

Comparison of ultrasound-guided versus blind interventions for supraspinatus tendinopathy: a cadaveric study.

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DOI:

10.32098/mltj.03.2019.06

LEVEL OF EVIDENCE: 2B

SUMMARY

Background. The treatment of supraspinatus tendinopathy remains a challenge for the health professional. This study aims to analyze the precision of needle interventions in lesions of the supraspinatus tendon when conducting them in an ultrasound-guided or non-ultrasound guided (blind) manner.

Methods. Study on cadaver with infiltrations performed under ultrasound control or blind after randomization of the parts and participants. Twenty fresh cadaveric shoulders and 30 practitioners with experience using musculoskeletal ultrasound and doing needle interventions. Each practitioner performed 4 ultrasound-guided and 4 unguided punctures. This provided 240 punctures that were analyzed in 3 different anatomical cuts, thus providing a database of 720 measurements for statistical analysis.

Results. Statistically significant differences were observed ($p < 0.0001$) in the distance to the bullet point between the ultrasound-guided and the non-guided infiltrations. It was estimated that the unguided punctures were performed on average 10mm farther from the bullet point than the 'ultrasound-guided' punctures. The ultrasound-guided punctures demonstrated 95% precision while the unguided punctures had a precision rate of 12.5% ($p < 0.0001$).

Conclusion. Interventions of the supraspinatus tendon should be performed in an ultrasound-guided manner to facilitate administration of the treatment in the proper area.

KEY WORDS

injections; interventions; tendon; treatment; usget; ultrasound guided

BACKGROUND

The treatment of supraspinatus tendinopathy remains a challenge for the health professional. The current literature advocates for multidisciplinary work among physicians, physiotherapists and rehabilitators to treat this pathology (1,2). Invasive therapies (in which the injured tendon is punctured) either for the application of galvanic currents (3,4), biological therapies (4,5) or analgesics (6,7,8) are a widespread therapeutic tool today.

The supraspinatus tendon insertion area (SSP) at the level of footprint is the area most frequently affected in a rotator

cuff (RC) injury (**Figure 1**). Jeong et al. (9) has shown the anterior area of the SSP, at about 9-10mm posterior to the biceps tendon, as the area at greatest risk of injury (**Figures 2A-B**).

Until relatively recently, needle interventions had only been carried out blind (anatomical landmark-guided). However, with the arrival of ultrasound and its rise, it has been shown that using it improves precision in the infiltration procedure (10). Ultrasound provides an easy-to-use tool with high image quality, does not irradiate and has a moderate economic cost (11). Precision in carrying out injected

therapies should be the highest priority. Literature already reports that infiltrations that are not properly done in some areas may worsen the symptoms or make the applied therapy ineffective (12,13).

Multiple treatments have been described that may be useful in the treatment of supraspinatus tendinopathy (4). The main basis of most of these treatments is that the product or technique to be applied must be administered in a specific area of the tendon (area of injury). Mainly, these treatments are with Platelet Rich Plasma (PRP), Ultrasound-guided galvanic electrolysis (USGET), or corticosteroids (4,7,8).

As far as the authors know, this is the first work that analyzes the precision of ultrasound-guided and blind punctures inside the supraspinatus tendon (area of injury or bullet

point) with the aim of providing guidelines for action in future interventions.

MATERIALS AND METHODS

The Ethics and Experimentation Committee of our University (num. 03272015) approved the study and meet the ethical standard of this journal (14). The study was carried out in the dissection room of the Faculty of Medicine of our university using 20 upper members from cadavers donated to science. All the donors were serologically tested to rule out infectious-contagious diseases (HIV, hepatitis B and hepatitis C) before starting the study. Of the 20 donors, 12 were women and 8 men, with an average age of 82.3 years

