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Research Article

Clinical Measurement of Intravertebral Pressure During Vertebroplasty and Kyphoplasty

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Background: Vertebroplasty (VP) and kyphoplasty (KP) are emerging procedures for almost immediate pain relief when treating osteoporotic or osteolytic fractures. The main reported complication is polymethylmethacrylate (PMMA) leakage, which may lead to compression of neural structures or embolism. Different authors have proposed that intravertebral pressure (IP) is an important factor determining the risk for leakage, although so far only limited information has been gathered from clinical and experimental studies. There is also a lack of understanding of the IP during conventional interventions in VP and KP in the clinic.

Objective: 1) To compare the intravertebral pressures of compressed vertebrae and adjacent normal vertebrae. 2) To measure the IP of compressed vertebrae during VP and KP.

Setting: An interventional pain management practice, a medical center, major metropolitan city, in the People's Republic of China.

Methods: Thirty-five patients (with 40 compressed vertebrae and 35 adjacent normal vertebrae) were randomly allocated for intravertebral pressure measurements. Cannulas were placed bipedicularly into the posterior third of each vertebral body. Either PMMA or a balloon was injected into the vertebral body through the right cannula. A manometer was connected to the cannula in the left pedicle, and heparin was injected to verify the pressure measurement system.

Results: The range (minimum-maximum), average IP, and the standard deviation of the compressed vertebrae were 0-39 mm Hg and 24.5 ±11.3 mm Hg; and that of adjacent normal vertebrae were 3-16 mm Hg, 7.3 ± 4.2 mm Hg. Furthermore, the average IP for Phase 1 (before PMMA injection) for VP was 23 ±11.9 mm Hg; the maximum IP recorded during injection was 169 ± 46.8 mm Hg and the IP for 10 minutes after injection was 33 ±9.4 mm Hg. Meanwhile, the highest IP recorded for KP patients was 142 ±39.6 mm Hg. The average IP for Phase 1 (before balloon inflation) was 24 ±12.7mmHg; Phase 2 (peak IP during the balloon inflation) was 63 ± 25.8 mm Hg; and Phase 3 (after balloon inflation/before PMMA injection) was , and 18 ± 10.8 mm Hg. The IP for 10 minutes after injection in KP patients was 36 ± 8.5 mm Hg.

Limitations: The flow rate was manually controlled, which is in line with clinical routine, and was kept at approximately 0.1 mL/s. Because the speed of injection was controlled by hand, an exact injection rate could not be assured, leading to some inaccuracy when comparing the IP of VP and KP patients. Each patient was injected with a different PMMA volume. Because PMMA injection was performed to a satisfactory vertebral body filling and limited by any signs of extravasation, it was difficult to maintain a constant injection volume, unlike in vitro studies. Other factors such as the damage to the vertebral shell or the degree of osteoporosis might also have affected the intravertebral pressure.

Conclusion: This study showed that the IP of compressed vertebrae was significantly higher than that of adjacent normal vertebrae. There was a significant increase in IP during the PMMA filling in VP and KP; the IP of compressed vertebrae was not significantly reduced by the balloon inflation in KP, and no statistically significant differences in IP were found during all common stages of PMMA filling in VP and KP.

Key words: Vertebroplasty, kyphoplasty, intravertebral pressure, PMMA leakage.

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Percutaneous augmentation of vertebral bodies with polymethylmethacrylate (PMMA), which has been reported to be an effective surgical procedure for patients suffering from osteoporotic or osteolytic fractures, has been rapidly increasing as a treatment over the last decade.

Vertebroplasty (VP) was initially introduced in France in 1984 by the interventional neuroradiologist Herve Deramond (1). It has since been widely used to treat spinal fragility fractures, restore vertebral body stiffness and strength, and most importantly, to provide immediate pain relief (2-4). Kyphoplasty (KP) was first employed by an orthopedic surgeon, M. A. Reiley, in 1997 as a treatment for vertebral compression fractures. In this procedure an inflatable balloon is introduced into the collapsed vertebral body. This procedure elevates the endplates and restores the vertebral body height,; thereby creating a void to be filled with PMMA, thus minimizing the associated kyphotic deformity (5).

