Clinical Application of a Modified Bone Cement Pusher in Percutaneous Vertebroplasty Combined with Multi-Target Negative Pressure Rotary-Cutting Technique in Puncture Biopsy for Bone Tumors

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Abstract

Purpose To assess the efficiency and safety of a modified bone cement pusher in percutaneous vertebroplasty (PVP) combined with a multi-target negative pressure rotary-cutting technique in puncture biopsy of bone tumors.

Methods The biopsy performed with the modified bone cement pusher commonly used in PVP, and a multi-target negative pressure rotary-cutting technique. A total of 120 patients with spinal and pelvic tumors undergoing needle biopsy in our department were recruited and assigned to new biopsy device group (group A, n=60) or and conventional biopsy device group (group B, n=60). The puncture time, positive rate, consistency rate, and dependence rate between group A and B were compared to assess the efficiency and safety of the new device.

Results No biopsy-related complications were reported in both groups. The puncture time (39.44 ± 8.885 min vs. 61.61 ± 9.880 min), positive rate (96.67% vs. 61.67%), consistency rate (96.55% vs. 81.8%), and dependence rate (100% vs. 83.33%) were significantly superb in group A compared with those in group B (all $P < 0.05$). Patients in group A did not require repeated biopsies, and sufficient samples were obtained through the needle trajectory in PVP. All patients with a definite diagnosis were managed with appropriate treatments.

Conclusions Featuring high safety, positive rate and consistency rate, the new device can be performed to collect sufficient pathological samples from multiple angles. Wide clinical replication can be expected considering its evident diagnostic efficiency for bone tumor.

Introduction

Early diagnosis and timely treatment are critical for the prognosis of bone tumors. The diagnosis of bone tumors is established on a combination of clinical, imaging and pathological characteristics[1,2]. However, imaging indexes may vary significantly among individuals. Pathological examinations, as a result, exert determinacy in the accurate diagnosis and selection of therapeutic strategies. A biopsy is the main method to collect tissue samples for pathological examination[3,4]. Compared with open surgical biopsy, CT-guided percutaneous biopsy has been widely applied for bone tumors because of its higher safety, simpler procedures and less complications[5,6,7]. However, the biopsy through a thin needle or a cannula is restricted by low repeatability, contamination in surrounding tissues, insufficient tissue, and high false positive rate. In particular, osteogenic bone tumors have usually a sclerotic bone hardly to be penetrated by a thin needle or a cannula. How to safely, easily and accurately collect bone tumor tissues through biopsy is critical for a definite pathological diagnosis. In the present study, we designed a device using a modified bone cement pusher in PVP and a multi-target negative pressure rotary-cutting technique, and tested its efficacy and safety in puncture biopsy of bone tumors.

1 Methods

1.1 General information

A total of 120 patients with spinal and pelvic tumors undergoing puncture biopsy in our department were recruited and assigned to the new biopsy device group (group A, n=60) and the conventional biopsy device (group B, n=60). Among 40 patients with spinal tumors and 20 with pelvic tumors in group A, 43 presented with osteogenic bone destruction, and 17 with osteolytic bone destruction. Among 40 patients with spinal tumors and 20 with pelvic tumors in group B, 30 presented with osteogenic bone destruction and 30 with osteolytic bone destruction.

1.2 Biopsy devices

A 64-slice spiral CT machine, disposable thoracentesis package, 100 ml of normal saline, 10 ml of 2% lidocaine hydrochloride injection, heparin sodium injection, a novel puncture biopsy device (Figure 1) We have applied for a patent (the patent number was ZL 2019 2 2137859.8) and a conventional puncture biopsy device (Figure 2) were used in this study. We modified the injection cannula of the bone cement pusher used in PVP. Its smooth edge was serrated with proper size, thickness, rigidity and strength.

1.3 Preparation for puncture biopsy

Routine blood test, coagulation factor test and imaging examinations were performed. Informed consent was obtained prior to puncture biopsy. Eligible were patients who were in good general conditions, could maintain a supine or prone position for a minimum of 30 min, presented normal routine blood and coagulation indexes, and had intact skin at the site of puncture.