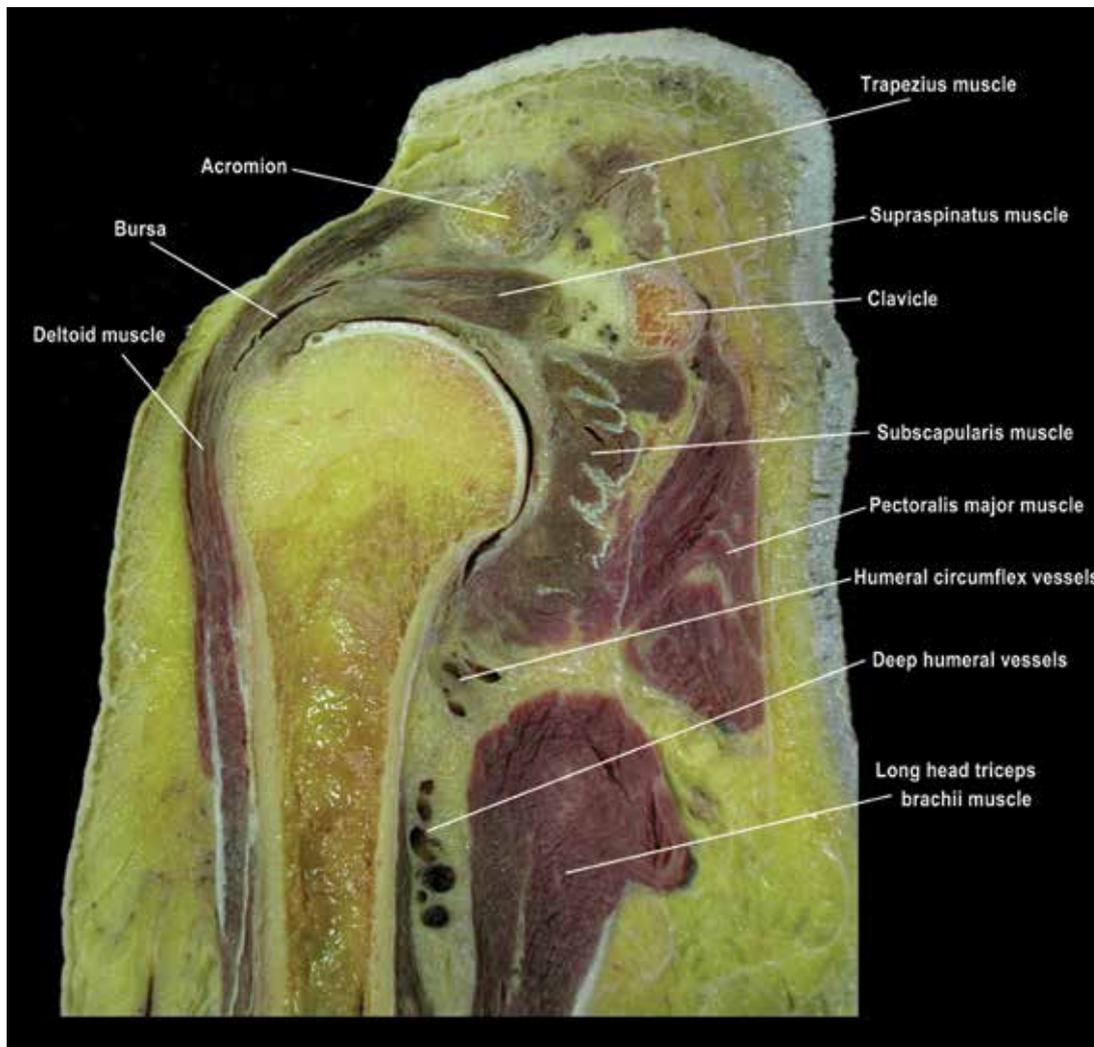


Figure 1. Coronal section of the glenohumeral joint showing the most relevant anatomical structures.

