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Combined transcatheter arterial embolization and rehabilitative treatment for adhesive capsulitis refractory to conservative treatment

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ABSTRACT

Objective: To determine the safety and efficacy of treating adhesive capsulitis refractory to conservative treatment with a combination of TAE(transcatheter arterial embolization) and early physical therapy in our clinical experience.

Methods: Observational and prospective study in a single general hospital. A total of 98 patients with adhesive capsulitis were evaluated and 14 of these patients were diagnosed of resistant to conservative treatment. 9 of these patients accepted combined TAE and rehabilitative treatment. Angiogram of the axillary artery was obtained to provide detailed information about the arterial supply to the glenohumeral capsule. A coaxial microcatheter was used for selective catheterization of arteries supplying the hypervascularized area. Small amounts of suspended microparticles formed by diluting 500 mg imipenem and 500 mg cilastatin sodium were injected. Between 72-96 hours after embolization, patients resumed rehabilitation withphysical therapy until their clinical situation stabilized.

Results: Significant differences were found in VAS (visual-analogue-scale) and functionality. Comparing VAS measurements at night and during activity showed that pain decreased significantly and progressively with respect to the baseline measurements; moreover, the decrease in pain during activity was evident from the first week after the procedure. Significant improvements in flexion and abduction with respect to the baseline measurements were observed at all timepoints after TAE. Statistically significant improvements in the quickDASH questionnaire were observed at third and sixth months after TAE. No complications were observed.

Conclusion: Embolization of arterial branches in the shoulder capsule combined with early rehabilitation was effective combination in adhesive capsulitis refractory to conservatory treatment.

Abbreviations: TAE= transcatheter arterial embolization; VAS = visual analog scale; ROM = range of motion; QuickDASH= Quick Disabilities of Arm, Shoulder and Hand.

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INTRODUCTION

Adhesive capsulitis is characterized by shoulder pain and progressive loss of active and passive mobility[1–5]. The prevalence is 2 % to 5 % in the general population and 10 % to 30 % in diabetics; it is more common in women and in patients 40 to 60 years old[3]. Sometimes both shoulders are affected[6]. Adhesive capsulitis occasionally develops after trauma or surgery, but it is usually idiopathic[3].

The diagnosis is clinical, although there are no firmly established diagnostic criteria[1,7]. Plain-film X-rays of the shoulder should be done, but the findings are usually normal and other imaging studies are occasionally necessary for the differential diagnosis. Characteristic signs on ultrasonography and magnetic resonance imaging include thickening of the inferior glenohumeral ligament, coracohumeral ligaments, and axillary pouch as well as infiltration of the rotator interval, this thickening and contraction of the shoulder joint capsule and surrounding synovium is better defined by MRI[8–13].

Adhesive capsulitis is defined as a self-limiting condition, with different stages (painful, mobidity limitation and clinical recovery) and symptoms length between months to years. This classic presentation no longer predominates and many authors do not consider adhesive capsulitis as a disease with spontaneous resolution, then early treatment is normally recommended to improve ROM and shoulder pain[1,4,14,15]. Conservative treatment with analgesics, physical therapy, and exercises at home is the first-line approach; occasionally, minimally invasive interventions such as intra-articular infiltration or suprascapular nerve block are necessary[4,16,17]. Although most patients respond satisfactorily to conservative treatment, up to 30 % of cases are refractory to treatment, and up to 7 % require surgery[4,18–20]. No single approach to the treatment of adhesive capsulitis is universally considered the most effective[2,15].

In recent years, many therapeutic alternatives are being investigated in order to delay surgical indication once conservative treatments fail and mobidity and functional limitation persist. Based on studies reporting that increased vascularization and accompanying nerves could cause pain and chronic inflammation, Okuno et al.[25] reported promising results for presurgical transcatheter arterial embolization (TAE) of the arterioles that supply areas of increased vascularization in shoulder areas with capsular thickening[10,21–25]. The rationale for this treatment is that occluding or markedly reducing arteriolar blood flow induces ischemia in the inflamed capsular tissue, decreasing the pressure on nerve endings adjacent to these vessels and thereby reducing inflammation and pain[20,25–29], and then continue with physical rehabilitation treatment which would have a synergistic effect on the clinical improvement[3,15]. There are some manuscripts available focused on TAE intervention in knee osteoarthritis, tendinophaty or, entensopathy resistant to conservative treatment[10,21–25]. We aimed to determine the effectiveness of treating adhesive capsulitis refractory to conservative treatment with a combination of TAE and early intensive physical therapy in our clinical experience.

