	185	10	2
Moscow	2.7	1.0	27	4	0

The precision used again varied across sites: Atlanta and Moscow measured to the nearest 1/2 cm, while Cairo and Bombay measured to the nearest 1 cm. The protocol for Schober's requires the assessor to mark points 0.5 cm below and 10.0 cm above S2 with the patient in neutral flexion/extension (Modified Schober's uses 15 cm above S2). The patient is asked to flex forward, and the increase in the distance is recorded. An increase of 5 to 8 cm is considered normal. Apparently, the Atlanta site used the regular Schober distance (10 cm), while the other sites used the modified distance. Further, the Atlanta site recorded 5 cm for all measures greater than or equal to that number, while the other sites merely recorded the overall increase in length. This has the effect of decreasing the mean value for the Atlanta group as compared to the others, but does not explain why the Moscow data were similarly smaller. These baseline measures were statistically different ($F = 113.7847$, $p < 0.0001$).

DISCUSSION

It appears that the four core instruments were appropriately chosen for research on subacute low back pain. The means and standard deviations of baseline measures indicate they are capable of measuring change in both directions. However, there were great differences in mean values across sites. The Tokyo subjects appeared to be the most healthy in terms of disability (Oswestry) and pain (VAS). In terms of depression (Zung), subjects from Atlanta reported the lowest scores. Conversely, subjects in Moscow provided the highest disability and pain levels while the Bombay population showed the highest degree of depression. In terms of lumbar flexibility (Schober), patients in Bombay and Cairo displayed

high averages while Atlanta and Moscow had low averages. There are several possible explanations for the variations across sites including:

- Assessment methodology - different protocols were used to administer the instrument. This clearly applies to the Schober test as the Atlanta group used a 10 cm superior mark while the other groups apparently used the modified 15 cm mark. Methodologies could have differed for the three surveys as well even though they were self-administered. Perhaps the person who handed out the surveys provided different verbal instructions to the patient which could have influenced both the magnitudes of the scores and the number of omissions.

- Assessor bias - assessors from various sites provided different measurements of the same phenomenon. This occurred at the Atlanta site for Schober's Test since measures greater than 5 cm were all recorded as 5 (which the assessor considered normal), while other sites recorded the actual measurement. Assessor bias does not apply to the self-administered surveys. However, if the patient was illiterate, and the survey had to be read to them, then the assessor could influence the results.

- Severity of condition - different types of patients enrolled at different sites. The Atlanta group had very stringent inclusion criteria including pain duration between two and six weeks (subacute). Other sites had predominantly chronic patients. A critical examination of subject recruitment and patient demographics is needed to determine if the condition of patients was similar across sites. The advertisement language and placement of ads could potentially influence the type of patient attracted to the study. Patient occupation (e.g. white collar versus blue collar) could also affect the baseline information.

- Language - translation of the three surveys into native languages resulted in subtle, but influential changes in the manner that patients interpreted the questions. These effects were probably minimal, as original versions compared well to translated/back-translated versions.

- Culture - some cultures are reluctant to complain about their health while others freely broadcast health problems. This factor might contribute more than any other to the significant differences in scores across sites. This issue was addressed by Dr. George Ehrlich at the WHO meeting in Kuala Lumpur. He pointed to three tribes in Nigeria where one is forbidden to talk about pain, the second displays an attitude similar to western cultures, and the third actively complains about pain as part of their religion. Further, the wording of a question can have vastly different ramification across societies. For instance, a question asking if a patient's condition affects their ability to bathe sounds straightforward. To a person in a developed country, this question asks if they can turn on a faucet, climb into the bath/shower, and have the mobility/flexibility to wash themselves. To a person in an undeveloped country, this question might also ask if the person has the ability to fetch water from a well that could be a considerable distance away.

Though all four instruments are probably capable of detecting change for a given patient, it may be difficult to compare effectiveness of interventions across sites. For instance, how does a 10 point drop in Oswestry from 25 to 15 compare to a 12 point drop from 50 to 38? Should one use absolute difference or percent? Further, it is unlikely that studies can employ a single intervention while employing a cohort comparison group from another study.

REFERENCES:

Baker DJ, Pynsent PB, Fairbank JCT. *The Oswestry Disability Index revisited: its reliability, repeatability and validity, and a comparison with the St Thomas's Disability Index.* In: Roland MO, Jenner JR, Eds. *Back pain: new approaches to rehabilitation and education.* 1989. Manchester, England: Manchester University Press, 174-186.

Dequeker J, Panayi G, Pinus T, Grahame R. *Medical management of rheumatic musculoskeletal and connective tissue diseases.* New York, Marcel Dekker, 1997, 41.

Fairbank JCT, Couper J, Davies JB et al. *The Oswestry Low Back Pain Disability Questionnaire.* Physiotherapy, 1980, 66:271-273.

Ferraz MB, Quaresma MR, Aquino LRL et al. *Reliability of pain scales in the assessment of literate and illiterate patients with rheumatoid arthritis.* J Rheumatol, 1990, 17:1022-1024.

Hedlund JL, and Vieweg BW. *The Zung Self-rating Depression Scale: a comprehensive review.* J Operat Psychiatry, 1979, 10:51-64.

Jegede RO. *Psychometric properties of the self-rating Depression Scale (SDS).* J Psychol, 1976, 93:27-30.

Lambert MJ, Hatch DR, Kingston MD et al. Zung, Beck, and Hamilton. *Rating scales as measures of a treatment outcome: a meta-analytic comparison.* J Consult Clin Psychol, 1986, 54:54-59.

Main CG and Waddell G. *The Detection of Psychological Abnormality in Chronic Low Back Pain using Four Simple Scales.* Pain, 1984, 2:10-15.

McCormack HM, Horne Djde L, and Sheather S. *Clinical applications of visual analogue scales: a critical review,* 1988.

McKegney FP, Aronson MK, and Ooi WL. *Identifying depression in the old.* Psychosomatics, 1988, 29:175-181.

Scott J and Huskisson EC. *Vertical or horizontal visual analogue scales.* Ann Rheum Dis, 1979, 38:560.

Stratford PW, Binkley J, Solomon P et al. *Assessing change over time in patients with low back pain.* Phys Ther, 1994, 74:528-533.

Toner J, Gurland B, and Teresi J. *Comparison of self-administered and rater-administered methods of assessing levels of severity of depression in elderly patients.* J Gerontol, 1988, 43:136-140.

Tanaka-Matsumi J and Kameoka VA. *Reliabilities and concurrent validities of popular self-report measures of depression, anxiety, and social desirability.* J Consult Clinc Psychol, 1986, 54:328-333.

Yesavage JA, Brink TL, Rose TL et al. *Development and validation of a geriatric depression screening scale: a preliminary report.* J Psychiatr Res, 1983, 17:37-49.

4. PHARMACOLOGIC THERAPIES

Professor Valentina Nassonova; Dr N. Toroptzeva; Dr A. Burdeiny
(Institute of Rheumatology of RAMS, Moscow, Russia)

Dr Joan von Feldt; Adjunct Professor, George E. Ehrlich; Adjunct Professor, *
(University of Pennsylvania, Philadelphia, Pennsylvania, USA)

Pain in the back is the commonest symptom leading to visits to physicians of different profiles; especially general practitioners, rheumatologists, neurologists, orthopaedists and others. It is very important to assume that patients with back pain have pathological causes for their backache and the nature of it is to be determined. In spite of modern numerous diagnostic procedures the nature of backache appears to be non-specific or mechanical in the majority of cases. The majority of low back pains recover more or less spontaneously in days or weeks. Subacute or chronic backache needs pharmacological pain control for facilitation of physical activity and quality of life.

The conservative management of low back pain includes first of all patient's education, bed rest (for the short time), rational physical activity, exercise - such as their posture, lifting, carrying, working and sitting. This acceptable behaviour programme in many patients with back pain may be effective, but not in those who are suffering from recurrent or chronic low backaches. Main aims of pharmacological management of low back pain are:

- SYMPTOMATIC CONTROL OF PAIN
- PREVENTION OF DISABILITY

Medical supplies are widely used for the decrease of pain in different painful conditions, including acute and chronic back trouble. There are several types of medications prescribed to relieve low back symptoms, including "simple analgesics", NSAIDs, muscle relaxants and antidepressants. All drugs should be used for a limited period of time and constantly monitored for the efficacy and safety.

ACETAMINOPHEN (PARACETAMOL)

Acetaminophen is reasonably safe and was acceptable for treating patients with low back problems. It was demonstrated in the comparative study on osteoarthritis, that acetaminophen reducing pain is uncontroverted (Bradley J, Brandt K, Katz B, 1991). Acetaminophen in one clinical trial on low back pain was attested as an acceptable drug (Postacchini F, Facchini M, Palieri P, 1988). Since that acetaminophen is the first choice drug in patients with low back pain as "simple analgesics" in dose 1-2 g up to 4 g per day. Acetaminophen seems to be effective and safe, having fewer interactions with other drugs, not expensive. The therapeutic objective for its use in acute low back problems is pain relief. As a rule, a "simple analgesic" should be given on a regular basis for fixed duration to pain control and not intermittently.

Tolerability of acetaminophen is rather satisfactory, according to the information about its gastrointestinal intolerance and ulceration. But liver damage may follow proionged high doses. Acute fulminant hepatitis and liver necrosis have been reported after even single excessive doses (Fowler PD, 1987). Pain relief dosage had to be selected individually. It is important to pay attention to patients who simultaneously used or had prior usage of alcohol that predisposes to acetaminophen hepatotoxicity.

NONSTEROID ANTI-INFLAMMATORY DRUGS (NSAIDS)

NSAIDs are a class of medication which have analgesic and antiinflammatory properties due to inhibited prostaglandins family. Some patients with low back pain have quite marked secondary inflammatory elements and require antiinflammatory agents. For example, aching and stiffness in the back aggravated by rest going for an hour or less should respond to NSAIDs. All NSAIDs have analgesic properties in low doses and anti-inflammatory in the high ones. In modest doses marketed for self-medication, they afford pain relief sometimes better than acetaminophen (Von Feldt JM, Ehrlich GE, 1998). Namely, ibuprofen, naproxen sodium and ketaprofen can be bought in modest dosage without prescription.

There are only few clinical trials on some NSAIDs in double-blind manner for acute and chronic low back pain. Three studies found NSAIDs superior to placebo for pain relief from 1 week to 2 months of symptom duration. Diflunisal and Naproxen Sodium were shown to be much better than placebo in patients with chronic low back pain (Berry H, Bloom B, Hamilton EBD, Swinson DR, 1982). Diflunisal 500 mg twice daily was shown to be superior to placebo: excellent and good results were in 77% in Diflunisal group and only in 23% in placebo one (Jalgemann V, 1978). Double blind parallel study on piroxicam versus indometacin was demonstrated to be equally effective in back pain, but tolerability of Piroxicam was better (Videman T, Osterman K, 1984).

In our experience of treatment with NSAIDs of backache several drugs were used for this purpose (diflunisal 1000 mg/day, clinoril (sulindac) 300 mg/day and diclofenak Na 125 mg/day + tizanidin 4 mg/day, piroxicam 40mg/day). All drugs were given for a period of 10-12 days as a therapeutic trial and continued if were efficacious and well tolerated. After 10-12 days of treatment all indices became better: Oswestry was diminished in all groups of patients, especially in diflunisal group. However, the individual patients reported better pain relief from some NSAIDs as compared with others. For this reason Brooks and Day (1991) suggested that patients change to a different NSAID if no relief was reported after 2 weeks trial. The choice might best be made according to the speed of the onset of effect, half-life, duration of effect, past history of the patient, complicating features and the physician's experience and familiarity with the prescribed medication (Von Feldt JM, Ehrlich GE, 1998).

Potential complications of NSAIDs are well known: gastrointestinal intolerance, including erosions, ulceration, bleeding, perforation and death are the major risks. Special epidemiological studies on NSAID safety demonstrate that severity of gastrointestinal complications occur in approximately 1-2% of patients systematically using NSAIDs. Intolerability is higher in patients with risk factors such as older age, especially women, previous peptic ulcer disease, smoking and alcohol consumption. The concomitant administration of misoprostol (generally 200 mg three times daily, available also in combination with Diclofenac) reduces the risks of gastric erosions and ulceration, but adds to the direct expense of treatment (Walt R, 1992). Also misoprostol side effects are known to be connected with prostaglandin's activity.

As the majority of low back pain syndromes are self-limited, chronic administration of medication is rarely necessary, but the indications are determined in the course of treatment (Deyo, 1996; Koes et al, 1997).

MUSCLE RELAXANTS

The therapeutic objective of muscle relaxants in low back pain is the concept of skeletal muscle spasm secondary to pain, or enlargement of pain. Deyo's overview summarizes the current status of these drugs (Deyo RA, 1996). There is no simple opinion about efficacy of muscle relaxant in backache. The

conclusion of the meta-analysis of 12 studies was that muscle relaxants are probably, but not certainly, more effective than placebo in decreasing symptoms of acute low back problems. There was no evidence that the addition of a muscle relaxant adds to the efficacy of NSAID. But high degree of such kinds of complications of muscle relaxants as drowsiness and dizziness creates a hazard, especially when driving (Von Feldt JM, Ehrlich GE, 1998).

ANTIDEPRESSANT MEDICATIONS

According to panel recommendations antidepressant medication are not acquired in the treatment of low back pain (Bigos SJ, et al, 1994). Antidepressants seem to promote better nighttime rest, not more. At the same time antidepressants produce side effect such as drowsiness, dryness of the mouth, orthostatic hypotension and others (Von Feldt JM, Ehrlich GE, 1998).

OPIOID ANALGESICS

Codeine, as an opioid analgesic, in combination with acetaminophen, is commonly given to patients with acute low back problem for temporary pain relief. Comparison of acetaminophen with codeine to diflunisal found no significant difference between groups in pain relief or functional improvement (Brown FLJ et al, 1986; Mancie HLJ, King DE, DeForge B, 1986). No statistics were reported to support codeine or oxycodone plus aspirin or acetaminophen in three groups of patients with acute backache (Wiesel SW et al, 1980).

A recent recommendation of such drugs for selected patients based predominantly on practical experience, because no controlled studies were found, produced a spate of comments (Von Feldt JM, Ehrlich GE, 1998). Applications of oral opioids have been accompanied by different side effects. Subjects receiving acetaminophen with codeine were suffering from dizziness, fatigue, inability to concentrate, impaired vision, drowsiness, nausea and constipation (Brown FLJ et al, 1986; Mancie HLJ, King DE, DeForge B, 1986). In one study (Muncie, 1986), 35% of patients receiving acetaminophen with codeine had to discontinue the medication because of intolerable side effects (Mancie HLJ, King DE, DeForge B, 1986). Prolonged use of opioid analgesics is associated with the development of tolerance and physical dependence. The risk of developing physical dependence with short-term use of opioids has also been reported (Heishman SJ, Stitzer ML, Bigelow GE, Liebson IB, 1989). These side effects are an important concern in conditions that can become chronic such as low back problems (Bigos SJ et al, 1994).

ORAL STEROIDS

In spite of the evidence of symptoms compatible with possible inflammation (morning stiffness for example) a few controlled studies have not demonstrated a difference in efficacy between corticosteroid and placebo treatment groups (Pomenoy R et al, 1997). In addition potential serious complications are well known.

INJECTION THERAPY

TRIGGER POINT AND LIGAMENTOUS INJECTIONS

The substantiation of the opinion that trigger points in the paravertebral area are responsible for causing, or perpetuating, backache is still controversial. Trigger point injections of saline, lidocaine, corticosteroid, or a combination of these, into paravertebral soft tissue (muscles) have been produced for relief of acute back pain. One study found no difference in pain relief within 2 weeks posttreatment (Frost FA, Jessen B, Siggard, Anderson JA, 1980). On the contrary, another experience found signifi-

cantly greater pain relief at 3 months follow up for the two groups receiving steroid injections than for the group receiving injections of local anaesthetic alone (Bourne IH, 1984). Potential risk of trigger point injection, nerve injury and haemorrhage as a limited research evidence for treating acute low back pain appears equivocal (Bigos SJ et al, 1994).

FACET JOINT INJECTIONS

The theoretical bases is that some patients with low backache have a "facet syndrome" with pain arising from facet joints and the pain usually being aggravated by extension of the spine (Jackson RP, 1992). The AHCRP reviews five studies that used facet injections for chronic back pain demonstrated no significant differences between groups for pain relief or functional disability (Bigos SJ et al, 1994). The facet injections include infection, haemorrhage or nerve injury, and also a chemical meningitis. Besides, the procedure is frequently done under fluoroscopic guidance with X-ray exposure and is rather expensive, future use may be limited.

EPIDURAL INJECTIONS

Epidural injections are frequently met in patients with radiculopathy or lumbar spinal stenosis. Epidural injections of local anaesthetics, corticosteroids or narcotics into the epidural space could reduce inflammation or irritation at that site. The AHCPR reviewed a number of studies that used epidural corticosteroids (Bigos SJ et al, 1994). Two studies of epidural injections for management of acute back pain with radicular symptoms found no significant difference in pain relief immediately posttreatment or in the long-term follow-up (Cuckler JM et al, 1985; Mathew SJ et al, 1987). In patients with chronic pain, three studies reported short-term relief from corticosteroid injections (Bush K, Hillier SA, 1991; Dilke TF, Burry HC, Grahame R, 1973; Ridley MG et al, 1988) although two other studies reported no difference between groups (Klenerman L et al, 1984; Snoek W, Weber H, Jorgensen B, 1977). One study demonstrated pain relief beyond 1 month and these findings resonate with experience (Von Feldt JM, Ehrlich GE, 1998). Potential adverse side effects include incorrect placement of the epidural needle, headache, fever, inadvertent spinal tap and, rarely, epidural abscess (Von Feldt JM, Ehrlich GE, 1998). The use of morphine with or without corticosteroids can cause respiratory depression (Hopwood MB, Abram SE, 1993; Rocco AG et al, 1989). Rocco and co-workers found that an increased risk of treatment failure was associated with prolonged duration, nonradicular diagnosis, lack of employment and smoking. Alcohol use was associated with decreased risk of treatment failure (Rocco AG et al, 1989).

Aldrete looked at the group of 551 patients with severe back pain, found temporary lumbar epidural catheter infusions with bupivacaine and fentanyl via disposable infusion pumps to be effective in relieving chronic low back pain for extended periods (Aldrete JA, 1997).

Epidural infections are invasive and rarely accompanied by serious potential risks. At the same time this treatment may be a reasonable palliative opinion for patients who have contraindications for surgery.

ACUTE LOW BACK PAIN

Acute low back pain occurs after acute injury or heavy (even moderate) physical exertion. Most patients turned to the physician, first of all general practitioner. The majority of physicians treat such kind of patients with bed rest and analgesics, muscle relaxant and mild opioid such as codeine. Many patients will improve during several days or 2-4 weeks.

At the beginning of treatment a physician is to explain the necessity of bed rest, rational physical activ-

ity, exercises for improving posture, correcting lifting, carrying, working and sitting. It is necessary to turn attention to the patient that prolonged bed rest is harmful from the possibility of quick development of muscle atrophy, bone mineral loss and cardiopulmonary deconditioning. Early return to work has had not only medical but also a socio-economical reason. It is very important to remind the patient about avoiding recurrent back injury by modifying poor habits and to teach back and abdomen muscle strengthening exercises.

The first type of medication - "simple analgesics" are more effective and safe. NSAIDs from over-the-counter repertoire on analgesic dosage or an antiinflammatory dosage is needed (morning stiffness and other). Often, the patient is still able to work and continues daily living activities and adding a muscle relaxant may be sufficient to reduce back pain to tolerable levels. Serious opioid analgesic could be prescribed to the patient suffering from hard backache or if a patient is functionally impaired from back pain to restore activation. In both cases opioid may be prescribed for a short time only.

Ageing patients deserve special consideration. The acute pain associated with osteoporotic vertebral fractures usually require opioid analgesics or combinations of NSAIDs with mild opioid as a first line of treatment. In this population monitoring of side effects can be significant. Adverse reactions on narcotics are different. Among them constipation, altered mental status with increased risk of falling and extra fracture could be observed. NSAIDs also have numerous side effects in dose-dependent manner, including gastrointestinal bleeding, decreased renal blood flow with subsequent rise in BUN and creatinine, altered mental status. Judicious use of an appropriate NSAIDs and close observation of older patients may decrease danger of side effects and may diminish total narcotic dose and undesirable reactions accordingly. The last may to help the older patients to improve their early mobility, which they need.

Some patients need muscle relaxants for promotion of sleep and modifying pain in nocturnal time.

Older patients with osteoporotic vertebral fracture use calcitonin for acute and chronic management. Calcitonin exerts an analgesic effect and is rather safe. The intranasal administration of calcitonin seems to be more effective in producing analgesia than parenteral administration.

CHRONIC BACK PAIN

The treatment of chronic back pain is very difficult and pharmacological approaches are only part of multidisciplinary problem. According to modern point of view management of patients with chronic back pain is the aim of multidisciplinary team, including physiotherapist, psychiatrist, rheumatologist, chiropractor, orthopaedic surgeon and other specialists. Pharmacological treatment of chronic low back pain is a part of many-sided programme, but the main objective drug control of pain is improving the quality of life and physical activity.

Combination of analgesic therapy, including "simple analgesics", NSAIDs, muscle relaxant and sometimes a low dose of mild opioid analgesic may be safer than treatment with maximum dose of each medication individually. A sleep disturbance is often associated with chronic back pain and therefore the low dose of antidepressant may be useful. Some researchers have hypothesized that the medication may possibly have a pain-relieving effect in addition to antidepressant properties. At the same time antidepressant medication can produce a variety of side effects including dry mouth, drowsiness, constipation, orthostatic hypotention and other.

The systematically treatment of patients with chronic back pain with opioids is still controversial because of the risk of physical dependence. These side effects are an important concern in conditions

that can become chronic, such as low back problems (Bigos et al, 1994).

Invasive modalities, such as epidural corticosteroids, in chronic low back pain may be reasonable step in refractory patients, especially in those who have contraindications for surgery.

CONCLUSION

Low back pain is a symptom of different conditions connected with spine. In spite of modern diagnostic procedures, the nature of backpain appears to be non-specific in many cases. There are acute, subacute and chronic types of low back pain, which have common and distinguish approach of pharmacologic management. A list of drugs with analgesic actions is so enormous that some relief of pain for acute, subacute and even chronic low back pain is becoming reality. Future studies of pharmacologic approaches in treatment of low back pain have to include definite outcome measures to enhance comparability and to elaborate most effective and safe combined programme (The World Health Organization, 1995).

APPENDIX

The Institute of Rheumatology of RAMS carried out a comparative study to objectively evaluate the efficacy of treatment of low back pain patients under the criteria suggested by WHO – Oswestry Disability Questionnaire, Modified Somatic Perception Questionnaires (MSPQ) and modified Zung score (MZS), VAS, and Schober's test.

40 patients with LBP syndrome - 14 females (average age 46 yrs) and 26 males (average age 49 yrs) with spinal pain duration from 2 to 4 weeks, were separated into four groups. 11 patients received Clinoril, 300 mg/day; 15 patients, Diflunisal, 1000 mg/day; 9 patients, Diclofenac Sodium 125 mg + Tizanidin 4 mg/day and; 5 patients, Piroxicam, 40 mg/day. All drugs were given for the period of 10-12 days as a therapeutic trial until improving back condition.

Each patient in these four groups filled out the Oswestry Disability Questionnaire and in two last groups – MSPQ and MZS before and after treatment to assess psychological condition of the patient. Schober's Test and VAS were used for registration of back function also – before and after treatment. Every answer and index had certain quantitative assessment. Treatment of the data was carried out according the methods of paired variants using Student t-criterion.

RESULTS

In all 4 groups of patients on the background of therapy one could notice improvement of functional condition of patients evaluated by the Oswestry Disability Questionnaire. Thus, in the 1st group of patients having clinoril the average level of disability was 44% before and 32% after the treatment ($p<0.002$). In the 2nd group having Diflunisal 55% and 24% correspondingly ($p<0.0001$), in the 3d group having Diclofenac in combination with Tizanidin 60% and 35% correspondingly ($p<0.003$) and in the 4th group having Piroxicam 49% and 30% correspondingly ($p<0.005$).

In the 3d and 4th groups the assessment according to the MZS simultaneously demonstrated that patients with LBP syndrome were in the risk group according to the depressive condition; in the course of treatment their psychological condition improved ($p<0.01$ and $p<0.05$ for 3d and 4th groups correspondingly).

Proposed by WHO Committee questionnaires and indices for registration of back function for the assessment of LBP patients condition could be used for monitoring of treatment efficacy in such patients on the background of administration of different medications.

The analysis of psychological LBP patients' condition by modified questionnaire of somatic condition and modified Zung score demonstrated that their psychological discomfort decreased in the course of treatment and the functional activity of spine became better.

Assessment of efficacy of different NSAIDs by questionnaires proposed by WHO Low Back Pain Initiative

Drug	No of Patients	No of days	Questionnaire	Before Treatment	Average Difference at the end of Treatment	P
Clinoril (300mg/d)	11	10	Oswestry (%)	44±4	-12±3	<0.002
			Modified	3.1± 0.3	+1.4±0.4	<0.003
Diflunisal (1000mg/d)	15	10	Oswestry (%)	55±4	-31±4	0.0001
Diclofenac (125mg/d)	9	12±0.6	Oswestry (%)	60±5-	-25±6	<0.0003
+			Modified	4.83±0.8	2.5±.6	<0.01
Tizanidin (4mg/d) Schober's (cm)			Modified Zung (score)	28±5	-6± 2	<0.01
			VAS (mm)	56±6	-34±9	<0.005
			MSPQ	5.3±1.2	-1.0±0.4	<0.05
Piroxicam (40mg/d)	5	11.4±0.75	Oswestry (%)	49±6.8	-19.4±6.8	<0.005
			Modified	3.1±0.2	+1.1±0.6	<0.05
			Modified Zung (score)	28±5.9	-4.6±3.6	<0.05
			VAS (mm)	48.2±8.8	-28.2±9.9	<0.05
			MSPQ	6.8±1.5	-3.2±1.7	>0.05

REFERENCES:

Aldrete JA. *Extended epidural catheter infusions with analgesics for patients with noncancer pain at their homes.* Reg Anest, 22(1):35-42, 1997.

Berry H, Bloom B, Hamilton EBD, Swinson DR. *Naproxen sodium, diflunisal, and placebo in the treatment of chronic back pain.* Ann Rheum Dis, 1982, 41:129-132.

Bigos SJ, Bowyer OR, Braen GR et al. *Acute low back problems in adults. Clinical practice guideline No 14. AHCPR Publication No 95-0642 Rockville, Maryland:* Agency for Health Care Policy and Research, Public Health Service. US Department of Health and Human Services, Dec.1994.

Bourne IH. *Treatment of chronic back pain. Comparing corticosteroid - lignocaine injections with lignocaine alone.* Practitioner, 228:333-338, 1984.

Bradley J, Brandt K, Katz B. *Comparison of an antiinflammatory dose of ibuprofen, an analgesic dose of ibuprofen and acetaminophen in the treatment of patients with osteoarthritis of the knee.* N Engl J Med, 325:87-91, 1991.

Brooks PM, Day RO. *Nonsteroidal antiinflammatory drugs - differences and similarities.* N Engl J Med Jun 13; 324: 1716-1725, 1991.

Brown FLJ, Bodison S, Dixon J, Davis W, Novoslawski J *Comparison of diflunisal and acetaminophen with codeine in the treatment of initial or recurrent acute low back pain.* Clin Ther , 1986, 9 Suppl C: 52-58.

Bush K, Hillier S A. *Controlled study of caudal epidural injections of triaminolone plus procaine for the management of intractable sciatica.* Spine, 16:572-575, 1991.

Cuckler JM, Bernini PA., Wiesel SW. et al. *The use of epidural steroids in the treatment of lumbar radicular pain. A prospective, randomized, double-blind study.* J Bone joint surg (Am) 67:63-66, 1985.

Deyo RA. *Drug therapy for back pain. Which drugs help which patients?* Spine, 21(24) :2840-2849, 1996.

Dilke TF, Burry HC, Grahame R. *Extradural corticosteroid injection in management of lumbar nerve root compression.* Br Med J 16:635-637,1973.

Fowler PD. *Aspirin, paracetamol and non-steroidal antiinflammatory drugs. A comparative review of side effects.* Med Toxicol 2:338-66, 1987.

Frost FA, Jessen B, Siggard, Anderson JA. *A control double-blind comparison of mepivacaine injection versus saline injection for myofascial pain.* Lancet, 8 (8167): 499-501, 1980.

Heishman SJ, Stitzer ML, Bigelow GE, Liebson IB. *Acute opioid physical dependence in humans: effect of varying the morphine-naloxone interval.* J Pharmacol Exp Ther Aug; 250(2):485-91,1989.

Hopwood MB, Abram SE. *Factors associated with failure of lumbar epidural steroids.* Rg Anesth 18(4): 238-243, 1993.

Jackson RP. *The facet syndrome. Myth or reality?* Clin Orthop 279:110-121.1992.

Klenerman L, Greenwood R, Davenport HT et al. *Lumbar epidural injections in the treatment of sciatica.* Br.J.Rheumatol, 23:35-38, 1984.

Koes BW, Scholten RJ, Mens JM et al. *Efficacy of Nonsteroidal anti-inflammatory drugs for low back pain: a systematic review of randomized clinical trials.* Ann Rheum, Dis.56(4): 214-223, 1997.

Mancie HLJ, King DE, DeForge B. *Treatment of mild to moderate pain of acute soft tissue injury: diflunisal Vs acetaminophen with codeine.* J.Fam.Prac. 1986 Aug:23(2): 125-7.

Mathew SJ, Mills S, Jenkins V et al. *Back pain and sciatica: controlled trials of manipulation, traction, sclerosant, and epidural injections.* Br.J.Rheumatol. 26: 416-423, 1987.

Pornenoy R, Dove V, Joseph H et al. *Pain management and chemical dependency: Evolving perspectives* JAMA 278: 592-593, 1997.

Postacchini F, Facchini M, Palieri P. *Efficacy of various forms of conservative treatment in low back pain. A comparative study.* Neuroorthopedics. 1988, 6(7); 28-35.

Ridley MG, Kingsley GH, Gilson T et al. *Outpatient lumbar epidural corticosteroid injection in management of sciatica.* Br.J.Rheumatol.48: 295-299,1988.

Rocco AG, Frank E, Kaul AF et al. *Epidural steroids, epidural morphine and epidural steroids combined with morphine in the treatment of past-laminectomy syndrome.* Pain, 36: 297-303, 1989.

Snoek W, Weber H, Jorgensen B. *Double blind evaluation of extradural methylprednisolone for herniated lumbar discs.* Acta Orthop.Scand. 48:635-641, 1977.

Videman T, Osterman K. *Double-blind parallel study of piroxicam versus indomethacin in the treatment of low back pain.* Ann.Clin.Res.16, 156-160,1984.

Von Feldt JM, Ehrlich GE. *Pharmacologic therapies. Lowback pain.* Physical Medicine and Rehabilitation.Clinics of North America.V.9, No 2, p.473-485,1998

Walt R. *Misoprostol for the treatment of peptic ulcers and anti-inflammatory-drug-induced gastro-duodenal ulceration.* N.Eng.J.Med., 372:1575-1580, 1992.

Wiesel SW, Cuckler JM, Deluca F, Jones F, Zeide MS, Rothman RH. *Acute low back pain: an objective analysis of conservative therapy.* Spine, Jul/Aug: 5(4): 324-30, 1980.

World Health Organization. *Third WHO Informal consultation on the comprehensive approach to low back pain treatment* (1995).

5. LOW BACK PAIN (LBP): PHYSICAL THERAPY APPROACH

Wiliam Habib Chahade, MD, Ph.D.
(Rheumatologist, Director, Rheumatology Department, Hospital do Servidor Público Estadual de São Paulo (HSPE), Brazil;
Professor of Post-Graduation in Rheumatology (FMUSP and HSPE), São Paulo, Brazil)

Linamara Rizzo Battistella, MD, Ph.D.
(Physiatrist, Director, Rehabilitation Medicine Division, Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo (FMUSP), Brazil;
Professor of Discipline of Physiatry, School of Medicine, Pontifícia Universidade Católica de São Paulo, São Paulo, Brazil)

Maria Cristina Biasoli, PT
(Physical therapist, Low Back Pain Study Group, Rheumatology Department, Hospital do Servidor Público Estadual de São Paulo, São Paulo, Brazil)

Therapeutic management of low back pain is often arbitrary and based on the caring health care professional's personal experience. Less frequently, management is based on clinical data produced by comparative investigations employing scientific methodologies in multidisciplinary units combining the skills of a rheumatologist, physiatrist, physical therapist, occupational therapist, orthopaedist, social worker, psychologist and/or psychiatrist and rheumatology/rehabilitation nurses (Ehrlich GE, 1973; Gerber LH, Hicks JE, 1988; Hicks JE, Nicholas JJ, 1988).

