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ORIGINAL ARTICLE

Adjuvant dexamethasone with bupivacaine prolongs the duration of interscalene block: a prospective randomized trial

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Abstract
Purpose To identify the effects of adding two different doses of dexamethasone on the duration and quality of interscalene block in patients undergoing shoulder surgery in ambulatory surgery settings.
Methods The study design was reviewed and approved by the University at Buffalo Institutional Review Board for Human Subjects. After obtaining informed consent, a total of 90 patients undergoing shoulder surgery using interscalene block with 0.5% bupivacaine (40 mL) were assigned randomly to one of three groups: control patients, "Group C," who received no additive; low dose, "Group L," who received additional dexamethasone 4 mg; and high dose, "Group H," who received dexamethasone 8 mg in addition to 0.5% bupivacaine. Postoperative analgesia was assessed using the numeric rating scores of pain and the postoperative consumption of acetaminophen 325 mg + hydrocodone 7.5 mg tablets. Analysis was by intention to treat. Statistical significance was tested using a two-way analysis of variance and a nonparametric analysis of variance for consumption of analgesics.
Results Four patients were excluded from the study due to either a failed block or inadequate follow-up. The duration of analgesia was significantly prolonged in both Group L (21.6 ± 2.4 h) and Group H (25.2 ± 1.9 h) compared with Group C (13.3 ± 1.0 h) ($p < 0.05$). Similarly, the duration of motor block was longer in both Group L (36.7 ± 4.1 h), and Group H (39.2 ± 3.9 h) compared to Group C (24.6 ± 3.3 h) ($p < 0.05$). Postoperative analgesic consumption for the first 48 h was significantly lower in Group L (6.5 [4–8] tabs) and in Group H (5.5 [4–7] tabs) vs. 9.5 [8–12] tabs in Group C ($p < 0.01$). There were no adverse events related to dexamethasone during the 4-week follow-up period.
Conclusion The addition of dexamethasone to bupivacaine significantly prolonged the duration of the motor block and improved the quality of analgesia following interscalene block. There was no difference in the duration of analgesia and motor block between low-dose and high-dose dexamethasone.

Keywords Pain · Surgery · Interscalene block · Steroids · Local anesthesia

Introduction

Postoperative pain management is an important component of perioperative care, and one that—if inadequate—can lead to postoperative stress and chronic pain syndromes. Opioids are associated with increased incidence of nausea and constipation, which may be prohibitive in a significant number of patients [1, 2]. Peripheral nerve block is used commonly in clinical practices due to its simplicity and higher margin of safety. Regional plexus block can provide effective postoperative analgesia with minimal gastrointestinal side effects compared to opioid-based analgesia. However, the duration of analgesia after a single injection nerve block is not sufficient for a comfortable transition to oral analgesics [3]. Continuous peripheral nerve blocks have been used to provide a period of extended analgesia.

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These techniques have generally failed to gain popularity in outpatient settings due to a higher incidence of catheter migration, anesthetic leakage, pump malfunction, and the utilization of health care personnel for follow-ups [4, 5].

Several additives have been trialed to prolong the duration of single-injection peripheral nerve blocks and analgesia by inducing local vasoconstriction and delaying the diffusion of local anesthetic away from the site of injection [3, 6]. Epinephrine is the agent added most often to the local anesthetics. Addition of long-acting glucocorticoid steroids (e.g., triamcinolone and methylprednisone) to local anesthetics is used routinely to treat chronic pain syndromes [7]. The beneficial effect of steroids in postoperative pain relief has been described, although the type of steroid and route of administration are still being debated. The addition of dexamethasone to a local anesthetic to prolong the duration of analgesia has recently been explored [8–10]. However, no study has compared different doses of dexamethasone following a peripheral nerve block.

The present work is a prospective, open-label, randomized study examining for the first time the analgesic properties of low and high doses of dexamethasone. Therefore, we test the hypothesis that the analgesic effect of dexamethasone is dose dependent, and that high-dose dexamethasone will result in a longer duration of analgesia following interscalene block for shoulder surgery.

