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Review Article

Efficacy of epidural steroid injections for low-back pain and sciatica: a systematic review of randomized clinical trials

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Summary The purpose of the study was to assess the efficacy of epidural steroid injections for low-back pain. Data was obtained using computer-aided search of published randomized clinical trials and assessment of the methods of the studies. Twelve randomized clinical trials evaluating epidural steroid injections were identified. Data was extracted based on scores for quality of the methods, using 4 categories (study population, interventions, effect measurement, and data presentation and analysis) and the conclusion of the author(s) with regard to the efficacy of epidural steroid injections. Method scores of the trials ranged from 17 to 72 points (maximum 100 points). Eight trials showed method scores of 50 points or more. Of the 4 best studies (> 60 points), 2 reported positive outcomes and 2 reported negative results. Overall, 6 studies indicated that the epidural steroid injection was more effective than the reference treatment and 6 reported it to be no better or worse than the reference treatment. There appeared to be no relationship between the methodological quality of the trials and the reported outcomes. In conclusion, there are flaws in the design of most studies. The best studies showed inconsistent results of epidural steroid injections. The efficacy of epidural steroid injections has not yet been established. The benefits of epidural steroid injections, if any, seem to be of short duration only. Future research efforts are warranted, but more attention should be paid to the methods of the trials.

Key words: Low-back pain; Sciatica; Epidural steroid injection; Review; Randomized clinical trial; Methodology

Introduction

Low-back pain and sciatica continue to be an important medical and socio-economical problem in society (Frymoyer 1988; Lawrence et al. 1992). Decisions regarding optimal management are not easy to make for physicians and therapists involved with the care of patients with low-back pain (LBP). There are many therapeutic interventions available; however, none seems to be clearly superior (Deyo 1983; Spitzer et al. 1987). The Quebec Task Force on Spinal Disorders reported in 1987 that the efficacy of most interventions had not been demonstrated by sound randomized clinical trials (Spitzer et al. 1987). In a series of articles we reassess the available randomized clinical trials, including those articles published after 1987, in order to evaluate the scientific evidence regarding common interventions for LBP. In earlier papers we have reported on the efficacy of exercise therapy, spinal manipulation and mobilization, bed rest and orthoses, traction therapy, and back schools (Koes et al. 1991a,b, 1994a,b; Heijden et al. 1994). In this article we focus on the efficacy of epidural steroid injections for LBP and sciatica. The use of epidural steroid injections is under debate (Nelson 1993; Anonymus 1994). Figures on the magnitude of their use have not yet been published, although some authors believe they are widely used (Kepes and Duncalf 1985; Ridley et al. 1988). Kepes and Duncalf concluded, in a review published in 1985, that the rationale for the use of epidural steroid injection had not been scientifically proven (Kepes and Duncalf 1985). One year later Benzon, evaluating more or less the same literature, was somewhat more optimistical and concluded that LBP of mechanical origin, especially accompanied by signs of

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nerve-root irritation, may respond to epidural injections (Benzon 1986).

The debate concerning this treatment is also illustrated by the recent recommendations of the Australian National Health and Medical Research Council Advisory Committee on epidural steroid injection. One of their recommendations was that they could neither endorse nor proscribe the use of epidural steroid injections. In view of the potential hazards involved in the technique, it should be used only after obtaining informed consent by the patient and after obtaining approval of an (hospital) ethics committee. Furthermore, the committee stated that use is to be restricted to radicular pain only, except in the pursuit of a research study. These recommendations were endorsed by the Workcover Corporation in their guidelines for the management of employees with back injuries (Workcover 1993). Others report routine use of epidural steroid injections for LBP and sciatica routinely "on the basis of two randomized controlled trials showing benefit" (Bowman 1993).

The rationale of using epidural steroid injections for the treatment of LBP and sciatica includes the anti-inflammatory action of the drug (Benzon 1986). These inflammation processes (including nerve-root edema) are observed in cases with prolapsed intervertebral discs and/or compressed nerve roots. Regarding the localisation of the injection it is argued that epidural injections are theoretically preferred over intramuscular injection on the idea of deposition of the drug into the affected area and of less systemic effects from lower blood levels of steroid (Benzon 1986).