METHODS

STUDY DESIGN

This prospective observational study included patients diagnosed with adhesive capsulitis according to clinical and radiological criteria who underwent intensive physical therapy (consisting in 30 minutes of kinesiotherapy performed by a physiotherapist to restore ROM and function, and electrotherapy to improve pain (5 days per week plus home exercise two or three times every day) and on-demand analgesic drug treatment if patient refers severe pain, until reaching clinical stability at our center in the period comprising January 2018 through July 2019. Our institutional review board approved the study protocol, and all patients provided written informed consent. Patient's confidentiality was ensured in accordance with current legislation. The study protocol follows the Strengthening the reporting of observational studies in epidemiology (STROBE) statement, *Figure 1* presents a flow diagram for this trail.

RECRUITMENT OF PARTICIPANTS

Two physicians specialized in rehabilitation medicine selected patients with a poor response to treatment, defined as symptoms persisting longer than three months with persistent limitation of at least two axes of ROM (≤120º flexion and/or abduction or ≤50º external and/or internal rotation with the shoulder at 90º abduction) after at least six weeks of rehabilitation. Patients aged >18 years without systemic disease, previous shoulder fractures, or shoulder surgery history were referred to the interventional radiology department for TAE.

PROCEDURE. INTERVENTIONAL RADIOLOGY DEPARTMENT

Under local anesthesia, percutaneous arterial access was obtained using a 5-F introducer sheath (Terumo, Tokyo, Japan) via the common femoral artery or a 5-F introducer sheath via the radial artery. First, an arteriogram of the axillary artery was obtained using different types of catheters (4-F or 5-F Glidecath C2, vertebral curve, or Simmons) (Cook®, Bloomington, Indiana and Terumo®, Tokyo, Japan)

to provide detailed information about the arterial supply to the glenohumeral capsule (thoracoacromial, suprascapular, circumflex scapular, and anterior and posterior circumflex humeral arteries and coracoid branch). Next, we used a 1.9-F coaxial microcatheter (Parkway Soft; Asahi Intecc, Nagoya, Japan) for selective catheterization of the artery or arteries supplying the hypervascularized area, identified by early vascular filling, hyperemia, anomalous vessels, or early venous return. After identifying the abnormal vessels small amounts (0.2 cc–0.4 cc) of suspended microparticles (10 µ– 70 µ) formed by diluting 500 mg imipenem and 500 mg cilastatin sodium (Aurovitas, Teramo, Italy) in 5 cc to 10 cc of iodinated contrast material, were infused as the embolic agent, based on previous literature[20,21]. These compounds are slightly soluble in water, that exert temporary embolic effects, flushing afterward with similar amounts of normal saline solution until the hypervascularized areas were excluded (*Figure 2*). All procedures were done under fluoroscopic guidance. The endpoint of embolization was complete or nearly complete stasis of flow in the feeding artery without reflux of embolic agent to undesired arteries[30]. Patients remained under observation for adverse events and were discharged the day after the procedure with instructions for analgesia and exercises at home. Technical success was defined as the selective embolization of the artery/arteries of shoulder joint that shows pathological findings previously described.

OUTCOME MEASURES

Between 72 and 96 hours after embolization, patients resumed intensive physical therapy in order to improve ROM until their clinical situation stabilized.

We recorded the following variables:

- Demographics (age, sex, dominance, profession, diabetes, laterality) and information about the patient's adhesive capsulitis (time since onset, duration of rehabilitative treatment before and after embolization).
- Clinical variables, assessed before (baseline) and one week, one month, three months, and six months after embolization and intensive physical therapy:
- ROM (active and passive flexion and abduction, and passive internal and external rotation with the shoulder at 90° abduction, measured by goniometry);active and passive ROM means how far patient's joint can move on its own and during relaxed state with assistance, respectively.