Methods

Patients and study design

The study protocol was reviewed and approved by institutional review boards at hospitals affiliated with the University at Buffalo. All patients between the ages of 18 and 78 undergoing arthroscopic shoulder surgery were identified, and informed consent was obtained from them. Study information brochures were mailed to patients 1 week before surgery. Patients were excluded from the study if they were diagnosed with a clinical condition in which performing interscalene brachial plexus block was contraindicated [i.e., patient refusal, history of coagulation disorder, international normalized ratio (INR) >1.5, skin infection at the site of the block, pre-existing neuropathy involving the upper limb, drug dependency, systemic steroid use within the last 6 months of surgery, patients with peptic ulcer disease, diabetes mellitus, renal and hepatic disease, and pregnancy].

All patients received interscalene brachial plexus block using bupivacaine 0.5% with epinephrine 1:200,000. A total volume of 40 mL of local anesthetic was selected to provide the highest rate of success of interscalene block administered blindly using the nerve stimulation technique. Patients were randomized using a randomization table for two treatment groups and one control group. Patients were assigned randomly to one of three groups: Group C, with no addition of dexamethasone; Group L, with the addition of dexamethasone 4 mg, and; Group H, with dexamethasone 8 mg in addition to 0.5% bupivacaine. These doses were selected because other clinical studies have reported using similar doses. A dexamethasone sodium phosphate (American Regent, Shirley, NY, USA) preparation was used in this study. This preparation contains sodium bisulfite 4.37 mg and benzyl alcohol 10 mg as added preservatives.

Interscalene brachial plexus block

The block was performed by an anesthesiologist who was blinded to the preparation and randomization process. After establishing intravenous access, standard ASA monitors (ECG, noninvasive blood pressure, and pulse oximetry) were applied, and supplemental oxygen was provided at 2 L/min via nasal cannula. Moderate levels of sedation were provided by intravenous administration of midazolam 1–2 mg and/or fentanyl 50–100 μg before the block. A nerve stimulation technique with a Stimuplex® (B Braun, Bethlehem, PA, USA) needle and a stimulator were used. After proper location of the nerve (deltoid muscle twitch response <0.6 mA), the study solution was injected in incremental 5 mL boluses with intermittent aspiration. Following completion of the block, all patients were induced with the intravenous administration of propofol 2 mg/kg. Anesthesia was maintained by a mixture of oxygen/air and sevoflurane (1.0–1.5 MAC) delivered via a laryngeal mask airway. Patients were assessed by an anesthesiologist for the occurrence of early-onset complications and adverse events (i.e., pneumothorax, bleeding and hematoma) prior to their discharge from the post-anesthesia care unit. One case of pneumothorax occurred during the study period. That patient was admitted to the emergency room for tube thoracostomy and was excluded from the study.

Data collection procedure

The success of the block was not assessed before the start of surgery due to time constraints. However, all patients were assessed for the extent of nerve block before discharge from the post-anesthesia care unit. Patients received a survey upon discharge, and were asked to mail it back in a self-addressed envelope. All patients were approached by the study nurse, who provided them with education regarding the survey forms and postoperative pain management prior to their discharge. Postoperative pain was

treated with oral administration of acetaminophen 325 mg + hydrocodone 7.5 mg as necessary in all patients. Patients were advised to take one or two tablets if the pain intensity exceeded 3 (0, no pain; and 10, worst pain imaginable) on the Numerical Rating Score (NRS). If the pain persisted, patients were advised to take ibuprofen 400 mg. They were asked to indicate the time after discharge when the oral analgesic was taken initially due to pain. Duration of analgesia was reported as the time in hours from the time of discharge when patients felt pain from the incision for the first time at an intensity of >3 on NRS. Total analgesic use also was recorded as the number of acetaminophen + hydrocodone tablets and the amount of ibuprofen consumed by the patient within the first 72 h. Duration of the motor block was calculated from the time of completion of the nerve block to the time when the patient was able to abduct the arm at least 2 inches away from the body. A research nurse blinded to the treatment groups performed all follow-up phone calls and collected the survey forms.

