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Local Anaesthesia Efficacy as Postoperative Analgesia for Open Shoulder Instability Surgery: A Prospective Randomised Controlled Study

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Abstract

Background and objectives: The aim of present study was to evaluate for the first time, the clinical effect of local anaesthetic infiltration as postoperative analgesia in open shoulder surgery for anterior-inferior instability. The comparison of the local infiltration and interscalenic brachial plexus block to a control group test the local anaesthetic efficacy in this surgery.

Methods: 78 patients scheduled for open shoulder surgery were enrolled and randomly assigned to one of three groups: local infiltration anaesthesia (LIA), interscalenic brachial plexus block (IBPB) and control (C). All patients received standardized general anaesthesia and all injections were performed with the same dose and volume of anaesthetic. The number boluses delivered by a PCA pump applied at the end of surgery and the visual analogue score (VAS) at 0, 2, 4, 6, 12, 18 and 24 hours after intervention were recorded. A patient satisfaction score was also assessed.

Results: Mean bolus consumption of the rescue analgesic, compared to C, was significantly less both in the LIA and IBPB groups ($P<0.05$). The IBPB group showed VAS scores that were significantly better than C group at all time points ($P<0.05$). The VAS scores for LIA group were clinically comparable to IBPB, and only at the 2 and 6 hours, postoperative time points there were no significant differences found in respect to the C group. IBPB and LIA showed comparable patient satisfaction scores.

Conclusion: The local anaesthetic infiltration as postoperative analgesia appears to be a clinically valid alternative, statistically comparable to IBPB, with no clinical meaningful adverse effects.

Keywords: Local anaesthesia; Local infiltration analgesia; Open shoulder surgery; Shoulder instability surgery

Introduction

Open shoulder surgery for anterior-inferior instability is a common procedure that may lead to severe postoperative pain. In recent years, various studies have demonstrated the need for valid anaesthetic techniques which allow adequate control of postoperative pain in order to facilitate recovery and favour early mobilization and rehabilitation [1,2]. Moreover, adequate management of postoperative pain continues to be a challenge after ambulatory surgery.

Postoperative pain is usually managed by a variety of methods, including single shot and continuous interscalenic brachial plexus block (IBPB), patient-controlled analgesia (PCA) with opioids, continuous wound infiltration with local anaesthetics [2,3].

IBPB is an effective anaesthetic and analgesic technique for open shoulder surgery that requires skilled personnel. Nonetheless, it can be associated with severe acute adverse effects that are potentially devastating in addition to complications involving the peripheral nervous system [4,5]. These latter events, even if reported to a lesser degree, are evident when large case studies are examined, and can lead to a high level of patient discomfort that may interfere with postoperative assessment and function [3,6,7].

Discordant results have been reported regarding local injection of anaesthetics in the intra-articular region for control of postoperative pain after shoulder surgery [3,8], similar to subacromial injection [5,9,10] and block of the suprascapular nerve [11].

Conflicting results were also highlighted for local anaesthetics directly administrated to the operative site by either continuous infusion or infiltration [12].

Most of the studies in the literature have investigated a continuous local anaesthetic infiltration in arthroscopic shoulder surgery and not in open shoulder surgery and specifically in the antero-inferior shoulder surgery [2,3,5,9,10]. Furthermore, not all have compared the local infiltration anaesthesia and the IBPB with a control group using the same volume and dose of anaesthetic in order to provide rigour to the study and to give the most appropriate clinical evaluations and comparisons.

The purpose of the present controlled, prospective, randomized study is to evaluate for the first time, the postoperative analgesic efficacy of local anaesthetic infiltration and IBPB in open shoulder surgery, compared to the control group (C). We assume that there were no meaningful clinical differences between local infiltration analgesia (LIA) and IBPB.

Methods

The Ethics Committee of the Concordia Hospital approved the

protocol of the study for Special Surgery, Rome, Italy.

A pilot data had demonstrated that the mean of bolus consumption in the 24 postoperative hours was 3.6 ± 1.7, 2.6 ± 1.1 and 4.6 ± 0.9 for LIA, IBPB and C respectively. To detect a clinic difference of 0.8 boluses with a 0.5 SD, it was calculated that 20 subjects for each group to provide a power of 90%, at a type I error rate of 0.05. However, 24 patients in each were enrolled to compensate missing data.

