

Is there an indication for spine surgery in the treatment of chronic back pain or deformities?

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Citation

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Abstract

Background It is rarely questioned that spine surgery is indicated in the treatment of chronic back pain, instabilities and deformities once conservative measures have failed. However the conservative treatment options do not seem to be standardized well enough, to allow the deduction of a clear indication guideline for the surgical intervention. The indication for spine surgery as the last option for chronic pains and deformities, however, can only be valid when the treatment can be regarded as evidence based. In view of the high risk of the intervention a level of evidence of II has to be claimed. Aim of this review was to reveal the evidence there is for spine surgery today and by this to enable a better patient advice. Methods A systematic review has been performed using the Pub Med database. Literature has been searched for the key words „spine surgery“, „prospective controlled study“ or „prospective controlled trial“ or „randomized controlled trial“ and „outcome“. Only prospective controlled studies that have considered the treatment versus the natural history have been included. Results No controlled study has been found to reveal evidence that supports spine surgery as a treatment, not in any of these short, mid or long-term based studies searched within this review. Only retrospective reviews have been found, some with a drop-out rate which would not allow any conclusion. RCTs have been found to investigate and compare different approaches of spinal surgery against each other. Conclusions (1) No evidence has been found in terms of prospective controlled studies to support surgical intervention in the treatment of chronic low back pain and deformities. (2) Conservative treatment with physiotherapy and specific methods of bracing according to the latest standards as described should be regarded as the treatments of choice. (3) In the light of the unknown long-term effects of surgery and in the light of the lack of evidence that surgery might change signs and symptoms of pains and deformities a Randomised Controlled Trial (RCT) is long overdue. As long as this is not provided, there is no medical indication for spine surgery if it is not indicated because of an emergency. (4) The indication for spine surgery should be the function of conservative specialists in order to allow the exclusion of any indication biases by the surgeon, which may be affiliated to the spinal implant industry.

BACKGROUND

It is rarely questioned that spine surgery is indicated in the treatment of chronic back pain, instabilities and deformities once conservative measures have failed. However the conservative treatment options do not seem to be standardized well enough, to allow the deduction of a clear indication guideline for the surgical intervention. The indication for spine surgery as the last option for chronic pains and deformities, however, can only be valid when the treatment can be regarded as evidence based. In view of the high risk of the intervention a level of evidence of II has to be claimed (Weiss et al. 2008, Weiss and Goodall 2008a, Weiss and Goodall 2008b, Weiss 2008, Weiss 2007a, Weiss 2007b).

The indication for surgery for scoliosis for instance, historically has been set to a curve of 50° Cobb (Hopf 2000),

however to the experience of the author this limit of degrees has been changed by the time by the surgical community and today curves of less than 35° are operated on for reasons not supported by current scientific knowledge (Fig. 1, from Weiss 2007a). The patients are confronted with health risks by some surgeons that do not arise for patients with Adolescent Idiopathic Scoliosis (AIS), while only a little part of the population of AIS patients operated on really suffer because of their appearance enough to justify surgery with all its risks (Weiss et al. 2008, Weiss and Goodall 2008a, Weiss and Goodall 2008b, Weiss 2008, Weiss 2007a, Weiss 2007b). But even more than that: Still today there is no proof that surgery might change signs and symptoms of scoliosis (Hawes 2006, Hawes and O'Brien 2008).

AIS is a relative benign condition Weinstein et al. 2003, Haefeli et al. 2006) and therefore the indication for surgery

is clearly psychological (Goldberg et al. 2001). In a recent publication (Dolan and Weinstein 2007) claims were made for a “need for surgery” which seems somewhat contradictory and this is why it is necessary to take a closer look on the indications for surgery in this specific population (Hawes 2006, Hawes and O’Brien 2008, Weiss 2008).

One might take it as a proof that there are correction effects after surgery. On the other hand the primary correction effects are not stable (Hawes 2006, Hill et al. 2002), not even for one year, and neither back shape nor self esteem have been corrected satisfactorily by the surgical intervention (Bettany et al. 1995) which demands a scientific view on the outcome after surgery.

To justify the long-term risks of spinal surgery, which can be estimated to be > 25% (Dickson et al. 1990, Weiss and Goodall 2008a), the procedure applied should be proven and prospective controlled studies should be available to show a clear superiority of surgery to observation only.

Surgery for chronic back pains and chronic disc disease may be a risky endeavour as well, however there is no systematic review on this topic, yet. One review was found about spine surgery in the geriatric patient. The authors state that ‘Spine surgery is one of several options the geriatric patient may consider for symptomatic relief, but the literature describing the safety and efficacy of spine surgery in older patients is inconclusive and at times confusing (Cloyd et al. 2008).’ Not rarely, there is need for a later re-operation (Kim et al. 2007, Papadopoulos et al. 2006, Palma et al. 2008) and the results of this usually are worse than after first operation (Palma et al. 2008).

