radiologists did not take into account the location of nodules when the ROC curves were estimated, so some false-positive responses in actual ECC cases could be counted as true-positive responses. Furthermore, radiologists were allowed to indicate only one CR on each segment, so additional false-positive responses and/or true-positive responses might have been obtained if radiologists were allowed to indicate two or more lesions in one segment. Although almost all observer performance studies that employ ROC analysis have been done under these limitations, their results are generally considered useful.

Conclusion

The present CAD programs do not contribute to improved diagnostic accuracy for the detection of ECCs on CTC. The present CAD analysis algorithm demonstrated an inferior performance in detecting flat-type lesions compared to that for protruding lesions. Further investigation is required to clarify the specific features of flat lesions that would improve the performance of the CAD algorithm. Moreover, the reader's experience in diagnostic CTC reading would be considered in the evaluation of the clinical utility of CAD for detecting ECCs.

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CLINICAL INVESTIGATION

Transcatheter Arterial Chemoembolization (TACE) with Lipiodol to Treat Hepatocellular Carcinoma: Survey Results from the TACE Study Group of Japan

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Abstract The purpose of this study was to retrospectively clarify the current status in Japan of TACE using Lipiodol together with anticancer agents to treat hepatocellular carcinoma (HCC). We retrospectively surveyed 4,659 (average annual total) procedures for HCC over the years 2002–2004 at 17 institutions included in the TACE Study Group of Japan. The survey included six questions that were related mainly to TACE and Lipiodol for HCC treatment. The most frequently applied among the 4,659 procedures at the 17 institutions were TACE (2,310; 50%) and local ablation (1,395; 30%). Five of the institutions applied 201–300 procedures and 4 applied 101–200. Lipiodol was used in "all procedures" and in "90% or more" at seven and nine institutions, respectively. Almost all institutions applied 4–6 (mean, 5) ml of Lipiodol during TACE to treat tumors 5 cm in diameter. In conclusion, this survey clarified that TACE using Lipiodol and anticancer agents is a popular option for HCC treatment in Japan.

Keywords Hepatocellular carcinoma · Transcatheter arterial chemoembolization · Lipiodol · Survey results · Japan

Introduction

The rate of hepatocellular carcinoma (HCC) is increasing and transcatheter arterial chemoembolization (TACE) seems to be becoming more important as a treatment strategy [1, 2]. Although much information about TACE

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for treating HCC has been published [1–36], we consider that to understand the current status of TACE for HCC would be valuable in Japan, where TACE has been applied for more than 20 years [3–22]. We also consider that the concomitant use of iodinated oil (Lipiodol; Lipiodol Ultra-Fluide; Guerbet Co.) for more than 20 years [3–23] should be reviewed [24–26, 32–36]. Although the efficacy of Lipiodol for hepatic TACE has been generally recognized for more than two decades, and segmental or subsegmental TACE using Lipiodol is considered a more effective and less invasive tool for treating localized HCC [9–17], Lipiodol (distributed by Terumo Co. in Japan) has not yet been approved for this application in Japan and other countries. We thus believe that urgent effort is required to obtain official permission from the Pharmaceuticals and Medical Devices Agency (PMDA) of the Japanese Ministry of Health, Labour and Welfare to apply Lipiodol in this manner, based on incontrovertible evidence of expansive usage and value. Therefore, we organized the TACE Study Group in Japan to retrospectively study the issue using a questionnaire at 17 institutions where TACE is frequently applied. We intended to gain fundamental data about TACE and other treatment options for patients with HCC that would reflect the actual use of Lipiodol in clinical practice and its benefits. Our findings should facilitate understanding of the current status of HCC therapy in Japan and establish a foothold for regulatory approval of Lipiodol not only in Japan, but also in other countries.

Materials and Methods

The TACE Study Group distributed questionnaires to 20 institutions throughout Japan and 17 (85%) of them responded regarding 4,774 procedures for HCC including 2,264 TACE (average total per year) during the years 2002–2004. We analyzed the replies to six questions (Q1–Q6) regarding TACE and Lipiodol for the treatment of HCC.

Q1 Annual approximate total of HCC procedures during the years 2002–2004 at the institution.

When 100 procedures were displayed as one average annual frequency unit for convenience in data comparisons, the replies were classified as number of procedures per year per institution as follows: 1, ≤100; 2, 101–200; 3, 201–300; 4, 301–400; 5, 401–500 and 6, ≥501.

Q2 Annual number of individual therapies selected for HCC treatment.

a, Surgery; b, local ablation comprising PEIT (percutaneous ethanol injection therapy), PMCT (percutaneous microwave coagulation therapy), RFA (radiofrequency ablation); c, TACE; d, TACI (transcatheter arterial chemoinfusion therapy); e, CAIC (continuous arterial infusion chemotherapy); f, Cx (systemic chemotherapy); g, RT (radiotherapy).

Q3 Rate of use of Lipiodol in TACE.

Q4 When Lipiodol was not used, reasons why, and methods of TACE.

Q5 Rate of use of Lipiodol in TACI.

Q6 Volume of Lipiodol applied during TACE to treat tumors 5 cm in diameter (clinical stage I).

a, 3–4 ml; b, 4–5 ml; c, 5–6 ml; d, 6–7 ml; e, Other ( ) ml.

Results

Replies (R1–R6) to the questions (Q1–Q6) were as follows.

R1 Four institutions each applied 101–200 and 201–300 procedures per year; three applied ≤100, one applied 401–500 per year, two applied 301–400 per year, and one applied 501 or more per year.

R2 Table 1 reports the annual total of HCC treatments and annual numbers (rate) of the top four individual therapies at 17 institutions. Of the treatments applied at the 17 institutions, the most frequent was TACE (2,264 of 4,774; 47%), followed by local ablation (1,443; 30%), TACI (898; 19%), and resection (341; 9%). The mean annual total of procedures was 281 at 17 institutes. The mean rates of each procedure at these institutions were as follows: TACE, 47%; ablation, 30%; and TACI, 19%.

The total average frequency of TACI in addition to TACE, which treats cancer using a catheter inserted into the hepatic artery, accounted for approximately 66% of the total HCC treatments at 17 institutes.

R3 Regarding Lipiodol in TACE under the premise that Lipiodol is used to prepare a miscible liquid of anticancer drugs (usually Lipiodol emulsion is mixed with anticancer and nonionic contrast agents), seven and nine institutions replied that Lipiodol was used in "all procedures" and in "90% or more," respectively. One institution claimed to

Table 1 Annual total of HCC treatments and annual number (rate) of the top four individual therapies at 17 institutions

Institute	Total therapies/yr	Resections/yr	Ablations/yr	TACE/yr	TACI/yr
Total 17	4,774	391 (8%)	1,443 (30%)	2,264 (47%)	898 (19%)
Mean of 17	281	23 (8%)	85 (30%)	133 (47%)	53 (19%)

Note: TACI, transcatheter arterial chemoinfusion therapy

use "80% or more," but the exact rate was 89%. When the rate of Lipiodol use in TACE at all institutions was calculated simply from all reported TACE over 3 years at 17 institutions, the ratio reached 6,328 of a total of 6,740 TACE (94%) procedures.

R4 Except for the 7 institutions (41%) that used Lipiodol in all TACE procedures, 5 of the 10 institutions that did not use Lipiodol for some TACE procedures replied that Lipiodol might impair hepatic function and 3 replied that they were considering other options. One respondent indicated that TACE did not include Lipiodol at their institution because the therapeutic effect was sometimes limited. Six institutions replied that only gelatin sponge particles are used with anticancer drugs in TACE when Lipiodol is not used.

R5 The rates of Lipiodol use in TACI varied. Although six institutions (35%) used Lipiodol in more than 80% of TACI procedures and four institutions (24%) used it in 40–80%, three institutions (18%) used it in only 20–40 procedures and four institutions (24%) did not use Lipiodol in TACI at all.

R6 The volume of Lipiodol used in TACE to treat tumors 5 cm in diameter in the absence of obviously disrupted liver function (clinical stage I) was 5–6 ml (c) at eight institutions (47%), 6–7 ml (d) at five (29%), 4–5 ml (b) at three (18%), and 3–4 ml (a) at one. The average volume (dose) of Lipiodol applied during TACE for HCC 5 cm in diameter (clinical stage I) essentially reflected the tumor volume as indicated by the diameter (cm) at many of the institutions.