One of the major reasons for the increasing application of these minimally invasive techniques is that they provide immediate and effective pain relief after the procedure. Biomechanical data comparing the mechanical stabilization by VP and KP have yielded similar results (6). KP is even sometimes referred to as "balloon-assisted vertebroplasty." Meanwhile, manufacturers and proponents of both devices (VP and KP) describe their individual advantages. KP proponents routinely point out the reduced likelihood for PMMA leaks with this procedure, as compared with VP (7). This is thought to occur because the injection of PMMA in VP is purportedly under "high pressure," whereas KP fills a void created by the balloon inflation and is therefore "low pressure" (8).

There is an increasing interest in the clinical results and complications of these surgical techniques. The main reported complication is PMMA extravasation, which may lead to compression of neural structures or embolism (9). Different reasons for the uncontrolled flow of PMMA have been discussed. Its viscosity, injection rate, volume, and individual vascularization of the vertebral body are currently regarded as potential reasons for the uncontrolled flow. However, the role of intravertebral pressure (IP) in the generation of PMMA leakage remains unclear.

A growing number of biomechanical studies have investigated IP during VP or KP. Baroud et al (10) reported that the vertebral shell influenced the generation of pressure because it confined the flow of PMMA in the vertebral body, but the presence of the shell contributed trivial effect to the injection pressure, which was much larger than the intravertebral shell pressure (10). Reidy et al (11) reported that percutaneous VP produced higher intravertebral pressures in vertebrae containing a simulated lytic metastasis than in intact vertebrae. Pressures generated in the tumor specimens were sufficiently elevated to cause embolic phenomena (11). In another important study, Weisskopf et al (12) investigated the IP in the central portion of a cadaveric vertebral body during injection of PMMA in both VP and KP. They suggested that the IP measured during PMMA augmentation in cadaveric spines was lower in KP than in VP. In the KP group, a relative increase of the IP was registered at the terminal state of PMMA delivery when the cavity was overfilled (12). However, there is still a lack of understanding of the IP during conventional VP and KP interventions in the clinic.

In this study, we compared the intravertebral pressures of compressed vertebrae and adjacent normal vertebrae, and measured the IP of compressed vertebrae during conventional VP and KP interventions.

Methods

Patient Population

Thirty-five patients (23 women, 12 men; aged 55-86 years, mean age 73.7; 40 compressed vertebrae; 35 adjacent normal vertebrae) were randomly allocated for intravertebral pressure measurements. Candidates were selected from patients admitted to the orthopedic department for VP or KP due to osteoporotic vertebral compression fractures. Patients selected for pressure measurements had sustained between one and 2 vertebral compression fractures.

Measurements

The following procedural steps were performed for testing.

(1) To determine the IP of the compressed vertebra and an adjacent normal vertebra:

The left pedicles of the compressed vertebra and an adjacent normal vertebra were both cannulated via a transpedicular approach with an 11-gauge bone biopsy needle. The working cannulas were then placed in the posterior third of the vertebrae. Radiographs were taken to confirm correct cannula placement. A manometer was connected to the cannulas in the left pedicle of the compressed vertebra and an adjacent normal vertebra, and heparin was injected to verify the pres-

sure measurement system The IP of the compressed vertebra and an adjacent normal vertebra were recorded by the experimental setup (Fig. 1).

(2) To test the IP during VP or KP:

The left cannulas were kept in the left lateral third of the posterior third of the vertebra to test the IP during VP or KP. The right pedicle of the compressed vertebra was cannulated via a transpedicular approach with an 11-gauge bone biopsy needle. PMMA was injected through the right cannula. The IP of the compressed vertebra was recorded at different intervals during conventional VP and KP. In KP, a balloon was introduced through the right cannula and inflated to a different volume in each patient (Fig. 2). PMMA was injected following a visual appraisal of its viscosity. It

