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Hiermit erkläre ich, die Dissertation mit dem Titel

"Analyse der Ergebnisse von traumatischen Wirbelfrakturen im Brust- und Lendenwirbelbereich klassifiziert als A3 - Frakturen nach Magerl, versorgt durch Kombination von perkutaner posteriorer transpedikulärer Osteosynthese und Ballon-Kyphoplastie"

eigenständig angefertigt und keine anderen als die von mir angegebenen Quellen und Hilfsmittel verwendet zu haben.

Bochum, den 28. Juli 2022 ……..

Aus der Klinik für Neurochirurgie und Wirbelsäulechirurgie

(Direktor Prof. Dr. med. R. Martinez-Olivera)

Universitätsklinikum Bergmannsheil der Ruhr-Universität Bochum

Analyse der Ergebnisse von traumatischen Wirbelfrakturen im Brust- und Lendenwirbelbereich klassifiziert als A3 - Frakturen nach Magerl, versorgt durch Kombination von perkutaner posteriorer transpedikulärer Osteosynthese und Ballon-Kyphoplastie

INAUGURAL-DISSERTATION

zur Erlangung des Doktorgrades

der Medizinischen Fakultät der

Georg-August-Universität zu Göttingen

vorgelegt von

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Alexandria, Ägypten

Göttingen 2022

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Analysis of the results of traumatic vertebral fractures in the thoracic and lumbar region classified as A3 - fractures according to Magerl, supplied by combination of percutaneous posterior transpedicular osteosynthesis and balloon kyphoplasty

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Index of Abbreviations

AO	Arbeitsgemeinschaft für Osteosynthesefragen
BW	Thoracic vertebra
CT	Computer tomography
LW	Lumbar vertebra
MRI	Magnet resonance tomography
PACS	Picture Archiving and Communication System
RIS	Radiological Information System
VAS	Visual analog scale

1 Introduction

1.1 Classification of vertebral body fractures

There are different types of vertebral body fractures. Not only their location makes them different but other important factors such as the stability of the fracture and/or presence of neurological compression, which may lead to a neurological deficit makes them different.

Vertebral body fractures are challenging to diagnose and treat. In all cases is the goal of treatment to reduce the pain, stabilize the fracture and relief the neural compression when present. Establishment of fracture stability is determined by limiting segmental displacement or development of structural deformity (White und Panjabi 1978). After relieving the pain due to the vertebral body fracture and establishing stability, mobility can be restored.

For better management of vertebral body fractures the development of a fracture classification was essential.

In 1970 the first columnar model for spinal stability based on the sagittal profile of the spine was proposed (Holdsworth 1970), which was relevant for the treatment of vertebral body fractures. The spinal column would be divided into an anterior and posterior part according to the sagittal profile. Spinal instability is then defined by the rupture of the posterior column.

Several years later White and Panjabi (1978) described instability as rupture of posterior longitudinal ligament and annulas fibrosis together. In other words,

not only the disruption of the posterior column described by Holdsworth (1970) made the vertebral body fractures unstable.

In year 1982 vertebral body fractures were re-classified according to the mechanical failure of the vertebral column. The work of Allen et al. (1982) and Rudol et al. (2014) based on plain radiograms categorised the vertebral body fractures into vertical compression, lateral flexion, compression flexion, compression extension, distraction extension, and distraction flexion fractures.

The introduction of new imaging techniques has with no doubt improved the demonstration of vertebral body fractures. Computer-tomography and the reconstruction of the spine scans helped in developing a 3-dimensional model and hence better understanding of the fracture mechanism, stability of the vertebral column and the presence or absence of neurological compression.

The first three-column model of the vertebral column was described by Denis et al. (1983). The anterior column was described as the anterior longitudinal ligament, anterior wall of the vertebral body and anterior annulus fibrosus. The middle column was described as the posterior annulus fibrosus and posterior longitudinal ligament. Posterior column as pedicels, facet joints, articular processes, neural arch and interconnecting ligaments.

For a better and more precise description of the vertebral body fractures in terms of damage and degree of instability Magerl and colleagues established in year 1994 the AO (Arbeitsgemeinschaft für Osteosynthesefragen) classification for vertebral body fractures and injuries (1994). The classification described three major categories for vertebral body injury. Category A: vertebral body compression, category B: anterior and posterior element injury

with distraction and category C: anterior and posterior element injury with rotation (figure 1).

In our study we based our treatment strategy for acute vertebral body fractures on type A3 according to Magerl classification for vertebral column injuries (Magerl et al. 1994).

1.1.1 Magerl classification for vertebral body fractures

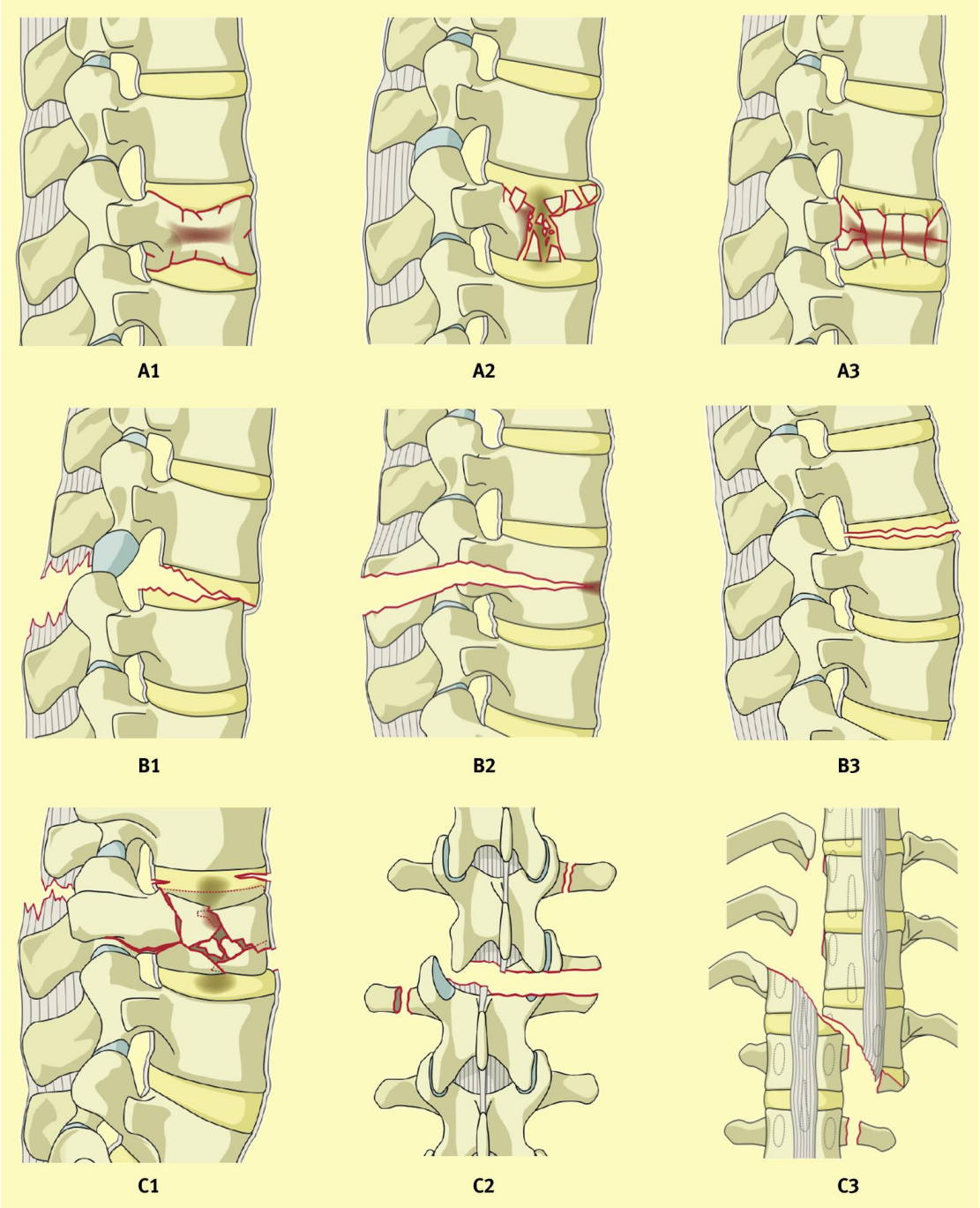


Figure (1): Fracture types and groups within each type in the Magerl AO classification of spinal injuries. (A) compression injuries: A1, impaction; A2, split; A3, burst. (B) distraction injuries: B1, posterior, predominantly ligamentous; B2, posterior, predominantly osseous; B3, anterior, through the disk. (C) torsion injuries: C1, type A with torsion; C2, type B with torsion; C3, torsional shear injuries. Copyright of AO Spine International, Switzerland, permission granted by Elsevier, No. 220628-024726 (Rudol 2014).

