The Michel Benoist and Robert Mulholland yearly *European Spine Journal* Review

A survey of the “medical” articles in the *European Spine Journal*, 2012

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Introduction

The dust had hardly settled on my contribution to the 2011 European Spine Journal Review before I was asked to look at the 2012 production. As usual I have found a wealth of good clinical and research papers, coming from various continents, and demonstrating the increasing impact of the *European Spine Journal*. As usual, the majority of the articles are surgically oriented. Nevertheless, there is still a sub-category of papers, which primarily interests non-surgical specialists. I have selected a few articles which in addition to their excellence all supply new information and implications for future research. In general, and over the years, it has been

rewarding to observe that spinal research work has resulted in beneficial therapeutic improvements and better patient care. As emphasized in a recent Editorial of the Journal, the symbiosis between clinicians and scientists will hopefully continue and progressively improve.

Basics

The paper by Bisshop et al. [3] published in March calls attention to the impact of bone mineral density (BMD) on shear strength and stiffness of the lumbar spine following laminectomy. It is admitted that laminectomy without fusion can be a source of instability, postoperative spondylolisthesis, and possibly fracture of the pars interarticularis. In vitro studies have also shown that both shear stiffness and strength are reduced after laminectomy. The purpose of the present study was to evaluate the importance of this reduction, as well as the influence of BMD and disc degeneration. Laminectomy was performed on ten human lumbar spines. Motion segments L2–L3 were isolated. Shear force and stiffness were measured. The paper provides a full description of the specimen preparation and of the biomechanical testing procedure. Measurement of BMD was performed pre- and post-laminectomy and disc degeneration was graded on MRI in two groups: mild or severe degeneration. Laminectomy reduced shear force by half, relative to a high BMD. An interaction between BMD and laminectomy was also found. Disc degeneration had no effect on the shear properties. In clinical practice, measurement of BMD before laminectomy should be done routinely. A low BMD could be a critical factor to perform an additional fusion, as well as to inform the patient to avoid demanding tasks and activities. Surgery for lumbar stenosis is now frequently performed in aging patients.

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Osteoporosis is frequent and requires an additional medical treatment.

It is now admitted that radicular pain caused by a discal herniation results from a combined effect of a mechanical compression on the nerve root, with a local release of inflammatory mediators, essentially specific cytokines. In the March issue de Souza Grava et al. [8] describe an experimental animal model aiming to detect the presence of inflammatory cytokines in a normal intervertebral disc in rats. The second objective was to investigate whether a previous exposure of the IVD tissue by specific anti-cytokine antibodies could modify the pain behaviour induced by application of nucleus pulposus (NP) on the L5-RDG in rats. Behavioural tests were used to evaluate the mechanical and thermal hyperalgesia in the hind paws of the rats. Three cytokines: TNF alpha, IL1 beta and Cinc1 were detected in the disc tissues. The treatment by specific antibodies decreased the thermal and mechanical hyperalgesia. It was also disclosed that a prolonged maintenance of contact of the nerve with the inflammatory cytokines induced a sensitization of the neurons, which was detected in the experiment by persistence of the animal pain behaviour even after removal of the inflammatory cytokines. This finding is in keeping with chronification of the pain observed in humans in cases of neuropathic pain. I strongly recommend reading this fine piece of work, which also suggests therapeutic implications.

Transforaminal steroid injections

The paper by Quraishi [27] in the February issue aimed at assessing the efficacy of steroid epidural injection for the treatment of sciatica when using the transforaminal route, a target-specific approach. This study is a well-designed systematic review and meta-analysis based on the five randomized controlled trials extracted from an extensive search of the literature. The results showed that only three of the five studies had a follow-up of 3 months with pain and disability outcome. Only one study had a follow-up of 12 months. Overall, 187 patients received steroid and anaesthetic injection treatment, while 181 patients received anaesthetic or saline injection alone as a control. The meta-analysis showed that when appropriately performed, transforaminal steroid injection resulted in improvement in pain, but not in the ODI score at short term, and this effect was maintained at 12 months in one study.