Figure 1 shows an example of a HCC measuring 38 × 45 mm with typical CT patterns that was treated by subsegmental TACE for S5 using 4 ml (6 ml of Lipiodol emulsion) of Lipiodol mixed with 30 mg of doxorubicin (dissolved in 2 ml of nonionic contrast medium and saline) followed by injection with gelatin sponge particles.

Discussion

The rate of HCC is increasing worldwide including in Japan [1, 2]. As HCC frequently presents as multiple lesions, invades surrounding tissues, and is usually accompanied by liver dysfunction, indications for resection or local ablation are restricted even now when earlier stages of HCC are being increasingly diagnosed owing to advances in imaging technology. In addition, multiple lesions frequently recur not only after surgery but also after ablation therapy such as radiofrequency ablation. Therefore, TACE is an important option for HCC treatment and the procedure involves the use of iodized oil (Lipiodol) all over the world.

The efficacy of TACE using Lipiodol for HCC has remained controversial despite evaluations, long-term discussions, and various randomized trials. Whereas some randomized control study findings have questioned the utility of TACE [25–27], more recent reports, also including some randomized studies [24, 30–32], have recognized the value of TACE using Lipiodol [5–23, 33–36]. The most important factors in choosing TACE are to obtain favorable therapeutic effects and to reduce adverse side effects. Thus, the dose of Lipiodol mixed with anticancer drugs should be individually adapted to the tumor size, number of tumors, and hepatic function of each patient. However, the dose of Lipiodol in most randomized control studies was uniform and not adapted to individual needs [25, 26, 31, 33, 36]. We believe that these studies missed the effect of TACE because the doses of Lipiodol and anticancer agents were not optimized, and furthermore, TACE was not repeated before recurrence was diagnosed by imaging, including CT, after the first TACE. However, TACE using Lipiodol is gradually becoming recognized worldwide and randomized control studies seem unnecessary since TACE already seems proven to confer a significant benefit on HCC [2, 24, 30–32].

The present retrospective study clarifies the current status of TACE including the use of Lipiodol for the treatment of HCC at representative institutions that participated in the TACE Study Group in Japan. The results obtained from 17 nationwide institutions showed that although the approximate annual total of HCC procedures over the past 3 years differs at each facility, several hundred HCC procedures per year are performed at the midsize to large leading institutions and >200 treatments are performed annually at more than half of all surveyed institutions. Thus, TACE accounts for 50–60% of all HCC procedures at institutions involved in the TACE Study Group of Japan. Focal radiofrequency ablation therapy is becoming widely prevalent in Japan for localized small HCC lesions. However, TACE has also become a popular strategy for such tumors owing to the use of microcatheters and Lipiodol mixed with anticancer agents, as well as gelatin sponge particles, which are popular for segmental or subsegmental Lipiodol TACE. The excellent effects of segmental or subsegmental Lipiodol TACE in terms of the absence of damage to surrounding normal hepatic tissue have already been proven by histopathological and clinical findings [9–14, 21]. Chemoembolization using Lipiodol combined with percutaneous radiofrequency thermal ablation therapy is becoming another treatment option for HCC, as a larger sphere of ablation can be induced [20]. Repeated TACE with Lipiodol for the recurrence with various collateral pathways is also very useful and important to positively impact the survival of patients with HCC [22]. Therefore, the results of this survey and of most published studies indicate that TACE is an indispensable therapeutic tool that is frequently applied worldwide to treat various types of HCC [2, 4–24, 28–36].

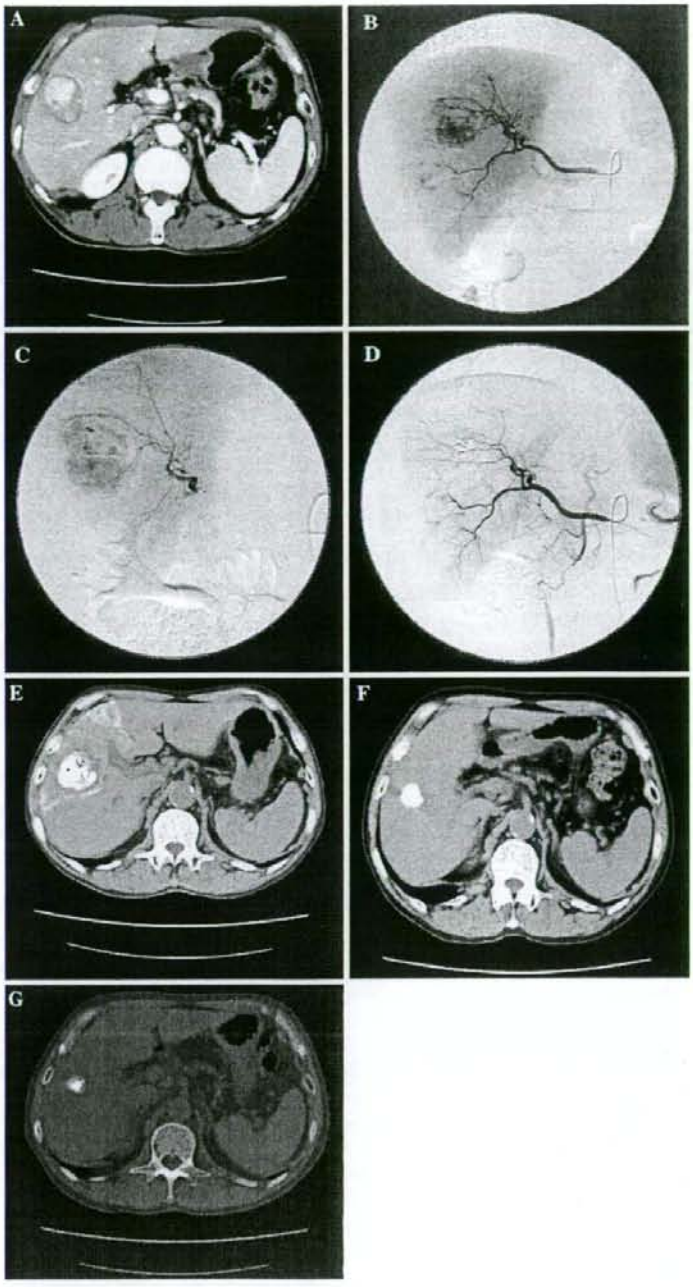

Fig. 1 Hepatocellular carcinoma 38 × 45 mm in diameter showing typical CT profiles and treated with subsegmental TACE using Lipiodol. Subsegmental TACE was performed using 4 ml of Lipiodol (6 ml of Lipiodol emulsion) mixed with 30 mg of doxorubicin in 2 ml of nonionic contrast medium and saline, followed by injection of gelatin sponge particles. **(A)** CT shows hypervascular HCC in S5. **(B)** Hepatic angiogram also demonstrates hypervascular HCC in S5. **(C)** Superselective hepatic angiogram via the anterior-inferior branch (A5) shows hypervascular tumor in S5. **(D)** Hepatic angiogram after subsegmental TACE for S5 shows disappearance of tumor vessels and visualization of surrounding hepatic arteries. **(E)** CT 1 week after subsegmental TACE: Lipiodol is visualized in the embolized S5 area, as well as in the tumor. **(F)** CT 1 year after subsegmental TACE shows homogeneous tumor accumulation of Lipiodol. **(G)** Two years after subsegmental TACE, CT shows dense accumulation of Lipiodol and tumor shrinkage. This tumor did not recur

The efficacy of Lipiodol in TACE for HCC has been recognized by several investigators worldwide [4–24, 28–36], whereas only a few articles indicate contrary findings [25–27]. Although the rate of TACE for HCC differs slightly among institutions, this survey shows that >90% of HCCs treated by TACE included Lipiodol. However, although Lipiodol is generally used as a useful carrier of anticancer agents in Japan and elsewhere, it is not legally permitted for hepatic TACE in Japan. Legal permission to use Lipiodol must be based on clear evidence of expansive usage and value. Therefore, we retrospectively surveyed 17 leading Japanese institutions to generate some fundamental data about the use of hepatic TACE with Lipiodol for treating HCC. Seven institutes used Lipiodol in all TACE procedures, nine used Lipiodol in >90% of them, and one used it in >80%, indicating that Lipiodol/TACE is widely perceived as beneficial.