Magerl (1994) described the burst fractures as A3. The vertebral body is comminuted with affection of at least one endplate. The posterior column is intact. The posterior vertebral body is always involved which may result in a retro-pulsed bone fragment in the spinal canal.

Magerl (1994) further divided the burst fractures with partial comminution according to superior, inferior, and lateral variants into A3.1, A3.2.

A burst fracture in which the vertebral body is completely comminuted was described as A3.3. They are usually unstable in flexion-compression. The spinal canal is narrowed by retro-pulsed bone fragments, and the incidence of neural injuries is very high.

A3.3 fractures were further subdivided to 3 different subtypes. In fractures of the type A3.3.1 the vertebral arch is usually intact. The posterior wall of the vertebral body is fractured with fragments retro pulsed into the spinal canal.

In A3.3.2 fractures, the lamina or spinous processes are split vertically. These fractures are usually associated with kyphotic angulation of the spine due to the wedge-shaped comminuted vertebral body.

In A3.3.3 fractures, the height of the comminuted vertebral body is evenly reduced. The lamina or spinous processes are split vertically.

1.2 Non-surgical treatment of acute vertebral body fractures

Not all vertebral body fractures have to be treated surgically. Depending on the type of vertebral column injury, stability of the fracture, the presence of associated neurological deficit and last but not least, the general medical condition of the patient, many fractures can be treated conservatively. Irrespective of whether surgical or conservative management of the fracture is intended, the ultimate goal of the therapy is to reduce pain and avoid vertebral column deformities.

Pain treatment in cases of acute vertebral body fractures is always challenging. It usually includes a mixture of one or more of non-steroidal anti-inflammatory drugs and/or opioids. The doses differ according to the intensity of pain and mobility of the patient. In adequate doses, the medication can reduce bone pain or pain due to muscle spasm or nerve compression. However, long-term use of painkillers for weeks or months can lead to several complications. Most commonly encountered side effects are epigastric pain due to peptic ulcer or superficial gastric erosions and renal damage. Other adverse side effects as allergic reactions, constipation especially with opioid therapy or platelet dysfunction and hence hemorrhage may also occur.

Another effective method to reduce pain and avoid structural deformity or worsening of an existing one is bed rest. Activity modification reduces pain and therefore the doses of painkillers by reducing the movement across the fracture site. Nevertheless, bed rest for prolonged time can lead to osteoporosis, deep vein thrombosis, lung infection especially by elderly patients, and bedsores.

Based on the fact that bone heals physiologically, back bracing remains the main corner stone of conservative medical treatment of all vertebral body fractures. It supports the fracture site and reduces all traction forces at the level

of injury. Therefore, it is very effective in healing the vertebral body fracture (Wood et al. 2003). Furthermore, back bracing lowers the risk of developing a vertebral column deformity such as kyphosis or scoliosis. Similarly to bed rest, it reduces pain due to bone-bone friction and muscle spasm (Wood et al. 2003).

Back bracing represents an easy and effective way to deal with vertebral body fractures. On the other side of the coin, there are limitations for back bracing. Patients with associated abdominal injuries, prolonged ileus, chest trauma or multiple arm and leg fractures are not suitable for back bracing (Lewandrowski 2004). Furthermore, back bracing by severe vertebral column deformity may not be feasible and reduction of the fracture would never be attained.

When indicated, conservative treatment of acute vertebral body fractures may provide bone healing, pain reduction and to a certain extent avoid vertebral column deformity. Mal-union, non-union or worsening of a pre-existing neurological deficit adds extra challenges to this modality of treatment.

1.3 Surgical treatment of acute vertebral body fractures

Surgical intervention is usually indicated in cases of acute vertebral body fractures with neurological compression and or instability. The approach to the fractured vertebrae is tailored according to the site, structure and instability of the fracture. In case of neurological deficit, the surgical procedure must include decompression of the neural structures at the site of fracture.

Nowadays, posterior transpedicular screw fixation is one of the most popular and preferred surgical intervention for cases of acute vertebral body fractures. It provides reduction and re-stability of the fractured vertebra through anterior, middle and posterior columns in a safe technique (Korovessis et al. 2006).

However, reconstruction of the anterior column and maintaining the sagittal balance remain less than ideal. Furthermore, the presence of intraspinal bone fragment makes it difficult to decompress the neural structures only from a posterior approach.

Anterior surgery for acute vertebral body fractures was introduced in the early 1980s. Through an anterior approach, the fractured vertebrae will be removed, the spinal canal can be freed from any bone fragments and the neural structures can be decompressed anteriorly. The bone defect is then bridged with a synthetic implant or bone graft. The anterior approach to the fractured vertebral body showed better results than the posterior approach in restoration of the sagittal balance and effective reconstruction of the anterior column (Beisse et al. 2005; Kaneda et al. 1984).

Both techniques have the risks of pseudoarthrosis, instrument-failure, dislocation, and infection (Acosta et al. 2005).

Ideally is a 360° combined anterior and posterior fixation of the comminuted fracture necessary to achieve stability and reconstruct the anterior column to prevent vertebral column deformity such as kyphosis (Keynan et al. 2006).

As in other aspects of modern surgery, minimal invasive surgery has given rise to better techniques that are less traumatising to the tissue structures and safer with fewer complications.

Percutaneous posterior transpedicular screw fixation was introduced as a minimal invasive alternative to open posterior approaches with less trauma to tissues and hence less pain after surgery with good results (Kawaguchi et al. 1996; Palmisani et al. 2009; Pelegri et al. 2008).

Moreover, the work of Wild and his colleagues (Wild et al. 2007) showed no significant difference in the results between patients treated with percutaneous transpedicular screw fixation and those who were treated with conventional open posterior transpedicular screw technique.

Furthermore, percutaneous posterior transpedicular screw fixation represents a good solution for patients with instable vertebral body fractures associated with multiple trauma injuries, obesity and or bronchopulmonary disease where surgical intervention is necessary (Logroscino et al. 2009).

With the same minimal invasive pattern, the introduction of kyphoplasty made the augmentation of the anterior column possible. This technique allows the reduction of the vertebral body fracture, restoration of the vertebral body height and hence augmentation of the anterior column (Acosta et al. 2005).

Similarly, to the conventional 360°, combined open posterior transpedicular screw fixation and anterior surgery of the fractured vertebral body, minimal invasive posterior transpedicular screw fixation combined with kyphoplasty of the fractured vertebral body may stabilise the fracture as well as restore the anterior column.

1.4 Aim of the work

To analyse the results of acute thoracic and lumbar vertebral body fractures classified as A3 fractures according to Magerl classification (1994), managed by combination of percutaneous posterior transpedicular osteosynthesis and balloon kyphoplasty.

The resulting kyphosis of the fractured vertebral body will be measured according to the radiological examination and calculated Cobb angle values before and after the surgical procedure. The impact of the vertebral fracture will

be measured according to Cobb angle changes. Further changes of the vertebral body reduction after surgery will be for two years followed up.

Low vertebral body reduction values after surgery and maintenance of the reduction over two years suggest that the combination of percutaneous posterior transpedicular osteosynthesis and balloon kyphoplasty is an effective method for treatment of acute vertebral body fractures classified as A3 according to Magerl (Magerl et al. 1994).

2 Patients and Methods

Our study analysed the results from 48 patients with acute vertebral body fractures of the lumbar or thoracic spine classified as A3 according to Magerl et al. (1994) that were treated with percutaneous posterior transpedicular screw fixation combined with kyphoplasty between January 2012 and May 2015 retrospectively. In total, 43 patients were operated at Magdeburg City Hospital and 5 patients at Bochum Bergmannsheil University Hospital (Germany).

The patients did not have any neurological deficits or compression of neural structures that would require an open conventional anterior or posterior surgery. All the patients were clinically examined before and after surgery.

Pain due to the fractured vertebral body was assessed using the visual analogue scale (VAS).

Radiological diagnostic images for patients before and after surgery included

-Digital anterior-posterior and lateral X-rays of the fracture site using Siemens Mobilett XP (Siemens, Forchheim Germnay) device.

-Computer tomography with sagittal and coronal reconstruction of the fracture site using SOMATOM definition AS 64 CT scanner (Siemens, Forchheim Germany) device.

-Magnetic resonance imaging (MRI) using Siemens Aera 1,5 Tesla (Siemens, Forchheim Germany) device.

Using the Picture Archiving and Communication System (PACS) and Radiological Information System (RIS) software, variables were analysed and the Cobb angle was measured.

