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PERIOPERATIVE INTRAVENOUS ADMINISTRATION OF CORTICOSTEROIDS TO IMPROVE THE OUTCOME OF TOTAL SHOULDER ARTHROPLASTY: STUDY PROTOCOL OF A TRIPLE-BLIND RANDOMIZED CONTROLLED TRIAL

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ABSTRACT – ***Objective:*** Total shoulder arthroplasty (TSA) is among the most frequently performed orthopedic procedures, yet effective postoperative pain management remains crucial. Perioperative administration of corticosteroids (CS) has been proposed to alleviate postoperative pain, reduce nausea incidence, enhance early joint mobility, and attenuate the inflammatory response, potentially shortening hospital stays and accelerating recovery without increasing complication rates. Nonetheless, robust, high-quality evidence is still required to confirm the safety and long-term efficacy of perioperative CS use.

Methods and Analysis: A triple-blinded randomized controlled trial was developed to assess the impact of intravenous perioperative CS administration in patients undergoing TSA, with follow-up extending to 10 years post-surgery. Participants will be randomly assigned (1:1) to receive either CS in addition to standard perioperative analgesia (treatment group) or standard analgesia alone (control group). The primary outcome is the mean daily postoperative pain at rest during the first three days after surgery, quantified with the 0-10 numeric rating scale (NRS). We hypothesize that intravenous CS will provide superior pain relief than control. Secondary endpoints include safety profile in terms of adverse events, length of hospital stay, postoperative nausea, opioid consumption, inflammatory markers, blood glucose levels, range of shoulder motion, time to mobilization, and changes in patient-reported outcome measures (PROMs) over time.

Ethics and Dissemination: The study protocol was approved by the Cantonal Ethical Committee of Ticino, Bellinzona, Switzerland. Written informed consent will be obtained from all participants prior to enrolment. Findings will be shared through conference presentations and publication in peer-reviewed journals.

Conclusions: This trial will provide important evidence on the role of perioperative CS in TSA, assessing both safety and efficacy. The results will clarify whether the benefits of CS extend beyond immediate postoperative pain relief, potentially offering sustained improvements for patients following TSA.

Protocol Version: Version 4.0 (10 December 2024).

Trial Registration Number: NCT04507412 , ClinicalTrials.gov.

KEYWORDS: Arthroplasty, Corticosteroids, Shoulder, Injection, Protocol, RCT.

INTRODUCTION

Total shoulder arthroplasty (TSA) has been performed at a rapidly increasing rate in recent years[1,2], with arthroplasty registers showing a 5-fold increase in operations compared with a decade earlier[3]. Shoulder prosthetic surgical techniques and implant designs are improving, and the applications have been expanding since the introduction of the reverse total shoulder procedure[4-6]. As the popularity of shoulder arthroplasty procedures is increasing, they are also placing a growing strain on healthcare systems, both through the rising number of patients treated and the associated economic costs[7]. In recent years, considerable efforts have focused on minimizing patient discomfort and accelerating postoperative recovery, with the ultimate goal of shortening hospital stays and reducing the overall cost of TSA[1].

Effective postoperative pain management is essential for accelerating recovery and mobilization, thereby reducing the length of hospitalization[2,3]. Post-operative pain management often depends on opioid use; however, their side effects and negative influence on recovery[5,6] have driven the search for alternative strategies[8]. In this context, corticosteroid (CS) supplementation has been shown to effectively reduce pain and, consequently, postoperative opioid consumption after arthroplasty[9,10]. Additional reported benefits include a lower incidence of nausea and vomiting, improved postoperative range of motion, and a reduced systemic inflammatory response[9]. Collectively, these advantages can contribute to shorter hospital stays without increasing the risk of complications, such as local infections or hyperglycemia-related issues[10]. For example, a recent meta-analysis[9] in patients undergoing total knee arthroplasty (TKA) confirmed the effectiveness of CS in alleviating postoperative pain without raising infection risk.

