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Can Musculoskeletal Tumors be Diagnosed with Ultrasound Fusion-Guided Biopsy?

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Abstract

Background Percutaneous biopsy for musculoskeletal tumors commonly relies on imaging adjuncts including ultrasound (US), CT, or MRI. These modalities however have disadvantages (US) or are cumbersome, not universally available, and costly (CT and MRI). US fusion is a novel technique that fuses previously obtained CT or MRI data with real-time US, which allows biopsies to be performed in an US suite. It has proven useful in various body systems but musculoskeletal applications remain scarce. Our goal is to evaluate the fusion technology and determine its ability to diagnose musculoskeletal tumors.

Questions/Purposes We determined whether biopsies performed via US fusion compared with CT guidance provide equivalent diagnostic yield and accuracy and allow quicker biopsy scheduling and procedure times.

Methods Forty-seven patients were assigned to undergo either US fusion (with MR, n = 16 or CT, n = 15) or CT-guided biopsies (n = 16). We evaluated adequacy of the histologic specimen (diagnostic yield) and correlation with surgical pathology (diagnostic accuracy). We determined scheduling times and lengths of the biopsy.

Results US fusion and CT-guided biopsy groups had comparable diagnostic yields (CT = 94%; US/MRI = 94%; US/CT = 93%) and accuracy (CT = 83%; US/MRI = 90%; US/CT = 100%). US fusion biopsies were faster to schedule and perform. All procedures were safe with minimal complications.

Conclusions US fusion provides a high diagnostic yield and accuracy comparable to CT-guided biopsy while performed in the convenience of an US suite. This may have resulted in the observed faster scheduling and biopsy times.

Level of Evidence Level II, diagnostic study. See Guidelines for Authors for a complete description of levels of evidence.

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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Introduction

Image-guided percutaneous biopsy of musculoskeletal lesions is an effective diagnostic method that allows rapid identification of neoplastic and other conditions [10]. The advantages of percutaneous biopsy are low morbidity, accuracy, and cost-effectiveness [2, 7, 12]. Traditional imaging adjuncts have consisted of ultrasound (US) [2], CT [2], or MRI [5]. Each of these techniques has advantages and drawbacks. US provides real-time feedback to the operator. Its use however is limited because many intraosseous and deep soft tissue lesions may not be readily

visible [4]. CT is reliable and provides a high diagnostic yield ranging from 70% to 93% [6, 18, 19, 21]. CT fluoroscopy, ideal for percutaneous biopsies, is not readily available in many facilities. Moreover, the amount of radiation incurred during the procedure ranges from 0.025 to 3.35 mSv during various image-guided procedures [13, 17]. Additionally, real-time feedback is not provided as needle placement and image acquisition cannot be performed simultaneously. MRI guidance has failed to gain popularity owing to difficulties accessing the bore of the magnet, prolonged intervention times, hurdles with scheduling, and scarcity of experts comfortable with the technique. MRI also requires specialized biopsy equipment and rigorous training of personnel and radiologists [5].

The use of US fusion technology, although novel to the field of musculoskeletal diseases, has been established in other specialties. It uses computer software that fuses a DICOM set of CT or MR data with real-time US. Fusion uses a navigation system allowing accurate determination of the US probe in space. The operator then identifies, on the US, known anatomic landmarks that serve as reference points. These landmarks are identified on the CT or MR image. The embedded software then fuses the two images. The process allows the operator to identify any area via US and the software will localize the corresponding area or structure on the CT or MRI cut. Accuracy reports of the technique come mainly from the work of Schlaier et al. [20], whose experiments showed an accuracy of 1.08 mm to 1.6 mm when US/MRI fusion was used for localization of small spheres and arrows. Radiation oncologists have used fusion of US images with CT scans for radiotherapy [22] and prostate brachytherapy [8, 9]. Its use also has been documented in neurosurgery for intraoperative localization [16]. Perhaps the field that has made the most use of this technology is hepatic surgery where intraoperative localization by US is essential to treatment. Several series suggest a clear benefit in US fusion with navigation to enhance intraoperative detection rates of liver lesions [11, 14, 24]. The use of US fusion in the diagnosis or treatment of musculoskeletal conditions has been limited. Klauser et al. [15] reported on a series of sacroiliac joint injections and showed that US and CT fusion allowed reliable injection of the target area.