1.4 Biopsy groups and Methods

1.4.1 New puncture biopsy device group (group A)

(1) Spinal tumors

Approaches through the pedicle, costovertebral joint or lateral vertebra were set in the biopsy for the spinal tumor. Puncture targets, entry points and angles were marked with preoperative CT. After routine sterilization and draping, local anesthesia was performed by injecting 2% lidocaine hydrochloride into the periosteum of pedicles with a long, thin needle. Through a 1-cm longitude incision, the modified needle was inserted through the pre-determined entry point and angle. The guide wire was withdrawn once having approached the pedicle of vertebral arch. Subsequently, the injection cannula of the bone cement pusher was inserted into the vertebral needle trajectory created according to PVP procedures, and fixed. A 60 ml syringe connected to the end of the injection cannula of the bone cement pusher, in which a

negative pressure spring was placed, was slowly inserted into the tumor lesion for aspiration. During the rotary cutting by the serrated edge, columnar tissues with a diameter of the inner injection cannula were collected, placed in normal saline containing heparin, and filtered using sterilized gauze. The injection cannula of bone cement pusher was extubated, while the vertebral needle trajectory was retained for repeated biopsies using the rotary-cutting technique at different angles and depths, until satisfactory samples were obtained. Biopsy samples were finally fixed in 4% formalin and sent for pathological examinations.

(2) Pelvic tumors

The entry point was set within the scope of skin incision. Puncture targets, entry points and angles were determined by preoperative CT. The biopsy procedures for pelvic tumors were similar to those for spinal tumors.

1.4.2 Conventional puncture biopsy device group (group B)

(1) Spinal tumors

Approaches through the pedicle, costovertebral joint or lateral vertebra were selected in the puncture biopsy for spinal tumors. Puncture targets, entry points and angles were determined by preoperative CT. After routine sterilization and draping, local anesthesia was performed by injecting 2% lidocaine hydrochloride into the periosteum of pedicles using a long, thin needle. Through a 1-cm longitudinal incision, the conventional needle was inserted through the pre-determined entry point and angle, and advanced to the pedicle of the vertebral arch. Biopsy samples were collected by the rotary-cutting technique, placed in normal saline containing heparin, filtered using sterilized gauze and fixed in 4% formalin for pathological examinations.

If the tissue without lesion was punctured, the above steps were repeated again to obtain the pathological tissue by repeated puncture.

(2) Pelvic tumors

The entry point was set within the scope of skin incision. Puncture sites, entry points and angles were determined by preoperative CT. The procedures of puncture biopsy for pelvic tumors were similar to those for spinal tumors.

1.5 Evaluation index

The puncture time, positive rate, consistency rate, and dependence rate between group A and B were compared to assess the efficacy and safety of the new device. In detail, positive biopsy was defined as the definite diagnosis or qualitative diagnosis of samples; and negative biopsy as failure to obtain samples, or samples having no pathological diagnostic values and leading to inaccurate qualitative diagnosis. The consistency was defined as agreement between diagnoses based on biopsy samples and postoperative results. The dependence was defined as patients' cooperation and satisfaction during the puncture biopsy.

1.6 Statistical Processing

SPSS 21.0 statistical software was used for analysis. The measurement data were expressed as mean $\pm$ standard deviation ($\bar{X} \pm S$) and the counting data as a percentage (%). T-test was used for measurement data, the chi-square (χ^2) test or non-parametric test was used for counting data, and $P < 0.05$ was considered statistically significant.

2 Results

No puncture-related complications were reported in both groups. The puncture time was significantly shorter in group A than in group B (39.44 ± 8.885 min vs. 61.61 ± 9.880 min, $P < 0.05$). Besides, the positive rate (96.67% vs. 61.67%), consistency rate (96.55% vs. 81.8%), and dependence rate (100% vs. 83.33%) were significantly higher in group A than in group B (all $P < 0.05$) (Table 1).

