ORIGINAL ARTICLE

Evaluation of the efficacy of ropivacaine injection in the anterior and middle scalene muscles guided by ultrasonography in the treatment of Thoracic Outlet Syndrome

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SUMMARY

A clinical, placebo-controlled, randomized, double-blind trial with two parallel groups.

OBJECTIVE: to evaluate the efficacy of ropivacaine injection in each belly of the anterior and middle scalene muscles, guided by ultrasonography, in the treatment of Nonspecific Thoracic Outlet Syndrome (TOS) compared to cutaneous pressure.

METHODS: 38 patients, 19 in the control group (skin pressure in each belly of the anterior and middle scalene muscles) and 19 in the intervention group (ropivacaine). Subjects with a diagnosis of Nonspecific Thoracic Outlet Syndrome, pain in upper limbs and/or neck, with no radiculopathy or neurological involvement of the limb affected due to compressive or encephalic root causes were included. The primary endpoint was functionality, evaluated by the Disabilities of the Arm, Shoulder, and Hand - DASH scale validated for use in Brasil. The time of the evaluations were T0 = before the intervention; T1 = immediately after; T2 = 1 week; T3 = 4 weeks; T4 = 12 weeks; for T1, the DASH scale was not applied.

RESULTS: Concerning the DASH scale, it is possible to affirm with statistical significance (p> 0.05) that the intervention group presented an improvement of functionality at four weeks, which was maintained by the 12th week.

CONCLUSION: In practical terms, we concluded that a 0.375% injection of ropivacaine at doses of 2.5 ml in each belly of the anterior and middle scalene muscles, guided by ultrasonography, in the treatment of Nonspecific Thoracic Outlet Syndrome helps to improve function.

KEYWORDS: Thoracic Outlet Syndrome. Myofascial Pain Syndromes. Anesthetics. Ultrasonics. Ultrasonography, Interventional.

INTRODUCTION

Thoracic Outlet Syndrome (TOS) is a group of disorders characterized by the compression of the brachial plexus and subclavian vessels at any point of the thoracic outlet region[1-3]. It includes painful, sensorial, and motor manifestations on the neck, shoulder, upper limb, and shoulder girdle region. Among the reasons for the symptoms, is the compression of the subclavian vessels and brachial plexus during the journey through the thoracic outlet[1,3,4].

The current medical literature makes a distinction between the vascular and neurogenic syndrome and considers five types of the syndrome, i.e., arterial

TOS, venous TOS, and traumatic neurovascular TOS, which are of vascular etiology, and those of neurogenic origin, i.e., true neurogenic TOS and disputed TOS[5,6].

However, given that the estimated prevalence of the cervical rib in the general population is 0.5% to 2%[5,7,8] and of neurogenic TOS is 1 per millions [5,9]; statistically, the presence of a cervical rib *per se* does not constitute a diagnosis for neurogenic TOS[9,10].

The neurogenic presentations correspond to up to 95% of TOSs, with no clear quantification between its true and disputed varieties. These presentations are clarified by physical examination, in which the neurogenic variety is associated with complaints such as muscular atrophy and positive electrophysiological examination[4,8,11-13].

The treatment options for TOS may be conservative, such as stretching, massage, compression, drug injections on the trigger point with lidocaine, ropivacaine, bupivacaine, and botulinum toxin[14-17].

In the literature, the most prevalent references of injections in scalene muscles relate to the use of bupivacaine[18-20] or lidocaine[20]. However, there was no sustained improvement of function because there was only a single evaluation immediately after the application. Considering there was no scientific rigor in the studies carried out and their results were not impressive — and, in large part, non-reproducible — in this study, we opted for the use of ropivacaine, due to its lower toxicity than that of bupivacaine.

Therefore, this study sought to answer the following question: What is the efficacy of the treatment based on the ultrasound-guided anesthetic blocking of the anterior and middle scalene muscles for improving functionality and pain in Thoracic Outlet Syndrome patients?

METHODS

This is a randomized, placebo-controlled, double-blind clinical trial with parallel groups.

We included in this study subjects who met the inclusion criteria with pain in the upper limbs and/or neck without radiculopathy or neurological involvement of the limb affected due to compressive encephalic root causes.

Those included were required to undergo a simple radiography examination of the neck at the swimmer's view to verify the presence of a cervical rib.