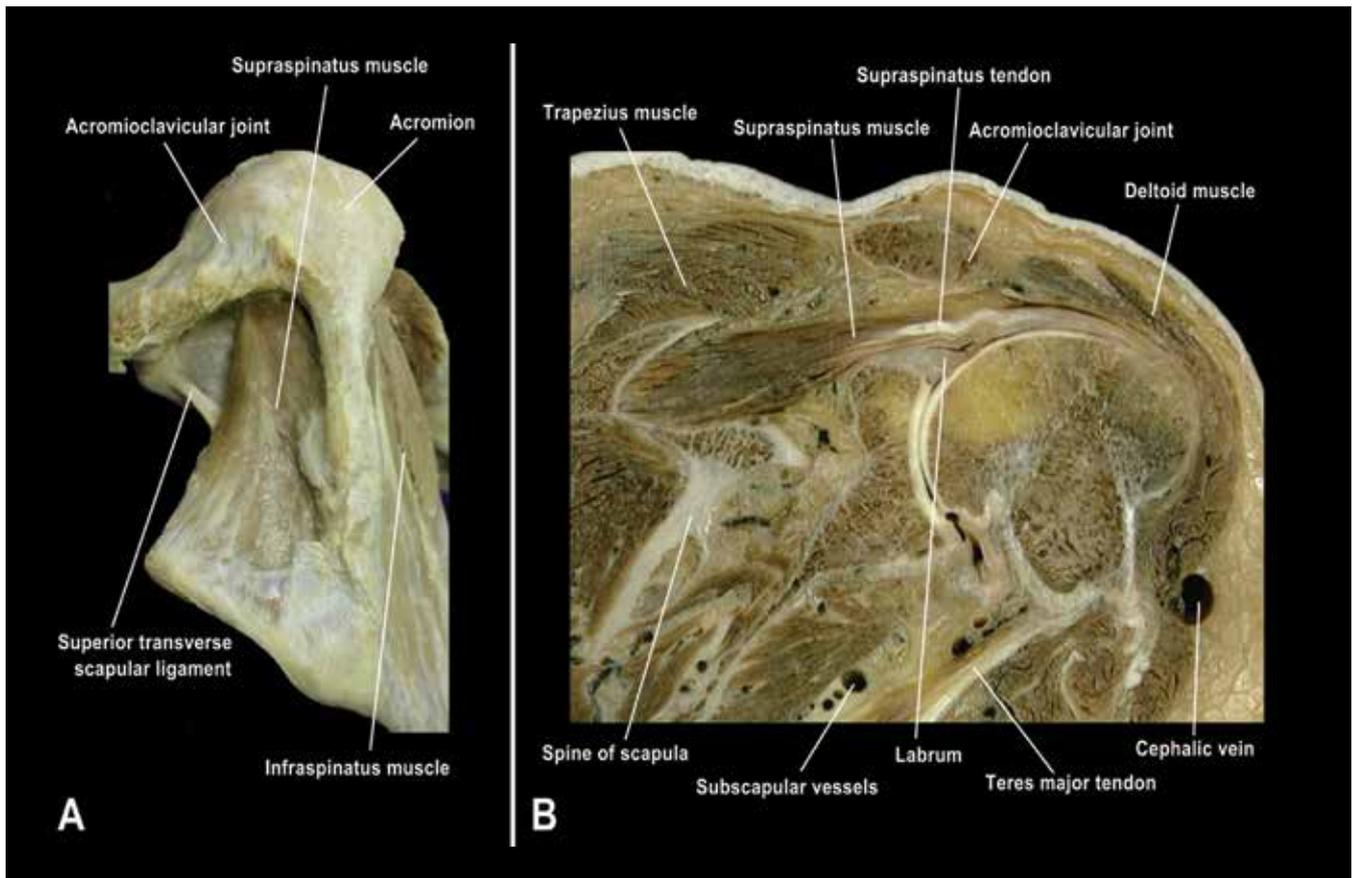


Figure 2. A. Top view of the right supraspinous fossa where the tendons are identified Supraspinous and infraspinous. **B.** Coronal section of the gleno-humeral joint showing the prolongation of the supraspinatus muscle to its tendinous and insertion part.

(range 71-100 years). There were 9 right shoulders and 11 left shoulders.

The presence of scars and/or shoulder deformities that could interfere with the results of the study was then assessed and the upper limbs of the trunk were separated with scapulo-thoracic disarticulation and clavicular sectioning near the sternoclavicular joint. The upper extremities were stored frozen at -40°C for up to 2 hours before use.

To perform the study, each upper limb was placed in a support that fixed the body of the scapula, thus exposing the shoulder in an anatomical position.

Thirty practitioners performed the infiltrations. The practitioners had an average age of 36.9 years (range of 25 to 59 years), experience of 6.9 years (range of 2 to 25 years) in invasive therapies with needles and average experience of 3.3 years (ranging from 1 to 15 years) in the use of musculoskeletal ultrasound.

