Outcome of anterior lumbar interbody fusion: a retrospective study of clinical and radiological parameters

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Abstract

Objective. This study aims to critically evaluate the long-term results of stand-alone anterior lumbar interbody fusion (ALIF), without use of rhBMP-2, as a therapeutic option for symptomatic patients with degenerative disc disease (DDD). Furthermore this study intends to identify predictive parameters for anterior lumbar interbody fusion outcome.

Methods. A retrospective cohort study with additional telephone interview to obtain missing data was performed. All patients who underwent a L4-L5 and/or L5-S1 ALIF-procedure in the period between 2006 and 2011 were identified. The medical files of 123 patients with 154 fusion levels were reviewed. All patients were contacted by phone to gather supplementary and missing information. Pain and functionality scores (Visual Analogue Scale [VAS] and Oswestry Disability Index [ODI]), radiological (intervertebral disc height, Modic and Pfirrmann classifications) and different clinical parameters were gathered.

Results. The mean age at surgery of the population was 46.2 years. Overall, 59 female and 64 male patients were included in the study. The mean visual analogue scales (VAS) for back and leg pain improved significantly ($P<0.001$) with 5 and 4.4 points respectively at 3 years follow-up. Modic-type I changes are associated with a better improvement in VAS-score for back pain ($P=0.026$), Pfirrmann-grades IV and V and an intervertebral disc height of less than 5 mm are associated with a better improvement in leg pain (respective P-values: 0.045 and 0.033). Overall, 89% of patients would reconsider the surgical intervention.

Conclusions. The ALIF-technique is a durable treatment option for patients with DDD. This study suggests different predictive parameters for treatment outcome.

Key words

ALIF, DDD, treatment outcome, prognostic parameters

Conflict of Interest

The authors declare that they have no conflict of interest.

Introduction

Anterior lumbar interbody fusion (ALIF) is a well-known and widely used lumbar fusion technique. The indications for ALIF are matter of ongoing debate, but in a broader perspective, this is the case for all fusion techniques for treatment of degenerative spine disorders. ALIF was described in the 1930s but its use in clinical practice rose steeply since the 1990s, as was the case with all spinal fusion procedures *[+ figure 1]*. The reasons for this last ascertainment are divers, but among the most important are the availability of better spinal implants, ameliorated surgical technique and a changing mindset of the spinal surgeon triggered by new biomechanical insights. There are several prospective and retrospective studies concerning ALIF, without the use of rhBMP-2. Most of them however lack long-term follow-up and a large study population. The aim of this retrospective study is to examine the long-term clinical results in a large patient cohort.

Methods

Study Design

This study was designed as a retrospective cohort study with an additional telephone interview to obtain missing data. Electronic files and paper charts of all patients who underwent an anterior lumbar interbody fusion in the period of 2006 until 2011 were reviewed. No additional technical investigations or clinical examinations were performed. No interventions after 2011 were included in order to obtain a minimum follow-up period of 3 years. Only the L4-L5 and/or L5-S1 levels were included. The indication for surgical intervention was made by the individual surgeon. It was based on a correlation between clinical parameters such as lumbosciatica, loss of spinal reflexes, motor weakness, sensory loss and paresthesias on one hand and the presence of the different components of degenerative disc disease (DDD) such as decrease in disc height, presence of disc bulging or herniation, osteophytosis and Schmorl's nodules on spinal imaging on the other. A discrepancy between the clinical examination and the spinal MR-imaging deemed a level nonsurgical. Patients with spondylolisthesis, traumatic spine injury or bacterial spinal infections were excluded. All patients were treated conservatively for at least three months prior to surgery, with physical therapy, medication and/or infiltrations. The study was approved by the local ethics committee (registration number: B670201318652) in October 2013.

Study Population

At baseline, the cohort included 166 patients with 200 fusion levels. Next, patient files of patients who could not be contacted by telephone or who refused cooperation were excluded (n=13). Also excluded were files of which preoperative imaging and/or three-year follow-up parameters could not be retrieved (n=30). Ultimately, 123 patients with 154 fusion levels were eligible for statistical analysis.

