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Artigo Original

Comparison between concentrated bone marrow aspirate and corticoid in gluteal tendinopathy

Comparação entre o aspirado de medula óssea concentrado e o corticóide na tendinopatia glútea

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ABSTRACT

INTRODUCTION Adult gluteal tendinopathy is part of a group of pathologies of Greater Trochanteric Pain Syndrome (GTPS). This disorder is characterized by pain, functional limitation and loss of local strength. The diagnosis is made from clinical examination associated with complementary exams (Ultrasound or Magnetic Resonance). **OBJECTIVE** Comparative study between standard treatment and bone marrow aspirate concentrate (BMAC) for the treatment of gluteal tendinopathies. The randomized clinical trial selected patients diagnosed with gluteal tendinopathy at a university hospital and divided them into two groups: (G1) bone marrow aspirate concentrate and (G2) Corticosteroids injection. **RESULTS** 48 patients were selected, of which 40 were monitored for 06 months, with an improvement in scores in both groups. Patients who were submitted to the BMAC treatment had a statistically significant improvement in VAS scores and Lequesne scores compared to standard treatment. There was an improvement in the assessment of the quality of life in both groups with no statistically significant difference. **CONCLUSION** BMAC arises as an alternative to the standard treatment of gluteal tendinopathy, proving to be a safe technique and with promising results when combined with multidisciplinary team behavioral therapy.

KEYWORDS: Tendinopathy, bone marrow aspiration and hip.

RESUMO

INTRODUÇÃO A tendinopatia glútea adulta faz parte de um grupo de patologias da Síndrome Dolorosa Trocantérica (SDT). Esse distúrbio é caracterizado por dor, limitação funcional e perda de força local. O diagnóstico é feito a partir de exames clínicos associados a exames complementares (ultrassonografia ou ressonância magnética). **OBJETIVO** Estudo comparativo entre tratamento com corticóide e aspirado de medula óssea concentrado (BMAC) para o tratamento de tendinopatias glúteas. **MATERIAL E MÉTODOS** O ensaio clínico randomizado selecionou pacientes diagnosticados com tendinopatia glútea e os dividiu em dois grupos: (G1) aspirado de medula óssea concentrada e (G2) injeção de corticosteróide . **RESULTADOS** Foram selecionados 48 pacientes, dos quais 40 foram monitorados por 06 meses, com melhora nos escores nos dois grupos. Os pacientes que foram submetidos ao tratamento com BMAC tiveram uma melhora estatisticamente significativa nos escores de EVA e nos escores de Lequesne em comparação ao tratamento padrão. Houve uma melhora na avaliação da a qualidade de vida em ambos os grupos, sem diferença estatisticamente significativa. **CONCLUSÃO** O aspirado de medula óssea concentrada surge como uma alternativa ao tratamento padrão da tendinopatia glútea, provando ser uma técnica segura e com resultados promissores quando combinada à terapia comportamental de equipe multidisciplinar.

Ensaio Clínico Randomizado.

PALAVRAS CHAVE: Tendinopatia, aspirado de medula óssea e quadril

INTRODUCTION

Tendinopathy is a tendon disorder characterized by pain related to activity, local edema, focal tenderness on palpation and decreased strength in the affected area (1). Adult gluteal tendinopathy is the subject of several scientific studies due to the prevalence of this pathology. Commonly described as “hip bursitis” it is currently referred to as Greater Trochanteric Pain Syndrome (GTPS). GTPS covers several diseases of the peritrochanteric space of the hip, such as tendinopathy of the gluteus medius and gluteus minimus muscle, snapping Hip and trochanteric bursitis (2).