In a previous systematic review based on the same papers, Buenaventura et al. [7] also concluded that results of their analysis provided moderate evidence (level II-1) for short-term pain relief and moderate evidence (level II-2) for long-term improvement. As indicated and discussed in Quraishi's paper, an equivalent positive effect between

steroid and lidocaine has been detected in studies using a local anaesthetic as a control. The effect of lidocaine persisting a few weeks and outlasting the normal duration of an anaesthetic is unexpected and difficult to understand. The risk of an intra-arterial injection of particulate steroids, wisely emphasized in Quraishi's article, is low. However, a recent review by Wybier et al. [34] reported that since 2002, 12 cases of sudden paraplegia immediately following epidural steroids injection have been documented. Of the 12 patients reported by Wybier, 8 had previous surgery and in 10 patients the injection route was foraminal. The need to be vigilant must be stressed even though transforaminal injections are always performed with fluoroscopy and contrast injection.

Epidural injection of anti-interleukin-6 in sciatica

Anti-interleukin-6 is currently used with proven efficacy in the treatment of rheumatoid arthritis. The article by Ohtori et al. [26] in the October issue deals with epidural injection of an anti-interleukin-6 receptor antibody (tocilizumab) in patients with a sciatica continuing for at least 1 month. All 60 elderly patients had lumbar spinal stenosis. Only patients, who showed monoradiculopathy were evaluated. Thirty patients received a single nerve block of lidocaine and tocilizumab while 30 others received a nerve block of lidocaine and dexamethasone. Both groups were homogeneous at baseline. They were evaluated by a VAS pain scale and ODI at 1, 2, and 4 weeks after infiltration. The results indicate that application of anti-IL6 receptor monoclonal antibody produced significantly more pain relief during the 4 weeks following injection than the corticoid group. There was also a significant improvement in ODI score in the tocilizumab group when compared with the dexamethasone group at 4 weeks. No adverse event was observed. These interesting results suggest that IL-6 might be one cytokine capable of inducing sciatica when applied on the nerve root. In the discussion, the authors report that high levels of IL-6 have been found in the CSF of patients with lumbar canal stenosis and radicular pain. The reader will find in the excellent discussion a summary of the characteristic features of IL-6 and a recapitulation of the experimental and clinical effects of anti-TNF alpha, a cytokine previously studied in the same indication. Future studies with a longer follow-up will hopefully confirm these promising results.

Raloxifene for osteoporosis

Lippuner et al. [21] have published an excellent article in the December issue on the use of raloxifene in osteoporosis. Raloxifene is a selective estrogen receptor

modulator (SERM). It has been approved for prevention and treatment of osteoporosis in post-menopausal women in the U.S. and the E.U. The treatment of osteoporosis by raloxifene results in a significant reduction of osteoporotic vertebral fractures. There is also a reduction in non-vertebral fractures, including hip, wrist and ankle, but the difference with a placebo is not significant. Clinical trials with raloxifene have also shown effects on the incidence on invasive breast cancer, reducing the risk of invasive estrogen-receptor positive breast cancer, but not in estrogen-receptor negative breast cancer. On the safety side, raloxifene increases the risk of venous thromboembolic events. Raloxifene also increases the risk of fatal stroke in post-menopausal women at increased coronary risk, but not in post-menopausal women with osteoporosis at low risk for coronary events. In addition, raloxifene increases the incidence of hot flashes. Taken together, the use of raloxifene comprises a number of indications and contra-indications. In the present study, a group of Swiss experts in the fields of menopause and metabolic bone diseases first identified key individual patient characteristics relevant to the prescription of raloxifene. A consensus was reached as to how these insights could be translated into decision-making in daily practice. The paper contains a synopsis of the major RCTs on the treatment of raloxifene in post-menopausal women with osteoporosis and proposes a practical algorithm for prescription of raloxifene.