Under the premise that Lipiodol is used in miscible solutions of anticancer drugs, seven and nine institutions replied that Lipiodol was used in "all" and in "90% or more" of procedures, respectively. One institution replied that Lipiodol was used in "80% or more" of procedures, but the actual frequency was almost 90%.

Although Lipiodol is used in about 40% of all TACE procedures, it is not used at about 60% of institutions in <10% of TACE procedures. This is due to potential impairment of hepatic function among patients with poor liver function or a huge HCC that would require a large volume of Lipiodol. Therefore, TACE is occasionally performed with a reduced amount of Lipiodol mixed with anticancer agents, or a first TACE might use only gelatin sponge particles without Lipiodol and anticancer agents for HCC >10 cm in diameter. A second TACE might include a small volume of Lipiodol mixed with anticancer agent after the tumor has been reduced. When only gelatin sponge particles are used in TACE, some institutions nevertheless essentially agreed that TACE can include Lipiodol mixed with an anticancer agent.

This variable use of Lipiodol in TACI indicates that HCC treatment policies differ among institutions. The total frequency of transcatheter arterial therapy (total of TACE and TACI continuous arterial infusion therapy), which treats cancer using a catheter inserted into the hepatic artery, accounted for 60% of the total HCC procedures. The most frequently applied was TACE, followed by local ablation and TACI. These methods accounted for approximately 90% of all HCC therapies. The average volume of Lipiodol used for TACE for HCCs 5 cm in diameter was almost 5 ml, which reflected the tumor volume and was verified in this survey. Our basic criteria regarding the dose of Lipiodol used for TACE state that that average dose (ml) is roughly equal to the tumor diameter (cm). This is reflected in the tumor volume shown in Fig. 1. We already proposed criteria to select the dose of injected Lipiodol for each patient based on tumor size [9–12, 14, 16]. These criteria have generally been agreed on and are applied in Japan. Therefore, we believe that the survey responses regarding the Lipiodol dose were quite uniform.

A recent article describing the mechanism of action of chemoembolization using Lipiodol in Japan helps to elucidate and support the present study [37].

A prospective cohort study of transarterial chemoembolization for unresectable hepatocellular carcinoma in 8,510 patients has been reported [38]. However, the focus of the contents of registration and the questionnaire of that report is completely different from that in the present study.

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ORIGINAL ARTICLE

ACTA RADIOLOGICA

Improvement in Respiratory Function by Percutaneous Vertebroplasty

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Tanigawa N, Kariya S, Kojima H, Komemushi A, Shomura Y, Tokuda T, Ueno Y, Kuwata S, Fujita A, Terada J, Sawada S. Improvement in respiratory function by percutaneous vertebroplasty. Acta Radiol 2008;49:638–643.

Background: Percutaneous vertebroplasty (PVP) improves back pain and corrects spinal misalignment to some extent, and thus may improve respiratory function.
Purpose: To retrospectively investigate changes in respiratory function after PVP.
Material and Methods: 41 patients (mean age 72.0 years, range 59–86 years; 39 women, two men) who had undergone PVP for vertebral compression fractures (37 thoracic vertebral bodies [Th6–Th12] and 50 lumbar vertebral bodies [L1–L5]) caused by osteoporosis visited our hospital for follow-up consultation between January and June 2005. At this follow-up consultation, respiratory function testing, including percent forced vital capacity (FVC%) and percent forced expiratory volume in 1 s (FEV_1%), was performed. We retrospectively compared these values with those taken before PVP using a Wilcoxon signed-rank test.
Results: FVC% was 85.2 ± 30.3% before PVP and 91.5 ± 16.8% at follow-up (mean 10 months after PVP), which represented a significant difference ($P<0.003$). No significant difference in FEV_1% was detected. Regarding the number of treatment levels, that is, single vertebroplasty versus multiple vertebroplasty, no significant difference in improvement of FVC% was confirmed ($P=0.1$). FVC% was abnormally low (≤ 79%) before PVP in 16 patients and improved to within normal range postoperatively in six of these patients (38%).
Conclusion: PVP improves preoperatively decreased lung function, but this improvement takes time.

Key words: Osteoporosis; percutaneous vertebroplasty; respiratory function

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Vertebral compression fracture due to osteoporosis causes not only back pain, but also spinal misalignment, particularly kyphosis. Kyphosis of the thoracic spine in turn causes rib cage deformity. In this manner, vertebral compression fracture reduces the activities of daily living (ADL) (1), causes respiratory dysfunction due to rib cage deformity, and increases the prevalence of lung diseases (2, 3).

Mortality rates in osteoporotic women who have been clinically diagnosed with vertebral compression fracture are 15% higher than in those without compression fracture (4). Furthermore, mortality rates are 23–34% higher in osteoporotic women with severe multiple compression fractures or kyphosis than in women without these conditions, and this is primarily related to compromised pulmonary function as a result of thoracic and lumbar vertebral fractures (2).

Percutaneous vertebroplasty (PVP) was first reported in 1987 (5). Since then, PVP has been performed to alleviate pain caused by various types of vertebral compression fracture, and dramatic effectiveness in this regard has led to frequent use (6–9). PVP is also useful for back pain caused by compression fractures due to osteoporosis and has contributed greatly to improvements in ADL (6, 10, 11).

Since PVP improves back pain and corrects spinal misalignment to some extent, we hypothesized that respiratory function might also be

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ORIGINAL ARTICLE

Percutaneous vertebroplasty performed by the isocenter puncture method

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Abstract
Purpose. The aim of this study was to clarify the usefulness of the isocenter puncture (ISOP) method.
Materials and methods. We investigated 73 vertebral bodies that had undergone percutaneous vertebroplasty (PVP) by the ISOP method, 118 vertebral bodies that had undergone the puncture simulation method, and 33 vertebral bodies that had undergone the conventional method. The items to be examined included the success rate (SR) of the median puncture of the vertebral body and the procedure time. The puncture accuracy and fluoroscopy time were also measured for the ISOP method.
Results. The SR was significantly higher and the procedure time significantly shorter when using the ISOP method rather than the conventional method. However, no significant differences were observed between the ISOP method and the puncture simulation method. The errors between the puncture needle tip and the puncture target point in the ISOP method were an average of 1.52, 2.08, and 1.87 mm in each of the horizontal, ventrodorsal, and craniocaudal directions. The fluoroscopy time when operating on one vertebral body was an average of 5.8 min.
Conclusion. The ISOP method is considered to be a useful approach while also reducing the puncture time and the fluoroscopy time.

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Key words ISOP method · Percutaneous vertebroplasty · Unilateral transpedicular approach · Isocenter marker · PVP

Introduction

Percutaneous vertebroplasty (PVP), a rapidly acting treatment for pain caused by a compressed fracture of the vertebral body, is increasingly being used worldwide. PVP is generally performed using a C-arm radiographic system and puncturing the vertebral arch pedicle percutaneously under X-ray fluoroscopy. The puncture approach includes both the unilateral and bilateral transpedicular approaches. The unilateral transpedicular approach is relatively difficult to perform as it requires advancing the tip of a puncture needle to the midline of the vertebral body. Therefore, some institutions use the bilateral transpedicular approach. However, the unilateral transpedicular approach may decrease the number of punctures required during such surgery.[1,2]

We have therefore developed an isocenter puncture (ISOP) method[3], which is a puncture support method for the unilateral transpedicular approach. The ISOP method allows pinpoint targeting and puncturing of a target within the vertebral body under X-ray fluoroscopy.

We herein describe the results of PVP using the ISOP method and compare the findings with those achieved with the puncture simulation method[2] using the puncture angle measured by the preoperative CT examination and those by the conventional puncture method, as a historical control, while also examining the usefulness of the ISOP method.

Materials and methods

This study was approved by the ethics committee at our institution.