Pathologies that affect the periarticular hip space should be included in the range of options for differential diagnosis. Traumatic injuries from the origin of the rectus femoris muscle in its direct portion result in a painful condition in the anterior aspect of the hip and a strength deficit for knee extension. The Ischiofemoral Impingement Syndrome affects patients who have reduced horizontal offset, narrowing the space located between the proximal femur and the ischium, causing groin or gluteal pain due to entrapment of the quadratus femoris muscle and adjacent structures. Athletic pubalgia affects young patients who, in general, regularly practice sports and complain of groin pain due to a chronic inflammatory process in the pubic symphysis associated with adductor muscle group tendinopathy (3). Clinical studies demonstrate a high prevalence of Greater Trochanteric Pain Syndrome (GTPS), in particular from the sixth decade of life. In a cohort with patients from 50 to 79 years old, the prevalence of unilateral GTPS in woman was 15% while 8.5% had bilateral pain, while among men 6.6% had unilateral pain and 1.9% bilateral (4).

The standard treatment established for gluteal tendinopathies is based on an

extensive rehabilitation protocol. We used physical agents (ultrasound, electrical stimulation, and cryotherapy) seeking relief from the pain state. Kinesiotherapy aims to reestablish the function of that muscle group through proper movement, postural realignment and muscle stretching (5). The use of analgesic and anti-inflammatory medications is routinely indicated for moments of more intense pain. Rest must be proportional, and the reorientation of sports practices must be monitored throughout the recovery process (5).

As an invasive method, the local injection of corticosteroids is often used as a tool that aims to reduce the local inflammatory process, decrease pain and, as a result, improve the functional condition of the affected hip. Surgical treatment is reserved for cases standard treatment-resistant and may vary from tendon debridement to reinsertion of the affected tendon in its footprint (6).

The challenge for the next few years is to establish a change in concepts regarding tissue regeneration. It is possible, clinically plausible and financially viable. There has been an increasing interest in bone marrow aspirate concentrate (BMAC) applications and tissue engineering approaches in surgical practice to treat damaged or lost tissues as a cause of sports or traumatic injuries (7). This occurs as a result of several factors, including increasing familiarity with bone marrow derivatives from mesenchymal stem cells. Recently, new techniques such as the application of growth factors, gene transfer, and cell therapy, indicate good chances of becoming effective biological therapies in the future. Many groups have been successful in introducing markers and therapeutic genes in ligaments and tendons (8).

OBJECTIVE

To compare the efficiency of bone marrow aspirate concentrate (BMAC) with corticosteroid injection in the treatment of gluteal tendinopathies.

METHODOLOGY

Group of Participants

The present study included 48 patients with clinical and radiological diagnosis of gluteal tendinopathy, of both sexes, aged between 18 and 73 years old. Nuclear magnetic resonance exams of these patients were analyzed, and the ultrasound was performed at the outpatient clinic. All patients agreed to participate in the study and signed the Informed Consent Form. All patients received the same physiotherapy treatment protocol, recommendation to change their lifestyle and analgesic drug treatment.

Exclusion Criteria

Infection in the surgical site and had comorbidities that contraindicated the surgical procedure.

Monitoring Plan

Monitoring visits took place before the procedure and one, three and six months after stem cell grafting or corticosteroid injection. The Visual Analogue Scale (VAS), Lequesne Index (functional score) and EuroQol-5D (quality of life score) questionnaires were used on the day of the procedure and on monitoring visits to compare the evolution of the condition.

Randomization

The patients included in this study were randomized in a computerized system to one of the two groups: bone marrow aspirate concentrate (G1) or corticosteroid treatment (G2).

Procedures

The procedures for the collection and injection of cells were performed in a surgical center under sedation and analgesia. The patient was placed in the supine position, conventionally to hip surgery. Bone marrow aspirate was obtained with a Jamshidi needle in

the anterior iliac crest, under spinal anesthesia and mild sedation. This needle was introduced about 5 cm deep towards the cancellous bone of the iliac crest so that its tip was located between the inner and outer tables. About 100 ml of bone marrow was aspirated through 10 ml plastic syringes containing anticoagulant. All syringes containing bone marrow aspirates were grouped in sterile surgical grade and their contents were transferred to a blood collection bag. An automated and closed system was used to separate and concentrate the fraction of mononuclear cells obtained from bone marrow aspirate (Sepax®).