Despite these favorable results and the growing evidence supporting perioperative CS supplementation, the findings reported for TKA may not be directly transferable to TSA, and there remains a lack of high-level evidence from randomized controlled trials (RCTs) providing robust data on CS efficacy in patients undergoing this type of procedure. Research involving perioperative pain management for TSA requires further exploration with a high-level study design and evidence in order to optimize the recovery after this common procedure. Additionally, the impact of perioperative CS supplementation on long-term outcomes remains underexplored. Addressing this gap is crucial, as the intensity of acute postoperative pain has been linked to the risk of developing chronic postoperative pain[11,12]. In this light, the benefits of CS perioperative administration could extend beyond short-term pain relief, offering long-term advantages for patients undergoing TSA.

Study Aim and Trial Design

A triple-blinded RCT was developed to assess the effectiveness of perioperative systemic intravenous CS supplementation (treatment group) in TSA patients, both in the immediate postoperative period and over a 10-year follow-up, compared with the routine perioperative analgesia protocol without CS supplementation (control group). The trial uses a 1:1 allocation ratio. The primary objective is to determine the clinical benefits and safety of CS supplementation, with the hypothesis that it offers superior pain relief in TSA patients. Secondary outcomes encompass hospital length of stay, postoperative nausea, opioid use, inflammatory response, blood glucose levels, shoulder range of motion, time to shoulder mobilization, patient satisfaction, and longitudinal evaluation of patient-reported outcome measures (PROMs), as well as possible adverse events (AEs) related to the procedure.

METHODS AND ANALYSIS

This study is a triple-blind RCT with a study protocol designed according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting guidelines[13]. Trial registration number: NCT04507412.

Eligibility Criteria

Inclusion criteria:

- Patients scheduled for primary unilateral TSA
- Age 50 to 85 years old
- Body mass index 18.5 - 35 kg/m^2
- Patients willing to sign the informed consent form
- Written informed consent obtained

Exclusion criteria:

- Contraindications to CS or non-steroidal anti-inflammatory drugs (NSAIDs)
- Revision TSA
- Concomitant CS treatment
- Pregnant or breastfeeding women
- Other clinically relevant pathological conditions (ASA IV)
- Uncontrolled diabetes mellitus
- Known or suspected non-compliance, alcohol or drug abuse
- Inability to adhere to study procedures (e.g., due to language barriers, psychological conditions, dementia, etc.)
- Participation in another investigational drug study within 30 days prior to or during the current study
- Previous participation in this study
- Enrolment of the investigators, their family members, employees, or other dependent individuals

Interventions

All patients undergo TSA performed by experienced, shoulder-specialized orthopedic surgeons. Perioperative CS are given intravenously as a bolus prior to anesthesia induction. To reduce potential confounding factors, all patients receive the same standardized anesthesia induction protocol. The anesthesiologist prepares the injection syringe according to the patient's randomization group. For those allocated to CS administration, a 50 mL syringe containing 9 mg of dexamethasone is prepared. The commercial product used contains 4 mg of dexamethasone sodium phosphate per mL (equivalent to 3 mg of dexamethasone per mL). Accordingly, 3 mL of commercial product solution (corresponding to 9 mg of dexamethasone) is combined with 47 mL of 0.9% saline (NaCl) to yield a total volume of 50 mL for injection. Conversely, for those randomized to no CS supplementation, the anesthesiologist prepares a 50 mL syringe containing only saline solution (NaCl 0.9%). The surgeon remains blinded as they are not involved in the injection process, which is carried out by the anesthesiologist prior to anesthesia induction. Both syringe preparations are visually indistinguishable, ensuring concealment of group allocation. To minimize confounding factors, all patients follow a standardized postoperative analgesia regimen consisting of 1 g paracetamol four times daily, ibuprofen 400 mg three times daily, and, if required, subcutaneous morphine 5 mg up to six times daily. Postoperative CS administration is avoided. Patients are typically discharged three to five days after TSA implantation, depending on their clinical condition. Thromboprophylaxis and analgesics as needed are prescribed for the first six postoperative weeks.

