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Original article
**EXTERNAL VERSUS ENDOSCOPIC ULTRASOUND: NON-
INFERIORITY ASSESSMENT FOR VISUALIZATION OF VARIOUS
STRUCTURES OF INTEREST IN THE SHOULDER**

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ABSTRACT

Introduction: Certain structures and pathologies can be difficult to reveal under videoscapy alone during arthroscopic surgery. Ultrasound can be a useful contribution in arthroscopic diagnostic and therapeutic procedures. The main aim of the present study was to assess equivalence between endoscopic and external ultrasound for shoulder exploration. Secondary objectives comprised qualitative assessment of endoscopic ultrasound images and comparative assessment of acquisition time between the two techniques.

Material and methods: An anatomic non-inferiority study was conducted on 6 shoulders from 3 subjects with a mean age of 84 years. After ultrasound examination by a radiologist specializing in osteoarticular imaging, shoulder arthroscopy was performed by a single specialized surgeon, using an ultrasound endoscope. Number of visualized structures and image quality were assessed by independent observers.

Results: Ten of the 11 structures of interest (91%) were visualizable on endoscopic ultrasound, versus 4 (36%) on external ultrasound ($p < 0.05$). Mean endoscopic acquisition time was 9.5 ± 6.3 minutes [range, 5 ; 22]. In the 11 structures, image quality was better on endoscopic than external ultrasound, except for the acromioclavicular joint, where quality was better on external ultrasound, and the lateral side of the rotator cuff, where quality was equivalent.

Conclusion: The present study demonstrated equivalence between endoscopic and external ultrasound for shoulder exploration.

Level of evidence: IV, Non-inferiority cadaver study

Key-words: Endoscopic ultrasound, External ultrasound, Imaging, Arthroscopy, Shoulder, Feasibility, Complications

INTRODUCTION

Shoulder arthroscopy is widely used in a variety of pathologies: rotator cuff calcification, long head of the biceps tendinopathy, subacromial bursitis, joint stabilization following instability, acromioclavicular arthropathy, chondropathy or osteoarthritis of the shoulder in young patients, and rotator cuff lesions [1][2][3][4][5][6][7][8][9]. In some cases, these pathologies can be difficult to reveal on simple intra-articular videoscscopy.

Ultrasonography is an imaging technique using ultrasound waves to provide quantitative and qualitative information on the physical properties of tissue. Images are constructed from 2-way pulse travel time (time of flight: ToF) in the tissue within which the ultrasound waves propagate, using a probe that is moved around by the operator on the surface over the organ to be explored. The contribution of external ultrasound in visualizing the various lesions has been studied [10].

An ultrasound probe using an arthroscopic portal gives direct access to deep structures of interest in the shoulder. We previously reported such a probe, developed initially for intra-articular knee-joint cartilage assessment, and confirmed feasibility in arthroscopic shoulder procedures [11]. It is now necessary to compare the respective contributions of intra-articular endoscopic ultrasound and external ultrasound.

The present study hypothesis was that endoscopic shoulder ultrasound enables imaging of at least as many anatomic structures as external ultrasound, with image quality that is at least equivalent.

The main objective was to compare imaging of specific shoulder structures between endoscopic and classical external ultrasound in an ex-vivo study of anatomic subjects.

Secondary endpoints comprised image quality on endoscopic ultrasound, and comparative acquisition time between the two techniques.

MATERIAL AND METHODS

A non-inferiority study included 6 cadaver shoulders from the LADAF (*Laboratoire d'Anatomie Des Alpes Françaises*) anatomy laboratory, in collaboration with the TIMC-IMAG (*Techniques de l'Ingénierie Médicale et de la Complexité – Informatique, Mathématiques et Applications, France*) medical engineering team.

Cadaver studies come under the funeral legislation regulating donation; declaration to the CNIL (*Commission Nationale de l'Informatique et des Libertés*) data protection commission is not required.

The prototype intra-articular endoscopic ultrasound probe was the M 15 (Cartimage Médical SASTM, in partnership with TIMC-IMAG). It had a 15 cm x 4 mm catheter (Figure 1). The 13 mm distal ultrasound detector

comprised 64 sensors with 11 MHz central frequency providing endoscopic and arthroscopic ultrasound images. In its present state of development, it does not enable Doppler imaging. Image acquisition was performed by a surgeon experienced in shoulder arthroscopy.

External ultrasound used an ALOKA IPF-1503 probe with 15 MHz central frequency. Image acquisition was performed by a radiologist experienced in osteoarticular imaging.

Preselected structures of interest comprised, in the glenohumeral space, the intra-articular part of the long head of the biceps, the glenoid and humeral cartilages, the superior, medial and inferior glenohumeral ligaments, the glenoid labrum and the deep side of the rotator cuff and, in the subacromial space, the superficial side of the rotator cuff, the inferior side of the acromion, and the acromioclavicular joint.