Table 1
Comparison of the evaluation indices between the Groups A and B($\bar{X} \pm S$)

Item	puncture time(min)	positive rate(%)	consistency rate(%)	dependence rate(%)
Group A(N=60)	39.44±8.885	96.67% (58/60)	96.55% (56/58)	100% (60/60)
Group B(N=60)	61.61±9.880	61.67% (37/60)	81.8% (30/37)	83.33% (50/60)
T/ χ^2	13.03	22.282	6.304	10.909
P-value	.000	.000	.012	.001

Among the 58 patients with positive biopsy results in group A, 56 showed consistency with postoperative pathological diagnosis (Figure 3), including 23 with metastatic tumors (Figure 4), 20 with primary tumors (5 with osteosarcoma, 3 with Ewing's sarcoma, 5 with giant cell tumor of bone, 1 with schwannoma, 4 with chordoma, and 2 with chondrosarcoma), 2 with hemangioma, 5 with myeloma, 4 with lymphoma, and 2 with spinal tuberculosis.

Among the 37 patients with positive biopsy results in group B, 30 showed consistency with postoperative pathological diagnosis (Figure 5), including 15 with metastatic tumors (Figure 4), 9 with primary tumors (4 with osteosarcoma, 3 with giant cell tumor of bone and 2 with chordoma), 3 with myeloma, 2 with lymphoma and 1 with spinal tuberculosis.

Discussion

Pathological examination is the golden method for diagnosing bone tumors, proposing treatment strategies and assessing therapeutic efficacy[8,9]. Pathological samples are usually collected through open surgical biopsy or puncture biopsy. The former is featured by sufficient samples and high accuracy up to 98%[10]. However, it is limited by high medical cost, massive trauma, and contamination in surrounding tissues[8]. Characterized with simple procedures, less complications and high accuracy percutaneous biopsies are commonly used for bone tumors, including fine-needle aspiration biopsy and cannula puncture biopsy[11]. Sufficient biopsy samples are essential to pathological diagnosis[12]. In fine-needle aspiration biopsy, however, insufficient samples are collected, and their quality are often reduced due to the squeezing force from the narrow needle trajectory[13,14,15]. Cannula puncture biopsy is usually performed for avoiding complications of open surgery and obtaining sufficient samples with a high diagnostic value[16,17]. For deep spinal and pelvic tumors, fine-needle aspiration or cannula puncture biopsies are less recommended, considering their low repeatability, tissue contamination, incapability to penetrate the sclerotic bone, insufficient samples and high false negative rate. It is necessary to develop a safe, convenient and precise device suitable for the puncture biopsy of spinal and pelvic tumors.

PVP is extensively performed in the treatment of osteoporotic vertebral compression fractures or pathological fractures[18,19,20]. Only a small amount of vertebral pathological tissues can be collected through the screw-rod system of PVP[21,22]. As a result, it is not routinely used in the puncture biopsy of vertebral bone destruction. We considered that the injection cannula of the bone cement pusher used in the PVP can be modified for collecting sufficient samples, because it has a larger diameter. Through serrating its edge with proper size, thickness, rigidity and strength, we developed a novel puncture biopsy device. Under the guidance of intraoperative CT, the puncture needle can be inserted and rotated for cutting bone tumors, through which columnar tissues with the same diameter of the inner injection cannula are repeatedly collected at different angles and depths. This allows for an innovation in bone biopsy: bone cement pusher in PVP combined with multi-target negative pressure rotary-cutting technique.

In the present study, bone tumor patients who had already lost the optimal opportunity for surgery and needed chemotherapy and/or radiotherapy were excluded, and some of them gave up treatment. All patients with a definite diagnosis were appropriately treated. Compared with conventional puncture biopsy device, our new device shortened the puncture time, and increased positive and consistency rates. No complications were reported, and the dependence rate reached 100%. Using the new puncture biopsy device, we did not need repeat puncture in group A. Moreover, the new device significantly reduced the

risks of pedicle rupture and contamination of the needle passage, because the vertebral needle trajectory was maintained for repeated biopsies at different angles and depths. Using conventional devices, the puncture biopsy for spinal and pelvic tumors is limited by long puncture time, low positive rate and poor compliance. Attributive factors may be included as follows: the tumor is anatomically deep, leaving insufficient tissue for sampling or even normal tissue mis-collected, repeated biopsies increase pain and psychological disorders in patients, thus worsening their compliance; error may also appears in pathological diagnosis.