Conservative treatment for chronic non-specific neck pain

Monticone et al. [24] have conducted a randomized controlled trial exploring the efficacy of adding treatment of behavioural factors to a program of rehabilitation with physiotherapy for chronic non-specific neck pain. In this study published in the August issue, 80 patients were randomly assigned to either a rehabilitation program or to a cognitive behavioural therapy added to rehabilitation. Physiotherapy consisted of active and passive mobilization of the neck with exercises. Cognitive behavioural therapy consisted of gradually recovering physical activities and treating psychosocial characteristics of chronic pain, such as fear of movement, catastrophising and reduction of social relationships. The programs were delivered by physiotherapists, experts in manual therapy and specially trained in cognitive behavioural therapy. The outcome measurements were numerating pain rating, the neck pain and disability scale, and the Short-Form SF 36. Questionnaires were completed pre- and post-treatment and 12 months later. The results of the statistical analysis show that in a group of non-specific neck pain patients the addition of cognitive-behavioural therapy to physiotherapy

does not yield better results. Both groups showed improvements in pain, disability and quality of life without significant differences between the two groups. The paper contains an excellent discussion and review of the literature.

Economic evaluations are necessary for the appropriate use of financial resources. The paper by Driessen et al. [9] published in August updates the present knowledge of cost-effectiveness of conservative treatments for chronic neck pain. The article is a systematic review of economic evaluations conducted on the basis of randomized controlled trials. Only five evaluations could be included according to the inclusion criteria. A detailed description of the five studies is provided. A marked heterogeneity between studies prevented the authors from pooling the data. Heterogeneity was related to numerous factors regarding methodology and socio-political differences. Interpretation of the results is presented according to three comparisons of cost-effectiveness: manual therapy as compared to other therapies, physiotherapy compared to other therapies, and other therapies as compared to any control. The overall results indicate that manual therapy consisting of spinal mobilization and manipulation is more cost-effective than general practitioner care, or physiotherapy consisting of functional exercises, relaxation and stretching. Acupuncture was also found to be cost-effective at short term. However, the authors conclude that the small number of economic evaluations coming from single studies prevent drawing firm definite conclusions on the cost-effectiveness of conservative treatments for non-specific neck pain.

Scheuermann's disease

The study by Ristolainen et al. [29], which appeared in the May issue investigates the clinical evolution of untreated Scheuermann patients after a 37-year follow-up. Patients identified from the authors' patient registry had baseline radiographs of the thoraco-lumbar spine. The study deals exclusively with the so-called classic thoracic Scheuermann with at least three consecutive 5° wedge-shaped vertebrae or at least one vertebra with over 10° wedging. The apex of kyphosis had to be in the thoracic spine. A postal questionnaire including anthropometric data and questions concerning back pain disability, general health and quality of life was sent to the study group and compared with a representative sample of the Finnish adult population. Forty-nine of the responding individuals had a classic Scheuermann's disease. Patients included in this cohort had a higher risk for back pain than controls and reported a poorer quality of life than controls. However, patients were able to work normally when compared with controls.

There was no correlation of back pain and the degree of kyphosis. Limitations of the study were the small number of responding patients and absence of radiological follow-up. However, the information obtained from this study is interesting considering the paucity of long-term prognosis studies of the disease.

Modic changes

Three papers were published in 2012 exploring the clinical implications of Modic changes, which remain unclear. Previous studies have reported controversial and contradictory results.

The article by Sorlie et al. [30] in the November issue deals with a cohort of 178 consecutive patients who underwent a lumbar microdiscectomy for low-back and radicular pain caused by a one-level disc herniation. The purpose of the study was to investigate whether the presence of Modic I changes on preoperative MRI predicted continuation of low-back pain 12 months post surgery. MRI scans were evaluated by two independent radiologists with a high interobserver reliability. The primary outcome measure was a VAS for back pain; secondary outcome measures were VAS for leg pain, ODI, EQ-5D, work status and self-reported benefit of surgery. Thirty-six patients (20 %) had Modic I or mixed I/II changes at any level. The improvement in leg pain was equal in patients with or without Modic I at 12 months. However, patients with Modic I changes had less improvement in back pain than patients without Modic I. A subgroup analysis of smokers and non-smokers showed that smokers with Modic I had no significant improvement in back pain post surgery.