ISOP method concept and procedures

The isocenter of the C-arm radiographic system is the center of the radiation field and the center of the C-arm rotation. Therefore, regardless of how the C-arm rotates, the isocenter always remains at the center of the radiation field and the center of the monitor screen. The ISOP method applies this principle, and therefore adjusting the puncture target to the position of the isocenter becomes essential with this method. For this purpose, we created a black dot-like isocenter marker (ICM; Toshiba Medical, Tokyo, Japan), which is constantly illuminated at the center of the fluoroscopic monitor screen (Fig. 1).[2] We set the anterior one-third median site of the vertebral body as a target point.

The procedures of the ISOP method start with positioning the puncture target point at the isocenter. The first step is a frontal view on the fluoroscopic monitor. The examining table is moved as necessary to align it with the median of the vertebral body with the ICM (Fig. 2a). Next, the lateral view is used with the C-arm tilted 90° for guidance. The examining table is moved so that the anterior one-third median site of the vertebral

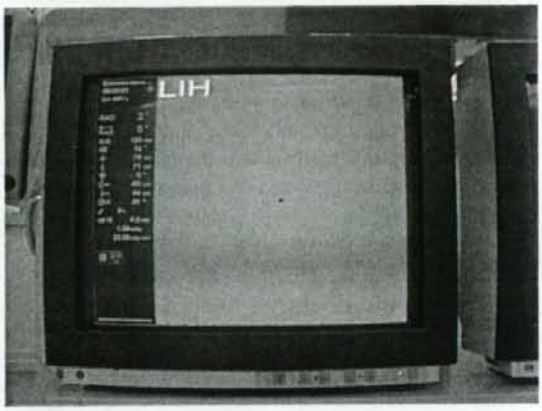

Fig. 1. Isocenter marker (ICM)

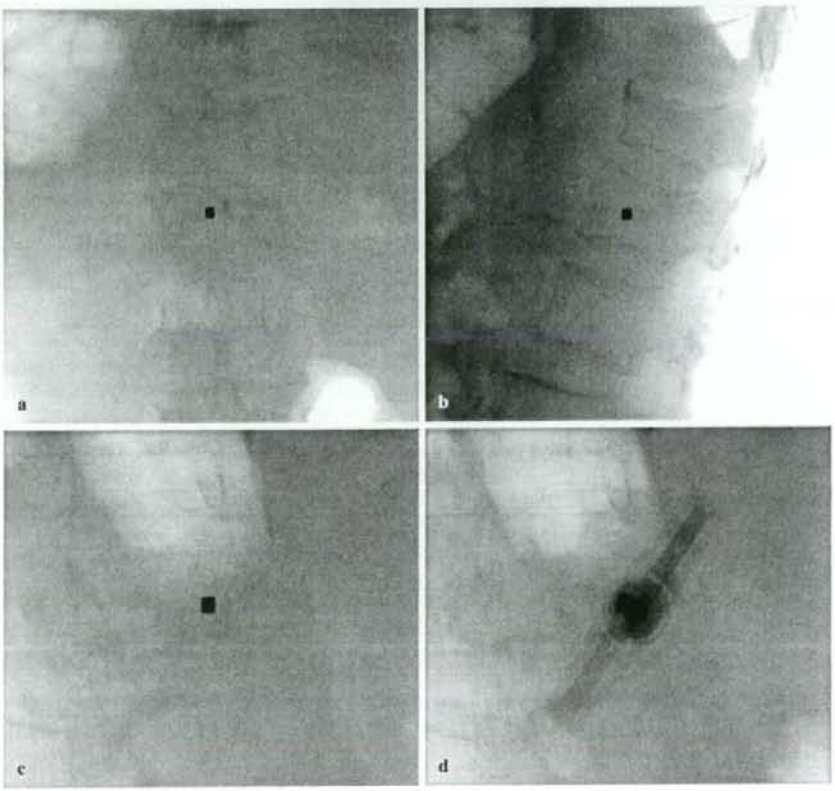

Fig. 2. Positioning. **a** In the frontal view, the ICM is aligned with the median of the vertebral body. **b** In the lateral view, the ICM is aligned with the anterior one-third median site of the vertebral body. **c** The C-arm is moved in a three-dimensional manner so the ICM is aligned with the center of the shadow of the vertebral arch pedicle. **d** The shadow of the puncture needle becomes a *dotted line* and is aligned with the ICM

body is aligned with the ICM (Fig. 2b). After carrying out these steps, the positioning of the isocenter marker in regard to the patient's position is completed. Consequently, regardless of how the C-arm rotates, the puncture target point is now aligned with the ICM at all times.

Next, the direction of the puncture direction is determined by rotating the C-arm in a three-dimensional manner so the ICM overlaps the center of the pediculus arcus vertebral image (Fig. 2c). With this step, the puncture direction is determined under fluoroscopy.

After confirming the cutaneous puncture site on the skin and administering local anesthesia, the puncture is performed while maintaining the puncture direction so the puncture needle overlaps the ICM in a point-like manner under fluoroscopy (Fig. 2d). When the needle reaches a depth of 1–2 cm in the vertebral arch pedicle, and the assistance of the needle is thus no longer required, the monitor is switched to the lateral fluoroscopic image, and the puncture needle is moved forward until the needle tip reaches the ICM (Fig. 3a). When moving the needle forward, a hammer is used as required. After the puncture needle tip has reached the ICM in the lateral image, the monitor is returned to the frontal fluoroscopic image to confirm that the puncture needle tip is aligned with the ICM (Fig. 3b), thereby completing the puncture by the ISOP method.

Materials

A total of 122 patients (224 vertebral bodies) underwent fluoroscopic PVP. They were then divided into three groups. Table 1 represents the characteristics of those groups. The first (group A) comprised 41 patients (73 vertebral bodies) who had undergone PVP by the ISOP method from January 2006 to March 2007. The second group (group B) comprised 58 patients (118 vertebral bodies) who had undergone PVP by the puncture simulation method from September 2004 to January 2006. The third group (group C) comprised 23 patients (33 vertebral bodies) who had undergone PVP without using the ICM from June 2002 to May 2004.

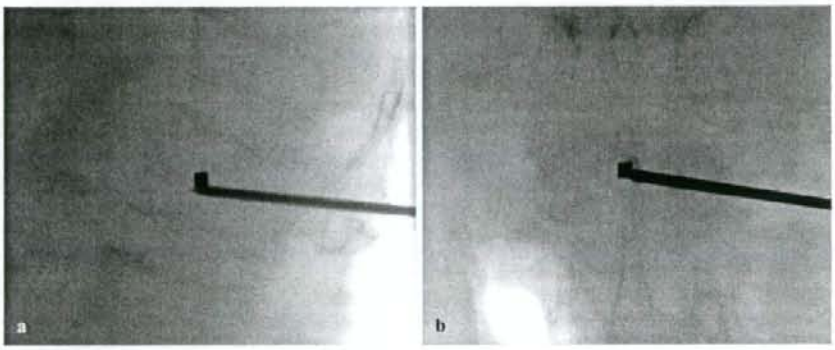

Fig. 3. Verification.
a Lateral view: the puncture needle tip overlaps the ICM.
b Frontal view: the puncture needle tip overlaps the ICM

Table 1. Summary of patients

Characteristic	ISOP method (group A)	Puncture simulation (group B)	Conventional method (group C)
Cases (vertebrae)	41 (73)	58 (118)	23 (33)
Male/female	8/33	11/47	9/14
Age (years), average/range	68.3/37–90	67.2/33–91	73.9/30–87
Location (case)	Th7 (1), Th8 (2), Th10 (3), Th11 (2), Th12 (12), L1 (18), L2 (14), L3 (10), L4 (9), L5 (2)	Th5 (1), Th6 (3), Th7 (2), Th8 (6), Th9 (8), Th10 (4), Th11 (10), Th12 (14), L1 (12), L2 (16), L3 (18), L4 (18), L5 (6)	Th8 (2), Th11 (1), Th12 (4), L1 (4), L2 (6), L3 (4), L4 (5), L5 (7)
Underlying disease (cases/vertebrae)			
Osteoporosis	34/58	45/81	11/15
Bone metastasis	7/15	13/37	11/17
Multiple myeloma			1/1

Methods

For all groups, we measured the success rate of the median puncture of the vertebral body (SR)[1,2] and the time required to perform a needle puncture successfully. The SR was evaluated by three radiologists during the procedure. It was judged by macroscopic evaluation of whether the needle tip reached the median of the vertebral body and by objective evaluation of whether the bone cement was distributed beyond the median of the vertebral body. These evaluations were done by using examples from previous observations of Kim et al.[1] For cases of failure, puncture was performed from the opposite side or from the same side after removing the needle. Fisher's exact test was used to evaluate all groups.