The physician caring for the subject with LBP needs to precisely ascertain the stage of the disease, the presenting features and symptoms, the biomechanical changes, the severity of the referred pain, the changes of the paravertebral muscles, and the psychological consequences of the disease. Additionally, its causes should be sought as well as the disease's mode of presentation, that is, acute, recurrent, subacute or chronic. It is also important to determine the patient's acceptance of previous treatments, the degree of incapacitation for routine activities, the effects of planned exercises and the ergonomics of the patient's professional activities. The social and economical issue regarding matters of workers compensation is also a challenge because of patient simulation.

Low back pain is perhaps the best example of the shortcomings of the disease-illness paradigm as a simple model of disability (Meenan R, 1988).

Although back pain is a common cause of disability, a few cases display an anatomical abnormality accounting for the clinical findings and symptoms. Even in cases where a diagnosis of herniated disk is attained, the patient's degree of disability may show no bearing with severity of the symptoms.

Most patients with low back pain respond to a course of conservative management. However, the components of nonoperative therapy that are effective in treating and preventing low back pain continue to be debated in the literature (Borenstein D, 1996, Borenstein D, 1998).

Lahad et al (1994) reviewed a total of 190 papers to find 64 studies that discussed the efficacy of back and aerobic exercises, education, mechanical supports, and risk factor modification (cessation of smoking and weight reduction) for the prevention of back pain in asymptomatic individuals. Despite the fact that only a few data support their beneficial role, exercises that strengthen back and abdominal muscles are the intervention associated with a decreased rate in the frequency and duration of low back

pain (Faas A, Van Eijk JTM, Chavannes AW, Guybbels, 1995; van Tulder MW, Koes BW, Bouter LM, Metsemakers JFM, 1997). Minimal evidence exists for education, and there are insufficient data confirming efficacy of mechanical supports and no evidence for risk factor modification as a mean of preventing low back pain. The generalization of these data to the general population must be made with caution because the published studies were conducted in the workplace.

In this paper, we discuss some therapeutical alternatives and rehabilitation programmes for idiopathic low back pain and for those cases of low back pain caused by biomechanical imbalance (Gerber LH, Hicks JE, 1988; Hicks JE, Nicholas JJ, 1988).

REST

A two to three-day bed rest is recommended for mild to moderate cases whereas a period of 1 to 2 weeks of rest can be recommended for cases where radiculopathy is present. It is likely that a bed rest period of over three days does not decrease the disability rate. Rest should be on a hard surface, in a conformable supine position, with the lower limbs flexed. Interestingly, several reviews, including the Quebec Task Force (1987) and the Agency for Health Care Policy and Research (AHCPR) guidelines, have noted some benefit from limited rest and did not note any benefit from therapeutic exercise in the acute setting of mechanical low back pain (Scheer SJ, Radack KL, O'Brien DR Jr, 1995; Scheer SJ, Robinson RD, Weinstein SM, 1997).

Rhythmic and smooth stretching exercises are recommended once the symptoms begin to subside (pain, paravertebral muscle spasm and antalgic scoliosis). In-bed lumbar traction is usually not recommended at this stage. Postural education and biomechanics should be initiated as early as possible. The patients should be encouraged to remain as active as tolerated early in the course of LBP. Malmivaara et al (1995) have shown the benefits of using return to graded functional activities in the management of low back pain, rather than a specific time of rest or structured exercise programme.

PHYSICAL THERAPY

Accurate diagnoses of the causes of the LBP and treatment objectives play a definitive role in the determination of the type of physical therapy to be employed for LBP. Several treatment modalities have been recognized to date. However, very few control studies have definitely determined efficacy rate and outcomes. Pain syndromes are known for their multifactorial features and the different limitations, regarding the methodologies hinder the performance of randomized studies in the determination of clinical efficacy of specific treatment modalities. Additionally, a placebo effect can be present in up to one third of the cases receiving physical therapy (Turner JA et al, 1994).

The relief of acute pain demands local superficial or deep heat or ice pack therapy. TENS (transcutaneous electrical nerve stimulation) is an alternative to relief the pain. It is easier to perform and well tolerated by the patients as a procedure to obtain analgesia.

Exercises are the cornerstone in the physical therapy and rehabilitation. This topic will be discussed in further detail elsewhere.

The Lumbar traction is less used as treatment because, in certain situations, it can increase the pain.

Postural education, health ergonomics applied to the workplace and at home should also be recommended. Schools for vertebral column rehabilitation – back school - have been producing good outcomes in diminishing the frequency of LBP.

Main Treatment Modalities for rehabilitation and physical therapy employed for LBP (Faas A, Van Eijk JTM, Chavannes AW, Guybbels, 1995; Graves JE et al, 1990; Van den Hoogen HJM et al, 1997).

Symptoms	Therapy
Pain	Rest, heat, ice, TENS massage, Hydrotherapy
Mechanical	Education, rest, braces, belts, Isometric and stretching exercises
Muscle weakness	Flexion extension exercises under supervision, global postural rehabilitation

In chronic cases with acute bouts of pain, the employment of braces and abdominal supporting belts (elastic belts) are effective in diminishing the pain. However, the abdominal belts should be worn only for a brief period of time to avoid atrophy and weakness of the abdominal wall.

There is no clear-cut agreement about the indications of physical therapy for low back pain. For instance, Van de Hoogen et al (1997) completed a prospective study cohort of prognostic factors for the resolution of low back pain. Forty percent of the eligible patients dropped out of the study, biasing the results for patients with more severe disorders, so that patients who received physical therapy had a slower improvement rate.

Treatment management planning, for patients with chronic manifestations, should take into account the affective and the nociceptive components of the pain. The delay in the recovery of patients with low back pain may be related to other factors unrelated to the patient's clinical status. Recovery can be strongly influenced by psychological and occupational factors. It should also be remembered that chronic low back pain patients become physically unfit, requiring a more comprehensive assessment. Specific management of chronic LBP should include the following points: self-application, easiness, low cost, and satisfactory efficacy.

THERMAL AGENTS

The application of heat or ice in the lumbar region aims at controlling the pain, muscle contraction, and the inflammatory reaction in certain cases.

HEAT AND COLD

Heat and cold have been known for some time to reduce pain. They appear to do so by equalizing the temperature gradient between injured and non-injured tissues. In addition to relieving pain, these modalities have other actions, including effects on flexibility, joint stiffness, blood flow, and inflammation. To take advantage of these properties, both for treating pain and other conditions, numerous heating and cooling devices have been developed.

SUPERFICIAL HEAT MODALITIES

Heating modalities create both local and reflex effects. The local response is an increase in tissue temperature and metabolic rate. The reflex effects include both regional and generalized responses. The regional responses increases blood flow to the treated area and muscle relaxation. The generalized responses include increased blood flow to he contralateral limb, sedation and relaxation, sweating, and body thermoregulation. The local responses are more vigorous as a rule.

Heating modalities are generally prescribed based on their ability to heat the body tissues either superficially or more deeply.

Superficial heat causes a reflex increase in blood flow to the skin and muscles below the heat as well as increasing blood flow in the skin of the limbs distal to the site of the heating. In conditions of painful muscle splinting, such as acute neck or back strain, superficial heat may provide significant relief of pain.

There are a number of different superficial heating devices. Wet or dry heat includes hot pads, hydrotherapy and infra-red.

DEEP HEATING

When tissues deeper than 3 to 5mm need to be warmed, superficial heating agents cannot reach them. There are three types of deep heating modalities. Only one, ultrasound, is used with any great frequency, chiefly indicated for chronic backache, to increase extensibility of the connective and muscle tissue.

Microwaves are electromagnetic radiation forms which are preferentially absorbed in water-containing tissues. They mainly heat muscle. Microwave diathermy is relatively safe and easy to use. On the other hand, it does not usually offer a clear-cut advantage over ultrasound. If available, and if selective muscle heating is desired, it may be a good option to use. Short waves forms are only used for selected patients without neurological lesions.

GUIDELINES FOR USE OF THERAPEUTIC HEAT

- When using superficial heating modalities, the patient should not lie on top of the heating source. This is more likely to cause skin burns because the pressure from the body weight masks the pain and prevents capillary blood flow from dissipating the heat.

- When using heat to help increase flexibility, it should be accompanied and followed by prolonged gentle stretching. Heat alone, without the stretching, will not increase flexibility. As a rule, the highest dose of heat that can be tolerated without producing tissue damage is required to have an effect on flexibility. This technique is mainly used to treat contractures.

- Heat increases blood flow to the tissues being warmed. This increase in blood flow may help to resolve inflammation in some cases. In other instances, it aggravates the inflammation. It may be followed by massage to reduce oedema.

- The increase in blood flow "washes out" the heat. Thus, after a certain amount of time, prolonging the heating session is no longer useful. For most superficial heating sessions, 20 to 30 minutes of heat application is useful. For deep heating, 5 to 10 minutes per field is used.

- Heat increases blood flow to the tissues being warmed. This increase in blood flow may help to resolve inflammation in some cases. In other instances, it aggravates the inflammation. It may be followed by massage to reduce oedema.

- The increase in blood flow "washes out" the heat. Thus, after a certain amount of time, prolonging the heating session is no longer useful. For most superficial heating sessions, 20 to 30 minutes of heat application is useful. For deep heating, 5 to 10 minutes per field is used.

- Let the patient's sensation of warmth guide treatment. For ultrasound, a useful technique to achieve optimal heating is to go right up to the point of pain and then back off on the intensity slightly.

- Vigorous heating is not generally indicated in acute injury or in inflamed joints. In these situations it may worsen the inflammation.

CRYOTHERAPY

Cold application is commonly used in musculoskeletal conditions, especially after acute injury. It helps decrease tissue inflammation and swelling. It also helps to decrease pain sensation, either by acting as a counter irritant or by blocking pain transmission directly.

COLD MODALITIES: Ice Packs
Vapocoolant Spray

Cold produces vasoconstriction, which decreases blood flow to the area being treated. Thus, the cooling effect is not "washed out" as quickly as with heat, and the effects are more long-lasting. When the tissues are cooled enough to cause damage, there is an axonal-reflex mediated vasodilation that increases blood flow to prevent frostbite. This level of cooling should not be approached in a clinical setting.

Cryotherapy is usually used in the first 1 to 2 days after injury. It is commonly applied for 10 to 20 minutes every 1 to 2 hours as tolerated. It can also be used before or after exercise to decrease inflammation. In states of painful muscle splinting it can reduce pain and relax the muscle.

THERAPEUTIC HEAT AND COLD

Both therapeutic heat and cold have the physiologic effect of ameliorating pain and muscle spasm (Weber DC, Brown AW, 1996). Heat also has the benefit of increasing extensibility of collagen when combined with stretching. Cold can decrease swelling if applied after early trauma.

As a rule, either heat or cold can be used for soft tissue pain depending on patient preference. Cold application may be used later on. Myofascial pain often responds to ice massage. A helper massaging with an ice block in the direction of the muscle fibres until deep cooling, pain relief, and muscle relaxation are achieved performs this. This can either precede or follow an exercise or stretching session.

ELECTROTHERAPY

- TENS (high and low intensity) and other modes of electrical stimulation.

- Galvanic currents, iontophoresis, dyadynamic currents, electroacupuncture, interferential current, and so.

ELECTRICAL MODALITIES

Transcutaneous neuronal electrical stimulation (TENS) modulates pain by applying electrical impulses to the skin. There are two basic types: high frequency, low intensity TENS (conventional TENS), and low frequency, high intensity TENS (electro-acupuncture). Conventional TENS works due to the "gate" theory of pain. Presented simply, this involves incoming cutaneous sensory and proprioceptive impulses carried through larger myelinated nerve fibers, which inhibit pain impulses carried more slowly by

unmyelinated nerve fibers at the level of the dorsal column of the spinal cord. The faster impulses arrive at the dorsal first and "close the gate," forestalling propagation of the slower pain impulses (Shealy CN, Mauldin CC Jr, 1993).

The second type of TENS, high voltage galvanic stimulation or electro-acupuncture utilizes a more pronounced "jolt" of electrical stimulation, which increases endogenous opioid substances in the brain. Electro-acupuncture may be less useful in the treatment of some pain disorders because of the painful nature of the stimulus itself.

The advantage of TENS is that it is non-invasive. Several different electrodes and stimulator settings should be utilized before discontinuing it for failing to relieve pain. Individual response to TENS is the rule. There are a few contraindications to TENS. Theoretically, it may cause malfunction of cardiac pacemakers. Hypersensitivity to the electrodes (skin irritation) occasionally necessitates discontinuation, but can be minimized if different electrodes are used.

MOBILIZATION TECHNIQUES

- Manipulation - These are passive mobilizations indicated for acute backaches of facet syndromes. An experienced professional should carry it out. Usually this procedure is not beneficial in cases of low back pain lasting longer than thirty days. There are also no studies demonstrating that manipulation reduces the incidence of chronic backache.

- Massage - It is an interesting procedure utilized together with other techniques for relief of pain and decreases the muscle tension.

- Hydrotherapy - Different forms of hydrotherapy may be used (hydrokenesitherapy and hydromassage among others). It relieves backache by degravitation of the spinal column and the heat, permits limbering-up exercises aimed at increasing muscle force, and corrects of lumbar hyperlordosis.

- Lumbar traction - This can be mechanical or electrical attempting to produce continuous or intermittent stretching of the vertebral ligaments to achieve a small separation between them. Nowadays, it is rarely indicated and in general its use is debatable. Studies have shown that although it is well tolerated, it is not helpful in controlling sciatic pain and backache, except in some special cases which are unpredictable beforehand. Major forces can be applied if the patient tolerates the procedure. However, there is no evidence of its direct effect on reducing pain, although it can decrease the pressure within the disc. The physician should determine whether there is improvement during traction, otherwise it should be discontinued. Indication of traction, combined with prior use of heat or muscle relaxants, can aid in the mechanical action of traction (Gerber LH, Hicks JE, 1988, Medeiros L, 1996).

CORSETS

In the absence of marked spinal instability, lumbar pathologies, especially during the acute stages, can require a comfortable appliance: a corset is well accepted for short periods. It must limit lordosis and increase intra-abdominal muscle support without limiting movement. Its continuous use can promote the appearance of osteoporosis and weakening of abdominal muscles. The latter can be avoided by progressive physical activity and stretching exercises. The patients should be encouraged to remove the appliance whenever possible, so long as the pain is under control and the functional characteristics of the lumbar segment can be liberated. Elastic support girdles can help to decrease painful symptoms.

Exercises and Static Imbalance (Bienfait M, 1995; Bookhout M, 1996; Denys-Struyf G, 1995; Piret S, Béziers MM, 1992; Souchard Ph.E, 1996)

The role of exercise differs in patients with subacute and chronic low back pain from those with acute pain. Patients with chronic low back pain have weakness of the abdominal, trunk, and lower extremity musculature. Weakness in these muscle groups may predispose patients to associated recurrence or persistence of low back pain. Studies have shown that exercise programmes for strengthening trunk musculature in subjects with chronic low back pain are successful in producing increased strength. One study, using a graded-exercise programme in patients with subacute low back pain (7 to 9 weeks in duration), was successful in restoring patients to occupational functional activities and in facilitating return to work (Kellett KM, Kellet DA, Nordholm LA, 1991).

Programmed postural reduction exercises permit teaching correct postural stances, improving flexibility, stability and balance. Educational programmes, including back school have been reported to improve individual patients with low back pain (Roland M, Dixon M, 1989). Nevertheless, recently, Daltroy et al (1997) studied 4,000 postal workers in a five-year controlled trial of back school education for prevention of LBP. The education programme included three hours of training and four reinforcement sessions. The rate of LBP injuries was the same, both in the treatment and in the control groups. Postural education training for the postal employees may not be useful for decreasing work injuries. Questions remain concerning the applicability of this study to all work situations.

Populational tendencies in patients with chronic low back pain, described by Mayer et al (1985) demonstrated a reduction in performance of trunk extensor and flexor muscles when compared with a control group. Greater involvement of the extensors led to an inversion of the percentile relationship between flexors and extensors torque in patients with chronic low back pain in isokinetic evaluation. These tendencies are observed both in men and women with chronic pain and are more evident in females.

In another study, Mayer et al (1989) evaluate the computerised tomographic scan images of the transverse area of the paravertebral and psoas muscles in chronic low back pain patients during the postoperative period. The authors correlated reduction of muscle density to reduction in isokinetic performance.

According to Hides et al (1996), multifidus muscle atrophy recovers only with difficulty after an episode of low back pain. The author speculates the existence of a reflex inhibitory mechanism of this muscle during mechanical dysfunction of the lumbosacral area, similar to the quadriceps reflex inhibition due to knee disorders. Painful afferent stimuli would activate a long reflex pattern. Damage of the posterior rami, which inervate the paravertebral muscles, as observed after back surgery, is not necessary to promote intense atrophy of these muscles. The authors also say that this atrophy is already present after three weeks of pain. They describe the ultrasonographic evaluation of the transverse diameter of the multifidus muscles in the first acute episode of low back pain of mechanical origin in 41 patients. Atrophy of that muscle was frequently present. Patients of this study were divided into two groups. One group of patients performed supervised and specific exercises to strengthen the multifidus muscle. After ten weeks, ultrasonographic evaluation showed decrease of muscle atrophy in the group treated with exercises. Persistence of atrophy was observed in the conventionally treated group. These findings were also present in patients with no pain and who had returned to normal functional level. The author concludes that multifidus atrophy after mechanical low back pain will not spontaneously remit and can be responsible for recurrence in a large percentage of cases. Specific exercises for the recovery of this muscle must be prescribed in the treatment of these patients.

Reflex inhibition should be considered due to mechanical disorders, to a lesser segmental mobility, and in some cases due to the presence of myofascial and ligamentous pain in the dorso-lumbar area.

The lesser involvement of trunk flexor muscles, observed in many studies related to chronic low back pain, may be explained by: a) the absence of a specific reflex inhibitory mechanism, b) a smaller number of joints related to these muscles and c) a greater activation of these muscles in daily activities.

Trunk extensor muscles deficiency should be considered in planning rehabilitation programmes for chronic low back pain patients. Specific exercises should be included for the strengthening of these muscles.

Kraus (1994) developed a simple methodology for the clinical evaluation and detection of muscle deficiencies involved in postural disorders. He also described a systematic sequence of exercises to correct these deficiencies.

Some studies describe reversion of paravertebral muscle atrophy in patients with low back pain of mechanical origin after a specific training (Hides JA, Richardson CA, Jull GA, 1996; Rissanen A, Kalimo H, Alaranta H, 1995). The group studied by Rissanen et al (1995) performed weight resisted exercises; the group studied by Hides et al (1996) performed isometric exercises with visual feedback of ultrasonography of the multifidus muscle.

Other approaches proposed in the literature include isometric training in multiple angles of trunk flexion using equipments (Graves JE et al, 1990) and isometric training with surface eletromiography feedback (Asfour S et al, 1990).

Isokinetic training was described by Timm (1987, 1995) and showed to be the most effective approach for functional recovery of chronic low back pain patients when compared to physical modalities, back school and conventional exercises. The group trained in isokinetic equipment presented the lowest rates of recurrence and the greatest rates of return to work in a 5-year follow-up. Some examples of postural exercises for the chief static imbalances will be given. We know that backaches are commonly associated with neural compressions, i.e., herniated discs and arthroses. These elements are usually what bring on the imbalances. In order to control these problems a thorough knowledge of their correction is necessary, utilizing well-oriented and specific exercises indicated by qualified professionals. Among the more common alterations are hyperlordoses, kyphoses, scolioses and flat back.

I. LUMBAR HYPERLORDOSIS

A balanced lordosis is one in which the pubic symphysis is aligned with the mentonian symphysis (Mezieres occipito-scapulo-sacral alignment). It is normally considered a compensation curve.

Lumbar hyperlordosis is the compensation of a static postural imbalance, caused by ascending or descending alterations. These determine biomechanical vertebral modifications, bearing in mind that pelvic anteversion and lumbar lordosis go hand in hand. When the problem is in an ascending direction, i.e., imbalances that begin from the lower limbs (for example, flat feet in which there is inadequate support of the feet on the ground causing internal rotation of the knees or external rotation of the tibia, bilaterally and whose compensation leads to internal rotation of the femur), result in primary pelvic anteversion and compensation of this imbalance (Fig. 1) will lead to lumbar lordosis.

On the other hand, pelvic anteversion is also possible due to weakness of the muscles of retroversion (oblique fibers of the gluteus major and the pyriform) (Fig. 2). Several causes for the problem in a descending direction, (i.e., lumbar lordosis is primary, followed by pelvic anteversion) are:

- Lack of tonicity of the gluteal muscles with hypertonia of the psoas muscle.
- Contraction of the lumbar muscles with retraction of the tonic part of the psoas.
- Spondylolisthesis due to rupture of the isthmus of L5 (anomaly of the lumbo-sacral transition).

II. KYPHOSIS AND LUMBAR FLATTENING

Kyphosis and lumbar flattening are almost always pathological and not just a compensation of static postural imbalance.

When the alteration occurs in a descending direction, in the case of a flat dorsum, compensation takes the form of lumbar flattening (Fig. 3).

Kyphosis occur when the problem is in an ascending direction or in the lumbar region itself, in cases of thigh-femoral anomaly or fractures with anterior flattening of the lumbar vertebrae (at L1, L2 levels).

III. LUMBAR SCOLIOSIS

These are usually ascending processes due to rotational imbalance of the lower limbs that produce compensations in horizontal pelvic rotation. Minor differences in length between lower limbs that cause frontal pelvic imbalance are also possible (Figs. 4A & 4B).

Although exercise programmes may play an important part in muscle strengthening and prevention of future or recurrent injuries, there may also be important psychological benefits. Patients with low back pain may have a "fear" of exercising, and a supervised programme may allay this fear and encourage these patients to develop increased strength and the ability to participate in functional activities. Ideally, a programme of supervised aerobic activity should be recommended, because of the link between aerobic activity and endogenous opiates, with potential benefits on depressive symptoms.

EXERCISES FOR POSTURE CORRECTION

I. LUMBAR HYPERLORDOSIS

The following muscles should be limbered up gluteus (Fig. 5), paravertebral (Fig. 6), iliopsoas (Fig. 7), pyriform (Fig. 8) and the anterior muscular chain (Fig. 9), scalene, intercostal, diaphragmatic, and abductor muscles, the psoas, and anterior leg muscles).

II. KYPHOSIS AND LUMBAR FLATTENING

The following muscles must be well limbered: paravertebral (Fig. 10) and the ischiotibial muscles (Fig. 11) and the posterior muscular chain (Fig. 12), sural triceps, ischiotibial and deep muscles of the hips and posterior paravertebrals).

III. LUMBAR SCOLIOSIS

It is important to correct the frontal (Fig. 13) and rotational (Fig. 14) imbalance of the pelvis.

REFERENCES:

Asfour S, Khalil TM, Waly SM, Goldenberg ML, Rosomoff RS & Rosomoff HL. *Biofeedback in back muscle strengthening.* Spine, 15:510-513, 1990.

Bienfait M. Os *desequilíbrios estáticos.* São Paulo, Summus Editorial, 1995.

Bookhout M. *Exercise as an adjunct to manual therapy.* Educational Seminar, Minnesota, American Physical Therapy Association, 1996.

Borenstein D. *Epidemiology, etiology, diagnostic evaluation, and treatment of low back pain.* Current Opinion in Rheumatology, 8:124-129, 1996.

Borenstein D. *Epidemiology, etiology, diagnostic evaluation, and treatment of low back pain.* Current Opinion in Rheumatology, 10:104-109, 1998.

Daltroy LH, Iversen MD, Larson MG, Lew R, Wright E, Ryan J, Zwerling C, Fossel H & Liang MH. *A controlled trial of educational programme to prevent low back pain injuries.* N Engl J Med, 337:322-328, 1997.

Denys-Struyf G. *Cadeias musculares e articulares.* São Paulo, Summus Editorial, 1995.

Ehrlich, GE. *Total management of the arthritic patient.* Referral resources: Rheumatologists, special centres, and physical therapy. In: Ehrlich GE, (ed), Philadelphia, JB Lippincott, 1973, p. 209-222.

Faas A, Van Eijk JTM, Chavannes AW & Guybbels JW. *A randomized trial of exercise therapy in patients with acute low back pain: efficacy in sickness absence.* Spine, 20:940-947, 1995.

Gerber LH & Hicks JE. *Rehabilitative management of rheumatic diseases.* In: Hicks JE, Nicholas JJ & Swezey RL. (eds.). Handbook of rehabilitative rheumatology. Atlanta, American Rheumatism Asssociation, 1988, p. 81-110.

Graves JE, Pollock ML, Foster D, Leggett SH, Carpenter DM, Vuoso R & Jones A. *Effect of training frequency and specificity on isometric lumbar extension strength.* Spine, 15:1272-1279, 1990.

Hicks JE & Nicholas JJ. *Treatments utilized in rehabilitative rheumatology.* In: Hicks JE, Nicholas JJ & Swezey RL. (eds.). Handbook of rehabilitative rheumatology. Atlanta, American Rheumatism Association, 1988, p.31-79.

Hides JA, Richardson CA & Jull GA. *Multifidus muscle recovery is not automatic after resolution of acute, first episode low back pain.* Spine, 21:2763-2769, 1996.

Kellett KM, Kellet DA & Nordholm LA. - *Effects of an exercise programme on sick leave due to back pain.* Phys Ther, 71:283-293, 1991.

Kraus H. *Muscle deficiency.* In: Rachlin ES. (ed.). Myofascial pain and fybromialgia. St.Louis, Mosby, 1994, p.385-414.

Lahad A, Malter AD, Berg AO & Deyo RA. *The effectiveness of four interventions for the prevention of low back pain.* JAMA, 272:1286-1291, 1994.

Malmivaara A, Sakkinen U, Aro T, Heinrichs ML, Koskenniem L, Kuosma E et al *The treatment of acute low back pain – bed rest, exercise, or ordinary activity?* N Engl J Med, 332:351-355, 1995.

Mayer TG, Smith SS, Keeley J & Mooney V. *Quantification of lumbar function Part 2: Sagital plane strength in chronic low-back pain patients.* Spine, 10:765-772, 1985.

Mayer TG, Vanharanta H, Gatchel RJ, Mooney V, Barnes D, Judge L, Smith S & Terry A. *Comparison of CT scan muscle measurements and isokinetic trunk strength in postoperative patients.* Spine, 14:33-36, 1989.

Medeiros L. *Reabilitação das lombalgias.* Arq. Fisiatria, 35: 85-92, 1996.

Meenan R. *Disability.* In: Hicks JE, Nicholas JJ & Swezey RL, (eds.). Handbook of rehabilitative rheumatology. Atlanta, American Rheumatism Association, 1988. p. 149-165.

Piret S & Béziers MM. *A coordenação motora: aspecto mecânico da organização psicomotora do homem.* São Paulo, Summus Editorial, 1992

Rissanen A, Kalimo H & Alaranta H. *Effect of intensive training on the isokinetic strength and structure of lumbar muscles in patients with chronic low back pain.* Spine, 20:333-340, 1995.

Roland M & Dixon M. *Randomized controlled trial of an educational booklet for patients presenting with low back pain in general practice.* J R Coll Gen Pract, 337:322-328, 1989.

Scheer SJ, Radack KL & O'Brien DR Jr. *Review article: randomized controlled trials in industrial low back pain relating to return to work. Part 1. Acute interventions.* Arch Phys Med Rehabil, 76:966-973, 1995.

Scheer SJ, Robinson RD & Weinstein SM. *Industrial rehabilitation medicine. 2. Case studies in occupational low back pain.* Arch Phys Med Rehabil, 78:S-10—S15, 1997.

Shealy CN & Mauldin CC Jr. *Modern medical electricity in the management of pain.* Phys Med Rehabil Clin North Am, 4:175-186, 1993.

Souchard Ph.E. *O stretching global ativo: a reeducação postural global a serviço do esporte.* São Paulo, Manole Editora, 1996.

Timm KE. *Case studies: use of the Cybex® trunk extension flexion unit in the rehabilitation of back patients.* J Orthop Sports Phys Ther, 8:578-581, 1987.

Timm KE. *Management of the chronic low-back pain patient: a retrospective analysis of different treatment approaches.* Isokinetics Exerc Sci, 5:43-49, 1995.

Turner JA, Deijo RA, Loeser JD, Vonkorff M & Fordyce WE. *The importance of placebo in pain - treatment and research.* JAMA, 271:1609-1614, 1994.

Van den Hoogen HJM, Koes BW, Deville W, van Eijk JTM & Bouter LM. *The prognosis of low back pain in general practice.* Spine, 22:1515-1521, 1997.

van Tulder MW, Koes BW, Bouter LM & Metsemakers JFM. *Management of chronic non-specific low back pain in primary care: a descriptive study.* Spine, 22:76- 82, 1997.

Weber DC & Brown AW. *Physical agent modalities.* In: Braddom, RL (ed.). Physical medicine and rehabilitation. Philadelphia, WB Saunders, 1996. p.449-463.

ACKNOWLEDGEMENT

* We would like to express our gratitude to Miss Ester Leite Ribeiro Bueno, for her invaluable Cupertino with the drawings.

TEXT OF THE FIGURES

Figure 1 - Aspect of the secondary lumbar hyperlordosis as a result of the lower limbs imbalances.

Figure 2 - Primary lumbar hyperlordosis associated to the weakness of the pelvis' retorversor muscles.

Figure 3 - Lumbar retification as consequence of dorsal straight alteration.

Figures 4A and 4B - Postures of rotational (A) and frontal (B) pelvic compensations, which are determined by ascending lumbar scoliosis.

Figure 5 - With feet on the floor, bend the knees. Lift the hips keeping the gluteal muscles contracted for 15 seconds.

Figure 6 - On your knees, sit on your heels, with palms on the floor stretch the upper limbs frontally.

Figure 7 - Lie on a table, bend one of your legs and let the other leg dangle over the table. With one hand, the therapist stabilizes the hip and with the other, forces the knee of the extended leg downward.

Figure 8 - Stretch legs out on the floor, bring one of them toward the abdomen, supporting one of the hands on the ankle (the tibia remains perpendicular to the trunk).

Figure 9 - Anterior muscular chain.

Figure 10 - While lying on a firm surface, place four balls under the lumbosacral region, carrying out rhythmic motions of lifting and lowering the pelvis while alternately contracting and relaxing the abdominal muscles. In the same position rotate the pelvis, alternately to the right and to the left.

Figure 11 - While lying on a firm surface, keep the left leg extended on the floor, raise the right leg and hold it behind the knee, with flexing the foot. Repeat the same exercise on the other side.

Figure 12 - Posterior muscle chain.

Figure 13 - Lie down on a large roll of hard foam rubber, attempting to invert the lateral curve and stretch the contralateral paravertebral muscles. Use respiration to aid in stretching.

Figure 14 - Lie down and gradually raise the legs upward, clasping them at the waist, maintaining flexion of the feet; the hips are supported on the floor, and the arms are raised.

