Evaluation of Intraosseous Pressure during Pelvic Percutaneous Cement Injection: An In Vitro Study in Swine

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Background: A minimally invasive procedure for symptomatic pelvic bone metastasis is a feasible option for advanced cancer patients, and bone cement injection plays an essential role. Pulmonary embolism caused by thrombus, fat, or tumor emboli is a major complication related to bone cement injection, and increasing intraosseous pressure is a predisposing factor. This study aimed to quantify the degree of pressure change in the pelvic bone during percutaneous bone cement injection and investigate whether there is a significant decrease in intraosseous pressure when a decompressive route is additionally established.

Methods: Bone cement injection into the acetabulum of swine pelvises by simulating the actual surgical procedure in terms of the injection method, bone cement, and surgical instruments was performed while recording the intraosseous pressure. Twenty swine pelvises were used and grouped into a decompression group and a non-decompression group. Bone cement injection and pressure measurement were conducted in the same way in both groups, but an additional decompressive route was established for each pelvis in the decompression group. Continuous variables were compared using the Mann-Whitney test.

Results: The mean amount of injected bone cement was 19.8 mL and 20.3 mL and the mean speed of bone cement injection was 0.14 mL/sec and 0.12 mL/sec in the decompression group and the non-decompression group, respectively. The mean peak intraosseous pressures was 10.5 kPa with decompression and 37.8 kPa without decompression, and the difference was statistically significant (p < 0.01).

Conclusions: Intraosseous pressure during bone cement injection into swine pelvises was similar to that during vertebroplasty or kyphoplasty. When the additional decompression route was established, the intraosseous pressure decreased to one third the level.

Keywords: Pelvis, Percutaneous, Pressure, Bone cement, Decompression

The pelvis is a common anatomical location for bone metastasis in patients with advanced cancer. Pelvic bone metastasis causes refractory pain and gait disturbance in many patients. However, major reconstruction surgery for pelvic bone metastasis is often not possible because of the patient’s general condition.¹-⁴ Percutaneous procedures with or without radiotherapy are feasible palliative treatment options for pelvic bone metastasis.⁵-¹¹ Bone cement is often injected percutaneously to reduce the extent of surgery for bone metastasis. Bone cement injection is sometimes performed for augmentation after metal fixation or alone as a minimally invasive surgery. Most areas where bone cement injection is performed alone are often flat bones rather than long bones, and typical areas include the spine and pelvis.⁶,¹¹,¹²
though several studies have investigated pulmonary embolism and enhancement of intraosseous pressure (IOP) during vertebroplasty or kyphoplasty of the spine,13-19 few studies have evaluated the IOP during percutaneous bone cement injection on the pelvis. Each vertebra has only two anatomical routes for accessing the vertebral body for bone cement injection, and these are the pedicles. Unlike vertebroplasty or kyphoplasty, which uses secure injection routes through the vertebral pedicles, the pelvic bone is relatively wide, and it is possible to create multiple routes into the medullary space easily and safely. Therefore, when injecting bone cement into the pelvic bone, the decompression routes can be made consciously. This study aimed to quantify the degree of pressure change in the pelvic bone during percutaneous bone cement injection and to investigate whether there is a significant decrease in the IOP when a decompressive route is additionally established.

METHODS

Ethics Statements
This study did not require Institutional Animal Care and Use Committee approval as it used animal carcass bones.

Study Design
In this study, the IOP was measured during bone cement injection in 20 swine pelvic bones. The fresh swine pelvic bones were collected 3 days after the pigs were slaughtered at 22–26 weeks of age. The swine pelvises were divided into the decompression and non-decompression groups. For negative control of the decompression effect, a custom-made airtight plastic chamber and amputated lower extremities without pelvis were utilized. For the experiment with a plastic chamber, two syringes of 30 mL without plungers were bonded airtightly to make the plastic chamber with two openings. Bone cement was injected on one side and pressure was measured on the other side. For the experiment with human bones, metaphysis of long bones was experimented in the same method as swine pelvic bones without a decompression route. The pelvic bone of a human cadaver was not available. To overcome anatomical differences between the pelvic bone and long bones, experiments using human long bones were conducted in the metaphysis area, which was filled with cancellous bone.