There is also some discussion on the value of injection of a local anaesthetic solution (e.g., lidocaine). In some controlled trials lidocaine cum corticosteroid is compared with lidocaine alone (as placebo injection). Whether injection with lidocaine may be used as a placebo injection is not clear since there are no studies available which compared, for example, an injection with saline with an injection with lidocaine. However, a study performed by Coomes in 1961 showed that an epidural injection with an anaesthetic was more effective than bed rest. Also theoretically there might be some specific effects of an injection with a local anaesthetic including "interruption of sustained neural activity that produced and perpetuated the pain, relaxation of paraspinal muscle spasm, and resolution of accompanying reflex sympathetic dystrophy" (Benzon 1985). Thus, using an injection of local anaesthetic instead of an injection with saline may lead to less contrast between study groups in a controlled trial.

To determine the state-of-the-art regarding the efficacy of epidural steroid injections, we assessed the evidence from published randomized clinical trials systematically. Since even randomized clinical trials may show biased outcomes related to methodological shortcomings in the design, strong emphasis is laid on the methodological quality of the studies.

TABLE I

CRITERIA LIST FOR THE METHODOLOGICAL ASSESSMENT OF RANDOMIZED CLINICAL TRIALS OF EPIDURAL STEROID INJECTION THERAPY FOR LOW-BACK PAIN (for details, see Appendix I)

Criterion	Weight
Study population:	
A Homogeneity	2
B Comparability of relevant baseline characteristics	5
C Randomization procedure adequate	4
D Drop-outs described for each study group separately	3
E < 20% loss to follow-up	2
< 10% loss to follow-up	2
F > 50 subjects in the smallest group	8
> 100 subjects in the smallest group	9
Interventions	
G Interventions included in protocol and described	10
H Pragmatic study	5
I Co-interventions avoided	5
J Placebo-controlled	5
Effect:	
K Patients blinded	5
L Outcome measures relevant	10
M Blinded outcome assessments	10
N Follow-up period adequate	5
Data-presentation and analysis:	
O Intention-to-treat analysis	5
P Frequencies of most important outcomes presented for each treatment group	5

Methods

Selection of studies

A MEDLINE literature search was carried out for the period 1966–1993 (keywords (MeSH): backache, low-back pain (including all minor sub-headings)). In addition, the references given in relevant publications were further examined. Abstracts and unpublished studies were not selected. Studies had to meet the following criteria: (1) it concerned a randomised clinical trial; (2) one treatment regimen included one or more epidural steroid injection(s). Additional interventions were allowed; (3) the study subjects suffered from back pain and/or sciatica; (4) the paper was written in English.

Assessment of validity

After collection of the papers, all trials were scored according to the criteria listed in Table I. The criteria are based on generally accepted principles of intervention research (Feinstein 1985; Meinert 1986; Ter Riet et al. 1990). Similar criteria have previously been used in review articles concerning other therapeutic (conservative) interventions for LBP (Koes et al. 1991a,b, 1994a,b; Shekelle et al. 1992; Heijden et al. 1995). To each criterion a weight was attached. The maximum score was 100 points for each study. The methodological quality of the studies was assessed by two reviewers (R.J.P.M.S., J.M.A.M.) independently of each other. In a subsequent meeting the reviewers tried to reach consensus on each criterion they initially disagreed upon. Where disagreement persisted, a third reviewer (B.W.K.) made the final decision. The assessments resulted in a

