ORIGINAL PAPER
PŮVODNÍ PRÁCE

Posterolateral Fusion in Acute Traumatic Thoracolumbar Fractures: A Comparison of Demineralized Bone Matrix and Autologous Bone Graft

Posterolaterální fúze u akutních zlomenin thorakolumbální páteře: porovnání demineralizované kostní hmoty a autologních kostních štěpů

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ABSTRACT

INTRODUCTION

Alternative fusion expanders are in clinical use for instrumented posterolateral fusion (PLF) to avoid donor site morbidity in autologous bone graft (ABG) harvesting. Purpose of this study was to evaluate demineralized bone matrix (DBM) in PLF as alternative to the gold standard of ABG in acute traumatic vertebral body fractures of the thoracolumbar spine.

MATERIAL AND METHODS

We retrospectively identified 101 patients with acute traumatic vertebral body fractures of the thoracic and lumbar spine who were treated with instrumented PLF in our level one trauma center between 2005 and 2011. Patients with a primary paraplegia, osteodepriving disease or loss to follow-up had been excluded. Until August 2008, autologous bone graft harvested from the posterior iliac crest was used in PLF (control group n = 46). Starting September 2008, DBM was used as fusion expander in PLF (study group n = 16). Clinical and radiological evaluation was performed with a minimum follow-up of 18 months to assess the clinical and radiological outcome.

RESULTS

We found a fusion rate of 94% in patients undergoing PLF with the use of DBM and 100% with the use of ABG. There was one major complication of deep infection in the DBM group and two cases of superficial wound infection in the ABG group. We discovered a trend of reduced operating time with the use of DBM.

CONCLUSIONS

DBM leads to a similar fusion rate as the use of ABG in patients undergoing PLF for acute traumatic vertebral body fractures of the thoracic and lumbar spine. DBM is associated with reduced operating time.

Level of evidence III: case-control study

Key words: demineralized bone matrix instrumented posterolateral fusion, acute traumatic vertebral body fracture, thoracolumbar spine, autologous bone graft.

INTRODUCTION

Instrumented posterolateral fusion (PLF) is a standard procedure in the treatment of acute traumatic vertebral body fractures of the thoracic and lumbar spine (22, 29). The use of autologous iliac crest bone graft as a fusion expander is considered the "gold standard". Autologous bone has ideal biological properties in terms of osteoinductivity, osteoconductivity, and osteogenesis (10, 19). Moreover, the lack of immunogenicity and the low risk of disease transmission are further advantages of autografts. Nevertheless, autologous bone is available in limited amounts and associated with an additional surgical procedure at the harvesting site, causing an increase in operation time, pain, and risk of infection at the donor site (19). Because of donor site morbidity in autologous bone graft harvesting, different homologous and synthetic preparations have found their way into clinical practice as alternatives or supplements to autografts (5, 10). Among these allograft preparations, the demineralized bone matrix (DBM) demonstrated the highest osteogenic potential in experimental studies (2, 9, 16, 21).

In 1965, Urist et al. (27) first described the effect of "formation by autoinduction," which characterizes the activation of matrix-associated osteoinductive proteins by demineralization of bone. DBM has been in clinical use for more than fifteen years, and several studies have demonstrated its fusion potential (11, 21). In degenerative spinal instability, a few studies have shown comparable fusion rates for DBM and autologous bone graft (ABG), (4, 12, 13, 28). To our knowledge, the use of DBM in instrumented PLF of traumatic vertebral body fractures has not been evaluated so far. The aim of this study was to compare the fusion rate of DBM and ABG in PLF of acute traumatic vertebral body fractures of the thoracic and lumbar spine and to clarify whether there are differences with special regard to complications.