The procedure time for needle puncture was defined from the start of the positioning to puncture completion. The procedure time for needle puncture did not include the time needed to prepare the bone cement or the time needed to inject the cement. For a comparison of the puncture time, Mann-Whitney's U-test was used.

In group A, the puncture error, fluoroscopy time, and adverse events were further examined. Because the puncture target point with the ISOP method is determined by the operator's visual estimation during the procedure, it is not necessarily the anterior one-third median site of the vertebral body. When the patient is moved after the puncture direction is determined, a slight misalignment is likely to occur between the puncture target point and the ICM. Therefore, to evaluate the puncture error in the ISOP method, we verified where the puncture needle tip is located on the image obtained before the cement injection and measured the positional error between the puncture needle tip and the ideal puncture target point. For the error between the puncture needle tip and the ideal puncture target point, we measured the lateral direction of the axis in the frontal view and the craniocaudal direction of the axis in the lateral view.

For the fluoroscopy time during the procedure, the time between the positioning and rotation digital angiography immediately after the procedure was thus measured. The examination of adverse events was based on their presence or absence during the procedure.

A single plane C-arm of Infinix celeve VC (Toshiba Medical) was used for X-ray fluoroscopy. The puncture needle, an osteo-site bone biopsy needle (13 gauge, 15 cm; Cook, Spencer, IN, USA) was used. For injecting the cement preparation, Osteoject (Integra NeuroScience, Plainsboro, NJ, USA) was used. PMMA (polymethylmethacrylate) was the bone cement, which was prepared by mixing 20 g of PMMA with 6 g of sterilized barium sulfate.

Table 2. Success rate ratio

Group	SR	Non-SR	Total
A	72	1	73
B	110	8	118
C	19	14	33
Total	201	23	224

SR, success rate

Results

Success rate of the median puncture of the vertebral body

The success rate (SR) for median puncture of the vertebral body was 98.6% (72/73) in group A, 93.2% (110/118) in group B, and 58% (19/33) in group C (Table 2). No significant differences were observed between groups A and B ($P = 0.15$). When comparing groups A and C, the SR was significantly higher in group A ($P < 0.05$).

In cases where a median puncture could not be successfully performed, either additional punctures were attempted from the opposite side or the same puncture was repeated. In all cases, satisfactory cement distribution to the lateral regions crossing the median was ultimately obtained.

Procedure time

The average procedure time for needle puncture for one vertebral body was 9.3 ± 3.8 min in group A, 11.2 ± 4.6 min in group B, and 30.9 ± 11.2 min in group C. No significant differences between groups A and B were observed regarding the puncture time ($P = 0.22$); however, the time was significantly shorter between groups A and C ($P < 0.01$).

Positional relation between the ideal puncture target point and the puncture needle tip—ISOP method

The average error in the horizontal direction was 1.52 ± 1.31 mm (maximum 5.92 mm), the average error in the ventrodorsal direction was 2.08 ± 1.50 mm (maximum 6.41 mm), and the average error in the craniocaudal direction was 1.87 ± 1.43 mm (maximum 5.81 mm). Figure 4 shows the positional relation between the ideal puncture target point and the puncture needle tip to each axis. As shown in Fig. 4b, we detected a tendency for the puncture needle tip to go slightly deeper toward the abdominal side of the vertebral body.

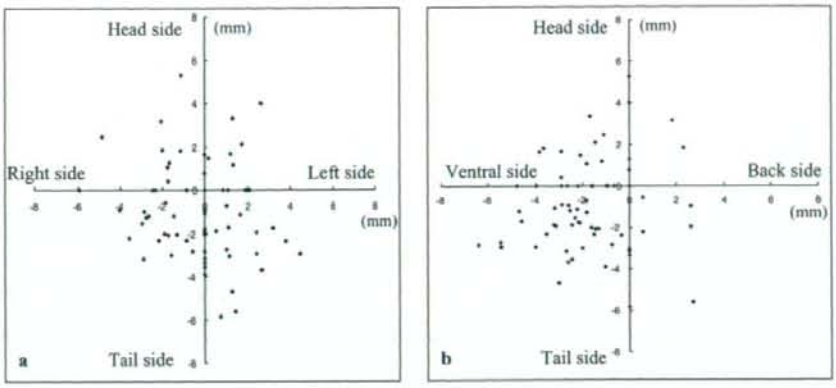

Fig. 4. Positional relation between the puncture needle tip and the puncture target point. **a** frontal view. **b** lateral view

Fluoroscopy time during the procedure—ISOP method

In group A, the average fluoroscopy times during the procedure were 5.8 ± 0.9 min for 23 cases of operating on one vertebral body, 8.97 ± 3.79 min for 8 cases of operating on two vertebral bodies, 9.33 ± 3.79 min for 4 cases of operating on three vertebral bodies, and 11.8 ± 2.83 min for 6 cases of operating on four vertebral bodies.

Adverse events—ISOP method

Two patients in group A had a fever after the procedure. Although the hospitalization period of these patients was extended by approximately 1 week, the symptoms were alleviated by antibiotic administration. No technique-related complications were observed.

Discussion

There have been only a few reported evaluations of PVP procedures, and most of them reported on cement distribution and leakage.[1–8] Many institutions select PVP using the bilateral transpedicular approach, thus expecting an even cement distribution within the vertebral body. Kim et al.[1] noted that if the unilateral transpedicular approach can achieve cement distribution across the median there are no differences in treatment effects compared to the bilateral transpedicular approach. In our examination, it was confirmed that by using the ISOP method the PVP success rate was 98.6%, and that even with the unilateral vertebral transpedicular approach bilateral cement distribution can be achieved if puncture is successfully performed with a target point of the anterior one-third median site of the vertebral body.

In group A, puncture had to be repeated in one case. In this case, it was attributed to body movement after positioning, whereby the ICM was misaligned from the puncture target point during the puncture. In this case, the ISOP method was applied again after removing the puncture needle. Favorable treatment effects were then obtained.

The puncture times were significantly shorter in group A than in group C, suggesting that the ISOP method contributes to a reduction of the puncture time in comparison to the conventional method.

In our hospital, before introducing the ISOP method, PVP had been implemented using the puncture simulation method.[2] With both the ISOP method and the puncture simulation method, there were no significant differences in the SR or the puncture time. Based on the above results, we speculate that no substantial differences exist between the ISOP method and the puncture simulation method. However, the puncture simulation method requires a preoperative CT examination and measurement of the puncture angle. Considering the labor hours and complexity, it is obvious that the ISOP method is a simpler, more useful puncture method.

Puncture accuracy in the ISOP method was an average of 2 mm in each of the horizontal, ventrodorsal, and craniocaudal directions. With this examination, except for case in which a second puncture was required owing to the patient's body movement (group A), the puncture needle tip reached the ICM in all cases, which is thus regarded as high puncture accuracy.

Reports on the amount of exposure and fluoroscopy time in the PVP are scarce.[10–12] Komemushi et al. have performed PVP by using the IVR-CT system and reported that the fluoroscopy time was 6.66 ± 2.45 min.[11] We used only a fluoroscopy device. The average fluoroscopy time for one vertebral body was 5.8 ± 0.9 min,

which was short, on average. In addition, Mehdizade et al. reported that the PVP fluoroscopy time under fluoroscopy was 10–60 min.[10] Compared to these reports, PVP under fluoroscopy by means of the ISOP method is believed to contribute to a significant reduction in the fluoroscopy time.

Conclusion

Compared to the conventional method, the ISOP method is thought to be a useful approach as it improves the PVP completion rate by using the unilateral vertebral arch pedicle approach; it also reduces the puncture time and fluoroscopy time. Thus, we speculate that the ISOP method is a more convenient technique than the puncture simulation method.

