Clinical Article

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Gelfoam Embolization Technique to Prevent Bone Cement Leakage during Percutaneous Vertebroplasty: Comparative Study of Gelfoam only vs. Gelfoam with Venography

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Conflict of Interest

The authors have no financial conflicts of interest.

ABSTRACT

Objective: Percutaneous vertebroplasty (VP) has been used for the safe treatment of osteoporotic compression fracture. However, cement leakage is the most common complication. To reduce the leakage of bone cement, we did the gelfoam embolization during VP. The purpose of this study is to compare the safety and feasibility of different two gelfoam embolization technique during VP.

Methods: Total 127 patients (146 level) who had the thoracolumbar osteoporotic compression fracture were enrolled. Group A was treated by gelfoam-only technique and, Group B was treated by gelfoam with venography technique. We compared the incidence of bone cement leakage between two groups using post-operative computed tomography scan and X-ray. **Results:** Seventy-four patients (81 levels) were treated with gelfoam-only technique (A), and 53 patients (65 levels) were treated with gelfoam with venography technique (B). There were 22 leakages on group A, and 19 leakages on group B. There was no statistical significant difference between two groups (Chi-square test, *p*-value =0.958). Incidence of leakage to spinal canal was 11 levels in Group A, 3 levels in group B, and there was statistical significant difference (Fisher's exact test, *p*-value=0.027).

Conclusion: Complication induced by the bone cement leakage are the most careful point during VP. Gelfoam embolization with venography is very easy and safe method. Gelfoam with venography technique could make lower the incidence of cement leakage to spinal canal.

Keywords: Osteoporosis; Compression fracture; Vertebroplasty; Gelfoam; Venography

INTRODUCTION

Percutaneous vertebroplasty (VP) has been widely used for pain relief and strengthening of weakened vertebral bodies for osteoporotic compression fracture.⁶⁾ However, the VP has the potential risk of serious complications such as infection, new fractures of the adjacent vertebral body and cardiopulmonary complications. Especially, leakage of cement after VP is one of the most serious complication and it has been reported between 38% and 75%.^{3-6,12,16)} To prevent this complication, the technique using gelfoam during VP has been reported. Although gelfoam technique could reduce the cement leakage, it still remains one of the major problems of vertebroplasty. Techniques to reduce these complications more effectively have been

studied include the intraosseous venography during VP.^{2,13,14}) We developed the technique for venography before VP by mixing contrast and gelfoam to avoid cement leakage via intravertebral venous flow or facture line. There had been no reports comparing gelfoam only technique and gelfoam with venography technique. The purpose of this study was to determine the safety and feasibility of routine pre-injection of gelfoam with venography during VP.

MATERIALS AND METHODS

Patients who underwent VP for painful osteoporotic thoracolumbar compression fracture by single surgeon form 2011 to 2015 were retrospectively reviewed. A total of 127 patients (146 levels) enrolled in this study.

Fractured levels were selected from the 9th thoracic spine to the 5th lumbar spine. All had suffered the severe back pain and tenderness for more than 2 weeks which did not respond to conservative treatment. The level of VP was selected on the basis of clinical symptom, magnetic resonance image, and radioisotope bone scan. We divided the groups: (A) gelfoam only technique group, (B) gelfoam with venography group. In 2011 to 2013, we used gelfoam only technique during VP. After that time, we developed gelfoam with venography technique, and newly developed technique was used from 2013 to 2015.

All procedures were performed as elective schedule under local anesthesia by only one experienced spinal neurosurgeon. After placing the patient in the prone position on the radiolucent table, the back was prepared and draped. Under the biplane C-am guided, the Jamshidi needle was introduced through the pedicle and advanced to the anterior third of the vertebral body to prevent the fenestration of anterior cortex. All procedures were performed via bipedicular approach.

In group A, the gelfoam sponge was cut into regular shape (5×5 mm). The gelfoam pieces were mixed with the 10 mL of normal saline using 10-mL syringe. And then, pre-procedural gelfoam embolization was performed without contrast using 5 mL of gelfoam on each side. After 1 minute, 1.5 mL of bone cement was injected per one Jamshidi needle (total 3 cc per level).