A small cell suspension was used for cell counting and viability testing in the site where the injection procedure was performed. It was made a sampling of the number of live cells, by staining with the anti-CD34 antibody and incorporation by Propidium Iodide.

BMAC

We injected 20 ml of the solution with BMAC in the footprint of the gluteal tendon using a standard 10mL syringe with a needle guided by ultrasound (Figure 1).

Figure 1. Ultrasound-guided BMAC therapy

Source: Elaborated by the Author

Corticosteroid injection

The injection was performed at the outpatient clinic in a proper room for the procedure under the rules of the Health Surveillance. After local anesthesia with 2 ml of 2% lidocaine without vasoconstrictor, it was performed the injection of 7 mg of betamethasone associated with 4 ml of 2% lidocaine without vasoconstrictor in a 0.7 x 30 mm needle. The procedure was guided by ultrasound equipment.

Data Analysis Plan

The software Statistical Package for Social Sciences (SPSS), version 14.0 for Windows® was used for the elaboration of the database, descriptive and analytical analysis. The normality of the variables was verified through the Shapiro-Wilk test, descriptive statistics and graphic analysis. The results are displayed through tables and graphs. Categorical variables are expressed in absolute and percentage values – n (%). Continuous variables with normal distribution were expressed as mean and standard deviation (±SD) and those with asymmetrical distribution, in median and interquartile range (IQR). The significance level adopted was 5% for all inferential analysis.

Ethical aspects

This work was elaborated pursued to Resolution 466/12, which regulates research involving human beings. The research project was submitted to and approved by the Research Ethics Committee of Hospital Universitário Professor Edgard Santos. CAE: 72236317200000049.

RESULTS

A total of 48 patients were evaluated. However, eight patients were lost during the monitoring of the study, thus 40 patients were kept in follow-up for six months and met the established rehabilitation protocol after the procedure. The rate of loss of follow-up was 16%.

Twenty (50%) males and twenty (50%) females participated in this study, with an average age of 46.1 years old (± 15.2 years old) for the BMAC group and an average age of 53.2 years old (± 12 years old) for the corticosteroid group. Most of the participants (57.5%) had completed high school and only 12.5% of the participants during the study period were in leave of absence and receiving the benefits by the National Social Security Institute - INSS. As for the comorbidities 47.5% had arterial hypertension and *diabetes mellitus* present in 30% of the cases. The high prevalence of depression in the studied sample draws attention when compared to the general population. A 22.5% prevalence rate of depression differs from the prevalence of the general population for the same age (4.4%), supporting the hypotheses already proven in other works that demonstrate a strong association between pathologies of a depressive nature and gluteal tendinopathy (Table 1).

Table 1 – Comparison of sociodemographic and clinical characteristics

Variables	**BMAC Group (n=15)**	**Corticosteroid Group (n=25)**	**p-value****
Age (Mean±SD)	46,1±15,2	53,2±12,0	0,110
Gender	**n(%)**	**n(%)**	
Male	10 (66,7)	10 (40,0)	
Female	05 (33,3)	15 (60,0)	
Education			
1st degree	04 (26,7)	10 (40,0)	
2nd degree	09 (60,0)	14 (56,0)	0,451
3rd degree	02 (13,3)	01 (4,0)	
NSSI	04 (26,7)	01 (4,0)	0,056
Comorbidities			
Arterial hypertension	05 (33,3)	14 (56,0)	0,165
Diabetes Mellitus	02 (13,3)	10 (40,0)	0,152*

Depression	05 (33,3)	04 (16,0)	0,255*
Sickle Cell Anemia	00 (0,0)	01 (4,0)	1,000*
Labyrinthitis	00 (0,0)	01 (4,0)	1,000*
Glaucoma	00 (0,0)	01 (4,0)	1,000*
Sports Activity			
Does not perform activity	02 (13,3)	20 (80,0)	<0,001
Pilates	03 (20,0)	02 (8,0)	
Soccer	05 (33,3)	01 (4,0)	
Water aerobics	03 (20,0)	00 (0,0)	
Academy	02 (13,3)	00 (0,0)	
walking	00 (0,0)	02 (8,0)	

n = number of participants;
SD = standard deviation;
INSS = National Social Security Institute.
* Fisher's exact test