We therefore asked whether the use of US fusion would: (1) provide equal diagnostic yield and accuracy, and (2) allow quicker scheduling of biopsies and shorter biopsy time.

Patients and Methods

We identified 60 patients with bone or soft tissue lesions that required a percutaneous core biopsy from September 2009 to August 2010. On review, seven patients had invalidated study consent forms as eligibility stipulated that study inclusion consent be obtained before the biopsy was performed. This left 53 patients who were assigned to CT-guided biopsy or US fusion-guided biopsy according to even or odd medical record number. This method was chosen for convenience as multiple clinicians and assistants participated in patient assignment throughout the duration of the study. All 53 patients consented to the study and were scheduled for percutaneous biopsy. Six patients were later dropped from the study: there was one death owing to medical reasons unrelated to the biopsy, four were lost to followup, and one withdrew consent and decided to have an open biopsy. This left 47 patients: 16 with US and MRI fusion, 15 with US and CT fusion, and 16 with CT-guided biopsies. Patients who were assigned to the CT group underwent CT-guided biopsies. Patients assigned to the US fusion group had their biopsy performed by either CT or MRI fused with US (depending on whether a CT scan or MR image was available at patient presentation). Thus every patient assigned to the US fusion group was able to undergo an US fusion-guided biopsy. We obtained prior Institutional Review Board approval.

An initial power analysis, based on two anticipated treatment groups (CT, US fusion) determined that a total sample size of 60 patients was needed. The number of patients enrolled was based on cost, availability, and statistical power. With the proposed sample size, we had 84% power to detect an effect size of 0.78 or greater at an alpha of 0.05 based on a two-sample t-test, using continuous variables. After data were collected, it was decided to base the analysis instead on a one-way ANOVA with three possible levels (CT, US and MRI, US and CT). With an appropriate post hoc test, this approach would allow for finer granularity in the analysis while keeping the option of a two-level approach in reserve.

There were no demonstrable differences attributed to age ($p = 0.285$; power $= 0.099$) or sex ($p = 0.851$; power $= 0.073$) among the three groups (Table 1). We had a wide variety of biopsy sites according to anatomic location (Table 2) and a wide variety of histopathologic diagnoses (Table 3). Lesions were classified as soft tissue

Table 1. Patient distribution and demographics

Biopsy method	Number of patients (n = 47)	Number of male patients	Number of female patients	Age (years)*
CT	16	8	8	59 (17)
US and MRI	16	9	7	49 (19)
US and CT	15	9	6	58 (16)

* Values are expressed as mean, with SD in parentheses; US = ultrasound.

Table 2. Anatomic sites that underwent biopsy

Anatomic site	CT	US and MRI	US and CT	Total
Neck	0	1	0	1
Paraspinal	1	0	0	1
Ribs/sternum	1	0	1	2
Pelvis	2	1	2	5
Femur/thigh	8	8	8	24
Arm	3	2	1	6
Forearm	0	1	0	1
Wrist/hand	0	1	0	1
Leg	1	0	2	3
Foot/ankle	0	3	0	3

Table 3. Histopathologic class by biopsy modality

Tumor diagnosis	CT (n = 16)	US and MRI (n = 1 6)	US and CT (n = 15)
Malignant			
Metastatic carcinoma	3	0	4
High-grade spindle cell sarcoma	1	3	1
Low-grade spindle cell sarcoma	1	2	1
Myxofibrosarcoma	0	1	0
Malignant peripheral nerve sheath tumor	1	0	0
Liposarcoma	1	0	0
Angiosarcoma	0	0	1
Synovial sarcoma	0	1	
Merkel cell carcinoma	0	1	0
Lymphoma	0	0	1
Benign			
Lipoma	2	2	1
Plasmacytoma	2	1	
Infection	0	0	1
Chondromyxoid fibroma	0	1	
Other benign	4	3	4
Inconclusive	1	1	1

or bone. There was no demonstrable preferential randomization to any study arm in patients with soft tissue or bone tumors ($p = 0.133$; power = 0.404). There were 17 bone lesions and 30 soft tissue lesions.

