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ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

Analysis of patients with adhesive capsulitis treated at the Kosovska Mitrovica Clinical Hospital Center over a two-year period

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SUMMARY
Introduction/Objective Adhesive capsulitis (AC) is a condition characterized by pain and significant reduction in active and passive movements in the glenohumeral joint, especially in external rotation. It is one of the most common and challenging clinical disorders encountered by orthopedic surgeons. AC is predominantly an idiopathic condition and has an increased prevalence in women and patients with diabetes mellitus and hypothyroidism. The etiology and pathogenesis are not entirely clear. Treatment options include conservative and surgical approaches, but the results remain controversial.
Methods The study included patients treated for primary (idiopathic) AC from June 2021 to June 2023 at the Kosovska Mitrovica Clinical Hospital Center. A total of 172 patients were treated. All were managed non-operatively with physical therapy and local intra-articular steroid injections. The patients were followed up on an outpatient basis monthly, then at six months, one year, and two years.
Results All patients were divided into two groups. The first group (87 patients) underwent physical procedures, while the second group (85 patients) received intra-articular corticosteroid injections. Patients that were treated with physical therapy were not administered injections of steroids, while the group of patients treated with corticosteroids were not given physical therapy. Patients were selected through randomization.
Conclusion Steroid injections may be beneficial in the early stages of the disease, especially in the first 6-8 weeks, but long-term results did not show any significant difference between the two groups of patients.
Keywords: adhesive capsulitis; shoulder; physical therapy; steroid therapy

INTRODUCTION

Primary adhesive capsulitis (AC) of the shoulder, or "frozen shoulder," is an aseptic inflammation of the joint capsule. It was first described in the late 19th century as a condition that is "difficult to define, difficult to treat, and difficult to explain" [1, 2, 3]. AC is a common cause of shoulder pain, restricted mobility, and disability [4]. The characteristic feature of this disease is spontaneous chronic pain with a gradual and progressive loss of both active and passive movements in the shoulder joint [2]. The prevalence of AC ranges 2–5% of the general population, although estimates vary from 0.5% to as high as 10% [3, 4]. It is about three times more common in the female population, usually occurring between the fourth and the seventh decade of life, but patients' ages can range 27–85 years [5]. It can be primary (idiopathic) or secondary. Primary idiopathic frozen shoulder (FS) is often of unknown cause but is frequently associated with other diseases and conditions, such as diabetes mellitus, and can be the first presentation in diabetics. According to some data, up to 20% of patients with diabetes mellitus develop AC [6, 7, 8]. Secondary AC can occur after shoulder injuries or immobilization (e.g. rotator cuff tendon tear, biceps tenosynovitis and calcific tendinitis, hemiparesis) [9, 10]

Despite its prevalence, FS is one of the least understood shoulder conditions. Its definition, classification, pathophysiology, diagnosis, natural course, treatment, and prognosis remain controversial [9]. Optimal treatment for AC has been the subject of significant debates, especially because the condition tends to resolve spontaneously months after the onset of symptoms [6]. The primary goal of the study was to compare the therapeutic effectiveness of local corticosteroid application and physical therapy in the treatment of AC.

METHODS

A prospective study included 172 patients who were randomly divided into two groups through randomization. Randomization was

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performed after obtaining written consent from study participants. Each patient completed a questionnaire that included the Oxford Shoulder Score. The patients were followed up on an outpatient basis over a two-year period from June 2021 to June 2023. The study extracted the following data: demographics (sex, age), duration of symptoms before treatment, comorbidities (diabetes mellitus, hypothyroidism), interventions (location and number of injections, doses and volume of corticosteroids, types of corticosteroids), assessment periods, and outcomes. Patients under 18 years of age, those with contraindications for corticosteroid therapy, patients with secondary AC (inflammatory, degenerative, metabolic), individuals in whom AC developed as a result of shoulder fractures, were not included in the research.

For all patients, a detailed medical history was taken upon admission, a complete clinical examination of the shoulder was performed, routine radiography and ultrasound examination were conducted. Inclusion criteria for the study were pain and limited range of motion. Symptoms were required to be present for at least five months before the start of the study. Shoulder pain should have been present at least 50% of the time during the day, with pain occurring on acute shoulder elevation, night pain, and pain during passive movements in at least two directions (abduction, flexion, external and internal rotation). Passive movements in the shoulder should have been reduced by more than 30%.

