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InSpace Balloon for the Management of Massive Irreparable Rotator Cuff Tears: A Systematic Review and Meta-Analysis

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Background: The best course of action for massive irreparable rotator cuff tears (MIRCTs) is not universally agreed upon. Numerous surgical techniques have been discussed. The implantation of a biodegradable spacer into the subacromial area has been documented since 2012 by several authors. The implantation method is touted as being simpler, repeatable, and less invasive than other solutions that are now available. The purpose of this systematic review and meta-analysis, being the first of its kind, was to evaluate the literature to see the efficacy of InSpace balloon (ISB) implantation in the management of MIRCTs.

Methods: Following Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines, and with 2 researchers assessing and analyzing each study separately, an extensive electronic search of the literature was conducted in the PubMed database from 1961 until July 27, 2022.

Results: Fourteen studies were included in this systematic review and three in the meta-analysis. Eleven out of fourteen studies favored ISB use for MIRCTs, while only three were against its use. All spacers were arthroscopically implanted in the subacromial space. Three studies were included in the meta-analysis. The differences in the compared outcomes were statistically insignificant.

Conclusions: A controversy about the use of ISB remains in patients with MIRCTs. Both good and bad outcomes were reported. However, the majority of patients had good clinical outcomes across several grading scales, radiographic evidence of improved impingement, and self-report that they would redo the procedure in hindsight. To draw more solid conclusions and have statistically significant results in the meta-analysis, more randomized controlled trials and comparative studies comparing this device to other treatments are needed.

Keywords: *Rotator cuff arthropathy, Massive irreparable rotator cuff tears, Subacromial balloon, Biodegradable spacer, InSpace balloon*

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The best course of action for massive irreparable rotator cuff tears (MIRCTs) is not universally agreed upon.[1] The described successful rate of conservative treatment varies greatly from as low as 33% to as high as 92%.[2] When surgeons do agree upon surgical intervention, selecting the best surgical procedure is still an open topic of debate.[3] Numerous surgical techniques have been discussed in relation to MIRCTs, including superior capsule reconstruction, subacromial decompression with biceps tenotomy or tenodesis, partial cuff repair, tendon transfer, tendon allograft, synthetic patch, and reverse total shoulder arthroplasty.[4] These techniques are linked to a protracted recovery time, cost, and a relatively significant risk of complications.[5-7]

The implantation of a biodegradable spacer into the subacromial area has been documented since 2012 by several authors.[8,9] The InSpace balloon (ISB) has demonstrated better shoulder kinematic restoration during gliding.[10] Although it cannot stop the humeral head from migrating in a static superior or anterosuperior direction, it can aid to keep the head centered during dynamic movements.[11] The biodegradable spacer is thought to degrade over a 12-month timeframe.[9] The implantation method is touted as being simpler, repeatable, and less invasive than other solutions that are now available. For this procedure, the patient is first positioned in a lateral decubitus or beach chair position. After local anesthesia, the lateral portal is used for the arthroscope and the dorsal for the balloon introduction. Using the introducer, the deflated balloon is implanted in the subacromial space under direct vision. Once in position, the introducer is unlocked and the ISB can be sealed and deployed.[12]

The purpose of this systematic review and meta-analysis, being the first of its kind, was to evaluate the literature to see the efficacy of ISB implantation in the management of MIRCTs.

METHODS

Systematic Review

The present study follows Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines. Two researchers assessed and analyzed each study separately. All of the citations and abstracts were previewed before examining the complete papers. Independent assessment of the articles ensured adherence to the standards and was to ensure the absence of any reviewer bias.

An extensive electronic search of the literature was conducted in the PubMed, Cochrane, and Google Scholar (pages, 1–20) database from 1961 until January 2023. The following keywords and Boolean operators ((subacromial) AND ((Balloon) OR (Spacer)) were used. A total of 301 articles were extracted. Titles and abstracts of retrieved articles were screened for applicability, followed by analysis of the entire text for eligibility. Studies included those written in English that contain data on the efficacy of the ISB to manage MIRCTs. Articles emphasizing other techniques or articles without significant information on the efficacy of the ISB were excluded. The 14 papers that fulfil the requirements were included in this review. The process is summarised in the PRISMA diagram (Fig. 1).