The practitioners were informed of the objective of the study. It was to perform infiltrations of the supraspinatus

muscle tendon to assess the usefulness of ultrasound. Ultrasound examination was performed with a 5-16MHz linear array transducer in longitudinal and transversal view in a real-time imaging mode in a standardized mode as described by Rutten et al. (15).

With the help of 5ml luer-lock syringes with 21G needles of 30 millimeters, a 1cc infiltration of colored natural latex was performed with randomization of the parts and the practitioners. Each practitioner conducted four ultrasound-guided and four unguided interventions, each on a different specimen, which made it possible to have a database of 240 infiltrations. To assess infiltration precision, the anterior part of the supraspinatus tendon (SSP) was considered the bullet point, about 9 to 10mm posterior to the tendon of the long head of the biceps brachii muscle and centered on the thickness of the SSP.

Once the infiltrations were done, the extremities were frozen at -40°C for 1 month. Then, serial cuts, 1cm thick on the sagittal plane, were made with the help of a verti-

cal band saw (Medoc BR 400, Medoc SA, Logroño, Spain) with a 4mm blade. Immediately after making the cuts, we proceeded to identify the three most significant serial cuts that allowed us to collect information on the location of the latex and photograph it (digital camera Canon G11 5x - 6.1-30.5mm 1: 2.8-4.5). This information (30 practitioners x 8 infiltrations x 3 cuts) made for a database of 720 measurements (360 echoguided and 360 blind) for its subsequent statistical analysis (**Figure 3A-B**)

For the computer analysis of the images, Fiji software was used. It is open source software focused on the analysis of biological images (°4). Using this software, the distance between the point to be infiltrated (previously predetermined bullet point) and where the infiltration had been done was calculated.

Statistical analysis was performed with SAS software v9.4 (SAS Institute Inc., Cary, NC, USA). The statistical decisions were made taking the value 0.05 as the level of significance. A validation of the internal consistency of the variables in the database as well as the out-of-range values and missing values was done to fully ensure their reliability. The main response variable was analyzed, this being the average distance to the point of the tendon to be treated (bullet point) in the different anatomical cuts, categorizing this mean as precision.

In the first place, since several punctures were made on the same tendon, the contrast of the inclusion of said random effect on the model was studied. Upon not obtaining statistically significant differences, the punctures were considered independent. A Kolmogorov-Smirnov test for normality of each study and a descriptive analysis of the data were performed. A box diagram of the mean distance to the center of the tendon and the table with the basic descriptive statistics (N, Medium, Std, Minimal, Q1, Medium, Q3, Maximum and Missing) is presented depending on whether the puncture was ultrasound-guided or unguided. The non-parametric contrast was performed for two independent samples: The Wilcoxon test was done to check whether there were differences in the distances to the center of the tendon between the punctures, ultrasound-guided and unguided.

For the evaluation of precision, a descriptive analysis of the data was performed, presented with a precision bar chart and the table with the basic descriptive statistics (N, Percentage) based on whether the puncture was ultrasound-guided or not. The Chi-Square independence test was carried out to check whether there were differences in the puncture precision distribution based on whether it was ultrasound-guided or not. The indicator, Precise (Completely Successful)