We excluded subjects with clinical instability and acute medical conditions, hypersensitivity to the medication administered, rotator cuff injury previously diagnosed by an imaging exam that explains the pain, and previously diagnosed fibromyalgia.

For the sample size calculation, we used the values obtained in a single prospective, randomized, double-blind study, conducted with diagnosed TOS patients, with pain for over three months and submitted to an injection of botulinum toxin type A[21]. We assumed a significance (alpha) of 0.05, double-tailed, and a power of 80%. We used the *Stata 10.1™* software. Thus, the sample size calculated was 38 patients, 19 in each group.

The recruitment of participants was carried out by the recruitment center of the Lucy Montoro Rehabilitation Institute, with its research headquarters in the Morumbi Unit, São Paulo/SP.

The process of recruitment, selection, intervention, and evaluation is presented in Figure 1.

Procedure: The procedure was conducted at the Surgical Center of the Institute of Orthopaedics and Traumatology (IOT) of the Medical School of the University of São Paulo. The patient was required to be at the center on the morning of the day of the procedure fasting for 8 hours. Following institutional protocols, all patients waited in a hospital bed until the marking on the skin was made prior to the procedure.

In the surgical center, with the patient lying in dorsal decubitus, a folded sheet was placed under the neck, and head was rotated approximately 20°

FIGURE 1. DISTRIBUTION OF THE VISITS.

Visit I – 1 week before the procedure
• Anamnesis
• Physical examination
• Dash scale
• Wash-out instructions
• Tables of recovery medication and side effects

Visit II – day of the procedure

Visit III – one week after the procedure
• Dash scale

Visit IV – 4 weeks after the procedure
• Dash scale

Visit V – 12 weeks after the procedure
• Dash scale
• Delivery of the tables of recovery medication use and side effects

Source: Prepared by the author.

to 30° contrary to the application side, exposing the sternocleidomastoid muscle region. Using a Sonosite MTurbo ultrasound device and a HFL38x 13-6MHz frequency linear transducer (FujiFilm SonoSite, Inc. 21919 30th Dr. SE, Bothell, WA, 98021, USA) to visualize superficial tissues, a preliminary assessment determined the location of the vascular structures, the anterior and middle scalene muscles, and the brachial plexus trunks.

The scalene muscles were scanned along their craniocaudal extension and better visualized in the images in its lower half. Once the structures were identified, the transducer was placed on both scalene bellies, on a cut in the short axis of the muscles. Before drilling, the Doppler mode was turned on to check for the presence of vessels in the path of the needle. The favorite needle approach to the anterior scalene muscle was in the medial to lateral direction, drilling through the sternocleidomastoid muscle, and medial to lateral for the approach of the middle scalene to decrease the likelihood of vascular lesion. Patients were not submitted to bilateral injections.

All hygiene, asepsis, and antisepsis care measures were performed both in relation to the patient and the research team.

Intervention: Using the hands-free technique, with no guide coupled to the transducer, the needle of the syringe is guided following the transducer plan and keeping the target, the belly of the muscle to be injected, in the center of the screen. The needle moves slowly, allowing for the adjustment of the entry angle, keeping the point under constant ultrasound visualization. Once the tip of the needle is seen in the belly of the target muscle, aspiration is performed to make sure it is not inside of the vessel. Only then, the solution is slowly injected, observing its dispersion in the belly.

The patients were randomized into two groups: intervention and placebo, described below.

Intervention group (1): The patients in this group received an ultrasound-guided injection in the anterior and middle scalene muscles, on the side where there was a complaint of pain, with 2.5 ml of a 0.375% ropivacaine solution in each belly, totaling 5 ml of the solution. The dilution was made with the aspiration of 2.5 ml of saline 0.9% and 2.5 ml of 7.5 mg/ml (0.75%) ropivacaine in a 5-ml syringe.

Placebo group (2): The patients in this group received skin pressure at the same locations of the ultrasound-guided applications, on the anterior and middle scalene muscles, on the side in which there was a complaint of pain, with the same needle-syringe assembly; however, without piercing the skin. The syringe for the control group was filled only with saline solution.

The evaluations were made before the procedure (T1), one hour after the procedure (T2), then at one week (T3), four weeks (T4) and 12 weeks (T5). The instrument used to assess the functional outcome was the Dash questionnaire (Disabilities of the Arm, Shoulder, and hand), validated and adapted for use in Brasil[22].