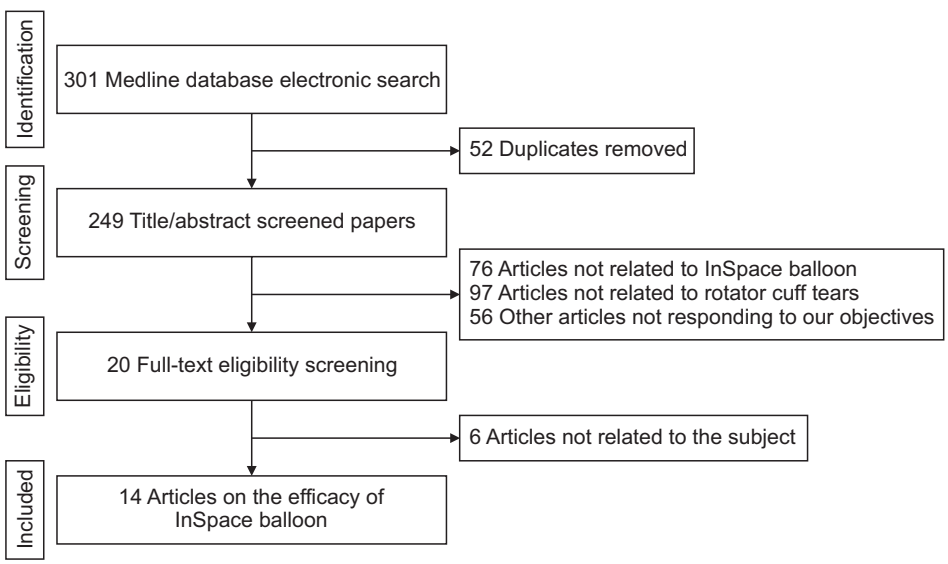

Fig. 1. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) flowchart for article selection process.

Meta-Analysis

Search strategy

The same search strategy was followed as the systematic review.

Study selection

Only studies meeting the following criteria were involved in the meta-analysis: (1) comparative studies: randomized controlled trials, prospective clinical trials, retrospective studies; (2) patients were treated with ISB; (3) ISB was compared to other modalities in the treatment of MIRCTs.

However, the studies meeting these criteria were excluded from the meta-analysis: (1) case reports, narrative or systematic reviews, theoretical research, conference report, meta-analysis, expert comment, and economic analysis; (2) non-relevant outcomes.

Data extraction

Two reviewers determined the eligibility of the studies independently. Extraction of the analyzed data was made from the included studies and it consisted of two parts. The first part consisted of the basic information containing the name of the authors, the title, the publication year, the journal, the volume, the issue, the pages, the study design, the sample size along with the size of each group of management, and the different types of bias suspected in each study. The second part consisted of the clinical outcomes, which were abduction, forward flexion, American Shoulder and Elbow Surgeons (ASES) score, Constant score (CS), visual analog scale (VAS) score, and EuroQol-5 Dimensions-5-Level (EQ-5D-5L). Any arising difference between the investigators was resolved by discussion.

Statistical analysis

SPSS was used for statistical analysis. Standardized mean differences and 95% confidence intervals (CIs) were used to study continuous data. If $p \leq 0.10$ or $I^2 > 50\%$ indicated significant heterogeneity, Q tests and I^2 statistics were employed to assess it. The random-effects model was able to handle the variables' high levels of variability. In contrast, if $p > 0.10$ or $I^2 < 50\%$, the fixed-effect model was chosen. When $p = 0.05$, statistical significance was shown.

Risk of bias assessment

Using the Cochrane risk-of-bias method, two authors (MD and AP) independently evaluated the potential for bias. Random sequence generation, allocation concealment, blinding of participants and study personnel to the study protocol, blinding of outcome assessment, inadequate outcome data, and selective reporting were all considered (Table 1).