Measurement of the IOP
The IOP was measured using an absolute pressure sensor (4260A; Kistler, Winterthur, Switzerland) at 100 times per second, and the measurement range of the absolute pressure sensor was 0–10 V, with an error range of 0.2% of the full-scale output. The IOP is dependent on cement viscosity, injection method, and bone quality.17 Therefore, to control confounding factors as much as possible, we used an experimental procedure and instruments that mimicked the real surgical procedure and instruments used for treating pelvic bone metastasis in our institution.20

Procedure of Bone Cement Injection
Bone cement (Exolent Spine; Elmdown S.R.L., Milano, Italy) was mixed for 1 minute and 30 seconds and divided into 1-mL syringes (1-mL Kovax-Syringe; Koreavaccine, Seoul, Korea). The routes for bone cement injection, decompression, and IOP measurement were made with 11-gauge needles (CAPO needle; Nexone Bio, Seongnam, Korea). The injection needle was placed 2 cm superiorly and posteriorly from the lateral end of the acetabulum. In only the decompression group, the additional needle for decompression was positioned at a point 2 cm higher than the tip of the injection needle. This needle was left open during the bone cement injection. The entry point of the needle for IOP measurement was set 2 cm posterior to the anterior superior iliac spine, and the needle tip was placed 5 cm superiorly from the injection needle tip. Bone cement injection was manually performed for 2 minutes and 30 seconds, with an allowance of discontinuity of cement injection when changing the 1-mL syringes between each injection. The mean maximal tripod finger grip of three orthopedic oncologists (JHK, HGK, and JWP), who regularly performed human percutaneous cement surgery in our institution, was measured by a custom-made finger grip meter. The cement was injected as much as possible by finger grip by one surgeon (JWP). Extruded cement via decompression route was collected and measured. For the decompression group, the amount of injected bone cement was calculated by subtracting extruded cement volume from the total injected amount. After the experiments, plain radiography and computed tomography were performed to confirm that a sufficient amount of cement was injected into the acetabular area (Fig. 1).

Statistical Analysis
The sample size was calculated by setting the alpha to 0.05, beta to 0.2 and the IOP reduction by decompression to 50%. According to previous studies on vertebroplasty or kyphoplasty, the expected baseline IOP without decompression was 50 ± 20 kPa. Continuous variables were compared using the Mann-Whitney test. Statistical analysis was performed using R ver. 4.1.0 software (R Foundation,
Vienna, Austria). All reported p-values were two-tailed, and p-values < 0.05 were deemed significant.

RESULTS

The IOP gradually increased with each injection. The increasing pattern had a stair shape because of the discontinuity of cement injection when the surgeons changed the 1-mL syringes between each injection. The global pressure peaked when the last injection was made and decreased spontaneously. Spontaneous pressure recovery was observed in only the bones (swine and cadaver) and not in the plastic chamber. The longest time for natural recovery of IOP was 79.7 minutes (Fig. 2).

The mean maximal tripod finger grip of the three orthopedic surgeons who regularly performed human percutaneous cement surgery in our institution was 120 N, and the mean injection speed during bone cement injection was 0.14 mL/sec with decompression and 0.12 mL/sec without decompression. The mean amount of bone cement was 20.1 mL (range, 11.7–29.8 mL), 19.8 mL (range, 11.7–24.3 mL), and 20.3 mL (range, 13.4–29.8 mL) in all spine pelvises, decompression group, and non-decompression group, respectively. In the decompression group, the injected bone cement was extruded via the decompressive route. The mean injected amount of bone cement was 25.7 mL (range, 16.1–44.0 mL) in the decompression group, and 5.9 mL (range 0.0–21.5 mL) of that was extruded cement (Fig. 1D). No significant difference was found in the amount of bone cement in the pelvis between the two groups (p = 0.58).

The mean peak IOP during bone cement injection was 10.5 ± 7.2 kPa with decompression and 37.8 ± 14.9 kPa without decompression (Fig. 3). The pressure difference during cement injection between the two groups was significant (p < 0.01), and the decompression effect was calculated to be 72.3% reduction.

DISCUSSION

Several previous studies have reported on the IOP during the percutaneous cementing procedure, and most studies on the IOP are related to vertebroplasty or kyphoplasty. The pelvic bone and vertebrae have similar features: both
are flat bones filled with cancellous bone in the axial anatomical location and have venous plexus without sufficient valvular structures. The IOPs during vertebroplasty and kyphoplasty were 38.1 kPa and 24.3 kPa, respectively. When vertebroplasty and kyphoplasty were performed in the compressed spine, the IOPs were 19.4 and 15.7 kPa, respectively. The IOP was 39.7 kPa for metastatic vertebrae and 6.83 kPa for intact vertebrae. Therefore, the IOPs measured in the present study were comparable to those reported in previous studies for the vertebrae.

