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Lumbar Supports for Prevention and Treatment of Low Back Pain

A Systematic Review Within the Framework of the Cochrane Back Review Group

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Study Design: A systematic review of randomized and nonrandomized controlled trials.

Summary of Background Data: Lumbar supports are used in the treatment of low back pain, but also to prevent the onset (primary prevention) or recurrences of a low back pain episode (secondary prevention).

Objectives: To assess the effects of lumbar supports for prevention and treatment of nonspecific low back pain.

Methods: The Medline, Cinahl, and Current Contents databases; the Cochrane Controlled Trials Register up to September 1999; and the Embase database up to September 1998 were all searched. References of identified trials and systematic reviews were reviewed and the Science Citation Index used to identify additional trials. Methodologic quality assessment and data extraction were performed by two reviewers independently. A quantitative analysis was performed in which the strength of evidence was classified as strong, moderate, limited or conflicting, and no evidence.

Results: Five randomized and two nonrandomized preventive trials and six randomized therapeutic trials were included in the review. Only 4 of the 13 studies were of high quality. There was moderate evidence that lumbar supports are not effective for primary prevention. No evidence was found on the effectiveness of lumbar supports for secondary prevention. The systematic review of therapeutic trials showed that there is limited evidence that lumbar supports are more effective than no treatment, whereas it is still unclear whether lumbar supports are more effective than other interventions for treatment of low back pain.

Conclusions: There continues to be a need for high quality randomized trials on the effectiveness of lumbar supports. One of the most essential issues to tackle in these future trials seems to be the realization of adequate compliance. [Key Words: Cochrane collaboration, effectiveness, lumbar supports, systematic review] **Spine 2001;26:377–386**

Low back pain (LBP) is a very common health problem in western industrialized countries. Lifetime prevalence of LBP exceeds 70%, with peak point prevalences between ages 35 and 55.[4] Furthermore, recurrent episodes of LBP occur very frequently, and a considerable number of people have permanent discomfort from LBP.[4] Chronic LBP is present in 3% to 7% of the population in western industrialized countries.[4] The impairment and disability associated with LBP frequently lead to absence from work and associated loss of productivity. The total costs of LBP to industry in 1988 in the United States were estimated to be between $26.8 and $56 billion (US).[26] In The Netherlands, the total costs of absenteeism and disability due to back pain—the indirect costs—were estimated at $3.1 billion and $1.5 billion (US), respectively, in 1991, whereas the total direct medical costs were estimated at $368 million (US).[38]

Lumbar supports are frequently used in the management of low back pain and are also a common intervention in industry to prevent back injuries.[9] Lumbar supports are provided as treatment to people who have LBP with the purpose of making the impairment and disability vanish or decrease. Lumbar supports are provided as intervention for prevention with the purpose of preventing the onset of LBP (primary prevention) or of preventing recurrent LBP episodes (secondary prevention). Although a large variety of preventive and therapeutic interventions are available for LBP, the efficacy of most of these interventions has not been demonstrated yet.[36,39]

Nachemson[27] reported the different desirable functions of a lumbar support: 1) to correct deformity; 2) to limit spinal motion; 3) to stabilize part of the spine; 4) to reduce mechanical uploading; and 5) to provide the miscellaneous effects of massage, heat, placebo. However, at present, the putative mechanisms of action of a lumbar support remain a matter for debate.[5,7,9,25]

Potential adverse effects of wearing a lumbar support that have been reported, are skin lesions, gastrointestinal disorders and muscle wasting,[7] higher blood pressure and higher heart rates.[23]

The growing popularity of lumbar supports has led to several studies investigating the preventive and therapeutic effects. These studies have already been summarized in several reviews, papers, and editorials on the effectiveness of lumbar supports for prevention[5,9,19,25,36] and for treatment.[20]

The present systematic review distinguishes itself from these reviews by evaluating the literature systematically using the up-to-date methodology recommended by the Cochrane Collaboration Back Review Group[40], by including the most recent literature up to September

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1999, and by reviewing lumbar supports in the context of both treatment and prevention.

The objectives of this systematic review were to determine whether lumbar supports are effective for prevention of nonspecific LBP and whether lumbar supports are effective for treatment of nonspecific LBP. Comparisons that were investigated were:

    1a. Lumbar support as intervention for prevention of LBP *versus* no intervention.

    1b. Lumbar support as intervention for prevention of LBP *versus* other types of prevention.

    1c. Lumbar support as supplement to another type of prevention of LBP *versus* the other type of prevention alone.

    2a. Lumbar support as intervention for treatment of LBP *versus* no intervention.

    2b. Lumbar support as intervention for treatment of LBP *versus* other types of treatment.

    2c. Various types of lumbar support.

■ Methods

Criteria for Considering Studies.

Types of Studies. Both randomized controlled trials (RCTs) and nonrandomized controlled trials (CCTs) were included. The CCTs were included because of the small number of available RCTs. There were no language restrictions.