2.1 Statistics

The provided data were statistically analysed using standardized Wilcoxon test. Statistical significance was defined when the p-values were below 0.05.

The Cobb angle measurements before the operative reduction of the fracture so as well as postoperative and during the follow-up period were documented. We performed the Friedman test to the related data and ran Chi-square analysis ${}^{Fr}\chi^2$. A high Chi- square ${}^{Fr}\chi^2$ statistic and low p-value less than or equal 0.05 suggest statistically significant difference in Cobb measures preoperative and postoperative and/or during the follow-up period.

2.2 Inclusion and exclusion criteria:

Table (1): Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
Acute vertebral body fracture of lumbar or thoracic spine with history of recent trauma	Pathological and osteoporotic vertebral body fractures
Single level vertebral body fracture of lumbar or thoracic spine classified as A3 according to Magerl et al. (1994)	More than one acute vertebral body fracture.
Intact neurologically	Presence of neurological deficit or neurological compression
Decompression surgery was not required.	A1, A2, B and C vertebral body fractures according to Magerl classification
Failure of the anterior vertebral column with kyphosis at the fracture level.	Patient not fit for surgery

The study was granted the approval of the Ethic-Committee of the Sachsen-Anhalt Medical Council No.47/19 and Ethic-Committee of the Ruhr University Bochum, Faculty of Medicine No. 19-6650-BR.

2.3 First surgical stage

The first surgical step is directed to reconstruct and restore the anterior column at the fracture site. Under general anaesthesia and cover of single shot antibiotic with the patient in prone position, two bone needles are inserted under fluoroscopy through two small skin incisions into the pedicels of the fractured vertebra. When they reach the posterior vertebral body, they are then exchanged with the working cannula.

Through the cannula two balloons (Kyphon-Medtronic, Meerbusch, Germany) were carefully inserted under fluoroscopy and inflated at the anterior part of the fractured vertebrae in order to restore the height, reverse the kyphosis and hence reduce the fracture. The balloons were then deflated and the two vertebral cavities right and left were filled with either polymethyl methacrylate (Kyphon x-pede Medtronic) or hydroxyapatite (Kyphon active os-Medtronic) under low pressure with continuous fluoroscopy to augment the attained reduction. After cement application, the working cannula was removed and the skin incisions sutured.

2.4 Second surgical stage

Further stabilisation of the fractured vertebral body through the anterior, middle and posterior columns was carried out by percutaneous transpedicular screw fixation under fluoroscopy according to the established technique (Foley et al. 2003). The two percutaneous systems used were either Sextant TM (Medtronic) or Horizon Longitude (Medtronic)

Table (2): Registered operative data

Registered operative data
Operation time
Size of the balloons used for kyphoplasty
Type of bone cement used during kyphoplasty
Type of the system used for the posterior percutaneous transpedicular fixation

Any postoperative complication observed was noted. The duration of hospital stay was also registered.

Patients were followed up for 2 years and had plain x-ray as well as computer tomography scans of the fractured vertebrae immediately (2-3 days), after 6 months, 1 year and 2 years after surgery.

2.5 Measuring the Cobb angle

The Cobb angle was used to measure the deformity and degree of kyphosis resulting from the acute vertebral body fracture. Also, after surgery, the Cobb angle was re-measured to evaluate the fracture reduction and loss of reduction over the follow-up period.

The Cobb angle is the angle formed between a line drawn parallel to the superior end plate of the superior adjacent vertebrae (in relation to the fractured

vertebrae) and a line drawn parallel to the inferior endplate of the inferior adjacent vertebrae (in relation to the fractured vertebrae) (Acosta et al. 2005).

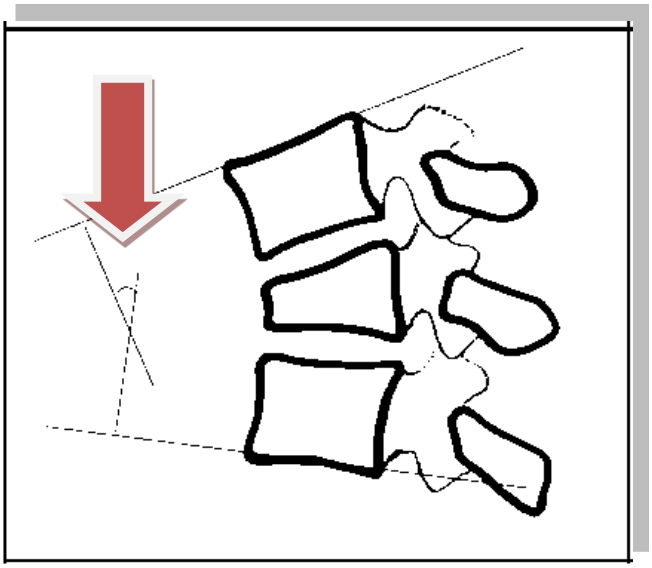


Figure (2): Diagram showing how the Cobb angle was measured

3 RESULTS

3.1 Demographic data

In our study, 32 patients were male corresponding to 66.7% of the studied cases and 16 patients were female 33.3%. Eleven patients representing 22.9% of the cases were in the age group 61-70 years. Only 5 patients were older than 80 years. In the studied cases the number of young patients below the age of 40y was 7. Seven patients were in the age group 40-50 years while nine patients were in the age group 51-60 years. In the age group 71-80 years were 9 patients of the studied cases.

The mean age of the studied patients was 58.8 years old (SD: 17.73, range: 26 - 88).

Table (3): Distribution of the studied cases according to demographic data (n = 48)

	n	**%**
Gender		
Male	32	66.7
Female	16	33.3
Age (years)		
<40	7	14.6
40 – 50	7	14.6
51 – 60	9	18.8
61 – 70	11	22.9
71 – 80	9	18.8
>80	5	10.4
Min. – Max.	26.0 – 88.0	
Mean ± SD.	58.83 ± 17.73	

3.2 Localization of the vertebral body fracture

The majority of the vertebral body fractures were in the thoraco-lumbar region with 18 cases of lumbar vertebra-1 (LW1) fracture and 9 cases with thoracic vertebra-12 (BW12) fracture. Eight patients had LW2 vertebral body fracture representing 25.8% of the studied cases.

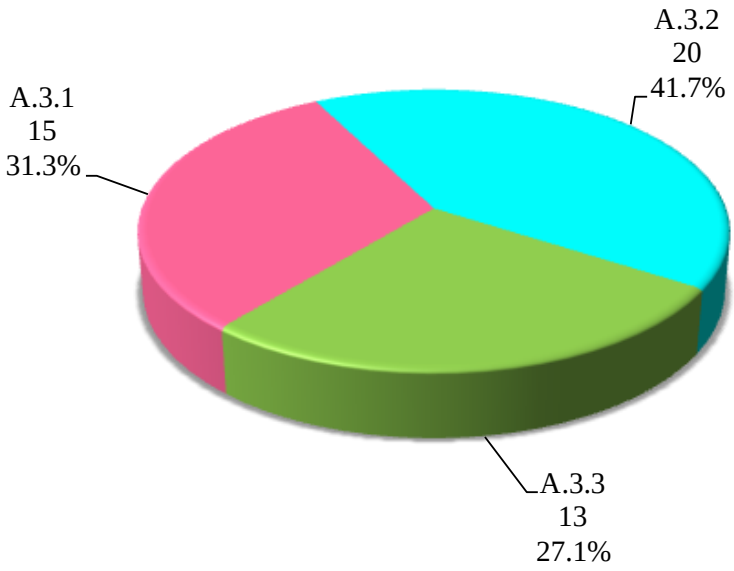
The total number of lumber vertebral body fractures was 31 cases representing 64.6% of the studied cases compared to 17 patients with thoracic vertebral body fracture representing 35.4% of the cases.

In the studied cases, 20 patients had A.3.2 fracture according to Magerl classification representing 41.7% of the cases. In total, 15 patients had A.3.1 fracture according to Magerl classification corresponding to 31.3% of the studied cases and 13 patients had A.3.3 fracture according to Magerl classification representing 27.1% of the cases.

Table (4): Distribution of the studied cases according to localisation of vertebral body fracture (n = 48)

Localisation of fracture	n	%
Thoracic vertebrae no.	**17**	**35.4**
2	1	5.9
5	1	5.9
6	1	5.9
7	2	11.8
8	1	5.9
10	2	11.8
12	9	52.9
Lumbar vertebrae no.	**31**	**64.6**
1	18	58.1
2	8	25.8
3	3	9.7
4	2	6.5

Figure (3): Distribution of the studied cases according to type of vertebral body fracture according to Magerl classification



3.3 Cement extravasation

In half of the studied cases, 24 patients, there was extravasation of cement during the kyphoplasty of the fractured vertebral body. The majority of cement leaks were in the disc space above the fractured vertebral body; 21 cases of the 24 patients with cement leak corresponding to 87.5% of all cases with cement leak. Ten cases had extravasation of cement in the lower disc space of the fractured vertebral body. Seven Patients had cement leak anterior to the fractured vertebral body and another seven patients had cement leaks lateral to the vertebral column. In all cases, no cement leak occurred in the spinal canal. Other from the literature, well-known complications of cement injection such as pulmonary embolism, neurological deficit or allergic reactions did not occur in our series.

