

## Personalized Therapeutic Ultrasound in Shoulder Disease: Multimodal Assessment and Results

Elisa Lioce<sup>1\*</sup>, Guiot C<sup>2</sup>, Bistolfi A<sup>3</sup>, Novello M<sup>2</sup> and Massazza G<sup>1,3</sup>

<sup>1</sup>School of Physical Medicine and Rehabilitation, University of Torino, Torino, Italy

<sup>2</sup>Department of Neuroscience, University of Turin, Corso Raffaello, Torino, Italy

<sup>3</sup>Department of Orthopaedics, Traumatology and Rehabilitation, AO City Health and Science, CTO Hospital, Torino, Italy

\*Corresponding author: Elisa Lioce, School of Physical Medicine and Rehabilitation, University of Torino, Torino, Italy, Tel: 0116707710/8166; E-mail: [elisa.lioce84@libero.it](mailto:elisa.lioce84@libero.it)

Received date: Jan 20, 2016; Accepted date: April 15, 2016; Published date: April 23, 2015

Copyright: ©2016 Lioce E, et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

### Abstract

**Introduction:** Therapeutic ultrasound (US) has been used in physiotherapy for more than 50 years to treat acute and chronic inflammatory diseases in joints, muscles, tendons, ligaments and so on. Despite of its widespread use in rehabilitative practice and the large number of studies, low scientific, statistically assessed evidences of therapeutic US effectiveness are available. As a matter of fact, details about the treatment modalities and the way in which the patients' feedback was collected are often missing. The aim of our study is to assess the therapeutic US effectiveness in shoulder disease management when a "customized" treatment to each patient is delivered and the clinical outcome is globally monitored.

**Methods:** Patients with shoulder pain who underwent rehabilitative treatment, including Ultrasound Therapy (US) in our Department of Physical Therapy and Rehabilitation Medicine at Turin University from May to September 2015 were enrolled. Clinical, functional and sonographic evaluation of the shoulder was performed before US treatment (T0), and at the end of the US therapy (T1) using Numeric Rating Scale, Constant Score, DASH questionnaire and sonography.

**Results:** Statistically relevant improvements of the clinical outcome were observed in all the considered parameters, with a significant reduction of shoulder pain and functional limitation in all patients. Sonographic images support clinical data.

**Conclusions:** Although studies involving a larger number of patients are required, the effectiveness of 'customized' US treatment evaluated with different approaches, including sonography, is assessable and lead to statistically significant results.

**Keywords:** Therapeutic ultrasounds; Joints; Muscles; Physiotherapy; Musculoskeletal disorders

### Introduction

Therapeutic Ultrasounds (US) is one of the most popular physical treatment used in physiotherapy for more than 50 years for acute and chronic inflammatory diseases in joints, muscles, tendons, ligaments and so on [1,2]. Its effectiveness has been recently questioned since scientific, evidence-based and robust outcomes are still missing [3,4].

Such controversial aspects may depend on the low quality of most clinical rehabilitative studies: in fact, despite of the large number of published reports on musculoskeletal disorders, including meta-analyses and reviews, the specific values of the US parameters and of the treatment modalities used (e.g. frequency, power, pulsed or continuous waves, fixed or 'massage' probe position, duration of the treatment) are seldom detailed. The issue of US dosimetry, which is related to the above parameter values, is becoming highly topical [5]. Moreover, the effectiveness of the US treatment is often evaluated only by using clinical tests and pain scores such as VAS or NRS, which give a subjective rather than quantitative and objective measure.

Another important issue is the frequent use of "protocols" which sets the same treatment parameters values (e.g. duration and treatment modalities) for all patients and all kind of diseases: performing standardized treatments may produce poor quality results both in clinical outcomes and in scientific studies.

The aim of this investigation is to make a further step toward quality treatment by applying to the clinics what we learned from our previous in vitro study on joint-mimicking phantoms in 2014. The temperatures measured at different depths were strictly depending from the US parameter values and the treatment modalities, and in order to induce the expected thermal effects and clinical advantages each patient should receive a "customized" treatment [6].

Moreover, in order to obtain an objective assessment of the US treatment effectiveness, patient evaluation should be multimodal, including clinical, functional and pain scores, but also a sonographic quantitative investigation of the local phlogosis and edema resolution. We, therefore, focused our study on shoulder inflammatory diseases, which are easily imaged by sonography.