The radiologist who performed the procedure had the discretion to override the study protocol if he or she judged the patient was randomized to a procedure less safe than the alternative. This safety measure initially was implemented owing to the novelty of the procedure and because our institution is a training center. As our radiologists had little experience with fusion biopsies before the study commenced, a concern was that a situation might arise where they would be uncomfortable performing this novel technique. The radiologist thus had the choice to revert to CT-guided biopsy if they thought that performing an US fusion-guided biopsy would be unsafe. However the opposite happened, in that the radiologists felt safer performing fusion-guided biopsy for several lesions. For example a lesion close to a major neurovascular structure was felt to be more amenable to US fusion guidance because US shows vessels and nerves in real time and obviates the need for using contrast media. US shows the push of the needle in respect to vital structures continuously, unlike CT which requires interruption of imaging every time the patient is moved away from the radiation field (gantry).

Patients in the control group underwent biopsy via CT guidance, which is an accepted standard technique at our institution. Patients in the experimental group underwent biopsy via US fusion guidance (FDA-approved imaging modality) by fusing MRI with US or CT with US. Images previously obtained by CT or MRI were loaded into a General Electric LOGIQ™ E9 Diagnostic Ultrasound System (General Electric, Milwaukee, WI, USA). If CT scans and MR images were available, it was left to the discretion of the radiologist to select the study that best delineated the mass. The modality chosen then was fused with the US at the time of the biopsy.

Patients were instructed to follow up with orthopaedic oncology 2 weeks after the biopsy. The followup range was 12 to 21 days. The time needed (in days) to obtain the biopsy and the actual biopsy time (in minutes) were recorded. We will refer to the former as waiting time and the latter as biopsy time. Any biopsy-site complications were noted and recorded. These included persistent tenderness, clinical evidence of infection, and palpable or visible hematoma. We also noted whether patients had any immediate complication that required operative intervention.

The adequacy of the histologic specimen then was recorded (ie, if the biopsy allowed the pathologist to formulate a histopathologic diagnosis). For patients who required later operative intervention, we noted whether the pathologic diagnosis obtained from the percutaneous biopsy specimen and that from the open procedure coincided. We will refer to the former as diagnostic yield and to the latter as diagnostic accuracy.

The biopsy technique was the same regardless of the imaging modality used for guidance (CT, US and CT fusion, US and MRI fusion). We used Jamshidi® (Cook Inc, Bloomington, IN, USA) or Ostycut® (CR Bard Inc, Tempe, AZ, USA) needles for bone biopsies and Temno® adjustable coaxial system (Cardinal Health, Dublin, OH, USA) or Tru-Cut® needles (Baxter Healthcare, Deerfield, IL, USA) for soft tissue biopsies. The bone biopsy needles

were used if the lesion was surrounded by a bony rim. The Jamshidi® needle was used for a thicker cortex and the Ostycut® for a thinner cortex. The Temno® was used for deep soft tissue lesions and the Tru-Cut® for more superficial lesions.

For US fusion-guided biopsies, previously obtained images by CT (Fig. 1) or MRI (Fig. 2) were loaded onto the General Electric LOGIQ™ E9 Diagnostic Ultrasound System by uploading a CD with DICOM-formatted studies. The US transducer then was placed in a plane corresponding to the imaging plane of the uploaded data set. The US fusion equipment includes a position-sensing device. Registration was possible by two electromagnetic tracking sensors connected with the positioning hardware on the US equipment and clipped on a bracket mounted on top of the ML 6–15, the 9L, and the L8-l8i-d transducers used for biopsy. A radiofrequency transmitter was placed in close proximity to the biopsy field. At all times, the distance from the transmitter to the receivers was kept at less than 70 cm. One or more corresponding anatomic landmarks were identified on the cross-sectional data set and the US; these points were locked in tandem. This process was repeated as many times as judged sufficient to obtain satisfactory overlap between the US and the MRI or CT data set. The integrated navigation software then fused the images and allowed real-time US guidance based on the CT or MR images in any plane deemed necessary for safe biopsy. The image displayed during the procedure allowed for a side-by-side display (Fig. 1B,C; Fig. 2B,C) or for an image overlay where US overlapped the CT or MR images. Once the US was fused, the real-time US scanning navigated through the virtual cross-sectional DICOM data set flawlessly in any plane with real-time reconstruction that matched the real-time data from the US. Biopsies were performed using the same instrumentation described above for CT-guided biopsies, which allowed us to perform a core biopsy of each lesion.