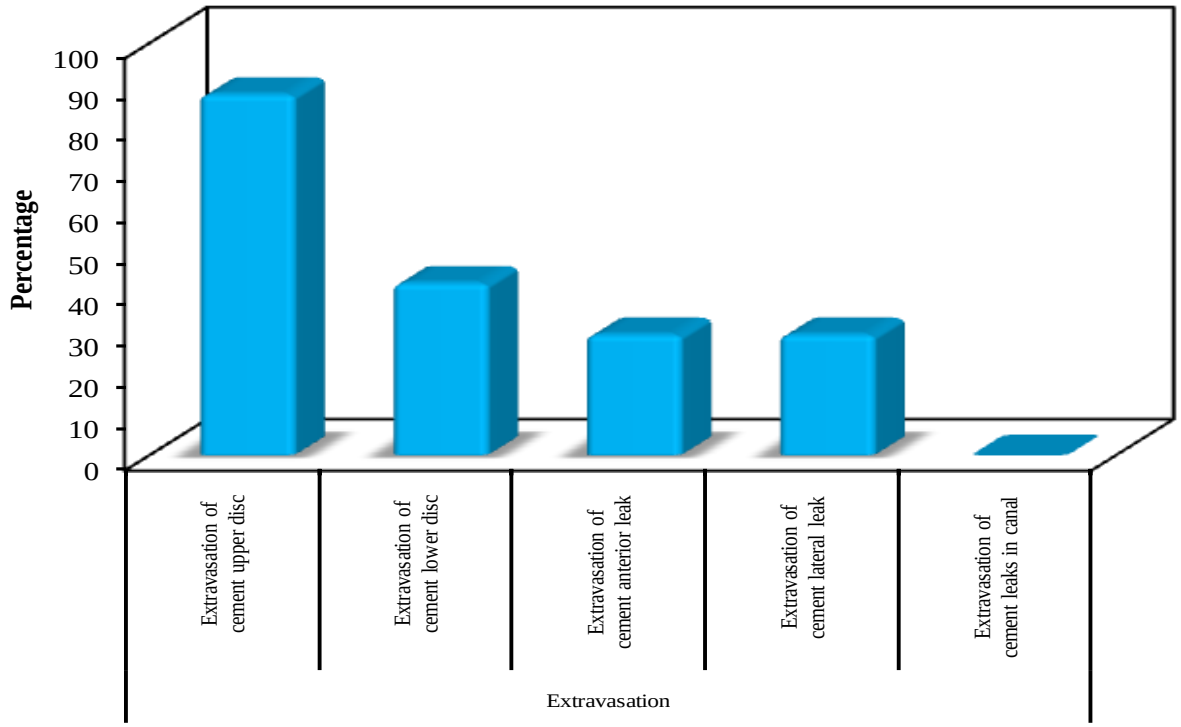


Figure (4): Distribution of the studied cases with cement leak according to site of extravasation of the cement

Furthermore, other complications due to surgery such as hardware failure, mechanical complications such as extra pedicular positioning of the screws, cerebrospinal fluid fistula, postoperative neurological deficits or deep wound infections did not take place.

3.4 Deformity analysis

To measure the kyphosis that resulted from the vertebral fracture, the Cobb angle was measured using the PACS software. The preoperative values ranged from 9.80° to 34.30° with a median value of 15.9°. There was a significant reduction of the Cobb angle immediately after the surgical intervention with values between 1.0° and 17.3° and median value of 4.75°. This showed a statistically significant reduction of the height of the fractured vertebrae with percentage of reduction at 64.9% and p value < 0.01

Over the 2 years follow-up period, there was a loss of the attained reduction of the fractured vertebrae. The median Cobb-angle value increased to 5.35° after 6 months, 5.80° after 1 year and 6.0° after 2 years. The percentage of reduction was therefore reduced from 64.9% to 60.5% after 2 years. The highest values for loss of correction after 2 years were noted with patients with associated osteoporosis.

Table (5): Descriptive analysis of the studied cases according to Cobb angle (n = 48)

	Preoperative	**Postoperative**				**$^{Fr}\chi^2$**	**p**
		Imm.	**6 months**	**1 year**	**2 years**		
Cobb angle							
Min. – Max.	9.80 - 34.30	1.0 - 17.30	1.90 - 24.10	2.0 - 18.10	2.20 - 20.50	105.930*	<0.001*
Mean ± SD.	16.71 ± 5.57	5.51 ± 3.16	6.15 ± 3.82	6.22 ± 2.81	6.33 ± 3.25		
Median	15.90	4.75	5.35	5.80	6.0		
p_0		<0.001*	<0.001*	<0.001*	<0.001*		
Mean difference		↓11.20 ± 5.22	↓10.55 ± 4.94	↓10.49 ± 5.19	↓10.38 ± 4.84		
% of reducation		64.93 ± 21.03	62.0 ± 19.69	60.51 ± 17.97	60.50 ± 18.45		

$^{Fr}\chi^2$: Chi square analysis for Friedman test
p_0: p value for Wilcoxon signed rank test for comparing between preoperative and each other periods
*: Statistically significant at p < 0.05

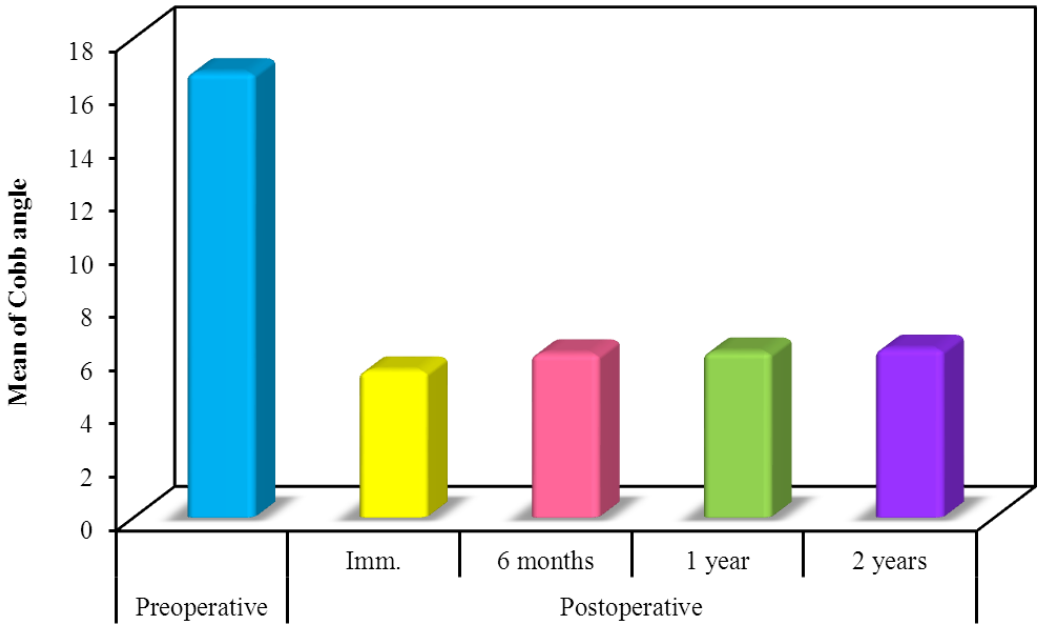


Figure (5): Descriptive analysis of the studied cases according to Cobb angle

The preoperative visual analogue scale values ranged from 6.0 to 10.0 with mean value of 8.9 and standard deviation of 1.3. Postoperative values ranged from 0.0 to 5.0 with mean value of 1.7 and standard deviation of 1.4. The visual analogue scale has dramatically improved after surgery from preoperative median value of 9 to postoperative median value of 2. This was statistically significant with $p < 0.01$

In our study, more than half of the cases (33 patients, 68.7%) had a Sextant system (Medtronic) implanted. 15 patients, 31.3% of the cases had Longitude Medtronic system (Medtronic) implanted. In 32 patients (66.7%), hydroxyapatite + polymethyl methacrylate (Kyphon Activ OS, Medtronic) was used as cement for the kyphoplasty. In the remaining 16 patients (33.3%), only polymethyl methacrylate (Kyphon X-pede, Medtronic) was used for the

kyphoplasty. In 29 cases (60.4%), a 20 mm balloon was used for the kyphoplasty. In only 2 cases of thoracic vertebral body fracture (4.2% of studied cases) a 10 mm balloon was used. In 17 cases (35.4%), a 15mm balloon was used for the kyphoplasty.