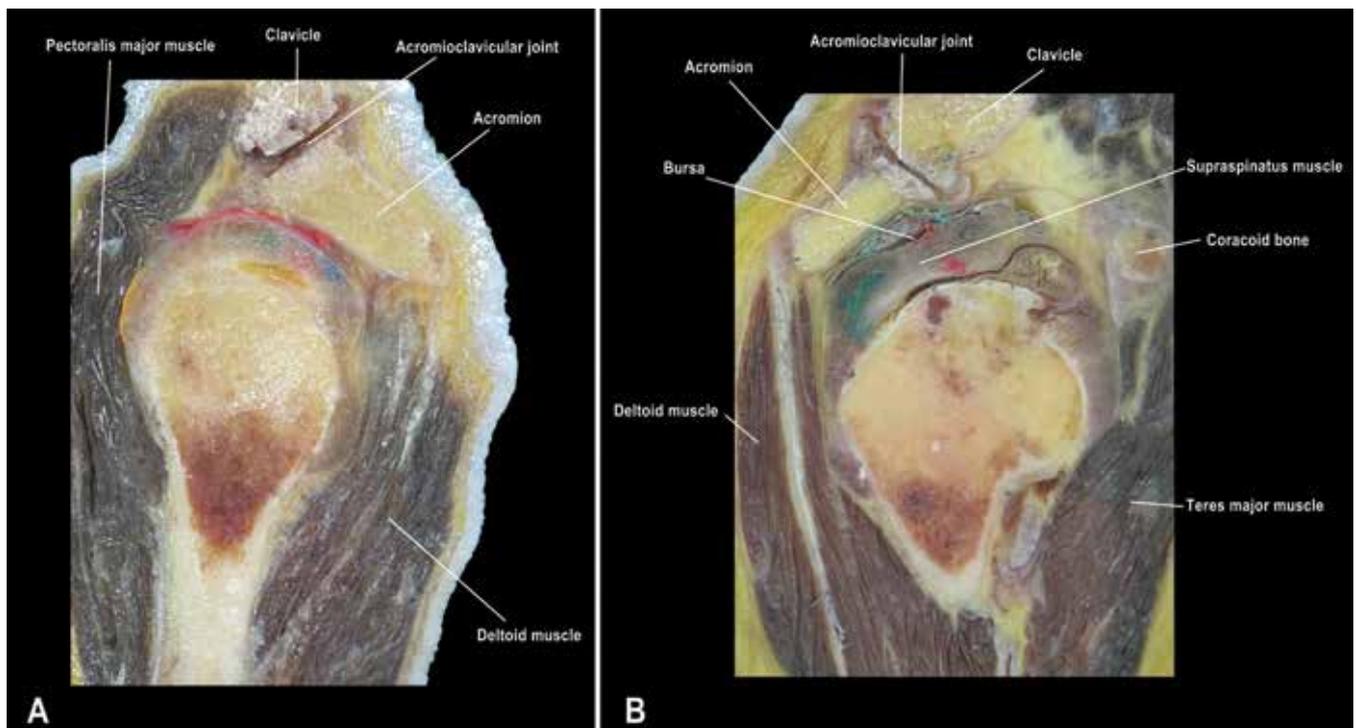


Figure 3 A-B. Coronal section of the glenohumeral joint. In colors, the punctures are identified (colored latex). It can be observed that without the ultrasound control, the infiltrations were made in the SSE tendon as well as in adjacent structures.

versus Not Precise (Partially Successful and Unsuccessful), was calculated.

RESULTS

A great difference was observed in the punctures depending on whether they were ultrasound-guided or non-guided (Figure 4). The median distance to the bullet point of the 120 unguided punctures is 14 (Q1=6.47, Q3=16.2). It is 2.91 in those that were Ultrasound-guided (Q1=2.47, Q3=3.41) (Table I).

Statistically significant differences are observed (Wilcoxon Two-Sample Test = 21072.5; p_value<0.0001) in the distance to the bullet point between those that were ultrasound-guided and those that were not. Specifically, it was seen that the mean in the unguided was 10 units higher than in ultrasound-guided. In addition, the median for the unguided puncture group was 14 when the ultrasound-guid-

ed puncture group had a maximum value of 9.5. All the ultrasound-guided punctures were below the median of the unguided punctures.

In ultrasound-guided punctures, we obtained an estimate of the mean distances to the bullet point of 3.05, 95% CI= [2.01, 4.09]. In contrast, we obtained an estimate in unguided punctures of the mean distances to the bullet point of 13.36, IC95%= [12.32, 14.4].

Statistically significant differences were detected (t Value = -13.8; p_value<0.0001) between ultrasound-guided and unguided punctures. The difference between ultrasound-guided and unguided punctures was -10.31mm, IC95% = [- 11.78, -8.84]. This means that it was estimated that the unguided punctures are performed on average 10mm farther from the bullet point than the ultrasound-guided punctures.

