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Title: Core needle percutaneous transpedicular vertebral body biopsy: A study of 128 cases.

Running title: Transpedicular vertebral body biopsy

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Abstract

Back ground: Percutaneous transpedicular vertebral body core needle biopsies have been performed consecutively since 1993 at our department to make histological diagnoses. This retrospective study describes the technique of percutaneous transpedicular biopsy and evaluates the effectiveness and accuracy of this technique.

Methods: One hundred and twenty-eight patients who had undergone percutaneous transpedicular core needle biopsy from T1 to L5 vertebral body lesions were evaluated. Biopsies were performed on 73 male and 55 female patients for vertebral body lesions. Sixty-five of these lesions were seen in the thoracic spine, 63 in the lumbar spine. The biopsies were carried out under local anesthesia except for the children, who underwent the biopsies under general anesthesia. Biopsy specimens were obtained by passing 8 or 11 gage needle biopsy instruments through the pedicle into the site of the lesion using C-arm fluoroscopy percutaneously. Histological analyses were performed, and the accuracy and effectiveness of this technique were evaluated.

Results: The pathologic evaluations were definitive in 120 patients including normal 12 cases, and not diagnostic in 8 patients. In the definitive 108 patients except for normal 12, the diagnoses were metastatic neoplasms in 65 patients, hematopoietic malignancies in 15 patients, osteoporotic fractures in 10 patients, tuberculous spondylitis in 8 patients, primary mesenchymal bone tumors in 5 patients, Langelhans cell histiocytosis in 2 patients, and suppurative spondylitis in 3 patient. In the not diagnostic 8 patients, the diagnoses of malignancy were established in 3 of these patients after second transpedicular core needle biopsy, the diagnosis was established in 3 of them by additional CT-guided needle biopsy, and 2 of them were diagnosed as multiple bone malignancies after biopsy of the other site bone lesions. Twelve patients, whose diagnoses were normal, were followed-up for more than 1 year, and none of them suffered from any kind of illness at that region. The accuracy of the results was different among the diagnostic categories. The diagnostic accuracies were 78.6 % in

primary neoplasms which include mesenchymal tumors, myelomas, lymphomas and Langelhans cell histiocytosis, and 97.0 % in metastatic neoplasm. There was a trend toward better accuracy in female patients (98.2%) than in male patients (90.3) , and in thoracic spine (96.9%) than in lumber spine (90.6%) , but the difference was not significant . In lumber spine , significant better diagnostic rate was seen in female patients (100%) compare to male patients (81.9%) .

Conclusion: Diagnoses were established in 128 of 120 patients (93.8%). The percutaneous transpedicular vertebral body core needle biopsy is a meaningful procedure to evaluate thoracic and lumbar vertebral body lesions.

Level of Evidence: Diagnositic Level ll. See Instructions to Authors for a complete description of levels of evidence.

Introduction

The vertebral body lesions are occasionally detected after the screening of patients for backache or malignancy somewhere with modern imaging techniques, such as computed tomography (CT), magnetic resonance imaging (MRI), bone scintigraphy and PET. Although these imaging interventions have high sensitivity, the specificity is low. Histological evaluation is required to confirm the correct diagnosis for further treatment of these lesions, and it is necessary to obtain the appropriate specimen for that purpose. The necessity of biopsy to make the differential diagnosis among the vertebral body lesion such as metastasis, osteoporotic fracture, infectious spondylitis is increasing today along with the expansion of the geriatric population.

Because of the relative inaccessibility, most physician would like percutaneous biopsy of the vertebral body lesion rather than the open procedure. However, biopsy of the vertebral body may cause some special concerns in such deeply situated lesion adjacent to vital organs. The reported complications of a closed vertebral body biopsy include pneumothorax, bleeding and neural injury even though CT-guided needle biopsies are utilized to diminish the rate of complications [Kattapuram 1991, Murphy].

The progress of the knowledge of vertebral pedicle morphometry developed the transpedicular fixation techniques in spine surgery [Zeindrick]. After experiences of these fixation techniques, percutaneous transpedicluar core needle biopsy for the lesion of the vertebral body started to be performed since 1993 in our department [Shiraishi]. The basic concept of this technique is close to the procedure introduced by Craig in 1956, but he might not have intended to pass the needle through the pedicle [Craig].

The purposes of this study are to report a precise technique for percutaneous transpedicular core needle biopsy of the vertebral body lesion and to evaluate the effect of this procedure to make histological diagnosis.