This study was submitted to and approved by the Research Ethics Committee of the Hospital das Clínicas - CAPPesq - FMUSP, CAAE: 01232012.0.0000.0068, under the opinion No 19568 on 09.05.2012 and by the Scientific Committee of the Department of Orthopaedics and Traumatology of the Medical Faculty of the University of São Paulo on the Official Communication/CC-DOT/160/2012, of 27.06.2012. All participants signed the informed consent form, authorizing their participation in the research, which was performed following the ethical standards required by Resolution no. 466/2012 (National Health Committee).

RESULTS AND DISCUSSION

Patients and controls were compared in relation to the variables age, gender, formal education, body mass index (BMI), physical activity, smoking, associated chronic diseases (p>0.05). In relation to gender, the predominance was of females in both groups, which is compatible with the results found by Finlayson et al.[21], who found a female percentage of 82%.

The Dash scale was evaluated before the beginning of treatment (initial visit) and in three subsequent moments (visitations III, IV, and V). There were no statistically significant differences between the CT and INT groups on the Dash scale at the initial moment

TABLE 1. DASH COMPARISON BETWEEN THE CT AND INT GROUPS

Group	CT	INT	p
Initial Dash	66.93±17.04	60.83±12.58	0.161
Dash Visit III	43.68±16.08	42.40±15.62	0.693
Dash Visit IV	49.90±17.62	35.53±21.37	0.034
Dash Visit V	52.09±22.25	39.17±21.04	0.075

Source: Prepared by the author.

and on visit III (a week after the intervention). On the other hand, we found that the Dash was significantly lower in the INT group on visits IV, and marginally significant on visit V (Table 1).

Since Dash is a scale, it is characterized as an ordinal numeric variable and, therefore, used to compare the groups in a non-parametric statistical test (Mann-Whitney).

The scale Dash measures the functionality of the upper limbs, including shoulder and arm. We observed the surprising and unique improvement evolution of the participants in the intervention group. In the initial assessment and one week after the procedure, no difference was observed between the groups. However, there was a significant reduction in both groups after one week, with no difference between them. However, on visit IV, it was possible to see a bigger difference between the groups, with greater improvement on the intervention group compared to the control, which was maintained on visit V, after 12 weeks.

In a statistically significant manner, it is possible to state that the intervention group showed a functionality improvement by the fourth week, and the improvement was maintained by the12th week. In addition, the intervention group also showed a statistical advantage over the control group.

Confirming the trend of improvement, the cohort published in 2015 by Braun et al.[23] used a isokinetic test before and after a lidocaine 1% injection administered without any imaging method for the scalene topography and found an improvement of various parameters.

After checking the percentage of improvement on the Dash scale, it is possible to observe two interesting and satisfactory results. There was a significant improvement in the control group by the last visit. The second piece of data, which was unexpected, was the improvement on the Dash scale of the intervention group, which was statistically significantly higher than on the control group.

On visit I, one week before the procedure, and on visit III, one week after the procedure, there was no difference between the Dash values of both groups, but there was an improvement in the Dash scale, with a reduction in values. Initially, the values in the intervention and control groups were 66 and 60 points, respectively, with no statistical difference between them. On the visit one week after the procedure, there was an improvement in both groups, now with 43 and 42 points, respectively. The minimum values for a

detectable improvement on the Dash scale are from 7.9 to 14.8 points. Therefore, there was a satisfactory detectable improvement, with a difference of 23 points in the control group, and 18 points in the intervention, values that exceed the minimum necessary to verify a detectable improvement.

However, on visit IV, after four weeks, the results were quite different. Whereas on the first week after the procedure, the values were similar and showed improvement, on visit IV, there was an antagonistic movement of the Dash values. While the Dash value in the intervention group continued to improve, with a reduction of the value, the control group showed worsening in relation to visit III, at one week. Moving forward to visit V, 12 weeks after the procedure, the values stabilized, with a slight worsening in both groups.

At this time, after 12 weeks, it was possible to see an improvement in the intervention group compared to the control, which was statistically significant even though the P-value was marginal (P=0.072) and there was an expressive percentage reduction in the Dash improvement in the intervention group, 38.65%, whereas in the control group there was improvement of 22.61%.