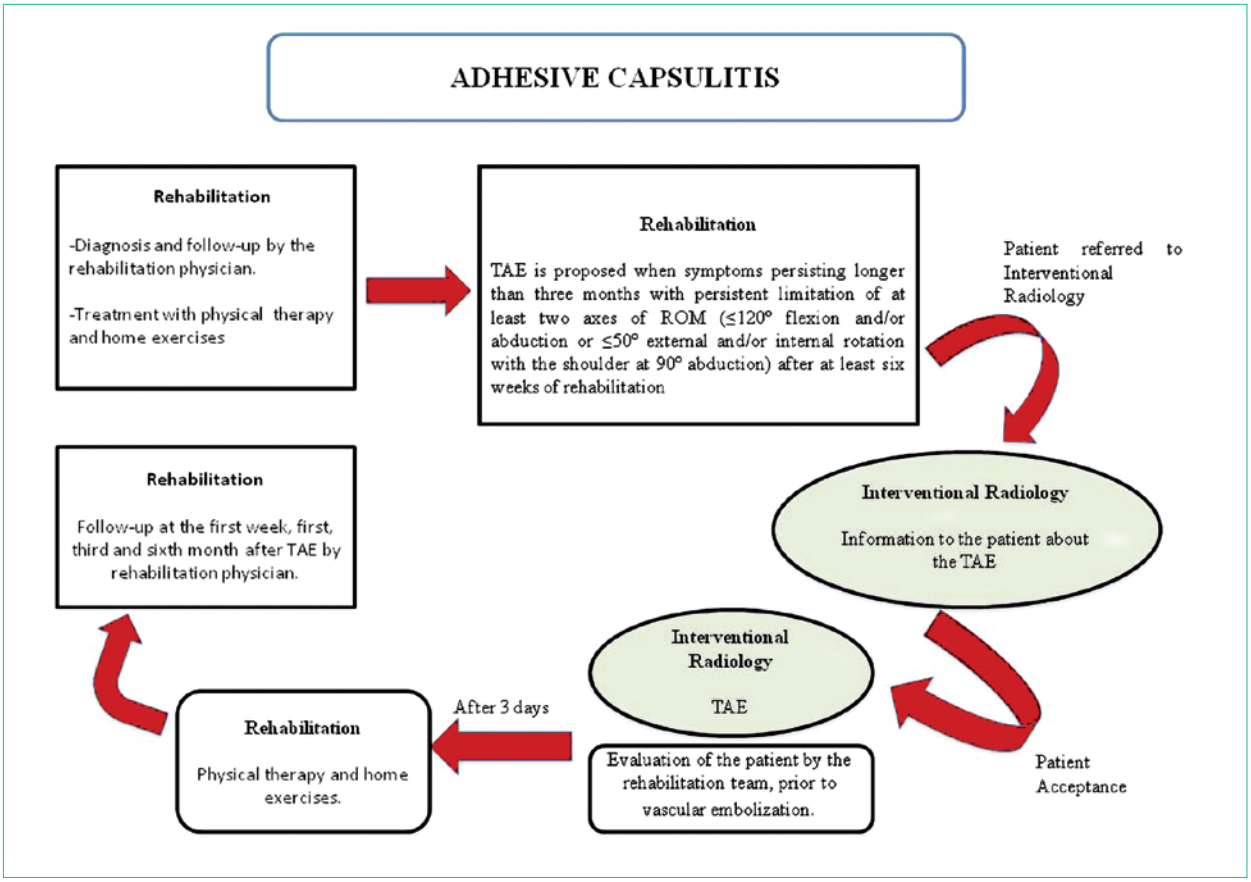

Figure 1. Flowchart illustrating patient selection and treatment.

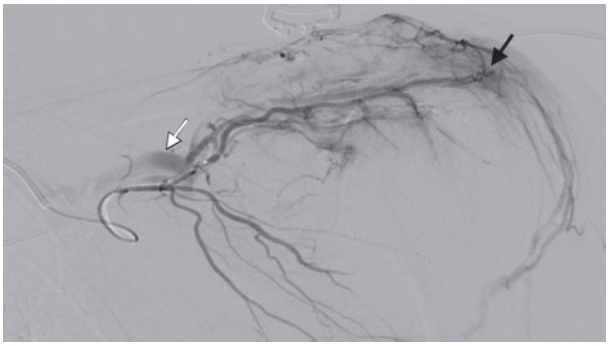

Figure 2A. Angiogram before TAE shows hypervascular areas (black arrow) and early venous return (white arrow).

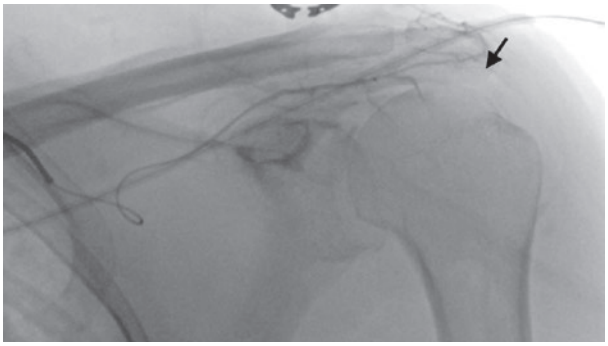

Figure 2B. Angiogram after TAE shows significant decrease in hypervascular areas (arrow).

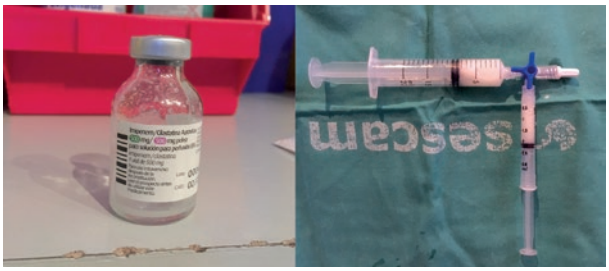

Figure 2C. Mixture of Imipenem and iodinated contrast solution before microcatheter embolization.