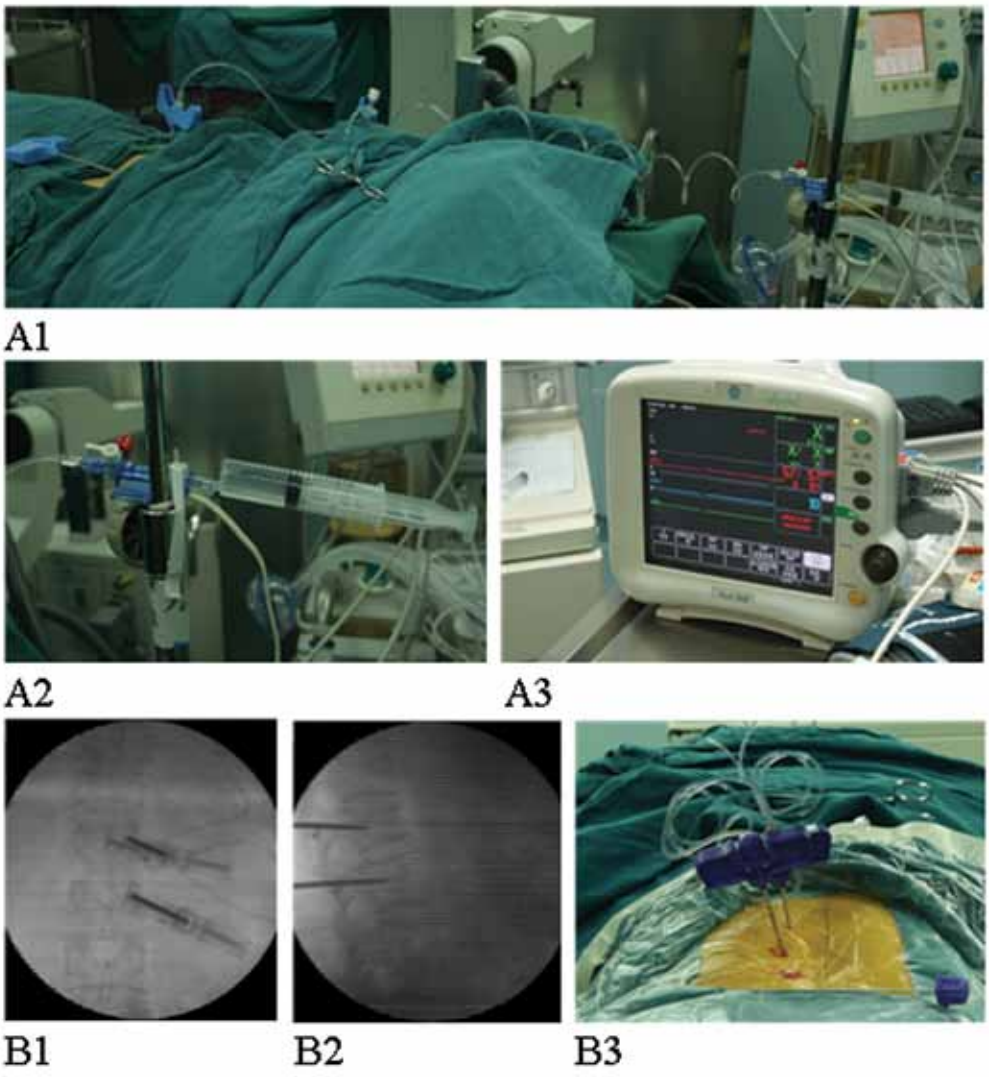

Fig. 1. *A1-A3, experimental setup. The intravertebral pressure was measured using a manometer (A3) connected to a cannula inserted in the posterior third of the vertebrae (A1) through a pressure sensor (A2). B1-B3, typical images showed the clinical measurement of the IP of compressed vertebrae and adjacent normal vertebrae. Cannulas were placed in the left lateral third of the posterior third of the vertebrae (B3). Radiographs were taken to confirm correct cannula placement (B1, anteroposterior radiograph; B2, lateral radiograph). (L1, compressed vertebra; L2, normal vertebrae). The IP of the compressed vertebra and adjacent normal vertebrae were recorded with the pressure measurement system.*

was performed to a satisfactory vertebral body filling and limited by any signs of extravasation. The PMMA was injected by hand at an average rate of 0.1 mL/s and introduced into the vertebral body via the same deliv-