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原著論文
Original Article

骨粗鬆症性圧迫骨折に対する経皮的椎体形成術のQOL評価

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Quality of Life Assessment in Patients with Osteoporotic Vertebral Compression Fracture Treated by Percutaneous Vertebroplasty

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● ***Abstract*** ●

Percutaneous vertebroplasty (PVP) has been accepted as useful procedure for pain relief in patients with compression fractures due to osteoporosis. However, the most of studies have used visual analogue score for evaluation of the usefulness of PVP. However, the previous reports suggested that osteoporotic compression fractures deteriorated patient's quality of life significantly. The purpose of our study was to assess the impact of PVP on the quality of life prospectively in patients with osteoporotic compression fractures.

After written informed consent was obtained, the visual analogue scale, the short-form (36-item) health survey(SF-36) scores, and Roland-Morris Disability Questionnaire (RDQ) score were measured at the time before PVP, a week, 1 month, 3 months, and 6 months after PVP. SF-36 measure mainly the systemic or non-specific QOL, and RDQ measures the disease specific QOL. The changes in outcome measure were analyzed by using analysis of variance. The score of SF-36 showed significant impairment of quality of life before PVP, but a significant improvement after PVP in both physical and mental status. The RDQ score also showed significant improvement up to 6 months after vertebroplasty.In conclusion, PVP contributes to the improvement of quality of life as well as pain relief.

Key words

- ***PVP (Percutaneous vertebroplasty)***
- ***QOL***
- ***SF-36***
- ***Roland-Morris Disability***
- ***Osteoporosis***

はじめに

骨粗鬆症性圧迫骨折の治療の最終的な目的は，患者quality of life（以下QOL）の改善である。椎体圧迫骨折はその原因の如何にかかわらず，疼痛や脊柱の変形・姿勢異常，これに伴う消化器系や呼吸器系の機能障害を引き起こし，そのため患者のQOLの大幅な低下をきたし，生命予後をも悪化させることが明らかとなっている[1]。

経皮的椎体形成術（以下PVP；percutaneous vertebroplasty）は，1990年代後半より急速に欧州や米国に普及し，日本においても1998年以降増加している。その一般的な治療効果判定方法としては，疼痛緩和の程度をVisual Analogue Scale Score（以下VAS）によって評価する方法がとられてきた。その一方で，最近は治療によってもたらされる成果（outcome）を評価するための新しい指標として，健康関連QOLがある。PVPの治療効果は，本来その除痛効果とその結果得られる患者QOLの向上をもって評価されるべきであるが，そのような検討報告は本邦においてまだなされていない。

今回著者らは，VAS値に加え包括的尺度と腰痛に関わる疾患特異的尺度を用いてPVPがQOLに与える影響を検討したので報告する。本研究は，当施設の倫理審査委員会における承認を得ている。

対象・方法

2006年7月から2008年1月までの間にPVPを施行した患者95例を対象とした。対象患者は椎体圧迫骨折による腰痛を主訴に来院し，PVPを施行された患者である。除外症例としては術前QOL評価表の未回収，術後に一度も回収されていない例，転移性椎体腫瘍例，PVP後の再発骨折例，整形外科的手術の術前の補強（前方固定）として施行された例とした。使用したQOL評価表には，包括的尺度についてSF36（MOS Short-Form 36-Item Health Survey），腰痛疾患特異的尺度についてRoland-Morris Disability Questionnaire（RDQ）を用い，PVP施行前後のQOLの変化を評価した。評価の時期は，発症してからPVP施行前1週間以内，およびPVP施行直後（1週間以内），1ヵ月後，3ヵ月後，6ヵ月後とし，PVPがQOLに与える影響を前向きに検討した。さらにPVPの治療成績，PVPの除痛効果の評価を体動時のVAS値で測定し，また合併症の有無について検討した。

PVPの除痛効果は，治療前1週間，治療後1週間，1ヵ月，3ヵ月，6ヵ月後に得た体動時のVAS値の変動により判定し，以下に示す著効，有効，無効の3段階に分類した。1）著効：治療後VAS値が0～2となる，または治療前より5以上低下している。2）有効：治療前からのVAS値の低下が2以上5未満である。3）は1），2）以外の場合とする。

PVPの適応は，放射線科と整形外科の診療連携に基づき，発症や経過，理学所見，画像検査所見，血液生化学所見など必要な諸検査を行った上で決定された。適応条件を以下に示す。1. 外傷の有無に関わらず椎体骨折を来たし，それによる胸背部痛や腰痛，腹痛などを主訴とし，安静や鎮痛剤などによる保存的治療に反応しない。2. 術前MRIにおいて骨折椎体がT1強調像で低信号，STIR像で高信号を呈する。3. 画像診断または病理組織検査により腫瘍性病変が除外されている。治療対象の椎体としては，Th5からL5の範囲内，椎体高（前，中，後）が隣接する非骨折椎体の1/3以上を保つ，1/3以上保たれていなくても，前後屈単純撮影において骨折椎体の椎体高が変化する偽関節様椎体を対象とした。また感染が疑われる場合には適応外とした。

経皮的椎体形成術

PVPはSingle-C-arm血管撮影装置（Infinix-Celeve VC：東芝medical社）を用い，局所麻酔下にてISOP（Isocenter Puncture）法[2,3]による経皮的な透視下穿刺でPVPを行った。使用した穿刺針は，骨生検針（Osteosite bone biopsy needle 13G or 15G，15 cm；Cook Inc., USA）を用い，セメント製剤は，20 g polymethylmethacrylate（PMMA；Surgical Simplex P；Japan Stryker Inc.）に6 gの滅菌硫酸バリウムを混合させ，骨セメント用注入器（Osteoject；Integra Neuro Science Inc.）を用いて注入した。治療後はベッド上で仰臥位となり帰室後2時間の安静を指示した。その後発熱やアレルギー反応，痛みの増強，麻痺，呼吸困難がなければ3日後に退院とした。その後は1ヵ月後，3ヵ月後，6ヵ月後に外来受診を行った。

QOL評価表

術前の評価表は外来受診時に渡し入院時に回収した。その後のVAS値とQOL評価表は郵送し回収した。

SF-36：MOS Short-Form 36-Item Health Survey

SF-36は，米国で行われた主要慢性疾患患者を対象とした医療評価研究であるMedical outcome studyに伴って作成された。SF-36は，36項目8下位尺度から構成される（Table 1）。1）身体機能（Physical functioning：PF），2）日常役割機能（身体）（Role physical：RP），3）身体の痛み（Bodily pain：BP），4）社会生活機能（Social functioning：SF），5）全体的健康感（General health perceptions：GH），6）活力（Vitality：VT），7）日常役割機能（精神）（Role emotional：RE），8）心の健康（Mental health：MH）[4-6]。

RDQ：Roland-Morris Disability Questionnaire

RDQは1983年に英国でMartin RolandとRichard Morrisが開発し[7]，使用されている腰痛疾患特異的尺度である（Table 2）。「腰痛」という疾患に特異的に反応する24項目からなる尺度であり，腰痛が日常生活に与えている障害の程度を評価する。各項目に「はい」「いいえ」で今日の状態を回答し，0～24点で得点化され，高得点ほど腰痛が日常生活に影響を与えていると評価しうる。日本語版RDQを使用した[8-12]。