TABLE II

RANDOMIZED TRIALS ON THE EFFICACY OF EPIDURAL STEROID INJECTIONS IN ORDER OF METHODS SCORE

Author	Scores for methods criteria [a]																Total score 100	Indication [b]	Conclusion [c]
	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P			
	2	5	4	3	4	17	10	5	5	5	5	10	10	5	5	5			
Snoek et al.	2	3	4	3	4	–	10	–	5	5	3	8	10	5	5	5	72	sciatica + neurologic signs + positive radiography	negative
Mathews et al.	1	3	4	3	4	–	10	–	5	5	3	4	10	5	5	5	67	acute and subacute LBP + sciatica + neurological signs	slightly positive
Breivik	1	2	4	3	4	–	10	–	5	5	3	6	10	–	5	5	63	chronic LBP + sciatica	positive
Cuckler et al.	2	4	4	3	4	–	10	–	–	5	3	2	10	5	5	5	62	lumbar radicular pain syndromes + positive radiography	negative
Bush and Hillier	2	3	–	3	2	–	10	–	–	5	3	6	10	5	5	5	59	sciatica	positive
Serrao et al.	2	4	–	3	4	–	10	–	–	–	3	6	10	–	5	5	52	chronic LBP	negative
Klenerman et al.	2	3	4	–	2	–	10	–	–	5	3	6	10	–	–	5	50	acute sciatica	negative
Dilke et al.	1	4	–	3	–	–	10	–	5	5	3	4	10	–	–	5	50	sciatica + neurological signs	positive
Rocco et al.	1	3	4	–	4	–	10	–	–	–	3	4	10	5	–	5	49	acute and chronic post-laminectomy pain syndrome	negative
Ridley et al.	2	4	2	–	2	–	10	–	–	5	3	4	10	5	–	–	47	sciatica + neurological signs	positive short-term only
Beliveau	1	–	2	3	4	–	10	–	5	5	3	2	–	–	5	5	45	sciatica	negative
Yates	–	–	–	–	–	–	5	–	–	3	4	–	–	–	–	–	17	LBP + sciatica	positive

[a] See Appendix I for details of criteria.

[b] The labels 'acute' and 'chronic' are according to the authors of the study.

[c] Conclusion of the author(s) of the study; positive conclusion = epidural steroid injection better than the reference treatment; negative conclusion = epidural steroid injection worse than or equally effective as reference treatment.

TABLE III

DETAILS OF TRIALS STUDYING THE EFFICACY OF EPIDURAL STEROID INJECTIONS FOR LOW-BACK PAIN

Authors	Epidural steroid injection/route (no. of patients)	Injections (n)	Reference treatment(s) (n patients)	Methods score	Results *
Snoek et al.	(i) 80 mg (2 ml) methyl prednisolone, lumbar route ($n = 27$)	1	(ii) 2 ml saline ($n = 24$)	72	% patients improved after 2 days with regard to LBP: (i) 33%, (ii) 25%; radiating pain: (i) 26%, (ii) 13%; sciatic nerve stretch tolerance: (i) 36%, (ii) 25%; subjective improvement: (i) 67%, (ii) 42%. % patients who underwent surgical treatment within 14 ± 6 months after treatment: (i) 58%, (ii) 52%. No statistically significant differences.
Mathews et al.	(i) 80 mg (2 ml) methyl prednisolone + 20 ml bupivacaine (0.125%), caudal route ($n = 23$)	1–3	(ii) 2 ml lignocaine, subcutaneously ($n = 34$)	67	% patients recovered after 1 month: (i) 67%, (ii) 56%. Not significant. After 3 months: (i) significantly more pain-free than (ii). No other significant difference.
Breivik	(i) 80 mg (2 ml) methyl prednisolone + 20 ml bupivacaine (0.25%), caudal route ($n = 16$)	1–3	(ii) 20 ml bupivacaine (0.25%) + 100 ml saline ($n = 19$)	63	% patients with considerable pain relief (before cross-over): (i) 56%, (ii) 26%
Cuckler et al.	(i) 80 mg (2 ml) methyl prednisolone + 5 ml procaine (1%), lumbar route ($n = 42$)	1–2	(ii) 2 ml saline + 5 ml procaine (1%) ($n = 31$)	62	Average subjective improvement after 24 h: (i) 42%, (ii) 44%. Not significant. Long-term follow-up (about 20 months) showed no significant differences.
Bush and Hillier	(i) 80 mg triamconolone + 25 ml procaine (0.5%), caudal route ($n = 12$)	2	(ii) 25 ml saline ($n = 11$)	59	Mean VAS (100 mm) (back and leg pain) at baseline, 4 and 52 weeks: (i) 39, 16, 14; (ii) 49, 45, 30. Mean SLR (degrees) at baseline, 4 and 52 weeks: (i) 44, 73, 80; (ii) 63, 65, 74. Short-term: (i) significantly better results (pain, SLR). Long-term: pain not significantly different. (i) straight leg raise significantly better (no data presented).

