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ORIGINAL ARTICLE

Safety and efficacy of hyperosmolar irrigation solution in shoulder arthroscopy

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Background: A hyperosmolar irrigation solution has been reported to be safe and have potential benefits for use during shoulder arthroscopy in an animal model study. In this study, the clinical effects of a hyperosmolar solution were compared with a standard isotonic solution when used for shoulder arthroscopy.
Methods: A prospective, double-blind, randomized controlled trial was performed to compare isotonic (273 mOsm/L) and hyperosmolar (593 mOsm/L) irrigation solutions used for arthroscopic rotator cuff repair. Primary outcomes focused on the amount of periarticular fluid retention based on net weight gain, change in shoulder girth, and pain. All patients were tracked through standard postsurgical follow-up to ensure no additional complications arose. Patients were contacted at 1 year to assess American Shoulder and Elbow Surgeon score, visual analog scale pain score, and the Single Assessment Numeric Evaluation shoulder scores
Results: Fifty patients (n = 25/group) were enrolled and completed the study. No statistically significant differences were noted between cohorts in demographics or surgical variables. The hyperosmolar group experienced significantly less mean weight gain (1.6 ± 0.82 kg vs. 2.25 ± 0.77 kg; $P = .005$), significantly less change in shoulder girth ($P < .05$), and a significantly lower immediate postoperative visual analog scale pain score ($P = .036$). At 1 year postoperatively, the differences between groups for American Shoulder and Elbow Surgeons, visual analog scale pain, and Single Assessment Numeric Evaluation were not significant ($P > .2$).
Conclusion: A hyperosmolar irrigation solution provides a safe and effective way to decrease periarticular fluid retention associated with arthroscopic rotator cuff surgery without any adverse long-term effects. Use of a hyperosmolar irrigation solution for shoulder arthroscopy has potential clinical benefits to surgeons and patients.
Level of evidence: Level I; Randomized Controlled Trial; Treatment Study

Keywords: Shoulder arthroscopy; irrigation solution; rotator cuff; hyperosmolar; cartilage; fluid extravasation

Surgeons use arthroscopic techniques to minimize complications while maximizing recovery and outcomes. Continuous irrigation is used during arthroscopic procedures to distend the joint and provide clear visualization. During the past few decades, various alterations to

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arthroscopic irrigation solution, including type, pH, temperature, and osmolarity, have been assessed for safety and efficacy. Currently, an isotonic solution, such as normal saline or lactated Ringer's at room temperature, is commonly used because each has been reported safe for joint irrigation during arthroscopy.[3,6,25,29] Although rare, surgical complications have been documented in shoulder arthroscopy from excess fluid irrigation.[20] Our research has focused on modifying the irrigation fluid used during arthroscopy to ameliorate excessive fluid extravasation into periarticular shoulder tissues.

Arthroscopic irrigation fluid can be delivered by gravity flow or pressurization. Recommendations are for fluid pressure to be maintained at ≤49 mm Hg below systolic blood pressure to safely preserve the clarity of view.[22] Fluid flow and pressurization maintained during lengthy arthroscopic procedures may cause substantial extravasation and retention of irrigation fluid into the periarticular tissues. Lo et al[17] reported an astonishing net weight gain of 3.95 ± 1.77 kg in patients after shoulder arthroscopy. Numerous studies delineate technical difficulties and complications associated with fluid extravasation and retention, such as the inability to complete the procedure as intended, tracheal obstruction, postoperative airway edema, and compromises that lead to prolonged intubation, excess weight gain, neurologic injuries, skin necrosis, and fluid overload.[5,10,13-19,21-24,26-29,31] In addition, fluid accumulated in the periarticular tissues during the operation is released back into the systemic circulation,[23] which may have implications for elderly patients and those with comorbidities such as cardiac and renal dysfunction.