The paper by Jensen et al. [17] in the November issue aims to investigate how Modic changes (MCs) developed in type and size in a 14-month period and whether changes of MCs were associated with clinical changes. Ninety-six patients with chronic non-specific low-back pain and MRIs at baseline and at 14 months follow-up could be used. Changes in type (I, II, III or mixed) and in size were collected at both end points and quantified. Association of MCs and evolution of LBP intensity during the 14-month period was calculated in odds ratios. Prevalence of MCs type I was 41 % at baseline and 36 % at follow-up. Approximately, 20 % of both types I and II disappeared. There was no association at baseline between MCs type I and LBP intensity. However, there was a lack of improvement in pain intensity when type I changes were disclosed at baseline and at follow-up, which was the principal message of this paper. In addition, change of size of MC type I from baseline to follow-up was not associated with modification in pain intensity. Large MCs type I at baseline usually remained so at follow-up.

It is generally admitted that Modic I changes are strongly associated with pain [16]. The paper by Keller et al. [18], which appeared in the March issue is a prospective clinical trial cohort study assessing the prevalence of Modic changes in chronic low-back pain. The objectives of the study were to evaluate the influence of Modic changes on the clinical course and to identify prognostic factors for recovery, the main outcome at 1-year follow-up. ‘Much better’ or ‘completely recovered’ defined recovery. One hundred and seven patients out of 269 were followed up at 1 year. Treatment consisted of one intervention with instruction of health-care technique. At baseline, Modic I changes were disclosed in 14 % and Modic II changes in 50 %. At 1-year follow-up, 40 % of patients had recovered. Neither Modic I nor II changes were associated with the clinical course of pain, evaluated on a numeric rating scale or other self-reported measures: ODI, FABQ-Work or FABQ-PA. However, in the multivariate analysis only education was strongly associated with recovery. In their conclusion, the authors point out that a biopsychosocial approach remains necessary when evaluating chronic LBP patients.

Exercise therapy and clinical outcome in non-specific low-back pain

Two interesting, important and remarkable papers published in 2012 concern the relationship between the clinical outcome of exercise therapy for chronic non-specific low-back pain and the changes of physical function such as mobility, muscular strength and endurance, which can be expected after an exercise program. The first paper by Steiger et al. [31] found in the April issue is a systematic review of exercise therapy trials for chronic LBP based on the 16 RCTs of non-randomized controlled trials extracted from 1,217 articles with a total of 1,476 patients. Data analysis showed that there was no clear evidence of a relationship between the clinical results on pain and disability and the changes on mobility, trunk muscle strength and endurance. The results are in keeping with the accepted fact that similar clinical results can be obtained with different types of exercise programs. The discussion explores the various possible explanations of the beneficial effects of exercise therapy. Based on the findings of their review, the authors propose a more global treatment approach and present new therapeutic suggestions.

Spine stabilisation exercises (SSE) are extensively used worldwide as a basic treatment of chronic low-back pain. They are considered effective and superior to usual care. However, the mechanisms of action generating improved clinical outcome are not elucidated. In the July issue, the article by Mannion et al. [22] examines whether clinical

improvement is greater in patients with an initial functional deficit of the abdominal muscles implicated in this type of exercises, and whether the clinical results can be attributed to the effects of the exercises on the trunk muscles. Pain intensity and disability (Roland-Morris) were evaluated pre and post 9 weeks of SSE along with psychological questionnaires. Simultaneously, the voluntary activation of the concerned abdominal muscles as well as their anticipatory activation were measured using ultrasound with Doppler imaging. The statistical analysis of the results showed that there was a significant improvement in pain and disability (VAS and Roland-Morris) after 9 weeks of therapy, but no clear correlation between the clinical improvement and the targeted muscle changes. The authors conclude that the therapeutic results cannot be attributed to any specific effects of the exercises. Interestingly, in multiple-regression analysis, there was an association between outcome and changes in one psychological variable: catastrophising. This association prompted the authors to conclude that further studies should aim at clarifying whether exercises have a “central effect” unrelated to muscle function. Other possible beneficial mechanisms of action are suggested.

