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Diagnostic yield of percutaneous core needle biopsy in suspected soft tissue lesions of extremities

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Abstract

Objective: This retrospective study was performed to investigate the diagnostic yield of percutaneous core needle biopsy (CNB) for suspected soft tissue lesions of the extremities.

Methods: The medical records of 139 consecutive patients who underwent percutaneous CNB for suspected soft tissue lesions of the extremities from January 2014 to December 2016 at a single institution were reviewed. The pathologic findings or clinical follow-ups were used to evaluate the performance of CNB. Alterations in the treatment regimen from pre- to post-biopsy were also analyzed. Complications, when present, were documented.

Results: In total, 141 biopsy procedures were performed in 139 patients. In total, 136 (96%) biopsies were successful, among which 5 were false-negative and 131 were diagnosed accurately. The sensitivity, specificity, accuracy, positive predictive value, and negative predictive value of CNB in the differentiation of malignant from benign lesions were 94%, 100%, 96%, 100%, and 90%, respectively. The treatment regimen was altered based on the biopsy findings in 25 cases. Two patients developed mild nerve injury but fully recovered during follow-up.

Conclusions: CNB is effective and safe, with high sensitivity, specificity, and accuracy for the diagnosis of soft tissue lesions, especially for differentiating malignant from benign lesions.

Keywords

Soft tissue lesions, core needle biopsy, extremity, diagnosis, accuracy, retrospective study

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Introduction

In modern clinical practice, accurate treatment depends on an accurate diagnosis. This rule should be strictly followed when managing patients with soft tissue lesions,[1,2] particularly because various types of soft tissue lesions exist, including tumors, tumor-like lesions, and infections. Malignant soft tissue tumors (STTs) alone have been stratified into 9 types and more than 100 subtypes.[3] These different types of tumors require different treatments,[4,5] some with medications[6] but others with surgery, and the surgeries for benign and malignant tumors also differ.[7] In addition, many clinical conditions, such as infection and tumor-like lesions, appear similar to STTs on radiological examinations. Therefore, establishing a histological diagnosis prior to initiating treatment is crucial for the management of soft tissue lesions.[8–10]

Many reports have described the use of percutaneous core needle biopsy (CNB) to diagnose soft tissue lesions.[7,11–14] In most studies, however, only STTs were included, while lesions with clinical and radiological appearances similar to those of STTs, such as infection or tumor-like lesions, were excluded. In addition, to the best of our knowledge, no prior reports have described clinical management changes that were based on CNB findings.

To further confirm the value of CNB, the present retrospective study compared the use of CNB for differentiating STTs, tumor-like lesions, and infections, taking special note of management changes that were based on the CNB results.

Methods

This retrospective study complied with the Health Insurance Portability and Accountability Act (HIPAA) and was approved by the institutional review board of our institution (a single tertiary care facility). The need for informed patient consent was waived.

Patients

The medical records of patients who underwent percutaneous CNB for clinically suspected soft tissue lesions of the extremities from January 2014 to December 2016 were reviewed.

The inclusion criteria were as follows: the lesion was beneath the deep fascia and >5 cm in diameter, definitive surgery was conducted after biopsy, and ≥ 6 months of clinical and radiographic follow-up was performed. Patients who met any of the following criteria were excluded from this study: the STT was an extension of a bone tumor, the lesion was in the retroperitoneal space, the patient had a history of surgery at the biopsied site <6 months prior to the biopsy, or the patient had a history of trauma to the biopsied site <3 months prior to the biopsy.

Biopsy procedure

The procedure was performed with 14G biopsy needles (SuperCore Biopsy Instrument; Angiotech, Vancouver, British Columbia, Canada), and all biopsies were performed under the guidance of either a color ultrasound system or spiral computed tomography (CT). When CT guidance was used, the radiologists operated the CT machine to guide the needle to the targeted lesion area.

Before each procedure, the clinical data and all medical images (X-ray, CT, magnetic resonance imaging [MRI], or positron emission tomography/CT) were reviewed and discussed in a multidisciplinary team setting involving radiologists, pathologists, and oncologic orthopedic surgeons. Assessment of the tumor stage and the presumed treatment were discussed. The following key points of the procedure were planned to

ensure a successful biopsy: the approach (to position the point of entry along the planned incision of the definitive surgery), the target site of the lesion, the necrotic area, imaging guidance, and the anatomical structures to avoid.

All biopsies were performed by experienced orthopedic oncologists with more than 5 years of experience in the field of bone tumors and STTs, with the patient under local anesthesia. We followed a well-documented standard procedure for image-guided biopsy.[7,11] To obtain representative and sufficient tissue, aspiration was repeated at different directions and depths. We routinely repeated the aspiration four to six times, obtaining a sample of 1.0 to 2.0 cm each time. If infection was suspected, portions of the sample were sent for microbiology, microscopy, culture, and sensitivity assays. Otherwise, the samples were fixed by 4% formalin and subsequently sent to the pathology department.