Although decreasing irrigation fluid pressure and volume and minimizing length of surgery may help minimize irrigation fluid extravasation and retention, these are not always practical for successful shoulder arthroscopy outcomes. We therefore sought to investigate other irrigation fluid variables that could be consistently controlled in shoulder arthroscopy with the potential for minimizing these problems. Use of a hyperosmolar irrigation fluid has this potential.

To use a hyperosmolar irrigation fluid for shoulder arthroscopy, it must be proven safe. Several studies have shown evidence to suggest that a decrease in the extracellular osmolarity, or hypo-osmolarity, may accentuate chondrocyte death after mechanical insult to the articular cartilage.[1,4,7,8] In contrast, Amin et al[2] reported chondroprotective effects of hyperosmolar arthroscopic irrigation solutions in the metacarpophalangeal joints of cows. Furthermore, an in vivo model created by Eltawil et al[12] found that hyperosmotic saline significantly reduced chondrocyte death associated with scalpel-induced injury and enhanced cartilage repair compared with normal saline.

More recently, data from a translational canine model suggested that doubling the osmolarity of normal saline was not associated with any detrimental effects on chondrocyte viability, extracellular matrix, or tissue water content of humeral or glenoid cartilage after 2 hours of arthroscopic shoulder irrigation.[9] In addition to providing important safety data, the canine shoulder arthroscopy study provided initial evidence for potential clinical benefit with respect to less fluid extravasation and retention in the hyperosmolar group compared with the normal saline group.

Based on preclinical safety and efficacy data, a prospective randomized clinical trial was designed to evaluate the effects of a hyperosmolar irrigation solution used during arthroscopic rotator cuff repair. The study hypotheses were that a hyperosmolar irrigation solution used for shoulder arthroscopy (1) would be associated with significantly less fluid extravasation, creating a significantly less weight gain and change to shoulder girth compared with lactated Ringer's solution, and (2) would show noninferiority to lactated Ringer's solution with respect to adverse events, postoperative pain scores, and 1-year patient-reported outcomes.

Materials and methods

A prospective, double-blind, randomized, controlled study was implemented. A prestudy power analysis based on previous data[17,30] determined a sample size of 50 patients (25 per group) should be included to reach the desired power of ≥0.8 using weight gain as the primary outcome measure. Patients scheduled for shoulder arthroscopy—to include inspection of the glenohumeral joint and subacromial space with rotator cuff repair based on clinical examination and diagnostic imaging findings—were enrolled in the study with documented informed consent. Patients undergoing concomitant biceps tenotomy or tenodesis were also included. The study excluded patients who were aged younger than 18 years, pregnant, or mentally disabled and those undergoing labral repair, capsular release, or distal clavicle excision.

Enrolled patients were randomized to a treatment group immediately before surgery by the draw of a sealed envelope by the circulating nurse in the operating room. The designated irrigation solution was denoted in the envelope, with equal numbers for each fluid type. Patients assigned to group 1, the standard-of-care control, received lactated Ringer's solution (273 mOsm/L; APP Pharmaceuticals, LLC, Schaumburg, IL, USA) in 3-L bags for arthroscopic irrigation for their procedure. Patients assigned to group 2 received a hyperosmolar solution (593 mOsm/L) for arthroscopic irrigation for their procedure. This solution was created by adding 120 mL of 23.4% saline (APP Pharmaceuticals) to a 3-L bag of lactated Ringer's solution. The bags used were identical in appearance. Epinephrine, at a concentration of 1 mg/L, was added to both irrigation solutions. The patients and participating surgeons remained blinded to type of irrigation solution used. Only the circulating nurse and research personnel were aware of group assignment.

Arthroscopic surgery

All operations were performed by 1 of 2 fellowship-trained orthopedic surgeons at a university-based tertiary referral center as same-day procedures. Patients were given an interscalene block by the anesthesiologist in the preoperative holding area. After induction of general anesthesia, patients were placed in the standard beach chair position, prepared, and draped for aseptic surgery of the affected shoulder with the extremity in an adjustable arm holder.

Diagnostic arthroscopy of the glenohumeral joint and subacromial space was performed using a 4-mm 30° arthroscope through