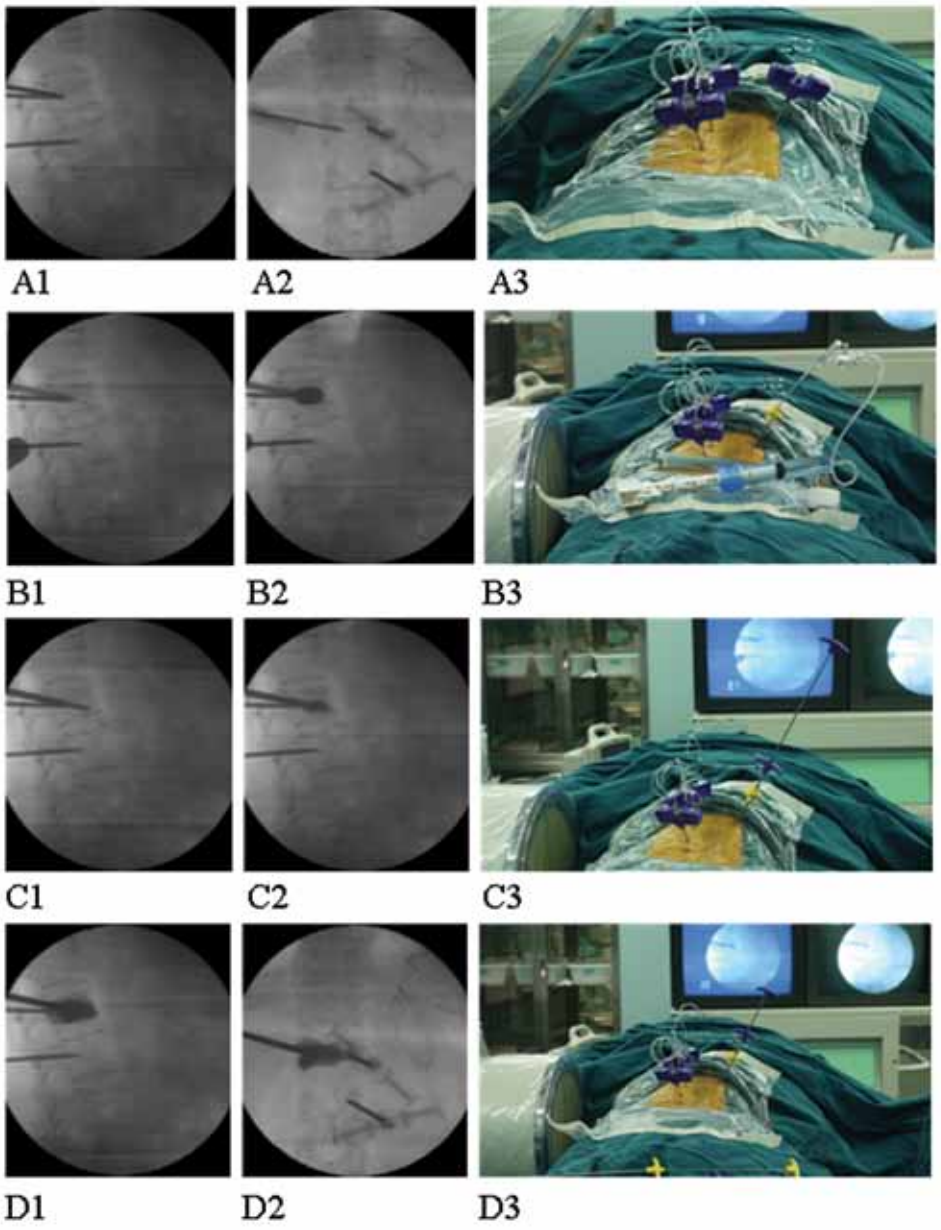

Fig. 2. *Clinical measurement of the IP of compressed vertebral body (L1) was performed during KP. The cannulas were kept in the left lateral third of the posterior third of the vertebra after testing the IP of the compressed vertebra and adjacent normal vertebrae. Sequential intraoperative and fluoroscopic images: A1-A3, the right pedicle of the compressed vertebral body was cannulated via a transpedicular approach with an 11-gauge bone biopsy needle. Then the IP was recorded as the data of the first stage (Phase 1). B1-B3, balloon was delivered to the position. Radiographs showed the balloon inflation during KP. Meanwhile, we recorded the peak IP in this process as the data of the second stage (Phase 2), then recorded the IP after balloon inflation as the data of the third stage (Phase 3). C1-C3, PMMA injection after the balloon removal. Likewise, the peak IP in this process was made as the data of the fourth stage (Phase 4). D1-D3, PMMA injection was performed to a satisfactory vertebral body filling. The left cannulas were still located in the primary place for 10 minutes after PMMA injection. The IPs were recorded by the manometer through the left pedicle at this time point (Phase 5). In addition, the process of testing IP during VP was performed via the similar regimen (without Phase 2 and Phase 3 because of no balloon inflation) as described for KP.*

ery device. Thus there was no difference in the length and diameter of the injection cannula.

Statistical Analysis

Data were calculated and presented as mean, and standard deviation for the IP of the various intervals during VP and KP by a statistician not involved with data acquisition. Statistical analysis for the difference between the values acquired from VP and KP was performed using the Student's t test for unpaired groups. A probability (P) value of less than 0.05 was considered as a significant difference. Statistical analyses were conducted using SPSS 11.0 (SPSS Inc., Chicago, IL).

Results