Few studies have focused on the IOP during orthopedic procedures besides percutaneous cement injection. During the intramedullary nailing process, in the case of reamed and unreamed nails, the IOP increased to 14 kPa and 354.6 kPa, respectively. When the femoral cement was pressed by an injector during hip arthroplasty, the IOP increased to 100–700 kPa. In the present study, the average maximum IOPs were 10.46 and 37.78 kPa with and without decompression, respectively. The increasing and naturally decreasing patterns were similar in both groups. Numbers in graphs were assigned according to the sequence of experiments on swine pelvises.

The safety range of IOPs during cementing procedures has been proposed in a few studies. Considering the clinical circumstances, it was reasonable to set the lower cutoff pressure for pelvic cementoplasty sufficiently to...
prevent bleeding from the tumor, and the upper cutoff was established to minimize complications, such as pulmonary embolism. In previous literature, 5 kPa was required to prevent back bleeding.\(^{26,29}\) For the upper cutoff, a study reported that the risk of fat embolism increased when the IOP exceeded 20 kPa.\(^{30}\) There was only one study that examined cement embolism after percutaneous cementoplasty in the pelvic bone, reporting an incidence rate of 11\% for pulmonary cement embolism and suggesting protective tendency of multiple percutaneous routes against pulmonary cement embolism.\(^{5}\) Although there were differences in embolism materials investigated in the two papers, if decompression had been performed so that the IOP could be < 20 kPa, safety was expected to improve. According to the results of the present study, the IOP during pelvic cementoplasty was more likely to be within the safe range in the decompression group than in the non-decompression group.

Cortical bones are not airtight or watertight structures and have fine pores; thus, natural pressure leakage was observed. As evidence of this, we observed bloody fluid oozing from the surface of the bone when bone cement was injected (Fig. 1D). Natural pressure leakage had two main effects on the IOP during percutaneous cementoplasty. First, the IOP was significantly lower than the injection pressure. The manual injection using a 1-mL syringe with 120 N of maximal tripod finger grip could generate 7,413 kPa by calculation, but the maximal IOP without a decompression route generated only 63.48 kPa. Second, the IOP decreased spontaneously over 79.9 minutes. This phenomenon was observed in only bones, not in the airtight plastic chamber.

To apply and confirm the IOP data of swine pelvises in human pelvisses, limited experiments were performed with a cadaver. The main limitation is that human pelvic bones could not be used. In order to overcome the anatomical difference, we tried to simulate the pelvic bone as much as possible by selecting the metaphysis area filled with a cancellous bone. The IOP data of the human cadavers were similar to those of fresh swine pelvic bones in the non-decompression group (Fig. 4).

This study has several limitations. First, it was an in vitro experiment using mainly swine pelvic bones; thus, data cannot be directly applied to live humans. As fresh pelvic bones from healthy swine were used, there was no cavity inside, and the bone quality may be better than that of older patients. In patients, cement injection into the pelvis is mainly attempted when performing minimally invasive surgery for bone metastasis. In other words, the bone quality may be poor and could have a pathological fracture or cavity, which was created by bone metastasis. Therefore, the decompression effect needs to be proven in an in vivo setting while performing minimally invasive surgery of the pelvis in patients with advanced cancer. Moreover, the quality of fascia and periosteum differs between that of healthy swine and metastatic cancer patients, and this may have affected pressure. Second, the injection speed and pressure were inconsistent since the injection was performed manually. Although manual injection by a surgeon was a limitation, it could be viewed as an advantage since the experiment was performed in the same setting as the actual surgery. The mean injection speeds during bone cement injection were 0.14 and 0.12 mL/sec with and without decompression, respectively. Notably, Loeffel et al.\(^{17}\) reported a small difference in the injection speeds in the range of 0.05–0.15 mL/sec, and this did not affect cement spreading.

In conclusion, even for pelvic cementoplasty without decompression, the IOP was significantly lower than that for unreamed nailing and femoral pressurization. Moreover, the decompression route significantly reduced the IOP during pelvic bone cement injection. This finding suggests that the decompression route could be protective against fat, thrombus, or bone cement embolisms in minimally invasive surgery including bone cement injection in humans.

**CONFLICT OF INTEREST**

No potential conflict of interest relevant to this article was reported.
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