The following physical procedures were used: transcutaneous electrical nerve stimulation, mobilization techniques, active range of motion exercises, and cryotherapy (application of ice).

We first anesthetized the skin of patients receiving corticosteroids with 2% lidocaine. Then, using ultrasound guidance, with 21-gauge needles, 2½–3" in length, we applied previously prepared solutions of betamethasone (7 mg/ml) into the intra-articular space of the shoulder joint. The injections were administered in outpatient conditions with the complete application of all antiseptic methods. The patient was positioned on their back with the arm by their side and in a sitting position with the arm straight in a neutral position. The first injection was given at the beginning of the treatment, the second after a month and a half, and the third three months after the first examination. We continued the follow-up of the patients on an outpatient basis in the sixth month, then in the first and second years.

We confirm that we have read the journal's position on issues involving ethical publication and affirm that this work is consistent with those guidelines. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards (Ethics Committee Decision No. 1814/11). Written consent to publish all shown material was obtained from the patients.

RESULTS

Depending on the type of variables and the normality of their distribution, data description is presented as n (%), mean ± sd, or median (min–max). Statistical hypothesis testing methods used included t-test, Mann–Whitney test, χ^2 test, and Fisher's exact test. Logistic regression with mixed effects was employed for modeling the relationships between dependent variables in repeated measurements and potential predictors. In multivariate regression models, predictors from univariate analyses that were statistically significant at a significance level of 0.05 were included. Statistical hypotheses were tested at a significance level (alpha level) of 0.05. All data were processed using IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp., Armonk, NY, USA) or the R programming environment (R Core Team, 2018).

During the study, we analyzed demographic data (sex and age). There were a total of 113 female participants (65.7%), while there were 59 males (34.3%). The youngest patient was 38 years old, and the oldest one was 69 years old, with a mean age of 53.76 years (Table 1).

The time from the onset of the first symptoms to the first examination lasted from five to 12 months with an average value of around eight months (Table 2).

The majority of patients with AC had diabetes mellitus (35 of them, 20.3%), 16 patients (9.3%) had issues with reduced thyroid function along with AC, while a total of 100 patients (58.1%) had no accompanying diseases. Glycated hemoglobin (HbA1c) was determined for all patients. If HbA1c was above 6.5%, the patient was classified as having diabetes mellitus, following international guidelines (Table 3).

Table 1. Sex distribution of patients

Sex		Frequency	Percentage	Valid percentage	Cumulative percentage
Valid	female	113	65.7	65.7	65.7
	male	59	34.3	34.3	100
	total	172	100	100	/

Table 2. Statistical indicator of pain-free period in adhesive capsulitis

χ^2 tests						
/	Value	df	Asymptotic significance (2-sided)	Exact sig. (2-sided)	Exact sig. (1-sided)	Point probability
Pearson χ^2	0.003[a]	1	0.960	1.000	0.544	/
Continuity correction	0.000	1	1.000	/	/	/
Likelihood ratio	0.003	1	0.960	1.000	0.544	/
Fisher's exact test	/		/	1.000	0.544	/
Linear-by-linear association	0.003[c]	1	0.960	1.000	0.544	0.127
N of valid cases	172	/	/	/	/	/

[a]0 cells (0%) have expected count less than 5; the minimum expected count is 29.16;
[b]computed only for a 2 × 2 table;
[c]standardized statistic is 0.050

Table 3. The relationship of comorbidities with adhesive capsulitis

Comorbidities		Group		Total
		Corticosteroids	Physical therapy	
Diabetes mellitus	count	18	17	35
	% within group	21.2%	19.5%	20.3%
Hyperthyroidism	count	6	10	16
	% within group	7.1%	11.5%	9.3%
Rest	count	11	10	21
	% within group	12.9%	11.5%	12.2%
No comorbidities	count	50	50	100
	% within group	58.8%	57.5%	58.1%
Total	count	85	87	172
	% within group	100%	100%	100%

Table 4. Statistical indicator of limited mobility in adhesive capsulitis

χ^2 tests						
/	Value	df	Asymptotic significance (2-sided)	Exact sig. (2-sided)	Exact sig. (1-sided)	Point probability
Pearson χ^2	1.053[a]	3	0.788	0.803	/	/
Likelihood ratio	1.064	3	0.786	0.803	/	/
Fisher's exact test	1.071		/	0.807	/	/
Linear-by-linear association	0.018[b]	1	0.893	0.901	0.471	0.049
N of valid cases	172	/	/	/	/	/

