








HYLAN G-F 20 VERSUS TRIAMCINOLONE IN THE TREATMENT OF PRIMARY SHOULDER OSTEOARTHRITIS. RANDOMIZED TRIAL

HILANO G-F 20 VERSUS TRIANCINOLONA NO TRATAMENTO DA OSTEOARTRITE PRIMÁRIA DO OMBRO. ESTUDO RANDOMIZADO

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ABSTRACT

Introduction: The aim of this study was to evaluate the effect of using an intra-articular injection of hylan G-F 20 (HA group) on primary shoulder osteoarthritis compared with an intra-articular triamcinolone injection (T group). **Materials and Methods:** The patients were randomized into 2 groups: in the HA group a single dose of intra-articular hylan G-F 20 was administered and in the T control group a dose of triamcinolone 20 mg was administered. The participants were evaluated at 1 week, 1, 3, and 6 months after the procedure. The patients were evaluated for pain, range of motion, Constant score, modified UCLA score, and SPADI. **Results:** Seventy patients met the inclusion criteria and were randomized to the HA (38) and T (32) groups. Improvements in range of motion were significant ($p > 0.05$). We observed decreases in the general visual analog scale (VAS) for pain in both groups, especially in the cases of mild and moderate arthritis that received hyaluronic acid (mean values from 8.1 initially to 4.9 after 6 months) ($p = 0$). **Conclusions:** Both injections led to a decrease in pain and an increase in patient satisfaction. The results tend to be better and longer lasting in patients receiving hyaluronic acid. **Level of evidence II b; Cohort study.**

Keywords: Shoulder. Osteoarthritis. Viscosupplementation. Hyaluronic acid. Injections, intra-articular. Corticosteroids.

RESUMO

Introdução: O objetivo deste estudo foi avaliar o efeito do uso de uma injeção intra-articular de Hilano G-F 20 (Grupo HA) na osteoartrite primária do ombro em comparação com injeção intra-articular de triancinolona (Grupo T). **Material e Método:** Os pacientes foram randomizados em dois grupos: no Grupo HA foi administrada uma dose única de Hilano G-F 20 intra-articular e no Grupo controle T foi administrada uma dose de 20 mg de triancinolona. Os participantes foram avaliados 1 semana, 1, 3 e 6 meses depois do procedimento. Os pacientes foram avaliados quanto à dor, amplitude de movimento, escore de Constant, escore UCLA modificado e índice SPADI. **Resultados:** Setenta pacientes satisfizeram os critérios de inclusão e foram randomizados para os Grupos HA (38) e T (32). As melhoras da amplitude de movimento foram significativas ($p > 0,05$). Observamos diminuições na escala visual analógica (EVA) geral para dor em ambos os grupos, principalmente nos casos de artrite leve e moderada que receberam ácido hialurônico (valores médios de 8,1 inicialmente a 4,9 depois de 6 meses) ($p = 0$). **Conclusões:** Ambas as injeções reduziram a dor e aumentaram a satisfação do paciente. Os resultados tendem a ser melhores e mais duradouros em pacientes que recebem ácido hialurônico. **Nível de evidência II b; Estudo de Coorte.**

Descritores: Ombro. Osteoartrite. Viscosuplementação. Ácido hialurônico. Injeções intra-articulares. Corticosteroides.

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INTRODUCTION

Osteoarthritis (OA) is the most common joint disease worldwide and affects more than 25 million people in the United States alone. The glenohumeral joint (GUJ) is the third most affected joint, after the knee and hip.¹

Although the actual prevalence of shoulder OA is difficult to determine, population studies have shown that approximately 20% of Japanese adults over 65 have radiographic evidence of glenohumeral OA.²

Unfortunately, there are still no known interventions that have been shown to delay the natural history of early OA. Eventually, these patients present worsening of pain and joint stiffness, generating functional limitations and decreasing quality of life.

The first step in treating primary glenohumeral OA is, with very few exceptions, conservative treatment, similar to that of other joints. Intra-articular injections (IA) are commonly used, more precisely represented by corticosteroids and hyaluronic acid (HA).³ Normally, surgical treatment is reserved after failed conservative treatment.

All authors declare no potential conflict of interest related to this article.