Clinical parameters

The Visual Analog Scale (VAS) and the Oswestry Disability Index (ODI) were used to assess the clinical status in the patient cohort. The VAS-score was used to describe the subjective intensity of low back

pain as well as leg pain and was assessed pre-operatively and at 3 months, 6 months, 1 year, 2 years and 3 years postoperatively as a routine clinical evaluation tool. The ODI was used to determine the daily functionality of our patients and was assessed preoperatively and at 3 years follow-up.

Radiological parameters

Examination of the preoperative MR imaging focused at 3 radiological parameters: intervertebral disc height, Modic and Pfirrmann classifications. The intervertebral disc height was measured in the middle of the anterioposterior distance using midsagittal T1 MR images. The endplate changes were described using the Modic-classification types I to III.[1] [table 1] The original Pfirrmann grading system (types I to V), as recently acknowledged by Shah and Ross[2], was used to classify the degeneration of the intervertebral disc itself.[3] [table 2] Postoperatively a control radiograph was obtained during admission to assess the in vivo localization of the implanted hardware. At three months follow-up a second control radiograph was used to screen for hardware related complications such as subsidence or hardware failure.

Phone interview

Missing information was retrieved by telephone interview and some supplementary questions were asked as well. We assessed the clinical satisfaction of our patients by asking the following question: "Would you reconsider the surgical intervention given your postoperative course and today's results?". The male patients were asked three supplementary closed questions to identify possible ejaculation problems: (1) the perception of your orgasm did not change after the surgery; (2) the volume of the ejaculate did not change after the surgery; (3) your urine has a turbid appearance after an ejaculation. The patients could answer "yes", "no", or "I have no idea". If the patient answered the two last questions positively, the likelihood of retrograde ejaculation was considered high. A formal diagnosis of retrograde ejaculation can only be made by testing of urinary samples, which however falls beyond the scoop of this retrospective study.

Surgery

All patients were operated on by a senior neurosurgeon from the department. In most, but not all, of the cases the thoracovascular surgeon performed the left-sided anterior abdominal approach. A Pfannenstiel or midline laparotomy incision was chosen. When necessary, the large vessels were mobilized. Standard discectomy was performed. The choice of type of cage was left to the discretion of the surgeon. All cages were filled with bone allograft from the bone bank of the hospital; no rhBMP-2 was used to enhance fusion. [picture 1 and 2 (supplied in powerpoint)]

Statistical analysis

The SPSS v23 (2015) statistical package was used for all analysis; a two-sided P-value of 0.05 or less was considered to indicate statistical significance. The Mann Whitney U test was used to compare continuous variables to each other; discrete variables on the other hand were compared using the Chi-square test.

Results

General features

In total 123 patients were included in the study cohort; 48% were female and 39% were smokers. The mean age at surgery was 46 years.

Preoperatively 58% of the patients had been suffering from back and/or leg pain for over 2 years, 64% had been unfit for work for over 3 months because of lumbar pathology and 36% had been using opioids for pain control. Previous posterior lumbar surgery was found in the history of 32% of patients.

In total 154 fusions were performed: 53% on the L4-L5 level and 47% on the L5-S1 level. The first three implants were always combined with anterior plate and screw fixation. The Ulrich lumbar cage consists of a one-piece plate-cage device. All fusions were performed with the following hardware: Zimmer® Trabecular Metal lordotic cages (Minneapolis, MN, USA), Medtronic® PEEK lordotic cages (Minneapolis, MN, USA), Stryker® PEEK lordotic cages (Kalamazoo, MI, USA) and expandable non-lordotic titanium cages from Ulrich® (Ulm, Germany). Postoperatively, 54% of patients returned to work and 4% received a dorsal column stimulation (DCS) device during follow-up. No patients received additional pedicle screw placement.

Pain and functionality [+ table 3]

Almost all patients suffered from both low back pain and leg pain: 8 patients suffered back pain and 4 patients suffered leg pain exclusively. The mean VAS-scores for back and leg pain at baseline were 7.20 and 5.79 respectively. At 3 years follow-up they improved markedly to 2.20 and 1.39 ($P<0.001$) *[+ figure 2]*. The postoperative changes in daily functionality are summarized in table 1. Again there is a considerable improvement ($P<0.001$). Overall, 77.2% of the patients improved 2 or more ODI-categories postoperatively, 17.1% improved 1 ODI-category, 4.9% remained status quo and 0.8% deteriorated.