There was no difference in the anesthetic management between the US fusion and CT guidance groups. For both groups routine anesthetic management consisted mainly of local anesthetic with 1% lidocaine.

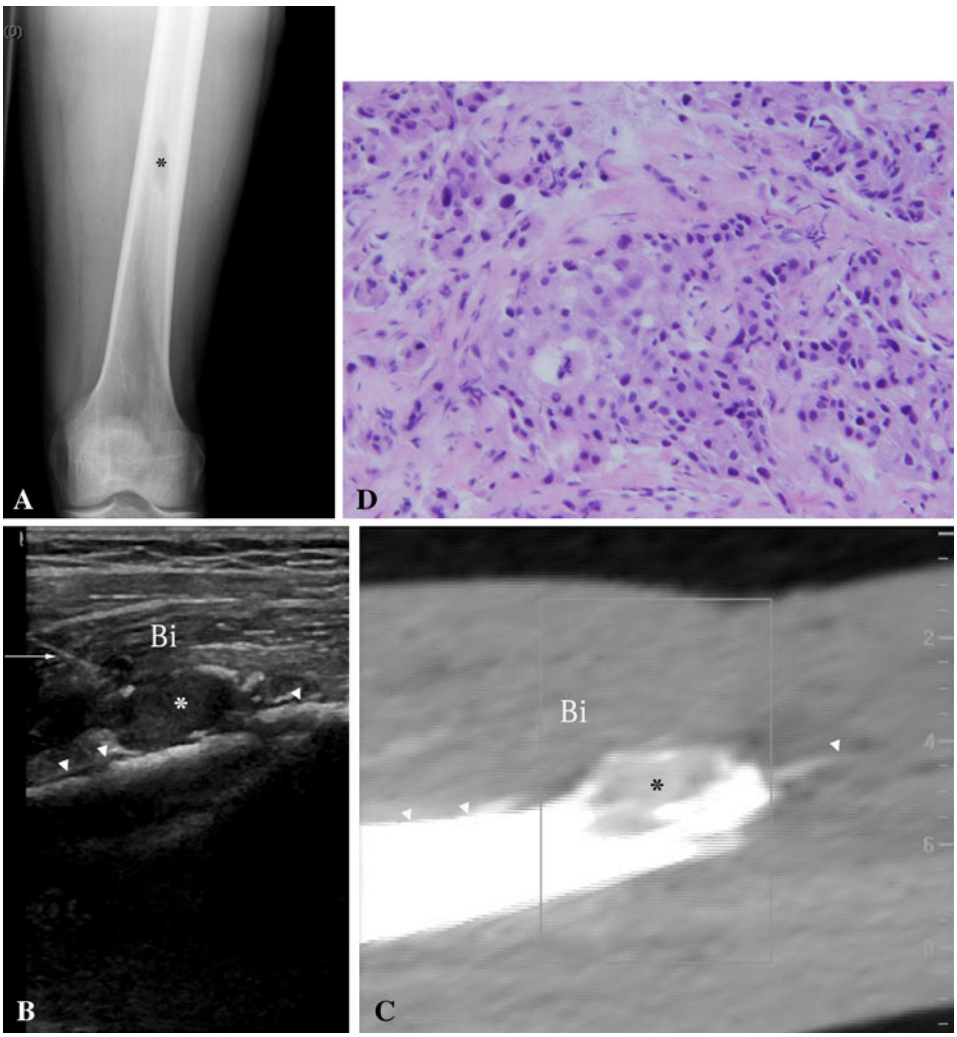

Fig. 1A–D (**A**) A conventional radiograph shows a single lytic lesion (asterisk) in a 55-year-old man. An US fusion image was obtained by using a previously acquired CT scan. (**B**) The US and (**C**) the CT scan components are displayed on the same monitor screen and move together when the US probe is moved (arrow = biopsy needle; asterisk = lesion; Bi = biceps femoris muscle; arrowheads = posterior femoral cortex). (**D**) The pathology specimen was consistent with metastatic adenocarcinoma (Stain, hematoxylin and eosin; original magnification, ×400).