The study was conducted at the Universidade Federal de São Paulo (UNIFESP), Escola Paulista de Medicina (EPM), Sports trauma Center, São Paulo, Brazil. Correspondence: Paulo Henrique Schmidt Lara. R. Estado de Israel, 636 - Vila Clementino, São Paulo, SP, 04022-001. phslara@gmail.com

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There are no randomized controlled trials in the literature comparing the effects of viscosupplementation (VS) with IA corticosteroid injection in the treatment of glenohumeral OA. The few published controlled studies always used IA injection of saline solution in the control group.^{4,5}

The aim of this study was to evaluate the effect of using intra-articular injection of hylan G-F 20 on primary shoulder osteoarthritis compared with intra-articular triamcinolone injection.

MATERIALS AND METHOD

This is a prospective randomized clinical trial, whose research project was approved by the Research Ethics Committee (CAAE 89081818.5.0000.5505) and was registered through the Brazilian Registry of Clinical Trials (ReBEC).

Between July 2017 and April 2018, 86 patients with primary glenohumeral OA were treated at the shoulder ambulatory clinic of the Sports Traumatology Center of our institution and at the private clinic of the main author, and of these, seventy-seven met the inclusion criteria.

The inclusion criteria for the study were as follows: primary glenohumeral OA, visual analogue scale (VAS) of pain greater than 3, failure of prior conservative treatment for at least 3 months, availability for outpatient follow-up for 6 months after the procedure and completion of the Informed Consent Form.

The exclusion criteria were as follows: previous surgery on the affected shoulder, previous viscosupplementation on the affected shoulder, presence of complete rotator cuff injury, presence of neurological injury to the affected limb, use of corticosteroid regardless of route of administration in the last 2 months, current use of immunosuppressive or anticoagulant therapy and cognitive deficit that compromised the interpretation of the questionnaires. Radiographic evaluation of true anteroposterior shoulder (AP) incidence was performed by the Samilson and Prieto classification⁶. Magnetic resonance imaging of the shoulder was performed to evaluate rotator cuff pathology. Associated injuries such as peri-articular calcifications and intra-articular free bodies were also noted when present in imaging studies. All exams were performed before intervention.

Regarding the rotator cuff findings from the MRI examination, in the HA group, twenty-one patients (56%) presented partial lesion of at least one of the rotator cuff tendons, and 17 (44%) presented only tendinopathy of the rotator cuff. In the T group, twenty-one patients (67%) presented partial lesion of at least one of the rotator cuff tendons, and 11 (33%) presented only tendinopathy.

For pain measurement, the visual analogue scale (VAS) was used, with which the patient scored, on a scale from 0 to 10, the intensity of his pain. The patients were asked about pain in four aspects: general pain in the affected shoulder, movement pain and nocturnal pain.⁷ Three functional questionnaires were applied to assess upper limb function: Constant⁸, modified UCLA⁹ and SPADI¹⁰.

The patients participating in the study knew they would undergo the procedure but were blinded to their medication. All infiltrations were performed by the same doctor in an outpatient setting, as well as all subsequent evaluations. The infiltrations and evaluations were not blinded by the attending physician. In the public ambulatory the medication was paid by the main author and at the private ambulatory the medication was paid by the patient.

The HA group received a single-dose IA injection of hylan G-F 20 48 mg 6 ml (Synvisc One®), while the T group received a single-dose IA injection of triamcinolone hexacetonide (Triancil®) 20 mg 1 ml diluted in 5 ml saline.

The procedure was performed in an outpatient setting, with the patient sitting on a stretcher, with his back to the doctor. Shoulder antisepsis and local anesthesia with 2% lidocaine 5 ml volume with

a 25-mm needle were performed. All infiltrations were performed through a posterior approach, at the same site used for the arthroscopic posterior portal, known as the soft spot of the shoulder, located 2 cm inferior and 2 cm medial to the posterolateral angle of the acromion. The needle is directed anteriorly towards the coracoid process.¹¹

All procedures were guided by ultrasound, a Xario 200 Platinum Toshiba device with a broadband linear transducer at a frequency of 5 to 12 MHz. Routinely, the posterior infraspinatus tendon was first identified, with the patient sitting on the stretcher with an adducted shoulder. With dynamic maneuvers of medial and lateral rotations of the shoulder, the humeral head and the posterosuperior portion of the glenoid cavity were identified (Figure 1).