Patient satisfaction survey

The survey questionnaire that was sent to the patients asked them about their overall satisfaction with the regional block for shoulder surgery and the quality of postoperative pain relief. Overall patient satisfaction was graded from 1 (strongly dissatisfied) to 5 (strongly satisfied, and would recommend to others). During a postoperative telephone interview, the study nurse questioned all patients for late occurrence of any adverse event (i.e., interscalene site infection, redness) and neuropathy. Telephone interviews were conducted 14 and 28 days following surgery. Patients were instructed to self-report any serious adverse event for a period of up to 1 year after the procedure. Comments and verbatim also were collected as a part of the quality improvement process. Data were collected by the study nurse and analyzed by the investigating team.

Statistical analysis and data handling

The study was designed as a prospective, controlled, randomized trial with intention to treat. All data were collected from anesthesia research records and from survey information provided by the patients. Following the removal of any identifying patient details (e.g., name, date of birth, and social security number), data were entered into SPSS® 16.0 (IBM SPSS, Chicago, IL, USA). The primary outcome variables of the study were the duration of analgesia and the duration of motor blockade after an interscalene nerve block in the three study arms. Total analgesic consumption for the first 72 h postoperatively was the secondary endpoint variable. Power analysis was performed using one standard deviation change in the mean in the three study arms. Power for the primary outcome variables (i.e., pain and postoperative opioid usage) was 0.90 for the sample size used. This study was underpowered to detect the safety features of interscalene injection in patients requiring dexamethasone. Postoperative pain and opioid utilization were compared using a two-way analysis of variance, and the Bonferroni test was used as a post hoc test to identify intergroup differences. Nonparametric data were analyzed by cross-tabulation and Fisher's exact test. The logrank test (Kaplan–Meier) was used for time-to-event analysis of the treatment groups from the time of interscalene block to the time at which the patient reported a pain level >3. Data points were censored if the patient never had this level of pain within 72 h of surgery. Null hypotheses were rejected when p values were lower than 0.05.

Results

Between August 2007 and August 2008, 90 relatively healthy patients (ASA physical status 1/2) were entered into the study at the Excelsior Ambulatory Surgery Center. Four patients were excluded (two had unsuccessful blocks, one had pneumothorax, and one was unavailable for follow-up). The average age of the patients was 46.8 ± 4.1 years. All patients except for one in the control group were sedated preoperatively with intravenous midazolam 2 mg. Fentanyl was administered to a higher number of patients in Group L than in Group H and Group C ($p < 0.05$). The mean length of stay in the post-anesthetic care unit was similar in all groups. The majority of the patients (97.7%) did not receive any supplemental analgesics and were discharged with no pain. The duration of surgery was also similar among the groups (Table 1).

Table 1 Demographic data and dexamethasone doses

	Group C ($N = 28$)	Group L ($N = 28$)	Group H ($N = 30$)
Dexamethasone	None	4 mg	8 mg
Gender (M/F)	23/5	17/11	20/10
Body mass index (kg/m^2)	28.2 ± 5.1	28.4 ± 4.6	28.7 ± 5
Duration of surgery (min)	112 ± 37	103 ± 38	109 ± 31
PACU length of stay (min)	61 ± 20	60 ± 28	54 ± 15

The numerical data are presented as mean ± SD. There was no statistical significance in these variables