Types of Participants. For preventive trials, the study population had to consist of workers aged 18 to 65 years. For therapeutic trials, the study population had to consist of subjects with nonspecific low back pain. The RCTs and CCTs that included subjects with low back pain caused by specific pathologic entities such as infection, neoplasm, metastasis, osteoporosis, rheumatoid arthritis, or fractures were excluded.

Types of Interventions. Any type of lumbar support, flexible and rigid, for prevention or treatment of nonspecific LBP was included. Special types of lumbar supports for severe scoliosis and kyphosis were excluded, as were special lumbar supports after back surgery.

Types of Outcome Measures. Only preventive studies in which at least one of the following outcome measures was used were included: incidence of low back pain, duration of low back pain, absenteeism (percentage of the studied population, number of days), and back-pain–specific functional status (Roland Disability Questionnaire [RDQ], Oswestry scale). For therapeutic studies only RCTs and CCTs that used at least one of the following outcome measures were included: pain (visual analog scale [VAS], numerical rating scale [NRS]), overall improvement (percentage improvement, NRS), return to work (percentage of the population, number of days of absenteeism) and back pain specific functional status (RDQ, Oswestry scale).

Search Strategy for Identification of Studies.
Searches of Medline, Cinahl, and Current Contents databases; the Cochrane Controlled Trials Register up to September 1999; and the Embase database up to September 1998 were conducted. The search strategy recommended by the Editorial Board of the Cochrane Back Review Group was used.[40] Also screened were

Table 1. Methodologic Quality Criteria

Internal Validity Items
1   Was a method of randomization performed?
2   Was the treatment allocation concealed?
3   Were the groups similar at baseline regarding the most important prognostic indicators?
4   Was controlled for cointerventions which could explain the results?
5   Was the compliance rate (in each group) unlikely to cause bias?
6   Was the patient blinded?
7   Was the outcome assessor blinded?
8   Was the withdrawal/dropout rate unlikely to cause bias?
9   Was the timing of the outcome assessment in both groups comparable?
10 Was an intention-to-treat analysis used?

references in relevant reviews and identified trials, and the Science Citation Index was used to identify additional trials.

Methods.

Study Selection. Two reviewers (PJ, MWvT) ran the complete search strategy in Medline and Embase together. One reviewer (PJ) ran the search in Cinahl and Current Contents. Authors, title, subject headings, publication type, and abstract of the studies identified by the search strategy were downloaded. Studies that met the inclusion criteria were included in the review. A consensus method was used to resolve disagreements about the inclusion of studies, and a third reviewer (MNMvP) was consulted if disagreement persisted.

Methodologic Quality Assessment. The methodologic quality was independently assessed by two reviewers (PJ, MWvT). The reviewers were not blinded as to author, institution, and journal, because one of the quality assessors (MWvT) was very familiar with the literature and would have recognized blinded studies easily. The other quality assessor (PJ) was a layperson in the field of intervention research on back pain and not familiar with the literature. A consensus method was used to resolve disagreements concerning the assessment of the methodologic quality of the RCTs and CCTs included in the review. A third reviewer (MNMvP) was consulted if disagreement persisted. If the article did not contain sufficient information on one or more of the criteria, the authors were contacted for additional information. If the authors could not be contacted or if the information was no longer available, the criteria were scored as unclear.

The methodologic quality of the studies was assessed using the criteria list recommended by the Cochrane Back Review Group for Spinal Disorders.[40] Only the items reflecting the internal validity of the RCTs and CCTs were used to assess the methodologic quality (see Table 1). The item regarding the blinding of care providers was not included in the quality assessment, because blinding of care providers for lumbar support use seems impossible. Each item was scored as either positive, negative, or unclear. A validity item was scored as positive when the available information regarding that item did not show any bias and negative when no information at all was provided regarding that item or when the available information showed any bias. A validity item was scored as unclear when the available information regarding that item was too scarce to make a conclusion regarding potential bias.

Data Extraction. Using a standardized form, one reviewer (PJ) extracted data considering characteristics of the study population (age, gender), type of work performed by the study population (in prevention trials), type of LBP (with or without radiation, in treatment trials), duration of LBP (acute or chronic, in treatment trials), type of study (RCT or CCT), duration of intervention period, timing of follow-up measurements, characteristics of the studied intervention (type of lumbar support, the number of hours per day the subjects were prescribed to wear the lumbar support, duration of intervention period), characteristics of the control intervention (type, intensity, duration of intervention period), adverse effects due to the interventions, compliance, and the final results for each outcome measure on the effectiveness of lumbar supports. The reviewer compared these findings to data regarding the same characteristics of the same studies published in other reviews.[20,36] The reviewer was not blinded as to author, institution, and journal of the reviews.