MATERIAL AND METHODS

We retrospectively identified 101 patients with acute traumatic vertebral body fractures of the thoracic and lumbar spine that were treated with instrumented PLF in our at a level one trauma center between 2005 and 2011. Until August 2008, ABG harvested from the posterior iliac crest was used in PLF. After August 2008, ABG was replaced by DBM as a fusion expander in PLF in order to avoid donor site morbidity. Over the course of the entire duration of this study, there was no further deliberate change of treatment strategy concerning decision making, operative procedures, or postoperative care.

All patients were evaluated routinely in intervals of 6 weeks, 3 months, 12 months, and 18 months after surgery. This assessment included a subjective evaluation of pain, a physical examination, and conventional radiographs in two planes. The primary outcome measure of this study was the achievement of a stable posterolateral fusion of the affected spinal segment. The segment was rated as fused when there was no pain in the clinical examination and when radiographic signs of consolidation were apparent.

Inclusion criteria:

– Acute vertebral body fracture of the thoracic and lumbar spine.
– No clinical signs of a spinal cord injury – grade E according to the Frankel classification of spinal cord injuries (7).
– Instrumented posterolateral fusion with autologous bone graft or demineralized bone matrix.
– Minimum follow-up of 18 months.

Exclusion criteria:

– Grade A-D according to the Frankel classification of spinal cord injuries (7).
– Osteodepriving disease (e.g. osteoporosis/osteogenesis imperfecta).
– Age < 16 years.
– Lost to follow-up.

Patient management

All patients were primarily attended by a senior trauma surgeon and evaluated with a CT scan. The initial treatment was performed according to the standard protocol of Advanced Trauma Life Support (ATLS), (25). The analysis and classification of the vertebral body fracture of the thoracic and/or lumbar spine were conducted by a senior trauma surgeon according to the AO classification system for thoracic and lumbar injuries (17).

In cases of a segmental instability of the spine, as in complete burst fractures or disco-ligamentary injuries, permanent stability was achieved by PLF. Additional ventral stabilization was performed in cases of high grade instability caused by the disruption of the intervertebral disc (Type B or C) or the comminution and apposition of the fragments in complete burst fractures (Type A3 or higher). For monosegmental ventral fusion, a tricortical iliac crest bone graft was inserted and secured by plate osteosynthesis. As a replacement of the vertebral body, an expandable vertebral body was implanted in patients with a comminution of the complete vertebral body. In case of a ventral stabilization, a second procedure was performed within one week after the initial PLF. In cases with an unclear disco-ligamentary stability, the posterior ligamentous complex and involvement of the intervertebral disc were evaluated by MRI.

The course of the surgeries was developed on the basis of early total care with regard to the general condition of the patient and the requirements of the concomitant injuries. Since we excluded patients with primary paraplegia, all evaluated cases were subacute.

Operative procedure

Under general anesthesia, the patient was placed in a prone position with support of the pectoral and pelvic area in order to relocate the fracture in a slack position. Preoperatively, a first generation cephalosporin was administered as perioperative antibiotic prophylaxis. A median approach with an incision of the skin and fascia thoracolumbalis and a detachment of the autochthone back muscles was performed in order to expose the entry points of the pedicular screws. The Universal Spinal System (USS, Synthes Inc., Oberdorf, Switzerland) was used for dorsal instrumentation according to AO principles. The facet joint cartilage was resected, and the bone graft was applied to achieve PLF. Until August 2008, autologous cancellous bone was harvested from the posterior iliac crest. Therefore, an additional incision lateral of the spina iliaca posterior superior had to be made. After the harvesting of the ABG, the defect was filled with a resorbable collagen matrix. A subfascial drain was inserted to prevent a postoperative haematoma. Starting September 2008, DBM (DBM, Synthes Inc., Oberdorf, Switzerland) was applied as a fusion expander for PLF. A volume of 5 ml of DBM was used for the fusion of one or two segments. For both groups an intertransverse fusion was done in rotational injuries (AO type C)

Postoperative care

Radiographs in two plains and a CT scan of the affected segments were obtained postoperatively. Patients were mobilized in a rigid corset under physiotherapeutic instruction. In intervals of 6 weeks, 3 months, 12 months, and 18 months, all patients were evaluated routinely including a physical examination and radiographs in two planes. The removal of the posterior instrumentation was considered 12 months after the stabilization at the earliest. If the patient requested prior implant removal, an additional computed tomography was obtained to assure consolidation.