Materials and methods

The present study was a retrospective review and was approved by our institutional review board. A total of 128 percutaneous transpedicular core needle biopsies were performed consecutively between 1993 and 2011 by 2 authors (HS and JN) in our orthopaedci department. The patients were referred to our department under the diagnoses of possible pathognomonic lesions in the vertebral body of the thoracic and/or lumbar spine. In plain radiographs and/or CT, the lesions included destructive, lytic, and sclerotic lesions and suspected pathologic fractures or infectious disease. Also the lesions in which abnormal accumulation in bone scintigraphy or PET and the lesions in which some abnormal signal intensity was observed in MR during screening for some malignancies were indicated for biopsy.

Biopsy specimens were obtained after inserting the T-Lok^{TM} Bone Marrow Biopsy Needle (Medical Device Technologies INC, Gainesville FL, USA) trephine 8 gouge (4.5 mm) or 11 gouge (3.0 mm) cannula with tapered dilator in the lesion. The trephine needle is a toothed, bone cutting cannulated sleeve needle. Biopsies were performed for vertebral lesions of 73 male and 55 female patients ranging in age from 6 to 89 years old (61.3 years old on average). The vertebral body lesions were evaluated from T1 to L5, and 65 of these lesions were seen in the thoracic spine, 63 in the lumbar spine. In cervical spine, the biopsy is usually done through the anterior approach so that the cervical spinal body lesion are not included in this series.

Percutaneous transpedicular core needle biopsies were carried out using a high-resolution image intensifier and a radiolucent operating table. The fluoroscope units used were Biplane Fluoroscopy ZS 30 (Shimazu, Kyoto Japan) or Serial Vision VERSA 100R (Shimazu, Kyoto Japan).

Mepivacaine was administrated for local anesthesia from the skin to the deep layer along the planned needle tract in all patients except for 3 patients, whose ages were 8, 11, and 12 years old respectively, all who had undergone general anesthesia. Local anesthesia was done by the operator, and the patients were monitored with an automated

blood pressure cuff and a pulse oximeter. The general anesthesia, the three patients underwent, was controlled by anesthesiologists.

The precise transverse pedicle width and the pedicle angle in the axial plane that could avoid the complications were measured by preoperative CT and/or MRI. The high-resolution image intensifier is canted until the X-ray beam is collinear with the sagittal pedicle angle decided from the lateral views of the thoracic or lumbar spine. A round to oval pedicle shadow should be observed in a PA view.

The patients with destruction of the pedicle were excluded in this study because we needed not to pass the biopsy needle to the vertebral body.

A 2 to 3 mm incision is made by a needle to pass a cannulated trephin sleeve with the tapered dilator by way of the pedicle to the vertebral body. The cannula with tapered dilator is oriented collinear with sagittal and axial pedicle angles and concentric with the center of the pedicle shadow (Figure 1A). As the tapered dilator and trephine sleeve pass through the pedicle and enter the body, the tapered dilator is withdrawn when it has gotten to the suspected lesion site, which was confirmed by the lateral view of the spine (Figure 1B). The tapered dilator should never be inserted into the depth of the expected affected site to prevent the destruction of the specimen material. This insertion method is almost the same as the technique of the pedicle screwing procedure in spine surgery. The needle usually can make a smooth passage without requiring additional strong force. If the procedure is difficult to progress because of the adjacent bone to the affected site is too tight to insert the trephine needle, the direction of the needle should be changed.

The cannulated trephin sleeve is twisted in a clockwise and anticlockwise movement repeatedly to separate the affected tissue from the surrounding tissue and to get the specimen inside the sleeve. If the trephin sleeve proceeds deeply enough to the targeted area, the sleeve is withdrawn in twisted motion. When an adequate material could not be retrieved on the first trial, the direction of the needle is altered to be able to

get appropriate specimens under the image guidance. The constancy of the circumferential walls of the pedicle must not be destroyed for preventing the contamination from neoplasm or infection and hematoma formation in the spinal canal.

After a 2-hour observation without any symptoms suggestive for complications, the outpatients are permitted to return to their homes. If some new symptoms suggest complications after discharge from the hospital, they can complain of their conditions to the operating physician by telephone. For the in-patients, the subjective symptoms are reported to the operating physician by co-medical stuff.

The main specimens obtained are sent for histological analysis. Bacteriological studies are also performed in the cases suggestive for having infectious disease. The specimens were histologically examined by one of the authors (TS). Following four types of the diagnoses were rendered: True positive means some definitive pathological diagnosis was made from the specimen, true negative means the specimen was considered normal bone, false negative means some diagnosis was made at the initial biopsy but the diagnosis was denied finally, false negative means the specimen was not diagnostic at the initial biopsy, but some definitive diagnosis was made finally by some modalities. The accuracy of the biopsy was confirmed by the clinical course and response to the treatment or comparing the histological findings between the biopsy specimen and the surgical specimen or additional biopsies.