3.5 Comorbidities

All the vertebral body fractures in our study had a traumatic cause such as road traffic accident, falling on the back or direct trauma to the vertebral column. These patients had other associated traumatic injuries (47 cases, 97.9%) such as bone fracture and/or lung contusion and/or scalp wound and/or abdominal organ injury. Nine patients (18.8%) gave a history of osteoporosis with ongoing medical treatment. In total, 24 Patients, 50% of the studied cases, had hypertension as an associated disease.

3.6 Surgery time

The operative time ranged from 59 minutes to 185 minutes with a mean value of 99.4 min. and standard deviation of 30 min. According to operating dates, the first 5 operations had the longest operating time ranging from 120 to 185 minutes. The last 2 operations had the operating time of 59 and 73 minutes.

3.7 Hospital stay time

The postoperative hospital stay ranged from 4-29 days. The mean postoperative stay was 7.4 ± SD 4.4 days and a median value of 6 days. A patient stayed 29 days after the operation due to pneumonia not related to surgery. Due to a superficial wound infection after surgery another patient stayed in the hospital for 12 days till the surgical wound healed.

3.8 Cases

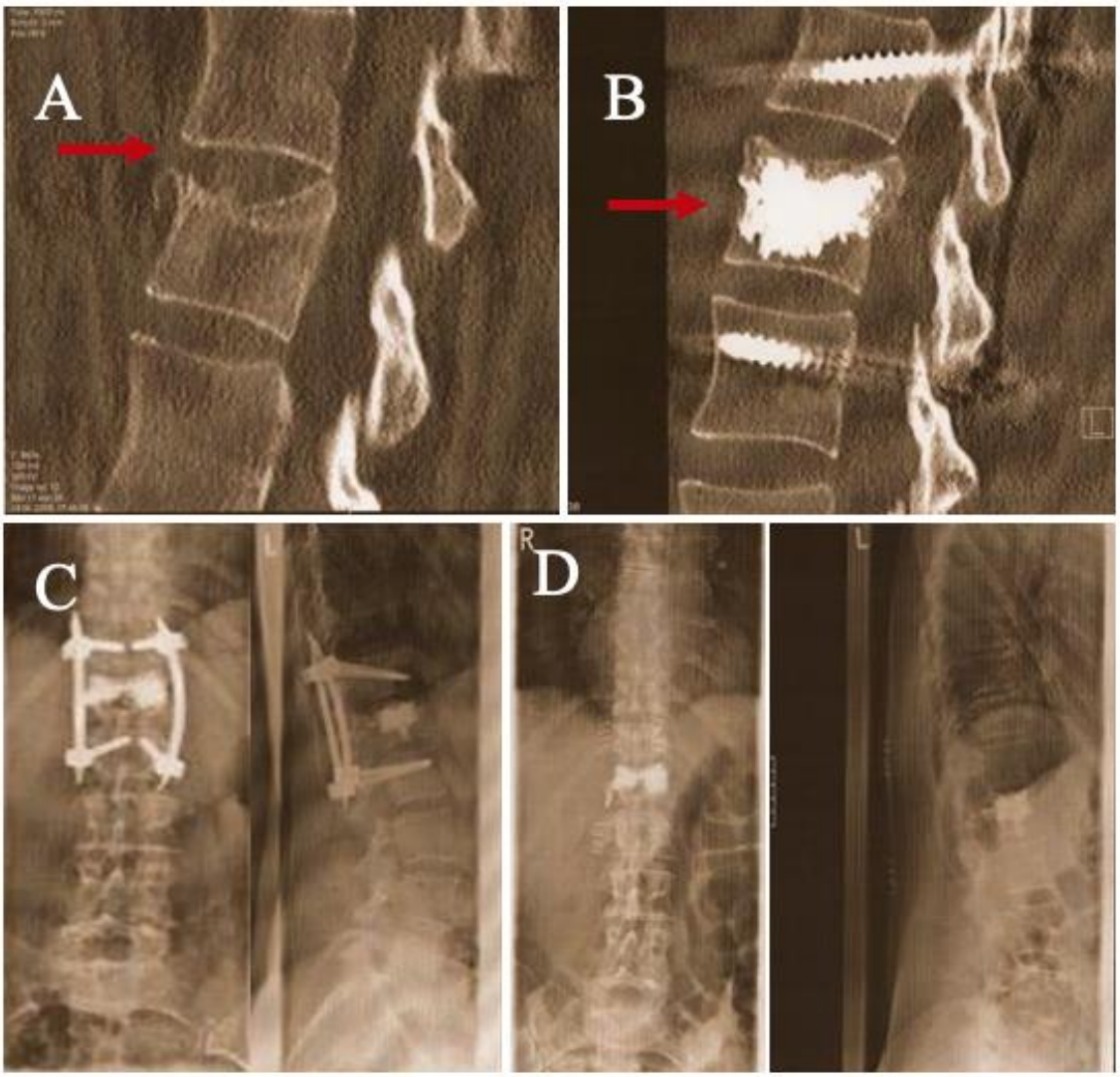


Figure (6): Case 1. (A) Sagittal reconstructed CT showing A.3.1 fracture (red arrow) (B) Postoperative sagittal reconstructed CT scan of the same patient showing the surgical treatment of the fracture and reversal of the kyphosis (red arrow) (C) Postoperative plain X-ray anterio-posterior and lateral views of the same patient showing minimal loss of reduction after 2 years (D) Postoperative plain-X-ray after removal of the percutaneous stabilizing system after 2 years.

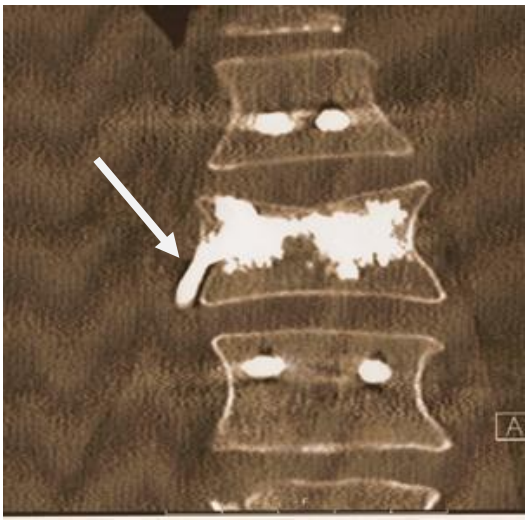


Figure (7) Case 2. Coronal reconstructed CT scan showing lateral extraspinal cement extravasation (white arrow) through the fracture line of the involved vertebra.

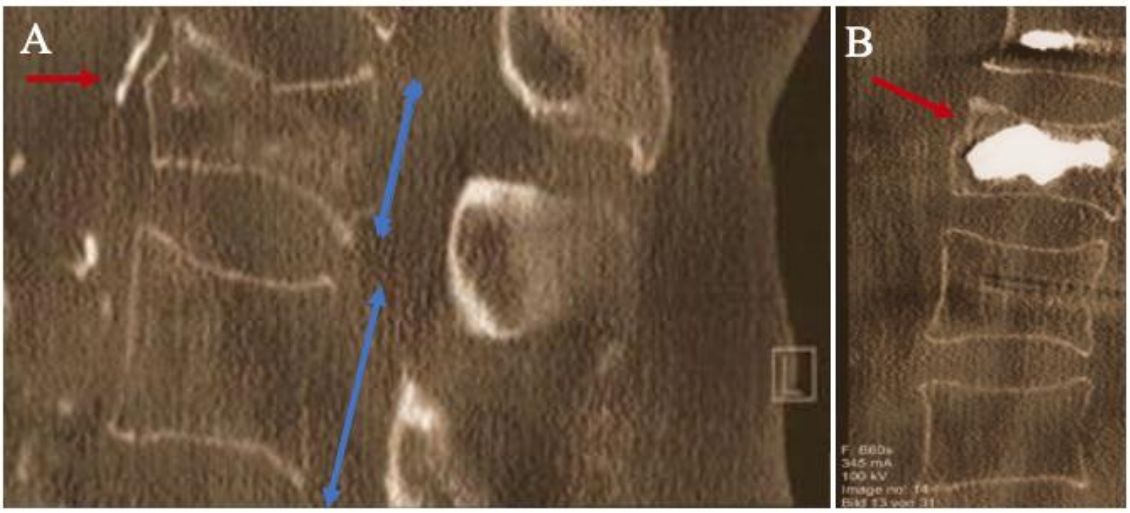


Figure (8) Case 3. (A) Sagittal reconstructed CT scan showing A.3.3 fracture (red arrow) and loss of vertebral height in comparison to next vertebral body (blue arrows) (B) Postoperative sagittal reconstructed CT scan of the same patient showing reduction and cement augmentation of the fracture (red arrow).