1. Shoulder's functional movements of daily activity (anterior reach—hand to the neck with the elbow as far back as possible (example, useful to wash the hair); posterior reach—index finger as high as possible on the spine (example, useful to fasten a bra).
2. Subjetive shoulder's pain evaluated on a visual analog scale (VAS) from 0 to 10, which 0 means no pain and 10 maximum pain, at three timepoints: at night, at rest during the day, and during activity).
3. Upper limb's functionality evaluated by Quick Disabilities of Arm, Shoulder and Hand (quickDASH) self-administered questionnaire at baseline and three and six months after embolism and intensive physical therapy. The quickDASH scores 11 items on a scale from 0 to 100, with 0 representing the absence of disability and 100 total disability.
4. At discharge from rehabilitative treatment, patient satisfaction was measured on a scale ranging from 0 to 10, with 0 representing total dissatisfaction and 10 total satisfaction.

DATA ANALYSIS

We report quantitative variables as means ± estándar deviations and medians (interquartile ranges) and qualitative variables as frequencies (percentages). To compare variables between different timepoints within subjects, we used the Wilcoxon signed-rank text for quantitative variables and chi-square tests or Fisher's exact test for qualitative variables, as appropriate. Significance was set at $p<0.05$ SPSS software (version 20.0; SPSS, Chicago, Illinois) was used for all analyses.

RESULTS

During the study period, a total of 1250 patients (excluding those with fracture, luxation, or surgery) were evaluated in the rehabilitation department for shoulder pathology. Of these, 98 were diagnosed with adhesive capsulitis. Adhesive capsulitis was considered refractory to treatment after 34 weeks of mean period of intensive physical therapy in 14 patients, who were referred to the interventional radiology department as candidates for TAE; 5 patients decided not to undergo TAE. Thus, we studied 9 patients (median age, 47 (45-52) years; 6 (66.7 %) women (*Table 1*). All patients were right-handed; adhesive capsulitis affected the left shoulder in 5 (55.6 %). None of the patients were actively working; 7 (77.8 %) were on temporary disability leave for adhesive capsulitis, and 2 were unemployed. The median time from onset to the first assessment at rehabilitation department was 28 (18-32) weeks, and all patients had undergone rehabilitative therapy (median duration, 8 (6-11) weeks). Technical success was obtained in all patients. The embolized arteries showed pathologic findings in selective angiography, as hypervascularized area, identified by early vascular filling, hyperemia, anomalous vessels, or early venous return. The procedure consisted of embolization of a single pericapsular artery in 1 (11.1 %) patient, of two arteries in 5 (55.6 %) patients, and of three arteries in 3 (33.3 %) patients. The arteries that most frequently showed hypervascularization and early venous return were the anterior humeral circumflex and thoracoacromial

Table 1. Demographics data and clinical findings during follow-up (pre and post TAE). P value was calculated between basal and six month after TAE. Significant p <0.05. (M: male; F: female; R: right; L; left)

	PATIENTS									P value
	1	2	3	4	5	6	7	8	9	
Sex	M	M	F	F	F	F	M	F	F	
Age (years)	44	56	45	52	47	46	51	45	52	
Diabetes	No	No	Yes	No	No	No	Yes	No	No	
Shoulder	L	R	R	R	L	L	L	R	L	
ROM (Degrees)										
FLEXION										
Active										p < 0.003
Basal	90	100	80	110	90	100	110	110	110	
One week	120	110	90	110	90	80	110	110	120	
1 month	120	110	90	115	120	115	110	120	130	
3 months	120	110	90	130	140	130	110	130	150	
6 months	130	120	110	135	160	145				
Passive										p < 0.05
Basal	100	105	90	115	100	120	120	120	120	
3 months	130	110	100	130	150	140	120	135	160	
6 months	120	120	100	125	160	130				
ABDUCTION										p < 0.003
Active										
Basal	85	80	90	110	60	100	160	105	125	
One week	150	150	90	130	60	100	160	130	125	
1 month	160	150	90	160	120	150	160	140	160	
3 months	160	150	100	170	160	160	160	160	170	
6 months	160	150	100	170	160	180				
Passive										p < 0.04
Basal	100	90	95	115	60	120	160	110	135	
3 months	180	160	105	180	170	160	160	180	180	
6 months	180	160	105	180	160	180				
External rotation										p < 0.014
Basal	50	40	20	50	20	60	40	45	50	
One week	60	60	40	50	30	60	40	45	50	
1 month	70	65	35	50	70	40	50	60	50	
3 months	70	65	40	65	70	70	50	80	80	
6 months	60	70	45	70	90	90				
Internal rotation										p < 0.022
Basal	40	20	30	65	0	40	15	45	20	
One week	40	40	30	55	30	50	15	65	40	
1 month	50	40	30	60	60	60	15	70	70	
3 months	50	40	30	55	60	70	20	70	70	
6 months	60	70	35	90	85	80				
PAIN (VAS)										
Night pain										p < 0.017
Basal	0	3.5	6	3.6	5.8	1.2	7.5	2.8	1.5	
One week	0	0	6	0	0	0.9	3.8	3.6	2.5	
1 month	0	0	4	0	0	0.1	1.8	0	2	
3 months	0	0	1	0	0	0.1	0	1.2	0	
6 months	0	0	1.5	0	0	0.1				
At rest during day										p >0.52
Basal	0	0	0	3.2	0	5.2	0	0	0	
One week	0	0	0	0	0	1.6	0	0	0	
1 month	0	0	0	0	4.9	3.0	0	0	0	
3 months	0	0	1.5	0	0	0	0	0	0	
6 months	0	0	1.0	0	0.9					
During activity										p < 0.002
Basal	4	7.6	6	3	7.8	5	8.5	4.7	4.5	
One week	0	3	5	2.2	1.4	4.8	5	4.2	3.5	
1 month	0	0.9	4.1	2.6	1.8	1.6	6.3	3.5	3	
3 months	0	1.1	4.2	0	1.8	1.6	0	0	1.5	
6 months	0	1	3.7	0	1	0.5				
FUNCIONALITY (QuickDASH Questionnaire)										
QuickDASH										p < 0.01
Basal	45	29	66	41	77	50	89	45	59	
3 months	18	23	48	14	14	28	61	9	30	
6 months	11	23	48	9	14	11				