Conclusion

Collectively, we modified the bone cement pusher in PVP and used it with multi-target negative pressure rotary-cutting technique in the puncture biopsy of bone tumors. The new device could realize repeated collection of biopsy samples, simplify puncture procedures, reduce complications and medical cost, and increase positive rate. It was also suitable for needle biopsy of spinal infectious lesions and bone neoplastic lesions of extremities, especially in the latter. This was a single-center retrospective study with a small sample size. Our findings should be validated in multi-center institutions with a large sample size.

Declarations

Ethical committee approval

The present study has been performed in accordance with the Declaration of Helsinki and was approved by the Ethics Committee of the General Hospital of Ning Xia Medical University. All methods were performed according to relevant guidelines. Informed consent was obtained from each patient's guardian.

Data availability statement

Due to the nature of this research, participants of this study did not agree for their data to be shared publicly, so supporting data is not available.

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Authors' contribution statement

Ningkui Niu and Zongqiang Yang designed the study. Jing Tang and Ningkui Niu were involved in the manuscript writing. Jing Tang and Hongbao Ma collected the clinical data. Zongqiang Yang, Jing Tang and *Linan Wang* analyzed the data. Jing Tang revised the draft. All authors read and approved the final manuscript.

Declaration of Competing Interest

The authors declare that they have no conflict of interest.

References

1. Barragan-Campos H M, Jimenez-Zarazua O, Mondragon J D (2015) Diagnosis and Treatment Options of Spinal Metastases. *Rev Invest Clin* 67: 140–157.
2. Epstein N E, Hollingsworth R D, Silvergleid R (2015) Spinal surgeons need to read patients' studies to avoid missing pathology. *Surg Neurol Int* 6: S313-S317. <http://doi.org/10.4103/2152-7806.159379>.
3. Ozsarlak O, De Schepper A M, Wang X, De Raeve H (2003) CT-guided percutaneous needle biopsy in spine lesions. *JBR-BTR* 86: 294–296.
4. Gul S B, Polat A V, Bekci T, Selcuk M B (2016) Accuracy of Percutaneous CT-Guided Spine Biopsy and Determinants of Biopsy Success. *J Belg Soc Radiol* 100: 62. <http://doi.org/10.5334/jbr-btr.985>.
5. Y L, Hf Y, Du Y, Xx X (2009) Related factors of diagnostic yield of CT-guided percutaneous biopsy for bone tumors. *Radiol Practice* 24: 1345–1347.
6. Garg V, Kosmas C, Josan E S, Partovi S, Bhojwani N, Fergus N, Young P C, Robbin M R (2016) Computed tomography-guided percutaneous biopsy for vertebral neoplasms: a department's experience and hybrid biopsy technique to improve yield. *Neurosurg Focus* 41: E17. <http://doi.org/10.3171/2016.4.FOCUS1614>.
7. Ortiz A, Marden J (2017) *Image-Guided Percutaneous Spine and Rib Biopsy: Tools and Techniques*. Springer International Publishing.
8. Oue T (2016) *Biopsy of Tumor*. Springer Japan.
9. Gasbarrini A, Boriani L, Salvadori C, Mobarec S, Kreshak J, Nanni C, Zamparini E, Alberghini M, Viale P, Albisinni U (2012) Biopsy for suspected spondylodiscitis. *European review for medical and pharmacological sciences* 16.
10. Holzapfel B M, Ludemann M, Holzapfel D E, Rechl H, Rudert M (2012) [Open biopsy of bone and soft tissue tumors: guidelines for precise surgical procedures]. *Oper Orthop Traumatol* 24: 403–415, 416–417. <http://doi.org/10.1007/s00064-012-0190-7>.
11. Tehranzadeh J, Tao C, Browning C A (2007) Percutaneous needle biopsy of the spine. *Acta Radiol* 48: 860–868. <http://doi.org/10.1080/02841850701459783>.
12. Kang M, Gupta S, Khandelwal N, Shankar S, Gulati M, Suri S (1999) CT-guided fine-needle aspiration biopsy of spinal lesions. *Acta Radiol* 40: 474–478. <http://doi.org/10.3109/02841859909175570>.