Serrao et al.	(i) 10 ml saline + 80 mg prednisolone (epidural) + 3 ml dextrose (5%, i.t.), lumbar route ($n = 14$)	1 (pair)	(ii) 10 ml saline (epidural) + 2 mg midazolam + dextrose (3 ml, 5%, i.t.) ($n = 14$)	52	No. of patients reporting initial improvement and after 2 months: (i) 3, 5; (ii) 10, 7. No significant differences for pain and activity scores. (ii) significantly less self-administered medications.
Klenerman et al.	(i) 20 ml saline + 80 mg methyl prednisolone, lumbar route ($n = 19$)	1	(ii) 20 ml saline ($n = 16$) (iii) 20 ml bupivacaine (0.25%) ($n = 16$)	50	No. of patients improved or cured according to clinician: (i) 15, (ii) 11, (iii) 11, (iv) 10 No significant differences.
		4s	(iv) dry needling, interspinous ligament ($n = 12$)		
Dilke et al.	(i) 10 ml saline + 80 mg methyl prednisolone, lumbar route ($n = 51$)	1–2	(ii) 1 ml saline ($n = 48$)	50	No. of patients not returned to work at 3 months: (i) 3 of 36, (ii) 14 of 35. Difference is significant. No differences in no. days of bed rest and days in hospital. No. of patients reporting none and not severe pain after 3 months: (i) 16, 24; (ii) 8, 20.
Rocco et al.	(i) 50 mg lignocaine + 75 mg triamcinolone (10.9 ml), lumbar route ($n = 8$). (ii) 50 mg lignocaine + 75 mg triamcinolone + 8 mg morphine (10.9 ml) ($n = 7$)	1–3	(iii) 50 mg lignocaine + 8 mg morphine (10.9 ml) ($n = 7$)	49	Mean improvement on VAS after 1 month: (i) 0.9, (ii) −0.6 (deterioration) (iii) 0.4. No. of patients reporting long-term relief: (i) 1, (ii) 0, (iii) 0. No significant differences.
Ridley et al.	(i) 10 ml saline + 80 mg methyl prednisolone, lumbar route ($n = 19$)	1–2	(ii) saline (2 ml), interspinous ligament ($n = 16$)	47	% patients reporting improvement after 2 weeks: (i) 90%, (ii) 19% Short-term (i) significantly better in relieving pain.
Beliveau	(i) 40 ml procaine (0.5%) + 80 mg (2 ml) methyl prednisolone, caudal route ($n = 24$)	1–2	(ii) 42 ml procaine (0.5%) ($n = 24$)	45	No. of patients improved or completely relieved during 3 months follow-up period: (i) 18, (ii) 16. No significant difference.
Yates	(i) 60 mg triamcinolone (3 ml) + 47 ml saline (−) (ii) 60 mg triamcinolone (3 ml) + 47 ml lignocaine 0.5%) (−)	1–4	(iii) 50 ml saline (−) (iv) 50 ml lignocaine 0.5%) (−)	17	(i) and (ii) better than (iii) and (iv) regarding improvement in straight leg raising. No data on patient level presented.

* Results of the most important outcome measures according to the authors of the study.
$P < 0.05$ were taken as significant.

hierarchical list in which higher scores indicate studies of higher methodological quality. The outcome of the studies will be discussed in relation to their methodological scores.

Outcome of the studies

A study is judged to be positive if the authors conclude (in their abstract or conclusions) that the epidural steroid injection therapy is more effective than the reference treatment. Usually this meant that the difference in effect for the primary outcome measure was statistically significant on the conventional 5% level. In a negative study the authors reported no differences between the study treatments, or even better results in favour of the reference treatment.