Outcomes

The primary outcome of this RCT is the mean daily postoperative pain at rest during the first three days after surgery, quantified with the 0-10 numeric rating scale (NRS). This is a validated self-assessment tool consisting of an 11-point numeric scale, with 10 reflecting the worst possible pain and 0 indicating no pain[14-16].

The secondary outcomes are:

- Pain outcomes:
  - Post-operative shoulder 0-10 NRS pain at 3, 6, 12, 24, 60 and 120 months
  - PainDETECT at 6, 12, 24, 60, and 120 months: PainDETECT is a self-administered questionnaire comprising seven items assessing the quality of pain symptoms, without the need for a physical examination. A score of ≤12 suggests that a neuropathic pain component is unlikely (<15%), a score of ≥19 indicates a high likelihood of neuropathic pain (>90%), and an intermediate score (13-18) suggests a possible neuropathic component[17]. Although validated in spinal conditions and already applied in shoulder studies to investigate pain characteristics, its use in TSA is exploratory to assess potential neuropathic components of persistent postoperative pain[18].
- Functional outcomes:
  - Post-operative shoulder 0-10 NRS function in the first three postoperative days and at 3, 6, 12, 24, 60 and 120 months
  - Constant-Murley Score (CMS) at 2 and 6 weeks, and at 3, 6, 12, 24, 60 and 120 months. The CMS questionnaire consists of 8 questions (for a total score of 0-100, with 100 being the best score) evaluating pain, activity level, and range of motion. It is a reliable and validated score that can quantify shoulder pain and function[19]

  - American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES Score) at 2 and 6 weeks, and at 3, 6, 12, 24, 60, and 120 months. The ASES Score is a patient-reported validated score evaluating pain and function for daily living and leisure activities. A maximum of 100 points means maximum (normal) functionality and no pain[20]
  - Subjective Shoulder Value (SSV) at 2 and 6 weeks, and at 3, 6, 12, 24, 60, and 120 months. The SSV is a percentage of the subjective value of the shoulder given by the patient from 0-100%[21]
- Other outcomes:
  - European Quality of Life-5 Dimensions-3 Level (EQ-5D-3L) at 2 and 6 weeks, and at 3, 6, 12, 24, 60, and 120 months. The EQ-5D-3L is a "Health-Related Quality-of-Life Score" for cost-utility analysis and changes in general health after surgical operations, containing 5 questions with the maximum (best) score being 1[22]
  - Patient 0-10 NRS satisfaction at 2 and 6 weeks, and at 3, 6, 12, 24, 60, and 120 months
  - Post-operative nausea in the first post-operative days: both intensity and incidence are assessed (on a 0-10 NRS)[14]
  - Post-operative opioids and analgesics consumption: analgesic use is assessed using the Medication Quantification Scale (MQS), which is calculated for each drug by multiplying a consensus-based detriment weight for its pharmacological class by a dosage score. The values for all medications are then summed to obtain the total MQS score[23,24]
  - Postoperative inflammatory response: measured by hematic C-reactive protein (CRP) levels and erythrocyte sedimentation rate (ESR), recorded preoperatively and daily for the first three postoperative days, based on medical chart review
  - Time surgery-to-first mobilization: early mobilization is a key determinant of hospital stay duration; however, postoperative pain and other symptoms may prevent mobilization within the first postoperative day[25]
  - Rate of frozen shoulders: this is considered a complication occurring in up to 11% and is induced by postoperative inflammatory processes that can lead to adhesive capsulitis[26]. CS administration could lead to a decreased rate of incidence of this complication by decreasing postoperative inflammation
  - Hospital length of stay

Recruitment

Patients are recruited in the outpatient clinics of the Ente Ospedaliero Cantonale by trained members of the orthopedic surgery team in the Department of Orthopedics and Traumatology. Enrollment takes place after eligibility criteria are verified, following the scheduling of a TSA by a shoulder specialist. Study procedures are thoroughly explained to the patient, including the planned 10-year duration of the study follow-up, to minimize attrition. The patient then provides voluntary consent by signing the informed consent form (ICF).