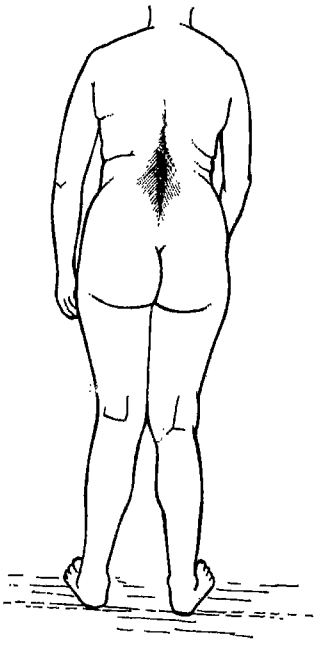


Figure 1

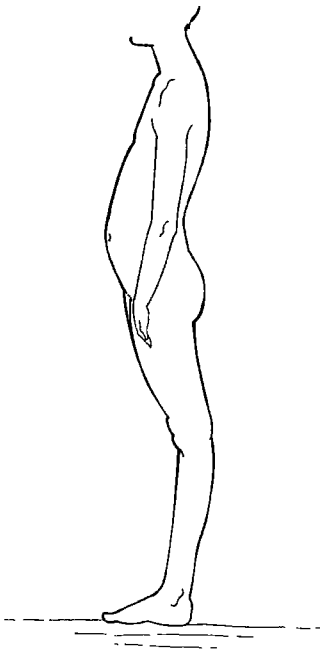


Figure 2

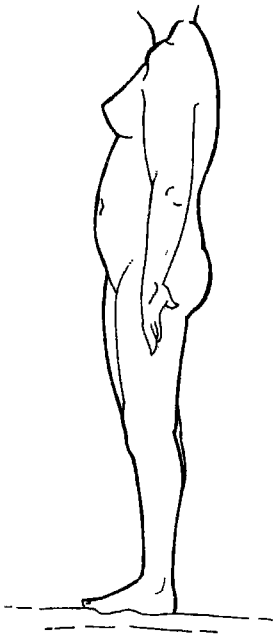


Figure 3

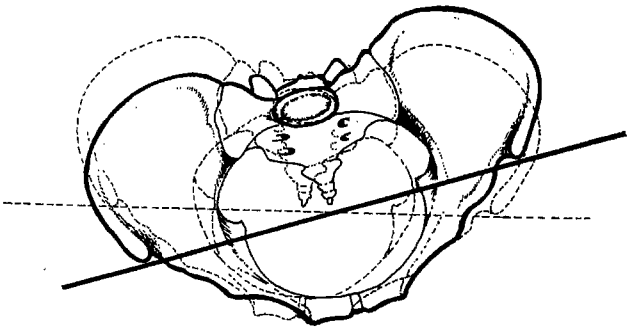


Figure 4A

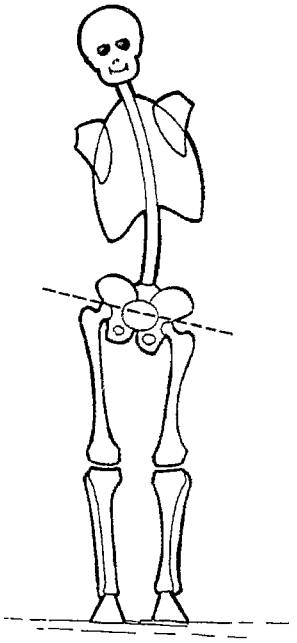


Figure 4B

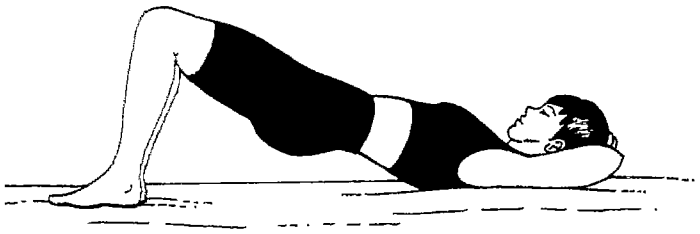


Figure 5

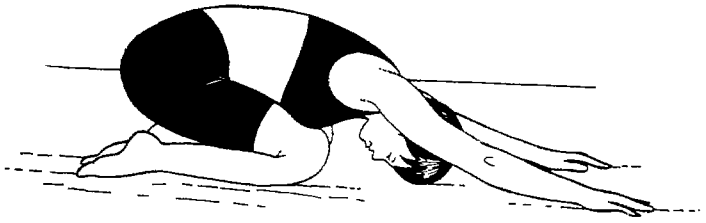


Figure 6

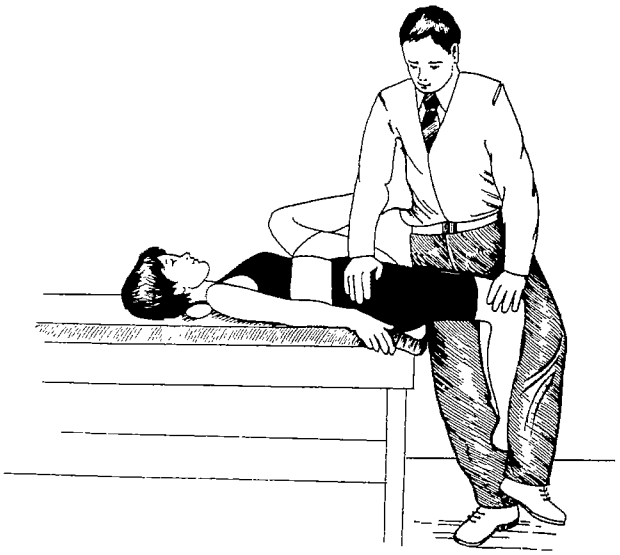


Figure 7

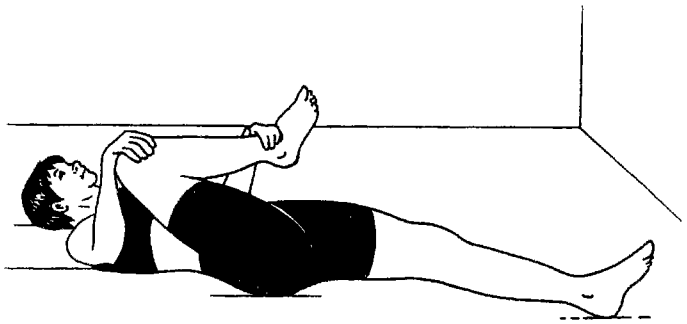


Figure 8

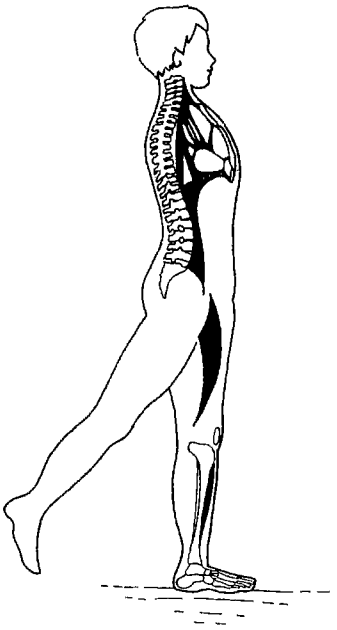


Figure 9

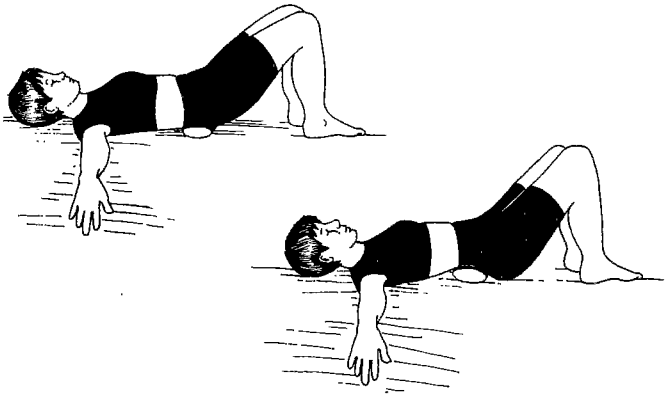


Figure 10

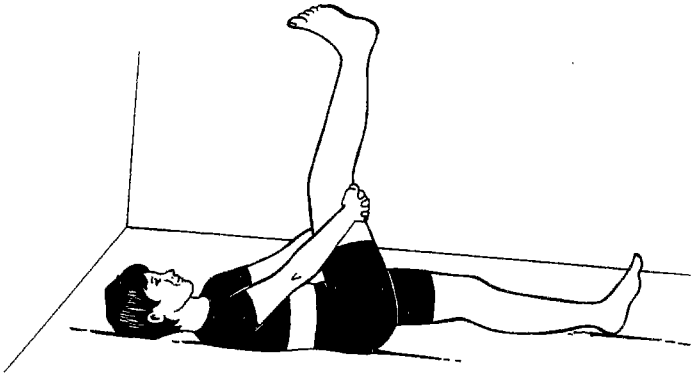


Figure 11

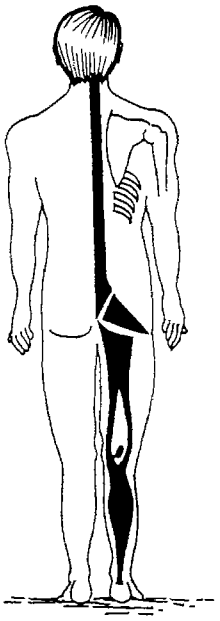


Figure 12

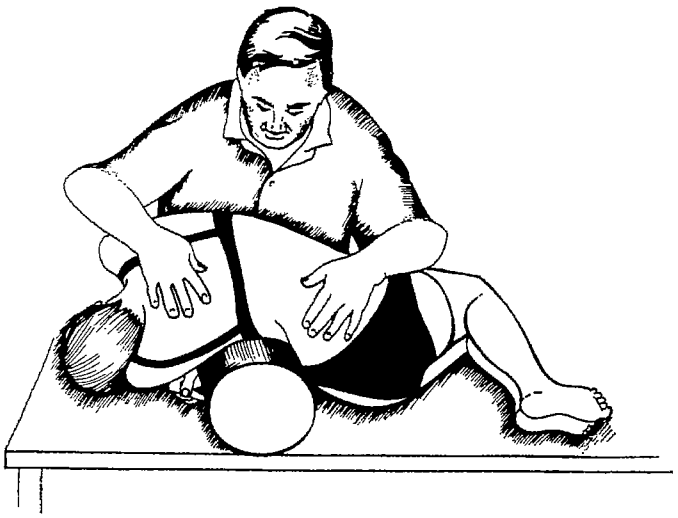


Figure 13

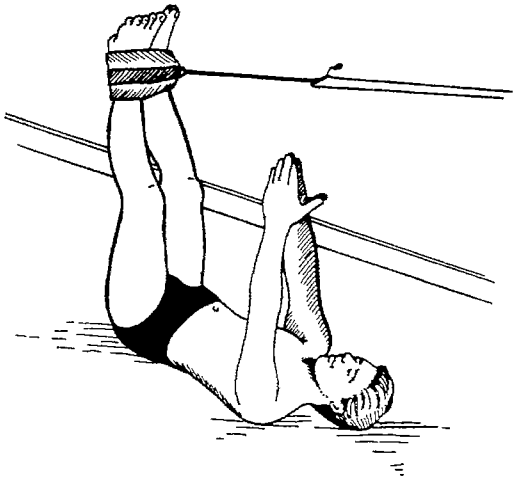


Figure 14

6. TREATMENT OF PATIENTS WITH LOW BACK PAIN USING SPA THERAPY

Professor C.F. Roques
(Professor of Physical Medicine & Rehabilitation, Paul-Sabatier University
Head, PMR Department, University Hospital, Toulouse, France)

SUMMARY

SPA therapy in randomized clinical trials (RCT) showed a significant reduction of the pain and drug consumption, an improvement of quality of life and disability in low back pain (LBP) patients. The superiority of SPA treatments versus similar conventional treatments has still to be established for LBP patients. The study of the specificity of the different thermo-mineral therapeutic products is still to be carried out; and the traditional specificity of sulphur or salt thermo-mineral products in the treatment of joint disorders has to be confirmed by RCT. The follow-up period for the RCT should be at least one year, to establish the effectiveness of the SPA therapy versus conventional similar or routine drug treatments. Manipulations (if necessary and possible), back school education and exercise therapy programmes could be easily undertaken during a SPA resort session which usually lasts for 3 weeks. SPA therapy and global management in SPA resort could be particularly beneficial for the patients who present some of the following criteria: disability or decreased quality of life due to LBP, occupational or familial integration disturbances due to LBP, contra-indications or excessive NSAID drugs consumption, lack of proximity of facilities for physical therapy and/or back school programmes.

INTRODUCTION

Low back pain is a very common clinical condition. A high life-lasting prevalence, an increasing cost, and a reduction of the quality of life of the involved patients characterises this major public health problem in industrialized countries. But LBP is such a particular clinical situation that the main symptom gives its name to this morbid condition. A more rational approach has been developed for the last years mainly based on the analysis of controlled studies. The WHO recently (1994) established methodological recommendations for a comprehensive approach to LBP treatment. Guidelines have been recently established in the Pannel of the American Health Care Policy and Research (Bigos SJ, Bowyer O, 1994) following the Canadian experience (Quebec Task Force on Spinal Disorders, 1987). Papers have recently investigated the Randomized Controlled Studies (RCT) (Koes BW et al, 1991; Koes BW, Scholten RJPM, Mens JMA, Bouter LM, 1995; Koes BW, Van Tulder MW, Van Der Windt WM, Bouter LM, 1994, Van Tulder MW, Koes BW, Bouter LM, 1997) but these papers never discussed the potential benefit of SPA therapy for patients with LBP. Nevertheless recent papers reporting RCT have demonstrated the interest of SPA therapy in the treatment of patients with LBP (Constant F, Collin JF, Guillemin F, Boulangé M, 1995; Guillemin F, Constant F, Collin JF, Boulangé M, 1994; Konrad K, Tatrai T, Hunka A, Vereckei E, Korondi I, 1992; Nguyen, M, Revel M, Dougados M, 1997). Therefore the purpose of this paper is to present the main scientific data obtained from these RCT in order to discuss the validity of these investigations and try to establish the position of the SPA therapy in the comprehensive management of LBP patients.

Methodology

The international medical literature was investigated using the Medline database (key words: spa therapy, health resort, low back pain, rheumatic diseases, randomized controlled trials). The methodological quality was verified according to the criteria established by the WHO and the quality score was measured using the Koe's criteria (Table I) (Koes BW et al, 1991) and the score (maximum 100) was established for the different studies (a high level of quality needs a minimum score of 50) (Koes BW, Bouter LM, Van der Heijden GJMH, 1995). Particular attention was paid to a) the number of the

patients; b) the specifics of the mineral treatment (number, frequency, duration of the sessions; therapeutic techniques used); c) the assessment tools used and the unawareness or masking of the practitioner who performed the assessment; and d) the statistics tests used.

RESULTS

Four controlled studies were found in the Medline database and analyzed. The number of papers was limited and therefore also the number of patients treated, but the population studied, the therapeutic and assessment techniques undertaken and the results obtained were quite similar and homogeneous (Table 2). The quality of the studies (Table 3) was high, as the scores were 50 and more. The spa treatment consisted mainly of hot mineral balneotherapy, used in all cases, and in mudpacks, massages, showers; the patients treated were compared to patients receiving routine drug treatment. The duration of the treatment was 3 to 4 weeks; the treatment was either daily or three times a week. In all the cases the pain reduction was assessed using the Huskisson's Visual Analogue scale and the drug consumption was measured by the number of tablets taken by the patients. Disability questionnaires, quality of life measurements, and lumbar stiffness measurements were also investigated. The statistical tests performed were in line with the data and the populations investigated, so we can conclude that these papers followed the WHO recommendations.

Globally, the results of the spa treatments were positive as LBP patients showed at the end of the treatment and at the follow-up assessments a significant reduction of the pain and drug consumption, an improvement of quality of life and disability, and a reduction of lumbar stiffness.

DISCUSSION

SPECIFICITY OF SPA TREATMENT

Actually, these studies demonstrated the efficiency of a physical treatment (hot balneotherapy, mudpacks, massages, showers, etc.) performed with mineral resources and delivered in a SPA resort to LBP patients. But these studies did not investigate the specificity of mineral techniques versus similar conventional techniques (tap-water baths, usual therapeutic muds). In the case of patients suffering from rheumatoid arthritis, Sukenik et al (1990) demonstrated the superiority of Dead Sea bath versus salt tap-water baths and the superiority of Dead Sea mudpacks versus conventional mudpacks (Sukenik S, Buskila D, Neumann L, Kleiner-Baumgarten A, 1992). In the case of patients suffering from osteoarthritis of the knee, Szucs (et al, 1989) and Wigler (et al, 1995) both demonstrated the superiority of SPA treatment versus similar conventional physical treatments (balneotherapy, mudpacks). Kranjc I, Turk Z (1992) observed, with LBP patients, the superiority of spa treatment over the similar conventional physical treatment but this investigation cannot be accepted, as the study suffered from a lack of randomization and as the population groups were different (age, occupation, severity of the symptoms). So, the superiority of spa treatments over similar conventional treatments has still to be established for LBP patients. This superiority can be assessed in term of health benefit or in term of cost/benefit ratio. The study of the specificity of the different thermo-mineral therapeutic products is still to be carried out; and the traditional specificity of sulphur or salt thermo-mineral products in the treatment of arthritic conditions has to be confirmed by RCT.

OCCUPATIONAL ASPECTS

LBP has very strong occupational consequences. This has not been considered in the papers published as none paid attention to the occupational status of the patients treated. This aspect needs further investigation.

LONG-TERM EFFICIENCY

The studies published showed the efficiency of spa therapy at the end of the treatment and for a follow-up period of 6, 9, 12 months. But such a period may be too short for such a chronic condition. Some patients treated were suffering back pain for one year or more when they were included in the study. So the minimum follow-up period should be one year to assess the patients; such a period would also permit the renewal of spa therapy, which is usually performed yearly, for a period of three or four years. The long-term efficiency could be assessed by pain measurements, quality of life improvement, health goods consumption reduction, and occupational integration measurements.

PARADIGM OF INVESTIGATION OF SPA THERAPY IN LBP

From the four papers we also observed the lack of an unanimously accepted and used paradigm of investigation of spa therapy in LBP. The assessment can be easily determined and so also the duration of the treatment. But the standardization of the treatments needs more development. The consequences and the modalities of the randomization have to be considered as they have ethical and practical consequences, but also as they introduce biases. The postponement of spa treatment to six months (Constant F, Collin JF, Guillemin F, Boulangé M, 1995; Guillemin F, Constant F, Collin JF, Boulangé M, 1994) is ethically and practically well accepted by the patients but it does not offer a sufficient minimum observation period of the control group.

SPA THERAPY AND THE COMPREHENSIVE CONSERVATIVE TREATMENT OF LBP

Recent papers investigated the different RCT of conservative treatment of low back pain (Koes BW et al, 1991; Koes BW, Scholten RJPM, Mens JMA, Bouter LM, 1995; Koes BW, Van Tulder MW, Van Der Windt WM, Bouter LM, 1994; Van Tulder MW, Koes BW, Bouter LM, 1997) and/or the daily utilization of these resources (Boden SD, Dreyer SJ, Levy HI, 1998; Rosen NB, Hoffberg HJ, 1998). "Strong evidence was found for the effectiveness of muscle relaxants and non-steroidal anti-inflammatory drugs and the ineffectiveness of exercise therapy in acute low back-pain; strong evidence also was found for the effectiveness of manipulations, back schools, and exercise therapy for chronic low back pain, especially for short-term effects" (Van Tulder MW, Koes BW, Bouter LM, 1997). The effectiveness (or ineffectiveness) of steroid injections, bed rest, transcutaneous electrical nerve stimulation, tractions, orthoses, behaviour therapy, and acupuncture need further investigation. The quality level of the future investigation should be increased as quality level of the analyzed RCT was insufficient: only 35% of the RCT of treatment of acute LBP and 25% of the RCT of treatment of LBP had a Koe's score of 50 and more (Koes BW, Bouter LM, Van der Heijden GJMH, 1995).

Trained practitioners can easily perform spinal manipulation if necessary and when the lack of contra-indications has been clearly established. Back school education is potentially beneficial for all the LBP patients. In spa resorts, the presence of qualified therapists makes it easy to organize back school programmes. And the great number of patients, gathered in the resort, enables to achieve homogeneous therapeutic groups. Some particular patients treated in the resorts could also benefit from an exercise therapy programme; the duration of the stay is however not sufficient to achieve such therapeutic programmes which need more time; but the patients could be instructed in the way of a self-continuous exercise therapy programme. Manipulations (if necessary and possible), back school education and exercise therapy programmes could so be easily undertaken during a spa resort session which usually lasts for 3 weeks.

Spa therapy and global management in a spa resort could be particularly beneficial for the patients who present some of the following criteria: disability or decreased quality of life due to LBP, occupational

or familial integration disturbances due to LBP, contra-indications or excessive NSAID drugs consumption, lack of proximity of facilities of physical therapy and/or back school programmes.

CONCLUSION

Spa therapy clinically improves LBP patients on a short and medium term. But the superiority of mineral products versus conventional similar products has still to be established for LBP patients. The SPA treatment, which also needs more standardization, could be advantageously completed by other beneficial treatments such as back school programmes and exercise therapy. The follow-up period for the RCT should be at least one year, to establish the effectiveness of the spa therapy versus conventional similar or routine drug treatments.

REFERENCES:

Bigos SJ, Bowyer O. *Acute low back pain in adults. Practical guideline* 14. Agency for Health Care Policy and Research Public Health Service, US Department for Health and Human Services, 1994.

Boden SD, Dreyer SJ, Levy HI. *Management of low back pain.* Phys Med Rehabil Clin North America, 1998, 9:419-433.

Constant F, Collin JF, Guillemin F, Boulangé M. *Effectiveness of Spa Therapy in chronic low back pain: a randomized clinical trial.* J Rheumatol, 1995, 22:1315-1320.

Guillemin F, Constant F, Collin JF, Boulangé M. *Short and long-term effect of spa therapy in chronic low back pain.* Br J Rheumatol, 1994, 33:148-151.

Koes BW, Bouter LM, Beckerman H, Van der Heijden GJMG, Knipschild PG. *Physiotherapy exercises and back pain: a blinded review.* BMJ, 1991, 302:1572-1576.

Koes BW, Bouter LM, Van der Heijden GJMG. *Methodological quality of randomized clinical trials on treatment efficacy in low back pain.* Spine, 1995, 20:228-235.

Koes BW, Scholten RJPM, Mens JMA, Bouter LM. *Efficacy of epidural steroid injections for low back pain and sciatica: a systematic review of randomized clinical trials.* Pain, 1995, 63:279-288.

Koes BW, Van Tulder MW, Van Der Windt WM, Bouter LM. *The efficacy of back schools: a review of randomized clinical trials.* J Clin Epidemiol, 1994, 47:851-862.

Konrad K, Tatrai T, Hunka A, Vereckei E, Korondi I. *Controlled trial of balneotherapy in treatment of low back pain.* Ann Rheum Dis, 1992, 51:820-822.

Kranjc I, Turk Z. *Results of a comparative study of the success of treatment of pain in the lumbar spine at the Moravske Toplice health spa, at the department of physical therapy and rehabilitation and at the department of rheumatology of the Maribor teaching hospital.* Reumatizam, 1992, 39:33-37.

Nguyen M, Revel M, Dougados M. *Prolonged effects of 3 week herapy in a spa resort on lumbar spine, knee and hip osteo-arthritis: follow-up after six months. A randomized controlled trial.* Br J Rheumatol, 1997, 36:77-81.

Quebec Task Force on Spinal Disorders. *Scientific approach to the assessment and management of activity related disorders.* Spine, 1987, 12(7s):s1-s59.

Rosen NB, Hoffberg HJ. *Conservative management of low back pain.* Phys Med Rehabil Clin North America, 1998, 9:435-472.

Sukenik S, Neumann L, Buskila D, Kleiner-Baumgarten A, Zimlicham S, Horowitz J. *Dead Sea bath salts for the treatment of rheumatoid arthritis.* Clin Exp Rheumatol, 1990, 8:353-357.

Sukenik S, Buskila D, Neumann L, Kleiner-Baumgarten A. *Mud pack therapy in rheumatoid arthritis.* Clin Rheumatol, 1992, 11:243-247.

Szucs L, Ratko I, Lesko T, Szoor I, Genti G, Balint G. *Double blind trial on the effectiveness of the Puspokladany thermal water on arthrosis of the knee-joints.* J R Soc Health, 1989, 109:7-9.

Van Tulder MW, Koes BW, Bouter LM. *Conservative treatment of acute and chronic non-specific low back pain.* Spine, 1997, 22:2128-2156.

Wigler I, Elkayam O, Paran D, Yaron M. *Spa therapy for gonarthrosis: a prospective study.* Rheumatol Int, 1995, 15:65-68.

Table I

Criteria List for a Methodologic Assessment of Randomized Clinical Trials of Physiotherapy Exercises for Back Complaints

(Koes BW et al, 1991; Koes BW, Bouter LM, Van der Heijden GJMH, 1995)
Maximum total score: 100 points

A - Description of inclusion and exclusion criteria (1 point). Restriction to a homogeneous study population (1 point).

B - Comparability of relevant baseline characteristics : duration of complaints, value of outcome measures, age, recurrences, and radiating complaints (1 point each)

C - Randomization procedure described (2 points) and excludes bias (2 points)

D - Drop-outs described for each study group separately, including reason for withdrawal (3 points).

E - Loss to follow-up : < 20 % loss to follow-up (2 points) ; loss to follow-up < 10 % (2 points).

F - > 50 subjects in the smallest group immediately after randomization (8 points) ; > 100 subjects (9 points). Interventions (25 points).

G - Physiotherapy treatment protocol established and described (5 points). All reference treatments put in a protocol and described (5 points).

H - Pragmatic study : Comparison with other treatment modality (5 points).

I - Co-interventions avoided in the design of the study (5 points)

J - Placebo-controlled : Comparison with placebo therapy (5 points). Measurement of effect (30 points).

K - Patients blinded, placebo-controlled : attemp at blindind (3 points) ; blinding evaluated and fully successful (2 points). Pragmatic study : Patients fully naive (3 points) ; time restriction (no physiotherapy exercises for at least 1 year ; 2 points) ; naive-nesse evaluated and fully successful (2 points).

L - Use (measured and reported) of pain, global measure of improvement, functional status (activities of daily living), spinal mobility, medical consumption (2 points each).

M- Each blinded measurement mentioned under point L earns (2 points).

N - Moment of measurement during or just after treatment (3 points) and after 6 months or longer (2 points). Data presentation and analysis (10 points).

O - Intention-to-treat analysis when loss to follow-up is less than 10 %. When loss to follow-up > 10 % : intention-to-treat and worst-case analysis that accounts for missing values (5 points).

P - Frequencies of most important outcomes presented for each treatment group. In the case of (semi) continuous variables : Presentation of the mean or median with a standard error of percentiles (5 points).

Table 2

Number of Patients				Diagnosis	Treatment		Statistics	Outcome	Results
	Spa.	Control	Drop-out		Spa.	Control		Measurements	
Konrad (9)	35	53	12	LBP	Bath	NSAID	Chi square	Pain	End of treatment - 1 year
				(3 months)	15 mn		paired-t-test	(VAS)	reduction of:
				±					•pain
				Sciatica	3/week			drug consumption	•drug consumption
					4 weeks				
Guillemin (4)	52	52	6	LBP	Bath 15 mn	Routine	Chi square	•pain	End of treatment - 9 months
				1 year	Shower 3mn	Drug		VAS	Reduction of:
					6/week	Therapy	t-test	daily duration	•pain
					3 weeks			•lumbar stiffness	•lumbar stiffness
								finger tip floor	•drug consumption
								Schober	
								•Waddell disab.	
								questionnaire	
								•drug consumption	

Table 2 cont.

Number of Patients				Diagnosis	Treatment		Statistics	Outcome	Results
	Spa.	Control	Drop-out		Spa.	Control		Measurements	
Constant (3)	63	63	5	LBP	Bath 10 mn	Routine	Chi square	•Pain	End of treatment - 6 months
				1 year	mud pack 20 mn	Drug	t-test	VAS	reduction of:
				Sciatica	Shower 2.5 mn	Therapy	Ancova	daily duration	•pain
				Excluded	6/week			•Lumbar stiffness	•Lumbar stiffness
					3 weeks			finger tip floor	•disability
								Schober	•drug consumption
								•Roland Morris	
								disab. quest.	
								•drug consumption	
Nguyen (11)	46	49	4	LBP	Bath	Routine	Chi square	•Pain	End of treatment - 6 months
				1 month	6/week	Drug	paired-t-test	VAS	Reduction of:
				Scatica	3 weeks	± physical	analysis	Lumbar stiffness	•pain
				Excluded		Therapy	of variance	•Waddell disab. quest.	•drug consumption
								•AIMS	improvement of quality life
								•drug consumption	

Table 3. Quality of the studies
(Koes BW et al, 1991; Koes BW, Bouter LM, Van der Heijden GJMH, 1995)

Items	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Total Score
Max. Theor. Score	2	5	4	3	4	17	10	5	5	5	5	10	10	5	5	5	100
Konrad (9)	1	3	2	0	4	0	10	5	5	0	0	6	6	5	5	0	52
Guillemin (4)	2	3	4	3	4	8	5	5	5	0	2	8	8	5	5	0	67
Constant (3)	2	3	4	3	4	8	5	5	5	0	2	10	10	5	5	0	71
Nguyen (11)	1	3	4	3	4	0	5	5	0	0	2	8	8	5	5	0	51

7. DESIGN OF A RANDOMIZED CLINICAL TRIAL USING CHIROPRACTIC VERSUS MEDICAL CARE AND RESULTS FROM CHIROPRACTIC TRIALS

Professor Kathryn T. Hoiriis; Professor Bruce Pfleger; Frederic C. McDuffie, M.D.; Medhat Alattar, M.B.B.Ch, D.C., M.S.; Edward F. Owens, M.S., D.C.; Susan Brown, Ph.D., D.C. (Life University, Marietta, Georgia, USA)

DESIGN OF A RANDOMIZED CLINICAL TRIAL

BACKGROUND

Debilitating low back pain (LBP) is a widespread problem in the adult population, and therefore, has become a major concern of health care providers worldwide. The general population has a lifetime estimate of 60-80% while 20% - 30% suffer from it at any given time. Allan and Waddell state that backache is almost universal (Allan and Waddell, 1989; Waddell, 1996). The high incidence is costly, socially and economically. The cost per episode of acute low back pain, based on charges from primary care providers, ranges from $435 to $783 (Carey et al, 1995). The possibility of simple back pain developing into chronic, disabling back pain is of great concern. Waddell (1996) reports that from 1955 to 1995, the number of days of work missed due to chronic low back disability has increased exponentially.

Back pain is often classified as either acute or chronic. Acute back pain is expected to resolve in 1-2 weeks, while chronic pain can be classified as lasting longer than 3 months, based on duration of an initial episode. Often, back pain is not confined to a single episode, but becomes recurrent (Von Korff and Saunders, 1996). A more specific, less studied classification of low back pain patients are those which may be labeled subacute. These patients have failed to recover during the 1-2 week acute stage, but have not yet entered the chronic or recurrent stages.

Many interventions have been used for all types of low back pain. Physical therapy utilizing mobilization and electrical modalities, medical therapy in the form of prescription and non-prescription drugs, back school, exercise, corsets, ice packs, bed-rest, manipulation, and chiropractic adjustments are among the many interventions used for low back pain (Brennan et al, 1994; Bronfort et al, 1996; Bronfort, 1989; Cote et al, 1994; Cramer et al, 1993; Godfrey et al, 1984; Berquist-Ullman and Larsson, 1977; Coxhead et al, 1981; Farrell and Twoomey, 1982; Gibson et al, 1985; Glover et al, 1974; Hadler et al, 1987; Hoehler et al, 1981; MacDonald and Bell, 1990; Mathews et al, 1987; Nwuga, 1982; Waterworth and Hunter, 1985; Zylbergold and Piper, 1981; Gemmell and Jacobsen, 1995; Pope et al, 1994; Postacchinni et al, 1988; Sanders et al, 1990; Meade et al, 1990; Triano et al, 1995).
A notable study comparing chiropractic care to hospital outpatient treatment for mechanical low back pain was reported in 1990 by Meade et al. The Oswestry pain disability questionnaire, straight leg raise and lumbar flexion were used as outcome measures for 741 patients randomized into groups at 11 chiropractic and hospital outpatients centres. Patients were monitored over a maximum of two years. Patient care was provided by chiropractors or by hospital staff. Results showed chiropractic care was more effective than hospital care in management of chronic or severe back pain especially over the long term. In addition, the study suggested that chiropractic care was more cost-effective than hospital out-patient treatment for back pain.

After a review of clinical and related research from 1974 through 1992 on the effectiveness of manipulation for LBP, Manga et al (1993) found that spinal care provided by chiropractors is more effective than any alternative intervention. The alternative interventions considered were manipulation by physiotherapists, electrical modalities, analgesics, exercise, corsets, heat, bed rest and massage. Other reviews found chiropractic care to be consistently more effective than comparitive interventions

(Anderson et al, 1992; Shekelle et al, 1992). Furthermore, there are studies which have shown chiropractic care to be a cost-effective and safe method of care for back pain (Meade et al, 1990; Carey et al, 1995; Johnson et al, 1989).

Koes et al (1993, 1996) conclude that the efficacy of manipulation for patients with acute LBP has not been convincingly demonstrated with sound randomized clinical trials (RCT). They further state that there has been no adequate demonstration of effectiveness in chronic pain sufferers. However, they do acknowledge there is an indication that manipulation might be effective for some subgroups of patients with low back pain, thereby justifying additional research efforts.

In 1994, the Agency for Health Care Policy and Research (AHCPR) of the U.S. Department of Health and Human Services, Public Health Service, released a report in which a twenty-three member panel performed an evaluation of published scientific evidence on LBP management (Bigos et al, 1994). This panel used pain of less than three months duration as a definition of acute LBP. The panel found that relief of discomfort could be accomplished most safely with non-prescription medication and/or spinal manipulation. The panel also recommended the use of muscle relaxants, but mentioned that up to 30% of the subjects might experience side effects (drowsiness). The AHCPR panel found no evidence of benefit from physical agents/modalities such as ice, heat, massage, traction, ultrasound, cutaneous laser treatment, transcutaneous electrical nerve stimulation (TENS), and biofeedback techniques. They also did not support trigger point, ligamentous, and facet joint injections nor the use of acupuncture.

The AHCPR panel commented that the methodology of chiropractic and other manipulative therapy studies suffered because of inadequate descriptions of baseline, demographic, and clinical characteristics (Bigos et al, 1994). Further, few studies used control groups and sample sizes were large enough to provide statistical power.

Anderson et al (1992) were also concerned that true control groups were absent from the studies they reviewed. Their findings indicate chiropractic care is consistently better than an array of comparison interventions for LBP (38 of 44 showed more pronounced effect sizes for the chiropractic group than the comparison group). They noted that meta-analysis of these studies has been difficult due to the wide variability in clinical protocol. Further, it was recommended that researchers strive for more consistency across trials, particularly in the nature of outcome measures, times of post intervention assessments, and description of technique.

Specific outcome measures were rarely used across different chiropractic studies although the visual analog scale (VAS) for pain was used in several (Gemmell et al, 1995; Pope et al, 1994; Postacchinni et al, 1988; Sanders et al, 1990; Triano et al, 1995) and the Oswestry Low Back Pain Disability Questionnaire has been used in at least two (Meade et al, 1990; Triano et al, 1995). Outcome measures used in other studies varied.