Physical activity was not practiced regularly. At the initial evaluation, 55% of the patients had not the habit of guided and regular sports. For the group that had a regular activity, soccer was the most prevalent activity (15%). However, all monitored patients reported having followed the protocol for changing their lifestyle habits with sports practices at least 3 times a week for 30 minutes. The guided activity involves a previous warm-up, physical exercise with cardiovascular stimulus and post-workout stretching. In this sample, gender, age, education, NSSI and comorbidities variables are homogeneous between groups.

Comparing the results between the initial moment and the sixth month of follow-up of the VAS score, there was a progressive reduction in pain in subjects treated with BMAC of about 67% and a reduction of approximately 34% in patients treated with corticosteroid injection with a value of "p" statistically significant p ($p < 0.001$). Comparing the values between the groups, the median at the end of the study was 2 in the group treated with

BMAC, against the median value of 4 for patients treated with corticosteroid injection. This finding had a statistically significant p-value (p <0.01).

The evaluation of the Lequesne score at the initial moment and after 06 months in the group treated with BMAC showed a reduction of 4 points and in the group treated with corticosteroid injection there was a reduction of 1.2 points with a statistically significant value (p <0.02) in the intra-group evaluation. The comparison between the groups showed a statistically significant reduction (p <0.03) inferring benefit of BMAC therapy.

The intra-group assessment of quality of life by EuroQol 5D, showed statistically significant values in both groups. Patients treated with BMAC had an average increase of 0.16 (p <0.002), whereas patients treated with corticosteroids there was an increase of 0.11 (p <0.01) at the end of the study. In the comparison between the groups, there was no statistically significant difference (Table 2).

Table 2. Intergroup and intragroup comparison of the Visual Analogue Scale and the EuroQol 5 D and Lequesne questionnaires.

Variables	**BMAC Group (n=15)**	**Corticosteroid Group (n=25)**	**p-value****
VAS	**Median (IQR)**	**Median (IQR)**	
Initial Moment	6.0 (5.0 – 7.0)	6.0 (4.0 – 7.5)	0.619
1st month	3.0 (2.0 – 4.0)	3.0 (2.0 – 5.0)	0.562
6th month	2.0 (2.0 – 3.0)	4.0 (2.5 – 6.0)	0.014
p-value**	0.001	0.001	
EuroQol 5 D	**Average±SD**	**Average±SD**	
Initial Moment	0.52±0.22	0.50±0.33	0.752
6th month	0.68±0.18	0.61±0.25	0.353
p-value**	0.002	0.016	
Lequesne			

Initial Moment	8.7±1.9	8.0±3.6	0.397
6th month	4.7±2.1	6.8±3.3	0.031
p-value**	<0.001	0.021	

n= number of participants.
IQR= interquartile range.
SD= standard deviation.
VAS=Visual Analogue Scale
** Intergroup comparison (independent t-test or Mann-Whitney)
*** Intragroup comparison (paired t-test or Wilcoxon)

The evaluation of the varied values (delta) of the outcomes of this study, obtained by subtracting the scores between the initial and final moments, resulted in values that demonstrate a median reduction of 3.5 points in VAS on the group treated with BMAC, while the corticosteroid group decreased by 1.6, presenting statistical significance. The Lequesne Index questionnaire happened in a very similar way, in which the BMAC group reduced 4 points and the group treated with corticosteroid injection reduced 1.1 points. EuroQol 5 D did not show any statistically significant difference between the groups, increasing the quality of life score by 0.16 and 0.12, in the BMAC group and the corticosteroid group, respectively(Table 3).

Table 3 – Intergroup comparison of the variability of the scores on the Visual Analogue Scale and the EuroQol 5D and Lequesne Index questionnaires.

