Original Article

The Insertion of a Subacromial Balloon Spacer Can Provide Symptom Relief and Functional Improvement at a Minimum 5-Year Follow-Up in Patients With Massive Irreparable Rotator Cuff Tears

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Purpose: To examine long-term patient-reported outcomes and range of motion in patients with massive irreparable rotator cuff tears (MIRCTs) who underwent subacromial balloon spacer implantation. **Methods:** A retrospective review of all patients who underwent subacromial balloon placement procedure for MIRCTs at our institution was conducted. Patients with adequate preoperative and postoperative data, with at least 5 years of follow-up, were included in our study. Outcome measures were range of motion (forward elevation), American Shoulder and Elbow Surgeon (ASES) score, and visual analog scale (VAS) score. Independent *t* test was conducted to check for statistically significant differences between preoperative and postoperative outcome scores, with $P < .05$ deemed significant. **Results:** Ten patients were identified: 4 were lost to follow-up beyond 2 years and were excluded. One was converted to an arthroplasty at the 1-year mark and was then lost to follow-up (conversion rate: 16.6%). Five patients had at least 5 years of follow-up after the balloon procedure and were involved in our case series analysis. Mean age was 63.1 years, and mean follow-up was 5.8 years (range, 5-7 years). Preoperatively, mean forward elevation was 110 degrees, mean ASES score was 40.68, and mean VAS score was 6.2. On follow-up, mean forward elevation was 163 degrees ($P = .007$), mean ASES score was 90.97 ($P = .001$), and mean VAS score was 0.9 ($P = .004$). All patients showed significant improvements in all outcome measures, and none had any significant complications. **Conclusions:** In this study, we found that the use of a subacromial balloon spacer can lead to good outcomes at a minimum 5-year follow-up in patients with MIRCTs. **Level of Evidence:** Level IV, therapeutic case series.

Massive irreparable rotator cuff tears (MIRCTs) present a difficult challenge to patients and orthopaedic surgeons alike.[1] Treatment options range from conservative nonoperative modalities such as physical therapy and oral nonsteroidal anti-inflammatory drugs to complex, robust surgical interventions such as tendon transfers and reverse total shoulder arthroplasties.[1] Each option comes with its own set of advantages and disadvantages, with varying utility depending on tear characteristics, patient factors, and goals of intervention.[1] Introduced in the United States over the past several years and recently receiving US Food and Drug Administration approval in August 2021, the subacromial interpositional balloon spacer offers a "middle-ground" approach for this complicated problem in a specific subset of patients. Indications for use include preserved range of motion with forward flexion greater than 90 degrees, mild to no glenohumeral osteoarthritis, preserved subscapularis function, and adequate deltoid function, among other criteria.[2-4] While the subacromial balloon procedure has been initially described as an isolated procedure, reports of its use along with other concomitant procedures involving the rotator cuff and the biceps tendon have been described.[5,6]

The balloon is composed of a biodegradable material that is inserted arthroscopically into the subacromial space, where it is then filled with saline to relieve impingement between the superior humeral head and inferior acromion surface.[2-4] Additionally, as the balloon avoids any bony work or extensive soft tissue

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debridement, it allows patients to have an accelerated rehabilitation course to reeducate and retension the surrounding glenohumeral muscles with minimal postoperative recovery time.[2-4]

Currently, there exists sparse long-term follow-up on patient-reported outcomes relating to the use of the subacromial balloon spacer for MIRCT in the United States. Although the balloon itself dissolves over 3 to 12 months postoperatively, the sustainability of the clinical benefits of the subacromial space requires investigation.[7] The purpose of this study was to examine long-term patient-reported outcomes and range of motion in patients with MIRCTs who underwent subacromial balloon spacer implantation. We hypothesize that the subacromial balloon spacer can lead to long-term efficacious results in patients with MIRCTs.