Written informed consent was obtained from each patient. A total of 78 patients scheduled for elective open surgery for antero-inferior shoulder instability were included. Specifically the surgical technique is described as the LaserJet procedure used to address antero-inferior shoulder instability, involves using coracoid transfer to stabilize the shoulder by the static action of the transferred bone block and by the dynamic action of the attached conjoined tendon sling. All patients were classified as ASA I-III, aged 18 year or older. Exclusion criteria were known allergies to drugs utilized in the study, inability to understand instructions, preoperative peripheral neuropathy, and contraindications to regional anaesthesia or history of opioid abuse. Patients were randomly allocated to three groups using a computer-generated list of random permutations. In the IBPB group, block was performed before induction of general anaesthesia by following Winnie's landmarks [13]. A 50 mm, 22-gauge needle (Polimedic), connected to a peripheral nerve stimulator (fine STIM nerve stimulator by Finella Medical, Italy), was introduced into the plexus sheath. Its position was judged adequate when the correct twitch (deltoid contraction) was elicited with a current output of 0.40 mA and 30 ml of levobupivacaine 0.5% (5 mg/ml) containing 1:200.000 epinephrine was injected. The success of the block was assessed before the beginning of surgical intervention using the pinprick test to evaluate the sensory block. Motor function was tested by asking the patient to abduct the arm at the shoulder joint against gravity flex the forearm at the elbow. The block was defined successful as complete loss of pinprick sensation at the skin dermatomes involved in the surgical field (from C4-7) and inability to abduct the arm and flex the forearm against gravity at the shoulder and elbow joints, respectively.

In the LIA group, after a negative aspiration blood test, 20 minutes before skin incision, 30 ml of 0.5% levobupivacaine (5 mg/ml) containing epinephrine 1:200.000 was injected. 15 ml in a multidiretional manner (fanning technique) on the periosteum of the coracoid process and 15 ml equally distributed superficially and on the depth on the deltoid-pectoral line at the site of surgical incision.

In the control (C) group, no nerve block or injections were performed.

The same investigator performed all the regional blocks.

All patients received standard general anaesthesia with intravenous propofol (2-2.5 mg/kg), fentanyl (2 µg/kg) and rocuronium (0.6 mg/kg) for induction and tracheal intubation. Controlled ventilation was started and anaesthesia was maintained with nitrous oxide (60%) and oxygen (40%) associated with continuous infusion of propofol (1-1.5 mg/kg/h). Intravenous ketorolac (30 mg) was also given to all patients during surgery. During the procedure, performed in a beach chair position, non-invasive blood pressure, heart rate, peripheral arterial oxygen saturation, end-tidal CO2 and electrocardiogram, were continuously monitored. After extubation, patients were immediately transferred to a Recovery Room where a patient controlled analgesia (PCA) intravenous pump (Gemstar-Abbott) was applied. The PCA pump was programmed to deliver a 2 µg/kg (in 10 ml of Na Cl 0, 9%, mg/ml) bolus of fentanyl as rescue medication. The lockout time was

30 minutes and the maximal dose was 300 µg in 4 hours. The number of boluses at 2, 4, 6, 12, 18 and 24 hours was evaluated.

Pain was assessed by a blinded observer at using a visual analogue scale (VAS) at 0, 2, 4, 6, 12, 18 and 24 hours postoperatively, where 0 was no pain and 10 was the worst pain. A global satisfaction score, ranging from 0 (not satisfied) to 10 (entirely satisfied), was also assessed at 24 hours after intervention. Nausea and vomiting were specifically recorded in addition to dyspnea, dysphonia and peripheral nervous system complications.

Statistical analysis was performed using the STATISTICA version 6.0 (StatSoft Inc, Tulsa, Oklahoma, USA). The amount of error that we decided to accept to determine the validity of our results was P<0.05 (or 5%). The VAS score was recorded at 0, 2, 4, 6, 12, 18 and 24 hours postoperatively and the area under the curve (AUC) was calculated and used as a suitable summary measure of the average effect for this variable. We also used analysis of variance (ANOVA) for repeated measures for the VAS to follow the variations with time. The number of levels of the between factor was three (control, IBPB and local), whereas the number of levels of the within group factor (i.e. time) was seven for the VAS. The consumption of boluses at the end of the 24 hours period and the degree of satisfaction of patients related to the type of received anaesthesia were evaluated by a one-way ANOVA between groups. We planned two post hoc comparisons (Dunnett's test, P<0.025) between the control group and the other treatment groups.