RESULTS

Systematic Review

Eleven out of fourteen studies favored ISB use for MIRCTs, while only three were against its use. All spacers were arthroscopically implanted in the subacromial space.

In favor of the ISB usage

Several studies reported the results of the ISB implantation; however, this was done without comparing it to another treatment. Senekovic et al.[13] followed 20 patients for 3 years and showed a mean improvement of 32 points on the total CS, starting at 6 months postoperatively and lasting until the end of the 3-year follow-up. The improvement of the subjective pain score, however, was started 1 week postoperatively and was sustained the whole follow-up period, reaching a reduction of 6.4 points.[13] Patients also saw improvement in activities of daily living and mo-

Table 1. Bias Assessment in the Studies Included in the Meta-Analysis

Study	Authors' judgement		
	Verma et al. (2022)[14]	Metcalfe et al. (2022)[15]	Malahias et al. (2021)[16]
Bias			
Random sequence generation (selection bias)	Low risk	Low risk	High risk
Allocation concealment (selection bias)	Low risk	Low risk	High risk
Blinding of participants and personnel (performance bias)	Low risk	Low risk	High risk
Blinding of outcome assessment (detection bias)	High risk	Low risk	High risk
Incomplete outcome data (attrition bias)	Low risk	Low risk	Low risk
Selective reporting (reporting bias)	Unclear risk	Unclear risk	Unclear risk

tions, improving by 9.4 and 7.7 points, respectively. Shoulder power improved, but this was not apparent until 18 months postoperatively. No adverse effects were reported except for 2 suspected cases of synovitis that were not statistically significant.[13] Senekovic et al.[17] performed a subsequent study, following patients for a duration of 5 years, demonstrating the sustainability of the improvement in the total CS.

Yallapragada et al.[18] followed 14 patients for a mean duration of 12.6 months and showed significant improvement in range of motion, a mean CS improvement of 29 points, a mean Oxford shoulder score of 22 points, absence of night pain, and a 40% increase in activities of daily life.[18] The only perioperative complication was one case of spacer migration. Gervasi et al.[19] followed 15 patients for 1 year after arthroscopic application of the biodegradable balloon in the subacromial space. Of the operated patients, 85% had a significant improvement in ASES and improvement of at least 15 points in their CS. These improvements started early postoperatively and were maintained through the end of the follow-up.[19] Similarly, Garcia Moreno et al.[20] followed 22 patients for 1 year after application of the ISB for MIRCTs. The mean improvement of the CS was 22.9 alongside a 5-point improvement in the VAS. Patient-reported outcomes showed that 73% were satisfied with the surgery and would choose it again.

In a retrospective study, Kaisidis et al.[21] examined 47 patients with an average of 2 years of follow-up and showed an average improvement of 32 points in the CS, 3.6 in the VAS, and 14.6 points in the shoulder range of motion. Furthermore, Malahias et al.[4] showed that the implantation of ISB in patients with MIRCTs had satisfactory clinical and functional mid-term outcomes. A study by Maman et al.[22] following 78 patients for an average of 56 months demonstrated the majority of patients had an improved range of motion and were satisfied with the functional outcome. Patients reported the duration that the positive effect of the ISB lasted was around 43 months, and 45 patients confirmed that they would undergo the procedure again in hindsight. However, 9 patients required conversion to reverse total shoulder arthroplasty after an average of 17 months. No complications were seen except superficial wound infections. Notably, it was found that body mass index, subscapularis repair, and the patient's age affected the outcomes.[22]

Ricci et al.[10] followed 30 patients for 2 years both clinically and radiographically. The CS almost doubled, starting at 39.75 preoperatively and reaching 66.8 at the end of the follow-up. This continual improvement plateaued at 18 months postoperatively. A reduction of pain and improvement of the range of motion, activity of daily living, and functional performance were also seen.[10] A new finding made possible by radiographic follow-up was increased acromiohumeral space postoperatively, going from less than 6 mm before the surgery to more than 7 mm after.[10]