Methods

After obtaining approval from our institutional review board, a retrospective chart review was conducted for all subacromial balloon patients who participated in the investigational device exemption trial from 2015 until the end of 2018. Patients involved in the trial had their 2-year follow-up results published in Verma et al.[6] In this updated case series, all patients who were randomized to the subacromial balloon spacer group from our institution and had adequate preoperative and postoperative follow-up of at least 5 years were included. Included patients adhered to the original trial's inclusion and exclusion criteria.[6] These included having a massive rotator cuff tear that was deemed irreparable, an intact subscapularis tendon, nonsevere glenohumeral osteoarthritis, ability to forward flex the shoulder to at least 90 degrees, preserved deltoid function, and no concurrent infection. A fellowship-trained shoulder and elbow surgeon (J.A.A.) with 20 years of experience performed the procedure for all patients.

Information on patients' sex, age at surgery, body mass index, Charleston Comorbidity Index, laterality, and balloon size was reported and included in our database. Conversions to other procedures or reoperations were reported, regardless if these occurred before or after the minimum follow-up period set in our study (5 years). Outcome measures reported included degree of forward flexion, American Shoulder and Elbow Surgeon (ASES) score, and visual analog scale (VAS) scores.

The minimal clinically important difference (MCID) was calculated and reported. An independent *t* test was used to explore whether any statistically significant differences existed between preoperative and postoperative outcome measures. Significance level was set at $P < .05$. Statistical analysis was conducted using the Statistical Package for the Social Sciences, Windows software version 25.0 (IBM SPSS, 2017).

Table 1. Demographic Characteristics of the Included Patients

Patient	Age, y	Sex	BMI	CCI
1	63	Male	25.99	4
2	59	Female	36.78	2
3	69	Male	29.57	3
4	70	Male	23.11	4
5	54	Female	21.14	2

BMI, body mass index; CCI, Charleston Comorbidity Index.

Results

A total of 10 patients underwent the subacromial balloon spacer placement procedure between 2015 and 2018. No patient underwent concomitant arthroscopic partial rotator cuff repair. Of these 10 patients, 4 were lost to follow-up beyond 2 years. One patient had to undergo reverse shoulder arthroplasty at 1 year following the balloon and was lost to follow-up afterward. The remaining 5 patients satisfied our inclusion criteria, as they had 5 years of follow-up following the subacromial balloon procedure and were included in our case series and subsequent analysis.

Five patients, 3 men and 2 women, underwent the subacromial balloon spacer placement procedure between 2015 and 2018 (Table 1). Mean age at surgery was 63.1 years. Mean follow-up was 5.8 years (range, 5-7 years). All patients had a massive irreparable posterosuperior rotator cuff tear, as evident by preoperative and intraoperative imaging and surgical evaluation (N = 5). Magnetic resonance imaging revealed severe fatty infiltration of the posterosuperior cuff in all five patients (N = 5). Preoperatively, mean forward flexion was 110 degrees (range, 90-160 degrees), mean VAS score was 6.2 (range, 3-8), and mean ASES score was 40.68 (range, 20.77-58) (Table 2). On postoperative follow-up, mean forward flexion was 163 degrees (range, 135-170 degrees), mean VAS score was 0.9 (range, 0-3.5), and mean ASES score was 90.97 (range, 69.9-100) (Table 2). As such, all patients exhibited significant improvements on long-term follow-up, with improvement of 53 degrees on forward flexion ($P = .007$), 5.3 points on VAS score ($P = .004$), and 50.29 points on ASES score ($P = .001$) (Table 2). Four of 5 (80%) patients achieved MCID for forward elevation and VAS, and all patients (100%) achieved MCID for ASES (Table 2).

Conversion rate to reverse shoulder arthroplasty was 16.6% (1 of 6 patients, excluding the 4 lost to follow-up beyond 2 years). Of the remaining 5 patients, 1 opted to undergo another subacromial balloon placement procedure on the same shoulder around 6 years following the initial surgery. There were no reported intraoperative or postoperative complications for any of the 5 patients.