Results

Seven cases were excluded from the statistical analysis, as they would have notably altered the evaluation of the VAS and the number of boluses during the postoperative period. Four of these cases had bleeding problems that required surgical revision within the first 24 postoperative hours, and the remaining three cases showed bronchospasm after extubation. Three groups were compared: 24 patients in IBPB, 24 patients in LIA and 24 patients in the C group.

Population data were comparable in all the three groups, as demonstrated in table 1.

The ANOVA for repeated measures of the VAS shown a significant effect on the type of anaesthesia ($F_{2,71}=73,023$; P<0.05) and the interaction between the within factor (i.e. time) and the treatment ($F_{12,426}=3,895$; P<0.05). The results of planned post-hoc tests are shown in figure 1. In particular, the IBPB group was always significantly lower than C group during the 24 hours postoperative period, while the LIA group differed from the C group at 0 and 4 hours and then at 12 ,18 and 24 hours. The different treatments were analyzed by the AUC (Table 2). The AUC of the IBPB and LIA groups were similar (51.9 ± 2.8 and 59.6 ± 3.4 respectively; table 2), while they were both significantly different from the C group (112.0 ± 5.4).
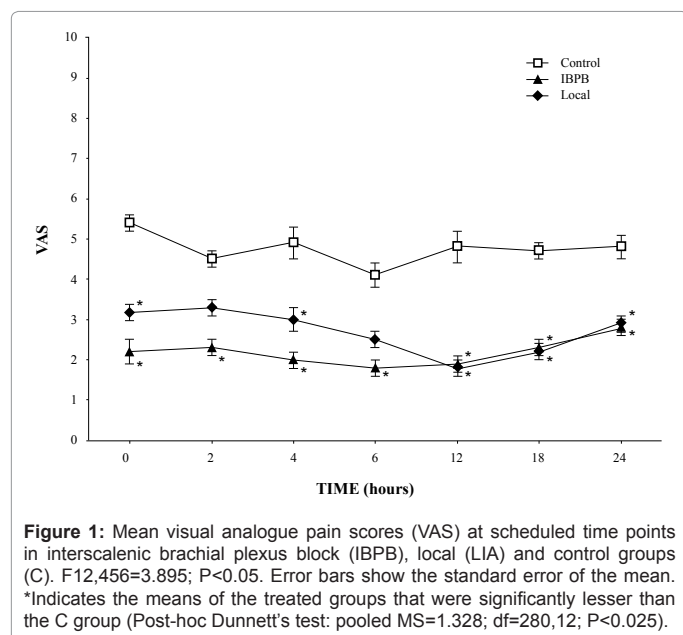
Variable	LA (n = 24)	IBPB (n=24)	C (n=24)
Age (yr)	55 ± 15	52 ± 19	54 ± 19
Weight (kg)	70 ± 15	74 ± 12	72 ± 15
Height (cm)	164 ± 10	165 ± 9	167 ± 10
Gender (male/female)	13/11	14/10	12/12
Surgical time (min)	40 ± 27	39 ± 25	45 ± 25
ASA I/II/III	8/9/7	9/10/5	8/10/6

Results are expressed as mean ± SD.
No statistically significant difference was found between groups.
ASA: American Society of Anaesthesiologists health classification

Table 1: Population data and surgical time in the three groups.

Figure 1: Mean visual analogue pain scores (VAS) at scheduled time points in interscalenic brachial plexus block (IBPB), local (LIA) and control groups (C). F12,456=3.895; P<0.05. Error bars show the standard error of the mean. *Indicates the means of the treated groups that were significantly lesser than the C group (Post-hoc Dunnett's test: pooled MS=1.328; df=280,12; P<0.025).

	AUC score	Bolus consumption	Satisfaction
Control	112,0 (5,4)	4,3 (0,8)	6,3 (1,2)
IBPB	51,9* (2,8)	2,6* (1,5)	8,0* (1,2)
Local	59,6* (3,4)	3,5* (1,5)	7,8* (0,9)

Table 2: Area under the curve (AUC) of the VAS score trends, mean of bolus consumption and patient satisfaction score at 24 hours postoperatively for the three groups. Standard deviation in brackets. *P<0.05 versus control group.