We first examined the intravertebral pressures of the compressed vertebra and an adjacent normal vertebra. Summarized data are displayed in Table 1. The range (minimum-maximum), average IP and the standard deviation of the compressed vertebra were 0-39 mm Hg, 24.5 ± 11.3 mm Hg, and that of the adjacent normal vertebra were 3-16 mm Hg, 7.3 ± 4.2 mm Hg. The results showed that the IP of the compressed vertebra was significantly higher than that of the adjacent normal vertebra. Meanwhile, we found that the IP of the individual compressed vertebra was 0 mm Hg, while a similar result was not found in the adjacent normal vertebra.

Next, we measured the intravertebral pressure at each time point during VP and KP. These data are summarized in Table 2. The average IP for Phase 1 (before PMMA injection) for VP was 23 ± 11.9 mm Hg,; the maximum IP recorded during injection was 169 ± 46.8 mm Hg,; and the IP for 10 minutes after injection was 33 ± 9.4 mmHg. Meanwhile, the highest IP in patients for KP recorded was 142 ± 39.6 mm Hg. The average IP for Phase 1 (before balloon inflation) was 24 ± 12.7 mm Hg; Phase 2 (peak IP during balloon inflation) was 63 ± 25.8mmHg; and Phase 3 (after balloon inflation/ before PMMA injection) was 18 ± 10.8mmHg. The IP for 10 minutes after injection in KP was 36 ± 8.5 mmHg. The relationship between IP and the phases of KP and VP during the various intervals of PMMA injection is summarized in Fig.3. These results showed that the average IP for Phase 4 was significantly higher than the IP of the other phases in VP and KP. There was a significant increase in IP during the cement filling in VP and KP. In KP, the average IP for Phase 3 had a slight reduction after balloon inflation, as compared to the IP for Phase 1. However, this reduction was not statistically significant ($P > 0.05$). Therefore the IP of the compressed vertebra was not significantly reduced by the balloon inflation in KP. No statistically significant differences in intravertebral pressures were found during the common stages of PMMA injection (Phases 1, 4, 5) in VP and KP.

Discussion

Vertebroplasty and kyphoplasty are emerging pro-

Table 1. *Summarized Data of the Intravertebral Pressure (mmHg) in the Compressed Vertebrae and Adjacent Normal Vertebrae*

	N	Level	Range(min-max)	average IP	SD
Normal vertebrae	35	T11-L5	3-16	7.3	4.2
Compressed vertebrae	40	T11-L5	0-39	24.5	11.3

Table 2. *Summarized Data of the Intravertebral Pressure (mmHg) During Vertebroplasty and Kyphoplasty*