## Methods

Patients with shoulder pain and functional limitation, due to biceps brachii long head muscle or rotator cuff tendonitis, bursitis, intra-articular effusion, without indication for surgical treatment, who entered our Department of Physical Therapy and Rehabilitation Medicine at Turin University, from May to September 2015 were enrolled.

### Inclusion criteria for the study were

- Clinical diagnosis of shoulder pain with tendons/bursa/articular phlogosis
- Rehabilitation program fully performed in our department following those criteria, 25 patients were recruitable.

Exclusion criteria were defined as follows:

- Comorbidities with contraindication for US treatment
- Neurological diseases or deficits (in particular affecting the painful shoulder)
- Pharmacological therapy with Nonsteroidal Anti-inflammatory Drugs or other anti-inflammatory local or systemic drugs, which could possibility bias the study results.

Following those criteria only 10 patients: 8 females and 2 males, mean age= 63.2 yrs, were selected.

The subjects received a detailed explanation of the study and gave written informed consent prior to participation. The study conformed to the guidelines in the Declaration of Helsinki and was approved by the local ethics committee (“Comitato Etico Interaziendale - AOU Città della Salute e della Scienza di Torino”, number 0070322). Table 1 shows clinical records with age, sex and dominant limb.

Patient	Sex	Age	Dominant limb
1	F	51	yes
2	F	63	no
3	F	84	yes
4	F	81	no
5	F	55	yes
6	F	73	no
7	F	68	yes
8	M	57	yes
9	F	48	yes
10	M	52	yes

**Table 1:** Clinical records with age, sex and dominant limb: 80% females, 20% males.

After a preliminary physiatric evaluation, each patient underwent US and other successive rehabilitative treatments.

The US therapeutic protocol is based on 10 sessions in consecutive days for an overall period of two weeks.

A multimodal assessment (clinical, functional and sonographic) of the actual pathology was performed before the US treatment (T0),

recording shoulder pain, ROM, strength, functional parameters and sonographic imaging.

Pain was estimated using the Numeric Rating Scale (NRS) [7]; Constant Score [8] and DASH scale [9] were used for shoulder's function evaluation.

A preliminary sonographic study was performed in order to quantify edema, phlogosis or effusion. Relevant images were saved and transferred on PC for further elaboration.

US treatments were then designed and performed by selecting the specific US parameters values and the treatment modalities for each patient in consideration of their specific clinical, functional and sonographic findings. In particular, the same apparatus (SONOPLUS 434 , Enraf Nonius, Rotterdam, NL) has been used for all patients, selecting a US intensity of 1.5 W/cm<sup>2</sup> and moving the probe on the skin with a 'massage-like' modality to avoid the formation of 'hot-spots'.

As far as the other US parameter values are concerned, a careful evaluation of the estimated depth of the lesion suggested the choice of the frequency of 1 MHz for deep and of 3 MHz for more superficial treatment sites.

Moreover, depending on the expected therapeutic increase in temperature at the lesion, the 'continuous' modality was selected to induce more heat deposition ( for a shorter time) while the 'pulsed' modality, with a Duty Cycle ( i.e. the US emitting time related to the total time length of the cycle) selected at 25% was preferred for longer time (10 min) treatments. Table 2 lists the clinical diagnosis and the specific treatment parameters for each patient.

PAZ.	Clinical Diagnosis	US frequency (MHz)	US Modality and (Duty Cycle)	US Session duration (min)
1	Impingements and tendonitis BBLC	3	pulsed (25%)	10
2	tendonitis BBLC	3	pulsed (25%)	10
3	frozen shoulder	1	continuous	5
4	frozen shoulder	1	continuous	5
5	Rotator cuff tendinopathy	1	pulsed (25%)	10
6	frozen shoulder	3	continuous	5
7	suvraspinal tendonitis and bursitis SAD	3	pulsed (25%)	10
8	Impingement syndrome	3	pulsed (25%)	10
9	tendonitis BBLC	1	pulsed (25%)	10
10	tendonitis BBLC and rotator cuff	3	pulsed (25%)	10

**Table 2:** Clinical diagnosis and US parameters selected.

The same procedure for result assessment was followed at the end of the US treatment (T1).

The sonographic examination was performed following a standardized procedure for the shoulder imaging [10] named

muskulo-skeletal ultra sonographic exam (MSUS), which satisfactorily detects the main findings of the phlogosis process.