Aim of this review was to reveal the evidence there is for spine surgery today and by this to enable a better patient advice.

Figure 1

Fig. 1.



METHODS

Exclusion/inclusion criteria for the selection of studies in this review

A systematic review has been performed using the Pub Med database. Types of studies included: clinical evaluations of surgery, which are prospective, controlled or randomised controlled. Meta analyses have been taken into account as well. The control group must have consisted of patient groups with observation as the only intervention. Therefore, only studies better than level III (Oxford Centre for Evidence-based Medicine) have been taken into account.

Literature has been searched for the key words „spine surgery” „prospective controlled study” or „prospective controlled trial” or „randomized controlled trial” and „outcome”. Only prospective controlled studies that have considered the treatment versus the natural history have been included.

Study selection: An electronic search was performed and the studies were planned to be selected based on title, abstract, and key words. When appropriate (a prospective controlled study has been assumed to investigate one of the interventions mentioned above) a full copy of the articles was printed to determine whether or not they met the inclusion criteria. Additionally, the references of all included

articles were checked for additional papers that might meet the inclusion criteria. If two papers were found analysing the same group of patients, the most recent paper or the one with the largest sample of patients was selected for inclusion.

RESULTS

No controlled study has been found to reveal evidence that supports spine surgery as a treatment, not in any of these short, mid or long-term based studies searched within this review. Only retrospective reviews have been found, some with a drop-out rate which would not allow any conclusion. RCTs have been found to investigate and compare different approaches of spinal surgery against each other.

Three Meta-analyses have been found, but none contained prospective controlled outcome studies (Winter and Lonstein 2003, Stasikelis et al. 1998, Maher et al. 1995).

As shown in another systematic review on surgical treatment of spinal deformities (Weiss and Goodall 2008b) there are some cohort studies and a retrospective study with a control group, which contains a large percentage of drop-outs, making it difficult to draw conclusions Dickson et al. 1995). There are some controlled studies investigating perioperative procedures like pharmacological measures or peripheral evoked potentials, to intra-operatively unveil the development of neurological problems (Weiss and Goodall 2008b), but the minority of the studies found look at complications more deeply (Weiss and Goodall 2008b). Randomized controlled studies have been found in the context with surgery (Thompson et al. 2007, Rajasekaran et al. 2007, Shen et al. 2006, Blumenthal et al. 2006, Lo et al. 2006), but none was related to outcome.

Many uncontrolled and controlled outcome studies are based on health related quality of life issues (Danielsson 2007, Watanabe et al. 2007, Andersen et al. 2006, Weigert et al. 2006, Watanabe et al. 2005, Niemeyer et al. 2005, Padua et al. 2002, Rinella et al. 2004, Merola et al. 2002, Wilson et al. 2002, Asher et al. 2003 and many more).

DISCUSSION

With respect to spine surgery, we can now report that there are no prospective controlled or randomised controlled studies to support the use of surgery in the treatment of chronic low back pains or deformities, and as pointed out by Hawes (2006) and Weiss and Goodall (2008a), signs and symptoms of scoliosis cannot be changed by surgery, nor can pain be prevented in these conditions.

One should respect the acute indications for spine surgery such as trauma, acute neurological deficit or in case of deformities the psychological indication for spine surgery when a patient is unable to cope with a deformity. The overused and wrongly assumed statement that there is an 'indication for surgery' (Dolan and Weinstein 2007), in spite of the known long-term risks (Hawes 2006, Hawes and O'Brien 2008, Weiss and Goodall 2008a, Weiss et al. 2008), when spoken by those in the medical profession could be seen to be used as a tool to frightening patients into having dangerous surgical procedures - as it is based upon scientifically unproven statements.

In their review 'A century of spine surgery – what can patients expect' Hawes and O'Brien (2008) where not able to find definite proofs for the use of spine surgery with respect to health related issues.

Figure 2

Fig. 2.



There are level III papers to support spine surgery however; most of them are without controls and the drop-out rate of participants in some of them seems rather high to make any reasonable conclusions. For instance, the paper by Dickson et al. (1995) retrospectively compares patients treated surgically with a return rate of approximately 70%, with a sample of patients that stayed conservatively (untreated) with a return rate of approximately 50%. The authors made the conclusion that the surgically treated patients had succeeded the patients 'not treated' surgically.