The rate of accurate diagnosis, including definitive pathological diagnosis and normal bone, was calculated and evaluated among the patients groups. All data were calculated for significance with computer software (SPSS 12.0 for Windows; SPSS Inc, Chicago, IL). We used Fisher exact tests to analyze categorical variables among the groups. The level of significance was set at $p < 0.05$.

Results

The pathologic evaluations were definitive in 120 (93.8%) patients including 12

cases with normal bone, and not diagnostic in 8 patients (6.3%) (Table 1) after the initial procedure. There were no post-procedure complications. In the definitive 108 patients except for the normal bone cases, the diagnoses were metastatic carcinoma in 62 patients, osteoporotic fracture in 10 patients, tuberculous spondylitis in 8 patients, multiple myeloma or plasmacytoma in 10 patients, malignant lymphoma in 5 patients, primary mesenchymal bone tumors in 5 patients, metastasis of sarcoma in 3 patients, Langerhans cell histiocytosis in 2 patients, and suppurative spondylitis in 3 patient. All of 7 patients with inadequate materials had diagnoses of having malignancies at the final follow-up. In three of these patients the diagnoses was established after the second transpedicular core needle biopsy, including myeloma, primary unknown carcinoma and primary osteosarcoma. In two of them the diagnosis was established by an additional CT-guided needle biopsy, and the diagnoses were multiple myelomas. Two of them were diagnosed as having multiple bone malignancies after biopsies of the other bone lesions, including metastasis of lung cancer and multiple malignant fibrous histiocytoma of bone.

Significant lower diagnostic rates were seen in the primary lesions compare to the metastatic neoplasms (Table 2). The final diagnoses of 95 patients with primary or metastatic neoplasms were hematopoietic diseases including myeloma or plasmacytoma in 13 cases, malignant lymphoma in 5, and Langerhans cell histiocytosis in 2 (Table 3). Primary mesenchymal tumors included 3 patients of osteosarcoma, 2 malignant fibrous histiocytoma 1 each of leiomyosarcoma and aneurismal bone cyst, respectively. The primary lesions of the carcinomas were prostatic carcinoma in 13 cases, lung in 9, breast in 7, thyroid in 4, two each in colon, kidney, liver, and ureter respectively, and 1 each in bladder, stomach, ovarium, uterus, thymus gland, pharynx, salivary gland, sinusoidal, and sweat gland, respectively. In 13 patients with metastatic carcinoma, the primary lesion could not be detected at the final follow-up time even after their deaths. The diagnoses of the metastatic mesenchymal malignancies were liposarcoma and

neurogenic sarcoma and osteosarcoma.

There was no false positive patient.

There was a trend toward better accuracy in female patients (98.2 %) than in male patients (90.3 %), however the a significant difference was not admitted (Table 4).

A significant difference was seen in the diagnostic rate of the male and female patients in the lumber spine, however the difference was not in the thoracic spine. (Table 5)

Twelve patients, whose diagnosis was normal, were followed-up for more than 12 months, and none of them suffered from any kind of disease at the biopsied region.

Staphylococcus aureus was disclosed by a cultured specimen from biopsy in the suppurative spondylitis case, however, the mycobacterium was not detected in the bacteriological investigation in the cases diagnosed as having tuberculosis.

Discussion

Definitive histological diagnosis has to be established before appropriate treatment of the musculoskeletal lesions. Percutaneous biopsy is applicable for histological and bacteriological evaluation of vertebral body lesions [Crajg, Dave, Vallas]. It is minimally invasive, an easy technique and quick to perform to obtain the specimens from the vertebral body with rare complications and lesser cost. It can be an reasonable alternative for CT-guided biopsy and replace more invasive open biopsy.

The percutaneous biopsy of the spine was introduced in 1935 [Robertson] and the pedicular approach to the vertebral body was reported in 1936 [Duncan]. However, the percutaneous transpedicular vertebral body biopsy has been adopted only recently. Stringham et al. reported 3 cases which had undergone image intensification percutaneous transpedicular vertebral body biopsies in 1994 [Stringham]. They

described the reason of the belated development of this procedure and stated it may be attributed to three explanations. First, the proximity of the pedicle to vital structures deterred closed biopsy attempts because of fears of injury. Second, the appreciation of the biopsy potential of vertebral body lesions through the pedicle has been limited. Third, the larger tissue samples retrievable with open biopsy make the open procedure (with radiographic guidance where indicated) the "gold-standard" to which all other biopsy procedures must compare [Stringham]. Without knowledge of their trials in the 3 cases, we started percutaneous transpedicular vertebral body biopsy in 1993 after our experience with the transpedicular fixation techniques.