Table 2. Preoperative and Postoperative Forward Elevation (FE), Visual Analog Scale (VAS) Score, and American Shoulder and Elbow Surgeons (ASES) Score of the Patients With Massive Irreparable Rotator Cuff Tears Who Underwent the Subacromial Balloon Implantation Procedure

	Forward Elevation (deg)			VAS			ASES			
Patient	Preoperative	Postoperative	MCID	Preoperative	Postoperative	MCID	Preoperative	Postoperative	MCID	Follow-Up, mo
1	90	170	Yes	8	3.5	Yes	26.62	69.87	Yes	72
2	100	135	Yes	4	0	Yes	58	100	Yes	86
3	160	170	No	8	0	Yes	40	100	Yes	72
4	110	170	Yes	3	1	No	58	88	Yes	60
5	90	170	Yes	8	0	Yes	20.77	97	Yes	60
Mean	110	163	NA	6.2	0.9	NA	40.68	90.97	NA	70

MCID, minimal clinically important difference; NA, not applicable.

Discussion

In this study, we demonstrated that a subacromial balloon spacer can be an effective option for patients with MIRCTs. Patients demonstrated good outcomes at 5-year follow-up without the use of more invasive treatment options. The subacromial balloon spacer has demonstrated its efficacy in numerous clinical reports and studies in literature. However, most of these studies were limited to short-term or mid-term outcomes.[6,8,9] One multicenter randomized clinical trial conducted by Verma et al.[6] compared the outcomes of the subacromial balloon with that of arthroscopic partial rotator cuff repair at 2-year follow-up and demonstrated significant improvement in patient-reported outcome scores in both groups, with no intergroup differences, demonstrating the efficacy of the balloon for treating these patients. Another study by Senekovic et al.[8] explored the functional results and safety profile of the balloon spacer for MIRCT patients and demonstrated significant improvement in Constant scores at 3-year follow-up. Finally, Berk et al.[9] conducted a systematic review with meta-analysis on the outcomes of the balloon spacer for MIRCTs and concluded that the short-term results of this device demonstrate it to be a safe and efficacious management options in the repertoire of shoulder surgeons. The conducted meta-analysis demonstrated significant improvements in Constant scores, ASES scores, Oxford Shoulder Score, and VAS scores, along with improvements in range of motion, at a mean follow-up of 30.4 months.[9] Other reports demonstrated the efficacy of the balloon spacer in the setting of MIRCTs,[10,11] but studies with longer-term follow-up have been limited.

The mechanism by which the subacromial balloon spacer works has been explored in the literature.[3,4,12] The balloon first exerts its spacer effect in the acromiohumeral interval, relieving the impingement and pain that results from the superior humeral migration exhibited in MIRCTs.[3,4,12] It also redistributes the forces among adjacent muscles in the shoulder, which helps these muscles compensate for the deficient rotator cuff, leading to improved function.[3,4,12] However, there have been speculations that the benefits of the balloon subside with its resorption in the balloon joint and that the main benefit is related to its spacer effect. Our results show that the balloon indeed has potential to provide long-term improvements in shoulder pain and function, and it can result in outcomes comparable to other more invasive management options, with a relatively easier rehabilitation period. We propose that the main mechanism behind the benefits of the balloon reside in it being a "rehabilitation accelerator." The pain relief provided by the balloon spacer early in recovery, as well as the minimal invasiveness of the procedure, allows patients to go into physical rehabilitation in a faster and more efficient manner, usually at around 10

to 14 days following the procedure. This accelerated rehabilitation process, along with the biomechanical effects of the balloon, can provide improvements in pain and function that can last several years, as seen by our patients. Accordingly, the subacromial balloon spacer can provide a suitable and efficacious treatment option for patients with MIRCTs. Future research should explore the longevity of the balloon on a larger group of patients to confirm its utility and benefits.

Limitations

This study is not without limitations. The single-series nature of this study limits its generalizability. The results would be substantially strengthened by including data from other surgeons involved in the Investigational Device Exemption study. Second, the sample size was small. We were also limited by the retrospective nature of our case series, which did not allow us to explore other patient-reported outcomes or functional scores; however, the ASES and VAS scores are considered reliable tools to measure function and pain for shoulder surgery patients worldwide.

Conclusions

In this study, we found that the use of a subacromial balloon spacer can lead to good outcomes at a minimum 5-year follow-up in patients with MIRCTs.

Disclosure

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