Postoperative thoracic myelopathy

The paper by Odate et al. [25] published in December presents six cases with progressive thoracic myelopathy, which appeared a few months after a long instrumented fusion from the thoraco-lumbar junction to the pelvis for degenerative lumbar disease. When myelopathy developed, five of the six patients had an adjacent segment upper-instrumented vertebral collapse. MRI and CT imaging also disclosed calcified oval-shaped formations, anterior and posterior to the cord at the disc level. In three of the six patients imaging studies also exhibited a calcified ligamentum flavum and a calcified herniated disc causing spinal stenosis. It is not clear whether the so-called upper-instrumented vertebral fractures appeared before or after the calcified lesions, including the ligamentum flavum. However, in the images presented by the authors, destructive lesions are striking and evoke destructive spinal arthropathies, which are a specific aspect of vertebral chondrocalcinosis. Apparently, none of the six patients presented systemic features (articular?) of CPPD disease, but abundant CCPD crystals and multinucleated giant cells were disclosed in the histopathology study in all patients.

The paper by Ha et al. [13] published in December reports seven cases of thoracic myelopathy following long instrumented fusion for degenerative lumbar disc disease. In these cases, the myelopathy was not related to crystal deposition. Symptoms of myelopathy including sensory deficit and gait disturbance appeared around 6 months after

the initial surgery. CT and MRI imaging disclosed that in all seven patients the myelopathy was related to hypertrophic ossified yellow ligaments at the adjacent level of the instrumented fusion. Six out of seven patients underwent decompressive laminectomy with an improvement of the JOA score. The average rate of recovery was 58.9 % with a follow-up ranging from 24 to 100 months. Histopathology confirms ossification of the yellow ligaments. There is no mention of crystal deposition. The article contains an interesting review of the literature and a discussion of the mechanisms of degenerative disease adjacent to instrumented fusion.

X-Stop

The X-Stop interspinous device is now more and more used for the treatment of stenosis of the spinal canal and of the foramen. The effect of this spacer is to mimic the clinical observation that patients with lumbar stenosis usually obtain pain relief in flexion and pain exacerbation in extension. The principle of the X-Stop device is to decompress the foramen and the spinal canal by limiting extension. The study by Wan et al. [33] in the March issue evaluates the biomechanical effect of the device on the foramen and the spinal canal. Measurements were made on eight patients with lumbar stenosis pre- and post-X-Stop implantation, using a novel CT/MRI and dual-fluoroscopic system (DFIS) described in detail in the paper. This 3D model permits more accurate measurements than those previously obtained in vitro or in vivo 2D. The results disclosed that the foramen area was significantly increased, both in height and width in extension and at standing. The segmental spinal canal length was significantly increased in extension. There was no significant disturbance at the adjacent levels, but the anterior disc space was reduced at standing. This study provides a biomechanical basis for the procedure. However, good future studies are still needed to confirm the clinical results, especially at medium and long terms.

Lumbar spinal stenosis

In the December issue Micankova Adamova et al. [23] published an important paper dealing with the natural evolution of lumbar spinal stenosis and predictors of clinical outcome. This is indeed the first prospective study with an evaluation at long-term follow-up. A group of 56 patients with clinically symptomatic mild to moderate LSS were re-evaluated after a mean period of 88 months. Patients were divided into two sub-groups: satisfactory outcome (unchanged or better clinical status) and an

unsatisfactory outcome (worse clinical status). At last follow-up, 34 patients (60.7 %) had a satisfactory outcome compared with 22 patients (39.3 %) for whom the clinical status deteriorated, including 10 % of patients who required surgical intervention due to failure of conservative treatment. The rate of surgery in this cohort is lower than those reported in previous studies. The results confirm that even after a long-term follow-up a substantial proportion of patients do not automatically deteriorate and remain unchanged or even improved by medical means described in the paper. Valuable information obtained in this study is the statistical analysis of entry parameters, predictors of success or failure of conservative therapy. A wide range of clinical, imaging and electrophysiological parameters is evaluated. Interestingly, electrophysiological abnormalities, such as pluriradicular involvement and abnormalities of the soleus H-reflex were predictive of deterioration. I strongly recommend reading this paper, which can be useful in decision-making.