[a]0 cells (0%) have expected count less than 5; the minimum expected count is 7.91;
[b]standardized statistic is -0.135

Table 5. The relationship between age and type of therapy

Case summaries						
Group	N	Mean	Std. deviation	Median	Minimum	Maximum
Corticosteroids	85	54.14	6.842	54	38	69
Physical therapy	87	53.38	7.071	54	37	68
Total	172	53.76	6.949	54	37	69

All patients who participated in the study had shoulder pain, often pain that was present even at night during the resting phase. Restricted movement, primarily in terms of external rotation, was present in 141 patients (82%), followed by abduction in 82 patients, or 47.7%, internal rotation in 47 patients (27.3%), and flexion in 53 patients (30.8%) (Table 4).

The total number of patients receiving corticosteroids was 85 (49.4%). Physical therapy was applied to 87 patients (50.6%) (Table 5).

During the observed period, there was an increase in the frequency of pain improvement ($b = 1.423$; $p < 0.001$), especially in the corticosteroid group ($b = 9.515$; $p < 0.001$). Overall, during the observed period, there was a significant increase in the frequency of movement improvement ($b = 1.736$; $p < 0.001$), with the corticosteroid group having a significantly higher frequency of pain improvement ($b = 3.545$; $p = 0.001$).

In the multivariate mixed-effect regression model with movement improvement as the dependent variable, variables that were statistically significant in univariate models at the significance level of 0.05 were included. Statistically significant predictors of movement improvement were the use of corticosteroids compared to physical therapy ($B = 4.232$; $p = 0.009$) and younger participants ($B = -0.270$; $p = 0.031$) (Table 6).

In the multivariate mixed-effect regression model with pain improvement as the dependent variable, variables that were statistically significant in univariate models at the significance level of 0.05 were included. Statistically significant predictors of pain improvement were the use of corticosteroids compared to physical therapy ($B = 8.481$; $p < 0.001$) and the absence of internal rotation ($B = -2.917$; $p = 0.022$) (Table 7).

DISCUSSION

Despite its prevalence, FS is one of the least understood shoulder conditions. It is a condition frequently encountered by rheumatologists, rehabilitation professionals, and orthopedic surgeons. The term "frozen shoulder" is often used loosely and mistakenly attributed to other shoulder limitations, such as rotator cuff tears or osteoarthritis. Subacromial pathology (e.g. rotator cuff tendinopathy, subacromial bursitis, and impingement syndrome) can also closely resemble AC in its early stages [4]. AC is known to be a benign and self-limiting disease that spontaneously resolves in about two years, but some patients remain symptomatic, with significant movement restrictions in the shoulder, even years after the onset of the disease [11, 12]. Only 59% of patients regain normal function after four years [13]. The American Shoulder and Elbow Surgeons define AC as a "condition of uncertain etiology characterized by significant restriction of both active and passive shoulder motion in the absence of a known intrinsic shoulder disorder" [3]. AC is characterized by pain, typically worsening at night, a poorly localized dull ache that can radiate to the biceps [14]. Impaired range of motion with forward flexion, abduction, external rotation, and internal rotation is a cardinal clinical finding for AC. In advanced disease, observing the patient's gait may reveal a loss of the natural swing of the arm during walking.

Diagnosis, pathophysiology, course, treatment, and prognosis remain unclear [9]. Diagnosis is primarily clinical, based on a well-taken history and a comprehensive clinical examination, requiring a comparative examination of both shoulders [15]. Ultrasonography has shown high accuracy for diagnosing AC of the shoulder. Therefore, it has the potential to be adopted as a desirable modality in diagnosing FS [16]. The method is fast, inexpensive, and offers dynamic possibilities for examining the subject in multiple planes. The sonographic parameters studied include the thickness of the coracohumeral ligament, increased soft tissue in the rotator interval (static parameters), and restriction of abduction and external rotation

Table 6. Mixed-effect regression models with movement improvement as the dependent variable