	Vertebroplasty	Kyphoplasty
N (Compressed vertebrae)	18	22
Level	T11-L5	T11-L5
Volumes of balloon inflation (Range, Mean)	-	1-3.5 mL, Mean 2.4 mL
Cement volumes (Range, Mean)	2-6 mL, Mean 3.8 mL	2-7.5 mL, Mean 4.6 mL
IP at different stages of VP or KP:		
Phase 1: Before cement injection in VP or before balloon inflation in KP	23±11.9	24±12.7
Phase 2: Peak IP during the balloon inflation in KP	-	63±25.8
Phase 3: After balloon inflation (before cement injection) in KP	-	18±10.8
Phase 4: Peak IP during cement injection	169±46.8	142±39.6
Phase 5:10minutes after injection	33±9.4	36±8.5

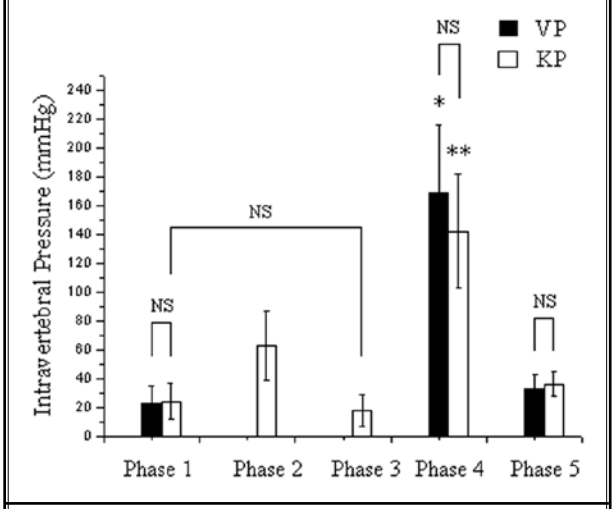

Fig. 3. *Average IPs for the different intervals were recorded during VP and KP. Phase 1: Before PMMA injection in VP or before balloon inflation in KP. Phase 2: Peak IP during the balloon inflation in KP. Phase 3: After balloon inflation (before PMMA injection) in KP. Phase 4: Peak IP during PMMA injection. Phase 5: 10 minutes after injection.*

* P < 0.05 Peak pressure during injection in VP versus the IP of other phases (before injection, 10 minutes after injection in VP); ** P < 0.05 Peak pressure during injection in KP versus the IP of other phases (before balloon inflation; Peak IP during the balloon inflation; after balloon inflation; and 10 minutes after injection in KP). NS, not significant.

cedures for almost immediate pain relief when treating spinal osteoporotic or osteolytic fractures. The main complication is PMMA leakage into adjacent structures (13-15) which can lead to spinal cord or nerve root compression (16-18) or pulmonary embolism (19-21). Different authors have proposed that IP is a determinant factor of the risk for leakage (7,14,22,23), although so far this has not been confirmed by clinical and experimental studies. The purpose of this study was to compare the intravertebral pressures of a compressed vertebra and an adjacent normal vertebra, and to quantify and compare the IP recorded from the compressed vertebral body during VP and KP in patients.

PMMA volume, vertebral shell (degree of damage to the vertebral shell), injection rate (flow rate), bone mineral density (BMD), and degree of osteoporosis are currently proposed as potential factors affecting IP. There is no definite answer for whether BMD has an influence on IP. Baroud et al (10) found no correlation between the injection pressure or the shell pressure and BMD. This finding was supported by a biomechanical study by Reidy et al (11), which also reported that there was no correlation between BMD and intravertebral pressure. However, Heini et al (24) reported a weak correlation between the injected PMMA volume and BMD in their biomechanical study.

The influence of injected PMMA volume on the IP and extravasation was discussed in several different studies. In an important clinical study, Ryu et al (14) reported that epidural leakage of PMMA after percutaneous vertebroplasty was dose dependent; the larger the amount of injected PMMA, the higher the incidence of leakage. In vertebral bodies, when < 2 mL was injected, the percentage of epidural leakage was 28%. When volumes in excess of 6 mL were injected into the vertebral body, the leakage rate rose up to 39% (14). Weisskopf et al (12) found in a cadaver study that in all cases extravasation occurred in the final stage of PMMA delivery, and in KP a relative increase of the IP was registered when the cavity was overfilled.