RESEARCH METHODS

PATIENT POPULATION: SIZE, INCLUSION/EXCLUSION CRITERIA AND RECRUITMENT. A sample size of 150 subacute low back pain patients was chosen as it represented a number that provided sufficient statistical power to detect a clinical intervention effect. The minimum detectable change in outcome measures was calculated through power analysis. Assumptions included three groups of fifty patients, _ = 0.05, _ = 0.80, and a sample variance computed from a pilot study (Grostic et al, 1994) using patients with chronic low back pain. Based on these assumptions, the minimum detectable differences for three of the outcome measures used in this study were:

Oswestry Disability Index	4.447
Modified Zung Index	3.952
Visual Analog Scale (for Pain)	1.711

Pain Classification. In this study, the duration and type of pain criteria were based on a specific time interval (Table 1). The duration of low back pain must have exceeded two weeks, thus eliminating acute LBP, which often improves without intervention. Recruitment was restricted to pain of less than six weeks duration to eliminate those patients who might be classified as chronic before the end of the study. Volunteers who had episodes of LBP in the previous 18 months (recurrent pain) did not qualify for participation.

Table 1. OVERVIEW OF CRITERIA FOR ACCEPTANCE

Age	Range of 21-59 years
Onset of low back pain	Minimum 2 weeks
Duration of low back pain	Maximum 6 weeks
Other LBP episode(s)	Minimum 18 months previous
Previous Chiropractic Care	Minimum 18 months
Previous Medical Care for LBP	Minimum 18 months

INCLUSION/EXCLUSION. A key point in the study design was the specific criteria for inclusion/exclusion to control factors, which could cause a wide variation in clinical outcome. The strictly enforced guidelines for patient recruitment are shown in Table 2. Anyone who had previous spinal surgery, previous traumatic spinal fractures, lumbar disc herniation, or diagnosed spinal stenosis was excluded. Other complaints which are known to cause back pain, including osteoporosis, ankylosing spondilitis, direct trauma, fibromyalgia, infectious endocarditis, inflammatory bowel disease, and spondyloarthropathy also eliminated the patient from participation. In addition, those volunteers who suffered with serious illness were not allowed to participate. The definition of serious illness includes unexplained weight loss, unexplained night sweats, morbid obesity, Crohn's disease, uveitis, chronic infectious diseases, HIV/AIDS disease, cancer, psoriasis, ulcerative colitis, uncontrolled diabetes, and uncontrolled cardiovascular disease. Anyone with a current cervical complaint and women who were pregnant were also excluded. Patients must have been at least 21 years of age, and the maximum age of acceptable patients was 59 years to eliminate specific geriatric concerns such as degenerative diseases, osteoporosis and compression fractures. Anyone with pending litigation such as worker's compensation cases, motor vehicle accident cases or other personal injury cases was not allowed to participate in this study. Volunteers who had received medical care for low back pain or chiropractic care in the previous 18 months were also excluded from the study.

The criteria for inclusion/exclusion were applied during the telephone interview and following the medical and chiropractic assessments. During these assessments, the medical doctor and attending chiropractic doctor agreed on whether each patient met eligibility requirements for inclusion.

Table 2. OVERVIEW OF CRITERIA FOR EXCLUSION

Previous Surgery	Spinal
Previous Fracture	Spinal
Current Serious Illness(es)	Cancer Diabetes Cardiovascular Disease Spondylitis Unexplained Weight Loss Unexplained Night Sweats Morbid Obesity Crohn's Disease Uveitis Chronic Infectious Diseases HIV Disease Psoiasis Ulcerative Colitis
Other Current Complaint	Cervical Pain
Traumatic Injury*	Work-Related Motor Vehicle Accident Other current or pending litigation for injury
Known Causes of Back Pain (Previous Diagnosis or Suspected)	Spinal Stenosis Lumbar Disc Herniation Osteoporosis Ankylosing Spondilitis Fibromyalgia Infectious Endocarditis Inflammatory Bowel Disease Spondyloarthropathy
Other exclusions	Pregnancy

*Acceptable if the back complaint is mechanical, non-specific, unresolved sprain/strain with pain lasting more than two weeks .

INTERVENTIONS. This study design utilized specifically designed interventions. Care was taken to see that the sham/placebo procedures mimicked true interventions as close as possible.

CHIROPRACTIC CARE. In this research study, the aim of chiropractic care was to remove spinal subluxations using chiropractic adjustments. A subluxation is defined as a complex of functional and/or structural and or pathological articular changes that compromise neural integrity and may influence organ system function and general health.

Chiropractic adjustments were provided during seven visits over a two-week period of active care. The presence of spinal misalignments and need for spinal adjustments was determined during the initial chiropractic evaluation. Criteria used to determine the presence of subluxations included spinal range of motion assessment, palpation, postural analysis, DTG (heat sensing thermocouple), radiographic structural analysis, and supine leg length inequality. Spinal adjustments were accomplished by using a specialized adjusting instrument and by hand.

CERVICAL ADJUSTING - Adjustments of the cervical spine were performed using a King KH-4 adjusting instrument. This instrument was specifically designed to perform spinal adjustments at the C-1 vertebral level (Atlas). The adjustments were accomplished by placing the patient in a lateral recumbent position with the head on a firm headpiece which facilitated the movement of atlas along the occipito-atlantal and atlanto-axial joint surfaces. The instrument stylus was placed on the soft tissue overlying the transverse process of atlas. A high-velocity, limited excursion (~3-4 mm) thrust was delivered along a vector which was primarily lateral to medial and determined through chiropractic radiographic structural analysis of the misalignment between the skull, C-1, and C-2 (Grostic, 1988). The adjustments were provided without gross or rotational movement of multiple joints such as those commonly associated with a "popping" or "cracking" noise.

FULL SPINE ADJUSTING - The chiropractor also used his (her) hands to adjust other spinal segments in the thoracic, lumbar, or pelvic areas as determined through palpation and radiographic structural analysis (Reinert, 1976). With the patient in either a prone or lateral recumbent position, a specific high-velocity, low-amplitude thrust was introduced to adjust a specific vertebral segment. In some instances this type of adjustment produced the well-known joint mobilization sound of "popping" or "cracking."

MEDICAL THERAPY. The drug therapy for this project involved the use of three muscle relaxants (Cyclobenzaprine HCl, Carisoprodol, Methocarbamol) and one analgesic (Acetaminophen). Cyclobenzaprine HCL acts to reduce tonic somatic motor activity primarily within the central nervous system. Carisoprodol produced muscle relaxation in animals by blocking interneuronal activity in the descending reticular formation and the spinal cord. Methocarbamol is thought to depress the central nervous system (PDR, 1993). Acetaminophen served as a rescue medicine for patients in all intervention groups. Table 3 lists the medications used in the study along with dosage and adverse reactions.

Table 3. MEDICATIONS

Drug A. Cyclobenzaprine HCl (Flexeril)
2.5 mg capsules
Served as a nighttime medication. The initial dosage was 5.0 mg nightly, but was allowed to be adjusted upward (doubled) or downward (halved) as needed. Common adverse reactions include drowsiness, dry mouth, and dizziness (PDR, 1993).

Drug B. Carisoprodol (Soma)
175 mg capsules
Served as a daytime medication. A 175 mg dosage was to be taken three times per day. Adverse reactions include drowsiness, dizziness, vertigo, ataxia, tremor, agitation, irritability, headache, depressive reactions, syncope, and insomnia. If side-effects to Drug A warranted discontinuing use, Drug B was substituted as the nighttime medication (PDR, 1993).

Drug C. Methocarbamol (Robaxin)
375 mg capsules
In the event that the patient did not tolerate Drug B, then Drug C was substituted. Drug C dosage was 750 mg taken three times per day. If no relief was obtained, then the dosage was allowed to be doubled. Adverse reactions include lightheadedness, dizziness, drowsiness, nausea, allergic manifestations (such as urticaria, pruritus, rash, conjunctivitis, and nasal congestion, blurred vision, headache), and fever (PDR, 1993).

Drug D. Acetaminophen (Tylenol)
500 mg tablets
The rescue medicine was taken as needed: one or two tablets (500-1000 mg) three times per day. Adverse reactions to Tylenol are rare, but sensitivity reactions may occur. Overdose may cause hepatic toxicity in some patients (PDR, 1993).

Consistency in instruction of patients concerning drug therapy was provided by use of a typed instruction sheet that was given to each patient by the medical doctor. The medical doctor also verbally explained the drug therapy programme. In addition, instructions were clearly printed on the bottle for each drug. The patient was given a log sheet to record usage of the four drugs and to record any side effects encountered. The log and any remaining medication were returned at the end of the two week period. The use of rescue medication was used as an outcome measure.

The phone number of the medical doctor was printed on the instruction sheet, on each bottle in the kit, and on the drug log sheet. The patient was instructed to call the medical doctor if further information was needed at any time during the drug care phase.

Patients receiving chiropractic adjustments also received placebo medication while patients receiving true medication also received sham chiropractic procedures; the blinded control group received both placebo medicine and sham chiropractic procedures.

SHAM ADJUSTMENTS. The sham spinal adjustments mimicked the true spinal adjustments as closely as possible with respect to dialogue, visit length, and physical contact, which promoted patient blinding to care groups and balanced the placebo effect across groups.

For sham adjusting procedures in the cervical spine, the adjusting instrument, instead of producing a thrust, was disabled and no stylus excursion occurred. The instrument stylus was positioned on the

skin over the mastoid process with the patient in a supine position. The supine position lessened the chance of inadvertent vertebral movement. For sham adjustments to other regions, the patient was placed in either a prone position or lateral recumbent position. The chiropractor placed his hands on a lateral muscular area, touching the skin without any resulting vertebral movement.

PLACEBO DRUG THERAPY. The medical kits were produced by an independent pharmaceutical lab. Each drug kit was labeled with a patient number and consisted of four bottles labeled as Drugs A, B, C and D. Following a randomization chart, bottles A, B, and C in kits which were to be provided to the control and chiropractic care groups, were filled with capsules containing an inactive placebo. The same color, shape, and size capsules were used for the true medication and the placebo medication. Bottle D contained Acetaminophen tablets (Tylenol, 500 mg), used as rescue medication for patients in all groups. Hence, the control group did have access to an active pain reliever.

SHAM RADIOGRAPHIC PROCEDURE. Patients who were in either the medical group or the control group did not have radiographic films taken. However, the patient was placed in proper radiographic positioning for six films, the rotor was engaged, but no exposure was made. The sham radiographic procedure helped to equalize patient contact and visit length among groups.

BLINDING AND RANDOMIZATION. To minimize patient, evaluator, and care-provider bias, information regarding intervention group assignment remained confidential whenever possible. This resulted in a partly double-blinded and partly triple-blinded study, as explained below.

All patients were blinded to the type of intervention they received. In the drug therapy group, sham spinal adjustments were given while in the spinal adjustment group, placebo medicine was given, and in the control group both placebo medicine and sham spinal adjustments were given (Table 4).

The project director was responsible for administering the outcome surveys and was blinded to group assignment. In addition, the medical doctor who distributed the medication/placebo kits and was blinded to group assignment. The chiropractic doctors who provided care had to know which patients received true chiropractic care, but they did not know if patients who received sham adjustments were in the control or drug therapy group. To minimize doctor-patient influence, scripts were used to control dialog, and patient contact and visit length were periodically monitored to assure consistency across groups.

Table 4. BLINDING

Group	Intervention	Patient	DC Care Provider	MD Assessor	DC Assessor
Group A	True Spinal Adjustments	Yes	No	Yes	Yes
	Placebo Medication	Yes	No	Yes	Yes
Group B	Sham Chiropractic	Yes	No	Yes	Yes
	True Medication	Yes	Yes	Yes	Yes
Group C	Sham Chiropractic Placebo	Yes	No	Yes	Yes
	Medication	Yes	Yes	Yes	Yes

A randomization chart, developed through the use of a computer programme, was used in the preparation of the medical kits and patient numbering scheme. The randomization was done in blocks of thirty numbers to equalize group assignment over time.

STATISTICAL ANALYSIS. The principal measure for assessing change in patients involved examination of pre-intervention and post-intervention values for each of the outcome measures. For each of the sets of data for the outcome measures, assessment of the aptness of the model assumptions was performed. If violations of normality, heteroscedasticity, non-independence of error terms, or the presence of outliers were detected, then remedial measures were performed to maintain parametric modeling where possible. If the remedial measures were unsuccessful in meeting parametric model assumptions, then non-parametric methods were employed.

The parametric test used for significant differences in means was analysis of variance (ANOVA). The ANOVA was two way (Intervention [I] Group x Assessments) seeking an Intervention Group effect. If such an effect was seen, Tukey pairwise comparisons were utilized to compare intervention pairs. This was followed by measurements of Effect Size to estimate the degree that the intervention influenced the outcome. If non-parametric tests were required, then the appropriate statistical test was the Kruskal-Wallis test for three or more intervention groups. In either case, an alpha level of 0.05 was used as a significance level, with corrections made for the number of outcome measures used.

PATIENT PROTOCOL. The fine-tuned experimental protocol was used in a clinical study at Life University. Consistency in all areas of patient contact was ensured by the use of scripts from initial patient contact by telephone to patient release at the end of the study. The patient flow from recruitment to follow-up is shown as a chart in Figure 1. The outcome measures were administered according to a fixed schedule (Table 5).

Table 5. SCHEDULE FOR ADMINISTERING OUTCOME MEASURES

Initial Visit	Oswestry Disability Index Modified Zung Visual Analog Scale for Pain Medication Kits Dispensed Global Impression of Severity
Two Weeks (Termination of care)	Oswestry Disability Index Modified Zung Visual Analog Scale for Pain Remaining Medication Counted Global Impression of Severity
Four Weeks (Follow-up)	Oswestry Disability Index Modified Zung Visual Analog Scale for Pain

PATIENT RECRUITMENT. Recruitment for the study was done through a number of methods including print media, flyers, radio, television, and word of mouth. Advertising copy described the study as "a clinical study conducted jointly by licensed Doctors of Chiropractic and Rheumatology."

Print media included local, regional, and alternative tabloid newspapers in addition to Life University newsletters and journals. In most cases print media was in the form of paid advertisements. However, on some occasions the media printed an informative report on the study that was placed within the body of the newspaper or newsletter.

Flyers were distributed to local companies and organizations where high incidence of low back pain occurred. Public service announcements (PSA) were played on local radio stations and cable access channels free of charge. Recruitment was also attempted through word of mouth by speaking to local business groups.

TELEPHONE INTERVIEW. Initial contact was through a telephone interview performed by a Doctor of Chiropractic. The interview represented the first stage inclusion/exclusion of patients (see Tables 1 and 2). The interviewer first established whether the patient met the inclusion criteria and then determined whether any condition existed which would necessitate exclusion. If the patient was able to meet the frequency of visits as demanded by the study protocol, he or she was scheduled for the initial evaluation. A record of each interview was kept

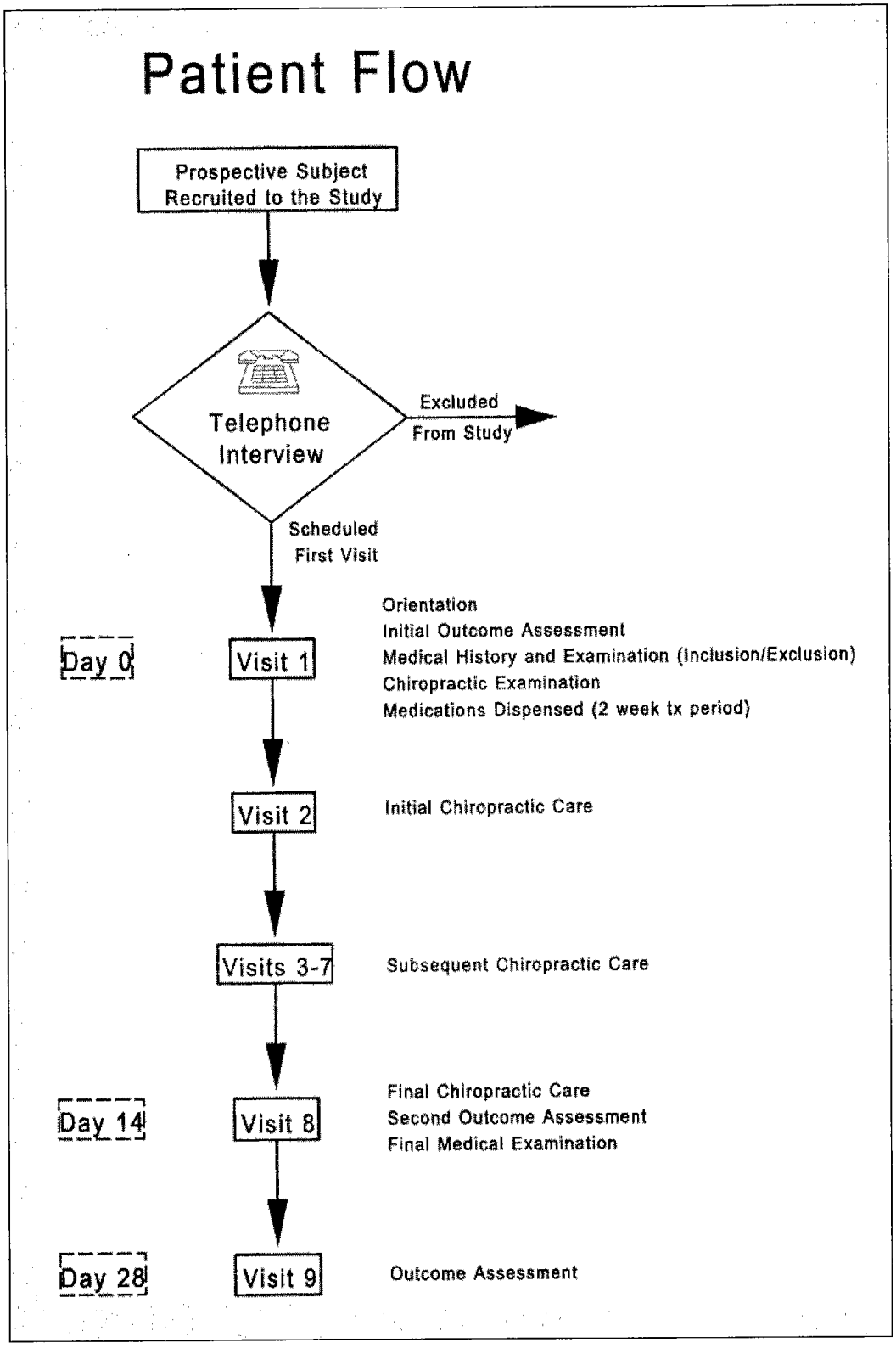
ORIENTATION AND INFORMED CONSENT. At the initial appointment, patients were first introduced to the Project Director, who was available to answer patients' questions and concerns throughout their participation. A 10 minute orientation videotape was shown which discussed the study and the personnel. The patient completed an entrance data form and then read and signed the informed consent in front of a witness.

INITIAL ASSESSMENT. The Project Director asked the patient to fill out the principal outcome measures, the Oswestry Disability Index and Modified Zung Index during the initial visit.

EXCLUSION, ASSESSMENT, AND RANDOMIZATION. After the patient completed these surveys he or she received a detailed case history and physical examination by both a doctor of chiropractic and a medical doctor to establish second stage patient eligibility. Radiographic technicians and facilities were available if the examination findings indicated imaging was needed in determining patient eligibility.

To provide an assessment of the severity of symptoms for each patient, the Global Impression of Severity Scale (GIS), consisting of four sub-scales describing limitations in activities of daily living and physical exam findings, was derived for purposes of this study. The GIS score ranged from 0 - 31 in increasing levels of severity and was based on the following:

- Limitations in Activities of Daily Living (ADL) - patient response was graded 0-4 and multiplied by two.
- Tenderness - scored from 0-4 based upon patient response to palpation by the medical doctor.
- Results from Schober's Test - for computation of the GIS score, the number was subtracted from five so that a high number indicates an abnormal condition. Normal change in the distance between the two points was 5-8 cm.
- Spasm - scored ranging from 0-4 based on palpation by the medical doctor
- VAS For Pain - a patient reported pain rating (0-10).


Patient Flow
Prospective Subject Recruited to the Study
Telephone Interview
Excluded From Study
Scheduled First Visit
Day 0
Visit 1
Orientation
Initial Outcome Assessment
Medical History and Examination (Inclusion/Exclusion)
Chiropractic Examination
Medications Dispensed (2 week tx period)
Visit 2
Initial Chiropractic Care
Visits 3-7
Subsequent Chiropractic Care
Day 14
Visit 8
Final Chiropractic Care
Second Outcome Assessment
Final Medical Examination
Day 28
Visit 9
Outcome Assessment

The chiropractor and medical doctor agreed on patient eligibility for the study after the initial examinations. Once accepted, the patient was assigned a number, which randomly assigned him or her to one of the three intervention groups: spinal adjustment, drug therapy or control.

The medical doctor gave each patient a kit containing four bottles. The bottles contained capsules and were labeled A, B, C, and D. Depending on group assignment, the capsules contained either placebo or true medications. The kit contained enough medication for 14 days.

CHIROPRACTIC ASSESSMENT. Each patient who was accepted to the study was provided a chiropractic examination at the initial visit. This examination determined the presence of spinal misalignments indicating subluxation and the need for spinal adjustments, and served as a baseline for determination of patient progress. The chiropractic examination included the following:

- Postural evaluation was done by visual assessment.
- Skin temperature asymmetry measurement in the cervical spine used a heat sensing thermocouple device.
- Palpation of the paravertebral musculature.
- Palpation for fixation of spinal articulations.
- Spinal range of motion.
- Functional leg length inequality check done by having the patient lie supine on a chiropractic table with the ankles and feet extending over the end. The patient's heels, gripped in the observer's hands, were aligned so that a visual estimation of inequality was made and recorded.
- Radiographic examination. Each patient underwent a radiographic examination on the first visit requiring a total of six radiographs and included the following views: lateral cervical, vertex, two nasium cervical views (pre/post first spinal adjustment), and anterior-to-posterior and lateral lumbar films. The films were required for chiropractic radiographic analysis, which was used to determine vectors for providing spinal adjustments.

  High-frequency radiographic equipment was used in conjunction with high-speed film, rare earth screens and lead compensating filters to achieve a 1200 film speed combination. Proper radiation shielding to minimize patient exposure was used. The total radiation dosage absorbed by the patient for the duration of the study was estimated at 975 mrad.

CARE PLAN - VISITS 2-7. Each patient attended a total of seven visits for spinal adjustment or sham adjustment, and self-administered two weeks of medication or placebo medication. The first and last visits of the two week intervention phase required 2 hours to complete. Interim and follow-up visits required only 30 minutes each.

FINAL ASSESSMENT - VISIT 8. At the end of the two weeks of active care each patient returned for the final physical assessments, as well as to complete a second set of outcome measures. As part of the final assessment, patients were asked two questions: Do you think you received actual chiropractic adjustments? Do you think you received actual medication? Their responses to these questions were used to assess the effectiveness of the blinding procedures.

FOLLOW-UP - VISIT 9. Each patient attended a ninth appointment four weeks after the initial visit. The patient was asked to complete a third set of outcome measures: the Oswestry, Zung, and VAS for pain. Each patient signed an "end of study" release form.

RESULTS FROM CHIROPRACTIC CLINICAL TRIALS

The WHO initiative on low back pain management helped establish two clinical trials investigating the effects of chiropractic care on patients with low back pain. One trial, yet to be completed, is being done in Marietta (Atlanta), Georgia, United States. The other trial has been completed and was done in Cairo, Egypt. The trial in Marietta represents a carefully controlled randomized clinical trial with three intervention groups: chiropractic, medical, and control. The trial in Cairo used a more broadly defined patient population, and each patient received chiropractic care. The results of both studies are summarized below.

MARIETTA

The study in Marietta is being conducted on the campus of Life University. A large number of personnel are involved in the project. Life University faculty include Bruce Pfleger, PhD (Director of Research), Kathryn Hoiriis, DC (Project Director), Roger Hinson, DC (Upper Cervical Analyst), Mark White, BS, DC (Full Spine Adjuster), Susan Brown, PhD, DC (Statistical Analyst), Omar Elsangak, MB.BCh (Data Co-ordinator), Gregoria Verzosa, BBA, DC (Patient Co-ordinator) and Medhat Alattar, MB.BCh, DC, MS (Director of the International Programs Department and committee member of the WHO initiative on Low Back Pain Management). Piedmont Rheumatology is providing the medical team which includes Frederic McDuffie, MD and Hayes Wilson, MD. The data presented here were analyzed by members of Life University, but an independent statistician from Emory University will analyze the data once the study has been completed.

The trial was designed to have completed data for 150 subjects with 50 each in the chiropractic, medical, and control groups. The results presented here are for the first 121 subjects enrolled. The sample sizes are further decreased due to subjects dropping out of the study. It should be stressed that these results are preliminary, and will not necessarily coincide with results obtained at the conclusion of the study. At that time, statistical methods will probably be enhanced to include the use of appropriate cofactors, which are thought to influence the data.

Data are provided for five outcome measures including three surveys (Oswestry, Zung, VAS), one range of motion measurement (Schober), and the amount of rescue medication used. The surveys were administered initially, immediately after the two-week intervention phase, and at a four-week follow-up visit. Range of motion was assessed at baseline and at two weeks. The amount of medication (acetaminophen) consumed during the two-week intervention phase was used as an additional outcome measure.

Results comparing baseline and two-week data are listed in Table 6. Data are reported for subjects who completed both sets of questionnaires. Rescue medication usage (500 mg acetaminophen tablets) is reported for subjects who completed both sets of questionnaires and turned in their remaining medication.

Negative mean values indicate that each of the three groups demonstrated improvement for disability (Oswestry), depression (Zung), and pain (VAS), with the largest improvements being seen in the chiropractic group. A mean increase in Schober for the chiropractic and medical groups represents an increase in flexibility, with a slightly higher increase in the medical group probably due to the adminis-

tration of muscle relaxants which creates laxity of back muscles. Acetaminophen was supplied to all three groups, allowing subjects to self-medicate as needed. The control group used the least amount of the analgesic. Analysis of Variance (ANOVA) revealed no statistically significant differences among groups in this preliminary analysis.

Paired t-tests were done within groups looking for statistically significant changes in the first four outcome measures. Significant improvements ($p<0.05$) were seen in the chiropractic group for disability, depression, pain and flexibility; the medical group for disability and pain; and the control group for pain.

Results comparing baseline and four-week data are listed in Table 7. Data are reported for subjects who completed all three sets of questionnaires. As the four-week data were collected two weeks after the conclusion of the intervention phase, these numbers help indicate lasting effects of the three interventions, albeit short-term.

Table 7 indicates subjects receiving chiropractic care had the greatest improvement in the disability, depression, and pain assessments. When examining mean changes at two and four weeks, the data indicate that the chiropractic and control patients continued to improve during the two weeks following the interventions, while the medical patients changed little. ANOVA revealed no significant differences across groups. However, paired t-tests revealed significant improvements in the chiropractic and medical groups for disability, depression, and pain, and in the control group for pain.

As the main thrust of the research study was to compare chiropractic care to commonly used medical care, these results are very encouraging. Patients under chiropractic care have demonstrated the greatest benefit in six of the eight outcome measures examined to date. Still, no significant differences among groups have developed. This may change, however, when the remaining 42% of the data are collected and tabulated.

CAIRO

The trial in Cairo represents a less robust design in that there was no randomization or control/comparison group. Each patient received chiropractic care, and analysis sought pre/post care differences for the same principal outcome measures chosen for the WHO initiative. The study was performed at two sites: the El-Aguoza Military Rehabilitation Center under the direction of Dr. Mohamed Reda Awad, and the Ain Shams University Faculty of Medicine Unit in the Department of Neurology under the direction of Dr. Anwar El Etribi. Dr. Rodney Earl Handly was the participating doctor of chiropractic at both sites and was responsible for all patient care. Dr. Omar Elsangak was the medical examining doctor, working primarily at the University clinic.

Patients at both sites suffered from back or neck pain, with or without radicular symptoms. The duration of pain varied widely, but nearly every patient would be classified as chronic using the criteria from the Marietta study. Data from patients at both Cairo sites have been combined for the analysis presented here. Patients completed baseline questionnaires before receiving one month of chiropractic care. All patients received upper cervical chiropractic adjustments, and many of the patients also received full-spine care. Patients were asked to come in two or three times per week for the first month of care, tapering to less frequent visits thereafter. A second set of surveys was administered after one month of care.

Results from the study are listed in Table 8. The improvements seen in the disability (Oswestry) and depression (Zung) scales are quite comparable to the Marietta data taken at four weeks, strengthening the results from both studies. The pain data (VAS) were collected differently in this study in that the second measurement was taken on the second patient visit, usually within a few days. A remark-

able decrease in pain levels was evident. The Schober results show that patients gained flexibility as well. The Global Impression of Severity Index (GIOSI) is an additional outcome measure that the medical doctor determined based on muscle spasm, flexion and lateral flexion range of motion, pain level, and limitations of daily activity. All five outcome measures showed highly significant improvement as evidenced by the computed paired t-value and associated p-value.

The study done in Cairo is weakened by a design that fails to incorporate a comparison group. These patient populations had chronic neck and low back pain afflictions that often last for years, and are very difficult to manage. Therefore, the strong results presented here, especially the quick reduction in pain level are also very encouraging.

Table 6. Two-Week vs Baseline Differences at Marietta

Outcome Measure	Chiropractic		Medical		Control		F	P
	N	Mean	N	Mean	N	Mean		
Oswesty	27	-3.67 (1)	26	-4.35 (2)	32	-5.75 (3)	0.254	0.776
Zung	26	-3.92 (1)	26	-0.77 (3)	32	-0.97 (2)	1.344	0.266
VAS	27	-1.55 (1)	27	-1.10 (3)	32	-1.54 (2)	0.317	0.730
Schober	27	0.39 (2)	27	0.44 (1)	32	-0.27 (3)	2.174	0.120
Medication	23	22.96 (3)	20	19.90 (2)	22	14.45 (1)	0.726	0.488

Note: Means calculated as baseline minus two-week data. Negative numbers represent improvements for Oswestry, Zung, VAS; positive numbers represent an improvement for Schober. Medication refers to number of 500 mg tablets of acetaminophen taken over two-week period (lower numbers were considered more desirable). Numbers in parentheses represent relative rank of three intervention groups with (1) being best and (3) being worst.

Table 7. Four-Week vs Baseline Differences at Marietta

Outcome Measure	Chiropractic		Medical		Control		F	P
	N	Mean	N	Mean	N	Mean		
Oswesty	25	-10.88 (1)	21	-4.86 (3)	27	-6.59 (2)	1.151	0.322
Zung	24	-4.33 (1)	21	-0.57 (3)	26	-4.04 (2)	1.912	0.356
VAS	13	-2.76 (1)	17	-1.55 (3)	20	-1.85 (2)	1.056	0.356

Note: See Table 1 for further explanation

Table 8. One-Month vs Baseline Differences at Cairo

Measure	N	Baseline	One-Month	Change	t	P
Oswestry	150	41.7	29.7	-12.0	10.06	<0.001
Zung	196	21.6	18.3	-3.3	4.95	<0.001
VAS	136	5.63	2.92*	-2.71	16.88	<0.001
Schober	119	6.31	7.49	1.18	9.93	<0.001
GIOSI	116	17.51	10.70	6.81	14.89	<0.001

* Second VAS measurement taken at second visit, usually within a few days.

REFERENCES:

Allan DB, Waddell G. *An historical perspective on low back pain and disability.* Acta Orthop Scand, 1989, 60:1-23.

Anderson RM, Meeker WC, Wirick BE, Mootz RD, Kirk DH, Adams A. *Meta-analysis of clinical trials of spinal manipulation.* JMPT, 1992, 15(3):181-194.

Bergquist-Ullman M, Larsson U. *Acute low back pain in industry. A controlled prospective study with special reference to therapy and confounding factors.* Acta Orthop Scand, 1977, suppl 170:11-117.

Bigos S, Bowyer OR, Braen GR et al. *Acute low back pain problems in adults.* Clinical practice guideline No. 14. AHCPR Publication No. 95-0642. 1994. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, US Department of Health and Human Services.

Brennan PC, Graham MA, Triano JJ, Hondras MA, Anderson RJ. *Lymphocyte profiles in patients with chronic low back pain enrolled in a clinical trial.* JMPT, 1994, 17:219-227.

Bronfort G. *Chiropractic versus general medical treatment of low back pain: a small scale controlled clinical trial.* Am J Chiro Med, 1989, 17:145-150.

Bronfort G, Goldsmith CH, Nelson Cf, Boline PD, Anderson AV. *Trunk exercise combined with spinal manipulative or NSAID therapy for chronic low back pain: A randomized, observer blinded clinical trial.* JMPT, 1996, 19(9):570-582.

Carey TS, Garrett J, Jackman A et al. *The outcomes and costs of care for acute low back pain among patients seen by primary care practitioners, chiropractors, and orthopaedic surgeons.* NEMJ, 1995, 333(14):913-917.