Specimens were fresh, with complete upper limbs, attached to the trunk. Six shoulders were explored (3 left, 3 right), from 3 subjects with a mean age of 84 years (Table 1).

Subjects were positioned semi-seated. The radiologist intervened first, so as to work on a specimen free of prior manipulation. The extra-articular probe explored the shoulder joint and subacromial space, visualizing the structures of interest and acquiring images. External exploration followed the usual shoulder ultrasound procedure, beginning with the vertical part of the long head of the biceps and screening for joint effusion, then with the reflection pulley and the horizontal part (the insertion being invisible). Passive testing checked for dislocation. Exploration then continued with the subscapularis tendon, positioning the shoulder in external rotation, then the supraspinatus, with the shoulder in retropulsion. The subacromial bursa was visualized perpendicular to the supraspinatus. Finally, the infraspinatus tendon was explored in internal rotation, and then the acromioclavicular joint. Each structure was visualized on axial and longitudinal slices [12].

Arthroscopic exploration followed the standard in-vivo surgical procedure. The limb was placed in 4 kg traction to decoapt the glenohumeral and subacromial spaces. A posterolateral portal was performed in the soft point of the Wolff interval, visualizing first the glenohumeral space. Then the endoscopic probe was introduced via an anterior portal, exploring glenohumeral structures of interest and taking ultrasound images. The arthroscope was then passed from the glenohumeral space toward the subacromial space, and a lateral subacromial portal was performed for bursectomy by shaver. Finally, the shaver was withdrawn and the endoscopic ultrasound probe was introduced into the subacromial space via the lateral portal to explore structures of interest and take images.

For each structure, an independent observer assessed visibility according to technique. Ultrasound images were photographed and numbered so that 3 osteoarticular imaging experts could, under single-blind, compare image quality between endoscopic and external ultrasound examination.

Acquisition times in each shoulder were also recorded and compared by the independent observers, and the operator was informed when they exceeded 20 minutes. Beyond this threshold, longer operative time would tend to increase the risk of secondary lesion and of surgery site infection. All data were recorded on assessment forms filled out during the procedure.

The main endpoint was the number of structures of interest visualized on endoscopic and external ultrasound respectively.

Secondary endpoints comprised assessment of image quality, and comparison of acquisition times.

Statistical analysis used XL-STAT 2019® software. Study quality was assessed on the STROBE checklist (“Strengthening the Reporting of Observational Studies in Epidemiology”) [13]. Imaging techniques were compared on chi² test. Parameters were assumed to be independent. Significant findings implied non-inferiority, while non-significant findings did not necessarily indicate any real difference. Classically, sample size should be at least 5, while here it was 3; even so, tests were applicable, as results were not continuous but dichotomous: visualization was 100% or else 0. The significance threshold was set at $p < 0.05$.

RESULTS

Ten of the 11 structures of interest (91%) were visualized on endoscopic ultrasound and 4 (36%) on external ultrasound. Table 2 presents the structures. There was a significant difference between techniques for the overall proportion of visualized structures on Cohen’s kappa coefficient: 0.178 (p-value = 0.0377). Only overall and not structure-by-structure analysis could be made, as sample sizes were otherwise too small for the Cohen-kappa test.

Comparison between techniques showed $\geq 83\%$ discordance in visualizing glenoid and humeral cartilage surfaces, deep side of the rotator cuff and inferior side of the acromion, with a non-significant trend for better visualization on endoscopic ultrasound (Table 3).

Endoscopic ultrasound visualization was also better for 8 of the 11 structures of interest (72.7%): long head of the biceps, glenoid and humeral cartilage surfaces, superior and medial glenohumeral ligaments, glenoid labrum, superficial side of the rotator cuff, and inferior side of the acromion. External ultrasound gave better image quality for only 1 structure (9.1%): the acromioclavicular joint. For the lateral side of the rotator cuff tendons, the 2 techniques were equivalent (Table 4). Figures 2, 3 and 4 show comparative images for the same structures of interest.

Mean acquisition time was 570 ± 377.1 seconds [range, 300 ; 1,320]: 9.5 ± 6 .minutes 3 [5 ; 22] in endoscopic ultrasound and 408 ± 143.2 seconds [240 ; 600] (6 minutes 48 seconds ± 2.4 minutes [4 ; 10]) in external ultrasound (Table 5). Cohen kappa showed no significant difference, with $\kappa = 0.41398$ (p-value=0.52). (Figure 5)

DISCUSSION

The statistical analysis demonstrated the non-inferiority of arthroscopic endoscopic ultrasound with respect to external ultrasound. The overall number of visualized structures of interest was significantly in favor of endoscopic ultrasound, with 6 structures non-visualizable on external ultrasound: glenoid and humeral cartilage surfaces, superior and medial glenohumeral ligaments, deep side of the rotator cuff and inferior side of the acromion. The lateral side of the cuff, on the other hand, was equally visualizable on both techniques, and visualization of the acromioclavicular joint was better on external ultrasound.