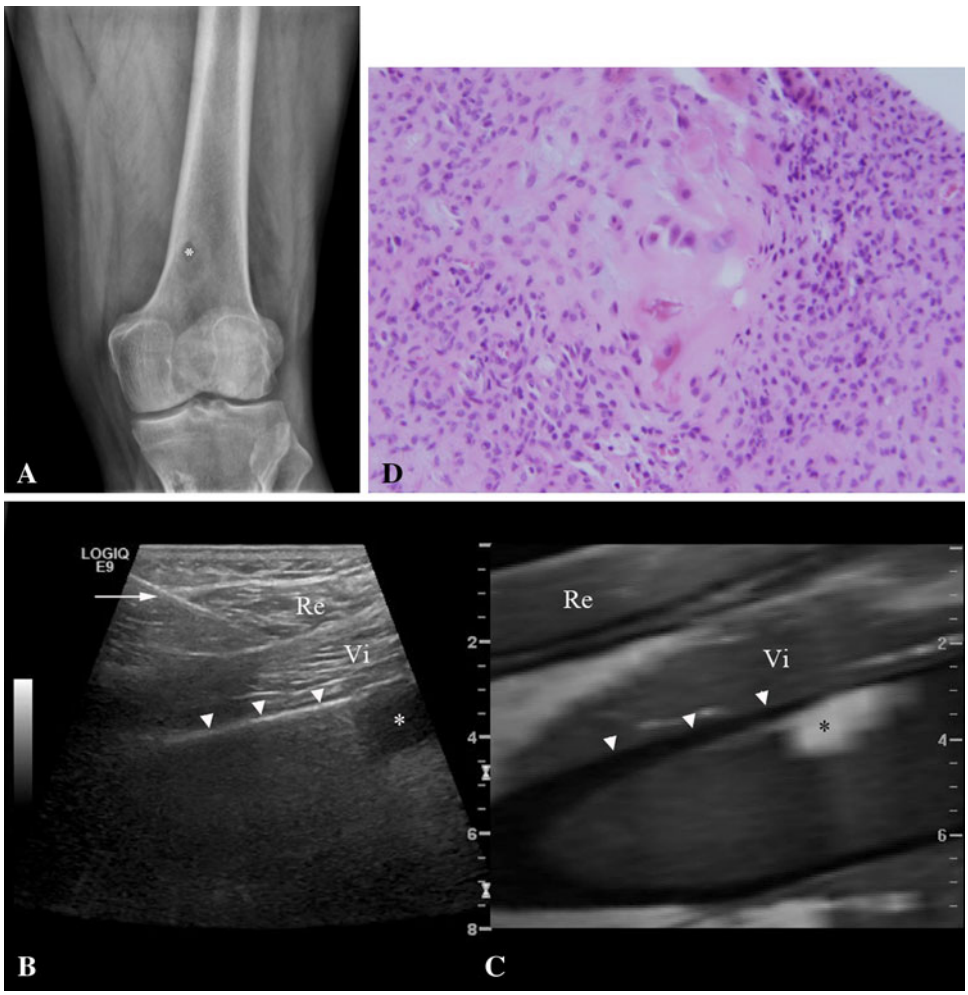

Fig. 2A–D (**A**) A conventional radiograph shows a distal femur lesion (asterisk) in a 52-year-old man with knee pain. An US fusion image obtained by using a previously acquired MR image is shown. (**B**) The US and (**C**) MR image components are displayed on the same monitor screen and move together when the US probe is moved (arrow = biopsy needle; asterisk = lesion; Re = rectus femoris muscle; Vi = vastus intermedius muscle; arrowheads = anterior femoral cortex). (**D**) The pathology specimen shows a mixture of hyaline cartilage and fibrous components classic for chondromyxoid fibroma (Stain, hematoxylin and eosin; original magnification, ×100).

To compare the three biopsy guidance systems we used a chi-square test for binary output variables (diagnostic yield and accuracy) and a Kruskal-Wallis one-way ANOVA on ranks (with Dunn's post hoc multiple comparison procedures) for continuous output variables (waiting time and biopsy time). Data were analyzed using SigmaStat® v3.5 (Systat Software Inc, Chicago, IL, USA).