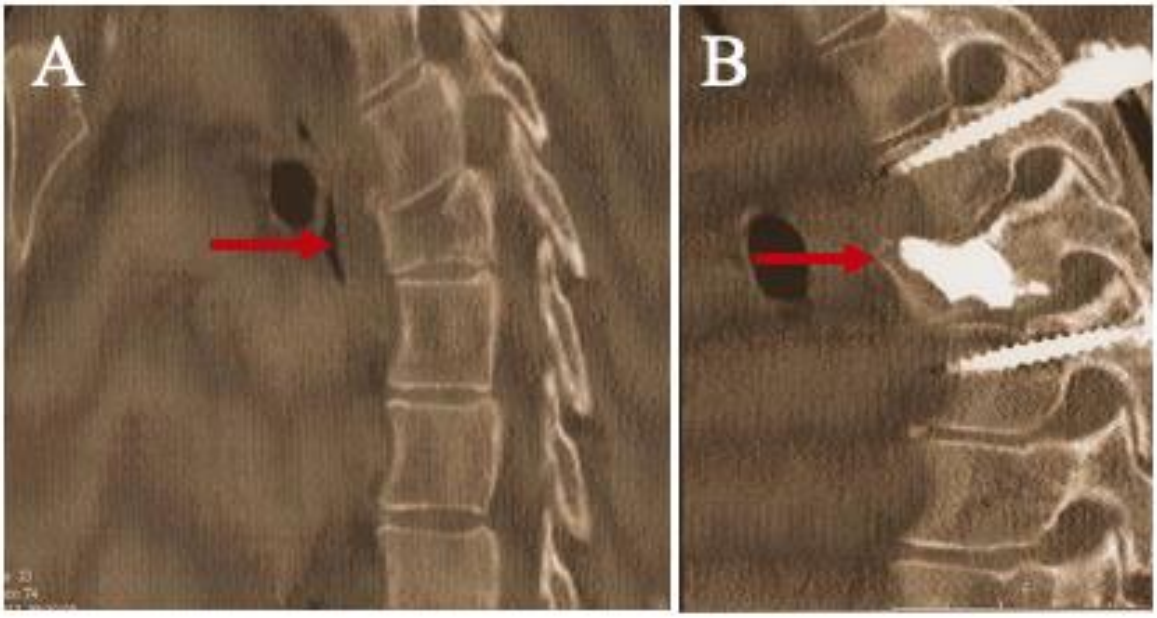


Figure (9) Case 4. (A) Sagittal reconstructed CT scan showing A.3.2 a thoracic vertebral fracture before (red arrow) (B) Postoperative sagittal reconstructed CT scan showing reduction of the thoracic fracture (red arrow).

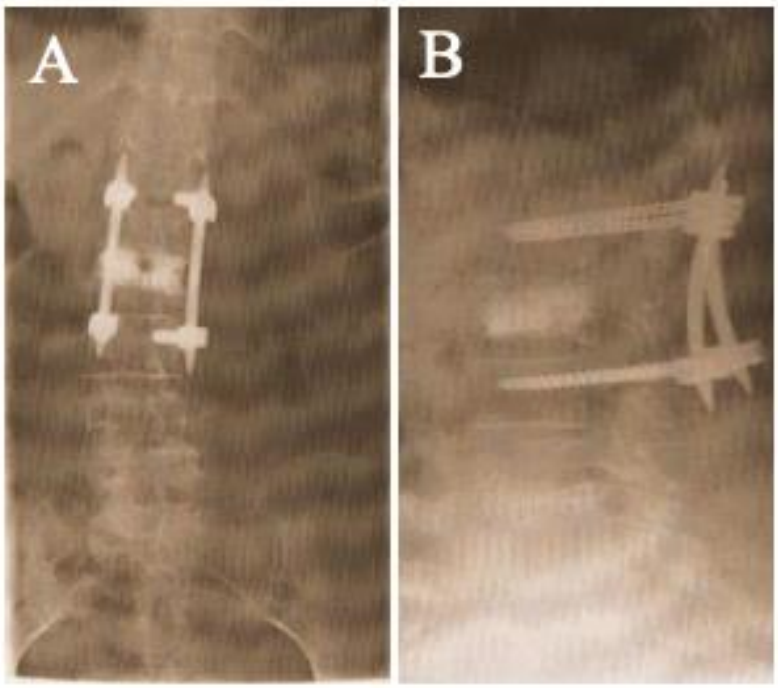


Figure (10) Case 5. (A) Plain x-ray a-p and (B) lateral views after 2 years of percutaneous stabilization and kyphoplasty showing reduction of the fracture without kyphosis.

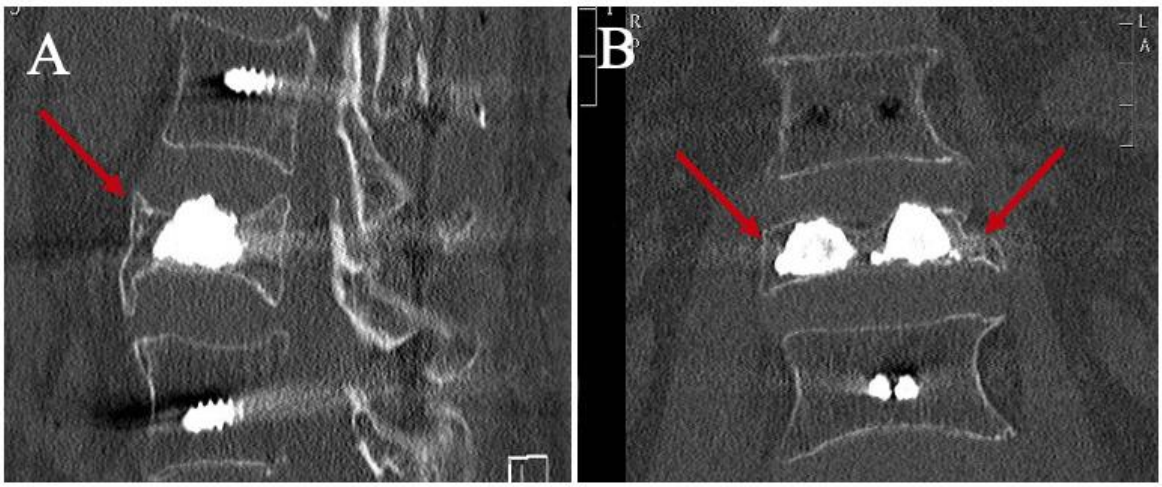


Figure (11) Case 6. (A) Postoperative sagittal and (B) coronal reconstructed CT scans of A.3.3 fracture (red arrows)

4 Discussion

Acute vertebral body fractures classified as A3 according to Magerl (1994) are unstable and require surgical treatment. Anterior column affection and the resulting kyphosis may inhibit fracture reduction. Moreover, a non-reduced vertebral body fracture with kyphosis applies further load on the anterior column, which may result in more pain or re-fracture in the affected segment (Gaitanis et al. 2005).

Therefore, reinforcing and restoring the anterior column helps the reduction of the fracture and improves the functional results after the operation (Freslon et al. 2008).

The combination of open posterior transpedicular screw fixation and anterior column reconstruction through anterior surgery proved an effective and efficient method to reduce the vertebral body fracture and stabilise it (Keynan et al. 2006).

In cases of acute vertebral body fracture without the need for neurological decompression, percutaneous transpedicular screw fixation showed similar results to open technique (Wild et al. 2007). Furthermore, intraoperative bleeding, postoperative pain and the total duration of hospital stay until discharge was less than open conventional technique (Rampersaud et al. 2006).

In our series, Sextant system (Medtronic) was used in 33 patients (68.8%) in cases of middle and lower lumber vertebral body fractures. With this system and technique, the rods are already pre-bent and can be only applied to the screws with a predefined amount of lordosis. Straight or in minimal kyphosis rod application, as in some cases of thoracic or upper lumbar vertebral body fractures is not possible. In such cases, 15 patients (31.3%) Horizon Longitude

(Medtronic) was used. The rod was modified to reduce the fracture and restore the sagittal balance according to the vertebral column segment.

The anatomical landmarks are one of the important guidelines in applying the screws using the open posterior transpedicular fixation technique. Knop et al. (2000) documented 6 to 7% error in non-navigated open pedicel screw application with fluoroscopy. In the present study, the screws were applied percutaneously under fluoroscopy. Postoperative CT scans showed no extra pedicular position of the screws or other errors of screw application.