Results

A total of 12 trials met the inclusion criteria and were included in this review. Of these, 5 trials were published between 1970 and 1980 (Beliveau 1971; Dilke et al. 1973; Breivik et al. 1976; Snoek et al. 1977; Yates 1978), another 5 between 1980 and 1990 (Klenerman et al. 1984; Cuckler et al. 1985; Mathews et al. 1987; Ridley et al. 1988; Rocco et al. 1989) and 2 were published after 1990 (Bush and Hillier 1991; Serrao et al. 1992). Tables II and III present the 12 trials in hierarchical order, according to their methodological quality.

Initially, there was agreement between the two independent reviewers over the criteria in 237 (66%) of the 360 items scored. Disagreement (34%) mainly occurred because of reading and interpretation errors. Most of the disagreement was solved in a subsequent consensus meeting. The third reviewer had to make a final decision in 5 instances, mainly relating to criterion (I) avoidance of co-interventions and the scoring of the paper by Yates (1978).

Table II shows the wide range in methodological scores (range: 17–72). There were 4 studies which scored more than 60 points (maximum score = 100), and another 4 studies scored between 50 and 60 points. The median score was 52 points, indicating the overall moderate methodological quality of the trials. The most prevalent methodological shortcomings appeared to be (B) non-comparability regarding relevant base-line characteristics, (F) the small size of the study populations included, (H) no pragmatic comparison with relevant existing treatment modalities, (I) co-interventions not avoided in the design or not comparable between the intervention groups, (K) no attempt to evaluate the blinding of patients with respect to interventions given, and (N) no long-term follow-up.

In one-half of the trials (n = 6) the authors reported better results from the epidural steroid injection in comparison to placebo injection (saline) (n = 4), injection with lignocaine (n = 2) or with bupivacaine (n = 1). In one of these trials epidural steroid injection was compared with saline as well as lignocaine (Yates 1987). In the other 6 trials the authors reported no differences or even worse outcomes of the epidural steroid injection compared to the reference treatment, i.e., placebo injection (saline) (n = 2), or injection with procaine (n = 2), midazolam (n = 1), bupivacaine (n = 1), dry needling (n = 1), or lignocaine and morphine (n = 1). In one of these trials epidural steroid injection was compared to saline, bupivacaine, and dry needling (Klenerman et al. 1984).

Of the 4 best studies from Table II (methodological scores > 60 points), 2 reported a favourable outcome of injection with epidural steroid in patients with (sub)acute and chronic LBP and sciatica. The other 2 reported no differences in effect between epidural steroid injection when compared to injection with placebo or with procaine in patients with herniated discs and lumbar radicular pain syndromes.

Of the 4 next best studies, with scores between 50 and 60 points, 2 reported positive results in (I) patients with sciatica and nerve root compression and (II) with lumbar radicular compression syndrome. Two others report negative results in patients with chronic LBP and in acute sciatic pain.

In general, there appeared to be no clear relationship between the methodological quality of the studies and their outcome. Fig. 1 shows the 6 studies reporting positive outcomes and the other 6 studies reporting negative outcomes of epidural steroid injections in relation to their methodological scores. The cumulative distribution curves of the 6 positive and 6 negative studies appear to be almost identical.

Complications

No major complications or side effects were reported in the trials presented in this review. Transient minor complaints after epidural steroid injections were reported by Serrao et al. in 1992 (8 patients with headache, 2 with nausea), Bush and Hillier in 1991 (1 female with irregular periods), Beliveau in 1971 (10 patients with mild headache: not clear from which group), Ridley et al. in 1988 (1 patient with headache), Rocco et al. in 1989 (1 patient with pruritis, 1 patient with nausea), Snoek et al. in 1977 (increased pain of sciatic distribution in a few patients). In the other trials no side effects were seen (Dilke et al. 1973; Klenerman et al. 1984; Mathews et al. 1987), while 3 trials did not report on side effects (Breivik et al. 1976; Yates 1978; Cuckler et al. 1985).

Discussion

Methodological quality

This review demonstrates some major methodological shortcomings in randomized trials evaluating the

efficacy of epidural steroid injections in LBP and sciatica. The small size of the study populations is a frequent problem in LBP research in general (Koes et al. 1995), but appeared to be a major problem in the trials included in this review. For this reason, studies may lack the statistical power to detect clinically relevant differences in effects between the interventions under study. Another problem with smaller sample sizes is that important (un)known prognostic variables might not be in balance between the study groups after randomisation. Such situations may lead to biased outcomes if, by chance, the patients in one group had a more favourable prognosis.