The strong point of the study was that, to the best of our knowledge, it was the first comparison between an endoscopic ultrasound probe specifically designed for arthroscopic exploration of deep structures and an external ultrasound probe. Other studies previously reported use of endoscopic ultrasound in arthroscopic assessment of knee cartilage [14][11].

The study shows certain limitations. Firstly, the specimens, from subjects with a mean age of 84 years, suffered from osteoarthritic degeneration. Some structures of interest were not present in some cases, with torn long head of the biceps tendon, or retracted full-thickness rotator cuff tear; thus non-acquisition was not due to technical problems with probe manipulation or to probe design, but simply to the anatomic status of the specimen.

Secondly, sample size was small (6 shoulders), limiting statistical power.

The study did, however, show that endoscopic ultrasound provided better image quality than external ultrasound in 8 structures: intra-articular part of the long head of the biceps, glenoid and humeral cartilages, superior and medial glenohumeral ligaments, labrum, inferior side of the acromion, and deep side of the rotator cuff tendons.

Image acquisition differed between the two techniques. The long head of the biceps was visualized on endoscopic ultrasound in its intra-articular part, while external ultrasound visualized its vertical part within the groove, as the latter probe cannot access the horizontal part due to interposition of the acromion and lateral quarter of the clavicle across the ultrasound trajectory, as highlighted by Mazaleyrat et al. [3]. Moreover, external ultrasound cannot visualize the acromion and deep side of the rotator cuff, which require intra-articular probing.

The endoscopic probe moves only on its rotational axis from the point of introduction via the arthroscopic portals, whereas the external probe can move in various axes, allowing better visualization of the acromioclavicular joint.

Exploration time did not significantly differ between the two techniques. Acquisition time was much less than the initially estimated 20 minutes in all but one shoulder, at a mean 9.5 ± 6.3 minutes [range, 5 ; 22].

Like in other reports, there were no lesions caused by probe manipulation in the 6 shoulders; this is an important point for in-vivo assessment of the this endoscopic ultrasound probe [11] [14] [15].

CONCLUSION

Image acquisition by a dedicated endoscopic ultrasound probe specifically designed for shoulder arthroscopy provided image quality at least as good as that of external ultrasound, and in some cases better. It also allowed imaging of some deep structures that are inaccessible to external ultrasound.

For some years now, orthopedic surgeons, and notably upper-limb specialists, have increasingly been training in ultrasound techniques for diagnostic and therapeutic purposes [16][1]. Endoscopic ultrasound probes such as the M15 combine the advantages of external ultrasound and those of arthroscopic exploration, extending access to deep shoulder structures and providing better image quality for diagnostic purposes and therapeutic decision-making or intraoperative assistance.

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Table 1: Anatomic characteristics, with age, gender and shoulder number.

Subject	Gender	Age (years)	Shoulders
1	Female	73	Shoulder 1: right Shoulder 2: left
2	Female	91	Shoulder 3: right Shoulder 4: left
3	Male	88	Shoulder 5: right Shoulder 6: left

Table 2: Structure visualization on endoscopic and external ultrasound, and comparison between the two

Structures	Visualization on endoscopic ultrasound (%)	Visualization on external ultrasound (%)	Comparison 1= superiority on external ultrasound 2= superiority on endoscopic ultrasound 3 = equivalence
Long head of the biceps	100	100	3
Glenoid cartilage	100	0	2
Humeral cartilage	100	0	2
Superior glenohumeral ligament	100	0	2
Medial glenohumeral ligament	100	0	2
Inferior glenohumeral ligament	0	0	3
Glenoid labrum	100	100	3
Deep side of rotator cuff	100	0	2
Lateral side of rotator cuff tendon	100	100	3
Inferior side of acromion	100	0	2
Acromioclavicular joint	100	100	3

Table 3: Concordance and discordance between endoscopic and external ultrasound visualization.

Structures	Percentage concordance	Percentage discordance
Long head of the biceps	66.7	33.3
Glenoid cartilage	0	100
Humeral cartilage	0	100
Superior glenohumeral ligament	83.3	16.7
Medial glenohumeral ligament	66.7	33.3
Inferior glenohumeral ligament	100	0
Glenoid labrum	50	50
Deep side of rotator cuff	16.7	83.3
Lateral side of rotator cuff tendon	100	0
Inferior side of acromion	0	100
Acromioclavicular joint	66.7	33.3

Table 4: Qualitative comparison between endoscopic and external ultrasound visualization per structure