Results

Fifteen of 16 patients (94%) in the CT group, 15 of 16 patients (94%) in the US and MRI group, and 14 of 15 patients (93%) in the US and CT group had a positive diagnostic biopsy, with no demonstrable difference in diagnostic yield among the methods (Table 4). Six patients in the CT group,10 in the US and MRI group, and five in the US and CT group required open surgical treatment and thus surgical pathology reports were available for review. Diagnostic accuracy was calculated for each modality. One patient in the CT group and one in the US and MRI group had a final surgical pathology report that did not correlate with that of the percutaneous biopsy. We thus obtained diagnostic accuracy of 83% for CT, 90% for US and MRI, and 100% for US and CT-guided biopsies. There was no demonstrable difference in surgical specimen accuracy among the methods (Table 5).

Table 4. Diagnostic yield by biopsy modality

Variable	CT	US and MRI	US and CT	p value (power)
Diagnostic	15	15	14	
Nondiagnostic	1	1	1	
Total	16	16	15	
Diagnostic yield	94%	94%	93%	0.700 (0.180)

The average waiting time was 3.5 days in the US and MRI group and 2.4 days in the US and CT group; both were shorter ($p = 0.009$ in both comparisons) than for the CT group for which the average waiting time was 8 days (Table 6).

The results of the post hoc test proved ambiguous when we analyzed the three study arms separately for effect of biopsy method on biopsy time. When US and CT and US and MRI fusion methods were considered together and compared with the CT group, the time of biopsy was shorter ($p = 0.035$) for the US fusion group (including US and CT and US and MRI) than for the CT group (Table 6).

One patient in the CT group had tenderness at the biopsy site at the time of the first followup that had resolved by the next visit. No other complications were reported.

Discussion

The use of percutaneous biopsy techniques has been a standard practice in the evaluation of musculoskeletal lesions, and studies have proven its safety and detection power [23, 25]. Various radiographic adjuncts, including US, CT, and MRI, have been used to improve detection and minimize complications. US fusion, which combines the detection power of CT and MRI with the advantages of US, seems well suited for musculoskeletal percutaneous biopsy. In lesions that are visible on US there is no need for the added complexity of a fusion-guided biopsy. However, in lesions that are not visible on US (deep soft tissue and intraosseous), the utility of US fusion is apparent. US detection rates theoretically would be increased by having simultaneous access to CT or MRI data. Similarly, US fusion would obviate the need to perform biopsies under CT or MRI guidance; both modalities lack real-time feedback and portend longer biopsy times [5]. We therefore determined whether, compared with CT guidance, biopsies performed via US fusion provided equivalent diagnostic yield and accuracy and allowed quicker biopsy scheduling and procedure time.

We acknowledge limitations of our study. First, as most of our patients ordinarily present with MRI or CT already done, we were limited to that modality when performing fusion-guided biopsy (ie, patients who present with either modality showing the lesion had this particular modality used in the fusion process). Such scenarios are commonly encountered especially in referral centers in which patients present with a full or partial workup already done. Many third-party payers have been more stringent regarding obtaining additional diagnostic tests. This has limited our ability to draw conclusions regarding the superiority of either US and CT and US and MRI fusion as compared with each other. Second, there was a selection bias since six patients were moved to the US fusion group in instances where the radiologist believed this would provide a safer procedure. Third, the total number of patients might have limited us in detecting superiority in some of our end points. Thus our study was underpowered and perhaps is best considered a pilot study. More definitive conclusions probably could be drawn with a larger sample. A higher-powered study also would allow a side-by-side comparison between biopsy methods as relating to bone versus soft tissue detection and cancer subtypes. This is a major limitation in most prospective studies of conditions with low incidence, such as musculoskeletal tumors. Finally, US fusion technology might be less applicable and the learning curve actually longer in centers where radiologists are ordinarily less facile in performing US-guided procedures. To obtain more meaningful results, ideally we would have a series of patients all having tumors invisible with plain US. Performing their biopsies by US fusion then would prove the usefulness of this modality in lesions that are not visible on US. In our series, we were able to perform the biopsy using US fusion for all patients who were assigned to the fusion group. This included patients with lesions invisible to plain US. The distinction however was not made as one of the premises of the study and our series of US fusions included all patients with musculoskeletal tumors, not solely those with lesions not detectable by US.