Another problem refers to the blinding of patients with respect to the interventions under study. Although it can be argued that patients will probably not be able to detect the content of the injections given, one should preferably evaluate whether the blinding was indeed successful by asking the patients to indicate which intervention they thought they had received.

The performance of an adequate injection technique and correct placement of the needle also needs attention. In our review most studies described the methods which they used in such a way that the procedure should be reproducible. On this criterion most studies scored the maximum number of points. Not one study, however, reported on the use of fluoroscopic guidance when performing the epidural injection. Since some studies reported on incorrect needle placement in considerable numbers of cases (up to 52% of the procedures) depending on the experience of the physician (El-Khoury et al. 1988; Renfrew et al. 1991), the lack of including fluoroscopy might have attributed to negative findings in some studies.

The reported methodological flaws are not unique for clinical trials evaluating the efficacy of epidural steroid injections. In general, the injection trials seem to score somewhat higher (median: 52; range: 17–72) than, for example, trials evaluating the efficacy of spinal manipulation and mobilization (median: 35; range: 20–56) (Koes et al. 1991a), exercise therapy (median: 40; range: 24–61) (Koes et al. 1991b) and back schools (median: 36; range: 16–70) (Koes et al. 1994), traction therapy (median: 36; range: 23–66) (Heijden et al. 1994), bed rest (median: 33; range: 23–82) and orthoses (median: 53; range: 35–61), Koes et al. 1994a).

Efficacy

To date, 12 trials have been performed to evaluate the efficacy of epidural steroid injections, 8 of which showed methods scores of 50 points or more. The trials showed inconsistent results of epidural steroid injections. Of the 12 trials, 6 reported positive results of epidural steroid injections and 6 others reported negative results. The positive studies and negative studies were more or less similar with regard to their methodological quality.

Complications

Only transient minor complaints (e.g., headache, nausea) which occurred after epidural steroid injections in the trials presented in this review, were reported. Although this finding might support the view that epidural steroid injections are safe, there is no consensus about this topic in the literature. Kepes and Duncalf (1985) report minor transient complications, e.g., headache, backache, leg pain, water retention (after large doses of steroid), and fever. Inadvertent dural punctures, the estimations vary between 0.5% and 2.5%, seem to occur frequently (Nelson 1990). More serious complications were also reported: epidural abscess, bacterial meningitis (Kepes and Duncalf 1985).

Benzon (1986) reports that in publications of large series of epidural steroid injection no major complications were observed. In addition to the major complications reported upon by Kepes and Duncalf (1985), Ling et al. (1993) report on a case of intraocular haemorrhages. Other complications were reported after steroid injection via the intrathecal route. Benzon (1986) concludes that epidural steroid injections are considered to be relatively safe. This conclusion might be justified given the relatively few reports on severe complications. However, the risk of serious complications is difficult to estimate since there are neither exact figures about the incidence of major complications, nor about the total number of epidural steroid injections given.

Study population

The choice of an adequate study population is crucial in an intervention study. Most studies included patients with LBP and sciatica (with neurological signs and positive radiography). Unfortunately, both positive and negative results of the trials were found in these patients.

A possible explanation for these varying outcomes is that the studies included prognostically heterogeneous study populations. If epidural steroid injection are effective only in (unknown) subgroups within these heterogeneous study populations the effects will be diluted. The characteristics of these sub-groups, if any, have yet to be determined in order to optimise the method of patient selection for future randomised clinical trials and also to optimise the indications for treatment in daily clinical practice. Some attempts in this direction have been reported for example by Jamison et al. (1991). They identified 4 factors that may predict a poor outcome 2 weeks after epidural steroid injection, i.e., a greater number of earlier treatments, high medication intake, pain not increased by activities

and pain increased by coughing. In addition a number of factors were identified which predicted a poor outcome after 1 year of treatment. These attempts may help to identity those patients who are most likely to benefit from epidural steroid injection. So far, there are no indications that epidural steroid injection might be effective in patients with (chronic) LBP without sciatica.