The diagnosis was made by two experienced pathologists in accordance with the 2013 World Health Organization Classification of Tumours of Soft Tissue and Bone.[3] When opinions on the pathological diagnosis differed, other pathologists were consulted as necessary until an agreement was reached. If lymphoma was suspected, immunohistochemistry and flow cytometry were routinely used to confirm the diagnosis. A definitive treatment plan was formulated according to the biopsy diagnosis. Intralesional or marginal excision was performed for benign lesions, and wide or radical excision was performed for malignant lesions. The pre- and post-biopsy treatment plans were compared.

Measurement and definitions

The procedure was defined as successful if the CNB yielded a definitive and specific diagnosis. The biopsy was defined as unsuccessful if the tissue was insufficient or atypical and a diagnosis could not be established.

The CNB results were assessed by the histopathologic findings of surgical specimens for patients who underwent definitive surgery (usually 7–10 days after the biopsy) or according to the >6-month follow-up data for patients who were managed nonsurgically.[15] The results were classified as true negative, true positive, false-negative, or false-positive on the basis of differentiation between malignant tumors and benign conditions. The specificity, sensitivity, positive predictive value, negative predictive value, and accuracy were calculated for the overall cohort.[16] A change in treatment management was defined as either a change in therapy (e.g., presumed surgical resection to nonsurgical treatment) or a change in the margins of surgical excision as described by Enneking et al.[17] (from radical or wide excision to marginal or intralesional).

In addition, procedure-related complications were recorded as minor or major (i.e., the patient's clinical workup was altered).[18,19] Finally, information on tract seeding or contamination of surrounding tissues was also collected.

Results

The study population comprised 139 patients (73 male, 66 female; mean age, 49.6 years; age range, 9–81 years). Of these patients, 121 had lesions for which no biopsies had been previously performed and had no history of surgery, and 18 had suspected recurrent masses (all 18 patients had undergone the primary surgery at another hospital).

In total, 141 percutaneous biopsy sessions were performed in these 139 patients; 135 biopsies were performed under color ultrasound guidance, and 6 were performed under CT guidance. A single biopsy session was performed in 137 patients, while 2 sessions were required in 2 patients each. Of the 141 biopsies, 5 were unsuccessful,

Table 1. Anatomical distribution of biopsy sites in 139 patients

	n
Total biopsy sites	139
Upper extremity	45
Subclavicular area	3
Axilla	2
Shoulder	15
Arm	11
Elbow	10
Forearm	4
Lower extremity	94
Iliac fossa	3
Buttock	13
Groin	9
Thigh	47
Knee	4
Leg	17
Foot	1

and the overall procedure success rate was 96% (136/141). Of the 136 successful cases, the surgical histopathological diagnosis was available for evaluation of the biopsy diagnosis in 112 patients, while the follow-up results were considered the gold standard for evaluation in 24 patients.

In the five unsuccessful cases, abnormal tissue was observed and malignancy could not be totally excluded; however, the sample was insufficient in two cases and the available tissue was atypical in three cases. Therefore, the pathologists were unable to make a sound diagnosis. Subsequently, two cases were lymphoma as confirmed by repeated biopsy, one was a desmoid fibroma based on an open biopsy, and two were highly differentiated liposarcoma and recurrent fibrosarcoma, respectively, each treated by definitive surgery.

The lesion sites biopsied were the upper extremity in 32% of patients (45/139) and the lower extremity in 68% (94/139) (Table 1); 47 sites were in the thigh, 17 in the leg, and 15 in the shoulder.

Table 2. Final diagnosis in 139 patients

	n
Total diagnoses	139
Malignancy	91
Synovial sarcoma	21
Liposarcoma	15
Fibrosarcoma	12
UPS	12
Lymphoma	6
Metastasis	5
Rhabdomyosarcoma	5
Leiomyosarcoma	4
Malignant peripheral nerve tumor	3
Alveolar soft part sarcoma	3
Myofibroblastic sarcoma	2
Follicular dendritic cell sarcoma	2
Soft tissue clear cell sarcoma	1
Benign lesion	48
Lipoma	15
Myositis ossificans	11
Desmoid fibroma	10
Nonspecific infection	6
Lymphadenitis (cat scratch disease)	5
Liponecrosis with calcification	1

UPS, undifferentiated pleomorphic sarcoma

Table 3. Final diagnosis by biopsy in 136 patients

		Final diagnosis		
		Positive	Negative	Total
Biopsy diagnosis	Positive	83	0	83
	Negative	5	48	53
	Total	88	48	136

Sensitivity, 94% (83/88); specificity, 100% (48/48); positive predictive value, 100% (83/83); negative predictive value, 90% (48/53); and accuracy, 96% (131/136)

With regard to the final diagnosis (Table 2), 91 patients had malignant tumors and 48 had benign lesions. The most common malignant tumor was synovial sarcoma ($n = 21$), followed by liposarcoma ($n = 15$). The most commonly diagnosed benign lesions were lipoma ($n = 15$) and myositis ossificans ($n = 11$).