Radiological parameters [+ table 4]

Modic-changes were found in 48% of patients: 14% had type I, 33% had type II and 1% had type III changes. A black-disc was found in 36% of patients; 16% showed no changes at all. This last group had advanced Pfirrmann stages or disc bulging/herniation. Overall, 4% of levels could not be classified due to a previous PLIF-intervention; these patients were excluded from statistical analysis concerning the different radiological parameters. Patients with a type I change show a substantial better clinical result (ΔVAS) at 3 years follow-up in comparison with patients with no Modic-changes ($P = 0.026$).

Overall 19% of the fused levels had an intervertebral disc height of 5 mm or less. These patients, when compared to the cohort with a higher intervertebral disc space, had a higher mean VAS-score for leg pain at baseline ($P = 0.034$) but at 3 years follow-up these patients showed less residual pain. The difference in VAS-scores (ΔVAS) between both groups is statistically significant ($P = 0.033$). The difference in VAS-scores (ΔVAS) for low back pain however is not ($P = 0.233$).

A Pfirrmann type IV or V intervertebral disc was found in 44% of all fused levels. These patients, when compared to the cohort with a Pfirrmann type I to III, suffered from more pronounced leg pain at baseline (P = 0.006) but showed only mildly better postoperative results. The difference in VAS-scores (ΔVAS) between both groups is statistically significant (P = 0.045). The difference in VAS-scores (ΔVAS) for low back pain again is not (P = 0.517).

Clinical parameters [+ table 5]

A history of smoking at the time of surgery was found in 39% of patients. Non-smokers had a small, but statistically insignificant clinical advantage (ΔVAS) in comparison to smokers for low back pain (P = 0.450) and leg pain (P = 0.208).

The mean age at the time of surgery was 46 years. Younger patients (< 36 years) had a significantly worse clinical improvement (ΔVAS) in comparison to older patients (> 57 years) for the leg pain (P = 0.043). Although the same observation can be made for the back pain, this result is not significant (P = 0.074). The younger patients had in 18% of cases a Pfirrmann type IV or V, the older patients in 46% of cases; this difference is significant (P = 0.024).

At the time of surgery 58% had suffered pain symptoms for over 2 years. The clinical results (ΔVAS) did not differ significantly in these patients compared with the other fraction with a shorter duration of back (P = 0.269) and/or leg pain (P = 0.893).

Overall 32% (n=39) of the patients had a history of prior lumbar surgery on the L4-L5 and/or L5-S1 level: 22% had undergone lumbar surgery once, 7% twice and 2% three times. The last surgical intervention was a microdiscectomy in 74% (n=29), PLIF in 15% (n=6) and a laminectomy in 10% (n=4) of cases. Overall 26 % of the fusions were performed on the same level as the last lumbar spinal intervention. These patients have the same clinical benefit (ΔVAS) for low back pain as the patients without previous surgery and also a better result (ΔVAS) for leg pain, although not statistically significant (P = 0.956).

At 3 months follow-up 21% were using opiates for pain control. These patients showed a far less satisfactory clinical improvement at 3 years of follow up (ΔVAS) for back (P = 0.034) and leg pain (P = 0.005) *[+ figure 3]*.

After 3 years 62% of the patients returned to work after rehabilitation. These patients showed better improvement (ΔVAS) in back pain then those who did not return to work (P = 0.012), but this was not the case for the leg pain (P = 0.987). Furthermore, 69% of patients who did not use opioids at 3 months postoperative would return to work in future, while this was only the case in 46% of patients who did use opioids at that time (P = 0.033).

Patient satisfaction

When asked directly on the phone 89% of patients would reconsider their surgical intervention. Both groups did not differ significantly in pain scores at baseline, but the group that would reconsider the intervention showed better improvement (ΔVAS) in back ($P < 0.001$) and leg pain ($P = 0.002$).

Complications

Deep venous thrombosis (DVT) occurred in 2% of patients but no pulmonary embolism (PE) was diagnosed. Minor wound problems (superficial infections and/or wound dehiscence) were diagnosed in 3% of patients. Hardware related problems were also minor, with subsidence being the only complication that occurred in 1% of patients. A high likelihood of retrograde ejaculation was identified in 9.5% of men. Moreover, 32% of these men experienced a changed subjective perception of their orgasm. In total 8% of men suffered from both conditions.