Table 1 The 8 domains of SF-36

身体面	精神面
身体機能	全体的健康感
日常役割機能（身体）	活力
身体の痛み	日常役割機能（精神）
社会生活機能	心の健康

Table 2 Roland-Morris Disability index

以下の項目は，腰が痛いときに起こることを表したものです。この中に，あなたの「今日」の状態にあてはまるものがあるかもしれません。項目を読みながら，今日のあなたの状態を考えてみて下さい。あなたの状態にあてはまる場合には「はい」に，あてはまらない場合には「いいえ」に○をつけて下さい。 今日，腰痛のために		
1	腰痛のため，大半の時間，家にいる	はい いいえ
2	腰痛を和らげるために，何回も姿勢を変える	はい いいえ
3	腰痛のため，ふだんよりゆっくり歩く	はい いいえ
4	腰痛のため，ふだんしている家の仕事を全くしていない	はい いいえ
5	腰痛のため，手すりを使って階段を上がる	はい いいえ
6	腰痛のため，いつもより横になって休むことが多い	はい いいえ
7	腰痛のため，何かにつかまらないと，安楽イス（体を預けて楽に座れる椅子，深く腰掛けた姿勢）から立ち上がれない	はい いいえ
8	腰痛のため，人に何かしてもらうよう頼むことがある	はい いいえ
9	腰痛のため，服を着るのにいつもより時間がかかる	はい いいえ
10	腰痛のため，短時間しか立たないようにしている	はい いいえ
11	腰痛のため，腰を曲げたりひざまずいたりしないようにしている	はい いいえ
12	腰痛のため，椅子からなかなか立ち上がれない	はい いいえ
13	ほとんどいつも腰が痛い	はい いいえ
14	腰痛のため，寝返りがうちにくい	はい いいえ
15	腰痛のため，あまり食欲がない	はい いいえ
16	腰痛のため，靴下やストッキングをはくとき苦労する	はい いいえ
17	腰痛のため，短い距離しか歩かないようにしている	はい いいえ
18	腰痛のため，あまりよく眠れない（痛みのために睡眠薬を飲んでいる場合は「はい」を選択して下さい）	はい いいえ
19	腰痛のため，服を着るのを誰かに手伝ってもらう	はい いいえ
20	腰痛のため，一日の大半を，座って過ごす	はい いいえ
21	腰痛のため，家の仕事をするとき力仕事をしないようにしている	はい いいえ
22	腰痛のため，いつもより人に対していらいらしたり腹が立ったりする	はい いいえ
23	腰痛のため，いつもよりゆっくり階段を上がる	はい いいえ
24	腰痛のため，大半の時間，ベット（布団）の中にいる	はい いいえ

統計解析

SF-36のスコアは8つの各々のドメインごとに国民標準値に換算し，RDQは素点を求めた。これらに関して，対応のあるデータ（PVP前後）でOne-Way Repeated-Measures ANOVA（一元配置の経時測定分散分析）を行った。またpost hocの多重比較は，最小2乗平均のTukeyのHSD検定を用いた。有意水準は5％である。統計パッケージとして，JMP（SAS Institute Japan）を使用した。

結果

調査期間中95症例に対してPVPを施行した。そのうち術前QOL評価表の回収がなされていない症例が5例，術後に一度も回収できなかった症例が8例，転移性椎体腫瘍例が5例，PVP後の再発骨折が3例，整形外科的手術との併用症例が4例であった。これらの症例を除き，調査対象症例数は70例となった。

調査表の回収例数（回収率）は70例中，1週間後49例（70％），1ヵ月後61例（87％），3ヵ月51例（73％），6ヵ月後53例（76％）であった。

SF-36の結果をTable 3に示す。各ドメインについて一元配置の分散分析を施行したところ，身体機能（PF）で$p=0.0012$，体の痛み（BP）で$p<0.001$，活力（VT）で$p<0.001$，心の健康（MH）で$p=0.0018$を示し，有意な改善が得られた。日常役割機能（身体）（RP）は$p=0.0897$，全体的健康感（GH）は$p=0.0648$，社会生活機能（SF）は$p=0.0667$，日常役割機能（精神）（RE）は$p=0.0963$と有意なQOLの改善を示さなかった。

さらに各期間ごとに多重比較としてTurkeyのHSD検定を施行した。身体機能（PF）では術前と1週間後では有意差が得られなかった（12.3±18.3 vs 17.5±19.0，Δ=5.2，95％信頼区間［以下CI］4.2-14.6）が，1ヵ月（12.3±18.3 vs 22.3±16.51，Δ=9.7，95％，CI 1.2-18.6），3ヵ月（12.3±18.3 vs 24.0±14.7，Δ=11.6，95％，CI 2.5-20.7），6ヵ月後（12.3±18.3 vs 23.5±18.9，Δ=11.2，95％，CI 2.3-20.1）に有意な改善が得られた。体の痛み（BP）では術前と1週間後ではQOL改善に有意差が見られ（25.0±6.9 vs 30.0±8.1，Δ=5.0，95％，CI 0.5-9.5），1ヵ月後（25.0±6.9 vs 34.1±8.4，Δ=9.1，95％，CI 4.9-13.3），3ヵ月後（25.0±6.9 vs 34.5±7.8，Δ=9.6，95％，CI 4.9-13.3），

Table 3 Summary of SF-36 item health survey mean scale scores at baseline (before intervention) and follow up (1week, 1-, 3- and 6- months), and results from the repeated measures ANOVA with the post-hoc multiple comparison.

	PF	RP	BP	SF	GH	VT	RE	MH
術　前	12.3±18.3	19.7±16.9	25.0±6.9	27.9±17.2	35.5±9.6	35.0±10.5	25.1±16.9	35.9±12.7
1週間後	17.5±19.0	19.7±13.9	30.0±8.1*	27.4±14.6	36.7±12.2	39.1±9.6	23.9±15.8	41.0±10.8
1ヵ月後	22.3±16.5*†	22.5±14.6	34.1±8.4*	31.8±15.2	39.5±11.5	40.8±10.3*	27.6±15.3	42.3±10.1*
3ヵ月後	24.0±14.7*	23.8±13.0	34.6±7.7*	33.7±12.4	40.1±9.1	42.1±9.3*	30.3±15.9	42.8±10.7*
6ヵ月後	23.5±18.9*	26.6±15.7	38.5±10.6*	33.8±15.5	39.7±9.5	44.0±10.6*	31.1±16.2	43.1±11.6*
repeated mesures ANOVA	p=0.0012	p=0.0897	p<0.0001	p=0.0667	p=0.0648	p<0.0001	p=0.0963	p=0.0018

†：術前と多重比較した結果　＊：$p < 0.05$

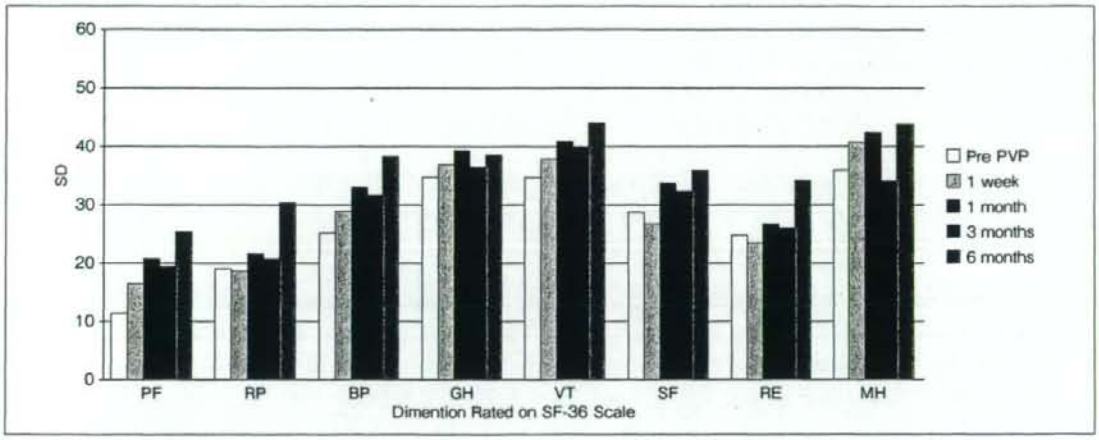

Fig.1 Mean SF-36

Bar graph shows changes in mean short-form (36-item) health survey (SF-36) scores from before intervention to 1-, 3- and 6- months follow-ups. Pre PVP = before percutaneous vertebroplasty. PF = Physical functioning, RP = Role physical, BP = Bodily pain, GH = General health perceptions, VT = Vitality, SF = Social functioning, RE = Role emotional, MH = Mental health.