arteries; in 5 (55.6 %) patients, both these arteries were embolized and in 3 (33.3 %) patients one of these arteries was embolized together with other arteries that showed hyperemia. After embolization, all patients underwent rehabilitative therapy (mean duration, 10 (6-12) weeks). No adverse effects of TAE were observed during or after the procedure.

OUTCOME MEASUREMENTS

Range of motion

Statistically significant improvements with respect to the baseline measurements were observed in active flexion and abduction at all timepoints after TAE. Three months after TAE, active flexion had improved by 30 % (100 º ± 11.18 basal vs.123.3 º ± 18.02 at three months after embolization) and active abduction by 60 % (101.66 º ± 28.8 basal vs. 154.44 º ± 21.27 at three months) (*Figure 3, A-B*); moreover, passive flexion had improved by 12 % (110 º ± 11.45 basal vs. 130.55 º ± 11.45 at three months) and passive abduction by 31.3 % (109.44 º ± 28.44 basal vs 163.88 º ± 23.95 at three months).

Improvements in external rotation with respect to the baseline measurements (41.66 º ± 13.69) were observed at one week (48.33 º ± 10.6) (p=0.05), but this improvement was significant only at three months (51.67 º ± 18.3), and six months (65.55º ± 13.09) after TAE (p<0.05), but measurements at three months and six months were not significantly different from those obtained one month after TAE. Significant improvements (p<0.05) in internal rotation with respect to the baseline measurements (30.55 º ± 19.27) were observed at all post-TAE timepoints (50.55 º ± 18.78 at one months, 51.66 º ±18.37 at three

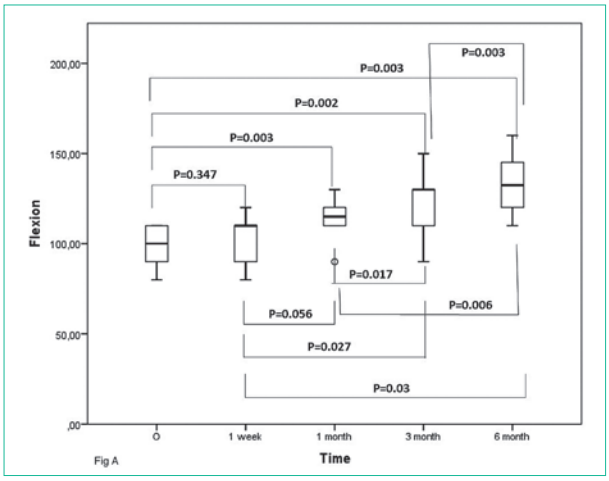

Figure 3. Comparisons of pain and in range of shoulder movement measured at different timepoints from baseline (before transcatheter arterial embolization) to 6 months after the procedure Figure 3A. Pain during rest.

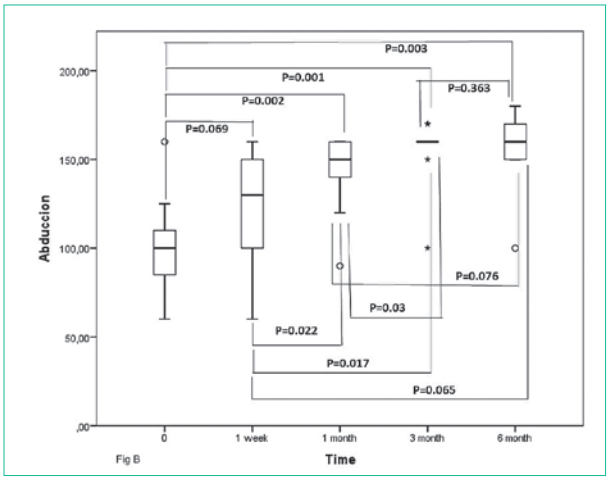

Figure 3B. Nighttime pain.