A retrospective study by Holschen et al.[11] compared standard of care treatment of MIRCTs to the same treatment with an added ISB implantation. Although both showed improved shoulder function, it was higher in the ISB group. However, pain relief was the same in both groups and ISB implantation showed no improvement in pseudo-paralytic shoulders.[11] Further improvement of shoulder function was also seen between 11 and 22 months, with larger improvement in the ISB group.[11]

A multicenter, single-blinded, randomized controlled trial by Verma et al.[14] compared 93 patients undergoing ISB implantation to 91 patients having a partial arthroscopic repair for MIRCTs with a follow-up of 2 years. The subjects enrolled in the InSpace group reported comparable ASES scores to the other group during the whole follow-up duration. However, the Western Ontario rotator cuff (WORC) score, the CS, and the range of motion were all better in the ISB group across multiple time points.[14] Operative time was significantly shorter in the balloon group. No complications were noted and 3 reoperations in the partial repair group were seen compared to 4 in the ISB group.[14]

Against the ISB use

Ruiz Iban et al.[23] reported inconsistent results with the use of ISB for MIRCTs. Following 15 patients for 2 years, 5 subjects required a conversion to reverse total shoulder arthroplasty and only 6 had a successful clinical outcome. Another case-control study comparing partial arthroscopic repair with vs without ISB implantation showed that although both groups had significant functional and clinical improvement with a trend in favor of the ISB group, the differences were not statistically significant.[16]

A double-blind, group-sequential, multicenter, randomized clinical trial by Metcalfe et al.,[15] when comparing arthroscopic debridement with ISB vs without it, showed a better outcome 12 months postoperatively based on the Oxford shoulder score, pain reduction, patient global impression of change, overall change, EQ-5D-5L, WORC index, CS, and range of motion in the latter. Additionally, worse results were reported in the female population.[15] The study, which would have had 221 patients, was stopped soon after the first half of patients underwent procedure due to ISB showing no benefit.[15] The indications

for the use of the balloon in this study were controversial including patients with subscapularis tears as well as forward elevation limited to approximately 60°. In addition, due to the pandemic, the majority of the patients that completed the follow-up for the study were evaluated remotely.

Meta-Analysis

Characteristics of the included studies

Only 3 studies[14-16] met the inclusion criteria and were included in the meta-analysis with 155 subjects in the ISB group and 156 subjects in the other treatment group. The main characteristics of the included studies are summarized in Table 2, with 2 prospective randomized comparative study, and 1 retrospective comparative study.

Range of motion

Two studies on 149 subjects and three studies on 311 subjects reported data on postoperative abduction and elevation angles. The results showed that when comparing both groups, the difference was statistically insignificant both in abduction (mean difference, –2.6; 95% CI –5.5 to 0.22) (Fig. 2) and elevation (mean difference, –0.4; 95% CI –5.7 to 5) (Fig. 3).

Quality of life

Two studies on 194 patients and two studies on 279 subjects provided pre- and postoperative VAS scores and EQ-5D-5L scores, respectively. The results showed that when comparing both groups, the difference was statistically insignificant both in VAS (mean difference, –0.11; 95% CI, –0.48 to 0.27) (Fig. 4) and EQ-5D-5L (mean difference, 0.51; 95% CI, –3.1 to 4.1) (Fig. 5).

Functional scores

Two studies on 194 subjects and three studies on 311 subjects reported data on pre- and postoperative ASES and CS, respectively. The results showed that when comparing both groups, the difference was statistically insignificant

Table 2. Main Characteristics of the Studies Included in the Meta-Analysis

Study	Method	Participant		Age (yr, mean ± SD)		Measured outcome	Follow-up time (mo)	Tear inclusion criteria
		InSpace balloon	Control	InSpace balloon	Control			
Verma et al. (2022)[14]	Randomized controlled trial	83	79 (Partial repair)	66.8 ± 7.7	64.7 ± 7.9	ASES scores, VAS pain score, Constant-Murley shoulder score, EQ-5D-5L score, active range of motion, complications and reoperations	24	Measuring ≥ 5 cm in diameter (Cofield classification) and involving ≥ 2 tendons
Metcalfe et al. (2022)[15]	Randomized controlled trial	56	61 (Debridement)	66.4 ± 7.6	67.3 ± 9	Constant score, range of motion, EuroQol EQ-5D-5L, adverse events	12	NA
Malahias et al. (2021)[16]	Retrospective comparative study	16	16 (Partial repair)	69.7 ± 9.1	65.7 ± 8.6	Visual analog scale, Constant score, ASES score, range of motion, complications, reoperations	12	2 Or more tendons involved with tear's size > 3 cm