Discussion

Fusion techniques in the treatment of degenerative disc disease at the lumbar level remain a controversial topic. Although there is no consensus amongst spine surgeons concerning indications or type of fusion technique used, fact remains that fusion techniques in the lumbar spine are every day practice in large spine centers.

The reason we chose the anterior technique in this patient cohort is, although it is considered more invasive, the technique has the principle advantage of obliterating the need to enter the spinal canal and manipulate the lumbar nerve roots during surgery, and especially during cage placement. Next, the anterior approach permits a more thorough removal of the intervertebral disk, and thus placement of a larger (one piece) cage than possible with posterior techniques, potentially enhancing fusion. Furthermore, the ALIF-technique is associated with less operative blood loss and subsequently a diminished need for blood transfusion. Last but not least, a major drawback of the posterior approach in our view is the wounding of the intrinsic back muscles.[4] As there are no high-quality randomized trials addressing the clinical superiority of one technique over the other at this moment, the choice of technique primarily depends on the surgeon's experience.

The patient population studied here represents an unselected patient cohort as seen in everyday practice. The mean age is young, 46 years. As frequently seen in clinical practice, almost 60% of these patients were suffering for more than two years of severe back and/or leg pain. So, most patients from the cohort are considered as suffering from "chronic low back pain".

This retrospective study shows that most patients after an ALIF-intervention report a significant improvement in pain and functionality scores on the long term. Almost 62% of them returned to work postoperatively, although they were preoperatively unable to work due to lumbar problems for more than three months. Although this study is inherently biased by its retrospective character and by the use of a telephone interview, the presented results are very similar as compared to the prospectively conducted papers recently published by Rao et al.[5] and Allain et al.[6] The

aforementioned studies although had a shorter mean follow-up period of 22 and 12 months and a patient cohort of 97 and 65 patients respectively.

Overall, a little more than 10% of patients would *not* reconsider the surgical intervention. These patients showed a mean improvement of 2 VAS-points of back and leg pain. The theoretical minimal improvement patients consider significant is termed the "minimum clinically important difference" (MCID).[7] Copay et al. published a MCID of 1.2 points for back pain and 1.6 points for leg pain: in this study however these figures seem to fall short of reality.[8]

Patients who used opioids for pain control 3 months postoperatively showed a less satisfying result at 3 years follow-up; in general they even tempt to deteriorate one year after the surgical intervention *[+ figure 3]*. Furthermore these patients were less likely to return to work in the next years of follow-up. The use of opioids 3 months postoperative could therefore be considered as a negative prognostic factor for pain control and work impairment.

Younger patients (< 36 years) show less clinical benefit after 3 years of follow-up in comparison to older patients. This result is dubious and might be biased by the fact that younger patients present less frequent with Pfirrmann-grades IV and V. This hypothesis explains the lower mean VAS-score for leg pain compared with the older cohort as well. Further evaluation should confirm the clinical value of an ALIF-procedure in the small population of young people with pronounced DDD.

These data further show that most patients have a pronounced albeit incomplete amelioration in pain scores at 3 months follow-up. However, after 6 months there is limited further improvement to be expected. This result seems contra-intuitive since traditionally the main goal of the procedure is bony fusion of two adjacent vertebral bodies and fusion probably cannot be reached in this short time period. According to a series published by Burkus et al. fusion is achieved in absence of rhBMP-2 in only 44% of cases after 6 months, in 66% of cases after 12 months and in 79% of cases after 24 months.[9] Consequently, one could argue that there seems to be an apparent discordance between fusion status and pain experience. Off course, the immediate immobilization of the vertebrae obtained by the use of a large cage with or without anterior plating has to be taken into account. Solid fusion, therefore, is probably more of a static radiological parameter while pain is the superior clinical parameter to assess the outcome of a fusion procedure. An important remark is that fusion itself was in fact not specifically studied here, because the overwhelming majority of patients only had X-ray controls immediately postop and at three months. Thereafter, surgical follow-up ceased since patients were doing well and they were sent back to the referring physician and/or GP.