The difference in consumption of boluses at 24 hours between groups was statistically significant by one-way ANOVA ($F_{2,71}$=10, 636; P<0.05), in details the C group consumed more boluses (4.3 ± 0.8) than the IBPB or LIA groups (2.6 ± 1.5 and 3.5 ± 1.5 respectively; table 2).

A similar result was obtained for the patient satisfaction score ($F_{2,71}$=20,103; P<0.05), which was 8.0 ± 1.2 for the IBPB and 7.8 ± 0.9 for the LIA groups, both of which were higher than the satisfaction score of the C group (6.3 ± 1.2). Mean satisfaction score and bolus consumption mean are also shown in table 2.

There were no differences in nausea and vomiting between groups (two for LIA and IBPB and three for C). Three cases of mild dyspnea and two occurrences of dysphonia were observed in the IBPB group.

Discussion

The present prospective, randomized, controlled study provides the opportunity to make several interesting considerations. Not surprisingly, IBPB gave the best results in terms of VAS and need for rescue medication. While it is worth noting the presence of slight dyspnoea and dysphonia in some patients, which could be expected with IBPB, the technique is both efficacious and effective as both an anaesthetic and analgesic for shoulder open antero-inferior instability shoulder surgery.

Local infiltration anaesthesia (LIA) showed an effective postoperative analgesia and should be stressed that at each time interval, the VAS values and the number of analgesic boluses did not show any significant differences between IBPB and LIA. The single local anaesthetic injection effectiveness for open shoulder surgery was previously poorly documented and not well defined [2,8,14], more data even if with discordant results have been reported that however

were more related to the continuous infusion of anaesthetics and arthroscopic setting [5,9,15-17]. Anyhow, a little clinical benefit of local infiltration was evidenced [3].

LIA demonstrated evident positive clinical outcomes, and superiority to those previously studied in shoulder surgery, rather similar to those revealed in total knee arthroplasty [18], where the LIA effectiveness was clearly evidenced [19]. However, it is difficult to directly compare the present results with other studies, for important methodological differences, since to our knowledge this is the first study of local anaesthesia with either control or IBPB groups in open shoulder instability surgery [2,8,10]. In particular, the comparison with a control group in relation with IBPB, the most commonly analgesic technique used in this surgery, using the same dose and volume of anaesthetics, allow improving the analgesic considerations.

It is worth mentioning that the local injection 20 minutes before intervention coupled with the use of long lasting anaesthetics [20-22], together with the addition of epinephrine [11,21], likely contributed to the overall positive results observed and by favouring absorption. As known the infiltration of the surgical site to favour a pre-emptive action, is the central feature of this technique eliminating generation and transmission of pain impulses at A-delta and C-type nerves and therefore nociceptive nerve endings from which they arise, and before central processing complicates matters [19,23]. It is also evident like the infiltration of coracoids periosteum, specifically in this type of surgery, is needed for good analgesic results, allowing guaranteeing the valid anaesthetic coverage of the most part of the anatomic site involved in the surgical procedure together with superficial and deep anaesthetic infiltration of the deltoid-pectoral line [24].

While the outcome measures suggest that IBPB is clearly effective for postoperative analgesia, LIA nonetheless provided adequate overall clinical results that were adequate and statistically comparable to IBPB. Moreover, LIA was associated with a similar high degree of patient satisfaction.

In particular, LIA also showed statistically significant differences in terms of both number of boluses and VAS with respect to the C group, and demonstrated a level of analgesia that was clinically and statistically comparable to IBPB, in terms of VAS, number of boluses and patient satisfaction.

Furthermore, it is important to remember that IBPB is an invasive procedure that may lead to serious complications [3-7] including the common risks associated with peripheral nerve block (nerve damage, local anaesthetic toxicity), risk of pleural puncture and devastating complication as cervical spinal cord damage and permanent paralysis and it should be performed by practitioners with appropriate experience.

The small studies on a limited number of patients that investigating the LIA technique proposed by the literature, have not reported any instances of local anaesthetic systemic toxicity despite the infiltration of large doses of local anaesthetic. Myotoxicity, in form of myopathy, has been described as the only rare side effect of local anaesthetic application [23].

In conclusion, while IBPB can be considered valid, it requires skilled personnel and may be associated with acute adverse effects and complications involving the peripheral nervous system [25,26]. LA injection appears to represent a novel, simple, clinically and statistically valid alternative for control of postoperative pain after open shoulder

surgery for anterior inferior instability that merits further investigation and attention.

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