SD: standard deviation, ASES: American Shoulder and Elbow Surgeons, VAS: visual analog scale, EQ-5D-5L: EuroQol-5 Dimensions-5-Level, NA: not applicable.

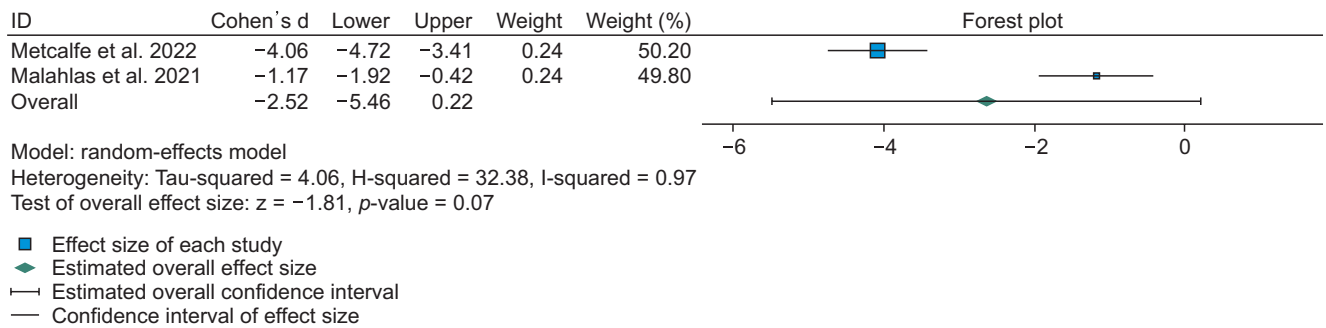

Fig. 2. Forest plot showing the delta abduction angles in InSpace balloon and other treatment groups for massive irreparable rotator cuff tear repair.

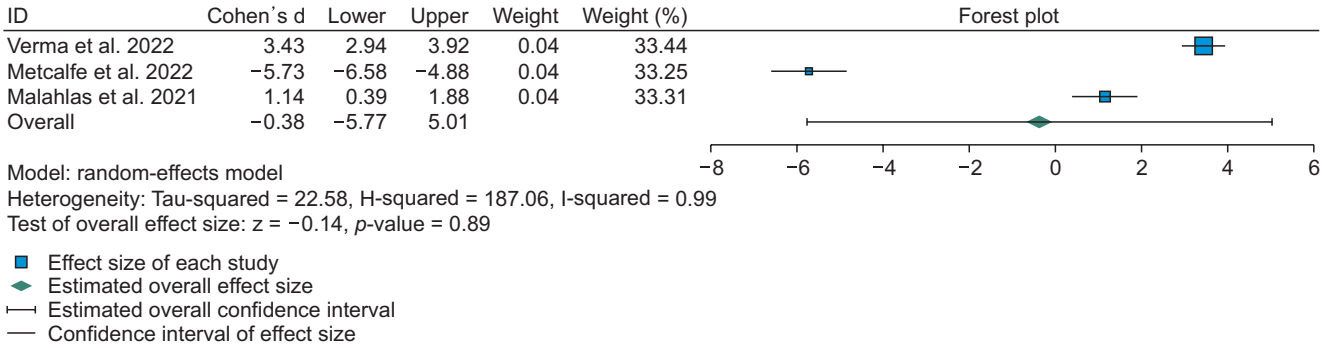

Fig. 3. Forest plot showing the delta elevation angles in InSpace balloon and other treatment groups for massive irreparable rotator cuff tear repair.