The development of new minimally invasive techniques such as kyphoplasty made it possible to treat acute vertebral body fractures without open anterior or posterior fixation. This modality of surgical treatment has proven to reduce the fracture, stabilise the affected segment, minimize pain and initiate early mobilisation (Garfin et al. 2006; Hartmann et al. 2012; Wardlaw et al. 2009). Moreover, kyphoplasty restores the vertebral body height and supports the anterior column through inflation of the balloons. This balloon-induced reduction of the fracture is maintained by cement injection into the balloon-preformed cavity in the vertebral body. Under fluoroscopy and in good surgical hands is the technique of kyphoplasty safe. However, complications such as extravasation of cement, pulmonary embolism, severe allergic reaction for cement, haemorrhage and occurrence of new neurological deficits were reported. In a study performed by McArthur and colleges (2009) they experienced complications in 0,5% of operated patients. The complications varied between pulmonary embolism, new neurological deficit and/or hemorrhage. In the present series, we observed one complication regarding kyphoplasty in 24 patients (50%) in the form of cement leakage, all of them extraspinal with no evidence of pulmonary embolism or neurological compression. The high rate of cement extravasation was due to the structure of

the comminuted fracture with bone discontinuity at different sites of the vertebral body.

No case of deep infection was reported in this study. This can be explained by the small size of scars and absence of dead space as in open conventional technique, usually leading to such complications. Only one patient developed a superficial wound infection, healed after debridement of the wound and initiation of adapted antibiotic therapy, without hardware removal.

In 32 patients (66.6%), the cement injected was Kyphon Active Os (Medtronic) which consists of polymethyl methacrylate and hydroxyapatite. This combination was shown to be biocompatible with bone and on long term would be resorbed and replaced with natural bone (Grafe et al. 2008; Korovessis et al. 2008b). This could be promising in treatment of young patients with acute vertebral body fractures. However, the fact that hydroxyapatite will be eventually resorbed may lead to loss of the attained fracture reduction (Blattert et al. 2009; Heo et al. 2009). In 16 patients (33.3%), Kyphon X-pede (Medtronic) was applied. It consists of polymethyl methacrylate. The number of patients and the length of follow-up are insufficient to bring out a significant difference in this series.

To prevent the loss of attained reduction by acute vertebral body fractures through the minimally invasive kyphoplasty, an additional posterior transpedicular fixation was demandable. Ongoing with the same concept of conventional open 360° fixation through posterior transpedicular fixation and anterior surgery, minimally invasive kyphoplasty and percutaneous transpedicular screw fixation could reduce the fracture, pain and prevent kyphosis on the long term (Pflugmacher et al. 2009).

A biomechanical study conducted by Mermelstein (1998) showed that injecting cement in the vertebral body will reduce the stress applied to the transpedicular screws at the same segment. Therefore, the combination of kyphoplasty and percutaneous posterior screw fixation is advantageous.

To prove the efficiency of the percutaneous kyphoplasty combined with percutaneous transpedicular screw fixation in reducing the vertebral body fracture we measured the kyphotic angle before and after surgery. Furthermore, to detect the loss of reduction after surgery we measured the kyphotic angle over 2 years follow-up.

In our series, the mean value of the kyphotic angle measured by Cobb technique decreased from 16.7° preoperative to 5.5° immediately postoperative and was 6.3° at 2 year's follow-up with a significant p value < 0.01. The percentage of reduction was 64.9% and 60.5% after 2 years. A high Chi- square ${}^{Fr}\chi^2$ analysis of 105.9 and low p-value < 0.05 showed statistically significant difference in Cobb angle measurers postoperative in relation to preoperative values with significant reduction. The results were similar to the study by Gu (2013) where they reported a mean preoperative Cobb angle of 17°, immediately postoperative reduction to 6.4° and 7.1° after 2 years. He (2013) reported mean preoperative Cobb angle of 12°, 3° postoperative and 4.8° after 2 years. Korovessis (2008a) reported a series of 18 patients who underwent the same procedures for the treatment of burst fracture of the lumbar spine (L1-L4), the kyphosis due to vertebral body fracture improved from mean value of 16° to 2° postoperatively. Fuentes (2010) reported a series of 18 patients who underwent percutaneous short-segment stabilization and balloon kyphoplasty for the treatment of burst fracture (Magerl A3.1 and A3.3) (Magerl et al. 1994). Similar to our results, the local kyphotic angle was reduced from mean value 14.4° before the operation to 5.2° at 2 year's follow-up.

The loss of reduction after two years could be attributed to collapse in the adjacent discs whose quality may be poorer after traumatic injury. Another hypothesis is the resorption of the injected cement in the vertebral body. Nowadays, there are many surgical modalities for treating an unstable traumatic vertebral body fracture. These different surgical techniques can be gathered under three main variants: long segment posterior pedicle screw fixation, combined posterior pedicle screw fixation and anterior stabilisation or the combined short segment posterior pedicle screw fixation and cement augmentation of the anterior column.

Significant loss of reduction was noted in all 9 patients with osteoporosis. This may be another reason for the gain in the kyphotic angle and re-kyphosis. A greater number of patients and longer follow-up are needed to study the osteoporotic related loss of reduction after traumatic vertebral body fracture treated by combined percutaneous kyphoplasty and percutaneous posterior transpedicular screw fixation.

This percutaneous technique requires a relatively short learning curve. The operation time varied enormously according to the surgeon and his experience in conducting the percutaneous technique. In this series, the mean duration of the intervention was 99.4 min with operating time ranging from 59 – 185 min. This was similar to results of Zairi (2012) 102 minutes and longer than the operating time in the study by Gu (2013) which was 75 minutes.

Tan and colleagues (2020) performed a meta-analysis study comparing the results of conventional combined anterior and posterior fixation to only posterior fixation in cases of thoracolumbar vertebral body burst fractures. They included five retrospective coherent studies (Been und Bouma 1999), (Briem et al. 2004), (Danisa et al. 1995), (Mayer et al. 2017) and (Schmid et al.

2012), with data of 170 patients, in which 71 cases were operated with combined anterior and posterior fixation.

In the present study, our mean age was 58.83 ± 17.73 years and that was lower than the group Briem et al. (2004) analyzed, with a mean age of 63 ± 49.6, higher than Been's et al. (1999) 26.8 ± 8.6 , Danisa's et al. (1995) 36.8 (13–63), Mayer's et al. (2017) 34 ± 10.6, and Schmid's et al. (2012) 39.3 ± 13.5.

Briem et al. (2004) reported a female incidence in the combined anterior and posterior fixation group of 60%. Schmid et al. (2012) described lower female incidence of 23.8%. Our female incidence was 33.3%.

In our study we experienced cement extravasation during kyphoplasty in 24 patients, representing 50% of the cases without further pulmonary embolization or neurological deficits. No hardware or deep wound complications were reported. Danisa et al. (1995) reported a 50% rate of complication by the combined anterior and posterior fixation group in the form of pneumothorax, thoracic duct injury or hardware failure. On the other hand, Mayer et al. (2017) reported no cases of hardware failure in the combined anterior and posterior fixation group.

The reported mean operating time for combined anterior and posterior fixation was by Danisa et al. (1995) 569 ± 121 minutes, Schmid et al. (2012) 213 ± 41 minutes. We had significant shorter operating time of 99.4 ± 29 minutes.

Tan et al. (2020) described a longer postoperative hospital stay in the groups with combined anterior and posterior fixation within one of the studies reaching 22 ± 7.0 days. In our study the postoperative hospital stay ranged from 4-29 days. The mean postoperative stay was 7.3 ± 4.3 days.

Regarding the correction of the Cobb angle, as mentioned before, our study demonstrated a significant reduction of the mean Cobb angle from preoperative 16.7° (range 9.8°-34.3°) to 5.5° (range 1.0°-17.3°) postoperative with mean change value of 11.2°. The conducted meta-analysis study by Tan et al. (2020) and colleagues, showed higher postoperative Cobb angle value in the combined anterior and posterior fixation groups with mean value of 8.5° (range 2.4°-18.5°) and lower percentage of fracture reduction with mean change value of Cobb angle 7.5°. Very interesting was the stable pattern of the Cobb angle during the follow up period. According to Tan et al. (2020) no significant loss of reduction occurred in the combined anterior and posterior fixation group during the follow up period. In our study there was a reported loss of the attained reduction of the immediate postoperative Cobb angle in the 2 years follow-up with final mean value of 6.3°.

Kyphoplasty combined with percutaneous transpedicular screw fixation has with no doubt proved to be an effective method of treating acute vertebral body fracture classified as A3 according to Magerl (1994).