The sensitivity and specificity of the diagnostic performance of CNB was 94% (83/88) and 100% (48/48), respectively (Table 3). The positive predictive value was 100% (83/83), the negative predictive value was 90% (48/53), and the accuracy was 96% (131/136). Among the five false-negative cases, three were diagnosed as lipoma by CNB and two were liponecrosis. All five of these cases were eventually proven to be liposarcoma.

The rate of clinical management changes based on the biopsy results was 18% (25 of 139 patients). In 18 patients, the pre-biopsy presumed surgical resection was changed to nonsurgical treatment because the biopsy results showed 6 cases each of lymphoma and myositis ossificans and 3 cases each of lymphadenitis (cat scratch disease) and chronic infection.

In the remaining seven cases, the surgical margin was altered based on the biopsy findings of myositis ossificans in four cases and chronic infection in three. For these cases, wide resection had been planned before the biopsy. After the biopsy, intralesional resection or debridement was actually performed. All of these post-biopsy alterations in management resulted in preservation of more normal tissue than would have been possible otherwise, resulting in better patient function.

After the procedure, 1.4% of patients (2/139) developed minor complications, one each in the shoulder and groin. Mild nerve injury was observed in these two patients. They presented with mild numbness and malfunction of the limb, but both recovered fully after 1 week of close observation. Finally, no tract seeding was observed.

Discussion

The major novelty and strength of our study is that not only STTs and tumor-like lesions but also lesions mimicking tumors were included in this evaluation of the diagnostic performance of preoperative CNB. This decision was made mainly because in clinical practice, all of these conditions should be differentiated in cases of suspected STT. The present study thus facilitated more objective and comprehensive evaluation of the performance of CNB than in previous studies of the application of CNB for diagnosis of STT. Furthermore, to the best of our knowledge, this is the first large-scale study to consider CNB-based changes in therapeutic management; we found that changes in management decisions occurred in 25 of the 139 patients (18%). This suggests that CNB may prevent unnecessary surgery and minimize the risk of over-resection of nearby normal tissue. This additional precision in diagnosis was clearly beneficial for patients in terms of maintaining function. Notably, no patients' pre-biopsy plan was intralesional or marginal resection with post-biopsy alteration to wide resection. The reasons for this are as follows. First, attainment of a safe surgical margin is our principal goal, especially for oncological orthopedists. Second, we usually identify the margin based mainly on the radiological appearance, especially that of MRI. For some benign lesions such as infection, myositis ossificans, and lymphadenitis, MRI can show a wide, high T2 area that appears very similar to the reactive zone around a malignant tumor. In combination with the benign biopsy result, this abnormal area on imaging would not be regarded as high-risk and would thus be preserved in the definitive surgery. However, to the best of our knowledge, very few malignant lesions appear radiologically similar to benign lesions, especially on MRI. Therefore, in the present study, no surgery plans were upgraded (i.e., resection of more tissue) after the biopsy.

Five CNBs were unsuccessful in the present study; two were due to insufficient samples, and three were due to atypical tissue. The pathologists encountered a

dilemma: they observed abnormal tissue but could not make a sound diagnosis based on the biopsied tissues. Therefore, at the end of the pathology report, they suggested that we either repeat the biopsy or perform an open biopsy. We routinely discussed this question among our team and explained it to the patients and their relatives. After an agreement was reached, we performed needle biopsy, open biopsy, or definitive surgery accordingly. Based on our limited experience, we advised caution in the management of nondiagnostic cases and ensured adequate communication with the pathologist, radiologists, and patients. Notably, the CNB procedure successfully delivered a definitive and specific diagnosis in 96% of cases. Our success rate was slightly higher than that reported by Battaglia et al.[20] In their study, sufficient material for histologic diagnosis was collected in 148 of 164 cases (90%). Our better performance was mainly due to the gauge of our needles (14G) being larger than that of their needles (15–18G). Additionally, our overall sensitivity, specificity, and accuracy for differentiation of malignancy were 94%, 100%, and 96%, respectively. These findings are consistent with previously published case series. Among 281 cases of STTs, Ferguson et al.[11] reported a 96% success rate for ultrasound-guided CNB. Another study of 65 STTs or bone tumors with soft tissue involvement showed that the sensitivity, specificity, and accuracy of ultrasound-guided CNB were 96%, 100%, and 97%, respectively,[21] and Woon and Serpell[22] reported a sensitivity of 91.3% and specificity of 100% in a study of 68 STTs. Strauss et al.[23] reported that the accuracy of differentiation of STT malignancy was 96.7% in a large-scale study of 426 cases. Notably, in a recently published meta-analysis by Kubo et al.,[24] the overall accuracy rate was only approximately 84%. The lower performance is due to half of the enrolled articles (16/32) being published more than 10 years ago (1996–2009), with some procedures being performed as early as 1975. Therefore, the needles, guidance machines, operators' skills, and other factors in those studies are sure to be much less advanced than those of recent studies. Together with these findings, our study confirms that preoperative CNB is valuable for the diagnosis of STTs, especially for the differentiation of malignant from benign lesions.