Our data suggest that the diagnostic yield and accuracy of US fusion-guided biopsy, either via CT or MRI, are

Table 5. Diagnostic accuracy by biopsy modality

Variable	CT	US and MRI	US and CT	p value (power)
Concordant	5	9	6	
Nonconcordant	1	1	0	
Diagnostic accuracy	83%	90%	100%	0.643 (0.117)

Table 6. Waiting time and biopsy time

Variable	US and MRI	US and CT	CT	p value
Time from request to biopsy (days)	3.5 (3.2)*	2.4 (2.5)*	8.0 (7.7)	0.009 (comparing either US and MRI or US and CT with CT)
Biopsy time (minutes)	36 (19)‡	35 (15)‡	53 (22)‡	0.035 (comparing US and MRI and US and CT with CT)

Values are expressed as mean, with SD in parentheses; items with the same symbol showed no demonstrable differences between groups; US = ultrasound.

reliably high and comparable to our series of CT-guided biopsies. The results in our series are consistent with those of previously published studies of CT and MRI-guided biopsies [1, 3, 12, 18]. We had three negative biopsies in our series. In the US fusion arm, there were two nondiagnostic biopsies. The first patient was in the US and CT group and had a benign-appearing posterior shoulder mass on preoperative imaging. The pathology specimen showed normal tissue with no evidence of neoplasia. Results were reviewed with our musculoskeletal pathologist who said that in the muscle there was a core of fatty incoherent tissue by visual inspection and it appeared there was an error in processing the specimen leading to a descriptive-only diagnosis of intramuscular lipoma. The second patient was in the US and MRI group and underwent biopsy of a wrist lesion that was read as nondiagnostic as the histologic examination showed only necrotic tissue with lymphoid cells. The patient then underwent an open biopsy that showed essentially the same findings and also was considered nondiagnostic. One patient in the CT group had a nondiagnostic biopsy of an iliac lesion. This patient was observed and on followup 3 months later had spontaneous improvement and radiographic regression leading to a retrospective diagnosis of insufficiency fracture.

We observed a shorter waiting time in the US fusion group, with biopsies being performed on average 5 days earlier than the CT-guided biopsies. This is because the CT scanners are booked primarily for diagnostic and interventional studies for the abdomen and neuropathology. Coordination of a CT-guided biopsy at our institution also requires more personnel than US-guided procedures. In contrast, the US fusion setup was readily available and dedicated to musculoskeletal procedures. All procedures were performed by dedicated musculoskeletal radiologists who share common clinic space with our orthopaedic staff. In many instances, radiologists were willing to schedule same-day biopsies. US fusion-guided biopsies also achieved faster biopsy times. We believe the presence of real-time feedback and continuously acquiring images throughout the biopsy allow for a smoother and faster procedure.

The complication rate was low in all arms of the study. We typically examined patients 2 weeks after the biopsy and this could have missed a few instances of immediate minor complications (tenderness, erythema) that would have happened within hours or days.

The main economic advantage of the US fusion biopsy is that already obtained CT scans or MR images (even with basic specifications) are used to perform a fusion process. This is in contrast to CT or MRI-guided procedures where there is a need to repeat the advanced imaging modality at the time of the biopsy. The cost of the US fusion-guided biopsy is then equivalent to the cost of performing a conventional US-guided biopsy, which is inferior to the cost of CT or MRI guidance. In our institution, US-guided biopsy is on average 14% less expensive than CT-guided biopsy. Our Medicare reimbursement for an US-guided biopsy is $34.83 (United States dollars [USD]), whereas reimbursement for CT-guided biopsy is $57.59 USD. The advantage, however is that these procedures eventually could be performed in office settings where access to CT or MRI scanners is not readily available.

Our results suggest US fusion technology is highly successful in performing musculoskeletal biopsies. Comparison to our CT-guided biopsy data and published CT and MRI detection rates shows comparable success with this new technology. The ability to readily schedule biopsies and the shorter procedure times should translate into shorter lead times and possibly an economic advantage at the institutional level. We believe larger samples and possibly a multicenter trial would confirm our findings.

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