A great difference was observed when analyzing successful punctures Vs the unsuccessful in terms of whether it

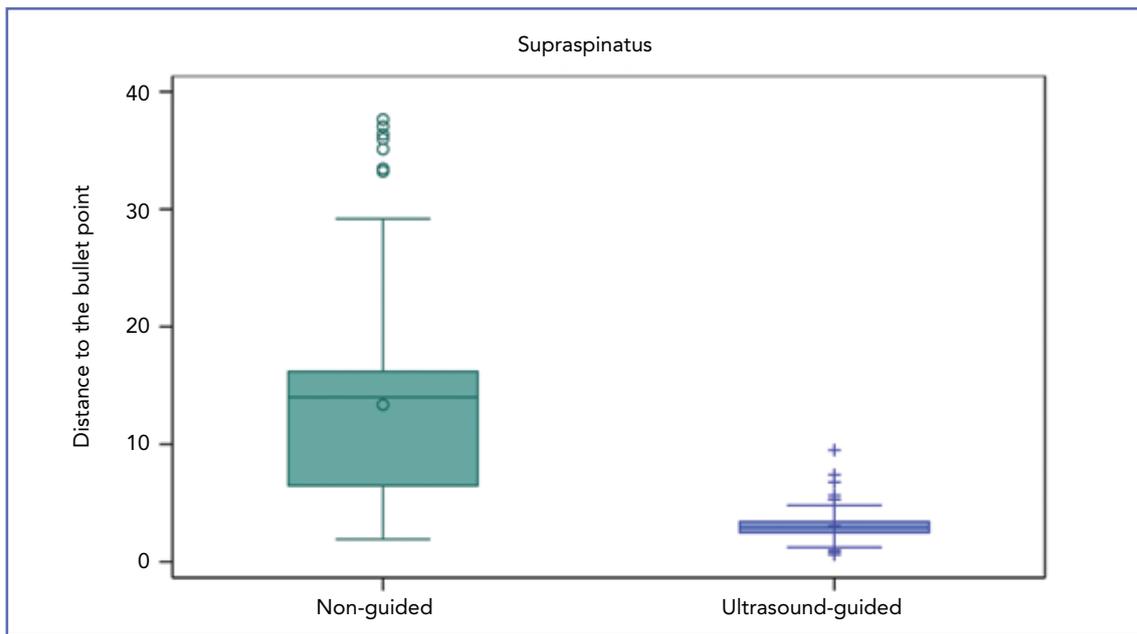


Figure 4. Bar chart showing the distance to the bullet point from the punctures.

Table I. Distance of the ultrasound-guided or blind infiltrations to the bullet point. The number, mean, standard deviation as well as median, minimum, maximum and quartiles are shown.

	Distance to bullet point								
	N	Median	Std	Min	Q1	Median	Q3	Max	Missing
Unguided	120	13.36	8.1	1.91	6.47	14.00	16.20	37.64	0
US-guided	120	3.05	1.19	0.61	2.47	2.91	3.41	9.50	0

was performed unguided or ultrasound-guided (**Figure 5**). Imprecise punctures corresponded to unguided punctures. Most of the unguided punctures were imprecise, 74 punctures (61.67% of the total of unguided punctures). Most of the ultrasound-guided punctures are successful, 114 punctures (95% of the total of ultrasound-guided punctures). There were statistically significant differences (Chi-Square Test = 166.87; p value<0.0001) in the distribution of the precision variable between the ultrasound-guided and unguided. Some 61.67% of unguided punctures were not precise. However, 95% of the ultrasound-guided punctures were successful.

In unguided punctures, an estimate of the puncture percentage was obtained (with Precise = Successful) of 12.5%, 95% CI = [7.66%, 19.75%]. On the other hand, an estimate of the puncture percentage was obtained in ultrasound-guided punctures (with Precise = Successful) of 95%, IC95% = [89.28%, 97.75%] (**Table II**).

Statistically significant differences were detected (t Value = 9.75; p value<0.0001) between ultrasound-guided and unguided punctures. The Odds Ratio for Precision = Successful between ultrasound-guided and unguided punctures is 133, IC95% = [49.51, 357.29]. This means that the Odds Ratio for Precision = Successful in ultrasound-guided punctures was estimated at 133 times the odds in the unguided.

DISCUSSION

The main objective of this study was to demonstrate the importance of the use of ultrasound in needle interventions of the supraspinatus tendon. Our hypothesis that ultrasound-guided interventions demonstrate greater precision than blind infiltrations has been validated.