Cote P, Mior SA, Vernon H. *The short term effect of a spinal manipulation on pain/pressure threshold in patients with chronic mechanical low back pain.* JMPT, 1994, 17:364-368.

Coxhead CE, Meade Tm, Inskip H, North WRS, Troup JDG. *Multicentre trial of physiotherapy in management of sciatic symptoms.* Lancet, 1981, 1:1065-1068.

Cramer GD, Humphreys CR, Hondras MA, McGregor M, Triano JJ. *The Hmax/Mmax ratio as an outcome measure for acute low back pain.* JMPT, 1993, 16:7-13.

Farrell JP, Twoomey LT. *Acute low back pain. A comparison of two conservative treatment approaches.* Med J Aust, 1982, 1:160-164.

Gemmell HA, Jacobsen BH. *The immediate effect of activator versus meric adjustment on acute low back pain: A randomized controlled trial.* JMPT, 1995, 18:453-456.

Gibson T, Harkness J, Blackgrave P, Grahame R, Woo P, Hills R. *Controlled comparison of short-wave diathermy treatment with osteopathic treatment in non-specific low back pain.* Lancet, 1985, 1:1258-1261.

Glover JR, Morris JG, Khosla T. Back pain: *A randomized trial of rotational manipulation to the trunk.* Br J Ind Med, 1974, 31:59-64.

Godfrey CM, Morgan PP, Schatzker J. *A randomized trial of manipulation for low back pain in a medical setting.* Spine, 1984, 9:301-304.

Grostic JD. *Grostic procedure notes, privately published.* Marietta, Georgia, 1988.

Grostic J, Hoiriis, K, Owens EF et al. *A controlled, double blinded study of low back pain management with upper cervical chiropractic care.* 1994. Unpublished pilot study.

Hadler NM, Curtis P, Gillings DB, Stinnett S. *A benefit of spinal manipulation as adjunctive therapy for acute low back pain: a stratified control trial.* Spine, 1987, 12:702-706.

Hoehler FK, Tobias JS, Buerger AA. *Spinal manipulation for low back pain.* JAMA, 1981, 245:1835-1838.

Johnson MR, Schultz MK, Ferguson AC. *A comparison of chiropractic, medical and osteopathic care for work related sprains and strains.* JMPT, 1989, 12(5):335-344.

Koes BW, Bouter LM, van Mameren H, Essers AH, Verstegan GJ, Hofhuizen DM, Houben JP, Knipschild PG. *A randomized clinical trial of manual therapy and physiotherapy for persistent neck and back complaints: Subgroup analysis and relationship between outcome measures.* JMPT, 1993, 16: 211-219.

Koes BW, Assendelft WJJ, van der Heijden MG, Bouter LM. *Spinal maipulation for low back pain: An updated systematic review of randomized clinical trials.* Spine, 1996, 21(24):2860-2873.

Life College, School of Chiropractic, Technique Manual. second edition., Marietta, GA: Life University, 1993.

MacDonald RS, Bell CMJ. *An open controlled assessment of osteopathic manipulation in nonspecific low back pain.* Spine, 1990, 15:364-370.

Manga, P., Angus DE, Swan WR. *Effective management of low back pain: it's time to accept the evidence.* JCCA, 1993, 37(4):221-229.

Mathews JA, Mills SB, Jenkins VM, Grimes Sm, Morkel J, Mathews J, Scott CM, Sittampalam Y. *Back pain and sciatica: Controlled trials of manipulation, traction, sclerosant and epidural injections.* Br J Rheumatol, 1987, 26: 416-423.

Meade TW, Dyer S, Browne W, Townsend J, Frank AO. *Low back pain of mechanical origin: randomized comparison of chiropractic and hospital outpatient treatment.* Br Med J, 1990, 300:1431-1437.

Nwuga VCB. *Relative therapeutic efficacy of vertebral manipulation and conventional treatment in back pain management.* Am J Phys Med, 1982, 2:143-146.

Physicians' Desk Reference (PDR). 1993. Medical Economics Data, Montvale, NJ.

Pope MH, Phillips RB, Haugh LD, Hsieh CJ, MacDonald L, Haldeman S. *A prospective randomized three-week trial of spinal manipulation, transcutaneous muscle stimulation, massage and corset in the treatment of subacute low back pain.* Spine, 1994, 19:2571-2577.

Postacchinni F, Facchini M, Palieri P. *Efficacy of various forms of conservative treatment in low back pain. A comparative study.* Neuro-Orthopedics, 1988, 6:28-35.

Reinert, OC. *Chiropractic procedure and practice, 4th edition.* Florissant, MO: Marian Press, 1976.

Sanders GE, Reinert O, Tepe R, Maloney P. *Chiropractic adjustive manipulation on subjects with acute low back pain: Visual analog pain scores and plasma B-endophin levels.* JMPT, 1990, 13:391-395.

Shekelle PG, Adams AH, Chassin MR, Hurwitz EL, Brook RH. *Spinal manipulation for low back pain.* Ann Intern Med, 1992, 117(7):590-598.

Triano JJ, McGregor M, Hondras MA, Brennan PC. *Manipultive Therapy versus education programmes in chronic low back pain.* Spine, 1995, 20: 948-955.

Von Korff M, Saunders K. *The Course of Back Pain in Primary Care.* Spine, 1996, 21(24):2833-2837.

Waddell G. Low Back Pain: *A Twentieth Century Health Care Enigma.* Spine, 1996, 21(24), 2820-2825.

Waterworth RF, Hunter IA. *An open study of diflunisal, conservative and manipulative therapy in the management of low back pain.* NZ Med J, 1985, 98:372-375.

Zylbergold RS, Piper MC. *Lumbar disc disease: Comparative analysis of physical therapy treatments.* Arch Phys Med Rehab, 1981, 62:176-179.

8. PSYCHOSOCIAL ASPECTS OF LOW BACK PAIN

Dr Jan Dequeker
(Rheumatology Unit, University Hospital, K.U.Leuven, B-3212 Pellenberg, Belgium)

Dr J.J. (Hans) Rasker and Dr Eric Taal
(University of Twente, Department of Rheumatology and Communication Science
AE Enschede, The Netherlands)

Back pains have affected man throughout recorded history and probably long before. In developed countries (Leino PL, Berg MA, Puska P, 1994), but also in developing countries (Darmawan J, Valkenburg HA, Muirden KD, Wigley RD, 1992), there is growing medical, social and political concern about our present epidemic of low back disability, occurring even below the age of 20 years (Leboeuf CH et al, 1998). Ever increasing medical and health care resources have not solved the problem. The problem is mainly concerned with common backache or non-specific low back pain. Nerve root problems and serious spinal pathology, such as tumour, infection and inflammatory disease are quite distinct (Garfin SR, 1998, Waddell G, 1992). Back incapacities now account for one-seventh of all sickness and invalidity benefit. Most alarming for the future, this is increasing faster than any other form of disability.

Low back pain is common and in general benign. Depending on how the question is framed, 75-85% of people report low back symptoms at some time in their life (Andersson GBJ, 1998). Up to 60% of normal people experience some low back symptoms each year. In adults, 90% of attacks of low back pain recover within 12 weeks, irrespective of the type of treatment or indeed whether they receive treatment at all (Andersson GBJ, 1998). From this perspective much low back pain may be better regarded as an everyday bodily symptom rather than due to any medical disease (Waddell G, 1992).

ACUTE AND CHRONIC PAIN

Acute and chronic pain are not only different in time but differ fundamentally in kind. Acute pains usually bear a relatively straightforward relationship to peripheral stimulus, nociception and tissue damage. There may be some understandable anxiety about the meaning and consequences of acute pain though experimental pain by its very nature lacks the emotional or affective dimension of clinical pain. But acute pain and disability are generally proportional to the objective clinical findings. Appropriate pharmacological, physical and even surgical treatments directed to the underlying physical disorder have a high success rate in relieving acute pain (Garfin SR, 1998).

Chronic pain may become progressive and a completely different clinical syndrome resulting in pain and disability disproportionate to the original physical problem. They become associated with fear-avoidance, psychological distress, depressive symptoms, failure to cope and adaptation to chronic invalidity. Chronic pain becomes a self-sustaining condition, which is resistant to traditional medical management. Purely physical treatment directed to a hypothetical but unidentified and possibly non-existent nociceptive source is then likely to be unsuccessful (Turner-Stokes L, 1993). It may even cause further physical damage. Pain clinics are now full of such patients who have undergone failed back surgery.

BIO-PSYCHO-SOCIAL ASPECTS OF LOW BACK PAIN

Medicine has, however, a much more ancient and richer lineage than science. Since before the time of Plato the relationship between mind and body has been held to be fundamental to human existence and to medicine. Aristotle recognized that man is a social animal who lives and acts - and falls ill - in a

social relationship with other human beings. Hippocrates emphasized that the doctor's practical role as healer cannot be separated from his social role of helping human beings to cope with illness and suffering.

There is no reason in principle why scientific treatment of disease should not be combined with human care of the patient. It is only because of the limitations of our human nature that increased time, training and concentration on the physical aspects of disease have led doctors to neglect the psychological and social aspects of illness. All doctors agree in principle with the need to treat each patient as a human being but when in busy clinics they too often get on with the business of treating perceived disease. There has been concern and criticism about this approach to medicine both from eminent members of the profession and thoughtful lay observers. A purely mechanistic approach may cure many serious diseases but only deals with one half - and not necessarily the more important half - of medicine's role in society.

Practical application of these humanitarian principles to the daily practice of medicine has fallen behind the physical treatment of disease.

Let us now see how the bio-psycho-social model can be applied to the clinical management of low back pain. This model has been shown to be more useful in understanding non-specific low back pain than the traditional physical or medical approach (Violinn E, 1997). Physical, psychological and social factors interact to determine the outcome of low back pain. The longer pain persists, the more likely it is that non-physical alterations are at play (Weiser SR, 1997).

Psychological factors refer to personality traits as well as perceptions of the social environment, and attitudes or beliefs about illness. Several of these factors have been associated with delayed recovery. For example, psychological distress and perception of severe disability are associated with poor outcomes (Nordin M, Skovron ML, Hiebert R et al, 1997). A positive attitude, such as the belief that one will return to work, may predict future work status (Cherkin DC, Deyo RA, Street JK, Barlow W, 1996), as may attempts to overcome pain instead of catastrophizing.

Social factors, including attitudes and behaviours of health care practitioners, family and friends, and socio-economic systems may influence the course of low back pain. Finally, the influence of health care professionals can be powerful. Information given to the patients that is vague, incomplete or inaccurate can have deleterious effect (Cherkin DC et al, 1996).

PSYCHOSOCIAL ISSUES IN THE PREVENTION OF CHRONIC LOW BACK PAIN

Among the broad category of variables that have been associated with chronic low back pain are personality, cognition and affect, pain behaviour and the social environment including family, friends, co-workers and health care workers.

Social factors that affect the course of low back pain include variables that originate outside the individual. Chronic illness is a dynamic process that results from an ongoing interplay between physical, social and psychological characteristics.

One never suffers alone in a chronic disease, therefore attention has to be given to the spouse and children of the sufferer. It is important that the close relatives know the diagnosis, the benign nature of the physical findings and the management of reintegration by encouraging self-care attitudes in the patient, rather than reliance on medical intervention only. Emotional support may not always be in the best interest of the chronic pain patient. Patients who have supportive spouses (spouses who are sym-

pathetic and accept the patient's disability status) have more pain and exhibit greater pain behaviours than patients whose spouses were not supportive (Flor H, Turk DC, Rudy TE, 1987).

The positive and negative role of health care providers on chronic low back pain are insufficiently emphasized. The family physician and the specialist often do not realize that with repeated investigation and use of expensive technology and impressive therapies they induce fear and chronicity in the patient and frustration for themselves. Overreliance on tests, physiotherapy and pain killers, without patient education, makes patients over-dependent on medical care, i.e. expecting a definite diagnosis and remedy for their pain. Many physicians are frustrated and have negative views of non-specific low back pain patients. It is well known from epidemiological surveys that there is little relation between X-ray or MRI findings at the spine and pain (Garfin SR, 1998). So physicians should not treat X-rays but human beings. Appropriate physician education at the undergraduate level and continued medical education may significantly enhance their perceived knowledge and confidence in their ability to manage chronic low back pain (Dequeker J, Rasker JJ, 1998). With a good history and clinical examination, together with clinical reasoning and positive attitude, the differential diagnosis of the low back pain problem can be resolved with confidence by excluding the specific low back pain from the non-specific low back pain syndromes.

Von Korff et al (Von Korff M, 1994) showed that a practice style consistent with back pain self-care, emphasizing patient education and active participation in the management of his/her back pain problem, was associated with higher satisfaction with the quality of patient education and with long-term pain and functional outcome.

Studies have underlined the possible damaging effects of diagnostic terms, i.e.. "you (35-year old man) have the back of an 80-year old man", on patient's (and the therapist's) attitudes and expectations (Nordin M, Cedraschi C, Vischer TL, 1998). Health care providers' beliefs about "typical" patients or "typical" patient characteristics, including genuineness versus malingering, may also carry deleterious effects for the therapist's (and the patient's) attitudes and expectations.

Unrealistic expectations may influence patient's outcome, whatever the type of treatment. Reliance on medical intervention only may induce the patient to think that recovery essentially depends on sophisticated diagnostic procedures and on a specific therapy (Deyo RA, 1996). Delusion may result from failure to meet these expectations and thus lead to disruptions in the patient-therapist relationship and doctor-shopping behaviour in the patient. Unrealistic expectations may foster worries concerning the recovery process and dramatize what should remain a benign condition (Nordin M, Cedraschi C, Vischer TL, 1998).

Health beliefs proved to be consistent determinants for both current health behaviours and history of health care utilization (Szpalski M et al, 1995). Indeed, the belief that low back pain would be a lifelong problem was associated with increased likelihood of seeing a health professional, bed rest, and medication use.

Iatrogenic factors leading to disability include the overemphasis on pain to guide treatment, inadequate diagnosis, and the overprescription of tests and rest.

PERSONALITY AND PSYCHOLOGICAL DISTRESS

The ardent search for a personality that predisposes an otherwise healthy individual to become a chronic pain patient has been abandoned. Recurrent clusters of personality traits found in chronic pain patients are now interpreted to be the result of illness and not the cause. The cumulative evidence,

however, suggests that acute patients who are preoccupied with their symptoms and are depressed and anxious fare more poorly than others (Weiser S, Cedraschi C, 1992).

COPING AND ILLNESS BELIEFS

Coping factors include coping and illness beliefs. Beliefs about illness and cognitive coping do not exist before pain begins, but they are developed at the onset of back pain and are important determinants of effect and behaviour. Therefore, the identification of these cognitive factors in acute illness may provide a basis for the prevention of chronicity.

Dysfunctional information processing and negative self-statements and beliefs may underly the development of chronic pain. However, not all people with chronic pain think dysfunctionally. Turk and Rudy (Turk DC, Rudy TE, 1990) identified a cluster of patients who seek treatment but also report relatively high levels of perceived self-control. So maladaptive coping and beliefs may be present in some patients and not in others.

The Glasgow illness model illustrates clearly the interaction between physical disorder coping, illness behaviour and social environment (Figure 1).

Waddell et al (Waddell G et al, 1984), measuring actual disability in chronic backache, found that the physical disorder accounts for almost half the total disability, while distress and illness behaviour together account for an additional one-third. The Glasgow illness model provides a visual representation of this analysis. It is an over-simplification to regard disability as the sum of physical disorder plus distress plus abnormal behaviour, and the whole of this discussion and the model try to show the overlap and interaction between these elements. The model also illustrates that, while illness may start with the physical disorder, its presentation to the doctor is largely in the form of illness behaviour. Although the analysis is based on a large group of patients, clinical assessment of the individual patient may be represented by variations of the same basic model. Most patients with backache can be understood and treated as a predominantly physical disorder with normal and proportionate illness behaviour (Figure 2a). Occasional patients, however, may develop distress and illness behaviour out of all proportion to the original physical disorder, and this may even become the major management problem (Figure 2b).

One of the many possible mechanisms behind chronic back pain (as well as other pain and fatigue syndromes, sometimes referred to as pain amplification syndromes in men and women) is a premorbid life and workstyle characterized by an excessive hyperactivity (Van Houdenhove B, 1986). From a psychodynamic point of view, it is argued that hyperactive individuals with a narcissistic personality structure or frustrated dependency needs may be particularly prone to somatization and passive-regressive illness behaviour. From a cognitive-behavioural perspective, it is hypothesized that such persons may tend to maladaptive coping with pain and disability, due to inadequate symptom-perception, negative self-concept, avoidance behaviour, physical deconditioning, and operant reinforcement of the sick-role. These observations may have important therapeutic implications for a subgroup of patients suffering from chronic idiopathic pain (Van Houdenhove B, Stans L, Dequeker J, 1992).

A good understanding of the various somatic, psychological and social factors that play a role in the development of the chronic pain condition in an individual patient should guide the planning of treatment. The patient must be offered clear and consistent information about his or her problems and what to do about them. If the patient understands the role of his coping and illness beliefs and other somatic and psychosocial factors, the patient will become more engaged in the therapeutic process. Increased adherence and improved efficacy of treatment are likely outcomes (Kerns RD, Jacob MC, 1993).

The management of chronic low back pain must become the shared responsibility of the patient and his doctor (family practitioner and specialist), with increasing emphasis on personal responsibility. The promotion of self-control responsibility will require a prolonged and active media campaign, directed not only at the general public but at the health care professionals through problem-oriented undergraduate teaching and continued medical education. Changes in the delivery of health could produce a significant reduction in iatrogenic disability and distress.

The essence of psychological treatment is to develop the individuals personal responsibility for their back pain and maximize their capacity to control and manage it. The limitations of the traditional disease model of back pain and the restricting role of the benefit system (and the nature of assessment for benefits) need to be recognized and completely reappraised if optimal psychological management is to be achieved (Main CJ, 1992).

Regional pains and skin sensitivity should not be misread as evidence of psychological illness.

Whatever its cause, depression needs treatment, whether by cognitive measures or medication, including psychotropic medication which has some analgesic potential. Cognitive and behavioural control of pain also has a place in management. Family counseling, narcotic reduction in some cases, psychological assessment, job placement and further education and retraining all need to be considered for patients with chronic back pain, as with other types of chronic pain.

At all times the aim of medicine is to make the patient better: treatment of disease is only a means to this and not an end in itself. We must treat patients rather than disease, and this means treating patients as human beings, who have a body and a mind. We have to develop a satisfactory doctor-patient relationship, and provide reassurance, advice and encouragement.

REFERENCES:

Andersson GBJ. *Epidemiology of low back pain.* Acta Orthop Scand (suppl 281), 1998; 69:28-31.

Cherkin DC, Deyo RA, Street JH et al. *Pitfalls of patient education: limited success of a programme for back pain in primary care.* Spine, 1996; 21:345-55.

Cherkin DC, Deyo RA, Street JH, Barlow W. *Predicting poor outcomes for back pain seen in primary care using patients' own criteria.* Spine, 1996; 21:2900-7.

Darmawan J, Valkenburg HA, Muirden KD, Wigley RD. *Epidemiology of rheumatic diseases in rural and urban populations in Indonesia: COPCORD Study stage 1, phase 2.* Ann Rheum Dis, 1992; 51:525-8.

Dequeker J, Rasker JJ. *High prevalence and impact of rheumatic diseases is not reflected in medical curriculum: the ILAR-Undergraduate Medical Education in Rheumatology (UMER) 2000 project. Together everybody achieves more.* J Rheumatol, 1998.

Deyo RA. Acute low back *pain: a new paradigm for management, limited imaging and an early return to normal activities.* Br Med J, 1996; 313:1343.

Flor H, Turk DC, Rudy TE. *Pain and families. II Assessment and treatment.* Pain, 1987; 30:29-46.

Garfin SR. *Degenerative conditions of the spine. Current diagnostic procedures and treatment modalities.* Acta Orthop Scand (suppl 281), 1998; 69:38-46.

Kerns RD, Jacob MC. *Psychological aspects of back pain.* Baillière's Clin Rheumatol, 1993, 7:337-56.

Leboeuf CH et al. *At what age does low back pain become a common problem?* Spine, 1998, 23:228-34.

Leino PL, Berg MA, Puska P. *Is back pain increasing?* Results from national surveys in Finland during 1978-1992. Scand J Rheum, 1994; 23:269-76.

Main CJ. *Psychological treatment.* In: Jayson MIV (ed). *The lumbar spine and back pain.* 4th Edition. Churchill Livingstone, 1992. 487-505.

Nordin M, Cedraschi C, Vischer TL. *New Approaches to the low back pain patient.* Baillière's Clinical Rheumatology, 1998:1-175.

Nordin M, Skovron ML, Hiebert R et al. *Early predictors of delayed return to work in patients with low back pain.* J Musculoskel Pain, 1997; 5:5-27

Szpalski M, Nordin M, Skovron ML et al. *Health care utilization for low back pain in Belgium. Influence of sociocultural factors and health beliefs.* Spine, 1995; 20:431-42.

Turk DC, Kerns RD. *Conceptual issues in the assessment of clinical pain.* Int J Psychiatry Med, 1983; 13:52-68.

Turk DC, Rudy TE. *The robustness of an empirically derived taxonomy of chronic pain patients.* Pain, 1990; 43:27-35

Figure 1: The Glasgow illness model. A diagrammatic representation emphasizing that the outward expression of physical disease is illness behaviour and that the symptoms and signs of illness behaviour must be distinguished from those of physcial illness (Dequeker J, Rasker JJ, 1998).

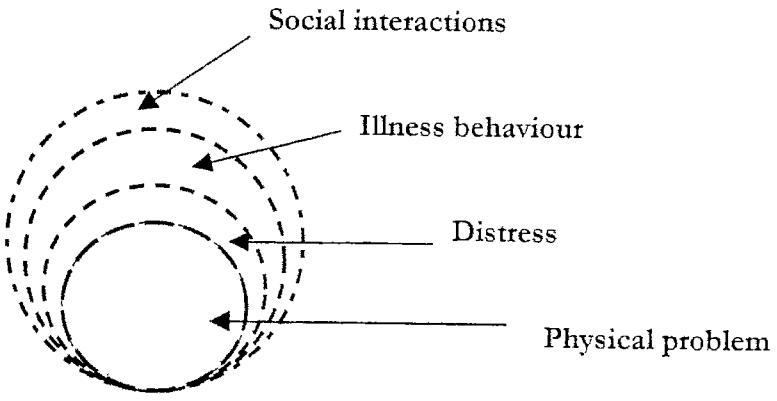
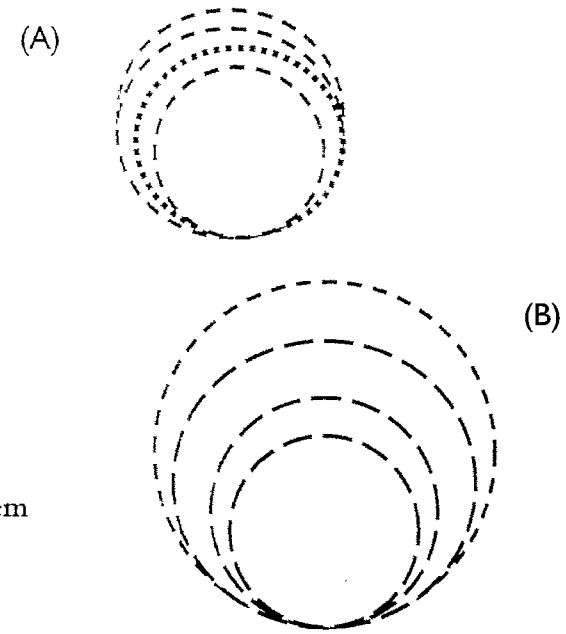


Figure 2: Variation of the relative importance of the different elements of illness in individual patients.



Turner-Stokes L. *Treatment and control of chronic arthritic and back pain.* Topical reviews reports on rheumatic diseases, series 2. Arthritis and Rheumatism Council, Jan 1993, N°23.

Van Houdenhove B, Stans L, Dequeker J. *Premorbid physical hyperactivity and chronic idiopathic musculoskeletal pain.* Eur J Pain, 1992; 13:71-5.

Van Houdenhove B. *Prevalence and psychodynamic interpretation of premorbid hyperactivity in patients with chronic pain.* Psychother Psychosom, 1986; 45:195-200.

Violinn E. *The epidemiology of low back pain in the rest of the world.* Spine, 1997; 22:1747-54.

Von Korff M. *Studying the natural history of back pain.* Spine, 1994; 19:2041-6.

Waddell G, Main CJ, Morris EW, Di Paola MP, Gray ICM. *Chronic low back pain, psychologic distress and illness behaviour.* Spine, 1984; 9:209-13

Waddell G. *Biopsychological analysis of low back pain.* Baillière's Clinical Rheumatology 1992; 6:523-57

Weiser S, Cedraschi C. *Psychosocial issues in the prevention of chronic low back pain - a literature review.* Baillière's Clinical Rheumatology, 1992; 6:657-84

Weiser SR. *Psychosocial aspects of occupational musculoskeletal disorders.* In: Nordin M, Andersson GBJ, Pope MH (eds). *Musculoskeletal Disorders in the Workplace: Principles and Practice.* Mosby, St. Louis, 1997: 51-61.

9. THE WORLD HEALTH ORGANIZATION LOW BACK PAIN INITIATIVE: CONCLUSIONS

Professor George E. Ehrlich

Non-specific low back pain is so common that it has been recognized as epidemic, perhaps even pandemic (CSAG Committee on Back Pain, 1994, National Health Service Health Publication Unit, Heywood, UK; Special Issue: Rueckenschmerzen: Eine Epidemie Unserer Zeit. Aertzliche Allgemeine, Medizin und Gesellschaft, Sonderdruck 7, 1994; 5: 1-27.; Bigos S., Bower O., Braen G. et al. *Acute Back Pain Problems in Adults. Clinical Practice Guideline No. 14.* AHCPR Publication No. 95-0642. Rockville MD: Agency for Health Care Policy and Research, Public Health Service, US Department of Health and Human Services, December 1994). Back pain is the most prevalent pain complaint and either the leading or second reason for disability (Silman AJ, Hochberg M.C.: *Epidemiology of the Rheumatic Diseases.* Oxford, Oxford University Press, 1993). And yet, it cannot be found in an international WHO ranking of common disabilities and public health problems. Perhaps the main reason for this discrepancy can be attributed to the failure to define back pain under a specific disease rubric. It thus becomes a set of symptoms in a syndromic grouping without a single putative etiology. Moreover, despite ubiquity, the response to back pain, even the reporting thereof to health care individuals and facilities, varies widely, with strong psychosocial overtones. Back pain is also subject to self-medication and resort to alternative medical approaches that generally go uncatalogued: chiropractic, herbal medications, acupuncture, yoga, acupressing, freezing, and other culturally conditioned treatments. Ample documentation attests to epidemics of back pain where job dissatisfaction is rampant and few reported back pains, even for the same type of exposure, where satisfaction with job and employer or supervisor is the rule. Moreover, in the vast majority of instances, the back pain is limited to a few weeks and spontaneously clears no matter what treatment approach – or none – was attempted. And once back pain becomes chronic, few treatments work well. So prevention of chronic back pain should be a major goal. The present document contains several disparate conclusions derived from several informal consultations of a WHO initiative augumented by ad hoc consultants. The hope is that it will supplement the recent comprehensive summaries (see references above, plus Swezey R., Editor, Low Back Pain, Physical Medicine Clinics of North America, 1998, Saunders W.B., Philadelphia; volume 9, number 2), and be of use also to the Bone and Joint Decade 2000-2010, for Prevention and Treatment of Musculo-Skeletal Disorders, a multidisciplinary consensus group under WHO co-sponsorship.

Many explanations have been offered for the high incidence and even greater prevalence of non-specific low back pain. The structure of the human skeleton was often blamed in the past, although an analysis of the anatomy surely must dispute that contention: the vertebral curves are obviously the most effective way to maintain erect posture. But obesity and pregnancy, both of which can distort lumbar lordosis, probably do provoke back pain on a mechanical basis. And sitting in chairs was long ago indicted for provoking back pain. Thus, contemporary civilization must number back pain as a consequence. Nevertheless, pre-industrialized setting and manual labor do not escape unscathed: back pain appears to be just as common, if not previously recorded, as the COPCORD studies make clear. So there is further evidence for the frequency of the symptom complex, making it all the more important to deal with the perceptions and consequences thereof. Thus, the emphasis of the WHO Low Back Pain Initiative on assessing treatment takes aim at the real problem, which in how to deal with this common malady. And there, while data confirm that the vast majority of complainants recover within a few weeks, the period during which pain and functional limitations predominate needs to be addressed in effective and cost-effective ways. Effective would define treatment that reduces pain – whether absolutely or to a level of tolerability – and improves function to permit continuation of the usual activities. Cost-effectiveness requires that this be done within fiscal constraints of burgeoning health expenditures, including in the calculations the potential costs of untoward reactions to the cho-

sen intervention and the loss of income and work and cost of services that prolonged invalidism adds. As was already stated in the prefatory chapters to the report, the many comparative studies of treatments published through the years provide scant data for meaningful comparisons. Many of these studies are not much more than unsupported testimonials that do not lend themselves to meta-analyses. The major summaries cited above cannot ultimately rate any intervention as so superior to obviate the others, but all confirm that surgery has perhaps the least to offer, even if the indications therefore are supported by evidence on imaging, as what is seen in those afflicted cannot often be distinguished from what is seen in those not afflicted.

The diagnostic categories that have been proposed include simple back pain alone, back pain with radiation into the leg(s), back pain with functional disease (malingering), back pain with diurnal periodicity (worse in the morning, improving during the day), and four more classes characteristic of underlying mechanical disease. Radicular syndromes and evidence of inflammation marshal specific therapeutic approaches, but non-specific syndromes are by far more common (estimate: virtually everyone will experience some back pain at some time) (Andersson GBJ, *Diagnostic considerations in patients with back pain,* PMR Clin N Amer, 1998, 9:309-22). Distinctions are made between symptoms and signs rationally explainable and those that are inappropriate on anatomic or physiologic bases. Generally, history and physical examination can differentiate among the possibilities, and the more expensive studies, including imaging, should usually be reserved for chronic or recalcitrant cases at a later time; most yield little useful information early on and are thus counterproductive to effectiveness and cost-effectiveness (Boden S, Swanson AL. *An assessment of the early management of spine problems and appropriateness of diagnostic imaging utilization.* PMR Clin N Amer, 1998, 9:411-17). The costs at present are staggering: in the Unites States, for instance, the direct medical costs are more that US$ 30 billion annually, total costs exceeding US$ 100 billion (Boden S, Dreyer SJ, Levy HI. *Management of low back pain.* PMR Clin N Amer, 1998, 9:419-33)! As other countries become more industrialized, their costs can be expected to rise as well; control of costs, as well as of the symptoms, becomes imperative.

The various recent meta-analyses and editorial summaries having drawn attention to the dearth of responsible studies, a number of controlled studies were undertaken recently. The widely touted back school was addressed as a preventive for low back injuries (responsible for some of the acute back pains and more often for chronic back pain) (Daltroy LH, Iversen MD, Larson MG et. al. *A controlled trial of an educational programme to prevent low back injuries.* N Engl J Med, 1997, 337:322-8). Despite its large scale, this study found no long-term benefits associated with training. This should have been predictable; Hadler (a sometime ad hoc advisor to the WHO Low Back Pain Initiative) has long held that "what you lift or how you lift matters far less than whether you lift or when", the subtitle of his recent editorial (Hadler NM. *Back pain in the workplace.* Spine, 1997, 22:935-40), a culmination of a series of his articles and books on this vexatious topic. In the article, he reiterated the insight that biomechanical factors matter less than workers' perceptions about the nature of their jobs (and more recently, about the respect for their work and position in the workplace and workforce).

While acupuncture has often been cited as a satisfactory treatment for low back pain, both acute and chronic, a recent meta-analysis of controlled studies has not been able to confirm this assertion *(Vantulder MW, Cherkin DC, Berman B, Lao L, Koes BW: The effectiveness of acupuncture in the management of acute and chronic Low Back Pain. A systemic review within the Framework of the Cochrane Collaboration Back Review Group, Spine, 1999; 24: 1113-23).* Indeed, few papers met methodologic quality standards, and those that did fail to demonstrate that acupuncture was better than no treatment at all. At present, therefore, acupuncture should not recommended as appropriate therapy.

The popularity in treatment decisions of massage, manipulation, and chiropractic adjustment was tested scientifically in several controlled trials (Carey TS, Garrett J, Jackman A., et.al. and the North Carolina Back Pain Project. *The outcomes and costs of care for acute low back pain amng patients seen by primary care practitioners, chiropractors, and orthopedic surgeons.* N Engl J Med 1995, 333:913-7; Cherkin DC, Deyo RA, Battie M et. al. *A comparrison of physical therapy, chiropractic manipulation, and provision of an educational booklet for the treatment of patients with low back pain.* N Engl J Med 1998, 339:1021-9, and studies reported in this publication).