There are different views about whether the injection rate (flow rate) affects the IP and extravasation (8,14,22,25). In an experimental study using a theoretical model, Bohner et al (25) reported that the most practical way to decrease the risk of extravasation is to increase the PMMA viscosity (inject it with a low flow rate). In contrast, Krebs et al (22) showed that no statistically significant differences were found between injection pressures with wide and normal syringes, and the flow rate didn't affect the IP and extravasation. Loeffel et al (26) supported this point that the injection speed had no significant effect on circularity and mean PMMA spreading distance in an experimental study.

The vertebral shell is important for the pressure generated in the vertebral body because the shell constitutes a confined space and restricts the flow of PMMA within it. The vertebral shell, as a boundary condition, is an integral component of the hydraulic resistance of a vertebral body and the hydraulic resistance is a key determinant of the intravertebral pressure (10). Baroud et al (10) reported that a closed fenestration resulted in a significant increase in the intravertebral pressure at the shell. During the injection, the shell pressure increased on average to approximately 3.54 ± 2.91 kPa. Conversely, an open fenestration resulted in an instant relaxation of the shell pressure to the ambient pressure of 0 kPa. Therefore the presence of the vertebral shell seems to be important for intravertebral pressure (10). Furthermore, Aebli et al (27) showed that creating an artificial opening or a vent in the vertebral shell could

reduce the IP and the risk of fat embolism; the extant method practiced by clinicians during VP and KP is to vent a vertebra through the contralateral pedicle (27).

In our clinical study, we first found that the IP of a compressed vertebra was significantly higher than that of adjacent normal vertebrae. This difference can be explained by the change in the volume of the compressed vertebra. Meanwhile, the IP of the individual compressed vertebra was 0 mmHg, while a similar result was not found in the adjacent normal vertebrae. This is related to the damage to the vertebral shell; the presence of a complete vertebral shell seems to be important for intravertebral pressure.

Furthermore, we found that there was a significant increase in IP during the PMMA filling in VP and KP, which suggested that it is mostly prone to leakage and fat embolism during this time. The study also showed that the IP did not obviously change, even if the cavity was produced by balloon in KP. It is worth noting that no statistically significant differences in IPs were observed during all common stages of PMMA injection (before, during, and after filling) in VP and KP. This result was different from traditional opinion (the injection of PMMA in VP is purportedly under "high pressure," whereas KP fills a void created by the bone tamp and is therefore "low pressure"). For example, a cadaver study by Weisskopf et al (12) suggested that a significantly higher central IP was measured in VP when compared with balloon KP during all stages of PMMA injection (12). This difference might be explained by the following possibilities: the volume of each patient's compressed vertebral body differed from that of other patients. And both the volume of the inflated balloon and the volume of the cement differed from patient to patient. The volume of balloon inflation was less than the PMMA volume in KP, thus a relative increase in the IP was recorded when the injected volume exceeded the capacity of the preformed cavity; in addition, any influence of blood pressure might affect the results, especially in KP. The blood would fill the cavity produced by balloon inflation quickly in vivo. This would be unlikely to happen in an in vitro study.

The current study has the following limitations: in line with clinical routine, our flow rate was manually controlled and kept at approximately 0.1 mL/s. Because the speed of injection was controlled by hand, an exact injection rate could not be guaranteed, and this could have contributed to some inaccuracy when comparing the IP of VP and KP. Further, the balloon was inflated into different volumes in KP, and each compressed vertebral body was injected with different PMMA volume. Because PMMA injection was performed to a satisfactory vertebral body filling and limited by any signs of extravasation, it was difficult to maintain the constant injection volume, unlike those in in vitro studies. Other factors such as the damage to the vertebral shell or the degree of osteoporosis might also affect the IP. Investigating all factors is beyond the scope of this study, and hence these factors should be examined in follow-up studies.

Conclusion

In summary, this study showed that the IP of a compressed vertebra was significantly higher than that of adjacent normal vertebrae; there was a significant increase in IP during the PMMA filling in VP and KP; the IP of a compressed vertebra was not significantly reduced by balloon inflation in KP; and no statistically significant differences in IPs were found during all common stages of PMMA injection in VP and KP.

Acknowledgments

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