Statistical analysis

Statistical analysis was performed using the software package SPSS (Version 19, SPSS Inc, Chicago, Illinois). All data were tested for normal distribution using the Shapiro-Wilk test. Descriptive data are given as mean ± standard deviation. The Fisher's exact test was used to compare the fusion rate and implant removal rate. For an analysis of the remaining data, the student's t-test was applied. The level of significance was defined at $p < 0.05$ for all tests.

RESULTS

Demographics

In 31 patients, DBM was used for PLF. 15 patients were excluded due to primary paraplegia (5 patients), osteodepriving disease (7 patients), and loss to follow-up (2 patients). One patient had received DBM in addition to an ABG and was therefore excluded. Finally, 16 patients were included in the DBM group (Fig. 1). In 71 patients, ABG was used for PLF. In this group, 25 patients were excluded due to primary paraplegia (3 patients), osteodepriving disease (5 patients), and loss to follow-up (16 patients). The patient mentioned above who had received ABG and DBM and was again excluded. Finally, 46 patients were included in the ABG group, representing the control group (Fig. 2). In total, data of 62 patients (16 DBM; 46 ABG) were available for analysis. The mean age of the included patients at the time of surgery was 43.5 ± 3.2, and 45.2 ± 2.5 years in DBM and ABG, respectively. The study cohort comprised 11 men (68.8%) and 5 women (31.2%) in DBM and 32 men (70.0%) and 14 women (30.0%) in ABG (Table 1). The distribution of the fractures to the vertebral sections is listed in Fig. 3. Table 2 shows the classification of fractures.

Clinical course and radiological outcome

The time span from the hospital admission to the operative procedure was similar in the DBM and the ABG groups with 1.9 d ± 0.8 and 2.8 d ± 0.4 days, respectively ($p = 0.25$). There was no difference in the instrumented and fused segments between both groups.

1 | 2

Fig. 1. Example of a posterolateral fusion with autologous bone graft 8 months after L1 fracture.

Fig. 2. Example of a posterolateral fusion with DBM of a L2 fracture (10 months after stabilization).

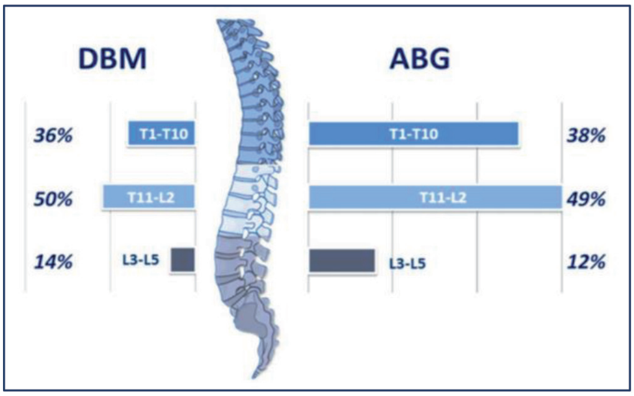

Fig. 3. Distribution of fractures.

Table 1. Demographic data

Demographic data	DBM	autologous	p
n	16	46	
Age (y)	43.5 +/-3.2	45.2 +/-2,5	0.71
Gender (f/m)	31% f / 69% m	30% f / 70% m	1.00

Table 2. Classification of fractures

Classification of fractures	DBM	autologous	p
Compression injury (AO Type A)	12	25	0.24
Distraction injury (AO Type B)	2	14	0.10
Rotation injury (AO Type C)	2	6	1.00
n	16	46	