Conventionally, open biopsy are preferred over closed needle biopsy in any part of the body because more tissue is available for histopathology with the higher diagnostic success rate. Accordingly, open biopsy was occasionally performed after failed needle biopsy or in special conditions such as much tissue volume being required. However, the morbidity associated with an open surgical procedure is the distinctive disadvantage of an open biopsy, and a closed needle biopsy is an incentive if the technique provides a high rate of accuracy in making a diagnosis with minimum complications.

The reported diagnostic success rates of the needle biopsy of the vertebral body lesion vary [Kattapuram 1992, Murphy, Debnam, Kornblum]. Kornblum et al. reported that adequate specimens were obtained in 87 % of cases with computed tomography (CT)-guided biopsy [Kornblum]. They also reported that thoracic level percutaneous biopsies had a significantly lower accuracy rate. These results were different from our results. The accuracy rate in this study was 96.9 %. Although there was no significant difference, thoracic spine had a better accuracy rate than that of the lumbar spine. The inferior success rate in the lumbar spine in this series may relate to the larger number of mesenchymal tumors and hematopoietic diseases in the lumbar spine, although there are no statistical difference between the lesion sites and the final diagnosis.

Kattapuram et al. and Fyfe et al. described that the inferior success rate of a closed biopsy is associated with the smaller size of needles used [Kattapuram 1992, Fyfe]. According to them, a crush artifact is one of the problems created by small needles [Kattapuram 1992]. Fyfe et al. reported a cadaveric study in which biopsy specimens of 2 mm or more in diameter can be expected to give a higher degree of diagnostic accuracy [Fyfe]. The sizes of the needle we used were 8 or 11 gouge, and they may have enough size to make an accurate diagnosis without a crush artifact. Because the pedicle allows passage of biopsy instruments that retrieve tissue core diameters larger than 2 mm, the diagnosis success rate of a percutaneous transpedicular biopsy may be close to the success rate of an open biopsy. Larger tissue core diameters also avoid the diagnostic problems created by a crush artifact. No diagnostic problems concerned to the crush artifact even though cannulation of the biopsy needle over a guide pin in this series, and the diagnosis success rate of our procedure were satisfactory.

Morphometric reports of the vertebrae have improved our understanding of pedicular anatomy and its potential utility as biopsy tructs. Misenhimer et al. reported that the pedicle was described as a thin shell of cortical bone filled with cancellous bone [Misenhimer]. They reported the average cancellous pedicle width (transverse inside diameter) from T1to L5 measured by sounding ranged from slightly more than 1 mm at T4 to slightly less than 6 mm at L5. Stringham et al. reported that a biopsy needle that will retrieve a tissue core diameter larger than 2 mm has an outside diameter of nearly 3 mm, and adequate space exists in most pedicles for transpedicular retrieval of substantial tissue specimens [Stringham]. Sufficient space may also exist for the insertion of biopsy needle at various angles to access any thoracic and lumbar vertebral body lesions. Specifically, we have never experienced any difficulties in performing percutaneous transpedicular biopsy in thoracic and lumbar spinal lesions.

Less than 3 mm transverse inner pedicle diameter is not a contra-indication for a percutaneous transpedicular needle biopsy. Zeindrick et al. reported average

transverse outside diameters of the pedicular isthmus in the thoracic and lumbar spine ranged between 4.5 mm at T5 and widest 18 mm at L5 [Zeindrick]. Saillant reported the narrowest pedicle diameter was 5 mm at T5 [Saillant]. Even though the inside pedicle diameters measure less than 3mm, percutaneous transpedicular needle biopsy could be safely performed because the outside pedicle diameter allows the operator to safely insert the instrument toward the vertebral body. However, the risk of contamination with neoplastic or infectious lesions with or without hematoma will increase if the cortical wall of the pedicle is destroyed, so that a gentle technique is necessary to prevent complications