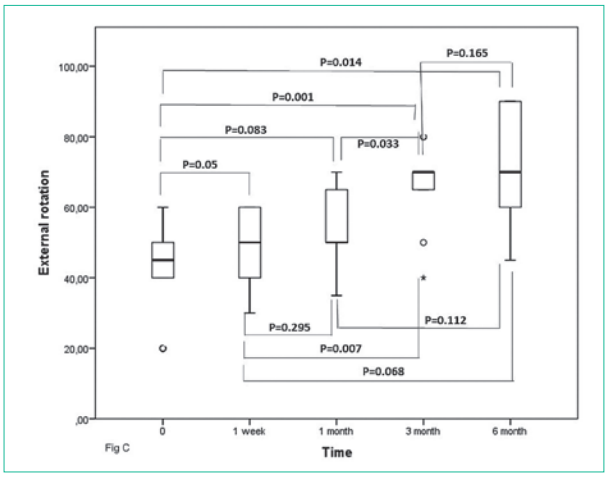

Figure 3C. Pain during movement.

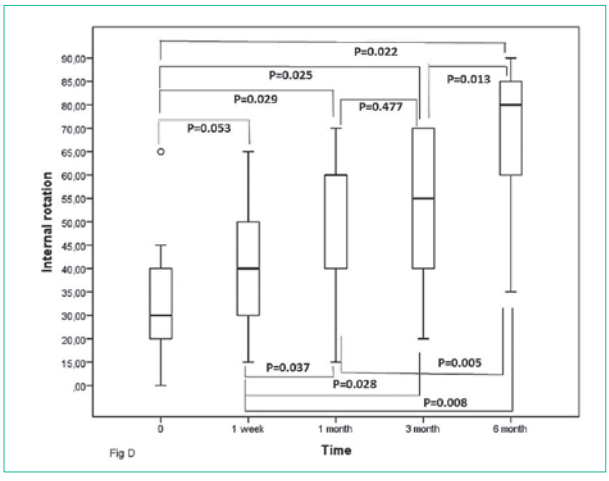

Figure 3D. Range of flexion.

months and 70 º ± 20.2 at six months), with the exception of one week (40.55º ± 14.88) after the procedure (p=0.53). External rotation had improved by 20º at three months and 34º at six months; internal rotation had improved by 21º at three months and 40º at six months. (Figure 3, C-D). Statistically significant improvements in active flexion (100 º ± 11.18 basal, 123.3º ± 18.02 at three months and 133.3 º ± 17.79 at six months) (p=0.003) and internal rotation (30.55 º ± 19.27 basal, 51.66 º ± 18.37 at three months and 70 º ± 20.2 at six months) (p=0.013) were observed between the measurements obtained at three months and six months.

Two patients were diabetic. One of these had no changes in angles of mobility after TAE and was referred for surgery; the other achieved only slight (10º) improvements in flexion, abduction, and external rotation.

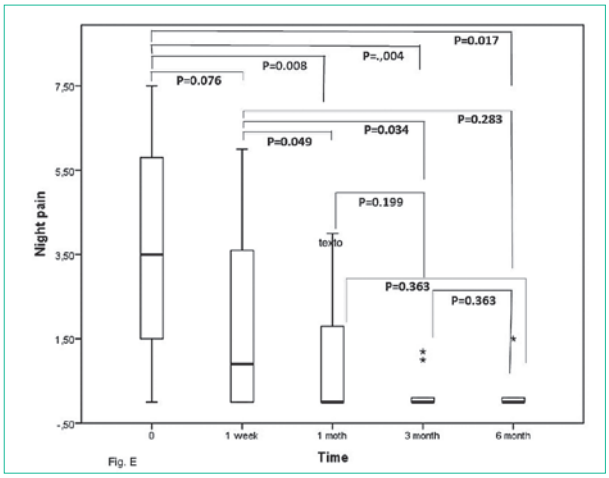

Figure 3. Comparisons of pain and in range of shoulder movement measured at different timepoints from baseline (before transcatheter arterial embolization) to 6 months after the procedure Figure 3E. Range of abduction.

Pain

Pain decreased progressively after the procedure. Comparing VAS measurements at night and during activity showed that pain decreased significantly and progressively until three months with respect to the baseline measurements (3.5 ±2.48 vs 0.25±0.48 and 5.67± 1.9 vs. 1.13 ± 1.38, respectively; p<0.05); moreover, the decrease in pain during activity was evident from the first post-TAE assessment one week after the procedure (3.23±1.75, p=0.011) (*Figure 3E, 3F*). In general, few changes were observed between VAS measurements three and six months after TAE. Improvements in pain measured at rest did not reach statistical significance in any of the periods (*Figure 3G*).