2.6 ± 0.3 segments were instrumented in the DBM group, and 2.5 ± 0.1 in the ABG group (p = 0.68). 1.68 ± 0.22 segments were fused in the DBM group, and 1.71 ± 0.18 in the ABG group (p = 0.59). The operative procedure was less time-consuming in the DBM group with a median duration of 87 minutes in comparison to 99 minutes in the ABG group (p = 0.39). In 75.0% of DBM patients (n = 12), ventral stabilization was performed in addition to PLF, in comparison to 46.0% with ABG patients (n = 21) (p = 0.08). Patients in both groups were discharged from the hospital after a similar duration of 19.7 d ± 1.4 and 18.5 d ± 1.2 days in DBM and ABG, respectively (p = 0.63). After 18 months, the PLF procedure was rated as fused in 93.8% of the patients in the DBM group (n = 15) and all patients in the ABG group (n = 46), (p = 0.26). The dorsal instrumentation was removed in 35% of all patients (n = 22), (Table 3).

Complications

There were two cases of surgical site infections requiring revision surgery due to superficial wound infection in the ABG group. Besides, there was one surgical site infection due to delayed deep infection in the DBM group. This 21-year-old female suffering from a burst fracture of the 1^{st} and 3^{rd} lumbar vertebral body after a fall from a distance of 6 meters developed a non-union due to low-grade infection around the 3^{rd} lumbar vertebral body seven months after the dorsoventral stabilization (Fig. 4).

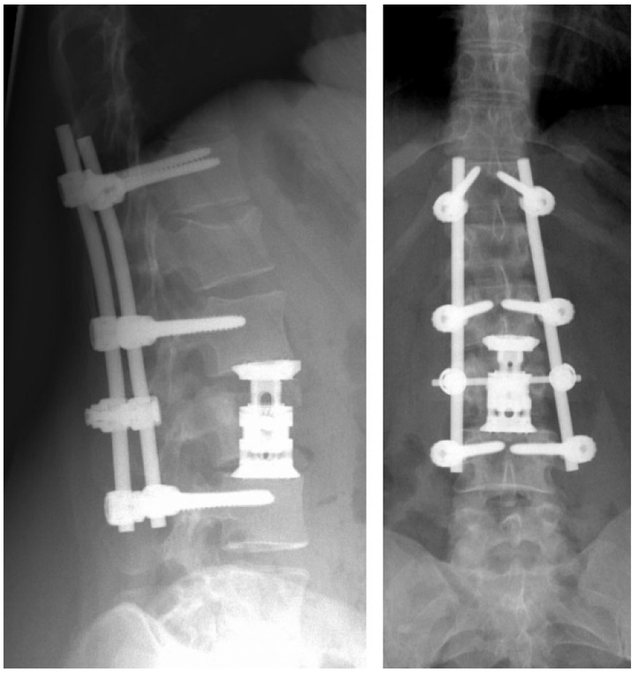

Fig. 4. 21-year-old female with a deep infection 7 months after posterolateral fusion and anterior vertebral body replacement of L3.

There were no side effects like allergic reactions or the transmission of infectious diseases recorded in our patients. The same applies for cases of neurological impairment after the operation or in the course of the follow-up examinations.

DISCUSSION

Over the past two decades, substantial advancements in the treatment of thoracolumbar injuries have been

Table 3. Perioperative data and follow-up

Perioperative data and follow-up	DBM	autologous	p
n	16	46	
Days trauma to surgery	1.9 d +/- 0.8	2.8 d +/- 0.4	0.25
Number of surgeons	8	12	0.79
OR-time (median)	87	99	0.39
Procedure	25% IPLF		
75% combined	54% IPLF		
46% combined	0.08		
Segments instrumented	2.63 +/- 0.33	2.48 +/- 0.13	0.68
Segments fused	1.68 +/- 0.22	1.71 +/- 0.18	0.59
Days in hospital	19.7 d +/- 1.4	18.5 d +/-1.2	0.63
Fusion rate	15 (94%)	46 (100%)	0.26
Surgical site infection (SSI)	1 (6 %)	2 (7%)	1.00
Implant removal	5 (31%)	17 (37%)	0.76