All patients were instructed not to use NSAIDs during the 6-month follow-up period, and in case of pain, were instructed to use acetaminophen 750 mg every 6 hours. Concomitant use of adjuvant therapies such as physical therapy and acupuncture was not considered in the evaluations. The patients were allowed to do such activities but there was not a protocol and it was not considered in our evaluation. Follow-up visits were as follows: visit 1 (when the initial assessment and procedure were performed), visit 2 (1 week after the procedure), visit 3 (1 month after the procedure), visit 4 (3 months after the procedure) and visit 5 (6 months after the procedure). In all visits, the 3 questionnaires were applied (Constant, modified UCLA and SPADI), as well as pain (VAS) and physical examination to measure range of motion (ROM). The patients were also asked about the occurrence of adverse effects.

Statistical methods

Statistical analysis of all information collected in this research was initially made descriptively through the mean, median, between minimum and maximum values, standard deviations and absolute and relative frequencies (percentages).

Patients who were classified according to Samilson and Prieto⁶ as mild and moderate arthrosis were considered in the same group to perform the analyses; this group was referred to as "nonsevere". In all conclusions obtained through inferential analyses, an alpha significance level equal to 5% was used.

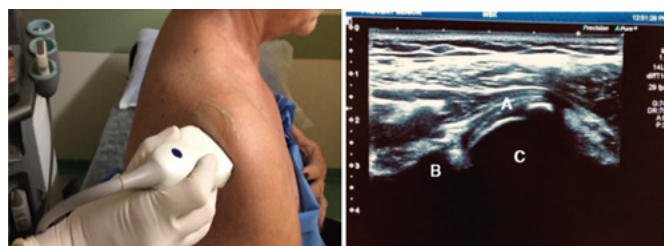


Figure 1. Left: technique for visualization of the posterior aspect of the right shoulder in coronal section. Right: ultrasound image: A) infraspinatus tendon, B) posterosuperior portion of the glenoid cavity, C) humeral head.

RESULTS

The sample selected in this study consisted of 77 patients (77 shoulders). With randomization, the HA group consisted of 41 patients, and the T group consisted of 36 patients. During follow-up, three patients from the HA group were excluded. In the T group, there was a loss of 4 cases. As the final study population, the HA group consisted of 38 patients, and the T group consisted of 32 patients. The mean age of patients in the HA group was 72.7 years, ranging from 57 to 87 years. The average age of patients in the T group was 72.2 years, ranging from 53 to 88 years. Regarding gender, thirty-six (95%) were female in the HA group, and 31 (97%) were female in the T group.

The initial anterior elevation in the HA group was 115 degrees and in the final follow-up (6 months) was 122 degrees. In the T group it was initially 112 degrees and at the final follow-up was 112 degrees. The initial lateral rotation in the HA group was 21 degrees and in the final follow-up (6 months) was 25 degrees. In the T group it was initially 19,5 degrees and at the final follow-up was 20 degrees. The initial abduction in the HA group was 88 degrees and in the final follow-up (6 months) was 95 degrees. In the T group it was initially 95 degrees and at the final follow-up was 85 degrees. There was not statistical difference regarding range of motion.

According to the Samilson and Prieto Classification⁶, in the HA group, nine cases (24%) were classified as mild arthrosis, fourteen (37%) were classified as moderate arthrosis and 15 (39%) as severe arthrosis. In the T group, four (12.5%) were classified as mild arthrosis, twelve (37.5%) were classified as moderate arthrosis and 16 (50%) as severe arthrosis. Although the groups were homogeneous in relation to severity, for statistical analysis, cases of mild and moderate arthrosis were grouped and called "nonsevere", and the remaining severe cases were called "severe". Thus, in the HA group, twenty-three cases (61%) were classified as "nonsevere" and 15 cases (39%) as "severe". In the T group, sixteen cases (50%) were classified as "nonsevere" and 16 (50%) as "severe".

Statistically, there was no significant difference regarding range of motion between the 5 visits performed in either the HA or the T group. Patients classified as having "nonsevere" arthrosis in the HA group presented ROM improvement only 6 months after the procedure while the same patients in the T group presented ROM improvement 1 week after the procedure. However, with the Kruskal-Wallis test, it was not possible to observe a statistically significant difference at a 95% confidence level.

Table 1 shows the average overall pain (VAS) at each visit according to the degree of arthrosis.