Vertebroplasty–kyphoplasty

Despite the improvement of treatment of osteoporosis, aging of the population has increased the incidence of osteoporotic vertebral compression fractures (OVCF). These fractures have serious social consequences, not only for the patients, but also for their families and for the public health services. The paper by Klezl et al. [19] in the September issue examines the social and functional consequences of balloon kyphoplasty now frequently used in the treatment of OVCFs. Data collected prospectively in one hospital spinal unit compared 53 patients undergoing balloon kyphoplasty for painful OVCFs in a 2-year period with a historical age-matched group of 51 consecutive patients treated medically. Patients were classified in six main groups according to their level of social functioning preoperatively and at subsequent follow-ups. The same data were available in the control group before the medical treatment and 1-year post-injury. Patients of this latter group were also classified according to their social functioning in the same manner. The results of the comparative analysis between groups are well summarized in the abstract. The mortality rate in the balloon kyphoplasty group was 11 % at 1-year postoperatively versus 22 % in the conservatively treated group. A drift to a lower level of social functionality was observed at 1 year in 21 % of the surgical group as opposed to 53 % in the conservatively treated group.

The main limitation of this study is related to the fact that the control group was documented, retrospectively. However, considering the paucity of studies evaluating the effect of kyphoplasty on the social status, information

provided by this study strongly suggests that balloon kyphoplasty is a valuable treatment option.

The study by Bornemann et al. [4] in the May issue aims at comparing a new form of kyphoplasty to conservative care consisting of analgesics, bracing and physical therapy. Sixty-five elderly patients (52 % females) with painful vertebral osteoporotic fractures were all treated for 6 weeks by conservative management. After 6 weeks, patients could choose either to continue the conservative care or to crossover to radiofrequency kyphoplasty. This is a new form of kyphoplasty injecting high-viscosity cement in the fractured vertebra and using radiofrequency to achieve consistency of the cement. At 12 weeks, patients who were still treated conservatively were again offered kyphoplasty. Outcome measures were a VAS (0–10) and the German version of ODI. Clinical success was defined as firstly a VAS pain improvement equal or higher than 2; secondly a final VAS equal or lower than 5; thirdly, no functional worsening on ODI. At baseline, patients had a high level of pain and disability. After 6 weeks of initial conservative care, only 1 out of 65 patients met the criteria for clinical success with a median VAS improvement at 0. In contrast, at the 6-week follow-up after kyphoplasty, 31 of 33 patients met the clinical success criteria. Moreover, among the 38 patients who continued conservative care for 6 weeks after the initial treatment, only five met the criteria of success after 12 weeks of treatment. In their conclusion, the authors emphasize the fact that in this study a vast majority of patients did not respond to conservative care as opposed to those who received the new form of kyphoplasty, where nearly all patients recovered rapidly. Therefore, the authors recommend offering radiofrequency kyphoplasty much sooner than after 6 weeks of conservative care. No complication was disclosed in this series and no conflict of interest was reported. This article is followed by a useful Reviewer's Comment by Alvarez Galovich [1], summarizing the critical remarks, which can be opposed to the study, and indicating the need for further studies to avoid overuse of this procedure.