Data Analysis. Many studies did not report the results in a way that enabled statistical pooling (for example, means with standard deviations for continuous data). Furthermore, studies were heterogeneous in study populations, interventions, and outcomes. Therefore, a meta-analysis was not performed, but the results were summarized qualitatively. A rating system was used, consisting of four levels of scientific evidence based on the design (RCT or CCT), the quality, and the outcome of the studies:

1. Strong evidence: provided by generally consistent findings in multiple high-quality RCTs.
2. Moderate evidence: provided by generally consistent findings in one high-quality RCT and one or more low-quality RCTs or by generally consistent findings in multiple low-quality RCTs.
3. Limited evidence: only one RCT (of either high or low quality) or generally consistent findings in CCTs; or conflicting evidence: inconsistent findings in multiple RCTs and CCTs.
4. No evidence: no CCTs or RCTs.

Multiple high-quality RCTs were defined as more than one RCT that fulfilled 50% or more of the validity criteria. Sensitivity analyses were also performed exploring the results when high quality was defined as fulfilling 40% and 60% or more of the validity criteria. Another sensitivity analysis was performed in which all scores of "unclear" on the internal validity items were assumed to be positive. Findings were considered to be generally consistent when at least 75% of the studies showed similar results.

Subgroup analyses for prevention were performed for primary *versus* secondary prevention and short-term follow-up (<6 months after randomization) *versus* long-term follow-up (6 months after randomization). Subgroup analyses for treatment were performed for acute *versus* chronic LBP and short-term follow-up (<6 months after randomization) *versus* long-term follow-up (6 months after randomization).

■ Results

Study Selection

The search strategy in the four databases resulted in the identification of 153 articles; 43 articles were identified in Medline, 93 articles in Embase, 6 articles in Cinahl,

and 11 in Current Contents. Because 17 articles were found in two databases, 4 articles in three databases, and 1 article in all four databases, the total number of potentially relevant articles was 125. Based on titles, subject headings, abstracts and journal types, the authors concluded that seven articles met the eligibility criteria.[10,17,21,24,35,37,41] The reviewers disagreed on or were not sure about inclusion of six studies.[2,13,15,18,22,32] All six articles were excluded after the full articles were read (Table 2).

The studies by Hsieh et al[17] and Pope et al[29] appeared to be reports of the same study. Both studies were used to assess the quality of the study and to extract relevant data.

Screening references of two reviews[20,36] resulted in identification of five additional studies.[1,3,8,31,33] In 1991, some additional data from the study of Walsh and Schwartz[42] were published in a letter to the editor. Screening the latest issue of the Cochrane library, resulted in identification of four RCTs, which had already been identified. Citation tracking in the Science Citation Index of the selected RCTs and CCTs resulted in identification of 42 articles. However, none of these studies met the inclusion criteria. Two additional studies came from the authors' personal files.[12,28] In summary, seven studies on prevention[1,3,12,31,33,37,41] were included in the present review and six studies on treatment.[8,10,17,24,28,35]

Methodologic Quality

The two quality assessors disagreed about 55 of the 227 validity items (24%). After one consensus meeting, all disagreements, mostly due to reading errors, were resolved.

The authors of the studies have been informed about the methodologic quality assessment. The addresses of two authors were not found.[10,35] The authors were asked whether they agreed with the scores and whether they could provide more information on the items that were scored as unclear. The authors of four studies responded to this request.[8,17,24,37] Seven scores were changed by this information: Four unclear scores and three negative scores were changed into positive.

Overall the methodologic quality of the studies included in the present review was low (Table 3). Only four

Table 2. Characteristics of Excluded Studies

Study	Reason for Exclusion
Amudsen, 1982	No control group.
Garg, 1992	The lumbar support was used as intervention for the transfer of patients and not as intervention for prevention or treatment of LBP.
Hamonet, 1993	No relevant outcome measures. The effect of a lumbar support was evaluated by measuring the activity level of the abdominal muscles.
Jonai, 1997	The effect of a lumbar support was evaluated by measuring the range and velocity of torso motion.
Larsson, 1980	No contrast for lumbar supports.
Marty, 1998	No contrast for lumbar support.
Spratt, 1993	No contrast for lumbar support.

Table 3. Methodologic Quality of Trials on the Effectiveness of Lumbar Supports

Studies	1	2	3	4	5	6	7	8	9	10
Prevention of low back pain										
Alexander	?	−	+	−	?	−	−	+	+	+
Anderson	−	−	−	−	+	−	−	?	+	?
Gaber	?	?	+	+	−	−	−	−	+	−
Reddell	?	−	+	−	−	−	−	?	+	−
Thompson	−	−	−	−	−	−	−	−	+	?
Van Poppel	+	+	+	−	−	−	−	+	+	+
Walsh	+	−	+	?	−	−	+	+	+	?
Treatment of low back pain										
Coxhead	+	−	?	−	−	−	−	−	+	+
Doran & Newell	?	?	?	?	−	−	+	−	+	−
Million	+	+	−	−	−	+	−	+	+	+
Penrose	?	+	?	−	?	−	−	+	+	+
Pope	+	+	+	+	+	−	+	−	+	−
Valle-Jones	?	−	?	+	−	−	−	+	+	+

of the 13 studies met the preset level for high quality of more than 50% positive scores.[17,24,37,41] Prevalent methodologic flaws were inadequate randomization procedure (items 1), no concealment of treatment allocation (item 2), no assessment of cointerventions (item 4) and compliance (item 5), and no blinding of patients (item 6) and outcome assessors (item 7).