Variables	Univariant		Multivariant	
	B	P	B	p
Groups (Corticosteroids/PT)	3.545	0.001	4.232	0.009
Sex (female/male)	-1.127	0.386	/	/
Age	-0.211	0.041	-0.270	0.031
Time, symptoms, first diagnosis	-0.421	0.291	/	/
Comorbidities				
Without	referent category		/	
Diabetes mellitus	-1.586	0.328	/	/
Hyperthyroidism	-1.830	0.397	/	/
Rest	0.436	0.821	/	/
Pain before treatment	21.183	0.995	/	/
Limited movement	-20.465	0.997	/	/
Outer rotation	-0.836	0.609	/	/
Inner rotation	1.595	0.251	/	/
Abduction	-2.581	0.051	/	/
Flexion	-0.981	0.461	/	/

PT – physical therapy

Table 7. Mixed-effect regression models with pain reduction as the dependent variable

Variables	Univariant		Multivariant	
	B	P	B	p
Groups (Corticosteroids/PT)	9.515	< 0.001	8.481	< 0.001
Gender (female/male)	-1.035	0.361	/	/
Age	-0.044	0.573	/	/
Time. symptoms. first diagnosis	0.187	0.588	/	/
Comorbidities/				
Without	referent category			
Diabetes mellitus	-1.328	0.337	/	/
Hyperthyroidism	-0.567	0.762	/	/
Rest	0.043	0.980	/	/
Pain before treatment	2.428	0.653	/	/
Limited movement	-	-	/	/
Outer rotation	1.795	0.196	/	/
Inner rotation	-3.103	0.021	-2.917	0.022
Abduction	0.289	0.789	/	/
Flexion	-2.730	0.036	-2.193	0.055

PT – physical therapy

during dynamic scanning. AC diagnosis is clinical, and the use of MRI should be reserved for evaluating other sources of shoulder pathology rather than confirming AC diagnosis [11, 14].

The pathophysiology of idiopathic AC is poorly understood [6]. For this reason, the treatment of this disease remains controversial. Thus, determining the biological pathophysiology of FS is a key milestone in developing new treatments for patients with FS [12]. The pathophysiology of this disease supports the theory that AC results from a complex chain of events starting with inflammation leading to fibrosis and contraction of the shoulder capsule, the so-called "inflammatory-fibrinous cascade" [3, 8, 14]. Collagen fibers adhere to the glenohumeral ligaments, tendons, and joint surfaces, causing contracture and stiffness of the joint. Therefore, even after inflammation subsides, adhesions persist, significantly restricting movements in the shoulder [10]. It remains to be discovered what triggers this cascade and leads to the acute onset of AC. Changes also occur in the surrounding periarticular tissue involving ligaments, tendons, and muscles. As a result, we get the FS. Patients cannot lift their arm above the shoulder, throw a ball, perform a movement behind the back, make a quick movement in the shoulder, and cannot sleep on the painful side. The shoulder joint capsule in AC contracts and significantly thickens, resulting in pain and stiffness of the shoulder capsule, leading to a reduction in the range of motion in the shoulder. Women with diabetes have a 25% chance of developing AC at least once in their lifetime. Patients with diabetes are often described as having a worsened disease course [5, 7, 10], explained by the theory that diabetes mellitus is a chronically inflammatory condition [11, 17], with an excessive concentration of glucose causing increased cross-linking of collagen and stabilization of connective tissue [12].

Treatment goals include pain relief, restoring movement, and regaining shoulder function [3]. Any treatment that reduces the duration of the disease to less than 24 months is considered a success in treatment, reflecting the severity and complexity of treating FS, which hinders normal daily activities for an extended period. Initial conservative treatment can be successful in up to 90% of patients. Most cases of AC can be treated within primary health care. Clinicians are encouraged to initiate treatment with patient education. In the initial inflammatory phase, it is crucial not to trigger a more significant inflammatory response by treatment procedures. The primary focus is to control pain and inflammation with analgesics and anti-inflammatory medications. In the second phase, when pain subsides, treatment includes ultrasound, pulsed magnetic field therapy, shockwave therapy, transcutaneous electrical nerve stimulation, laser, and interferential currents. Intensive stretching should still be avoided at this stage. Only in the third phase of the disease, an intensive physiotherapy protocol is implemented to achieve the maximum range of motion, strengthen muscles, and restore shoulder joint function [4, 12, 14].