Enough evidence can be found in the literature to support the need to use ultrasound in shoulder infiltrations (4,17-

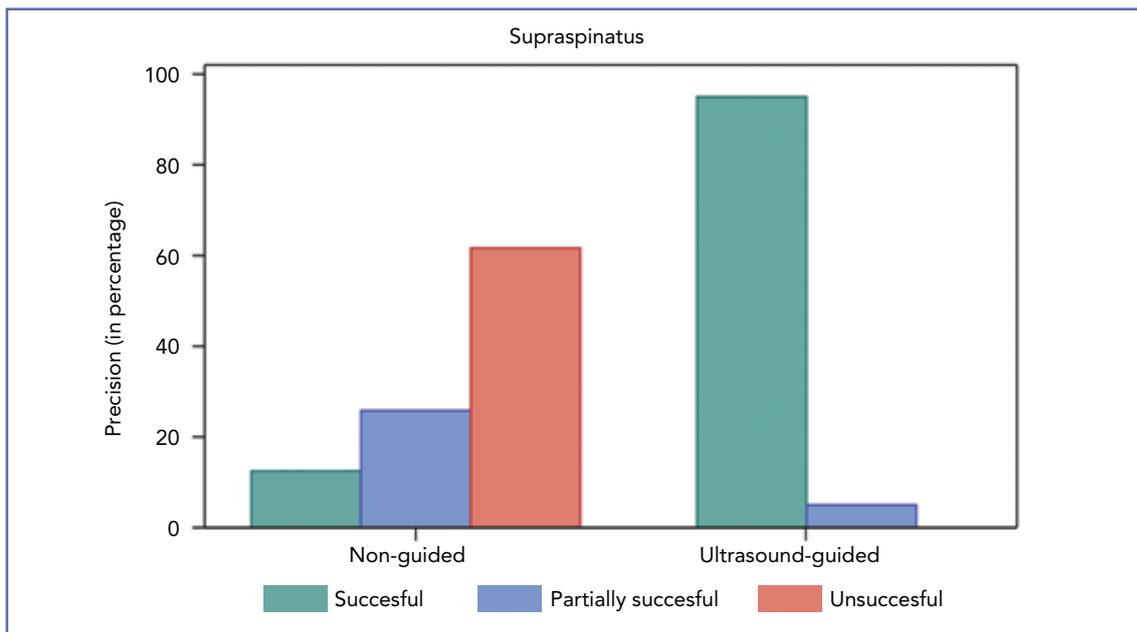


Figure 5. Bar chart showing the distance to precision of the ultrasound-guided or blind infiltrations.

Table II. Precision of ultrasound-guided or blind infiltrations. Results classified as successful, partially successful or unsuccessful.

	Precision						Total N
	Successful		Partially successful		Unsuccessful		
	N	%	N	%	N	%	N
Unguided	15	15.50	31	25.83	74	61.67	120
US-guided	114	95	5	0	0	0	120

19). In contrast, a recent Cochrane review concluded that the cost of ultrasound does not justify its use (20). Despite this, this study has important limitations such as obtaining a conclusion based on a single study (17,21).

To date, it must be kept in mind that the clinical results of an invasive technique that is not performed in an ultrasound-guided manner cannot be analyzed. Multiple studies show that, without ultrasound control, a very significant number of infiltrations end up outside the “target” site (8,17,19). Therefore, the clinical results do not correlate with said procedure (20). The current literature already states that glenohumeral infiltrations administered in the correct area improve the clinical outcome (22,23), while infiltrations outside this area can even cause tissue injuries (22).

Several authors have written of rotator cuff lesions originating in the anterior part of the cuff (insertion) spreading posteriorly with the passage of time (24,25). Recently, other authors have shown that the degenerative lesions originating in the infraspinatus tendon (ISP) spread towards the anterior aspect of the cuff (26,27). Subsequently, Kim et al., in an ultrasound study, described how a lesion of the RC generally occurred at the junction between the supraspinatus (SSP) and the infraspinatus (28). Finally, an important recent study found that the main area of injury shown in MRI is in the SSP insertion in a more anterior area, 9-10mm posterior to the biceps tendon (24). This has been the area that has been taken as an area to be treated in the present study. Thus, the ability to puncture only in said area with and without ultrasound has been analyzed.