Study Characteristics

Study characteristics are summarized in Table 4.

Prevention

Of the seven preventive studies five were RCTs,[1,12,31,37,41] and two were CCTs.[3,33] In three studies, it was reported that workers with a history of LBP were included, and in two studies it was reported that workers with current LBP were included. In the other studies no information was given about inclusion or exclusion of workers with a history of LBP or current LBP. One study excluded patients who were currently treated for back pain or back injury.[41]

The number and type of control interventions used in the preventive studies varied considerably. In all studies, the subjects were prescribed to wear the lumbar support at work. Only three studies presented data regarding compliance.[3,31,37] The compliance rate varied from 43% of the subjects who wore the belt at least half the time[37] to 80% of the subjects who wore the belt most of the time.[3] In two studies results of subgroup analyses were presented for subjects with a history of back pain. Van Poppel et al[37] showed that, within a subgroup of subjects with LBP at baseline, workers using a lumbar support had lesser days with LBP per month compared with workers without lumbar support. Barron[5] suggested, using data of Walsh and Schwartz[41], that workers with a history of LBP may be an appropriate population for consideration of prophylactic bracing in the workplace rather than the general workforce.

Treatment

All six studies on treatment were RCTs. None of the treatment studies included solely patients with acute LBP, and only one study included solely patients with chronic LBP.[24] Four studies included a mix of patients with acute, subacute, and chronic LBP.[8,10,17,35] One study did not give any information about the duration of the LBP symptoms of the patients.[28] The lumbar supports and control interventions used in the studies varied considerably. One study reported that any type of lumbar support was used.[8] Two studies used a lumbar support with rigid stays in the back,[15,24] whereas one study used a pneumatic lumbar support.[28] The other two studies did not provide much information about the type of belt.[8,35] In the study by Million et al,[24] two types of lumbar supports were compared. Only three studies reported the number of hours a day the lumbar support should be worn.[17,24,28] Compliance with wearing the belt was reported in only one study; 56% of the patients wore the belt more than 7 hours a day.[17]

Effects of Lumbar Supports in Prevention of Low Back Pain

Lumbar Supports Versus No Intervention. Four RCTs[1,12,31,37] and one CCT[3] included a no intervention group. One RCT was considered to be a high-quality RCT,[37] whereas three studies were considered to be low-quality RCTs.[1,12,31] None of these studies evaluated lumbar supports for secondary prevention and, therefore, a subgroup analysis for primary versus secondary prevention was not performed.

Four RCTs reported no differences in back pain injury or incidence of LBP after 3 months,[1] 6 months,[37] 8 months,[31] and 12 months.[12] In three RCTs, including the high-quality study, no differences were found in sick leave.[12,31,37] There is moderate evidence (Level 2) that lumbar supports do not prevent LBP.

Lumbar Support Versus Other Types of Prevention. Two RCTs were identified, one of high quality[37] and one of low quality.[31] In both, incidence of LBP and sick leave due to LBP were used as outcome measures. In both trials, these outcome measures did not show significant differences between intervention and control groups. There is moderate evidence (Level 2) that lumbar supports are not more effective than other types of prevention for LBP.

Lumbar Support as Supplement to Another Type of Prevention Versus the Other Type of Prevention. In two studies lumbar support plus back school was compared with the back school program alone in the prevention of low back pain.[33,41] In one of these trials, all subjects also were instructed in warming-up exercises.[33] One trial was considered a high-quality RCT,[41] the other trial was a CCT.[33] In both studies incidence of LBP (work injury) was used as an outcome measure, and in one of these, days absent from work because of back injury was also used as an outcome measure.[33,41] In both trials there was