made (18, 20, 22, 24, 29, 30). A better understanding of the biomechanical properties of the spine has been the basis for the development of improved implants and new operative techniques (18, 20, 22). Increased demands for minimal invasive procedures led to the implementation of alternative bone graft substitutes to avoid donor site morbidity (10, 19, 30). Generally, these substitutes are categorized into allografts, calcium ceramics, and recombinant cytokines, like the Bone Morphogenetic Proteins. In experimental studies DBM demonstrated the highest osteogenetic potential among those bone substitution materials (2, 9, 16, 19, 21). Although it is in clinical use for over 15 years now, very little is known about the DBM in PLF. Few studies evaluated DBM in PLF in degenerative spinal instability (12, 13, 28). Therefore, the present study aimed to assess the use of DBM in comparison to ABG in PLF of acute traumatic vertebral body fractures of the thoracic and lumbar spine with a special regard to fusion rate and potential complications.

The present results indicate a similar fusion rate in patients undergoing instrumented PLF with the use of DBM and ABG. The use of DBM was associated with reduced operating time and did not increase the complication rate in PLF.

DBM is an allograft bone substitute. During preparation, osteoinductive cytokines which are physiologically bound to collagen type-I are liberated by the demineralization with the use of hydrochloric acid (2, 27). Moreover, the microstructure and osteoconductive properties of DBM are preserved in order to provide cell migration, which is important for the osteointegration (2). Nevertheless, the osteogenic potential of DBM still is discussed controversially (5, 10). A major difference between the commercially available DBM materials is their carrier. The DBM used in our study contained sodium hyaluronate as a carrier. The compounds available from other distributers may contain glycerol, which can be cytotoxic in higher concentrations (5). Wildemann et al. (31) found large variations in the growth factor content in commercially available DBM materials, even within different lots of the same preparation. There is evidence that the bioactivity of eluted growth factors and not the overall amount of contained growth factors represents the osteoinductivity (2, 26, 31). However, further studies will have to evaluate this question in the future. Nevertheless, a recently published histological analysis of bone biopsies conducted 6-18 months after PLF showed significant new bone formation and decreasing residual DBM material depending on the period of time it was in situ (3). This supports the assumption of osteogenity of DBM.

Our patient cohort consists of mainly young, active, and predominantly male patients with an average age of 44.8 years. This is comparable to other studies on fractures of the thoracolumbar spine (22, 29, 14). In our study, patients with a neurologic impairment or known bone healing disorder were excluded to avoid any influence on the results regarding bone healing.

Evidence-based guidelines for the treatment of vertebral body fractures of the thoracic and lumbar spine are lacking (29, 15). Reinhold et al. presented a prospective controlled multicenter trial of 733 consecutive patients with an acute fracture of the thoracolumbar spine (22). In our study population, the rate of combined dorso-ventral procedures was higher than in Reinhold et al.'s population with 53.2% (33/62) and 43.5%, respectively. Unfortunately, Reinhold et. al. (22) do not provide detailed information on the subgroup of patients undergoing PLF. Generally, patients requiring a PLF procedure have a higher grade of instability with a need for additional ventral stabilisation. Regarding all our operations on fractures of the thoracic and lumbar spine, we found an overall PLF rate of 33.9% among 298 patients, which is equal to the PLF rate of 33.2% in Reinhold et al.'s population. In our DBM group, we found a trend towards additional ventral stabilisation in comparison to our ABG group. Reinhold et al. stated that there is a continuous increase in combined surgery compared to the MCSI I report in 1994-1996 (14). This might be partially attributed to the fact that 360° stabilization through a minimal invasive anterior approach allows for the reduction of the posterior stabilization to a short segment instrumentation avoiding large rod constructions (22, 29, 30).