Reported complications associated with closed needle biopsy for the skeletal lesions are pneumothorax, hematoma, tuberculous sinus tract and neural injury etc. [Murphy]. The estimated complications rate is 0.2 % in percutaneous skeletal biopsies [Murphy], and the rate may be higher in the vertebral lesions. They also reported a few cases of transient paresis, transient spinal paraplegia, meningitis and death [Murphy]. The rate of complications is thought to be related to the anatomic location of the lesion and the type of needles used [Kattapuram 1991]. However, such complications have never been seen in this study, which may be referable to the experience of the transpedicular fixation techniques with progress of the knowledge of vertebral morphometry. The passage for biopsy needles to the vertebral body can be provided by the pedicle without damaging the anatomical structures placed at risk if the extra-pedicular closed needle biopsy of the vertebral body is performed. The importance of maintaining the integrity of the medial and the inferior aspects of the pedicle was emphasized for the anatomic relationship of the pedicle to neural elements [Stringham]. High-resolution image intensifiers display sufficient detail of vertebral components to allow protection of the medial and inferior wall of the pedicle during biopsy, and injury of the neural elements can be avoided. The amount of tissue retrieved for histopathology contributing to a diagnostic success rate may be enough

without significant morbidity.

We believe that the potential complications and morbidities can be prevented utilizing the percutaneous transpedicular techniques from the results of this series, although Fidler and Niers reported that an open transpedicular approach has advantages to a percutaneous procedure to enable the physician to perform a block resection and to avoid damage to the wall of pedicle with possibility of contamination of the epidural space or paravertebral structures [Fidler]. Also, the cost associated with the open approach can be preserved.

From the reports of CT-guided vertebral body biopsies, the reliability was 94 % in osteolytic lesions and 75 % in sclerotic lesions [Brugieres], and it was more difficult to get a correct diagnosis in sclerotic lesions than that in mixed lesions [Ghelman]. Stroker and Kissan also reported lower adequacy rates for biopsies in sclerotic lesions [Stroker]. They recommended pursuing sclerotic lesions at least in dense areas. There is a possibility that it might be difficult to obtain adequate amount of the tissue in sclerotic lesions with a needle biopsy. In this study, accurate diagnosis was not obtained in one of the 12 sclerotic lesions, and we can not refer to the difference of reliability between the sclerotic and not sclerotic lesions, because of the small number of patients. But it might be one of the cause that the diagnostic rate of female was better than that of man in the lumber spine.

It should be evaluated futher in the future.

Dave reported that instruments passing through one vertebral pedicle are able to access more than 50% of the total volume of the vertebral body [Dave]. We believe that most vertebral body lesions except for the tissues directly anterior to the spinal canal, lateral edge areas of the vertebral body and superior and inferior edges of the posterior areas of the vertebral body are accessible by this technique (Figure 2). The lesions may not stay within these narrow areas, especially the malignant lesions, and the results of this study suggest that this procedure could be diagnostic for almost the whole

vertebral body. Greater latitude for angling instruments exists in the saggital plane than in the axial plane because the saggital pedicle diameter is greater than the transverse diameter [Zendrick]. An appropriate amount of the tissue can be retrieved by this method by performing in multiple directions.

Local anesthesia and an outpatient setting contribute to enhanced cost effectiveness. Local anesthesia also provides monitoring of the nerve root during a biopsy. Consequently, a percutaneous transpedicular biopsy of spinal lesions under local anesthesia has become the biopsy technique of choice, because there are rare potential complications, such as nerve injury, bleeding, pneumothorax and inadequate tissue for diagnosis.

Although this technique may have many advantages, the advantages and disadvantages in both CT-guided needle biopsy and this technique must be further evaluated by large numbers of cases. There is a possibility that these two techniques may be adopted in a complementary manner in accordance with local conditions and individual patient characteristics.

Conclusion

Transpedicular percutaneous biopsy of vertebral body lesions allows passage of biopsy instruments to most vertebral body lesions and the retrieval of sufficient tissue for diagnosis. The use of local anesthesia helps in continuous monitoring of neural elements function with cost effectiveness as it can be performed as an outpatient procedure. The decreased risk of hematoma, pneumothorax and nerve root injury makes the transpedicular approach to the vertebral body lesions an effective alternative to other procedures.

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Titles of Tables and Figure legends

Table 1. The numbers of the patients of the final diagnoses and level of the spinal segment.

Table 2. The diagnostic accuracy of the primary and metastatic neoplasms.

Table 3. The final diagnosis of primary and metastatic neoplasms.

Table 4. The diagnostic criteria and the spinal segment.

Figure 1. The cannula with tapered dilator is oriented collinear with sagittal (Figure 2A) and axial (Figure 2B) pedicle angles and concentric with the center of the pedicle shadow.

Figures 2. The theoretically inaccessible areas in axial (Figure 2A) and sagittal view (Figure 2B) by this technique are shown by shadows.