It is claimed that Modic-type I changes correspond with an increased chance in experiencing low back pain, because of ingrowth of fibrovascular tissue in the vertebral end.[10] This claim could nevertheless not be reproduced in this study. Although none of the assessed Modic-changes were correlated with more perceived back pain at baseline, Modic-type I changes could be linked to a better clinical result at 3 years follow-up. This is in contradiction with the results published by Djurasovic et al., who could not find a significant improvement in pain for patients with Modic-type I in a smaller retrospective study cohort.[11]

In contrary to the other Pfirrmann-grades, grades IV and V do correspond with a relative loss in disc height.[3] The patients corresponding with these more advanced stages of disc degeneration and those with an absolute intervertebral disc height of less than 5 mm were suffering more pronounced leg pain at baseline. Since a successful implantation of an interbody device can lead to a restore in disc height, it is not surprising that these patients report a better clinical outcome after 3 years of follow-up due to mechanical "re-opening" of the neuroforamen. The results of Djurasovic showed a comparable prognostic value of an intervertebral disc height of less than 5 mm.[11]

The overall non-urological complication rate after anterior lumbar interbody fusion is low in this series and there were no serious complications. Spinal implant related complications were very low and didn't necessitate new surgical interventions. Ejaculation problems on the other hand are a major concern in performing an anterior approach of the lumbar spinal column. The incidence of retrograde ejaculation after ALIF-procedures varies greatly between studies and there are no unequivocal methods to assess this complication. A recent study performed by Tepper et al. compared both a quantitative and a qualitative method to assess retrograde ejaculation in spinal surgery. They found a positive diagnosis through laboratory analysis of urine in 9.8% of patients.[12] This figure corresponds with the incidence quantitatively found in this study. Tepper et al. used a similar questionnaire for qualitative assessment, but they considered retrograde ejaculation present when the patient reported less or no ejaculate fluid. They report an incidence of 41.7% after qualitative assessment.[12] All patients in whom retrograde ejaculation could not be diagnosed with laboratory analysis scored negative on the questionnaire; all patients with proven retrograde ejaculation could be identified using the questionnaire, although 11 patients scored positively on the qualitative assessment and negative on the laboratory analysis. Tepper et al. concluded that the used questionnaire led to an overestimation of retrograde ejaculation.[12] The above mentioned figures indicate an excellent specificity and hence a good negative predictive value of the qualitative method. It could therefore be used in everyday practice to identify potential candidates for a more thorough qualitative assessment.

Conclusion

Stand-alone anterior lumbar interbody fusion without use of bone promotors is a durable treatment option for some patients with DDD. At six months postoperatively, maximum pain reduction seems obtained. Patient satisfaction after three years of follow-up is excellent as almost nine out of ten patients would reconsider the performed intervention. The overall complication rate is low with no major event observed in this series. Retrograde ejaculation in men on the other hand is a major drawback of the anterior approach. The Modic and Pfirrmann classifications and intervertebral disc height may have prognostic value in determining treatment outcome.

Box 1 – Illustrative case

A 64 year old man presents with long standing complaints of lumboischialgia. He is a non-smoker and worked as a plumber his whole life. Since 2.5 years he has a continuous and intense sensation of pain in his lower back (VAS: 8/10) with a pseudoradicular syndrome. He is still able to walk considerable

distances and has no apparent bladder problems. During clinical examination a point tenderness above the facet joints on the L4-L5 level is identified. Clinical examination shows no apparent motor nor sensory deficits in the lower limbs.

Magnetic resonance imaging of the lumbar spine points to a disk bulging on the L4-L5 level. The intervertebral disk height is diminished and all distinction between disk nucleus and annulus is lost corresponding with a grade IV degeneration as proposed by Pfirrmann. There are Modic type I endplate changes visible. [+ picture 3 and 4 (supplied in powerpoint)]

After careful consideration the patient was proposed an ALIF procedure to tackle his pain problem. A Medtronic PEEK cage was used to replace the intervertebral disk and restore the disk height. He visited the patient clinic for follow-up after three months with no residual complaints. A control X-ray did not show subsidence. He remained pain free up to now. We called the patient to assess possible urological complications but no perturbations were reported.

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Conflict of Interest

All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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