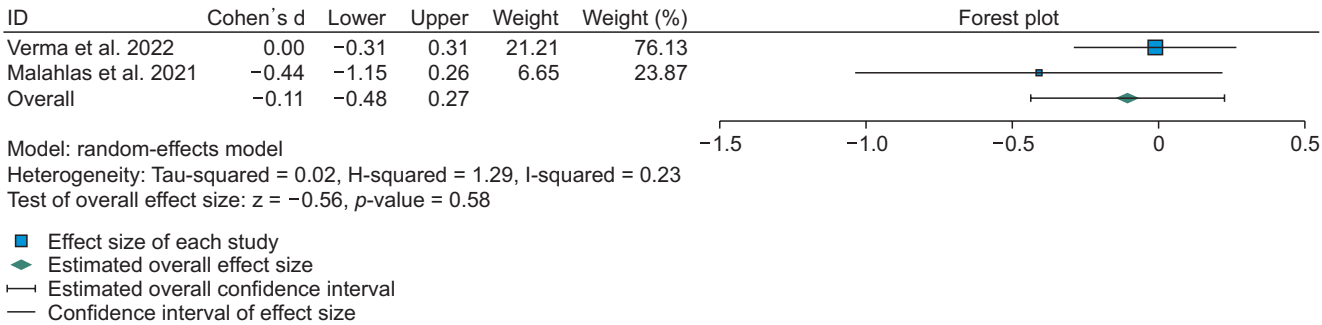

Fig. 4. Forest plot showing the delta visual analog scale in InSpace balloon and other treatment groups for massive irreparable rotator cuff tear repair.

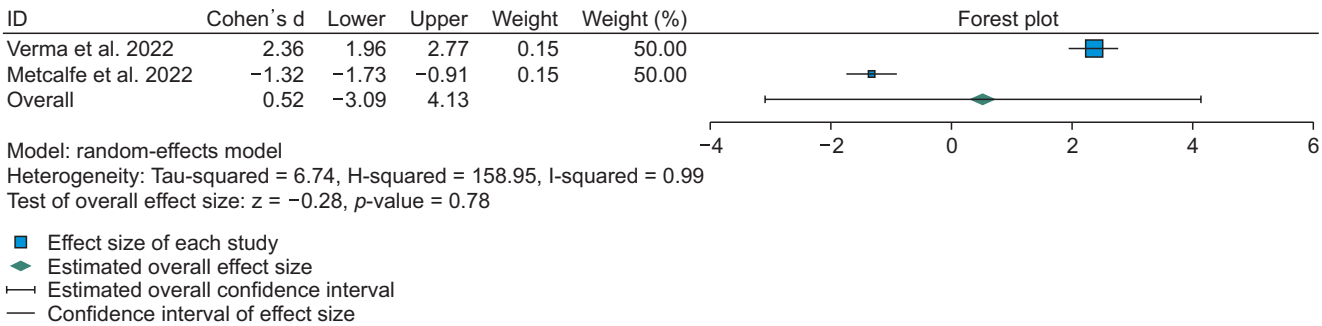

Fig. 5. Forest plot showing the delta EuroQol-5 Dimensions-5-Level in InSpace balloon and other treatment groups for massive irreparable rotator cuff tear repair.