Since there is no parallel for these values in the literature, it is difficult to seek comparisons. The improvement of performance in work and power shown by Braun et al.[23] happened after a non-ultrasound-guided lidocaine injection in the scalene muscles, with a single evaluation and no control group. Other authors who have proposed to register a randomized, double-blind study and verified functionality using the Dash tool, i.e., Finlayson et al.[21], did not see any improvement after the same period. By the end of 12 weeks, these authors found disappointing results, in which the negative variation, i.e., the Dash improvement, was less than 1 point in the control group, whereas in the control group submitted only to the injection of saline solution, the variation was 3.2 points of improvement on a Dash scale of 0-100 points. Among the groups, there was no improvement or statistical difference after six months.

CONCLUSION

In practical terms, it can be concluded that the injection of 0.375% ropivacaine in doses of 2.5 ml in each belly of the anterior and middle scalene muscles, guided by ultrasound, in the treatment of Disputed

Neurogenic Thoracic Outlet Syndrome, assists in the improvement of function (primary outcome). The measurement of functionality using the Dash tool was considered an objective measure.

The intervention group showed a significant improvement in the Dash scale by the end of the 12 weeks. On the first assessment after the procedure, there was a decrease in values, representing an improvement of function. However, the improvement was global, with no distinction between the groups. In subsequent evaluations, after four and 12 weeks, there was a greater difference in the values between the groups in a reverse movement: while the intervention group remained improving, the control group interrupted its curve of improvement and started presenting worsening values.

This study contributed in practice by presenting a proposal for an alternative method to improve the functionality of patients with Neurogenic Thoracic Outlet Syndrome, demonstrating that muscular blocking with anesthetics is an effective alternative in the TOS approach, in addition to describing the safety of ultrasound-guided therapeutic procedures.

Among the limitations, is the lack of literature to support the findings. The approaches proposed include the use of anesthetics, not restricted to only one of them, as well as the unjustified use of steroidal anti-inflammatory and botulinum toxin. Not only is the literature scarce, but there is also a lack of scientific rigor in the production of publications about non-surgical treatments.

Another point is the difficulty in the recruitment of patients, perhaps due to the lack of consensus and training of medical professionals for proper diagnosis of the syndrome, since there is still controversy in the literature.

RESUMO

Ensaio clínico, controlado por placebo, aleatorizado, duplo-cego, com dois braços paralelos.

OBJETIVO: *Avaliar a eficácia da injeção de ropivacaína em cada ventre dos músculos escalenos anterior e médio, guiada por ultrassonografia, no tratamento da Síndrome do Desfiladeiro Torácico Neurogênico inespecífico comparado com o toque cutâneo.*

MÉTODOS: *Trinta e oito pacientes, sendo 19 no grupo controle (toque cutâneo em cada ventre dos músculos escalenos anterior e médio) e 19 no grupo intervenção (ropivacaína). Foram incluídos sujeitos com diagnóstico de Síndrome do Desfiladeiro Torácico Neurogênico inespecífico com dor em membros superiores e/ou cervicalgia sem radiculopatia ou comprometimento neurológico do membro em questão por causas radiculares compressivas ou encefálicas. O desfecho primário foi a funcionalidade avaliada pela escala Disabilitie of the Arm, Shoulder and Hand – Dash, validada no Brasil. O tempo das avaliações foram T0 = antes da intervenção; T1 = imediatamente após, T2 = 1 semana, T3 = 4 semanas e T4 = 12 semanas, sendo que para o T1 não foi aplicado o Dash.*

RESULTADOS: *Com relação ao Dash, de forma estatisticamente significante (p>0,05), é possível afirmar que o grupo intervenção apresentou melhora da funcionalidade a partir de quatro semanas, e essa melhora se manteve até a 12ª semana.*

CONCLUSÃO: *Em termos práticos, conclui-se que a injeção de ropivacaína 0,375% nas doses de 2,5 ml em cada ventre dos músculos escalenos anterior e médio, guiada por ultrassonografia, no tratamento da Síndrome do Desfiladeiro Torácico Neurogênico inespecífico auxilia na melhora da função.*

PALAVRAS-CHAVE: *Síndrome do Desfiladeiro Torácico. Síndrome da Dor Miofascial. Anestésicos. Ultrassom. Ultrassonografia de intervenção.*

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