In group B, the pieces of gelfoam sponge was mixed with 3 mL of normal saline and 7 mL of contrast (Vispaque-320) using 10-mL syringe. And 5 mL of pre-procedural gelfoam embolization with contrast was performed on each side (**FIGURE 1**). Venography was done to identify the basivertebral plexus and any other large vessels or fracture line which the cement might leak. If there was an active venous flow or contrast leakage, we advanced the Jamshidi neelde a litte more (**FIGURE 2**). After 1 minute, 1.5 mL of vertebroplasty cement was injected per one Jamshidi needle (total 3 cc per level).

During bone cement injection, the C-arm was used to confirm whether there was any cement leakage. If any signs of cement leakage were suspected, the injection was stopped immediately, and injection was performed again after 1 minute waiting. If it was suspected that there was cement leakage along the vein according to the venography, we advance the Jamshidi needle a little and reinject the bone cement after 1 minute waiting. After the procedure, cement leakage was assessed using postoperative plain radiography and computed tomography (CT) scan. Based on obtained images, we classified cement leakage into 4 patterns: type 1 to the paravertebral muscle and soft tissue, type 2 to the paravertebral vein, type 3 to the disc space, type 4 to the spinal canal (**FIGURE 3**).¹⁴

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FIGURE 1. Preparation of Gelfoam with venography technique. (A) Gelfoam sponge was cut into 5×5 mm size. (B) Gelfoam pieces were mixed with 3 mL of normal saline and 7 mL of contrast material using 10-mL syringe.



FIGURE 2. (A) Venography before vertebroplasty showed leakage to the anterior vertebral body via fracture line (white arrow) and to the disc space (black arrow). (B) After advance of needle, no cement leakage was noted.

All statistical analysis were performed using SPSS ver. 14.0 (SPSS Inc., Chicago, IL, USA). T-test, chi-square test, and Fisher's exact test were used for statistical analysis. Statistical significance was accepted for p<0.05.

RESULTS

On this study, we classified into two groups; group A (gelfoam only technique) were 81 levels and group B (gelfoam with venography technique) were 65 levels. Group A consisted of 74 patients (54 females and 20 males); average age was 71 years (40–86). All patients had the severe osteoporosis (average bone mineral density [BMD] –3.1). Group B consisted of 53 patients (42 females and 11 males); average age was 73 years (46–95); those had also severe osteoporosis (average BMD –3.2). There was no statistical significance difference between two groups in patient demographics (**TABLE 1**). In comparison of cement leakage incidence, there were 22 leakages on group A, and 19 leakages on group B. There was no statistical significant difference between two groups in comparison of overall leakage incidence (Chi-

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FIGURE 3. Cement leakage classification. (A) Leak into the paravertebral muscle and soft tissue, (B) leakage into the paravertebral vein, (C) leakage into the disc space, (D) leakage into the spinal canal.

square test, *p*-value=0.958) (**TABLE 2**). In comparison of leakage pattern, type 1 was 1, type 2 was 11, type 3 was 1, type 4 was 11 levels on A group. On B group, type 1 was 1, type 2 was 14, type 3 was 5, type 4 was 3 levels (**TABLE 3**). There was statistical significant difference between groups in comparison of occurrence in type 4 leakage pattern (Fisher's exact test, *p*-value=0.027).

TABLE 1. Patients' demographics

| 01 | | | | |
|----------------------|-------------|-------------|-------|-----------------|
| Variables | Group A | Group B | Total | <i>p</i> -value |
| Patient number | 74 | 53 | 127 | - |
| Number of VP | 81 | 65 | 146 | - |
| Sex | | | | 0.250 |
| Male | 20 | 11 | 31 | |
| Female | 54 | 42 | 96 | |
| Age (yr) | 70.8 (±8.8) | 73.3 (±9.1) | - | 0.887 |
| Bone mineral density | 3.1 (±1.3) | 3.2 (±1.1) | - | 0.798 |

Group A: gelfoam only technique, Group B: gelfoam with venography technique.

VP: vertebroplasty.

Statistical analysis was done with Chi-square test



TABLE 2. Incidence of cement leakage between two groups

| Variables | Group A | Group B | p-value |
|-----------|---------|---------|---------|
| Leakage | 22 | 19 | 0.958 |
| Total | 81 | 65 | - |

Group A: gelfoam only technique, Group B: gelfoam with venography technique. Statistical analysis was done with Chi-square test.