Functionality

Regarding functional movements, maximum posterior reach before TAE ranged from the level of the sacrum to the level of the L1 vertebra; three months after TAE, it ranged from L4 to T11, a nonsignificant trend toward improvement (mean difference 2.88 vertebral levels, range 0-6). Anterior reach improved slightly non significant (p>0.05), but only between the baseline measurement and one week after TAE.

Statistically significant improvements in the quickDASH with respect to the baseline measurement (55.8±18.7) were observed three months after TAE (26.9± 17.3) (p=0.001) and six months after TAE (19.3±14.71,p=0.01). Improvement in the quickDASH between the measurements three and six months after TAE did not reach statistical significance (p=0.1). (*Figure 3H*).

Patient satisfaction

Mean VAS for patients" satisfaction was 8.63 (range 4-10); the lowest score (VAS 4) was awarded by a diabetic patient.

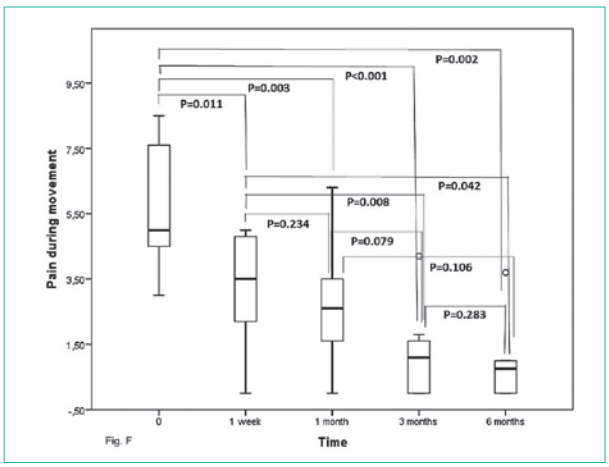

Figure 3F. Range of external rotation.

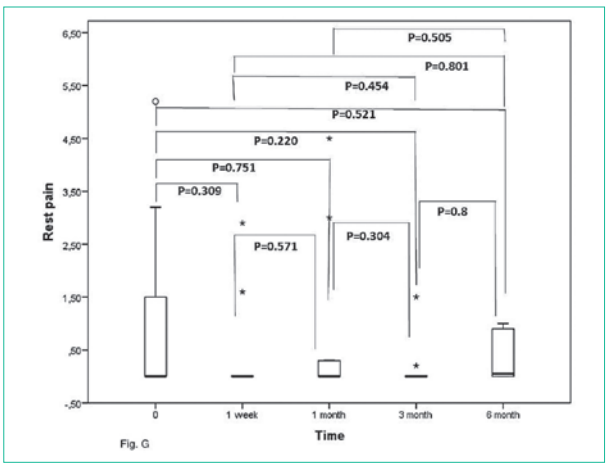

Figure 3G. Range of internal rotation.

DISCUSSION

Some authors have postulated that adhesive capsulitis is a complex chronic inflammatory process in which pericapsular angiogenesis and neurogenesis trigger the formation of fibrotic tissue, leading to contracture of the glenohumeral capsule[4,5]. Berghs et al.18 found that patients with adhesive capsulitis had significant angiogenesis, especially in the rotator interval, and that arthroscopic excision of neovessels resulted in early pain relief. Based on these reports, Okuno et al.[25,26] used TAE to treat adhesive capsulitis in two studies. Earlier, in 2013, these authors published their experience in the use of TAE for pain relief in chronic enthesopathies and tendinopathies, later similar studies reflected TAE impact on patients with osteoarthritis of the knee[20,31–37]. With the exception of a randomized controlled trial conducted by Landers et al.[33], these studies were all, like ours, observational.

The demographics characteristic of our group suggest that these results could be extrapolated to other studies[18,20,25]. Our results indicate the potential social repercussions of using TAE to treat adhesive capsulitis, because patients in our sample were on working age and 78 % of them were off work for disability resulting from this condition, who in our sample represents 78 % of them.

In our study, 14 patients were offered TAE to treat persistent restricted mobility. Our inclusion criteria were based on ranges of mobility, not on pain scores, because shoulder pain can result from multiple conditions and may confound diagnosis in the initial stages of adhesive capsulitis, decreasing progressively in later stages, when the condition is characterized by decreased active and passive mobility[4]. In this sense, our study differs from Okuno et al.[25,26] studies about adhesive capsulitis, in which TAE was proposed only for patients with pain (VAS>5). Moreover, unlike those authors, we did not exclude patients with partial tears of the rotator cuff, because partial tears are among the structural changes than can develop from adhesive capsulitis itself[4,26].