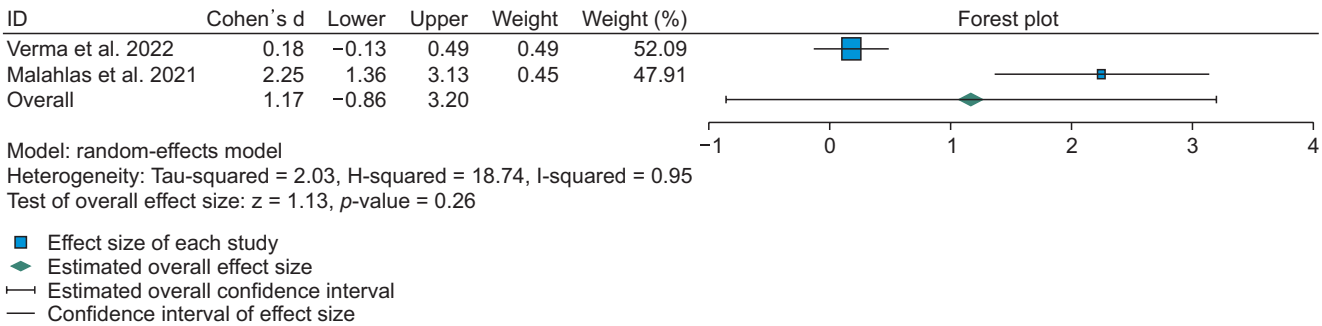

Fig. 6. Forest plot showing the delta American Shoulder and Elbow Surgeons score in InSpace balloon and other treatment groups for massive irreparable rotator cuff tear repair.

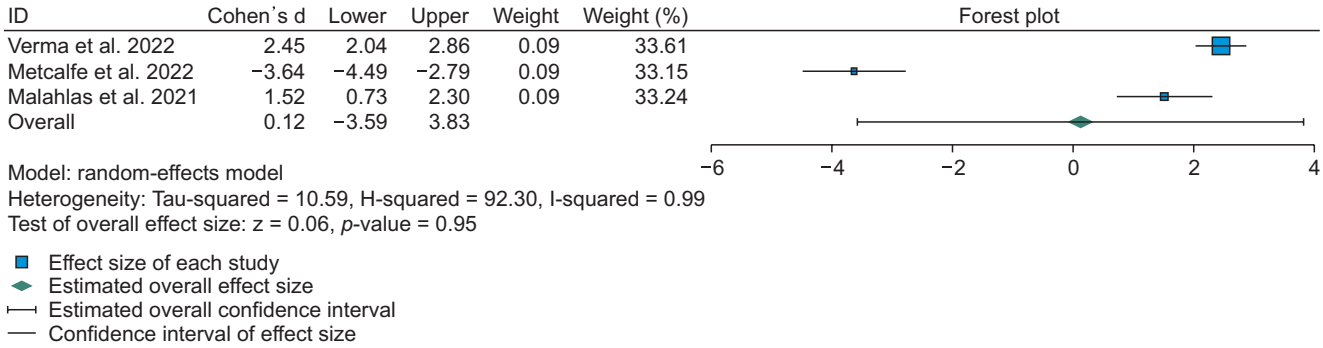

Fig. 7. Forest plot showing the delta Constant score in InSpace balloon and other treatment groups for massive irreparable rotator cuff tear repair.

both in ASES score (mean difference, 1.17; 95% CI, –0.86 to 3.2) (Fig. 6) and CS (mean difference, 0.12; 95% CI, –3.6 to 3.8) (Fig. 7).

DISCUSSION

Varied results were found when considering the use of ISB in patients with MIRCTs. The efficacy of this device is explained by the subacromial decompression that it creates, reducing rotator cuff contact pressure as well as preserving the function of the arch, ultimately decreasing subacromial friction during shoulder abduction.[13] The studies in favor of its use reported efficacy that was similar to other management techniques such as debridement with subacromial decompression and acromioplasty, debridement and bursectomy, and arthroscopic transfer of the latissimus dorsi.[24-26] However, the advantage of this technique is that it is a minimally invasive procedure with a short operative time that can be done with local anesthesia and it is proposed to be an easy procedure.[13,14,27] The main objectives of this device are to reduce pain and restore function of the joint. Most of the reviewed studies were in favor of the latter. The improvement in pain and shoulder function has been shown to start at an early postoperative stage and lasts 5 years, if not even longer.[17] Improvement after ISB degradation was noted.[11,14] This may be the result of the scar tissue formation or the improved muscle patterning of the force couple between the external and internal rotators, which itself is a result of the humeral head recentralization.[11] The improvements were not influenced by the severity of the disease, the age at time of surgery,[17] or whether there was an associated procedure involving the long head of the biceps such as tenotomy or tenodesis.[22] However, patients older than 65 years had higher ASES scores and were more inclined to repeat the procedure.[22] Patients that had an associated subscapularis repair achieved higher ASES scores but were less inclined to undergo the procedure another time, which may be explained by the pain following the repair and the long postoperative protocol.[22] Furthermore, patients with a body mass index greater than 25 had higher subjective shoulder value scores.[22] This finding was attributed to the assumption that higher BMI patients might have lower demands from their shoulder, making them less dissatisfied with the final outcome.[22] Metcalfe et al.[15] showed that results were worse in women, possibly due to mechanical factors such as deltoid size and strength, or biological factors such as host response to the ISB material. More studies are needed to confirm such findings. Furthermore, the analysis of the postoperative VAS and EQ-5D-5L in this meta-analysis resulted in no statistically significant differences between the ISB group and other treatment groups. Nevertheless, this is most probably due to the lack of studies comparing these two techniques. When considering the cost-effectiveness of ISB implantation, the device was compared to conservative treatment, rotator cuff repair, and reverse shoulder arthroplasty.[28,29] Although conservative treatment was the least costly, the InSpace device showed the most benefit for the cost.