Table 4. Characteristics of Included Studies

Study	Participants	Interventions	Outcomes	Notes
RCTs				
Alexander, 1995	Subjects: 60 health care workers; 48 women and 12 men. Mean age 37 years. Exclusion criteria: subjects who have had back surgery, current workers' compensation claims, cardiovascular problems, or were pregnant. Authors did not report whether workers with LBP or a past history of LBP were included in the study.	Preventive intervention: 1) Back belt group (n = 30). Belt at work for 3 months. Control intervention: 2) No intervention (n = 30)	Work-related back injuries and perception of physical pain. No significant differences.	The most common complaints: belt rode up, changed position, and increased perspiration. No data available regarding compliance.
Coxhead, 1981	Subjects: 334 patients with pain of sciatic distribution; 185 men and 149 women. Mean age 41.9, mean duration of symptoms 14.3 weeks. Exclusion-criteria: specific LBP, patients undergone trunk, lower-limb, or spinal surgery within the previous 3 months and pregnant and postpartum women.	Treatment intervention: 1) Fabric made lumbar support, 4 weeks (n = 124). No data on number of hours/day. Control interventions: 2) No lumbar support (n = 168).	Overall improvement, pain, return to work/ normal activities. No differences after 4 weeks, 4 months, and 16 months.	334 patients entered the study, 12 were later found ineligible. Of these 322 patients, 292 were assessed at 4 weeks. At 4 months 250 patients were assessed and at 16 months 258 patients were assessed. No data available regarding compliance.
Doran, 1975	Subjects: 456 patients with nonspecific LBP; 211 women, 245 men. Age 20–50, duration of symptoms: less than a week to more than 6 months. Inclusion criteria: 1) age 20–50 years, 2) painful limitation of movement in the lumbar spine and 3) suitable for any treatment.	Treatment interventions: 1) Corset (= 109), any type, 3 weeks. No data on number of hours/day. Control interventions: 2) Manipulation (n = 116), 2 treatments/wk 3) Physiotherapy (n = 114), any treatment except manipulation, two treatments/wk 4) Analgesic tablets (n = 113) 2 paracetamols/4 hours.	Pain Overall assessment by the doctor. No significant differences after 3 and 6 weeks, and 3 and 12 months.	456 patients entered the trial. At baseline 452 patients were assessed. After 3 weeks 395 patients were assessed, after 6 weeks 340, after 3 months 335, and after 12 months 262 patients were assessed. No data available regarding compliance.
Gaber, 1999	Subjects: 209 male workers whose jobs included manual material handling at an airport. The majority of the workers (77%) had no or only mild LBP at the start of the study.	Preventive intervention: 1) Synthetic lumbar support (n = 118), lumbar support use at work for 12 months. Control intervention: 2) No intervention (n = 91)	Pain score, medicine intake due to LBP, sick leave due to LBP. No differences in pain and sick leave; less medication intake in lumbar support group.	Of the 267 workers included at the start of the study only 209 have finished the study. Only data of these subjects is presented in the study. No data on compliance.
Hsieh, 1992	Subjects: 164 patients, 62 women and 102 men with nonspecific LBP and no sciatica. Median age 32 and mean duration of complaints between 3 weeks and 6 months. Inclusion criteria: 1) age 18–55 years, 2) LBP between 3 weeks and 6 months duration, 3) good health.	Treatment intervention: 1) Corset (n = 29), lumbosacral canvas corset with metal stays in the back. Corset use during waking hours, 3 weeks. Control interventions: 2) Spinal manipulation (n = 70), 3 times/ week. 3) Soft tissue massage (n = 37), 3 times/week. 4) TMS (n = 28), unit should be worn for 8 hours/day.	Pain, functional status. Only better functional status after 4 weeks compared to massage, not to manipulation and TMS. No differences in pain.	88% of the original patients completed the assessments at baseline and at 4 weeks. Data of RDQ and revised Oswestry are reported by Hsieh (1992) for a subgroup of 83 patients from the study population of Pope. Compliance: 65% wore the belt more than 7 hours a day during the intervention period.
Million, 1981	Subjects: 19 patients, 13 women and 6 men. No data available on mean age. Inclusion criteria: 1) over 18 years of age, 2) suffering from chronic nonspecific LBP 6 months, 3) not responding to any form of treatment.	Treatment intervention: 1) Corset and lumbar support (n = 9). Support is of rigid material. Corset use during the day, 8 weeks. Control intervention: 2) Corset (n = 10), lumbosacral corset use during the day, 8 weeks.	Subjective and objective index. Rigid support better subjective index after 4 and 8 weeks.	The subjective index is an overall measurement of the severity of symptoms and of the interference of these symptoms with normal activities. The objective index is an overall measurement of the straight leg raising and of spinal movements. No data on compliance.
Penrose, 1991	Subjects: 30 patients, 8 women and 22 men. Mean age 34 years (range 19–61 years). Patients were diagnosed as having muscular strain/sprain of the lower back by an orthopedic-neurologic examination. No information available on mean duration of complaints.	Treatment intervention: 1) Pneumatic lumbar support (n = 15). Lumbar support use during 6 hours/day, 5 days/week, 6 weeks. Control intervention: 2) No intervention.	Pain index; lumbar supports better after 1 hour, 3 weeks, and 6 weeks.	No data on compliance.