Another question, still unanswered, concerns the long-term effects of epidural steroid injections. Only 6 trials included a follow-up measurement after 6 months or longer. In most of these trials no long-term effects were found. The benefits of epidural steroid injections, if any, seem to be of short duration only.

Limitations

There are certain limitations to the methods used in this systematic review. Publication bias can not be ruled out, so it is possible that trials were missed trials because they were not published due to their (negative) results (Dickersin 1990). Furthermore, the two independent reviewers were not blinded with respect to the source and outcome of the trials. However, the methodological criteria used were quite strict and are easy to apply. These criteria have been used for a number of reviews on conservative interventions for low-back pain. In addition, Shekelle et al. (1992) used and validated this quality rating system in a recent meta-analysis of spinal manipulation. In their study the results appeared to be similar to the results obtained by the scoring method of Chalmers et al. (1981). One of the drawbacks of using this list of methodological criteria might be that trials showing a 'fatal mistake' (e.g., irrelevant outcome measures, drop-out rate exceeding 50%) may end up with a relatively high score because they meet the other criteria. Studies with the highest methods scores should therefore be checked regarding such fatal flaws. No 'fatal flaws' were identified in the best studies (methods scores > 60 points), although it can be argued that in the trial performed by Snoek et al. the single injection of 2 ml might be insufficient or that in this study the moments of effect measurement were not adequate (i.e., about 2 days after the injection and a follow-up after 14 ± 6 months). The same may hold for the study performed by Cuckler et al. who injected 7 ml into the epidural space between the third and fourth lumbar vertebrae.

Conclusions

In recent years 12 randomized clinical trials have evaluated the efficacy of epidural steroid injections for LBP and sciatica. One-half of the trials reported positive outcomes of epidural steroid injections and the other half reported negative outcomes. The critical assessment of the methods used in these trials revealed flaws in the design of most studies. Consequently, the efficacy of epidural steroid injection has not yet been established. The benefits of epidural steroid injections, if any, seem to be of short duration only. Future efficacy studies, which are clearly needed, should take into account the apparent methodological shortcomings. In addition, future research efforts should focus on determining which patients are most likely to benefit from epidural steroid injections. At this moment there are no indications that epidural steroid injections might be effective in patients with (chronic) back pain without sciatica.

Appendix I

OPERATIONALIZATION OF THE CRITERIA FROM TABLE I

Each criterion must be applied independently of the other criteria.

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

B Comparability for: duration of complaints, value of outcome measures, age, recurrence status and radiating complaints (1 point each).

C Randomization procedure described (2 points). Randomization procedure which excludes bias (e.g., sealed envelopes) (2 points).

D Information from which group and with reason for withdrawal.

E Loss to follow-up: all randomized patients minus the number of patients at main moment of effect measurement for the main outcome measure, divided by all randomized patients times 100.

F Smallest group immediately after randomization.

G Injection therapy explicitly described (5 points). All reference treatments explicitly described (5 points).

H Comparison with an existing treatment modality.

I Other medical interventions are avoided in the design of the study (except analgesics, advice on posture or use at home of heat, rest, or a routine exercise scheme).

J Comparison with a placebo therapy.

K Placebo-controlled: attempt of blinding (3 points), blinding evaluated and fully successful (2 points). Pragmatic study: patients fully naive (3 points), or time restriction (no injection therapy for at least one year) (2 points), naiveness 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, return to work (or to normal activities) (2 points each).

M Effect measurement (partly) by a blinded assessor (10 points).

N Moment of measurement during or just after treatment (3 points).
Moment of measurement 6 months or longer (2 points).

O When loss to follow-up is less than 10%: all randomized patients for most important outcome measures, and on the most important moments of effect measurement minus missing values, irrespective of non-compliance and co-interventions.
When loss to follow-up > 10%: intention-to-treat as well as an alternative analysis which accounts for missing values.

P For most important outcome measures, and on the most important moments of effect measurement. In the case of (semi)continuous variables: presentation of the mean or median with standard error or percentiles.

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