Florence, 2/11/2026

PREOPERATIVE AND POSTOPERATIVE USE OF CRYOTHERAPY IN ARTHROSCOPIC ROTATOR CUFF REPAIR: A CASE-CONTROL STUDY

STUDY PROTOCOL

A case-control design was utilized to examine patients undergoing arthroscopic rotator cuff repair at our institution. The study was conducted in accordance with the Declaration of Helsinki, Good Clinical Practices (GCP), and ISO 14155. Patient enrollment began after approval by the Regional Ethics Committee for Clinical Trials of the Tuscany Region on February 1st, 2023 (approval code: 21593_spe).

From April 2023 to April 2024 fifty patients undergoing arthroscopic rotator cuff repair received cryotherapy both preoperatively and postoperatively using a continuous cryotherapy device equipped with a recirculation system (DonJoy® IceMan® CLEAR^3), which delivers consistent cold therapy. These patients were compared to a control group of forty three patients who received standard postoperative cryotherapy with ice bags.

All procedures in both the case and control groups were consistently performed by the same surgeons, with extensive experience in shoulder surgery, ensuring uniformity in surgical technique

Inclusion criteria

Patients included in the study were required to meet the following criteria: age of 18 years or older, provision of signed and dated informed consent, and the presence of a surgically repairable rotator cuff tear. The diagnosis had to be confirmed through ultrasound and magnetic resonance imaging (MRI), along with positive findings in preoperative clinical tests.

Exclusion criteria

Exclusion criteria included individuals younger than 18 years of age and those who did not provide a signed and dated informed consent. Patients were also excluded if they had previously undergone surgery on the ipsilateral shoulder or had a recurrent rotator cuff tear. Additional exclusion criteria included the presence of associated glenohumeral instability or glenohumeral osteoarthritis related to a rotator cuff tear classified as greater than Grade 2 according to the Hamada classification.

Furthermore, patients with specific comorbidities were excluded from the study. These included vasospastic disorders such as Raynaud's syndrome, metabolic and vascular conditions including diabetes, cryoglobulinemia, and arteriosclerosis, as well as coagulation disorders. Local infections, impaired vascularization, and cold-related disorders, such as

cold hypersensitivity and paroxysmal cold hemoglobinuria, were also considered contraindications to inclusion in the study.

Patients were enrolled at the time of the pre-hospitalization outpatient clinical evaluation, during which all orthopedic documentations and the patient's clinical conditions were reassessed as well as anesthetic risk evaluation. Surgical consent form was acquired in the same setting.

Each patient in a consecutive series was assigned with a randomized progressive number. Allocation to the experimental arm of the study (patients undergoing cryotherapy) or the control group (patients receiving standard treatment) was carried out using Microsoft Excel's "RAND()" function (Figure 1).

Cryotherapy Protocol and Pain Management

The IceMan ClearCube/CLEAR3 device was applied 40 minutes before shoulder surgery and removed at the beginning of the sterile surgical field preparation. Rotator cuff repair was performed arthroscopically, with the patient positioned in the beach chair position under brachial plexus block anesthesia combined with deep sedation. At the end of the procedure the cryotherapy device was repositioned and reactivated with the patient in an arm sling.

Patients were provided with the device for home use and instructed to continue its application until the first follow-up visit, scheduled 20 days postoperatively. The recommended use of the device was 20 minutes, three times per day. Control group patients used a traditional ice pack for the same duration and frequency.

Perioperative Pain Management

All patients, regardless of group allocation, received multimodal analgesia according to the standard perioperative protocol. This included paracetamol 1000mg up to three times a day and a combination of dexketoprofen 75mg and tramadol 25mg every 12 hours in case of pain the first week postoperatively.

Additionally, patients in both groups were provided with a clinical diary to record the number of analgesic doses taken daily during the first postoperative week.

Study Endpoints

The **primary endpoint** of the study includes:

- **Assessment of pain levels**, measured using the Visual Analogue Scale (VAS) (scale 0 to 10) at predefined time points following arthroscopic rotator cuff repair.

The **secondary endpoints** include:

- Analgesic consumption, **assessed as the mean number of daily pain medication administrations during the first postoperative week**.
- **Assessment of functionality of the shoulder**: measured using the Constant-Murley Score (CMS) at 90 days.
- **Intraoperative visualization quality**, evaluated subjectively by the operating surgeon using a VAS for *surgical field visual clarity* (scale 0 to 3) with the hypothesis that preoperative cryotherapy device application may reduce synovial perfusion and intraoperative bleeding compared to preoperative standard ice bag application.
- **Surgical duration:** mean operative time (minutes), adjusted for the number of implanted anchors

Safety endpoint:

- **Incidence of adverse events** related to cryotherapy, including skin reactions or delayed wound healing.

Measured Variables

Pain and Functional Assessment

i. Patient-reported Visual Analogue Scale (VAS) for pain: Patients rated their pain on a scale from 0 (no pain) to 10 (worst pain possible). This assessment was carried out by the patients at multiple time-points: preoperatively (VAS 0), at 20 days (VAS 20) and 90 days (VAS 90) follow-up visits.

ii. Functional assessment: Functional recovery was evaluated using the CMS recorded at 90 days of follow-up.

Surgical Outcomes

- Surgeon-reported VAS for *surgical field visual clarity*: The operating surgeon assessed the visual clarity of the surgical field in relation to intraoperative bleeding using a three-point scale, where 1 indicates poor visibility and 3 indicates excellent visibility. [11]. This evaluation was associated with the recording of the systolic/diastolic blood pressure of the patient and the pressure of the arthroscopic pump every 15 minutes throughout the surgical procedure. Postoperative bleeding is expected to be negligible in most patients, except in case of adverse event.

- Surgical duration: The mean operative time expressed in minutes, adjusted for the number of implanted anchors, was compared between the study group and the control group.

STATISTICAL ANALYSIS

Descriptive statistics were calculated for all variables. The Shapiro-Wilk test was used to assess normality. Wilcoxon rank-sum tests evaluated group differences in VAS scores and painkiller consumption. A repeated-measures ANOVA (corrected for sphericity with Greenhouse-Geisser adjustments) assessed the impact of time on VAS scores, with an additional model adjusted for age. Statistical analysis was performed by an independent statistician, using SPSS 8.0 for Windows.