There are several theories regarding the mechanism of postoperative relief with the ISB. One suggestion is that the shoulder function and range of motion were improved due to the rehabilitation program and not the ISB.[4,23] However, the device itself can potentially help the patient's pain and function, thus enhancing the rehabilitation progression. This can further increase patient motivation during rehabilitation. Malahias et al.[16] suggested that based on a more recent study comparing arthroscopic partial repair with vs. without ISB implantation, it is the arthroscopic repair and not the balloon that relieves the pain. Conversely, a randomized controlled trial showed that patients with ISB were more likely to have an early recovery based on CS, ASES, WORC, and range of motion when compared to patients who have undergone partial

arthroscopic repair.[14] Furthermore, this study showed that patients in the ISB group were less likely to experience a reduction in their range of motion, with more subjects in the partial repair group having limitation of their range of motion at 2 years of follow-up.[14] This may be explained by a shorter operative time, reduced scarring, absence of bone instrumentation, and decreased postoperative pain allowing early rehabilitation.[14] When the postoperative range of motion, ASES score, and CS were analyzed in this meta-analysis, there was no statistically significant differences between the ISB group and other treatment groups. However, this may also be due to the lack of studies comparing these two techniques.

Concerning the use of ISB in pseudo-paralytic shoulders, two patients suffering from this pseudo-paralysis had poor outcomes.[11] In another study, however, a multivariate analysis showed that pseudo-paralysis was neither the causal factor nor directly associated with poor outcomes.[22] More studies about pseudo-paralytic shoulders and ISB implantation are needed to explain this controversy.

Strengths and Limitations

Admittedly, the strengths of this study are as follows: (1) this is the first systematic review and meta-analysis discussing this subject; (2) we only included comparative studies to increase the power of this meta-analysis; and (3) the selection process was more selective. This makes the study less heterogenous and decreases the risk of bias. However, this study also has limitations: (1) there were not that many trials in the literature to include; (2) inclusion and exclusion criteria for patients were different; (3) the number of included studies was limited; however, they were of good quality and there was less heterogeneity in the type of studies; (4) the data used for analysis were pooled and individual patients' data were unavailable, and this could limit more comprehensive analyses; and (5) the control group did not have the same procedure in the different studies included in the meta-analysis.

Conclusion

There is a controversy about the use of ISB in patients with MIRCTs. Many studies reported good and comparable outcomes to other management techniques, thus concluding ISB implantation is the better management due to the ease and cost-effectiveness of the procedure. The majority of patients had good clinical outcomes across several grading scales, radiographic evidence of improved impingement, and self-report that they would redo the procedure in hindsight. The results of the meta-analysis showed no statistical difference between ISB and other treatment methods. This is most likely due to the lack of comparative studies, resulting in only two studies being analyzed most of the time for each variable. Although the overall consensus of the systematic review seems to support ISB use for MIRCTs, more randomized controlled trials and comparative studies comparing this device to other treatments are needed to make definitive recommendations and guidelines.

CONFLICT OF INTEREST

JAA would like to disclose royalties from a company or supplier: DJO Global, Zimmer-Biomet, Smith and Nephew, Stryker, Globus Medical Inc.

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