In all instances, outcomes were similar regardless of the therapeutic mode employed, and primary care practitioner-applied treatments were the cheapest. Exercise programmes of various types, alone or as part of spa therapy (a traditional approach to low back pain), help shorten the duration and increase the quality of life of those afflicted. Spas still flourish in Europe, Japan, and parts of North America, often at sites of natural hot springs, where rehabilitation centres have been established and programmes for back pain treatment initiated. However, patient satisfaction was greatest for chiropractic, and this remains so in various trials, even if the outcomes otherwise are similar. Perhaps the time spent with the patient, accounts for some of this preference.

Some of the authors question whether the additional costs are justifiable on the basis of minor clinical and non-statistical superiority (Shekelle PG. *What role for chiropractic in health care?* N Engl J Med 1998, 339:1074-5). Other interventions similarly attain popularity among those who suffer the back pains (Kaptchuck TJ, Eisenberg DM. *The persuasive appeal of alternative medicine.* Ann Intern Med 1998, 129:1061-7). Standard medical treatments offer no more (van Tulder MW, Koes BW, Bouter LM. *Conservative treatment of acute and chronic non-specific low back pain: a systematic review of randomized controlled trials of the most common interventions.* Spine, 1997, 22:2128-56; Ehrlich GE. Commentary. ACP Journal Club May-June 1998, 65; Von Feldt JM, Ehrlich GE. *Pharmacologic therapies.* PMR Clin N Amer 1998: 9:473-87). Muscle relaxants add little; analgesics reduce pain but add the potential consequences that follow any drug treatments, and, in any event, are not curative either. Despite the fear of causing addiction, some recent advisories have recommended short courses of opioid analgesics. Corticosteroids, orally, parenterally or epidurally, offer no advantages. Facet joint injections rarely help. The dearth of effective and safe medications and the equivalent benefits obtained by physiotherapy, ergonomic and environmental considerations, psychosocial awareness and correction, and by eschewing prolonged bed rest, speak for a conservative approach to treatment, which, incidentally, also proves to be most cost-effective. By now it should be obvious that prevention of chronic pain should be a primary goal, although the factors that convert acute to chronic pain remain elusive. Because back pain is so poorly understood, the conversion of acute to chronic pain is often iatrogenic, and a compensation system that rewards prolongation of functional disability under the circumstances will ultimately fail the true interests of the patient.

APPENDIX 1.

EXPERIENCE FROM JAPAN
(Professor M. Homma)

PURPOSE

The purpose of this pilot study is to compare physical function and psychological assessment between patients with non-specific LBP and specific LBP by the outcome measures, and to elucidate the acceptability of outcome measures recommended by the WHO low back pain (LBP) initiative.

METHODS

This study was performed in three outpatient clinics of the Department of Internal medicine, Orthopedics and Rehabilitation of Keio University Hospital and a few affiliated Hospitals.

The consecutive ambulatory patients with LBP were enrolled. All questionnaires were distributed to the patients to complete them without additional instructions. (Since our final aim is to investigate patients with non-specific LBP, patients with few objective physical findings and with minor or equivocal reflex asymmetry or muscle weakness were enrolled. However, patients with cauda equina syndrome, major neurologic deficits, serious systemic diseases, major trauma, history of malignant diseases, or pregnant women which were inappropriate for these studies were excluded. Each participating doctor made the diagnosis of the underlying diseases.)

In this study, we used the three principal questionnaires of the Oswestry, and the modified Zung as well as visual analogue pain scale for outcome measures.

DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF PATIENTS WITH LBP

The number of patients with non-specific LBP was 22, and the control LBP patients who were diagnosed as specific LBP were 38.

The clinical and demographic data of these patients were shown in the table. In terms of gender, patients with non-specific LBP were 5 female and 17 male, and the age ranged 24 to 72, mean age 39.7

Patients with specific LBP including disc herniation, Spondyloarthrosis, osteoarthritis were 26 female and 12 male and the age ranged 17 to 74, mean age 45.1.

This data indicated that there was no significant difference between patients with non-specific and specific LBP in terms of age, gender, and classification of work activities.

CHANGE OF OSWESTRY DISABILITY SCORES AND MODIFIED ZUNG SCORES IN PATIENTS WITH NON-SPECIFIC LBP

The same questionnaires were given to all patients with LBP about 6 months later. In patients with non-specific LBP, two thirds of patients (15/22, 68%) were improved in the Oswestry scores, and a half of patients (9/19, 47%) were improved in the modified Zung scores. This suggested that there was no association between physical functioning and psychological assessment. The deterioration of the modified Zung scores might be due to anxiety disorder.

THE CORRELATION BETWEEN VISUAL ANALOGUE PAIN SCALE AND THE OSWESTRY DISABILITY SCORES OR THE MODIFIED ZUNG SCORES

The correlation between the pain scales and the disability scores or psychological assessments in all non-specific and specific LBP cases were investigated. There was a trend (n=60, r=0.6) for an association between the pain scales and the disability scores. However, the significant correlation between pain scales and psychological assessments was not found (n=60, r=0.17).

THE CORRELATION BETWEEN THE CHANGES OF VISUAL ANALOGUE PAIN SCALES AND THE CHANGES OF OSWESTRY DISABILITY SCORES OR THE CHANGES OF MODIFIED ZUNG SCORES FROM THE FIRST TO THE SECOND MEASUREMENT IN ALL PATIENTS WITH LBP.

The correlation between the changes of pain scales and the changes of the disability scores or the changes of psychological assessments from the first to the second measurement in all patients with LBP was investigated.

The significant correlation between the changes of pain scales and the changes of disability scores was found. However, there were no significant correlation between the changes of pain scales and the changes of psychological assessments.

NUMBER OF PATIENTS OF MISSING DATA IN EACH ITEM OF THE QUESTIONNAIRES FOR OUTCOME MEASURE IN 60 CASES.

Acceptability of questionnaires was assessed by examining the frequency of answering to individual items.

The figures showed the number of patients of missing data in each item of the questionnaires for outcome measures. The missing data for Question No. 8 (37%) in the Oswestry and Question No. 7 (42%) in the modified Zung, asking about the sex life, were most frequently found. This reason seems to be due to the moral standard specific for Japanese. Other items showing missing data for more than 6 patients (10%) in the modified Zung seem to be necessary for consideration to the questions.

Table 1. Demographic and clinical characteristics of patients with LBP
Patients Non-specific LBP 22 cases, Control (specific) LBP 38 cases

Characteristic	No. of Patients	
	Non-specific	Control (specific)
Age	40±s15 (24-72)	45±16 (16-74)
Male	5	12
Female	17	26
Underlying Disease	Musculoligamentous injury or Degenerative changes (?)	Disc herniation (15) Spondyloarthrosis (13) Osteoporosis (3) Other (7)
No. of patients seen in		
Internal Medicine		13
Orthopedic		41
Rehabilitation		6
Occupation		
White collar	10	11
Blue collar	3	6
House wife	6	10
Data not available	3	11

Table 2. Change of total scores of questionnaires in Oswestry and Modified Zung (months follow-up)

Number of cases of missing data in each item of the questionnaires for outcome measures in 60 cases

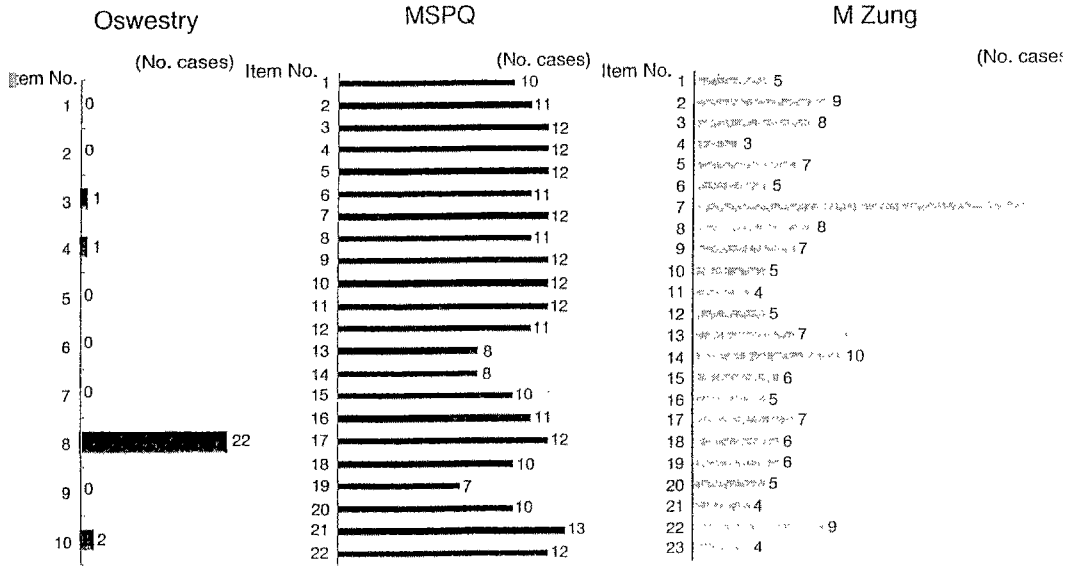


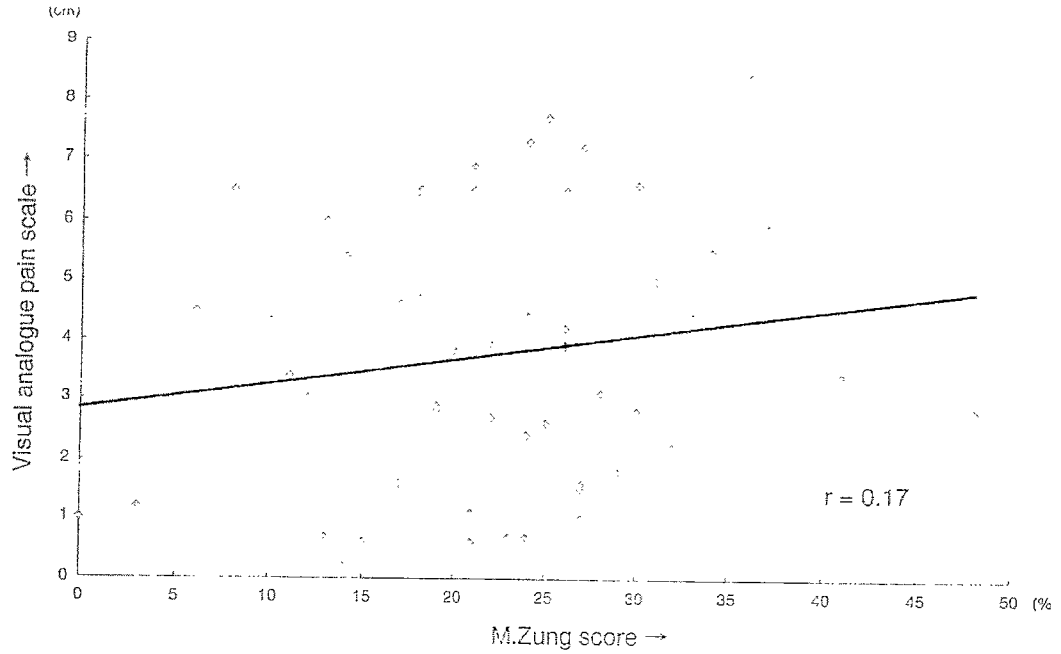
Table 3. Relationship between visual analogue pain scale and Modified Zung score in all cases

Change of total scores of questionnaires in Oswestry and Modified Zung (months follow up)

		Improved	Unchanged	Worse
Oswestry	Non-specific	18→8 (15)	(0)	14→20 (7)
	Control (Specific)	30→12 (23)	29→29 (3)	22→28 (12)
Modified Zung	Non-specific	29→19 (9)	(0)	20→26 (10)
	Control (Specific)	26→18 (17)	32→32 (1)	16→25 (19)

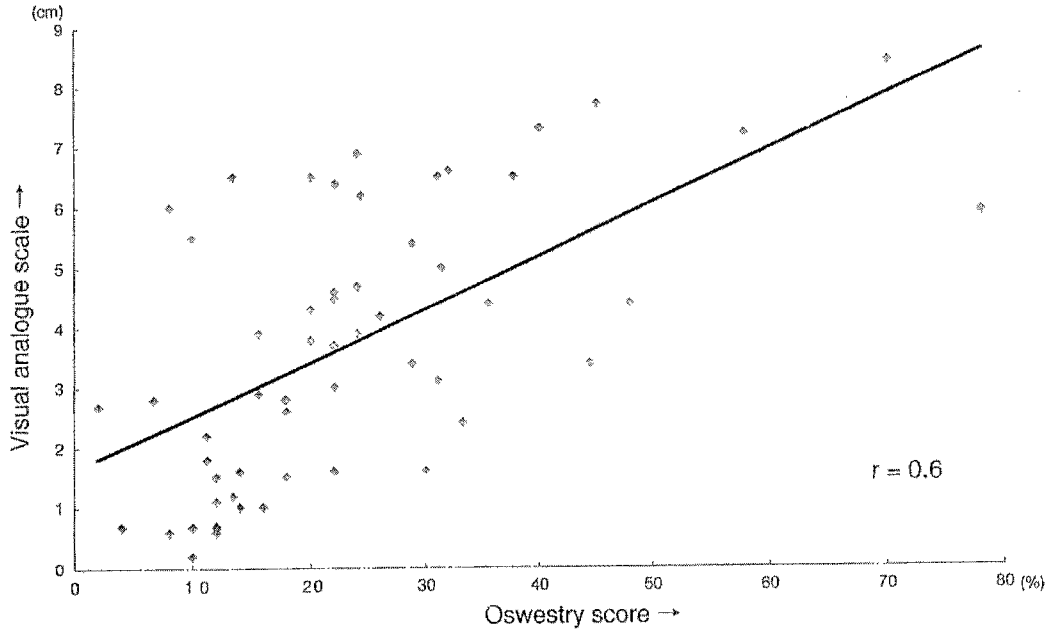
( ) : Number of Patients

Table 4. Relationship between visual analogue pain scale and Oswestry disability score in all cases



Relationship between visual analogue pain scale and Modified Zung score in all cases

Table 5. Correlation between the changes of pain scale and the changes of the modified Zung scores in patients with LBP from the first to the second measurement



Relationship between visual analogue pain scale and Oswestry disability score in all cases

Table 6. Correlation between the changes of pain scales and the changes of Oswestry disability scores in patients with LBP from the first to the second measurement

Correlation between the changes of pain scale and the changes of the modified Zung scores in patients with LBP from the first to the second mesurement

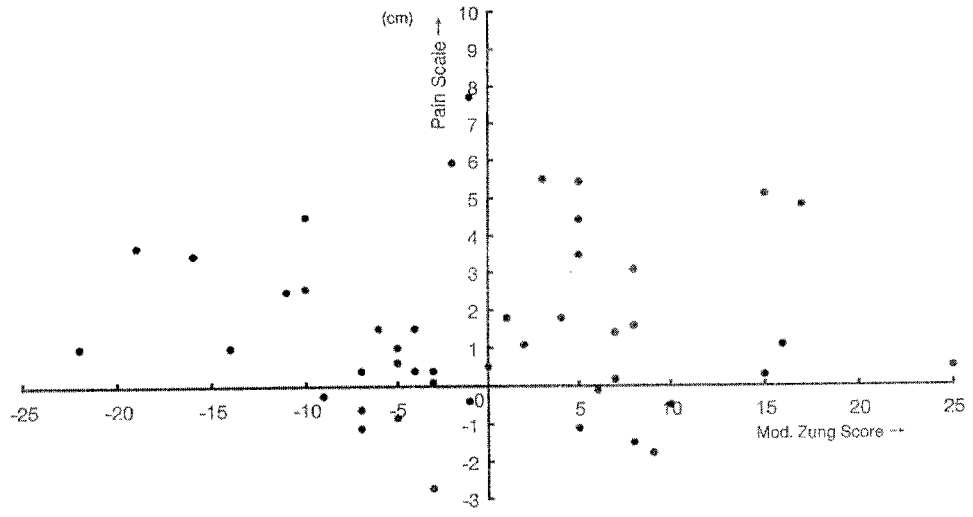
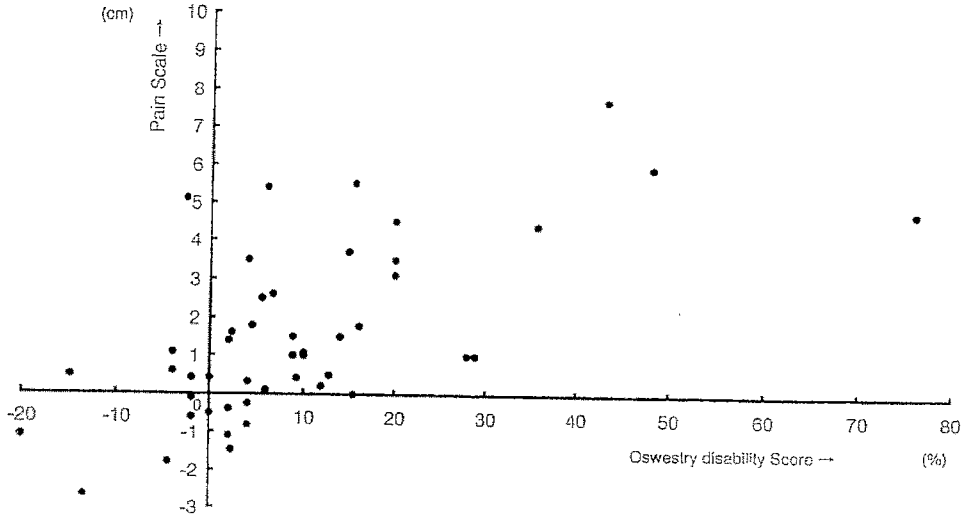


Table 7. Number of cases of missing data in each item of the questionnaires for outcome measures in 60 cases

Correlation between the changes of pain scales and the changes of Oswestry disability scores in patients with LBP from the first to the second measurement



APPENDIX 2.

EXPERIENCE FROM BRAZIL – PARTIAL REPORT ON THE EVALUATION OF PATIENTS WITH BACK PAIN

(Silvio Figueira Antonio, M.D.; José Carlos Mansur Szajubok, M.D.;
Rina Dalva N. Giorgi, M.D.; Sônia Maria Alvarenga Anti, M.D.;
Professor Wiliam Habib Chahade, M.D.)

The population currently under investigation is the ones who seek the Rheumatology Department of São Paulo State Hospital for Civil Servants; and to whom a clinical protocol and the abbreviated versions of the Oswestry, and the short form of McGill's, pain questionnaires are being applied.

Up to this moment, 67 patients have been surveyed and a clear predominance of female (59 patients = 88%) over male (8=12%) patients has been observed. The average age of the patients is 53.4 years old, within a rage between 22 to 84 years old.

As far as the individual habits are concerned, the vast majority of them do not practice any sporting activity and their leisure time is sedentary. It has also been observed that 21% of patients are smokers and only 6% stated that they drank alcoholic beverages.

As far as the Corporeal Mass Index (CMI, see enclosed table) is concerned, the following distribution has been found: 41.9% of the population has CMI <25; 41.9%=25 to 30; 12.9% has CMI = 30 to 35 and 3.2% has CMI >35.

An attempt has been made to evaluate the personality profile of the patients but it has been unproductive due to the frequent lack of co-operation of the interviewed persons. They do not accept personal questions. Almost all patients have complained of chronic back pain.

During the physical examination, at static inspection, 54.5% of the patients showed enhancing lordosis lumbar. Only 5% showed any march alternation and 8% showed some alteration in their neurological results.

Due to the fact that there could be inadequate understanding by the patients (owing to the social difference of population evaluated), in both Oswestry's and McGill's pain questionnaires (that have always been applied directly by different interviewing doctors), there are no patients that have self-applied the questionnaires.

The table enclosed shows the indices as found after the application of the Oswestry questionnaire. There is a variation between 0% up to 565.

We have had some difficulties in applying short-form McGill's pain questionnaire. The data are conflicting. If the onset is acute, there is a tendency for the patient to classify his pain within all possible options so that it will be classified, almost invariably as intense. We believe that this qustionnaire must be adapted to our target population.

Regarding Zung's questionnaire, we intend to apply it at a further opportunity in order to avoid a tiring interview. At this moment, our working group is determined to review every studied case with the objective of obtaining a long term therapeutic plan. We will also continue to work with a proposed protocol.

Fifteen descriptions are presented; the first 12 describe the sensory dimension of pain and the last refer to the affective dimension of pain. Our patients studied were unable to understand the purpose of this questionniare. However, in regard to the intensity of pain that give us a global dimension of the pain, the following results were obtained:

INTENSITY OF PAIN INDEX

0 = No pain	19.40%
1 = Mild pain	10.44%
2 = Discomforting	43.28%
3 = Distressing	7.46%
4 = Severe	5.97%
5 = Extreme	13.43%

APPENDIX 3.

AN INTRODUCTION TO AND EXPLANATION OF CHIROPRACTIC SCIENCE AND THEORY

By the President of Life University - Dr. Sid E. Williams

Chiropractic (from the Greek, meaning "done by hand") began in Davenport, Iowa, when an eclectic healer, DD Palmer, concluded that slight vertebral malalignments, which he called "subluxations", could be corrected through "adjustments" (a specific form of spinal manipulation). He began delivering these adjustments in 1895, and his son, BJ Palmer, continued his father's work by putting this new form of health care on a firm footing. Through his well-documented clinical work, BJ Palmer helped define and refine the art and science of chiropractic by formalizing precise procedures by which patients were diagnosed and provided care.

Doctors of chiropractic are concerned principally with the diagnosis, detection and correction of vertebral subluxations and act as direct-access health care providers, referring as necessary, otherwise establishing appropriate doctor-patient relationships. Based upon their initial assessment, Doctors of Chiropractic develop a care plan in which the frequency of visits typically tapers off as the condition resolves. Patients often are instructed in wellness procedures such as spinal hygiene, healthful living practices, musculoskeletal rehabilitation, and nutrition. The term subluxation was conceived to be a slight osseous displacement (less than a luxation or dislocation) with associated nervous interference. More recently, the term "vertebral subluxation complex" (VSC) was developed to include associated vascular, muscular, and connective tissue components (Lantz, 1990). Both psychological and physical stresses can give rise to subluxations, and there is evidence that the VSC can become a self-sustaining entity in which a spinal joint becomes fixated through a nociceptor-mediated positive feedback loop.

Chiropractic theory contends that the VSC can manifest itself both locally and globally. The local response involves injury to ligaments, tendons, discs, cartilage, joint capsules, and other tissues, initiating inflammation, muscle spasm, pain, and immobility (Ruch, 1997). As the nervous system can directly or indirectly affect all body tissues, a subluxation can influence an entire range of physiological functions extending to systemic and cellular levels. The effects of the VSC are not limited to the musculoskeletal system; subluxations may affect the immune system, viscera, and the body's ability to maintain homeostasis.

Chiropractors assess the osseous component of the VSC through x-ray, MRI, palpation, postural analysis, and other imaging methods. The neurological component of the VSC can be detected directly through somatosensory evoked potential testing, or indirectly through thermography, electromyography, or leg length discrepancy measurements.

Clinically, subluxations are corrected through adjustive procedures. The chiropractic adjustment is a very specific directional thrust applied to the area of a subluxated vertebra, utilizing parts of the vertebra and its contiguous structures as short levers to directionally reduce the predetermined articular malposition. A broad array of chiropractic techniques has been developed that collectively feature specific, high-velocity, low-amplitude applications of force and energy delivered either manually or with a hand-held or table-mounted chiropractic adjusting instrument. Chiropractic distinguishes itself from gross manipulative interventions in that the adjustive procedure is designed to precisely align spinal

components rather than merely free immobile joints. Chiropractic distinguishes itself from other health disciplines in that, through the removal of nervous system interference, the body's ability to heal is enhanced without the use of drugs or surgery.

In 1897, DD Palmer opened up the first school of chiropractic that still exists in Davenport, Iowa. Others followed, and significant progress has been made to standardize chiropractic education worldwide. The Council on Chiropractic Education, under the aegis of the United States Department of Education, was created to regulate the accreditation of institutions that offer chiropractic curricula in the United States. Currently, there are twenty-one accredited chiropractic colleges worldwide. In 1997, there were 14,710 students enrolled in the sixteen U.S. schools (Enrollment statistics from the U.S. Council on Chiropractic Education, Scottsdale, AZ, 1998). Chiropractic education is designed not only to convey relevant scientific knowledge, but also to develop appropriate clinical skills and proficiencies. The chiropractic student receives extensive training in all of the natural sciences, with emphasis on the relationship between the human spine and nervous system and its affect on general health and quality of life. All fifty states in the U.S. and many other countries license and regulate the practice of chiropractic; still other countries recognize chiropractic under general law. To receive licensure, candidates must be graduates of an accredited college of chiropractic and pass a series of state or national examinations. Doctors of Chiropractic must maintain their training through postgraduate education. The chiropractic scope of practice varies widely, generally emphasizing the detection and correction of the vertebral subluxation, though often including adjustment of non-spinal articulations.

Chiropractic research has been conducted since the profession's inception, with early efforts concentrating on instrumentation and technique development. Winsor's cadaver studies in 1921 demonstrated a strong correlation between particular visceral diseases and vertebral misalignment patterns (termed "minor curvatures"). Other work helped validate chiropractic by demonstrating that very small compressive forces (10-20 mmHg) were sufficient to suppress the firing of dorsal nerve roots (Sharpless, 1974), suggesting that small vertebral misalignments could indeed adversely affect nerve roots.

Early chiropractic success led to randomized clinical trials (RCTs) and comparative studies with other established interventions. Chiropractic has been shown to be effective in the management of back pain, and, in addition to challenging other treatments in efficacy, often was preferred by patients as demonstrated in a number of scientific comparative studies (Meade et al, 1990; Meade et al, 1995; Manga et al, 1993; Shekelle et al, 1992; Koes et al, 1996; Carey et al, 1995). The comparison studies as well as those demonstrating the cost-effectiveness of chiropractic care (Johnson et al; 1989, Jarvis et al, 1991) have led the US Government to recommend chiropractic adjustments (spinal manipulation) as a valid intervention for acute low back pain (Bigos et al, 1994). Less rigorous studies also have demonstrated chiropractic to be effective for other conditions, both musculoskeletal and non-musculoskeletal (see Rosner, 1997).

Unfortunately, chiropractic research, as well as that of non-traditional health care disciplines, must overcome obstacles that do not affect studies investigating medicine. The design of the RCT, which usually features double-blinding, is difficult to apply to chiropractic, as sham (placebo) chiropractic procedures, which must mimic the actual adjustments, can inadvertently provide benefit to the patient. Moreover, research focusing on patients who have already developed detrimental conditions may be taking an unfair or unrealistic approach, as theory suggests that chiropractic care is also valuable as a preventive measure.

In conclusion, the standardization and improvement of chiropractic education has been a significant factor in the establishment and recognition of the profession by various health care and governmental agencies. Chiropractic's credibility and acceptance continues to grow through its research developments. Clinical outcomes and patient satisfaction have also contributed greatly to the establishment of chiropractic as a separate and distinct profession.

REFERENCES:

Bigos S, Bowyer O, Braen G et al. *Acute Low Back Problems in Adults. Clinical Practice Guideline No. 14.* AHCPR Publication No. 95-0642. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services. December 1994.

Carey TS, Garrett J, Jackman A et al. *The outcomes and costs of care for acute low back pain among patients seen by primary care practitioners, chiropractors, and orthopaedic surgeons.* N Engl J Med, 1995, 333(14):913-917.

Enrollment statistics from the U.S. Council on Chiropractic Education. Scottsdale, AZ. 1998.

Jarvis K, Phillips R, Morris E. *Cost per Case Comparison of Back Injury Claims of Chiropractic Versus Medical Management for Conditions with Identical Diagnostic Codes.* J Occup Med, 1991, 33(8):847-52.

Johnson, MR, Schultz MK, Ferguson AC. *A comparison of chiropractic, medical and osteopathic care for work related sprains and strains.* J Manipulative Physiol Ther, 1989, 12(5):335-344.

Koes BW, Assendelft WJJ, Bouter LM, van der Heijden MG. *Spinal manipulation for low back pain: An updated systematic review of randomized clinical trials.* Spine, 1996, 21(24):2860-2873.

Lantz C. *The vertebral subluxation complex.* J Manipulative Physiol Ther, 1990, 13(1):56.

Manga P, Angus D, Swan W. *Effective management of low back pain: it's time to accept the evidence.* J Canadian Chiro Assoc, 1993, 37(4):221-229.

Meade TW, Dyer S, Browne W, Townsend J, Frank AO. *Random Comparison of Chiropractic and Hospital Outpatient Treatment for Low Back Pain of Mechanical Origin.* BMJ, 1990, 300:1431-1437.

Meade TW, Dyer S, Browne W, Townsend J, Frank AO. *Random Comparison of Chiropractic and Hospital Outpatient Treatment for Low Back: Results from Extended Follow Up.* BMJ, 1995, 311:349-351.
Rosner AL. *The Role of Subluxation in Chiropractic.* Des Moines, IA. FCER. 1997.

Ruch WJ. *Atlas of Common Subluxations of the Human Spine and Pelvis.* New York, NY. CRC Press. 1997.

Sharpless, SK. *Neurophysiology of Nerve Compression and Joint Fixation.* Boulder, CO. 1974.

Shekelle PG, Adams AH, Chassin MR, Hurwitz EL, Brook RH. *Spinal manipulation for low back pain.* Ann Intern Med, 1992, 117(7):590-598.

Winsor H. *Sympathetic Segmental Disturbances—II. The evidences of the association, in dissected cadavers, of visceral disease with vertebral deformities of the same sympathetic segments.* The Medical Times, 1921, 267-271.

APPENDIX 4.

OUTCOME MEASURES (QUESTIONNAIRES) IN MULTIPLE LANGUAGES

ENGLISH:

Name: _____ Patient No.: _____

Date: _____

Oswestry Disability Questionnaire

This questionnaire has been designed to give us information about how your back or leg pain has effected your ability to manage in everyday life. Please answer every section and **mark only the one box in each section which applies most to you.** We realize you may consider that two of the statements in any one section relate to you, but *please mark just the one box which most clearly describes your problem.*

Section 1: Pain Intensity

I have no pain at the moment	☐
The pain is very mild at the moment	☐
The pain is moderate at the moment	☐
The pain is fairly severe at the moment	☐
The pain is very severe at the moment	☐
The pain is the worst imaginable at the moment	☐

Section 2: Personal Care (washing, dressing, etc.)