Table 4. Continued

Study	Participants	Interventions	Outcomes	Notes
Reddell, 1992	Subjects: 896 fleet service clerks; 70 women, 572 men. Age range: 19–67 years. 26% of 642 subjects had suffered a previous back injury and 56% a previous back pain. No data available regarding subjects with current LBP.	Preventive intervention: 1) Weightlifting belt (n = 145), belt use at work, 8 months. 2) Belt plus training class (n = 127), belt use at work and 1 hour training class on spine anatomy and body mechanics. Control intervention: 3) Training class (n = 122), 1 hour training class. 4) No intervention (n = 248).	Lumbar injuries, lost work days case lumbar injury, restricted work days, case lumbar injury, compensation cost. No significant differences after 8 months.	Of the 896 clerks selected to participate in this study 642 were located and interviewed at the end of 8 months. Only data of these subjects is presented in the article. Compliance: 58% stopped using it before the end of 8 months. Complaints: heat production around the waist, the belt rides up and pinches ribs.
Valle-Jones, 1992	Subjects: 216 patients with nonspecific LBP; 97 women, 113 men and 6 "unknown." Mean age 43, median duration of symptoms 11 days. Inclusion criteria: 1) first episode of nonspecific LBP, 2) chronic nonspecific LBP, 3) acute exacerbation of a longer-standing problem.	Treatment intervention: 1) Back support (n = 111), elasticated with an attached silicone rubber pad of special shape, 3 weeks. Control intervention: 2) Standard therapy: advice on rest and lifestyle (n = 105).	Pain, limitation of activity, ability to work, use of analgesics, overall improvement; all significantly better in lumbar support group after 3 weeks.	No data on compliance.
Van Poppel, 1998	Subjects: 312 workers whose jobs included manual material handling. Workers who had a permanent partial work disability were excluded. Mean age 35.1. 172 subjects with previous LBP, 49 subjects with LBP at baseline.	Preventive interventions: 1) Lumbar support (n = 83), 6 months. 2) Lumbar support use at work plus education (n = 70), 6 months. Control intervention: 3) Education: 5 hrs. lifting instructions (n = 82). 4) No intervention (n = 77).	LBP incidence, sick leave due to back pain; no differences after 6 months.	A total of 312 workers were randomized of whom 282 were available for the 6-month follow-up. Compliance with wearing the lumbar support at least half of the time was 43%.
Walsh, 1990	Subjects: 90 male warehouse workers. Individuals currently being treated for back pain or back injury were excluded, although those with a prior history of back injury were not excluded. Mean age 29 years.	Preventive intervention: 1) A lumbosacral orthosis at work plus back school: a 1-hr training session on back pain prevention and body mechanics, 6 months (n = 30). Control intervention: 2) Back school (n = 30), 1-hr. training session. 3) No intervention (n = 30).	Work injury incidence, productivity, use of health care services, days lost from work by back injury. Days lost from work significantly better in lumbar support group.	A total of 90 workers were randomly assigned. Follow-up was obtained at 6 months from 82 workers. Only the data of these 82 workers is presented in the article. No data on compliance.
CCTs				
Anderson, 1993	Subjects: 266 workers in a grocery distribution warehouse. No data available on age. Authors did not report whether workers with LBP or a past history of LBP were included in the study.	Preventive intervention: 1) Back belt group (n = 266) A spandex belt with shoulder straps. Belt use at work for 12 months. Control intervention: 2) No intervention (2 other work sites).	Lower incidence of injury in back belt group.	The supervisors reported that over 80% of the workers wore the belts most of the time.
Thompson, 1994	Subjects: 60 hospital workers; both men and women. Authors did not report whether workers with LBP or a past history of LBP were included in the study. Age range 21–65 years.	Preventive intervention: 1) Weightlifting belt plus 8 hrs. back school and instructions on warm-up exercises (n = 41), thick woven, deformable nylon, daily use, 3 months. Control intervention: 2) Back school and 8 hrs. instructions on warm-up exercises (n = 19).	Incidence of LBP significantly lower in lumbar support group.	The authors stated that belt use resulted in less LBP. However, it is unclear how the authors came to this conclusion. At baseline a difference in frequency of LBP already existed. No data presented. No data on compliance.

no significant difference between the two intervention groups regarding incidence of LBP (work injury). In the high-quality study, a significant effect was found of wearing the belts in addition to a back school program on the number of days absent from work because of back injury.[41] Regarding the incidence of LBP, there is limited evidence (Level 3) that a lumbar support added to a back school program is not more effective than a back school program alone. However, there is limited evidence (Level 3) that a lumbar support added to a back school program

is more effective than back school alone regarding the number of days absent from work because of back injury.

Effects of Lumbar Supports in Treatment of Low Back Pain

Lumbar Support *Versus* No Intervention. In one low-quality RCT the effect of a lumbar support was compared with no intervention.[28] In this study, the pain index showed a significant effect in favor of the lumbar support group. There is limited evidence (Level 3) that lumbar supports provide some pain relief in patients with low back pain.

Lumbar Support *Versus* Other Types of Treatment. In four trials lumbar supports were compared with some type of treatment for LBP.[8,10,17,35] Only one trial was considered a high-quality RCT.[17] All four studies used pain as a main outcome measure. Only Valle-Jones et al[35] found a significant difference in pain in favor of the lumbar support group. In other three studies, including the high-quality RCT, no differences were reported. There is moderate evidence (Level 2) that a lumbar support is not more effective in reducing pain than other types of treatment.