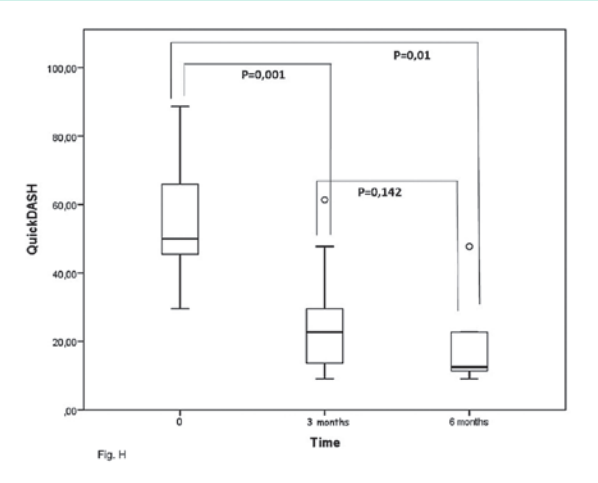

Figure 3H. QuickDASH questionnaire scores.

In the present study, angiography before embolization showed hyperemic areas in all patients, indicating hypervascularization that might be associated with the inflammatory process that leads to fibrosis in adhesive capsulitis[7,38].

One noteworthy finding of our study is the decrease in pain during activity, seen from one week after TAE and continuing through the six-month follow-up period. This decrease enabled patients to better tolerate and adhere to rehabilitative treatment. Pain at night also decreased significantly from one month after TAE. Nocturnal pain, the most characteristic type of pain in patients with adhesive capsulitis, can affect the quality of life and have repercussions in the emotional sphere[39]. Our patients" baseline scores for pain at rest were low; thus, there was little room for improvement, and this can explain the lack of statistically significant improvement in this symptom. Other authors have also reported improvements in pain after TAE, both in the short term (one week) and in the mid-term (six months), and different mechanisms have been suggested for these improvements[32,34,37]. Whereas early improvement could be related to a reduction in the stimulation of sensory nerves brought about by a decrease in the anomalous vascularization[37], the progressive decrease in pain up to six months could be related to the suppression of proinflammatory mechanisms secondary to the occlusion of neovessels as well as to the natural history of adhesive capsulitis[25,26,31,37].

Another interesting finding is the progressive improvement in all ranges of movement throughout the six-month follow-up period, especially the early improvement in external rotation in the first week after TAE. Okuno et al.[25,26] also found improvements in flexion and external rotation, but they did not assess other ranges of movement or anterior and posterior reach. Another difference between their studies and ours is that all our patients completed rehabilitative treatment before and after TAE; in our study the rehabilitation department selected patients to avoid bias in the results.

Using the quickDASH questionnaire, one of the most widely used instruments for assessing shoulder functionality, we found improvements at three months and further improvements at six months. Okuno et al.[25,26] used a different functional instrument, the American Shoulder and Elbow Surgeons scale, and also found improvements. The two patients in our series who had diabetes showed

the worst response to treatment, in terms of ROM, and these outliers brought down the overall means. Adhesive capsulitis is more prevalent among diabetic patients, who have worse symptoms and are more prone to treatment failure than the general population[6,19,40].

Residual limitations in function and/or pain have been reported after TAE or other treatments for adhesive capsulitis[26,41]. Although not all of the objective variables studied in our series improved, patient satisfaction was high (4 patients were rated their satisfaction as 10 on a 0—10 scale), probably because of improvements in the range of movements that are most important in daily life. After TAE, follow-up for at least six months is essential and follow-up for one year or more is recommendable. Although less than ideal, telephone follow-up can be acceptable to facilitate adherence. To date, the longest period of follow-up after TAE for adhesive capsulitis published is more than 12 months[26].

No complications or adverse events were observed during or after TAE. Other studies have also found that TAE is safe with shorter hospital stays and lower costs than surgery[25,26,31,36]. During the six-month follow-up period, adhesive capsulitis did not recur in any of our patients, although we cannot rule out later recurrence. If symptoms were to recur in the same shoulder or appear in the contralateral shoulder, a second TAE procedure could be considered[25,31].

LIMITATIONS OF THE STUDY

This study has various limitations. This single-center study included few patients, and the follow-up period was only six months. Moreover, we had no control group, thus, it is difficult to know to what extent patients" outcomes were influenced by the natural history of adhesive capsulitis. Well-designed multicenter studies with more patients and longer follow-up are necessary to confirm our findings.

CONCLUSSIONS

In our series of patients with adhesive capsulitis refractory to conservative treatment, embolization of arterial branches in the shoulder capsule combined with early and intensive rehabilitation was effective treatment, bringing about early improvements in pain, degree of movement in all planes, functionality, and patient satisfaction, without significant complications. These results should provide hope for the treatment of this incapacitating condition.

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