I can look after myself normally without causing extra pain	☐
I can look after myself normally but it causes extra pain	☐
It is painful to look after myself and I am slow and careful	☐
Need some help but manage most of my personal care	☐
I need help every day in most aspects of self care	☐
I do not get dressed, wash with difficulty, and stay in bed	☐

Name: Patient No.:

Date:

Section 3: Lifting

I can lift heavy weights without extra pain	☐
I can lift heavy weights but it gives extra pain	☐
Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed, e.g. on a table	☐
Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned	☐
I can lift only very light weights	☐
I cannot lift or carry anything at all	☐

Section 4: Walking

Pain does not prevent me from walking any distance	☐
Pain prevents me from walking more than 1 mile	☐
Pain prevents me walking more than 1/2 mile	☐
Pain prevents me walking more than 1/4 mile	☐
I can only walk using a stick or crutches	☐
I am in bed most of the time and have to crawl to the toilet	☐

Section 5: Sitting

I can sit in any chair as long as I like	☐
I can sit in my favorite chair as long as I like	☐
Pain prevents me from sitting more than 1 hour	☐
Pain prevents me from sitting more than 1/2 hour	☐
Pain prevents me from sitting more than 1/4 hour	☐
Pain prevents me from sitting at all	☐

Name: Patient No.:

Date:

Section 6: Standing

I can stand as long as I like without extra pain	☐
I can stand as long as I like, but it gives me extra pain	☐
Pain prevents me from standing for more than 1 hour	☐
Pain prevents me from standing for more than 1/2 hour	☐
Pain prevents me from standing more than 10 minutes	☐
Pain prevents me from standing at all	☐

Section 7: Sleeping

My sleep is never disturbed by pain	☐
My sleep is occasionally disturbed by pain	☐
Because of pain I have less than 6 hours sleep	☐
Because of pain I have less than 4 hours sleep	☐
Because of pain I have less than 2 hours sleep	☐
Pain prevents me from sleeping at all	☐

Section 8: Sex Life (if applicable)

My sex life is normal and causes no extra pain	☐
My sex life is and causes some extra pain	☐
My sex life is nearly normal, but it is very painful	☐
My sex life is severely restricted by pain	☐
My sex life is nearly absent because of pain	☐
Pain prevents any sex life at all	☐

Name: _____ Patient No.: _____

Date: _____

Section 9: Social Life

My social life is normal and causes me no extra pain	☐
My social life is normal but increases the degree of pain	☐
Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g. sports, etc.	☐
Pain has restricted my social life and I do not go out as often	☐
Pain has restricted my social life to home	☐
I have no social life because of pain	☐

Section 10: Traveling

I can travel anywhere without pain	☐
I can travel anywhere but it gives me extra pain	☐
The pain is bad, but I manage journeys over 2 hours	☐
Pain restricts me to journeys of less than 1 hour	☐
Pain restricts me to short journeys under 30 minutes	☐
Pain prevents me from traveling except to receive treatment	☐

ODI = _____ x 20 = _____ %

Name: _____ Patient No.: _____

Date: _____

Chronic Disability Index (Waddell)

Initial Assessment

Description	*Rating (1-9)*
Help needed/avoid heavy lifting (30-40 lbs or 3-4 yr old child)	
Sitting generally limited to 1/2 hour	
Traveling in car/bus generally limited to 1/2 hour	
Walking generally limited to 1/2 hour	
Standing generally limited to 1/2 hour	
Sleep disturbed regularly by back pain (2-3 times per week)	
Miss/curtail social activities regularly due to back pain (not sport)	
Diminished frequency of sexual activity because of back pain	
Help often required with socks/shoe laces/tights	

Total _____

Name: Patient No.:

Date:

Physical Impairment Index (Waddell)

Initial Assessment

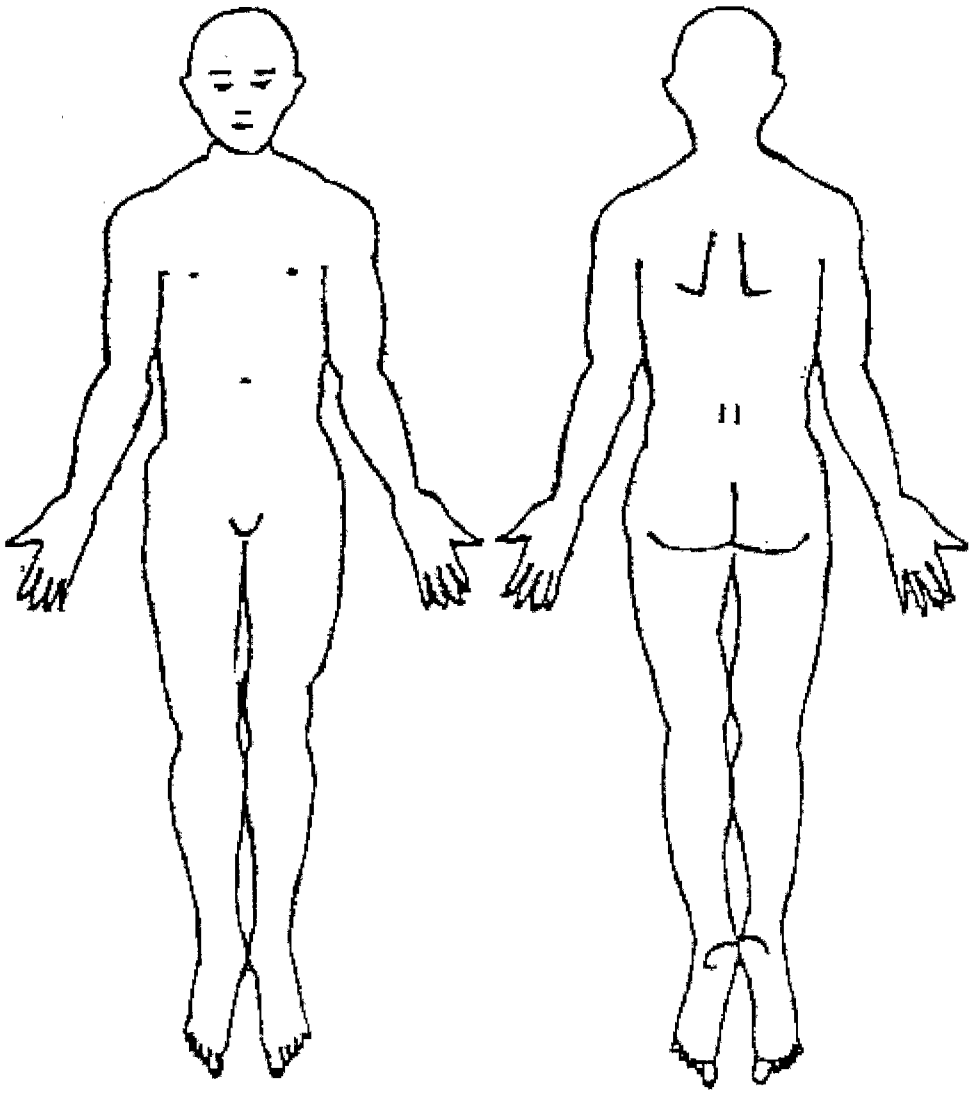
	Mathematical Constant		*28*
Major Problem (Pattern of Pain)	Back Pain	0	
	Back + Referred Leg Pain	3	
	Root pain	-2	
Time Pattern	Recurring	4	
	Chronic	8	
Previous Fracture	Transverse Process	1	
	Wedge Compression	2	
	Fracture/Dislocation	6	
Previous Back Surgery	None	0	
	One	3	
	More than One	6	
Root Compression	None	0	
	Doubtful	1	
	Definite	2	
	SUBTOTAL		+
Lumbar Flexion Schober	CMS x 2		-
Straight Leg Raising (left)	°/10		-
Straight Leg Raising (right)	°/10		-
	SUBTOTAL		-
	Approximate Total Bodily Impairment		%

Name: _____ Patient No.: _____

Date: _____

Mark the areas on your body where you feel these sensations. Use the symbols below and mark all the affected areas.

Numbness	Pins and Needles	Ache	Pain
= = = = = =	O O O O O	X X X X X	/ / / / / /
= = = = = =	O O O O O	X X X X X	/ / / / / /
= = = = = =	O O O O O	X X X X X	/ / / / / /



Name: _____ Patient No.: _____

Date: _____

Short-Form McGill Pain Questionnaire

Please select from the list below words that you would use to describe your pain:

	None (0)	*Mild (1)*	*Moderate (2)*	*Severe (3)*
Throbbing				
Shooting				
Stabbing				
Sharp				
Cramping				
Gnawing				
Hot/Burning				
Aching				
Heavy				
Tender				
Splitting				
Tiring/Exhausting				
Sickening				
Fearful				
Punishing/Cruel				

Please mark a cross on the line below to indicate the intensity of your pain:

No Pain _____ Worst Pain

Present Pain Index

Which of the following words explains your present pain?

0	No Pain	
1	Mild	
2	Discomforting	
3	Distressing	
4	Horrible	
5	Excruciating	

Name: _____ Patient No.: _____

Date: _____

Modified Somatic Perception Questionnaire

Please Describe how you have felt during the past week by placing a check-mark (✓) in the appropriate box. *Please answer all questions and do not think too long before answering.*

	Not at all	*A little/ Slightly*	*A great deal/ Quite a bit*	*Extremely/Could not have been worse*
Heart rate increasing				
Feeling hot all over				
Sweating all over				
Sweating in a particular part of the body				
Pulse in neck				
Pounding in head				
Dizziness				
Blurring of vision				
Feeling faint				
Everything appearing unreal				
Nausea				
Butterflies in stomach				
Pain or ache in stomach				
Stomach churning				
Desire to pass water				
Mouth becoming dry				
Difficulty swallowing				
Muscles in neck aching				
Legs feel weak				
Muscles twitching or jumping				
Tense feeling across forehead				
Tense feeling in jaw muscles				

Name: Patient No.:

Date:

Modified Zung Index

Please indicate for each question the answer which best describes how you have been feeling recently. *Please answer all the questions.*

	Rarely or none of the time (less than 1 day a week)	*Some or little of the time (1-2 days per week)*	*A moderate amount of time (3-4 days per week)*	*Most of the time (5-7 days per week)*
I feel downhearted and sad				
Morning is when I feel best				
I have crying spells or feel like it				
I have trouble getting to sleep at night				
I feel that nobody cares				
I eat as much as I used to				
I still enjoy sex				
I notice I am losing weight				
I have trouble with constipation				
My heart beats faster than usual				
I get tired for no reason				
My mind is as clear as it used to be				
I tend to wake up too early				
I find it easy to do the things I used to				
I am restless and can't keep still				
I feel hopeful about the future				
I am more irritable than usual				
I find it easy to make a decision				
I feel quite guilty				
I feel that I am useful and needed				
My life is pretty full				
I feel that others would be better off if I were dead				
I am still able to enjoy the things I used to				

APPENDIX 4.

OUTCOME MEASURES (QUESTIONNAIRES) IN MULTIPLE LANGUAGES

RUSSIAN

ВОПРОСНИК ОСВЕСТРИ

Этот вопросник предназначен для получения информации о том, в какой степени боль в спине или ноге повлияла на Вашу способность управляться в повседневной жизни. Пожалуйста, дайте ответ по каждому разделу и пометьте в каждом разделе ***ТОЛЬКО ОДИН КВАДРАТИК***, который имеет отношение к Вам. Мы понимаем, что в каждом разделе к Вам могут иметь отношение 2 утверждения, но, ***ПОЖАЛУЙСТА, СДЕЛАЙТЕ ОТМЕТКУ ТОЛЬКО В ТОМ КВАДРАТИКЕ, КОТОРЫЙ НАИБОЛЕЕ ТОЧНО ОПИСЫВАЕТ ВАШУ ПРОБЛЕМУ.***

_____

(фамилия, имя, отчество)

_____

дата

РАЗДЕЛ 1 - ИНТЕНСИВНОСТЬ БОЛИ

- ☐ В данный момент у меня нет боли
- ☐ В данный момент боль очень слабая
- ☐ В данный момент боль умеренная
- ☐ В данный момент боль достаточно сильная
- ☐ В данный момент боль очень сильная
- ☐ В данный момент боль настолько сильная, что даже трудно себе представить

РАЗДЕЛ 2–САМООБСЛУЖИВАНИЕ (УМЫВАНИЕ, ОДЕВАНИЕ и т.д.)

- ☐ Я в состоянии заботиться о себе, и это не вызывает дополнительной боли
- ☐ Я в состоянии заботиться о себе, но это вызывает дополнительную боль
- ☐ Забота о себе вызывает боль, и мои движения медленны и осторожны
- ☐ Я нуждаюсь в некоторой помощи, но справляюсь с большинством моих собственных забот
- ☐ Я нуждаюсь ежедневно в помощи по большинству аспектов самообслуживания
- ☐ Я не могу одеваться, моюсь с трудом и остаюсь в постели

РАЗДЕЛ 3 – ПОДЪЕМ ТЯЖЕСТИ

- ☐ Я в состоянии поднимать большой вес без дополнительной боли
- ☐ Я в состоянии поднимать большой вес, но это вызывает дополнительную боль
- ☐ Боль не позволяет мне поднимать большой вес, но я в состоянии это сделать, если он удобно размещен, например, на столе
- ☐ Боль не позволяет мне поднимать большой вес, но я в состоянии справиться с легким и средним весом, если он удобно размещен
- ☐ Я в состоянии поднимать только очень легкий вес
- ☐ Я не в состоянии ни поднимать, ни нести что-нибудь

РАЗДЕЛ 9 – ОБЩЕСТВЕННАЯ ЖИЗНЬ

- ☐ Я принимаю обычное участие в общественной жизни и это не сопровождается возникновением у меня дополнительной боли
- ☐ Я принимаю обычное участие в общественной жизни, но это способствует усилению выраженности боли
- ☐ Боль не указывает существенного влияния на мое участие в общественной жизни, но ограничивает мою активность, связанную с повышенной затратой энергии, например, занятия спортом и т.д.
- ☐ Боль сузила мое участие в общественной жизни, и я не бываю в обществе столь часто, как раньше
- ☐ Боль ограничила мою общественную жизнь домом
- ☐ Я не принимаю участия в общественной жизни из-за боли

РАЗДЕЛ 10 – ПЕРЕМЕЩЕНИЕ

- ☐ Я могу перемещаться всюду без боли
- ☐ Я могу перемещаться всюду, но это вызывает у меня дополнительную боль
- ☐ Боль сильная, но я справляюсь с перемещением в течение более двух часов
- ☐ Боль ограничивает мои возможности к перемещениям временем менее 1 часа
- ☐ Боль ограничивает мои возможности к коротким перемещениям до 30 минут
- ☐ Боль препятствует моему перемещению, за исключением поездок с целью получения лечения

_____ x 20 = _____%

(фамилия, имя, отчество)

ИНДЕКС НАРУШЕНИЯ ФИЗИЧЕСКОГО СОСТОЯНИЯ

(по Вадделю)

исходная оценка

Математическая константа			**28**
Главная проблема	**Характер боли**		
	Боль в спине	0)	
	Боль в спине + отраженная боль в ноге	3)	
	Корешкова боль	2)	
Временной характер	Рецидивирующая	4)	
	Хроническая	8)	
Предшествующий перелом	Поперечный отросток	1)	
	Клиновидная компрессия	2)	
	Перелом\смещение	6)	
Предшествующая операция на позвоночнике	Не было	0)	
	Одна	3)	
	Более одной	6)	
Сдавление корешка	Не было	0)	
	Сомнительное	1)	
	Определенное	2)	
ПРОМЕЖУТОЧНАЯ СУММА			**+**
Поясничное сгибание (тест Шобера)		см х 2	-
Подъем выпрямленной ноги (левой)		*o*\10	-
Подъем выпрямленной ноги (правой)		*o*\10	-
ПРОМЕЖУТОЧНАЯ СУММА			-
ПРИБЛИЗИТЕЛЬНОЕ НАРУШЕНИЕ ОБЩЕГО ФИЗИЧЕСКОГО СОСТОЯНИЯ			%

КРАТКАЯ ФОРМА ВОПРОСНИКА О ХАРАКТЕРЕ БОЛИ

(МакГилла)

_____ (фамилия) _____ (дата)

Пожалуйста, выберите из списка, расположенного ниже, слова, которые Вы бы использовали для описания Вашей боли:

	Нет	Слабая	Умеренная	Сильная
Пульсирующая	0)	1)	2)	3)
Стреляющая	0)	1)	2)	3)
Колющая	0)	1)	2)	3)
Резкая	0)	1)	2)	3)
Схваткообразная	0)	1)	2)	3)
Грызущая	0)	1)	2)	3)
Жгучая	0)	1)	2)	3)
Ноющая	0)	1)	2)	3)
Мучительная	0)	1)	2)	3)
При касании	0)	1)	2)	3)
Раскалывающаяся	0)	1)	2)	3)
Утомительная	0)	1)	2)	3)
Тошнотворная	0)	1)	2)	3)
Пугающая	0)	1)	2)	3)
Жестокая	0)	1)	2)	3)

Поместите вертикальной черточкой на нижележащей линии интенсивность Вашей боли:

Нет боли ●——————————● Наиболее сильная боль

БОЛЕВОЙ ИНДЕКС В НАСТОЯЩЕЕ ВРЕМЯ

Какое из следующих слов может объяснить Вашу боль в настоящее время:

0	Нет боли	
1	Слабая	_____
2	Вызывающая ощущение дискомфорта	_____
3	Внушающая беспокойство	_____
4	Ужасная	_____
5	Мучительная	_____
		_____

МОДИФИЦИРОВАННЫЙ ИНДЕКС ЦУНГА

Пожалуйста, укажите для каждого из этих вопросов, какой ответ наилучшим образом описывает то, как Вы себя чувствовали в настоящее время.
ПОЖАЛУЙСТА, ОТВЕТЬТЕ НА ВСЕ ВОПРОСЫ!

	Никогда	Иногда или редко (не чаще 1 дня в неделю)	Иногда (1-2 дня в неделю)	Достаточно часто (3-4 дня в неделю)
У меня подавленное и печальное настроение				
По утрам я чувствую себя лучше всего				
Периодически я плачу или хочу заплакать				
Мне трудно заснуть вечером				
Я чувствую себя никому не нужным				
Я ем столько же, сколько и раньше				
Я до сих пор получаю удовольствие от секса				
Я отмечаю, что теряю в весе				
У меня запоры				
Мое сердце бьется быстрее, чем обычно				
Я утомляюсь беспричинно				
Я мыслю также ясно, как обычно				
Я часто просыпаюсь слишком рано				
Мне легко справляться с обычными (повседневными) делами				
Я беспокоен (возбужден) и не могу держать себя в руках				
Я смотрю в будущее с надеждой				
Я более раздражителен, чем обычно				
Я легко принимаю решения				
Я испытываю чувство вины				
Я чувствую себя полезным и нужным				
Моя жизнь достаточно содержательна				
Я чувствую, что окружающим было бы лучше, если бы я умер				
Я по-прежнему способен радоваться обычным вещам				

APPENDIX 4.

OUTCOME MEASURES (QUESTIONNAIRES) IN MULTIPLE LANGUAGES

JAPANESE:

Oswestry 不自由（身体障害）度調査表

この質問表はあなたの背中・腰や下肢の痛みが、毎日の生活をすすめるうえで、どのように影響しているか、私達に教えてもらうために作成されました。各質問に答えて下さい。あなたにあてまる１つのボックス□だけに印をつけてください。私達は、いずれか１つの質問で２つの記述（文章）があなたに関係すると考えることはあると思います。しかし、あなたの苦痛を最も明確にあらわしているボックス１つだけに印✓を付けて下さい。

慶應義塾大学　病院、診療科（リハビリテーション科、整形外科、内科、その他）

名前：　　カルテ番号：

日付：平成　　年　　月　　日

設問　1 - 痛みの強さ

□　痛みは現時点で全くありません。
□　痛みは現時点で非常に弱いです。
□　痛みは現時点で中くらいです。
□　痛みは現時点でかなり強いです。
□　痛みは現時点でたいへん強いです。
□　痛みは現時点で想像できないほど最悪です。

設問　2 - 身の回りのこと（洗面入浴などの洗浄、着衣など）

□　私は余分な痛みを起こすことなく、身の回りのことを普通にできます。
□　私は身の回りのことを普通にできますが、余分な痛みを生じます。
□　身の回りのことをするのに痛みます。私はゆっくりと注意して行っています。
□　ある程度の助けが必要ですが、ほとんど身の回りのことを自分でできます。
□　私は自分の身の回りのことをする上のほとんどの点で毎日助けを必要とします。
□　私は着衣できず、体の洗い、洗面は困難を伴い、ベットに横になっています。

設問　3 - 物の持ち上げ

□　私は余分な痛みなしに重いものを持ち上げられます。
□　私は重いものを持ち上げられますが、余分な痛みを生じます。
□　私は痛みのため床から重いものを持ち上げられませんが、テーブルの上など丁度良い位置にある場合は、持ち上げられます。
□　私は痛みのため床から重いものを持ち上げられませんが、丁度良い位置にある場合は、軽－中程度の重さのものは持ち上げられます。
□　私は非常に軽いものだけしか持ち上げられません。
□　私はどんなものでも、持ち上げたり運んだりは全くできません。

設問　4 - 歩くこと

□　私は痛みで、どんな距離でも歩けなくなることはありません。
□　私は痛みのため１マイル（1.6km）以上歩けません。
□　私は痛みのため１／２マイル（800m）以上歩けません。
□　私は痛みのために１／４マイル（400m）以上歩けません。
□　私は杖や松葉杖を使ってようやく歩けます。
□　私はほとんど寝たきりで、トイレに這っていかなくてはなりません。

設問　5 - 座ること

- ☐ 私はどんな椅子でも、好きなだけの時間座っていることができます。
- ☐ 私は私に合った椅子に、好きなだけの時間座っていることができます。
- ☐ 私は痛みのために１時間以上座っていられません。
- ☐ 私は痛みのために１／２時間（３０分）以上座っていられません。
- ☐ 私は痛みのために１／４時間（１５分）以上座っていられません。
- ☐ 私は痛みのために全く座ることが出来ません。

設問　6 - 起立

- ☐ 私は余分な痛みなしに、好きなだけの時間立っていられます。
- ☐ 私は自分が望むだけの時間立っていられますが、余分な痛みを生じます。
- ☐ 私は痛みのために１時間以上立っていられません。
- ☐ 私は痛みのために３０分以上立っていられません。
- ☐ 私は痛みのために１０分以上立っていられません。
- ☐ 私は痛みのために全く立っていられません。

設問　7 - 睡眠

- ☐ 私の睡眠は痛みで妨げられることはありません。
- ☐ 私の睡眠は痛みで時折妨げられます。
- ☐ 私は痛みで６時間以上眠れません。
- ☐ 私は痛みで4時間以上眠れません。
- ☐ 私は痛みで２時間以上眠れません。
- ☐ 私は痛みのため全く眠れません。

設問　8 - 性生活（もし当てはまるなら）

- ☐ 私の性生活は正常で、余分な痛みを生じません。
- ☐ 私の性生活は正常ですが、多少余分な痛みを生じます。
- ☐ 私の性生活はほとんど正常ですが、たいへん痛みます。
- ☐ 私の性生活は痛みのため、たいへん制限されています。
- ☐ 私の性生活は痛みのため、ほとんどありません。
- ☐ 私は痛みのため、全く性生活はありません。

設問　9 - 社会生活

- ☐ 私の社会生活は普通で、余分な痛を生じません。
- ☐ 私の社会生活は普通ですが、痛みの程度を強くします。
- ☐ 痛みで、私のより活動的な興味のスポーツなどが制限される以外、私の社会生活に大きな影響を及ぼしません。
- ☐ 私の社会生活は痛みのため制限され、めったに外出しません。
- ☐ 私の社会生活は痛みのため家の中に限られています。
- ☐ 私の社会生活は痛みのため、全くありません。

設問　１０- 旅行

- ☐ 私は痛み無しに、どこへでも旅行できます。
- ☐ 私はどこへでも旅行できますが、余分な痛みを生じます。

☐ 私はひどい痛みを感じますが、２時間以上の旅行が出来ます。
☐ 私に痛みのため、１時間以内の旅行に制限されています。
☐ 私は痛みのため、３０分以内の小旅行に制限されています。
☐ 私は痛みのため、治療をする以外旅行しません。

総計　　ODI　　x 20=　　%
(Oswestry Disability Index)

M.S.P.Q.

一週間を振り返ってあなたはどんなふうに感じていたかを適当なボックス□にチェック✓して表して下さい。全ての質問にお答え下さい。あまり長時間考えないで答えて下さい。

	全くない	少しの／わずかの	多くの／かなりの	極めて／より悪かったことはなかった
心拍数が増えている。（動悸がする。）				
身体中が熱っぽい。				
身体中が汗をかいている。				
身体の特定の場所に汗をかいている。				
頚に拍動を感じる。				
頭ががんがんする。				
目が回る。（眩暈）				
目がかすんでぼんやりする。				
フラフラして気を失いそうである。				
全てが非現実的に思える。				
嘔気がする。				
胃がごろごろする。（胃がかき回される）				
胃が痛む。				
いらいらする。				
尿をしたい気分である。				
口の中が乾燥する（つばが出ない）。				
ものが飲み込みにくい。				
頚の筋肉が痛い。				
足が弱ったと感じる。				
筋肉がピクピク痙攣する。				
額全体に緊張（はった感じ）を感じる。				
顎の筋肉に緊張（はった感じ）を感じる。				

次の各質問で、最近どう感じているかをどの答えが最もよく表わしているかを示して下さい。（○印を付けて下さい。）
全ての質問にお答え下さい。

	ほとんど、全くない	いくらか、少しある	中程度ある	ほとんどいつも
	1日／週以下	1-2日／週	3-4日／週	5-7日／週
1. 私は落胆していて、悲しい。				
2. 私は朝が最も気分のよい時である。				
3. 私はしばらく泣き続ける、あるいは泣きたい気分である。				
4. 私は夜寝付きにくい。				
5. 私は誰も面倒みてくれないと感じる。				
6. 私は以前とおなじくらい食べられる。				
7. 私はまだセックスを楽しむ				
8. 私は体重が減っているのに気付く。				
9. 私は便秘に悩んでいる。				
10. 私の心臓の鼓動（どきどき）は、いつもよりはやい。				
11. 私は理由なく疲れる。				
12. 私の心は以前と同様晴れ晴れしている。				
13. 私は非常に早く目覚めがちである。				
14. 私は以前やっていたことを行うのに容易な事を見出している。				
15. 私は落ち着かず、じっとしていられない。				
16. 私は将来に希望を感じている。				
17. 私はいつもよりいらいらしている。				
18. 私は決心するのに容易に感じる。				
19. 私はたいへんうしろめたく感じる。				
20. 私は有用で必要とされていると感じる。				
21. 私の生活は非常に充実している。				
22. 他の人々は私は死んだらよくなるだろうと思っていると私は信じている。				
23. 私は以前からやってきたことをまだ楽しんでいる。				

下記の文章で、あてはまるところに○印を付けてください。

ST004C/104

慢性身体障害指標　(Waddell)　　初期評価

重いもの（３０～４０ポンド(14-18kg)あるいは３～４歳児）を持ち上げるのに助けが要るか、あるいは持ち上げることを避けます。	
椅子に座るのは普通３０分以内に限られています。	
自動車かバスでの旅行は３０分以内に限られています。	
歩くのは普通３０分以内に限られています。	
立っているのは普通３０分以内に限られています。	
睡眠は背部痛のためきまって妨げられます。（週に２～３回）	
背部痛のため社会活動（スポーツではない）はよく行えないか、少なくしています。	
背部痛のため性生活の頻度が減少しています。	
靴下／靴ひも／タイツを履くのにしばしば手助けが必要です。	

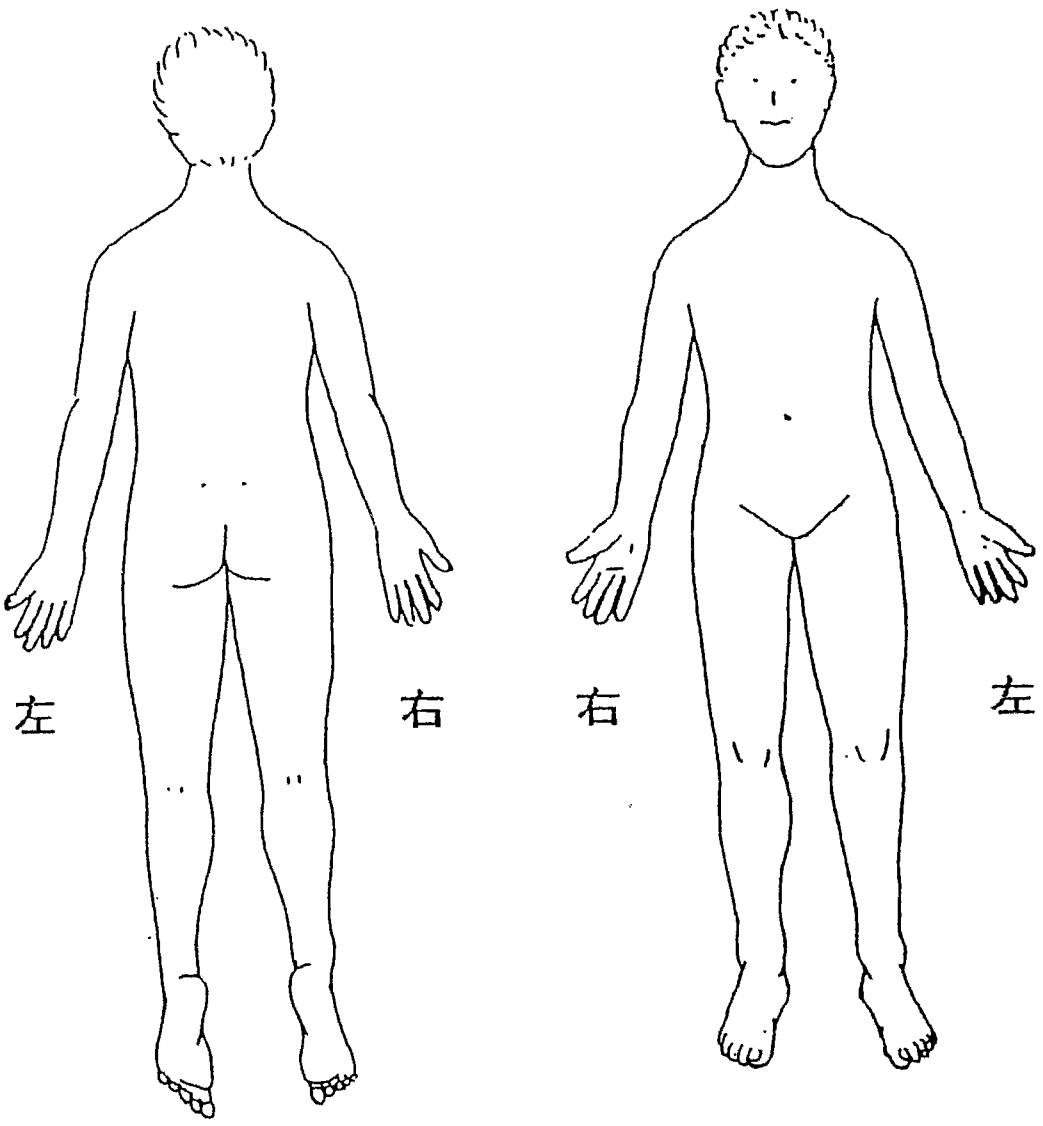
計

D.o.B.　　日付

あなたの身体でこれらの感覚を感じる場所を示してください。

記号を使ってください。　　すべての障害部位に印をつけてください。

しびれ	ちくちくする痛み	鈍痛（慢性疼痛）	鋭い痛み
----	OOOO	××××	////
----	OOOO	××××	////
----	OOOO	××××	////



簡略型　McGill 疼痛質問表

あなたの痛みを表わすのに適当な言葉を下のリストから選び、○印を付けて下さい。

	なし	軽度	中等度	高度
ずきんずきんする痛み	0)	1)	2)	3)
走るような痛み	0)	1)	2)	3)
刺すような痛み	0)	1)	2)	3)
激しい痛み	0)	1)	2)	3)
締めつけるような痛み	0)	1)	2)	3)
噛まれるような痛み	0)	1)	2)	3)
焼け付くような痛み	0)	1)	2)	3)
鈍痛（うずき）	0)	1)	2)	3)
重苦しい痛み	0)	1)	2)	3)
さわったり、おされると痛む	0)	1)	2)	3)
裂けるような痛み	0)	1)	2)	3)
疲れ消耗する痛み	0)	1)	2)	3)
吐き気を催すような痛み	0)	1)	2)	3)
恐怖,不安を感じる痛み	0)	1)	2)	3)
強くつねられた痛み	0)	1)	2)	3)

あなたの痛みの強さを示すように下の直線に×で印を付けて下さい：

痛まない ├──────────────────────────────┤ 最悪の痛み

現在の痛みの指標：

以下のどの言葉があなたの現在の痛みを表わしていますか。あてはまるところに○印を付けて下さい。

0	痛くない	_____
1	軽く痛む	_____
2	不快な痛み	_____
3	悲惨な痛み	_____
4	恐怖を伴うものすごい痛み	_____
5	耐え難い痛み	_____

◇医師記入欄◇

ST004C/105

身体障害指標　(Waddell)　　初期評価

算術定数			28
主要問題 痛みの型	背部痛 背部痛＋下肢関連痛 神経根痛	0) 3) -2)	
期間（時間）の様式	再発性 慢性	4) 8)	
骨折の既往	横突起 楔状圧迫骨折 骨折／捻挫	1) 2) 6)	
背部の手術の既往	なし 1回 2回以上	0) 3) 6)	
神経根圧迫	なし 疑い 確定	0) 1) 2)	
	小　計		＋
腰部屈曲Schoberテスト	cms ×2		－
伸展脚上げ試験（左）	0/10		－
伸展脚上げ試験（右）	0/10		－
	小　計		－
概算全身障害度			%

APPENDIX 4.

OUTCOME MEASURES (QUESTIONNAIRES) IN MULTIPLE LANGUAGES

PORTUGUESE:

Índice de incapacidade crônica
Cada NÃO que o indivíduo responder receberá um ponto. O número máximo de pontos (pior) é 9.

Índice de incapacidade física
Os escores obtidos na primeira seção serão somados a uma constante na parte superior da página, para fornecer um subtotal. O total para a segunda seção, que inclui os valores numéricos do teste de Schober e os testes de elevação da perna sem fleti-la, é subtraído e o resultado obtido é o escore de incapacidade percentual.

Escore de incapacidade de Oswestry
Cada seção contém 6 afirmações que recebem escores de 0, 1,2,3,4,5,6. Existem 10 seções. Os escores numéricos das afirmações selecionadas são somados, para fornecer um total em 50, que é convertido em porcentagem.

Questionário de dor de McGill abreviado
São apresentadas 15 descrições. As 12 primeiras refletem a dimensão sensorial da dor e as quatro finais abordam a dimensão afetiva. Podem ser calculados três escores: o escore total, o escore sensorial e o escore afetivo. A escala visual analógica de dor e esse índice de intensidade de dor fornecem uma medida da intensidade global da dor.

Referência:
Questionário de dor de McGill abreviado
Ronald Melzack
Pain 30 (1987): pp 191-197

Questionário de percepção somática modificado e de Zung modificado
São anexados modelos de obtenção de escore para esses dois índices. As seguintes referências podem ser úteis
1. The modified Somatic Perception Questionnaire
Main, C. J.
J. Psychosom. Res. 27;503-514, 1983
2. The Detection of Psychological Abnormality in Chronic Low Back Pain Using 4 Simple Scales
Main, C. J. Wadell, G.
Curr Concepts Pain 2:10-15, 1984

Apêndice A: Questionário de percepção somática modificado

Por favor, descreva como você se sentiu durante a última semana, assinalando o quadrado apropriado (✓)
Por favor, responda a todas as perguntas. Não pense muito antes de respondê-las.