Overall improvement was used as main outcome measure in three low-quality studies.[8,10,35] In only one study[35] was a significantly greater overall improvement found in the lumbar support group, whereas no differences were found in the other two studies. There is conflicting evidence (Level 3) that patients wearing a lumbar support do or do not show significantly more overall improvement than patients receiving another type of treatment. Return to work (or ability to work) was used as a main outcome measure in two low-quality studies.[8,35] In the findings of one study, there was no significant difference between the groups,[8] whereas in another, a significant difference was found in favor of the lumbar support group.[35] There is conflicting evidence (Level 3) that patients who use a lumbar support as treatment return to their work more quickly than patients who use another type of treatment.

In the high-quality study, two different back pain–specific functional status tests were used.[17] The RDQ showed a significant difference between the lumbar support group and the soft tissue massage group. The revised Oswestry Scale showed no significant difference between the groups. Therefore, there is conflicting evidence (Level 3) on whether lumbar supports improve back pain–specific functional status compared with other types of treatment.

Comparison of Different Types of Lumbar Supports. In one high-quality RCT[24] two different types of lumbar supports were compared: one with and one without a rigid insert in the back. Patients wearing the lumbar support plus rigid insert showed significantly more global improvement (on a subjective index) than those without the rigid insert. There is limited evidence (Level 3) that a lumbar support with a rigid insert in the back provides more overall improvement than a lumbar support without a rigid insert in the back.

Sensitivity Analyses

A sensitivity analysis was conducted to evaluate the influence of different thresholds for high quality on the overall conclusions. Another sensitivity analysis was conducted in which all unclear scores on internal validity items were considered positive.

Different Thresholds for High Quality. When a threshold of 40% was used for studies on prevention, one additional RCT was considered of high quality,[1] resulting in a total of three high-quality RCTs.[1,37,41] Consequently, the conclusion on the comparison of lumbar supports *versus* no intervention changed from moderate evidence to strong evidence that lumbar supports are not more effective in preventing back injury or LBP than no intervention.

When using a threshold of 40% for studies on treatment, the studies by Penrose et al[28] and Valle-Jones et al[35] were also considered of high quality. For the comparison of lumbar supports to other types of treatment, only the conclusion on pain intensity changed from moderate evidence (Level 2) that lumbar supports are not more effective than other types of treatment to conflicting evidence (Level 3). When compared with no intervention, limited evidence (Level 3) that lumbar supports are more effective than no intervention changed to moderate evidence (Level 2).

When a threshold of 60% was used for studies on prevention, the study by Walsh and Schwartz[41] changed from a high-quality to a low-quality RCT, but the evidence remained limited (Level 3). Using a threshold of 60% for studies on treatment, conclusions did not change, because the studies of Hsieh et al[17] and Million et al[24] were still high-quality studies.

All Unclear Scores Considered Positive. When all unclear scores were assumed to be positive, four studies on prevention[1,12,37,41] and five studies on treatment[10,17,24,28,35] were considered high-quality RCTs at the 50% cutoff. The conclusion regarding the comparison of lumbar support *versus* no intervention changed from moderate evidence (Level 2) to strong evidence (Level 1) that a lumbar support is not more effective in preventing LBP than no intervention.

The conclusion regarding the comparison, lumbar support *versus* another type of treatment, changed from moderate evidence (Level 2) that a lumbar support is not more effective in reducing pain to conflicting evidence (Level 3). The conclusion regarding the comparison of lumbar supports *versus* no intervention did not change—that is, there is limited evidence (Level 3) that a lumbar support is more effective than no intervention.

■ Discussion

Selection Bias

Despite the extensive search strategy used to identify all relevant studies on the effectiveness of lumbar supports, some studies may have been missed. The key words may not have been in accordance with the key words used in the search strategy of the present review, or the journals may have been indexed in other databases. To find out whether there are more trials published in nonindexed journals, the results of the hand searching that is currently being performed within the Cochrane Back Review Group are awaited.

Methodologic Quality

The two reviewers who assessed the methodologic quality were not blinded to authors, journal, and institution. Potential bias caused by the nonblinded quality assessment was expected to be low. First, there was no conflict of interest among the two reviewers—that is, the reviewers did not have any (financial or other) interest in positive or negative results. Second, one reviewer (MWvT) is an expert in the field of LBP and very familiar with the literature. Blinding this reviewer did not seem feasible. The other reviewer (PJ) was a layperson in the field of LBP. Blinding of such a reviewer did not seem necessary, because that reviewer was new to the field. Furthermore, the methodologic criteria list, the operationalization of criteria, and the final results of the assessment are presented, so readers can determine whether they agree with the conclusions.

The methodologic quality was defined by the internal validity criteria, which refer to characteristics of the study that may be related to bias. The methodologic quality of the studies included in the review was rather low. Only 4 of the 13 studies scored positive on 50% or more of the internal validity items and were considered high quality.[17,24,37,41] Methodologic flaws that were identified included the randomization procedure, the assessment of cointerventions and compliance, and blinding of patients and outcome assessors.