When patients experience the most pain, steroid injections can be beneficial in the early stages of the disease (especially in the first six weeks). However, long-term results show no significant difference between patients treated with steroids and control groups treated with other nonoperative methods. Most studies used only a single corticosteroid injection, while two studies used multiple corticosteroid injections [5, 7]. Intra-articular corticosteroid is widely used as a conservative treatment for AC due to its cost-effectiveness and patient acceptance [8, 12]. As AC is assumed to be an inflammatory and fibrotic disease, early treatment with intra-articular corticosteroid injections may reduce synovitis, limit the development of capsular fibrosis, and alter the natural history of the disease [5, 8, 9]. Our results confirm those reported by Van der Windt et al. [7], showing that the beneficial effects of corticosteroid injection are superior to supervised physiotherapy programs.

Based on the pathophysiology of AC, it could be assumed that corticosteroid injections would be most

effective in the earlier inflammatory stages of the disease, rather than in the later stages when fibrotic contracture is more evident. In a study by Kim et al. [17], a significant improvement in pain outcomes was observed after four weeks in diabetic patients receiving intra-articular steroid injections compared to those who did not receive any injection ($p = 0.020$).

CONCLUSION

The AC commonly encountered in general orthopedic practice is a condition of pain and stiffness with resultant functional impairment. Appropriate decisions regarding the treatment of AC require a comprehensive understanding of pathophysiology, the patient's overall health condition, functional requirements, symptom severity, and response to non-operative treatment. Most patients will experience complete resolution with conservative treatment; therefore, conservative therapy should be the first option. Given the recent increase in risk factors for AC, such as diabetes mellitus, research is needed to investigate whether the incidence of AC has also increased.

The results of this study show that in patients with AC a single intra-articular injection of corticosteroids applied under ultrasound guidance, along with a simple home exercise program, is superior to a physiotherapy program in improving shoulder pain and function after six weeks. Steroid injections may be beneficial in the early stage of the disease (especially within the first six weeks). Other important questions that remain to be clarified include whether the accuracy of needle placement, anatomical location, frequency, dose, and the type of corticosteroid affect effectiveness. With our study, we provide compelling evidence that intra-articular)corticosteroid is associated with better short-term outcomes than other treatments, with potential benefits extending into the medium term; therefore, we recommend their early use with a concurrent home exercise program. This can be complemented with physiotherapy to further increase the chances of symptom resolution within six months.

Conflict of interest: None declared.

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Анализа болесника са адхезивним капсулитисом лечених у Клиничко-болничком центру „Косовска Митровица“ у двогодишњем периоду

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САЖЕТАК

Увод/Циљ Адхезивни капсулитис је болест која се карактерише болом и значајним ограничењем активних и пасивних покрета у гленохумералном зглобу, нарочито у спољној ротацији. То је један од најчешћих, али и веома изазовних клиничких поремећаја са којима се сусрећу ортопедски хирурзи. Адхезивни капсулитис је претежно идиопатско стање и има повећану преваленцију код жена и код болесника са дијабетесом мелитусом и хипотиреозом. Етиологија и патогенеза су недовољно јасне. Лечење је конзервативно и хируршко, али су резултати и даље контроверзни.

Методе У рад су укључени болесници лечени од примарног (идиопатског) адхезивног капсулитиса у периоду од јуна 2021. до јуна 2023. године у Клиничко-болничком центру „Косовска Митровица“. Укупно су лечена 172 болесника. Сви су лечени неоперативно, физикалном терапијом и локално – инјекцијом стероида, интраартикуларно. Болесницима који су лечени физикалном терапијом није апликована инјекција стероида, док групи болесника који су лечени кортикостероидима нисмо укључивали физикалне процедуре. Болесници су праћени амбулантно једном месечно, потом на шест месеци, годину дана и две године.

Резултати Све болеснике смо поделили у две групе. Прва група (87) болесника подвргнута је физикалним процедурама, док су другој групи (85) апликоване интраартикуларне инјекције кортикостероида. Болесници су бирани рандомизацијом.

Закључак Инјекције стероида могу бити од користи у раном периоду болести, нарочито у првих шест до осам недеља, али дугорочни резултати нису показали никакву разлику између две групе болесника.

Кључне речи: адхезивни капсулитис; раме; физикална терапија; стероидна терапија