Participant Timeline

After the ICF signature, the patient and surgeon fill in the planned questionnaires. Follow-up evaluations are conducted on the first three postoperative days, at discharge, and then at 2 weeks, 6 weeks, 3 and 6 months, and 1, 2, 5, and 10 years after surgery. The follow-ups include a physical examination, completion of questionnaires and outcomes assessment as previously described. To mitigate the risk of attrition, particularly over long-term follow-up, we will maintain regular patient contact with reminders and flexible follow-up scheduling, using multiple communication methods (phone, mail, and electronic communication). Table 1 outlines the detailed participant timeline.

Table 1. Participant timeline.

Study Periods	Screening	Surgery	Discharge	Follow-ups							
Visit	V0	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10
Time	≥ 2 w before V1	0	5 d ± 2 d	2 w ± 2 d	6 w ± 1 w	3 m ± 1 w	6 m ± 2 w	1 y ± 1 m	2 y ± 1 m	5 y ± 1 m	10 y ± 1 m
Informed Consent Form	x										
Demographics	x										
Medical History	x		x	x	x	x	x	x	x	x	x
In-/Exclusion criteria	x										
Physical examination	x		x	x	x	x	x	x	x	x	x
Abduction force	x		x	x	x	x	x	x	x	x	x
Vital signs	x	x									
Laboratory tests	x										
Pregnancy test	x										
X-ray examination	x		x		x	x					
Shoulder ROM	x		x	x	x	x	x	x	x	x	x
NRS 0-10 pain	x	x	x	x	x	x	x	x	x		
NRS 0-10 function	x		x	x	x	x	x	x	x		
CMS	x			x	x	x	x	x	x	x	x
ASES Score	x			x	x	x	x	x	x	x	x
SSV	x			x	x	x	x	x	x	x	x
EQ-5D-3L	x			x	x	x	x	x	x	x	x
PainDETECT	x						x	x	x	x	x
Randomisation		x									
CS supplementation		x*									
Surgery		x									
NRS 0-10 nausea		x									
CRP, ESR	x	x									
Glycaemia		x									
MQS Score	x	x	x	x	x	x	x	x			
Time to first mobilization			x								
Length of stay			x								
Patient satisfaction				x	x	x	x	x	x	x	x
Treatment-related AE		x	x	x	x	x	x	x			
SAEs		x	x	x	x						

AE: Adverse Event; ASES Score: American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; CMS: Constant-Murley Score; CRP: C-reactive protein; CS: corticosteroids; d: day; EQ-5D-3L: European Quality of Life-5 Dimensions-3 Level; ESR: erythrocyte sedimentation rate; MQS: Medication Quantification Score; NRS: Numeric Rating Scale; m: month; ROM: range of motion; SAE: Serious Adverse Event; SSV: Subjective Shoulder Value; w: week; y: year; *only if the patient is randomized in the CS supplementation arms.

Blinding

This trial is a triple-blind RCT, with patients, surgeons, and outcome-assessing physicians/researchers blinded to treatment allocation. Only the anesthesiologists responsible for preparing and administering the syringes (with or without CS) during TSA are aware of the allocation; they do not participate in follow-up assessments. Patient blinding is additionally ensured as the intervention does not alter the planned surgical procedure. Unblinding of study personnel will occur only if required to manage adverse events. Otherwise, patients, surgeons, assessors, and all members of the study team will remain blinded. Patients may be informed of their allocation at the conclusion of the trial or in the event of study suspension or early termination.

Allocation

A total of 50 patients are randomly assigned in a 1:1 ratio (25 per group) to receive either perioperative systemic intravenous CS during their TSA surgery or no CS administration. Randomization is based on a computer-generated sequence and is carried out by members of the orthopedic research team responsible for study organization but not involved in any study procedures. The randomization list is password-protected and accessible only to team members with no direct role in the trial.

Adverse Events

AEs are monitored during surgery and at each follow-up visit, during which patients are asked to report any occurrences. All identified AEs are recorded in the patient's case report form (CRF). In accordance with Ethics Committee (EC) guidelines, serious adverse events (SAEs) are defined as events that result in death, are life-threatening, require hospitalization, or necessitate intervention to prevent permanent harm.