Apart from the avoidance of donor site morbidity, an argument for the use of alternative fusion expanders is reduced operation time. Kang et al. (13) recorded a mean difference in operation time of 26 minutes between the use of DBM and ABG harvested from the posterior iliac crest in PLF of 41 patients with degenerative spondylolisthesis. Looking at a mean operation time of 208 minutes, Kang reported a difference of 12.5% of the average operation time between both groups (13). We found a mean reduction in operation time of 12 minutes in the DBM group in comparison to the ABG group. The proportional difference between the two groups was 11.5% of the total operation time, which corresponds to Kang's results. In both studies, there was no significant difference between the DBM and the ABG group. The average operation time in our patients was 103 minutes. Regarding posterior stabilization of thoracolumbar fractures, our average operative time is below the results of most other studies: 152 min. (22), 153 min. (29), 100 min. (15), 224 min. (30).

The minimum follow-up in our study was 18 months. The female patient suffering from deep infection demonstrated a prolonged course. In all remaining patients, a final state concerning clinical and radiological results occurred within 12 months after the operation. Further examinations did not differ from this status. Other studies have periods of 13 to 30 months (13, 22, 24, 30). Histological studies on DBM in IPLF demonstrated that DBM residuals can only be found within the first 12 months after implantation. Thereafter, DBM is fully incorporated and fusion is complete (1, 3). Therefore, a period of 18 months seems viable for the analysis of the fusion rate.

The overall fusion rate of our patients after 18 months was 98.4%, with similar fusion rates in the DBM and ABG group. Other studies on PLF of thoracolumbar fractures also provide fusion rates between 95–100% (22, 29, 24, 30). Two studies comparing DBM with ABG in PLF of degenerative thoracolumbar instability indicate fusion rates around 85% (12, 13), whereas their fusion rate in the ABG group was 85% to 92% (12, 13).

The complication analysis of our study population demonstrated one serious complication in the DBM group with a deep infection of the implant after 7 months. The dorsal instrumentation as well as the vertebral body replacement had to be removed and the defect was filled temporarily with a PMMA inlay. Histological analysis showed the infiltration of neutrophil granulocytes but no signs of rejection reaction. Four months later, after the healing of the infection, the segment was bridged by another dorso-ventral stabilization. The patient did not sustain any further complication and returned to her normal course of life. Looking into the literature, this seems to be a rare but fateful course. Reinhold et al. also reported on a patient with deep infection and implant removal. They had to perform revision surgery on 2.0% of their 733 patients with thoracolumbar fractures within the first two years. In our study, in addition to the deep infection in the DBM group, two patients in the ABG group required revision surgery due to superficial wound infection. Other authors indicate a comparable, or even higher infection rate in the dorsal stabilization of the thoracolumbar spine of 0.7% to 11.9% (8).

In our population, the rate of the removal of the dorsal instrumentation was 35.4%. Wang et al. (30) reported a similar rate of implant removal among patients undergoing PLF in 30% of patients. In general, there is no evidence of disadvantages of remaining short segment posterior stabilization (23, 30). We recommend implant removal if the patient experiences discomfort due to the irritation of the implant for slim patients.

The study presented has a number of limitations. First of all, it has a retrospective design with a considerable number of patients who were excluded. Second, detailed radiographic information would have been favourable. Computed tomography is not part of the general follow-up examinations and therefore a bias might have influenced the fusion rate. However, other studies could show a good correlation of radiographic assessment and surgical exploration of fusion for CT scans as well as for plain radiographs (6). Finally, the methods of operative treatment were not standardized and the treating surgeons differed; however, this limitation represents the clinical reality.

CONCLUSION

The present study gives first results on the use of DBM in acute traumatic thoracolumbar fractures. DBM leads to a similar fusion rate as the “gold standard” of ABG in patients undergoing PLF with a reduced time of operation. DBM does not increase the complication rate and seems to be a viable bone graft material for PLF in traumatic thoracolumbar fractures. Further prospective randomized trials are recommended in order to confirm our findings and establish evidence-based guidelines for bone graft substitution in spine surgery.

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