13. Chauhan V,Gupta A,Gupta P,Maheshwari R,Juyal A, Batta V(2006)Role of fluoroscopic guided fine needle aspiration biopsy in spinal pathologies.Indian Journal of Orthopaedics 40.
14. Mohammad G,Alireza K,Ali M,Hasan R S,Amir R K,Parham S,Hengameh E,Soheil Sabzevari S G,Nima G,Salman Z, Maryam A(2013)103 case to case compare of Core Needle biopsy results with open biopsy one in skeletal tumor.Life Science Journal 10.
15. Shaikh H,Thawani J, Pukenas B(2014)Needle-in-Needle Technique for Percutaneous Retrieval of a Fractured Biopsy Needle during CT-Guided Biopsy of the Thoracic Spine.Interv Neuroradiol 20: 646–649. <http://doi.org/10.15274/INR-2014-10061>.
16. Kaltsikis I,Chourmouzi D,Drevelegas K,Potsi S,Moumtzouoglou A, Drevelegas A(2012)Core needle biopsy of spinal lesions under CT guidance: review of 79 cases.J Neurol Surg A Cent Eur Neurosurg 73: 199–203. <http://doi.org/10.1055/s-0032-1304217>.
17. Shrestha D,Shrestha R, Dhoju D(2015)Fluoroscopy Guided Percutaneous Transpedicular Biopsy for Thoracic and Lumbar Vertebral Body Lesion: Technique and Safety in 23 Consecutive Cases.Kathmandu Univ Med J (KUMJ) 13: 256–260. <http://doi.org/10.3126/kumj.v13i3.16818>.
18. Yimin Y,Zhiwei R,Wei M, Jha R(2013)Current status of percutaneous vertebroplasty and percutaneous kyphoplasty—a review.Med Sci Monit 19: 826–836. <http://doi.org/10.12659/MSM.889479>.
19. Markmiller M(2015)Percutaneous balloon kyphoplasty of malignant lesions of the spine: a prospective consecutive study in 115 patients.Eur Spine J 24: 2165–2172. <http://doi.org/10.1007/s00586-014-3751-7>.
20. Yaltirik K,Ashour A M,Reis C R,Ozdogan S, Atalay B(2016)Vertebral augmentation by kyphoplasty and vertebroplasty: 8 years experience outcomes and complications.J Craniovertebr Junction Spine 7: 153–160. <http://doi.org/10.4103/0974-8237.188413>.
21. Pagdal S S,Nadkarni S,Hardikar S M, Hardikar M S(2016)Role of Transpedicular Percutaneous Vertebral Biopsy for Diagnosis of Pathology in Vertebral Compression Fractures.Asian Spine J 10: 925–929. <http://doi.org/10.4184/asj.2016.10.5.925>.
22. Majeed S,Tom R,David C,Robert L,Shaishav B,John P, Saajid K(2016)Cost implications of routine bone biopsy in percutaneous vertebroplasty/kyphoplasty.The Spine Journal 16.

Figures

Figure 1

A Novel puncture biopsy device: A was PVP puncture of System. B was PVP cannula System. C was PVP of Drill used in vertebroplasty to biopsy. D,d We modified the injection cannula of the bone cement pusher used in PVP and Its smooth edge was serrated with proper size, thickness, rigidity and strength.

Multi-target negative pressure rotary-cutting technique: E was modified bone cement pusher. F was negative pressure device. G was negative pressure rotary-cutting puncture biopsy. The injection cannula of bone cement pusher was extubated, while the vertebral needle trajectory was retained for repeated biopsies using the rotary-cutting technique at different angles and depths. H was Puncture specimen of bone tumor.

Figure 2

Conventional puncture biopsy device: This device had not cannula, if the tissue without lesion was punctured, the puncture steps were repeated again to obtain the pathological tissue by repeated

puncture.

Figure 3

Among the 58 patients with positive biopsy results in group A, 56 showed consistency with postoperative pathological diagnosis (Figure 3)

Figure 4

classification of metastatic Carcinoma A and B

Figure 5

Among the 37 patients with positive biopsy results in group B, 30 showed consistency with postoperative pathological diagnosis (Figure 5)