Rho et al. [28] performed an interesting study, reported in the May issue, exploring the risk factors predicting new symptomatic vertebral compression fractures after percutaneous vertebroplasty or kyphoplasty. One hundred and forty-seven patients treated by vertebroplasty (PVP) or kyphoplasty (PKP) for an osteoporotic vertebral compression fracture (VCF) were followed up regularly at 2 weeks, 1 month, every 3 months during the first year after the procedure, and then on a yearly basis. The presence of a new vertebral osteoporotic fracture (NVCF) was detected on clinical symptoms and imaging studies including plain radiographs and MRI. Interestingly, the new fracture was treated by repeated PVP or PKP after 2 weeks of conservative treatment if the pain persisted. The same algorithm

had been followed with the initial fracture. Possible risk factors, which could predispose to a NVCF, were retrospectively studied. They include age, gender, BMI, BMD, level and number of the treated vertebrae, amount of cement injected, cement distribution, leakage of cement in the adjacent disc, and degree of deformation of the treated vertebra. Twenty-seven patients (18 %) had a subsequent symptomatic NVCF. The median time to new fracture was 70 days. Eighteen of the 27 new fractures were on the adjacent vertebra. Factors affecting NVCF were old age, PVP procedure, low BMD and leakage of the cement into the disc space. The most predictive factors were osteoporosis and cement leakage. In this paper, readers will find a comparison of the findings of this study with the data of the literature and an interesting discussion of the various risk factors, including the biomechanical changes induced by the injected cement.

Intensive behavioural cognitive management program and exercises in chronic low-back pain

In the July issue Van Hooff et al. [32] report the 2-year follow-up results of a prospective cohort treated by a short intensive behavioural pain management program. It is now admitted that a cognitive behavioural approach effectively reduces disability in chronic LBP patients. Ninety patients were entered in an evidence-based intensive cognitive pain management program developed by the UK Real Health Institute. This is a 2-week residential program following international guidelines. The aim of the intervention delivered by a psychologist, a physiotherapist and an occupational therapist is to improve daily functioning. Interesting results had been disclosed at 1-year follow-up. The present study evaluates whether the results are stable after 2 years. Outcome measures included the Roland-Morris Disability Questionnaire as a primary outcome, and SF36 to measure the health-related quality of life. Indicators for health care use and Visual Analogue Scales to measure pain were also evaluated. In 85 out of the 90 eligible patients the 1 year significant effects on daily functioning and quality of life were maintained. The use of medical consultations and pain medication had also significantly decreased. Most importantly, the majority of the participants were at work. The study has limitations recognized by the authors, especially concerning its external validity. However, it presents clinically relevant long-term effects, which are usually lacking in other reported interventions of this kind.

The paper by Froholdt et al. [12] published in December is a 9-year follow-up study of an original trial [6], which reported no difference in the outcome when comparing lumbar fusion and cognitive behavioural intervention after

1 year in patients with chronic non-specific low-back pain. Similar findings were disclosed when the same cohort was evaluated after 4 years [5]. In the present paper, the main outcome measure was ODI. Secondary outcome measures were pain, fear-avoidance beliefs, trunk muscle strength, with a specific focus on medications and return to work. 44 of the 58 patients allocated to cognitive intervention and exercises were available at 9-year follow-up; 18 of the 58 patients had undergone surgery. The results were analysed both with intention-to-treat and with an as-treated approach. Overall, there was no difference between the two groups at 9-year follow-up in the intention-to-treat analyses. The results are similar to those disclosed at 1- and 4-year follow-up. The two groups reported less pain and better function when compared with baselines. However, more operated patients were out of work and used medications when results were analysed according to the treatment received. This paper is a nice piece of work with an exceptional long-term follow-up. Limitations of the study are accurately discussed by the authors.

Predictors of outcome after disc prosthesis and rehabilitation for chronic low-back pain