In particular, articular effusion, rotator cuff or BLC tenosinovitis and bursitis were recorded and these inflammatory alterations were accounted for according to definitions in EBM.

To each alteration, a semi-quantitative score from 0 to 3 was given (0: no alterations; 1, 2, 3: low, mid and high inflammatory alterations). Single scores were added to give a total value (total score), indicating the global index of phlogosis of shoulder in each patient [11].

MSUS exam was performed before the US treatment session (T0) and at the end of the last US session (T1) by rehabilitation medical specialist, using an Edge Ultrasound System (Sonosite, USA) connected to a 7.5 MHz frequency probe.

Statistical significance is estimated by paired t Student test for all scores.

## Results and Discussion

Study results are shown in Table 3.

Patient	NRS T0	NRS T1	Constant T0	Constant T1	DASH T0	DASH T1	Eco T0	Eco T1
1	8	0	36	83	78	37	4	2
2	8	3	49	78	65	52	3	2
3	8	5	42	64	105	81	6	4
4	7	4	45	67	98	73	5	4
5	6	5	53	55	72	70	4	3

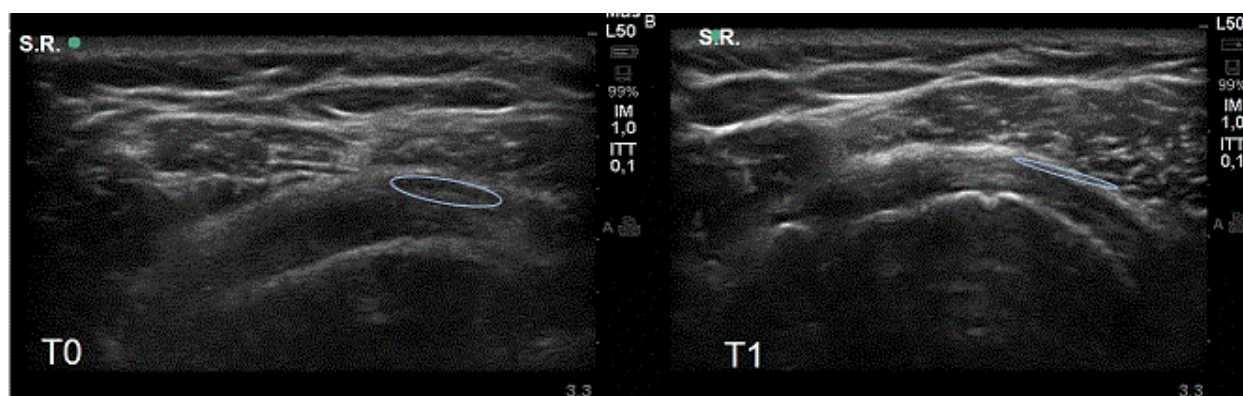
6	9	5	34	59	103	77	4	2
7	7	2	51	80	71	43	5	3
8	6	3	58	79	62	45	4	3
9	7	2	50	81	60	39	3	3
10	8	4	33	75	69	41	5	3

**Table 3:** Results of the study.

Statistical significance ( $p < 0.01$ ) was achieved for all parameters values (Table 4).

All patients enrolled in our study, which were treated at the best of our knowledge, selecting the parameter values of the US treatment according to the characteristics of their lesions, showed a significant reduction of shoulder pain and functional limitations. In particular, NRS and DASH scores significantly improved from T0 to T1. Sonographic imaging supports clinical data, showing a considerable reduction of bursa or tendon's area of phlogosis at T1 evaluation (Figure 1). All the scores assigned to the multimodal assessment system before and after the US treatment showed statistically significant improvements.

The previous experience obtained in monitoring temperatures in a realistic model (phantom) heated with US with different modalities have been useful in defining more precisely, which values of the US parameters and which treatment modalities would be optimal to induce the expected thermal effects for each specific patient.



**Figure 1:** Sonographic imaging.

When conventional, standard US therapy is delivered, clinical assessment with the same semi-quantitative scores described in this paper didn't succeed in reaching statistically significant pre-post differences [12].

The sonographic monitoring, allowing an objective quantitative assessment of the inflammatory states before and after the treatment, proved useful to improve the overall clinical quality.

Only one patient did not obtain a significant improvement in NRS score at T1 and in DASH score at T. This patient, affected by a rotator cuff degenerative tendinopathy, being younger than the average of patients involved in the study, could not stop her heavy work duty, with overuse of the shoulder, for the time of the US and rehabilitation treatment, severely restricting the anti-inflammatory and analgic effects of therapies.