Variables	**BMAC Group (n=15)**	**Corticosteroid Group (n=25)**	**p-value****
ΔVAS	-3.5±1.5	-1.6±1.8	0.001
ΔEuroQol 5 D	0.16±0.15	0.12±0.23	0.590
ΔLequesne	-4.0±2.0	-1.1±2.3	>0.001

n= number of participants.
VAS=Visual Analogue Scale
Independent t-test

DISCUSSION

There is a shortage of work in the literature that approaches tendinopathies, consequently, the number of patients being monitored is limited. The first two papers on the use of cell therapy for tendinopathy were published in 2012. A group of researchers from a sports medicine center in New York published a series of only eight cases of patients with patellar tendinopathy treated with bone marrow mesenchymal stem cells. A study developed in Brazil had an evaluation of 14 individuals. In the study of gluteal tendinopathy there are only case reports. In addition, there are a number of preclinical studies developed in other mammalian and in vitro species that seek to clarify the mechanisms of action of BMAC in tendinopathies (9,10,11).

Studies that used similar methods have a higher proportion of women treated with corticosteroid injection, whereas the studies that used BMAC demonstrate like this one, an equivalent proportion between genders. In studies that used corticosteroids for gluteal tendinopathy, pain at the end of the third month after the procedure was greater than five in VAS in about 40% of patients (4, 12, 13).

There is a common understanding in the literature that isolated therapy with the use of medications and physiotherapy or surgical treatment have poor results and with few benefits to the patient. The multidisciplinary treatment that involves changing lifestyle habits (frequent sports activity, weight loss, muscle strengthening and stretching), physiotherapy, control of underlying pathologies and pain, it achieves a favorable result for the well-being of the patient treated for the greater trochanteric pain syndrome (GTPS) (14, 15).

Several local adjuvant therapies have been used in the treatment of GTPS and the most widely used therapy is corticosteroid injection. The use of ultrasound for the injection of the trochanteric region with corticosteroids has brought new results to this treatment type. Long-

term studies demonstrate what was observed in this work. Corticosteroid injection therapy has a good clinical result in the first month of follow-up, but with the serial evaluation, patients return to a similar level of pain 02 to 06 months after the injection, that is to say, treatment with corticosteroids can reduce pain and inflammatory process for a short time. The risk of corticosteroids injection is related to inhibition of collagen synthesis and induction of programmed cell death. This results in reduced tendon resistance and risk of rupture (16, 17).

BMAC are already being used at an experimental level to treat tendon pathologies in different parts of the human body. The treatment of BMAC for patellar tendinopathy, rotator cuff, and lateral epicondylitis has shown good clinical results. (18, 19).

The treatment of the greater trochanteric pain syndrome does not depend on a punctual therapy. Treatment must be multidisciplinary, and it involves the control of comorbidities, changes in lifestyle habits and physical therapy (11). The comparison between the standard treatment that uses corticosteroid injection with the use of BMAC as a local adjuvant therapy has brought promising results to the technique.

CONCLUSIONS

The BMAC comes as an alternative to the treatment of hip tendinopathy with corticosteroids. The statistically significant results in the pain questionnaires (VAS) and Lequesne functional scale when compared to conventional local therapy with the use of corticosteroids, encourage this group of research. The technique proved to be safe and reproducible. It is very clear that the promising result depends on a multimodal treatment that involves several areas of health science.

Declaration of contribution of the authors

Cada autor contribuiu individual e significantemente para o desenvolvimento deste artigo.

Davi Araújo Veiga Rosário: Redação e realização de cirurgias.

Thiago Batista Faleiro: Redação e realização de cirurgias.

Bruno Adelmo Ferreira Mendes Franco: Redação e interpretação de dados.

Reinaldo Marchetto: Interpretação de dados e aprovação final da versão do manuscrito a ser publicado.

Gildásio de Cerqueira Daltro: Realização de cirurgias e aprovação final da versão do manuscrito a ser publicado.

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