We observed that 76% of the patients who received HA injection showed pain improvement after 1 month, and 71% had improvement after 6 months. Patients classified as "nonsevere" had better results than those classified as "severe". Both results without statistical difference. In the group that received the triamcinolone injection, we observed that 82% of the patients had pain improvement in the first week after the procedure, 76% had pain improvement after 1 month, 53% had improvement after 3 months and 32% showed improvement after 6 months compared to the initial assessment. In this group, the cases classified as "nonsevere" also obtained the best results. Table 2 shows the average per VAS evolution from movement pain to each visit by group.

We observed that 76% of patients who received HA injection showed improvement in pain after 1 month and that 63% showed improvement after 6 months compared with the initial assessment. The patients classified as "nonsevere" arthrosis had better results than those classified as "severe".

Table 3 shows the average VAS evolution of night pain at each visit and by groups.

We observed that 73% of the patients who received HA injection showed improvement in nocturnal pain after 1 month and that 66% improved after 6 months compared with the initial assessment.

Table 1. Mean VAS evolution of overall pain at each visit, by groups and degree of osteoarthritis (OA).

Group	Degree of OA	VAS overall pain				
		1st visit	1 week	1 month	3 months	6 months
HA	Severe	8,6	8	7,5	7,4	7,25
T		9,1	6,5	6	7	8,9
HA	Nonsevere	8,1	7	5	5	4,9
T		8,3	4,8	4,1	6,2	7,8

Patients classified as "nonsevere" had better results than those classified as "severe", but without statistical difference.

To verify in which visits the difference was observed, a Nemmenyi test was performed. For the HA group, there were improvements in visits at 1 month, 3 months and 6 months after the procedure, compared to the initial visit, for cases classified as "nonsevere". For cases classified as "nonsevere" in the T group, improvement was observed at only 1 week and 1 month after the procedure compared to the first visit.

Table 4 shows the evolution of the average obtained from the Constant questionnaire at each visit and by group.

With the Kruskal-Wallis test for comparison, in relation to the Constant questionnaire, in the HA group, the patients classified as "severe" arthrosis had a gradual improvement ($p=0,031$), while the same patients in the T group showed more evident improvement in the first week after the treatment ($p=0,007$).

Table 5 shows the mean evolution of the modified UCLA questionnaire at each visit and by group.

With the Kruskal-Wallis test for comparing the UCLA questionnaire between group visits, it is possible to see that in the HA group patients had a gradual improvement ($p=0,007$), while the patients in the T group showed more evident improvement in the first month after the treatment ($p=0,007$).

Table 6 shows the average evolution of the SPADI questionnaire results at each visit and by groups.

With the Kruskal-Wallis test to compare the SPADI questionnaire between the group visits, it can be noted that in the HA group patients had a gradual improvement ($p=0,007$), while the patients in the T group showed more evident improvement in the first month after the treatment ($p=0,007$).

No serious adverse effects has been reported. Six patients (8.6%) reported severe pain immediately after injection, 4 (10.5%) from the HA group and 2 (6.2%) from the T group. We had no cases of infection.

Table 2. Mean VNS evolution of movement pain at each visit, by groups and by degree of osteoarthritis (OA).

Group	Degree of OA	VNS movement pain				
		1st visit	1 week	1 month	3 months	6 months
HA	Severe	8,9	8,4	7,5	7	6,9
T		7,9	6	5,9	6,3	8,7
HA	Nonsevere	8,4	6,9	5,3	5,1	5,3
T		8,6	5	4,6	6,2	7,9

Table 3. Mean VAS evolution of night pain at each visit, by groups and degree of osteoarthritis (OA).

Group	Degree of OA	VNS night pain				
		1st visit	1 week	1 month	3 months	6 months
HA	Severe	8,4	7,6	6,6	6,9	7,4
T		7,6	5,6	5,4	6,4	8
HA	Nonsevere	7,3	5,7	4,1	3,9	4,1
T		8,5	4,4	4,4	6,5	8,1

Table 4. Average of the Constant questionnaire at each visit, by group and by degree of osteoarthritis (OA).

Group	Degree of OA	Constant score				
		1st visit	1 week	1 month	3 months	6 months
HA	Severe	37,4	41,6	47,9	50,4	51,3
T		44,4	58	53,8	49,8	42,2
HA	Nonsevere	56	62	71,3	73,2	77,2
T		53,7	67,6	68,8	63	51,2

Table 5. Average UCLA questionnaire at each visit, by group and by degree of osteoarthritis (OA).