	Não	Um pouco	Muito	Insuportável Não poderia ser pior
Aumento da freqüência cardíaca				
Sensação de calor em todo o corpo	0	1	2	3
Sudorese em todo o corpo	0	1	2	3
Sudorese em uma região particular do corpo				
Pulsação no pescoço				
Sensação de martelada na cabeça				
Tontura	0	1	2	3
Turvação da visão	0	1	2	3
Sensação de desmaio	0	1	2	3
Tudo parece irreal				
Náuseas	0	1	2	3
Palpitações no estômago				
Dor de estômago	0	1	2	3
Mal estar no estômago	0	1	2	3
Desejo de urinar				
Secura na boca	0	1	2	3
Dificuldade de engolir				
Dor nos músculos do pescoço	0	1	2	3
Fraqueza nas pernas	0	1	2	3
Contração ou tremor muscular	0	1	2	3
Tensão nos músculos frontais	0	1	2	3
Tensão nos músculos mandibulares				

Reproduzido, com permissão do editor, de Main CJ: The modified somatic perception questionnaire. J Psychosom Res 27:503-514, 1983

Questionário de percepção somática modificado

Por favor, descreva como você se sentiu durante a última semana, assinalando o quadrado apropriado (✓)
Por favor, responda a todas as perguntas. Não pense muito antes de respondê-las.

	Não	Um pouco	Muito	Insuportável Não poderia ser pior
Aumento da freqüência cardíaca				
Sensação de calor em todo o corpo				
Sudorese em todo o corpo				
Sudorese em uma região particular do corpo				
Pulsação no pescoço				
Sensação de martelada na cabeça				
Tontura				
Turvação da visão				
Sensação de desmaio				
Tudo parece irreal				
Náuseas				
Palpitações no estômago				
Dor de estômago				
Mal estar no estômago				
Desejo de urinar				
Secura na boca				
Dificuldade de engolir				
Dor nos músculos do pescoço				
Fraqueza nas pernas				
Contração ou tremor muscular				
Tensão nos músculos frontais				
Tensão nos músculos mandibulares				

Questionário de dor de McGill abreviado

Nome _____ Date _____

Por favor, escolha na lista abaixo as palavras que você utilizaria para descrever sua dor

	Moderada	Leve	Moderada	Intensa
latejante				
pontada				
facada				
aguda				
cãibra				
crescente				
queimação				
contínua				
dor em peso				
hipersensibilidade dolorosa				
dor intensa				
exaustiva				
desagradável				
terrível				
insuportável				

Assinale um X na linha abaixo para indicar a intensidade de sua dor

Sem dor |_____| pior dor possível

Índice da dor aqui:

Quais das seguintes palavras explicam sua dor aqui:

0 Sem dor _____
1 Leve _____
2 Incômoda _____
3 Aflitiva _____
4 Horrível _____
5 Insuportável _____

Questionário de Zung modificado

Por favor, assinale as respostas que melhor descrevem como você tem se sentido ultimamente. Por favor, responda a todas as perguntas

	Nunca	De vez em quando	Muito freqüente	Na maior parte do tempo
Sinto-me deprimido e triste				
Sinto-me melhor pela manhã				
Tenho crises de choro				
Tenho dificuldade de dormir à noite				
Acho que ninguém se importa				
Como na mesma quantidade que sempre comi				
Minha vida sexual ainda me dá prazer				
Acho que perdi peso				
Tenho constipação				
Meu coração bate mais rápido do que costumava bater				
Fico cansado sem nenhuma razão				
Não me sinto confuso				
Tendo a acordar muito cedo				
Acho fácil fazer as coisas que eu costumava fazer				
Fico inquieto e não posso ficar parado				
Tenho esperanças para o futuro				
Estou mais irritado do que de costume				
Acho fácil tomar uma decisão				
Sinto-me bastante culpado				
Acho que sou útil e necessário				
Minha vida é bastante plena				
Acho que os outros ficariam melhor, se eu morresse				
As coisas que me davam prazer, ainda me dão prazer				

Número do paciente |__|__|__| STOO4C/IO4

Índice de incapacidade crônica (Waddell) **Avaliação inicial**

Você:

Precisa de ajuda para carregar peso (13 a 18 quilos ou uma criança de 3 a 4 anos) ou evita fazê-lo ?	
fica sentado apenas por meia hora ?	
anda de carro/ônibus apenas por meia hora ?	
anda a pé apenas por meia hora ?	
fica em pé apenas por meia hora ?	
acorda regularmente com dor lombar (2-3 vezes por semana) ?	
deixa de comparecer ás atividades sociais regularmente por causa da dor lombar ou restringe-as (não inclui esportes) ?	
diminui a freqüência da atividade sexual por causa da dor lombar ?	
precisa de ajuda para calçar as meias/amarrar os sapatos/vestir-se ?	
Total	

Apêndice B: Questionário de Zung modificado

Por favor, assinale as respostas que melhor descrevem como você tem se sentido ultimamente

	Raramente ou Nunca (menos de 1 dia/ semana	De vez em quando (1-2 dias/ semana)	Muito freqüente (3-4 dias/ semana)	Na maior parte do tempo (5/7 dias/ semana)
1. Sinto-me deprimido e triste	0	1	2	3
2. Sinto-me melhor pela manhã	3	2	1	0
3. Tenho crises de choro	0	1	2	3
4. Tenho dificuldade de dormir à noite	0	1	2	3
5. Acho que ninguém se importa	0	1	2	3
6. Como na mesma quantidade que sempre comi	3	2	1	0
7. Minha vida sexual ainda me dá prazer	3	2	1	0
8. Acho que perdi peso	0	1	2	3
9. Tenho constipação	0	1	2	3
10. Meu coração bate mais rápido do que costumava bater	0	1	2	3
11. Fico cansado sem nenhuma razão	0	1	2	3
12. Não me sinto confuso	3	2	1	0
13. Tendo a acordar muito cedo	0	1	2	3
14. Acho fácil fazer as coisas que eu costumava fazer	3	2	1	0
15. Fico inquieto e não posso ficar parado	0	1	2	3
16. Tenho esperanças para o futuro	3	2	1	0
17. Estou mais irritado do que de costume	0	1	2	3
18. Acho fácil tomar uma decisão	3	2	1	0
19. Sinto-me bastante culpado	0	1	2	3
20. Acho que sou útil e necessário	3	2	1	0
21. Minha vida é bastante plene	3	2	1	0
22. Acho que os outros ficariam melhor, se eu morresse	0	1	2	3
23. As coisas que me davam prazer, ainda me dão prazer	3	2	1	0

Reproduzido, com permissão do editor, de Main CJ, Waddell G: The detection of psychological abnormality in chronic low-back pain using four simple scales. Curr Concepts Pain 2:10-15, 1984.

Escore de incapacidade de Oswestry

Esse questionário foi concebido para nos dar informações sobre como sua dor lombar ou dores na perna afetaram sua capacidade de realizar suas atividades diárias. Por favor, responda a todos os itens de todas as seções e assinale apenas o QUADRADO (☑ou ☒) que se aplica a seu caso. Entendemos que você pode considerar que duas das afirmações apresentadas em uma seção se aplicam a seu caso, mas, por favor, assinale apenas o QUADRADO que mais claramente descreve o seu problema.

Nome:
Número de registro: Data:

Seção 1 - Intensidade da dor

- ☐ Não sinto nenhuma dor no momento
- ☐ A dor é muito leve nesse momento
- ☐ A dor é moderada nesse momento
- ☐ A dor é severa nesse momento
- ☐ A dor é muito severa nesse momento
- ☐ A dor é a pior dor possível nesse momento

Seção 2 - Cuidados pessoais (tomar banho, vestir-se, etc)

- ☐ Posso cuidar de mim normalmente sem sentir nenhuma dor adicional
- ☐ Posso cuidar de mim normalmente, mas sinto um pouco de dor
- ☐ Sinto muita dor, quando cuido de mim. Por isso, faço as coisas lentamente e com cuidado
- ☐ Preciso de alguma ajuda para cuidar de mim, mas sou capaz de fazer a maioria das coisas sozinho, em termos de cuidados pessoais
- ☐ Preciso de ajuda para fazer a maioria das coisas, em termos de cuidados pessoais
- ☐ Não me visto, tomo banho com dificuldade e fico deitado na cama.

Seção 3 - Elevação de peso

- ☐ Posso levantar objetos pesados sem sentir nenhuma dor adicional
- ☐ Posso levantar objetos pesados, mas sinto um pouco mais de dor
- ☐ A dor me impede de levantar objetos pesados do chão, mas posso fazê-lo, se eles estiverem sobre a mesa, por exemplo
- ☐ A dor me impede de levantar objetos pesados, mas posso levantar objetos leves, se eles estiverem sobre a mesa, por exemplo
- ☐ Posso levantar apenas objetos muito leves
- ☐ Não posso levantar ou carregar nenhum objeto

Seção 4 - Marcha

- ☐ A dor não me impede de caminhar qualquer distância
- ☐ A dor me impede de caminhar mais de 1.600 metros (pouco mais de1,5 km)
- ☐ A dor me impede de caminha mais de 800 metros
- ☐ A dor me impede de caminhar mais de 400 metros
- ☐ Posso caminhar apenas, se estiver usando uma bengala ou muletas
- ☐ Fico deitado na cama durante a maior parte do tempo e tenho de me arrastar até o banheiro.

Seção 5 - Sentar-se

- ☐ Posso ficar sentado na poltrona durante o tempo que quiser
- ☐ Posso ficar sentado na minha poltrona favorita durante o tempo que quiser
- ☐ A dor me impede de ficar sentado por mais de 1 hora
- ☐ A dor me impede de ficar sentado por mais de meia hora
- ☐ A dor me impede de ficar sentado por mais de quinze minutos
- ☐ A dor me impede completamente de ficar sentado

Seção 6 - Ficar em pé

- ☐ Posso ficar em pé durante o tempo que quiser, sem sentir aumento da dor
- ☐ Posso ficar em pé durante o tempo que quiser, mas sinto dor
- ☐ A dor me impede de ficar em pé por mais de 1 hora
- ☐ A dor me impede de ficar em pé por mais de meia hora
- ☐ A dor me impede de ficar em pé por mais de dez minutos
- ☐ A dor me impede completamente de ficar em pé

Seção 7 - Sono

- ☐ Meu sono nunca é perturbado pela dor
- ☐ Às vezes, meu sono é perturbado pela dor
- ☐ Não posso dormir mais de 6 horas por causa da dor
- ☐ Não posso dormir mais de 4 horas por causa da dor
- ☐ Não posso dormir mais de 2 horas por causa da dor
- ☐ A dor me impede completamente de dormir

Seção 8 -Vida sexual (se apropriado)

- ☐ Minha vida sexual é normal e não me aumento da dor
- ☐ Minha vida sexual é normal, mas me causa um pouco de dor
- ☐ Minha vida sexual é quase normal, mas me causa muita dor
- ☐ Minha vida sexual é muito restringida pela dor
- ☐ Minha vida sexual quase não existe, por causa da dor
- ☐ A dor me impede completamente de teer atividade sexual

Seção 9 - Vida social

- ☐ Minha vida social é normal e não me causa nenhuma dor adicional
- ☐ Minha vida social é normal, mas aumenta a intensidade da dor
- ☐ A dor não tem nenhum efeito significativo na minha vida social, além de limitar minhas atividades mais intensas, como, por exemplo, esportes, etc
- ☐ A dor restringe minha vida social e não saio com freqüência
- ☐ A dor restringiu minha vida social ao ambiente doméstico
- ☐ Não tenho nenhuma vida social por causa da dor

Seção 10 - Viagem

- ☐ Posso viajar para qualquer lugar sem dor
- ☐ Posso viajar para qualquer lugar, mas isso me causa aumento da dor
- ☐ A dor é intensa, mas posso fazer passeios durante 2 horas
- ☐ A dor me permite fazer passeios no tempo máximo de 1 hora
- ☐ A dor me limita a fazer passeios que durem menos de 30 minutos
- ☐ A dor me impede de viajar, exceto para receber tratamento

ODI = _____ X 20 _____ %

Número do paciente |__|__|__|

STOO4C/IO5

Índice de incapacidade física (Waddell) Avaliação inicial

Constante matemática			28
Principal problema Padrão de dor	Dor lombar Dor lombar + dor irradiada para a perna Dor radicular	0 3 -2	
Padrão temporal	Recorrente Crônica	4 8	
Fratura pregressa	Processo transverso Compressão em cunha Fratura/deslocamento	1 2 6	
Cirurgia lombar pregressa	Nenhuma Uma Mais de uma	0 3 6	
Compressão de raízes	Nenhuma Duvidosa Definida	0 1 2	
	Subtotal		+
Flexão lombar de Schober	em X 2		-
Elevação da perna estendida	Esquerda Direita	°/10 °/10	- -
	Subtotal		-
Incapacidade corporal total aproximada			%

D.O.B. Data

Assinale as partes do corpo em que você apresenta as seguintes sensações
Use os símbolos. Assinale todas as áreas afetadas.

Adormecimento	Formigamento	Dor contínua	Dor
= = = =	o o o o	x x x x	/ / / /
= = = =	o o o o	x x x x	/ / / /

Esquerda Direita Esquerda Direita

APPENDIX 4.

OUTCOME MEASURES (QUESTIONNAIRES) IN MULTIPLE LANGUAGES

ARABIC:

استطلاع أوسوستري المعدل لتحديد مدى العجز عن آلام الظهر

التاريخ: _____

اسم المريض: _____ السن: _____ الجنس: ذكر ☐ أنثى ☐

الطبيب المعالج: _____ رقم المريض: _____

اقرأ من فضلك: لقد صمم هذا الاستجواب لكي يمكننا أن تعرف لأي مدى أثرت آلام ظهرك في مقدرتك على القيام بنشاطاتك اليومية . المرجو منك أن تجيب على كل قسم من الأسئلة بوضع علامة واحدة على الاختيار الذي ينطبق عليك أكثر انطباق ، ونحن نعلم أنك قد تشعر بأن هناك أكثر من إجابة واحدة قد تتمشى مع حالتك ، ولكن الذي نرجوه منك أن تضع علامة واحدة على اختيار واحد تعتقد أنه يصف مشكلتك تماما الآن:

القسم ١: شدة الألم

- ☐ الألم يجيء ويروح ويعتبر بسيطا جدا
- ☐ الألم بسيط ولا يتغير كثيرا
- ☐ الألم يجيء ويروح ويعتبر متوسطا
- ☐ الألم متوسط ولا يتغير كثيرا
- ☐ الألم يجيء ويروح ويعتبر عنيفا
- ☐ الألم عنيف ولا يتغير كثيرا

القسم ٢: العناية الشخصية (الاستحمام والليس ، إلخ)

- ☐ أنا لم أغير في طريقتي في الاستحمام أو الليس من أجل أن أتفادى الألم
- ☐ أنا لا أغير عادة من طريقتي في الاستحمام أو الليس حتى لو تسببت لي في بعض الألم
- ☐ الاستحمام والليس يزيدان من الألم ولكني بحثت في عدم تغيير طريقتي في القيام بهما
- ☐ الاستحمام والليس يزيدان من الألم وأرى أنه من الضروري أن أغير طريقتي في القيام بهما
- ☐ أنا عاجز نتيجة للألم أن أقوم أحيانا بالاستحمام أو بالليس دون معاونة شخص آخر
- ☐ أنا عاجز نتيجة للألم من أقوم بالمرة بالاستحمام أو بالليس دون معاونة شخص آخر

القسم ٣: الرفع

- ☐ أستطيع أن أرفع أحمالا ثقيلة بدون ألم زائد
- ☐ أستطيع أن أرفع أحمالا ثقيلة ولكنها تسبب لي ألما زائدا
- ☐ الألم يمنعني من رفع أحمال ثقيلة من فوق الأرض
- ☐ الألم يمنعني من رفع أحمال ثقيلة من فوق الأرض ولكني أنجح في ذلك لو وضعت هذه الأحمال بطريقة مناسبة (فوق ترابيزة مثلا)
- ☐ الألم يمنعني من رفع أحمال ثقيلة ولكني أنجح في رفع الأحمال الخفيفة والمتوسطة إذا وضعت بطريقة مريحة
- ☐ لا أستطيع أن أرفع إلا الأحمال الخفيفة

القسم ٤: المشي

- ☐ الألم لا يمنعني من المشي لأية مسافة
- ☐ الألم يمنعني من المشي لأكثر من كيلو واحد
- ☐ الألم يمنعني من المشي لأكثر من نصف كيلو
- ☐ الألم يمنعني من المشي لأكثر من ربع كيلو
- ☐ لا أستطيع المشي إلا باستخدام عصا أو على عكازة
- ☐ أنا أقضي معظم وقتي في الفراش وعلي أن أزحف إلى التوالت

القسم ٥: الجلوس

- ☐ أستطيع أن أجلس على أي مقعد
- ☐ لا أستطيع أن أجلس إلا في مقعدي المفضل لأية مدة كما أشاء
- ☐ الألم يمنعني من الجلوس لأكثر من ساعة واحدة
- ☐ الألم يمنعني من الجلوس لأكثر من نصف ساعة
- ☐ الألم يمنعني من الجلوس لأكثر من ١٠ دقائق
- ☐ الألم يمنعني من الجلوس قطعيا

القسم ٦: الوقوف

- ☐ أستطيع أن أقف لأية مدة ممكنة بدون ألم
- ☐ أشعر ببعض الألم أثناء وقوفي ولكن الألم لا يتزايد مع الوقت
- ☐ لا أستطيع الوقوف أكثر من ساعة واحدة من غير أن يتزايد الألم
- ☐ لا أستطيع الوقوف أكثر من نصف ساعة من غير أن يتزايد الألم
- ☐ لا أستطيع الوقوف أكثر من ١٠ دقائق من غير أن يتزايد الألم
- ☐ أنا أتجنب الوقوف لأنه يزيد من الألم في الحال

القسم ٧: النوم

- ☐ أنا لا أشعر بأي ألم في الفراش
- ☐ أنا أشعر بألم في الفراش ولكنه لا يمنعني من النوم
- ☐ لقد نقص نومي الليلي العادي بسبب الألم إلى أقل من الربع
- ☐ لقد نقص نومي الليلي العادي بسبب الألم إلى أقل من النصف
- ☐ لقد نقص نومي الليلي العادي بسبب الألم إلى أقل من ثلاثة أرباعه
- ☐ الألم يمنعني من النوم بالمرة

القسم ٨: الحياة الجنسية

- ☐ حياتي الجنسية طبيعية ولا تسبب لي أي ألم إضافي
- ☐ حياتي الجنسية طبيعية تسبب لي ألما إضافي
- ☐ حياتي الجنسية طبيعية ولكن تسبب لي ألم شديدا
- ☐ حياتي الجنسية محدودة بسبب شدة الألم
- ☐ حياتي الجنسية تكاد تكون منعدمة وذلك بسبب الألم
- ☐ الألم يمنعني من أي نشاط جنسي على الإطلاق

القسم ٩: الحياة الاجتماعية

- ☐ حياتي الاجتماعية عادية ولا تسبب لي أية آلام
- ☐ حياتي الاجتماعية عادية ولكنها تزيد من درجة ألمي
- ☐ الألم ليس له تأثير على حياتي الاجتماعية أكثر من الحد من هواياتي النشطة كالرياضة مثلا
- ☐ الألم يقيد حياتي الاجتماعية ويمنعني من الخروج في معظم الأوقات
- ☐ الألم قصر حياتي الاجتماعية على البقاء في المنزل
- ☐ أنا أكاد لا أستطيع أن أمارس حياتي الاجتماعية بسبب الألم

القسم ١٠: السفر

- ☐ أنا لا أشعر بأي ألم في السفر
- ☐ أنا أشعر ببعض الألم أثناء سفري ولكن ليس هناك نوع معين من أنواع السفر يجعله أسوأ
- ☐ أشعر بتزايد الألم أثناء السفر ولكن السفر لا يجبرني على الاتجاه إلى أنواع بديلة من السفر
- ☐ أنا أشعر بتزايد الألم أثناء السفر مما يجبرني على الاتجاه إلى أنواع بديلة من السفر
- ☐ الألم يمنعني من كل أنواع السفر
- ☐ الألم يمنعني من كل أنواع السفر إلا السفر وأنا راقد

OD1= Score x 20 = %

تحديد مدى العجز باستخدام استطلاع أوسوستري

١- هناك ١٠ أجزاء بالاستطلاع

٢- كل جزء يحتوي على ٦ أسئلة (نتائجهم تتراوح بين صفر - ١ - ٢ - ٣ - ٤ - ٥ -٦)

٣- تجمع القيمة العددية للناتج من كل جزء للحصول على نتيجة من ٥٠ (١٠ أجزاء X ٦ أسئلة) - (قيمة الاختيار الأول صفر)

٤- تحول هذه النتيجة لنسبة مئوية كالآتي:

OD1= Score x 20 = %

معدل العجز بطريقة أوسوستري المعدلة = الناتج x ٢٠ = ٪

نموذج ماك جل لاستطلاع حالة الألم

التاريخ: _____

اسم المريض: _____ رقم المريض: _____

- المرجو منك أن تختار من اللائحة التالية الكلمات التي ترغب في استعمالها لوصف الألم الذي تعاني منه.

صفة الألم	لا شيء صفر	خفيف ١	متوسط ٢	شديد ٣
نقح				
ألم زاعق				
طعن				
ألم حاد				
تقلصات				
قارص				
ألم حار (حارق)				
غير محدد				
ثقيل				
خفيف				
عنيف				
مجهد - متعب				
ممرض				
مخيف				
ضربات ملتوية				

المقياس البصري لتحديد درجة الألم

ضع علامة (X) على الخط أسفله لتحدد بها شدة الألم.

أسوء ألم ممكن ←——————————————→ لا يوجد أي ألم

١٠ صفر

مقياس الألم الحالي

أي من الكلمات التالية تصف حالة الألم الذي تعاني منه الآن.

ليس هناك ألم	صفر
متوسط	١
مقلق للراحة	٢
مجهد	٣
فظيع	٤
مهول وعديم الاحتمال	٥

حساب وتحديد الألم باستخدام نموذج ماك جل

١. هناك ١٥ كلمة لتحديد الألم - كل كلمة لها قيمة عددية
أول ١٢ كلمة تصف الإحساس
وآخر ٣ كلمات تصف درجة الشدة

يمكن حساب ٣ نتائج:

١- الناتج الكلي أو ناتج الإحساس بالألم أو ناتج درجة الشدة
٢- ناتج درجة التأثر من قياس الألم الحالي (صفر - ٥)
٣- ناتج الشدة باستخدام المقياس البصري لدرجة شدة الألم (أسوأ ألم (١٠) - لا يوجد ألم (صفر))

مراجع:

Melzack, Ronald: The Short-form McGill Pain Questionnaire. Pain, 30 (1987), pp. 191-197.

مقياس العجز الجسماني بطريقة وادال

تقييم أولي

التاريخ: _____

اسم المريض: _____ رقم المريض: _____

	المعامل الحسابي الثابت		٢٨
المشكلة الرئيسية (صورة الألم)	ألم ظهر	(صفر)	
	ألم ظهر + ألم ينتشر إلى الرجل	(٣)	
	ألم بسبب عصب رئيسي	(٢-)	
منهاج الوقت	متكرر	(٤)	
	مزمن	(٨)	
كسور عظام سابقة	كسر بالفقرات – بالنتوء العظمي المستعرض	(١)	
	كسر منضغط بالفقرات	(٢)	
	كسر / خلع	(٦)	
جراحات سابقة في الظهر	لا يوجد	(صفر)	
	واحدة	(٣)	
	أكثر من واحدة	(٦)	
ضغط على عصب رئيسي	لا يوجد	(صفر)	
	هناك شك	(١)	
	أكيد	(٢)	
المجموع قبل النهائي			(*) القيمة العددية للمعامل الحسابي الثابت (٢٨)
القدرة على ثني الجذع بطريقة شوبر	القيمة x ٢		
	____ x ٢		
رفع الطرف السفلي الأيسر	٥		
مع إبقاء الركبة مفرودة	١٥		
رفع الطرف السفلي الأيمن	٥		
مع إبقاء الركبة مفرودة	١٥		
المجموع قبل النهائي			
٪ المجموع التقريبي للدرجة الكلية للعجز الجسماني			____ ٪

- يضاف المجموع الناتج عن الجزء الأول إلى المعامل الحسابي الثابت أعلى الصفحة (٢٨) للحصول على المجموع قبل النهائي
- الجزء الثاني هو طرح القيمة العددية لاختبار شوبر (أيضا تطرح القيمة العددية لنتائج اختبارات رفع الطرف السفلي مع إبقاء الركبة مفرودة من المجموع قبل النهائي)
- يحول الناتج إلى نسبة مئوية

مقياس العجز المزمن (وادال)

تقييم أولي

التاريخ: _____

اسم المريض: _____ رقم المريض: _____

- ☐ بحاجة للمساعدة - يتجنب حمل أشياء ثقيلة (على سبيل المثال: ٢٠ - ٣٠ رطلا أو طفل عمره ٣ - ٤ سنوات)
- ☐ الجلوس عموما محدودلنصف ساعة
- ☐ الانتقال في سيارة /حافلة (أوتوبيس) محدود إلى نصف ساعة
- ☐ المشي عموما محدود إلى نصف ساعة
- ☐ الوقوف عموما محدود إلى نصف ساعة
- ☐ اضطراب في النوم بصفة مستمرة بسبب ألم الظهر (٢ - ٣ مرات أسبوعيا)
- ☐ عدم القدرة على الالتزام / اضطراب النشاطات الاجتماعية بصفة مستمرة بسبب ألم الظهر (عدا الرياضة)
- ☐ تناقص تكرار النشاط الجنسي بسبب ألم الظهر
- ☐ المساعدة مطلوبة باستمرار في لبس الجوارب (الشرابات) أو عقد رباط الحذاء

_____ المجموع الكلي

تحديد مقياس العجز المزمن بطريقة وادال

- تسجل نقطة واحدة لكل إجابة يجيب عليها المريض بـ (x)
- أقصى (أسوأ) نتيجة تمثل ٩ عن ٩ أسئلة

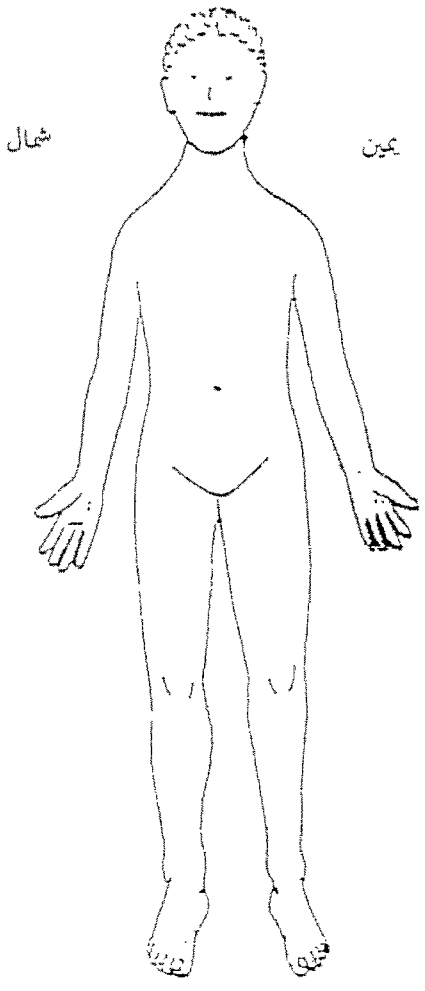
التاريخ: _____

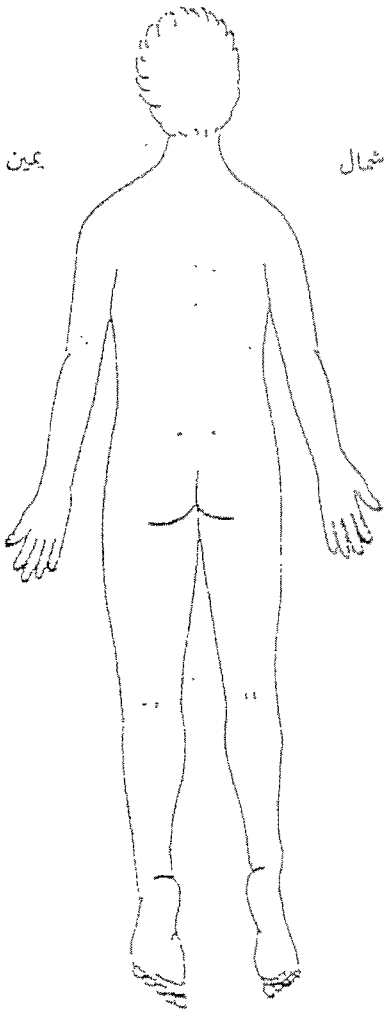
اسم المريض: _____ رقم المريض: _____

ضع علامة على المناطق التي تشعر بمثل هذه الآلام فيها

استخدم الرمز الدال على نوع الألم – ضع علامة على الجزء المتأثر بهذا الألم

ألم	وجع	دبابيس وأبر	تنميل
////	xxxx	ooooo	= = = =
////	xxxx	ooooo	= = = =
////	xxxx	ooooo	= = = =





النموذج المعدل لاستطلاع مدى الأعراض الجسمانية المصاحبة للألم

التاريخ: _____

اسم المريض: _____ رقم المريض: _____

- صف من فضلك كيف شعرت خلال الأسبوع الماضي وذلك بوضع علامة (√) في المكان المناسب.
- نرجو منك الإجابة على كل الأسئلة (لا تفكر كثيرا قبل الإجابة).

وصف الحالة	لا على الإطلاق	بسيط/خفيف	جامد/ ملحوظ الوطء	شديد/ليس من الممكن أن يكون أسوأ
ازدياد في عدد ضربات القلب				
الشعور بالحرارة في مختلف أجزاء الجسم				
العرق من كل الجسم				
العرق من أجزاء محددة في الجسم				
نبض بالرقبة				
خبط بالرأس				
دوخة				
زغللة بالنظر				
الشعور بالدوخة والهبوط				
كل شيء يبدو غير حقيقي				
الشعور بالغثيان				
المعدة مقلوبة				
وجع أو ألم بالمعدة				
تقلصات بالمعدة				
الرغبة بالتبول				
جفاف الفم				
صعوبة في البلع				
وجع في عضلات الرقبة				
وهن في الأطراف السفلية				
تقلصات في العضلات				
الشعور بالضيق في منطقة الجبهة				
الشعور بالضيق في عضلات الفك				

نموذج زانج المعدل

التاريخ: _____

اسم المريض: _____ رقم المريض: _____

- حدد من فضلك بالإجابة على الأسئلة التالية الوصف الدال على شعورك مؤخرا.
- الرجاء الإجابة على جميع الأسئلة.

وصف الحالة	لم يحدث أبدا أقل من يوم واحد في الأسبوع	من حين لآخر ١-٢ يوم في الأسبوع	يتكرر باستمرار ٣-٤ أيام في الأسبوع	معظم الوقت ٥-٧ أيام في الأسبوع
١. أنا أشعر بالحزن وكسرة القلب				
٢. الصباح هو الوقت الذي أشعر فيه أنني أتحسن				
٣. ينتابني البكاء وبعض الأحيان أشعر أنني سأبكي				
٤. أنا أعاني من صعوبة في النوم بالليل				
٥. أنا أشعر أنه لا يهتم بي أحد				
٦. أنا آكل مقدار الطعام الذي أنا متعود عليه				
٧. أنا ما زلت أستمتع بممارسة الجنس				
٨. أنا لاحظت أني أفقد وزني				
٩. أنا عندي مشاكل مع الإمساك				
١٠. ضربات قلبي أسرع من العادي				
١١. أنا أشعر بالتعب بدون سبب				
١٢. تفكيري ومخي صافي كالمعتاد				
١٣. أنا أستيقظ مبكرا عن ميعادي الطبيعي				
١٤. أجد سهولة في عمل الأشياء التي تعودت عليها				
١٥. أنا مضطرب ولا أستطيع الجلوس في مكاني				
١٦. أنا أشعر بتفاؤل في المستقبل				
١٧. أنا متهيج الأعصاب أكثر من الطبيعي				
١٨. أنا أستطيع أخذ قرارات بسهولة				
١٩. أنا أشعر بالذنب العميق				
٢٠. أنا أشعر أني مرغوب ومفيد				
٢١. أنا حياتي مليانة تماما				
٢٢. أنا أشعر أن الناس يفضلون لو أني مت				
٢٣. أنا ما زلت أستمتع بالأشياء التي تعودت عليها				

نموذج زانج المعدل والنموذج المعدل لاستطلاع مدى الأعراض الجسمانية المصاحبة للألم

- مرفق النماذج المستخدمة في تقييم هذه الاستطلاعات
- المراجع التالية يمكن أن تكون مفيدة:

1. Main, C.J.: The Modified Somatic Perception Questionnaire. J. Psychosom. Res. 27:503-514, 1983.
2. Main, C.J. and Waddell, G.: The Detection of Psychological Abnormality in Chronic Low Back Pain Using 4 Simple Scales. Curr. Concepts Pain. 2:10-15, 1984.