The minimal invasive technique allows early mobilization and discharge after surgery with fewer complications. The postoperative reduction of the kyphotic angle of the vertebral body fracture measured with Cobb angle was significant. Furthermore, over the 2 years follow up, the loss of reduction measured by the gain in the Cobb angle was reasonable. However, longer follow-up periods are necessary.

The percutaneous posterior transpedicular screw fixation combined with kyphoplasty provides the needed 360° fixation of the comminuted vertebral fracture with good support of the anterior, middle and posterior vertebral columns. It can safely substitute the conventional open combined anterior and

posterior surgery of the acute vertebral body fracture classified as A3 according to Magerl (1994).

A meta-analysis study performed by Tan and colleagues (2019) included six studies and compared patients with traumatic vertebral body fractures whom were treated with posterior pedicle screw fixation with others who were treated with combined anterior and posterior stabilisation. They concluded that there was no significant difference in the radiological, deformity and functional outcomes between posterior screw fixation versus combined posterior and anterior fixation of traumatic vertebral body fractures. The variable follow-up data showed no significance loss of reduction in both groups.

Similarly, the study conducted by Spiegl and colleagues (2018) and Uchida and colleagues (2010) comparing posterior versus combined anterior and posterior fixation of vertebral body fractures showed no significant difference in the postoperative reduction of the fracture as well as maintaining the reduction for the first 2 years.

Hughes et al. (2021) conducted a meta-analysis study that included 4 randomized controlled trials with 145 patients with traumatic vertebral body fractures. The study showed that the patients operated with combined anterior and posterior fixation had better outcome in terms of long-term maintaining the attained postoperative reduction of the fracture with no significant difference of the immediate postoperative correction. Furthermore, Operl et al. (2010) concluded that the postoperative reduction of traumatic vertebral body fractures was better in patients operated with combined anterior and posterior fixation rather than posterior fixation alone.

This difference in the outcome could be attributed to many different factors. For example, the heterogeneity of the posterior fixation group in the study

conducted by Hughes et al. (2021), some patients were treated with pedicle screws 2 levels above and one level below the fractured vertebrae. Others were treated with two segment pedicle screw fixation and bone graft. Also, patients operated with combined anterior and posterior fixation were heterogonous: some had plates fixated anteriorly, others were fixated with iliac crest and screws. These differences may all affect the results of reduction and long-term follow-up of the kyphosis. Moreover, the limited variable durations of follow-up may be another significant limitation for this study. Hughes et al. (2021) included 2 studies which were conducted in China, 1 study in Turkey and 1 study in Germany. The variability of the race and whether or not if included in the same group of patients to be compared may affect the results. Last but not least, the type of fracture plays an important role in determining the outcome as well as expected loss of reduction in follow-up period. This was not clearly mentioned in the study conducted by Hughes and colleagues (2021).

Similar to our study, Spiegl et al. (2018) also performed combined posterior screw fixation with kyphoplasty of the fractured vertebral body. They compared the results with the combined anterior and posterior fixation in management of the vertebral body fracture and found no significant difference in the postoperative results up to 2 years follow-up. This significantly showed that the combination of posterior pedicle screw fixation and kyphoplasty of the fractured vertebral body is effective in terms of fracture reduction and clinical outcomes as the combined 360° anterior and posterior fixation. However, this study has limitations as it was performed only for patients between age of 60 and 70. It also included other types of vertebral body fractures other than burst fractures e.g. B and A2 fractures according to AO classification. Furthermore, the small number of patients (29 patients) may be insufficient for a proper statistical analysis of the results.

Another determining factor in patients with traumatic vertebral body fractures is the presence or absence of neurological deficits. In our study, all patients included were neurologically intact. Therefore, a neurological decompression was not needed. This supported the percutaneous instrumentation and kyphoplasty. However, in cases where a neurological decompression is intended Tan and colleagues (2019) favoured the combined anterior and posterior decompression and fixation versus posterior decompression and fixation. The results of the study showed better neurological decompression through anterior defect.

The combined anterior and posterior fixation of vertebral body fractures allows a short posterior segment fixation and fusion versus long posterior segment fixation by posterior approach alone. Arguably, this helps in preserving the motion segments adjacent to the fractured vertebral body (Tan et al. 2019).

Longer operating time, extensive blood-loss and longer postoperative hospital stay remains a serious disadvantage of combined anterior and posterior fixation of the vertebral body fractures and favours an open or percutaneous posterior approach for stabilisation (Danisa et al. 1995; Hughes et al. 2021; Schmid et al. 2012; Spiegl et al. 2018; Tan et al. 2020; Tan et al. 2019). This is usually contributed to the narrow field of the operation corridor and the familiarity most surgeons have with the posterior approach rather than the anterior one. Smits and colleagues (2018) reported that new minimally invasive and endoscopic anterior approaches to the spine can effectively decrease blood loss and operating time.

Kyphoplasty combined with percutaneous transpedicular screw fixation has with no doubt proved to be an effective method of treating acute vertebral body

fracture classified as A3 according to Magerl (1994). The postoperative reduction of the kyphotic angle of the vertebral body fracture measured with Cobb angle was significant. Furthermore, over the 2 years follow-up, the loss of reduction measured by the gain in the Cobb angle was reasonable.

Several meta-analysis studies as well as several other studies have showed no significant difference in the radiological, clinical and functional outcome of patients treated with posterior pedicle screw fixation versus combined anterior and posterior stabilization of the fractured vertebral body (Hughes et al. 2021; Spiegl et al. 2018; Tan et al. 2020; Tan et al. 2019). Moreover, the minimal invasive technique allows early mobilization and discharge after surgery with fewer complications. The percutaneous posterior transpedicular screw fixation combined with kyphoplasty provides the needed 360° fixation of the comminuted vertebral fracture with good support of the anterior, middle and posterior vertebral columns. This hybrid technique does not address traumatic injured intervertebral discs hence a long-term loss of reduction may be higher compared to patients operated with a combined anterior and posterior stabilization. However, longer follow-up periods are necessary.

This study was conducted to patients with traumatic vertebral body fracture without neurological deficits. In cases of intended neurological decompression, this hybrid technique remains unsuitable and an open posterior or combined anterior and posterior approach should be used. Tan and colleagues (2019) were in favor of a combined anterior and posterior approach as the corporectomy provided better decompression of the neurological structures.

We acknowledge that our study has limitations. Longer postoperative follow up periods of the patients (more than 2 years) is important to detect further loss of reduction or clinical and/or neurological deterioration. There might be a bias

in selecting the patients to be included in our series as there was no randomization due to the retrospective nature of our study.

Last but not least we compared our results to other meta-analysis and systemic review studies as our study did not include patients operated with combined anterior and posterior fixation or long segment posterior fixation.

5 Summary

There are different methods for treating vertebral body fractures especially those without neurological deficits. For decades before, conservative therapy was the first line of treatment. Based on the fact that bone heals physiologically, many fractures may be treated conservatively, but the risks of secondary neurological complications due to the occurrence of local deformity such as kyphosis as well as the development of minimally invasive techniques have given rise to new surgical methods. The goal of treatment is the same in all cases; reduce pain, reduce the fracture and restore mobility.

Balloon kyphoplasty combined with percutaneous osteosynthesis provides an effective and safe surgical treatment for patients with traumatic A3 fractures according to Magerl (1994). Aside from reduction of the vertebral body fracture and the kyphotic deformity, it also instantly strengthens the anterior and middle spinal column by the solidification of the bone cement in the vertebral body.

The clinical results showed excellent pain reduction with minimal muscle trauma in a relatively short operation time. The wound healing process was fast with small scars. The patients could be early discharged without the need to wear brace.

From the literature as reported by McArthur (2009), a lot of complications due to kyphoplasty or due to the osteosynthesis were previously reported such as severe reaction to the cement, pulmonary embolus, extravasation of the cement inside the spinal canal and neurological deficits. The present series showed that the combination of percutaneous

kyphoplasty and osteosynthesis is very safe in the treatment of vertebral body fractures.

The radiological postoperative results showed reduction of the vertebral body fracture after surgery and correction of the kyphotic angle measured with Cobb technique. The loss of initially achieved correction was relatively small over a follow-up period of two years. The mean Cobb angle value increased to 6.1° after 6 months, 6.2° after 1 year and 6.3° after 2 years. The percentage of reduction was therefore reduced from 64.9% to 60.5% after 2 years. Patients with associated osteoporosis showed the highest values for loss of reduction indicating a possible relationship between osteoporosis and loss of correction.

The combination of percutaneous osteosynthesis and kyphoplasty may be an efficient alternative to conventional open surgery, but a greater number of patients and longer follow-up time are required in order to make definitive statement possible.

6 Literature

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