Currently there are different therapeutic options for the treatment of SSE tendinopathies (5). It is vital that their application be done correctly and in the precise area to be treated. In a recent systematic review, authors such as Filarido et al. found no differences between PRP infiltrations in the SSE tendon or surgery (29). Then again, Fitzpatrick et al. advocate for the use of leukocyte-rich PRP (LR-PRP) under ultrasound control in the treatment of these lesions in their meta-analysis (30). The ultrasound guided galvanic electrolysis technique (USGET) has also recently been proposed as a therapeutic option. It causes a controlled inflammatory reaction in the tendon to trigger the regenerative process (3,4). With subsequent eccentric work, the tissue is stimulated to give mechanical support to the biological treatment. Arias-Burúa et al. showed poor results with the use of electrolysis in tendinopathies of the supraspinatus (31). The difference in applied intensity should be highlighted

since Abat et al. (3) advocate for amperages of between 2 to 8 milliAmps while Arias-Burúa et al. (31) use 350 microAmps in their study. Although there is a substantial debate about the use of corticosteroids in tendon pathology, they are widely used (32,33). Currently, it is thought that the irrigation implied in the use of corticosteroids in tendons no longer justifies their use (7,34).

Another novel therapeutic approach includes the use of hyaluronic acid (35,36), this treatment enhanced viability, proliferation and expression of collagen type I in tendon derived cells.

Consensus on rotator cuff tears management was published recently by Oliva et al. (37) and should be taken as accessible guidelines in order to improve the quality of care and rationalize the use of the different treatment options.

The main limitation of the present study is the use of fresh cadaveric specimens. In those specimens, muscular tension during the injection cannot be determined by the practitioner. Being cadavers of the advanced in age (average of 82.3 years), the tendon of the supraspinatus can be found thin, making blind infiltration even more difficult.

Ultrasound-guided needle interventions have gained popularity in recent years (11). Although some studies indicate the lack of clinical differences that justify the cost of the ultrasound, no cost-effectiveness studies have so far been conducted (10,13,16-19,21,22) (**Table III**). For the time being, we must rely on studies of the precision of ultrasound-guided versus blind infiltrations. They clearly favor the use of ultrasound to improve precision.

In conclusion the present study clearly supports the use of ultrasound with needle procedures on the supraspinatus tendon, thus improving precision and making it possible to focus the treatment used in the correct area of injury. The novelty of this study resides in the evaluation of the injection therapy precision just on the spot of lesion (injured area), making the treatment more specific and valuable.

ACKNOWLEDGMENTS

To the department of anatomy of the UAB (Campus Bellaterra) for its collaboration in the project, especially to Manel Querol for his involvement and diligence.

Special mention to donors who have made this study possible with their altruism. We must also make mention of all the colleagues who helped us during the infiltrations in the cadaverous parts. We are also grateful to Eric L. Goode for his help in editing the manuscript.

Table III. Literature review of ultrasound versus blinded injections around the shoulder. (GH = glenohumeral, US = Ultrasound, RCT = Randomized Controlled Trial)

Blinded versus Ultrasound Guided Injections							
Lead Author	Year	N	Treatment area	Treatment applied	Imaging Used	Results	Study Design
Balint ³⁸	2002	6	GH joint	Fluid Aspiration	US / Blinded	US superior to blinded	Cohort
Naredo ³⁹	2004	41	Sub-acromial	Corticosteroid	US / Blinded	US higher accuracy	Cohort
Lee ⁴⁰	2009	43	GH joint	Corticosteroid	US / Blinded	US obtain greater clinical improvement	RCT
Soh ¹⁸	2011	101	Sub-acromial	Corticosteroid	US / Blinded	US obtain greater clinical improvement	Sist. review
Patel ²²	2012	80	GH joint	Cadaveric Study	US / Blinded	US higher accuracy	Cohort
Mattie ¹³	2015	162	GH joint	Diagnostic contrast fluid	Fluoroscopy / Blinded	Image guided better results	Cohort
Raeissadat ²³	2016	41	GH joint	Corticosteroid	US / Blinded	US obtain greater clinical improvement	RCT
Cole ⁴¹	2016	56	Sub-acromial	Corticosteroid	US / Blinded	No differences in the clinical outcome	RCT

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