In the present series, two CNB sessions were required in two patients. With the first biopsy specimen, the pathologists could only consider the possibility of a small cell tumor, and they recommended repeated biopsy to obtain more tissue for further investigation such as immunohistochemistry and flow cytometry. Fortunately, the second biopsy confirmed the diagnosis of lymphoma.

More importantly, five false-negative cases were encountered in this series, three of which were diagnosed as lipoma by CNB and two of which were liponecrosis. All five were eventually proven to be liposarcoma. Our findings also suggest that differentiation of low-grade liposarcoma from lipomas is difficult using CNB, as reported previously.[25] In a series of 143 cases, 14 were negative, and 4 of these negative cases were proven to be lipomatous lesions.[10] Similarly, in a study of CNB in 281 STTs, Ferguson et al.[11] reported that 3 of 8 negative cases were eventually diagnosed as lipomatous tumors. Because of this finding, the institution in that study has stopped performing image-guided biopsies of radiological low-grade lipomatous lesions and instead performs marginal excision directly.[11]

Given the discouraging diagnostic yield for suspected lipomatous lesions, we recommend either repeating the aspiration or performing open biopsy. If surgery without preoperative biopsy is chosen, then marginal excision other than intralesional excision should be performed.

There were no false-positive cases in our study, which compares favorably with published reports.[7,12,25] Given the high specificity (100%) and positive predictive value (100%) of the procedure, we recommend decisive initiation of treatment with a positive result.

In our study, two patients (1.4%) developed mild complications after CNB. After the biopsy, these two patients developed mild numbness and malfunction caused by injury to the lateral femoral cutaneous nerve and branch of the axillary nerve, respectively. This is similar to previous reports of complication rates of <1%.[26,27] Additionally, no tract seeding was observed because the needle was relatively thin and the biopsy tract was routinely resected during the definitive surgery. Therefore, our study adds to the accumulating evidence that CNB is a relatively safe procedure.

Our study has several limitations. First, it included 13 types of malignant tumors, 2 categories of benign tumors, and 4 types of non-tumor lesions. This variety of lesion types was due to the inherent complexity and heterogeneity of soft tissue lesions and somewhat affected the homogeneity of the study. Second, of the 136 successful procedures, surgical histology was used to validate the biopsy diagnosis in 112 cases; in the other 24 cases, biopsy samples were evaluated only by the clinical and radiological follow-up. This may have somewhat negatively affected the reliability of the results. A third limitation is that for economic reasons, immunohistochemical and molecular examinations were not performed for some patients. Nevertheless, our study contributes novel information that preoperative CNB for soft tissue lesions may lead to accurate treatment. Larger studies with longer follow-up periods are needed to provide further information regarding clinical decisions, and all samples should be subject to immunohistochemical and molecular examination.

In conclusion, our findings in 139 patients further support the value of percutaneous CNB in establishing the diagnosis of soft tissue lesions, especially when differentiating malignant and benign lesions. Our results suggest that this procedure is sensitive, specific, and safe. Therefore, we recommend the use of percutaneous CNB as a routine diagnostic workup procedure for patients with soft tissue lesions. For a suspected lipomatous lesion, however, aspiration should be repeated and open biopsy should be used when necessary.

Abbreviations

CNB: core needle biopsy; STT: soft tissue tumor; CT: computed tomography; MRI: magnetic resonance imaging

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Authors' contributions

Dianwen Qi designed the study; acquired, analyzed, and interpreted the data; and prepared the manuscript. Ming Zhao and Tongyu Hu acquired the data and reviewed and revised the paper. Guochuan Zhang designed the study and reviewed and revised the final version of the manuscript. All authors approved the final manuscript.

Availability of data and materials

The datasets generated and analyzed during the current study are not publicly available because of protection of the patients' privacy but are available from the corresponding author on reasonable request.

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

Disclaimers

The views expressed in the submitted article are our own and not those of the Third Affiliated Hospital of Hebei Medical University or the funder of the Key R&D Plan Project of Hebei Science and Technology Department.

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