Multidisciplinary rehabilitation programs including physical exercise and cognitive behavioural treatment have been shown to be effective in chronic low-back pain. Studies have also demonstrated that the same category of LBP patients can be successfully treated by surgery: fusion or disc prosthesis [6, 10, 11]. The problem is how to choose between these two alternatives. In this regard, I strongly recommend a careful reading of the paper by Hellum et al. [14] published in April, which yields interesting new information. The high-quality study aimed at evaluating whether some baseline characteristics could predict outcome in patients treated either by intensive rehabilitation or by disc prosthesis. One hundred and fifty-four patients with chronic low-back pain for at least 1 year underwent either a disc prosthesis ($n = 88$) or a full rehabilitation program ($n = 66$). Outcome measures included were ODI dichotomized to less than or greater than 15 points improvement and working at 2-year follow-up. Multiple variables tested for predictive value were registered at baseline and a multiple logistic regression analysis was used. Results summarized by the authors in their conclusions are as follows: shorter duration of LBP, Modic types I or II changes, and low fear-avoidance beliefs for work (FABQ-W) were the best predictors of success after disc prosthesis. High ODI, low distress and not using narcotics daily predicted better outcome of rehabilitation. Low FABQ-W and working at baseline were predictors of working at follow-up.

Lumbar kyphosis, back muscle strength and gastroesophageal reflux disease

The article by Imagama et al. [15] published in the November issue deals with the relationship between lumbar lordosis angle, poor sagittal balance, decreased back muscle strength, and the development of gastroesophageal reflux disease (GERD) in elderly patients. Previous studies had suggested that GERD could be influenced by modifications of the sagittal spinal balance. Two hundred and forty-five elderly individuals were examined in the framework of a health check-up including the evaluation of the spinal sagittal balance with “Spinal Mouse” and a specific questionnaire for GERD symptoms. Numerous other variables, such as back muscle strength, BMI, oral drugs per day, intake of NSAIDs and of bisphosphonates, alcohol intake and smoking were evaluated. The multivariate progression analysis showed that lumbar lordosis angle, sagittal balance, back muscle strength and drugs intake had significant effects on the presence of GERD. According to the authors, lumbar kyphosis could increase the intra-abdominal pressure with subsequent compression of the stomach and oesophagus cranially, inducing a decreased lower oesophageal sphincter pressure. This in turn could provoke symptoms of GERD. The study has limitations, which are well analyzed by the authors. This association deserves to be looked for in future studies of sagittal spinal balance.

Non-organic physical signs in low-back pain

The paper by Kumar et al. [20] in the November issue describes three novel tests intended to identify the non-organic causes of low-back pain in clinical practice. The three tests are well demonstrated in schematic drawings. They comprise the resistive straight leg raise test and the resistive forward bent test and the Heel compression test. The purpose of the study is to validate the three tests in predicting non-organic causes for low-back pain. Two hundred LBP patients were studied and separated into two groups: a secondary-gain motive group (SGM) and a non-secondary-gain motive group (non-SGM). The three new tests plus the Schober test and the Waddell’s five physical signs are performed on them. The statistical analysis correlates the test results, MRI findings and SGM status. The results are described in detail, providing the conclusion that the tests strongly predict SGM status in patients with low-back pain. According to the authors, the three tests are highly practical in clinical practice, probably more so than the Waddell’s signs which could be more useful for research. The authors very wisely remark that the assessment of behavioural signs is not a psychological

evaluation. They also state that the SGM status does not exclude a medical condition, true fear-avoidance of pain or of further injury or other psychological variables. Patients with SGM status need further attention and investigation.

Financial disclosures

In the July issue of the Journal, Bartels et al. [2] discuss the result of a study evaluating the effect of reporting a financial disclosure in the conclusion of an article. A literature search of articles on interspinous devices and cervical disc prostheses yielded 51 articles on interspinous devices, and 109 on cervical disc prostheses. Conclusions found in the abstract of the article were analysed and graded as positive, neutral, or negative according to the statements concerning the technique under investigation in the study. The qualification of the conclusion was correlated with the presence of financial disclosures by the authors of the article. Funding by commercially active parties was also analysed. In 40 articles, there was no need to report disclosure in the publication. The results of this study, based on 120 articles, clearly demonstrate the influence of financial disclosure and of funding on the conclusions of the articles. The important discrepancy found between the conclusions of articles reporting financial disclosure and funding versus articles without financial disclosure was principally related to the large number of papers with a neutral or negative conclusion if no financial disclosure was reported. This source of bias must be kept in mind when assessing the quality of an article, for example in the review process.

Conflict of interest None.

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