TABLE 3. Distribution of cement leakage pattern

| Туре | Group A | Group B | <i>p</i> -value |
|--------|---------|---------|-----------------|
| Туре 1 | 1 | 1 | 0.915 |
| Туре 2 | 11 | 14 | 0.199 |
| Туре 3 | 2 | 5 | 0.219 |
| Туре 4 | 11 | 3 | 0.027* |
| Total | 25 | 23 | - |

Statistical analysis was done with Fisher's exact test.

Type 1: paravertebral muscle and soft tissue, Type 2: paravertebral vein, Type 3: disc space, Type 4: spinal canal. *Statistical significance.

DISCUSSION

Leakage of cement after VP has been reported between 38% to 75%.^{1,3-6} Yeom et al.¹⁷ reported that leakage incidence was 76.3%, and Schmidt et al.¹⁵ found 29 leakage in 26 level. [REMOVED HYPERLINK FIELD] [REMOVED HYPERLINK FIELD] The leakage can lead to severe neurological or pulmonary complications.^{9,10} It has been reported that the gelfoam embolization technique could reduce cement leakage.¹ Since our hospital had been started the pre-procedural gelfoam embolization during VP, the leakage was markedly reduced. However, concerns about the risk of potential bone cement leakage still remain for young spine neurosurgeon.

Although controversy has existed, venography before VP is known as one of an effective method. If surgeon know venography pattern in advance, it would be helpful to prevent the cement leakage complication by controlling the needle tip position or cement amount. In addition, the agreement rate between the pattern of venography and cement leakage has been reported to be 83%.¹³

We studied of the incidence and pattern of bone cement leakage between groups which were performed gelfoam technique during VP with or without venography.

The leakage patterns of bone cement classified by many author were useful to decrease the complication.¹¹⁾ In this study, we classified the cement leakage pattern into four types. This four types were divided based on the direction of leakage and related structures. Type 1 is in case of leakage to the paravertebral muscle and soft tissue, type 2 is considered when cement leaks to paravertebral vessels, type 3 and 4 are classified when cement leaks to disc space and spinal canal. All patterns were decided using postoperative CT and X-ray by one neurosurgeon who performed the operation.

Overall incidence of cement leakage showed no significant difference between two groups. However, incidence of cement leakage to spinal canal (type 4) in gelfoam with venography group is low compared with gelfoam only group. One of most catastrophic complication of VP is induced by leakage type 4 (migraine to spinal canal). As leakage to spinal canal might cause serious complications like paraplegia or radiculopathy, gelfoam with venography technique could help to avoid leakage to spinal canal for young spine neurosurgeon. Gelfoam slows the injected cement and venous flow, and it could reduce the cement leakage to the spinal canal. And, it is possible to further reduce leakage incidence to the spinal canal by confirming whether there is a contrast leak through venography.

Our study have some limitations; First, all VPs were performed by only one surgeon who experienced more than 500 VP cases. Because VP is not a difficult surgery, surgeons familiar enough with VP has many experience to reduce the leakage of bone cement, so the overall leakage incidence may show no significant difference. If operations was performed by the beginner, the results would have been different. In general, experienced spine neurosurgeon have only below 2% complication rate of VP.⁷⁸⁾ Second, in this study, it was confirmed that the risk of cement leakage to the spinal canal can be reduced by performing venography during VP, but cement leakage that cannot be predicted by venography also exists. Intraoperative venography could confirm not only the large venous flow in the vertebral body, but also large fracture line where contrast can reach. However, the fracture line of the part where the contrast medium did not reach is not entirely certain by venography alone, but it can be known and avoided through preoperative CT scan.

Third, the total number of VP procedures is small. We limited on the T9-L5 spine level and only one neurosurgeon for the high degree of accuracy of study. Further study might be needed.

CONCLUSION

In our study, there was no statistical significant difference between gelfoam groups which applied venography or not. But gelfoam with venography make lower the incidence of cement leakage to spinal canal. This study has limitation that all this procedure was performed by only one skillful neurosurgeon and the bone cement leakage during VP will be higher from unexperienced operator. Therefore, the gelfoam with venography technique could be helpful for beginners.

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