Although the authors of 11 studies stated that the studies were designed to be randomized controlled trials, an appropriate method of randomization and concealment of treatment allocation was described in only three of the studies. Most studies did not report data on cointerventions or compliance. Van Poppel et al[37] and Reddell et al[31] reported low compliance. Compliance with wearing lumbar supports is very important, because it is impossible to find evidence for the effectiveness of lumbar supports if the subjects in a trial are not compliant with wearing them.[34] Blinding of subjects is difficult in trials on the effectiveness of lumbar supports. Only one study succeeded in blinding the patients.[24] Even more important is the blinding of the outcome assessor. However, in only 3 of the 13 studies was the use of a blinded outcome assessor reported.

The validity, reliability, and responsiveness of outcome measures were often not reported. Therefore, it is unclear whether the instruments actually measured what they were supposed to measure, whether they measured with consistency, and whether they measured change over time. Future studies should use valid, reliable, and responsive instruments to evaluate the effectiveness of preventive and therapeutic interventions.

Levels of Evidence

In this review, the authors refrained from statistical pooling because of the heterogeneity of study populations, control interventions, and outcome measures. The conclusions on the effectiveness of lumbar supports were based on a qualitative analysis of the strength of scientific evidence. The classification of the comparisons to a level of evidence was sometimes arbitrary. When results of several studies regarding a comparison did not entirely agree with each other, it was difficult to decide whether these results should be considered generally consistent findings or inconsistent findings. For example, if all trials were positive, it is obvious that the findings are consistent, but are findings also consistent if five of seven trials are positive or if four of seven are positive? The authors arbitrarily defined consistency when 75% or more of the studies had similar results. Extensive tables are presented so that readers can determine whether they agree with the classification of evidence in this review.

Effectiveness of Lumbar Supports

Seven preventive studies and six therapeutic studies were included in this systematic review. The results of the systematic review showed that there is no strong evidence in favor of or against the effectiveness of lumbar supports as intervention for prevention and treatment. Even in the sensitivity analyses, when the thresholds for high quality were changed from 50% to 40% and when all unclear scores were assumed to be positive, no strong evidence could be demonstrated in favor of lumbar supports.

The results regarding prevention showed that there was moderate evidence that lumbar supports are not effective in preventing LBP and that lumbar supports are not more effective than other types of prevention for LBP. The results of this review are in agreement with the point of view of the National Institute for Occupational Safety and Health (NIOSH) as presented in several reviews.[6,14,19] According to NIOSH, the current literature contains insufficient scientific evidence to support the use of lumbar supports as a primary preventive measure. In a systematic review, van Poppel et al[36] also reported inconclusive evidence in favor of or against the effectiveness of lumbar supports for primary prevention.

Information regarding the possible secondary preventive effects of lumbar supports was provided by subgroup analyses in two studies.[37,41] The results of these subgroup analyses indicated that workers with a history of LBP may be at reduced risk for recurrent episodes of LBP. However, to investigate the effectiveness of lumbar supports for secondary prevention, a randomized controlled trial focussing on this question should be conducted.

The results regarding treatment showed that there was conflicting evidence on the effectiveness of lumbar supports compared with other types of treatment. Koes

et al[20] concluded in their systematic review that the effectiveness of lumbar supports in the treatment of LBP remains controversial. According to the available international guidelines for the management of LBP in primary care, a lumbar support should not be prescribed for patients with acute LBP.[11]

Limited evidence was found in favor of a lumbar support with a rigid insert in the back compared with a lumbar support without rigid insert, indicating that some types of lumbar supports may be more effective in reducing LBP than others. Most studies included in the review did not provide detailed information about the type of lumbar support that was used. The scarce information showed that different types of lumbar supports probably were used. In some reviews, investigators commented that the type of lumbar supports that has been used in controlled studies, such as those by Walsh and Schwartz[41] and Reddell et al,[31] are not typically used or recommended in industry. Because there are now more than 70 types of lumbar supports for prevention[16] and more than 30 types for treatment of spinal disorders in use worldwide,[30] it would be interesting to know the specific effects of different types of lumbar supports.

■ Conclusions

Implications for Practice
The findings in this systematic review did not provide evidence that lumbar supports are or are not useful in the primary prevention of low back pain in industry. The results showed that there is conflicting evidence on the effectiveness of lumbar supports in the treatment of low back pain. Lumbar supports are not recommended for primary prevention and treatment of low back pain.

Implications for Research
Because none of the studies evaluated the effectiveness of lumbar supports in the secondary prevention of low back pain, future studies (if any) should focus on this topic. Future trials should be of high quality, and special attention should be paid to adequate compliance of the study subjects.

■ Key Points

- A systematic review of randomized and nonrandomized controlled trials was performed.
- The effectiveness of lumbar supports for prevention and treatment of nonspecific low back pain was evaluated.
- There was moderate evidence that lumbar supports are not effective for primary prevention, and no evidence on the effectiveness of lumbar supports for secondary prevention.
- There was limited evidence that lumbar supports are more effective than no treatment, whereas it is still unclear whether lumbar supports are more effective than other interventions for treatment of low back pain.

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