NRS T0-NRS T1			DASH T0-DASH T1		COSTANT T0-T1		SONO T0-T1	
Number of clinical records	10	10	10	10	10	10	10	10
Average Value	74,000	33,000	783,000	558,000	451,000	721,000	43,000	29,000
Standard dev.	0,9661	16,364	172,179	174,216	85,952	100,383	0,9487	0,7379
t	68,228		29,048		64,608		36,836	
P (statistical significance )	0,0000		0,0094		0		0,0017	
Comment: Difference between average value is statistically significant (p< 0.01)								

**Table 4:** Statistic analysis of pre-post multimodal evaluation.

The main limits of the study is the low number of patients involved, due to the very restrictive inclusion criteria (patients who underwent anti-inflammatory local or systemic therapy in the period T0-T1 were excluded to avoid bias in results).

### Conclusions

Although painful shoulder treatment with physical therapies, US in particular, is still an object of discussion, due to contradictory results of meta-analysis and revisions, our results show that treatment quality and ‘costumization’ lead to clinical results which are assessable with different semi-quantitative evaluation tools stating the functional improvement, the pain reduction and the sonographic evidence.

In order to stress the ‘evidence based’ [13] effectiveness of physical treatments in rehabilitation it is therefore mandatory both to improve their quality, tuning the treatment parameters according to the characteristics and level of the injury (personalized therapy vs. standard protocols) and assessing the clinical results using suitable semi-quantitative tools including sonography.

### References

1. van der Windt DA, van der Heijden GJ, van den Berg SG, ter Riet G, de Winter AF, et al. (1999) Ultrasound therapy for musculoskeletal disorders: a systematic review. *Pain* 81: 257-271.
2. Robertson VJ, Baker KG (2001) A review of therapeutic ultrasound: effectiveness studies. *Phys Ther* 81: 1339-1350.
3. Loyola-Sánchez A, Richardson J, MacIntyre NJ (2010) Efficacy of ultrasound therapy for the management of knee osteoarthritis: a systematic review with meta-analysis. *Osteoarthritis Cartilage* 18: 1117-1126.
4. Desmeules F, Boudreault J, Roy JS, Dionne C, Frémont P, et al. (2015) The efficacy of therapeutic ultrasound for rotator cuff tendinopathy: A systematic review and meta-analysis. *Phys Ther Sport* 16: 276-284.
5. Shaw A, Martin E, Haller J, Ter Haar G (2016) Equipment, measurement and dose-a survey for therapeutic ultrasound. *J Ther Ultrasound* 4: 7.
6. Lioce EE, Novello M, Durando G, Bistolfi A, Actis MV, et al. (2014) Therapeutic Ultrasound in physical medicine and rehabilitation: characterization and assessment of its physical effects on joint-mimicking phantom. *Ultrasound Med Biol* 40: 2743-2748.
7. McCaffey M, Beebe A (1989) *Pain: Clinical manual for nursing practice*. Mosby St.Louis, MO, USA.
8. Constant CR, Murley AH (1987) A clinical method of functional assessment of the shoulder. *Clin Orthop Relat Res*: 160-164.
9. Hudak PL, Amadio PC, Bombardier C (1996) Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder and hand). The Upper Extremity Collaborative Group (UECG) *Am J Ind Med* 29: 602-608.
10. Schneebeli A, Egloff M, Giampietro A, Clijsen R, Barbero M (2014) Rehabilitative ultrasound imaging of the supraspinatus muscle: intra- and interrater reliability of thickness and cross-sectional area. *J bodywork movement ther* 18: 266-272.
11. Iagnocco A, Perella C, Ceccarelli F, Tripodo FE, Alessandri C, et al. (2006) Ultrasonographic assessment of the response to Etanercept treatment in patients with rheumatoid arthritis. *Reumatismo* 58: 233-238.
12. Analan PD, Leblebici B, Adam M (2015) Effects of therapeutic ultrasound and exercise on pain, function, and isokinetic shoulder rotator strength of patients with rotator cuff disease. *J Phys Ther Sci* 27: 3113-3117.
13. Dong W, Goost H, Lin XB, Burger C, Paul C, et al. (2015) Treatments for shoulder impingement syndrome: a PRISMA systematic review and network meta-analysis. *Medicine (Baltimore)* 94: e510.