When assuming that (a) the surgically treated patients (who did not return) were not satisfied with their treatment and that (b), the ‘not treated’ patients (who did not return) did actually respond quite well and who then asked themselves, ‘why then, should we go back to a surgeon who has given us the wrong advice - undergo surgery’, one could come to the very opposite conclusion to that of the author. When one realises such possibilities as this it does indeed seem questionable; as to why a study with such assumed conclusions as this has been accepted for publication in a respected journal such as JBJS?

As early as 1973 (Moen and Nachemson 1999), Paul Harrington envisioned in the future a common database or registry of all Scoliosis Research Society (SRS) members’ patients with treatment results. Unfortunately the SRS failed to follow this vision until recently.

Instead of achieving evidence for surgical treatment on a higher level and instead of describing patient’s problems after surgery to increase patients’ safety, the surgical community is presenting large numbers of papers describing HRQL after surgery, perhaps to cover the lack of evidence in support of surgery (Danielsson 2007, Watanabe et al. 2007, Andersen et al. 2006, Weigert et al. 2006, Watanabe et al. 2005, Niemeyer et al. 2005, Padua et al. 2002, Rinella et al. 2004, Merola et al. 2002, Wilson et al. 2002, Asher et al. 2003 and many more).

Those studies containing psychological questionnaires are compromised by the dissonance effect (Crigger and Meek 2007, Kitayama et al. 2004, Simmons et al. 2004, Stone 2003, Moses et al. 1984). The dissonance theory describes the fact that a person realizing he has made the wrong decision or has actioned in a wrong way cannot stand the dissonance arising when realizing he was wrong. As a consequence consciously he will tell that he has taken the right decision or the right action and represent this in public. That means a patient not satisfied with a surgical treatment applied on him will not necessarily represent this as Moses et al. have described in their paper (1984):

“slim objective favorable outcomes correlate with high post-surgical patient satisfaction, while a considerable share of patients with whom a highly favorable outcome has been attained express relatively low post-surgical patient satisfaction. This paradoxical trend may be well understood when applying Cognitive Dissonance Theory. The whole pattern of results point again at highly complex and powerful psychological processes, some of them seemingly

irrational”.

There is also a scoliosis related paper (Haheer et al. 1995) showing that:” Patient satisfaction is subjective. It does not reflect the benefits of surgery with respect to the future preservation of pulmonary function in thoracic curves nor the prevention of osteoarthritis in lumbar curves.”

Therefore, out of all of these studies based on questionnaires, cited within this review, none provided objective evidence that supports the assumption that patients have experienced benefits from undergoing spine surgery for chronic low back pains and deformities, as long as the dissonance effect is not ruled out. Perhaps many patients cannot come to terms with the fact that they have made the wrong decision and instead continue to praise the surgeon, even though they objectively have had no benefits from the surgery (Moses et al 1984).

If we follow the results from this study no clear indication for surgery can be found which would be based on EBM. Therefore one should follow the lead to improve conservative measures of chronic back pain and deformity treatment proven effective (Weiss and Werkmann 2009a, Weiss and Werkmann 2009b, Weiss et al. 2009).

This seems even more important when one considers the possible long-term risks of surgical scoliosis treatment, which as shall be described below, are not conclusively agreed upon by all. When one considers that in patients with spinal deformities the 10 to 20 year risk for a re-operation may already be as high as 29% [13], the real long-term risks have to be estimated at > 30% (Hawes 2006, Weiss and Goodall 2008, Weiss et al 2008) and it is this fact the patient should be informed of before consenting to undergo this risky procedure.

The indication for spine surgery should be the function of conservative specialists in order to allow the exclusion of any indication biases by the surgeon, which may be affiliated to the spinal implant industry.

Although Pub Med is a largely complete database we would encourage to search more databases in order to allow the conclusions drawn here to be drawn definitely.

CONCLUSIONS

No evidence has been found in terms of prospective controlled studies to support surgical intervention in the treatment of chronic low back pain and deformities.

Conservative treatment with physiotherapy and specific methods of bracing according to the latest standards as described should be regarded as the treatments of choice.

In the light of the unknown long-term effects of surgery and in the light of the lack of evidence that surgery might change signs and symptoms of pains and deformities a Randomised Controlled Trial (RCT) is long overdue. As long as this is not provided, there is no medical indication for spine surgery if it is not indicated because of an emergency.

The indication for spine surgery should be the function of conservative specialists in order to allow the exclusion of any indication biases by the surgeon, which may be affiliated to the spinal implant industry.

In view of the high rate of complications [XX], the limited gains to be derived from spinal surgery should be assessed and clearly explained to patients before the procedure is undertaken [40].

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