Structures	Comparison 1: Endoscopic ultrasound superior 2: External ultrasound superior 3: Equivalent NA: Not applicable
Long head of the biceps	1
Glenoid cartilage	1
Humeral cartilage	1
Inferior glenohumeral ligament*	NA
Medial glenohumeral ligament	1
Superior glenohumeral ligament	1
Glenoid labrum	1
Deep side of rotator cuff	1
Lateral side of rotator cuff tendon	3
Inferior side of acromion	1
Acromioclavicular joint	2

* Inferior glenohumeral ligament not visualizable due to joint line impingement probably related to osteoarthritic degeneration

Table 5: Image acquisition time on endoscopic and external ultrasound (sec, min)

Shoulders	Acquisition time on endoscopic ultrasound		Acquisition time on external ultrasound	
	Seconds	Minutes	Seconds	Minutes
Shoulder 1	300	5	600	10
Shoulder 2	480	8	NA	NA
Shoulder 3	1,320	22	420	7
Shoulder 4	540	9	480	8
Shoulder 5	420	7	300	5
Shoulder 6	360	6	240	4
Mean	570	9.5	408	6.8
Mediante	450	7.5	420	7
Standard deviation	377.1	6.3	143.2	2.4

Figures

- Figure 1: M15 endoscopic ultrasound probe (Cartimage Medical SASTM, France)

- Figure 2: Superficial side of right cuff
 - A: external ultrasound
 - B: endoscopic ultrasound

- Figure 3: Right acromioclavicular joint
 - A: external ultrasound
 - B: endoscopic ultrasound

- Figure 4: Left shoulder long head of the biceps
 - A: external ultrasound
 - B: endoscopic ultrasound

- Figure 5: Boxplot of acquisition time on endoscopic and external ultrasound
 - (observer 1): endoscopic ultrasound
 - (radiologist): external ultrasound

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Figure 1:



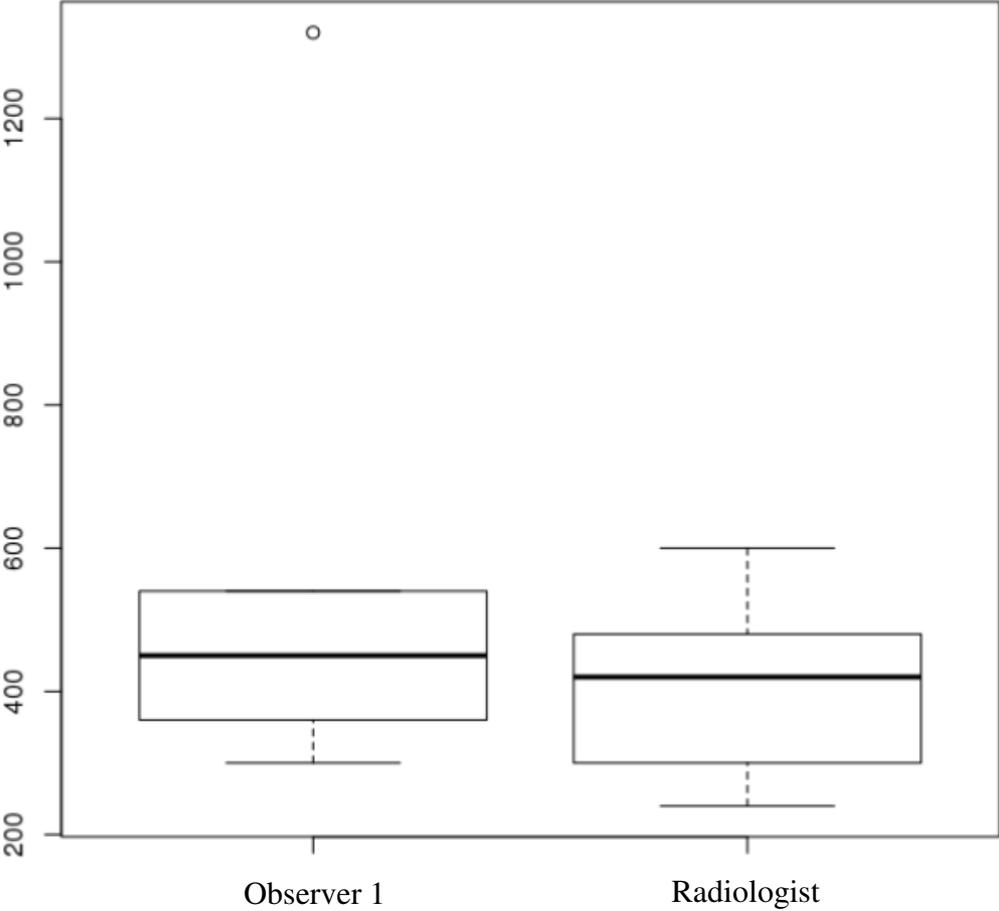
Figure 2:



Figure 4:



Figure 5:



No significant difference.