Group	Degree of OA	UCLA score				
		1st visit	1 week	1 month	3 months	6 months
HA	Severe	10,1	12,5	14,7	15,6	14,8
T		10,6	16,7	16,3	14,1	11,7
HA	Nonsevere	13,1	17,6	21,5	22	24,1
T		15,4	21,4	22	19	15,3

Table 6. Average SPADI questionnaire results at each visit, by groups and by degree of osteoarthritis.

Group	Degree of OA	SPADI score				
		1st visit	1 week	1 month	3 months	6 months
HA	Severe	77,8	69,1	65,1	65,5	67,3
T		81,6	70,3	72,3	76,7	84,4
HA	Nonsevere	73,3	65,3	51	48,3	42,4
T		72,8	53,8	51	60,6	73,8

DISCUSSION

Painful glenohumeral OA is often profoundly disabling and difficult to treat.¹² Shoulder arthroplasty is effective in both pain reduction and function improvement, but its use is limited by concerns regarding implant longevity, difficulties associated with possible revision surgery, and limited outcomes in individuals with degenerative rotator cuff injuries.¹³ IA injections of corticosteroids are very effective in reducing pain and inflammation in patients with painful OA, particularly during periods of clinical exacerbation.^{14,15} However, their relative short-term effect (1 to 3 weeks) may lead to the need for more frequent injections, which are associated with adverse effects on joint structures, including acceleration of soft tissue damage and hyaline cartilage.¹⁶ Regarding range of motion, even in cases where there was a statistically significant improvement in pain and / or functional questionnaires scores, the range of motion improvement was very subtle or did not occur, similar to previous study.¹⁷ The evaluation of the questionnaire scores also showed a gradual and longer-lasting improvement in those patients who received HA injection compared to those who received triamcinolone. Brander et al.¹⁸ in a pilot study in the USA, evaluated 36 subjects with moderate and severe glenohumeral OA with the purpose of determining the safety and efficacy of two fluoroscopy-guided IA injections of hylan G-F 20. They observed improvement in pain after 6 weeks, 3 months and 6 months.

Kwon et al.⁵ evaluated the results of 3 doses of IA injections of high PM hyaluronic acid with a control group that received saline. Only patients with shoulder OA and no concomitant intrinsic shoulder disease treated with IA HA injections showed statistically significant improvements in pain.

Similarly, Porcellini et al.¹⁹, in their prospective study, showed that HA treatment for glenohumeral OA significantly decreased pain and improved shoulder function for at least six months from the first injection.

In a recent systematic review and published meta-analysis of VS in glenohumeral OA, Zhang et al.¹⁷ determined that HA injection IA is safe and improves pain in patients with shoulder OA.

Several studies address the difficulty of accurately administering glenohumeral IA injections. Hegedus et al.²⁰ evaluated 103 IA shoulder injections performed by their team physicians through 3 access routes, all not guided by the imaging method: anterior, posterior and anterosuperior (or Nevaizer). They concluded that only 52.4% of the injections were successful, and the highest rates of extra-articular injection were identified in the posterior and Nevaizer accessions. Thus, we believe that the best technique for intra-articular GU injection is the one through which the physician has the most affinity-guided ultrasound approach whenever possible. In our study, the posterior approach was chosen, mainly because of the arthroscopic portal experience already used in routine surgical practice. Because it is an outpatient procedure, we believe that the approach used in the present study is efficient and easily applicable to physicians and surgeons, provided they are familiar with the posterior access route of the shoulder and the handling of the ultrasound device. But other studies have different approaches¹⁷ like the study of Brander et al.¹⁸ that used a anterior approach with fluoroscopic guidance.

The current study has some limitations. One is the fact that there was not a physiotherapy program. Another point is that the physician was not blind about the medication. A third point is that the follow-up was short considering the natural course of the osteoarthritis.

CONCLUSION

Viscosupplementation with a dose of hylan G-F 20, as well as intra-articular injection of triamcinolone, lead to decreased pain and increased satisfaction in patients with glenohumeral OA in the absence of complete rotator cuff injury. The results tend to be better and longer-lasting in patients receiving hyaluronic acid, as well as in patients with mild and moderate degrees of arthrosis regarding pain but with no statistical difference in functional scores.

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