Data Collection

Physicians (blinded) record the study data using paper-based CRFs. Afterwards, data are processed and collected into electronic forms. X-rays are stored at the Ente Ospedaliero Cantonale. The study data are stored in a password-protected spreadsheet on a server hosted at the Ente Ospedaliero Cantonale. Access is restricted to authorized research personnel specifically designated for the study.

Statistical Methods

The trial hypothesis is that perioperative intravenous CS supplementation decreases postoperative pain compared to the control group, without increasing (or possibly decreasing) the complication risk. The power analysis was performed assuming a 95% power and 5% probability of type 1 error (α=0.05). Based on earlier cohort studies, a standard deviation (SD) of 1.5 was used. A previously reported minimal clinically important difference (MCID) of 1.4 in postoperative NRS pain score between treatments was considered. Accordingly, 21 patients per group are needed. To compensate for a possible 20% loss to follow-up, 50 patients (25 per group) will be included. Quantitative variables will be presented as means with standard deviations. Differences between the two groups for continuous variables will be assessed using a two-sided *t*-test when data are normally distributed, or the Mann-Whitney U test otherwise. Dichotomous variables will be reported as absolute numbers and percentages, with group differences evaluated using the Chi-square test. Any deviations from the original statistical plan will result in a protocol amendment to be reviewed by the local EC. All modifications will be documented in the final publication report.

Data Monitoring

Designated authorized personnel from the Clinical Trial Unit of the Ente Ospedaliero Cantonale (CTU-EOC), an organization independent from the clinic and carrying out the trial procedures, will be in charge of the monitoring activities. Source and trial documents will be accessible for inspection by competent authorities if required. All parties involved will maintain the confidentiality of participant data.

Handling of Missing Data and Drop-Outs

Missing data will not be replaced. Drop-outs considered not evaluable for the primary outcome will be replaced by new patients. Follow-up losses of 20% are calculated within the number of planned participants so that the outcomes of the study remain statistically significant.

ETHICS AND DISSEMINATION

Research Ethics Approval

Ethical approval was confirmed on 15 September 2020 from the Cantonal EC of Ticino, settled at the Health Office, Via Orico 5, 6501 Bellinzona, Switzerland.

Confidentiality and Access to Data

Data are collected using CRFs and centrally processed at the Department of Orthopedics and Traumatology, Ospedale Regionale di Lugano, Lugano, Switzerland. Paper CRFs are kept in a locked area with restricted access, while electronic data are stored on password-protected servers. Access to patient data is limited to authorized research team members.

Scientific Relevance *and Broader Impact*

This study carries significant scientific value in the field of shoulder surgery and postoperative pain management. By investigating the efficacy of perioperative CS supplementation in TSA through a triple-blinded RCT, this study aims to fill an important gap in the existing literature. Postoperative pain control remains a key challenge in TSA, with major implications for patient recovery, hospital stay duration, and healthcare costs. This research has the potential to provide strong evidence on the effectiveness and safety of this intervention, clarifying whether it can improve postoperative pain relief while reducing opioid use and related side effects. Furthermore, by incorporating a comprehensive range of outcome measures – including PROMs, functional evaluations, and inflammatory markers – this study seeks to offer a holistic view of the impact of perioperative CS supplementation on multiple facets of recovery. The results could help refine surgical protocols, shape clinical practice guidelines, and ultimately enhance outcomes for patients undergoing TSA.

Ethics Approval:

The study was approved on September 15, 2020, by the local Ethics Committee, the Comitato Etico Cantonale (Study Identifier: ORL-ORT-020).

Informed Consent:

All patients will provide informed consent to participate in this study as per the study protocol.

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Authors' Contributions:
All authors contributed to the definition of the study protocol, and will participate in the study execution, from treatment and follow-up to analysis and dissemination.

Conflict of Interest:
The authors declare no conflict of interest.

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No generative AI and AI-assisted technologies were used in the writing process of this manuscript.

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