6ヵ月後（25.0±6.9 vs 38.5±10.6, Δ=13.5, 95%, CI 9.2-17.8）と有意な改善を示した。活力（VT）は1週間後には有意な改善が得られなかったが（35.0±10.5 vs 39.1±9.6, Δ=4.1, 95%, CI 1.3-9.5），1ヵ月後（35.0±10.5 vs 40.8±10.3, Δ=5.8, 95%, CI 0.7-10.6），3ヵ月後（35.0±10.5 vs 42.1±9.3, Δ=7.1, 95%, CI 1.9-12.4），6ヵ月後（35.0±10.5 vs 44.0±10.6, Δ=9.0, 95%, CI 3.9-14.2）と有意に改善した。心の健康（MH）でも同様に術前と1週間後の比較では有意な改善が得られなかった（35.9±12.7 vs 41.0±10.8, Δ=5.1, 95%, CI 0.77-11.0）が，1ヵ月後（35.9±12.7 vs 42.3±10.1, Δ=6.4, 95%, CI 0.91-12.0），3ヵ月後（35.9±12.7 vs 42.8±10.7, Δ=7.0, 95%, CI 1.2-12.8），6ヵ月後（35.9±12.7 vs 43.12±11.55, Δ=7.3, 95%, CI 1.6-12.9）と改善を示した（Fig.1）。

RDQの一元配置分散分析では（Fig.2），$p < 0.0001$を示し有意な改善が得られた。また各期間ごとの多重比較（Turkey）では術前と比較して1週間後（13.3±4.9 vs 16.7±4.4, Δ=3.4, CI 0.7-6.1），1ヵ月後（12.5±5.2 vs 16.7±4.4, Δ=4.2, CI 1.7-6.7），3ヵ月後（12.9±5.0 vs

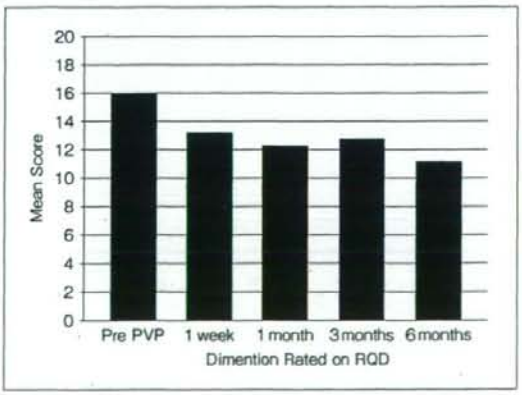

Fig.2 Mean RDQ

There was a significant improvement in outcome measures at 1 week that persisted throughout the follow-up.

16.7±4.4，Δ=3.8，CI 1.2-6.4），6ヵ月後（11.2±6.4 vs 16.7±4.4，Δ=5.5，CI 2.9-8.1）と同様にPVP施行後1週間後からQOLの改善が見られた。

PVPの除痛効果はPVP後1週間のVAS値評価で，著効47例（67.0%），有効18例（25.7%），無効5例（7.3%）であり，有効率は92.7%であった。合併症は70例中，1例でPVP後1週間の発熱，軽度肝機能障害を呈した。2週間後には肝機能障害は改善し，その間全身状態に異常は認められなかった。

考察

骨粗鬆症患者において，頻度の高い骨折部位は椎体であり，我が国では70歳代前半の25%，そして80歳以上の43%に発生する[13]。椎体圧迫骨折により椎体高の減少が生じても，骨癒合の進行と共に経時的に疼痛は軽減するものと考えられてきたが，近年，椎体内にvacuum cleft像を伴う偽関節例が報告され，骨折後に強い疼痛が遷延化する原因と考えられている。またこのような骨粗鬆症性椎体圧迫骨折に続発する偽関節は10.6～34.8%に発生すると報告され[14-17]，保存的治療を行っても数ヵ月以上にわたり強い疼痛が持続する。このような偽関節例を含む圧迫骨折患者にPVPが適応となる。

骨粗鬆症性圧迫骨折により神経症状を有することはまれであるにもかかわらず[18]，機能的，身体的，心理社会的な項目においてQOLは著明に障害され[19]，また痛みの他に活動性の低下，転倒恐怖にも影響することが報告されている[20]。海外における骨粗鬆症患者に対するPVPのQOL評価の報告では，97例のコホート研究で6～44ヵ月後の経過観察がなされ，6ヵ月後，および2年後においてPVPによるQOLの改善が得られている[21]。また30症例でVAS値およびSF-36を用いたQOL評価で，2週間後および15～18ヵ月の長期経過観察において除痛効果が得られており，QOLは治療後長期にわたり有意に改善していることが示されている[22]。

健康関連QOL尺度は，包括的尺度と疾患特異的尺度に分類される。包括的尺度は，多種の疾患を持つ人や健康と思われる人に共通する要素を広く測定するのに対し，疾患特異的尺度はその疾患に特有の症状やその影響する要素をより詳細に測定することを目的とする。今回我々は，信頼性および妥当性にすぐれたQOL評価表として[4-12]，包括的尺度であるSF-36および疾患特異的尺度であるRDQを用いた。

SF-36では国民標準値に基づくスコアリングを施行することにより，国民標準値50以下であれば国民平均以下の健康状態であることが分かる（Fig.1）。PVP施行前の得点では特に身体機能（PF），日常役割機能（身体）（RP）が20未満であり，身体的QOL低下が特に目立っていた。国民標準値を用いることで，各ドメインの尺度間ごとに疾病（椎体圧迫骨折）のインパクトを評価できる。またSF-36による8つのドメインの評価では，1ヵ月以降各時期と比較して特に身体機能面のQOLを表す「身体機能（PF）」，「体の痛み（BP）」の改善が見られ，また精神機能面のQOLでは「活力（VT）」，「心の健康（MH）」などのドメインが改善していることが分かった。また体の痛み（BP）は1週間後に優位な改善が得られ，その後1ヵ月以降で身体機能（PF）の改善が得られた。PVP後の患者QOLの改善が，PVP前と比較して1ヵ月後，3ヵ月後，6ヵ月後の多くの時期で有意に認められた。またPVP後の経過期間が長くなるほど，QOLが数値的に改善していく傾向が見られた。PVPでは除痛に早期に寄与し，その後経時的に身体的および精神的にQOL改善が得られると予想される。

RDQではPVP施行1週間後から改善を示し，1ヵ月後，3ヵ月後，6ヵ月後と各時期において術前と比較して改善が見られた（Fig.2）。また期間を経るにつれて改善幅が大きくなっている傾向があった。PVPが腰痛に関連したQOL改善に早期に影響を与えていることが分かった。Troutらも同様に1週間後にRDQで腰痛に起因するQOL改善に有意な結果が得られたと報告している[23]。SF-36による包括的な評価でも1週間後の体の痛み（BP）で改善が見られたが，SF-36の体の痛み（BP）が痛み全般を反映するのに対し，RDQは腰痛に特異的に反映している[24]。VASは最も一般的に用いられており，患者の痛みを反映し治療効果の評価について妥当であり簡便であるが[25]，PVPの効果を評価するには痛みのみならず，痛み以外の症状やQOL障害についても評価しうる要素を含んだ方法が必要と考え，SF-36とRDQを組み合わせて施行した。このようにSF-36やRDQ等の国際的な標準的QOL尺度で評価することで，椎体圧迫骨折に伴う苦痛による患者本人の著しいQOL低下と，PVPによるQOL改善効果を数量的に把握することが可能であった。椎体圧迫骨折は腰痛およびそれ以外の障害を引き起こす原因となるため，疾患特性を捉えたQOL評価を施行することが大切である。

調査対象となった患者70例におけるVAS値を用いた除痛率は93.1%であった。合併症は1例で軽度肝機能障害を伴う発熱（1/70）が出現した。その他明らかな合併症はなかった。2004年に発表されたFDAの報告によると，PVPの安全性，特に重篤な合併症の頻度は，1999年から2003年6月までの期間において，死亡数は3例である。この期間に施行された椎体形成術の総数は13万例から16万例とされており，死亡率は約5万例に1例の頻度とされ，PVPの安全性はほぼ確立されているものと考えられる[26, 27]。

高齢化社会に伴って骨粗鬆症性圧迫骨折の頻度は増え，また医療の世界における患者QOLを重視しようとする傾向は強くなっている。本邦ではこれまでPVPのQOL評価の報告はない。今後新しい治療法の有効性に言及する際，患者のQOL評価は重要な意味を持つと考えられ，QOLの向上・維持という患者立脚型の効果指標が必要である。客観的な指標をしようすることで，患者および医療側双方の共通の認識を図り，患者満足度を高めることが今後のPVPの普及や効果の検討に役立つものと考えられる。今回のPVP術前