PACU Post-anesthetic care unit

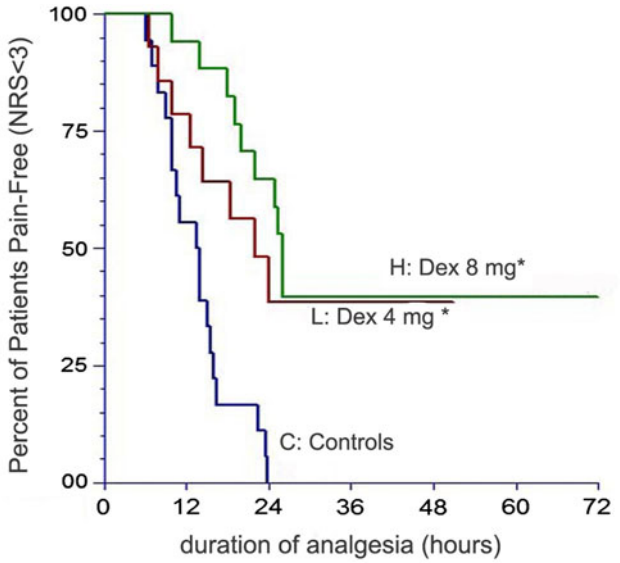

Fig. 1 Logrank test (Kaplan–Meier) analysis for the treatment groups from the time of interscalene block to the time at which the patient reported a pain level >3. Data points were censored if the patient never had this level of pain within the 72 h follow-up period. *Asterisk* denotes a statistically significant difference from Group C ($p < 0.05$)

The duration of analgesia, as measured in hours from the time of discharge until the time that the patients experienced pain at or greater than 3, was significantly longer in Group L and Group H patients (21.6 ± 2.4 and 25.2 ± 1.9 h) than in Group C patients (13.3 ± 1.0 h, $p < 0.05$). However, there was no difference in the duration of analgesia between Group L and Group H. Time-to-event analysis of the pain showed that both doses of dexamethasone prolonged the duration of analgesia when compared to bupivacaine alone (Fig. 1). Similarly, both dexamethasone groups had longer durations of motor block [36.7 ± 4.1 h (Group L) and 39.2 ± 3.9 h (Group H)] than Group C (24.6 ± 3.3 h, $p < 0.05$). Once again, there was no difference in the duration of motor block between Group L and Group H (Table 2).

Postoperative opioid consumption (the number of acetaminophen + hydrocodone tablets) was compiled for the first and second postoperative days. Analgesic consumption for the first postoperative 48 h was significantly lower in Group L (6.5, range [4–8] tabs) and in Group H (5.5, range [4–7] tabs) than in Group C (9.5, range [8–12] tabs) ($p < 0.01$). Although there was a trend for lower opioid consumption in Group H when compared to Group L, this difference did not reach statistical significance. Analgesic consumption on the third postoperative day was similar in all three groups (Table 2).

The majority of the patients (75.5%) were strongly satisfied, while 21.2% of patients were very much satisfied with the type of analgesia they had received. When they were asked whether they recommend this type of anesthesia for a family member, and/or would prefer to have the same type in the future, 91.9% of the patients responded positively. Four patients responded neutrally, and one patient was strongly dissatisfied with the procedure due to prolonged motor blockade lasting longer than 72 h postoperatively.

Discussion

Steroids were added to local anesthetic agents in order to prolong the duration of anesthesia and improve the quality of pain relief. This combination was used for both neuraxial route and peripheral nerve blocks [9, 11, 12]. We demonstrated that the addition of dexamethasone to

Table 2 Duration and quality of postoperative analgesia

	Group C ($N = 28$)	Group L ($N = 28$)	Group H ($N = 30$)
Duration of analgesia (h)	13 ± 4	22 ± 7*	25 ± 9*
Duration of motor block (h)	25 ± 15	37 ± 18*	39 ± 34*
Number of A + C tablets consumed in the first postoperative 48 h (median [range])	9.5 [8–12] tabs	6.5 [4–8] tabs*	5.5 [4–7] tabs*
Number of A + C tablets consumed on POD3 (median [range])	4.5 [3–5] tabs	3.5 [3–5] tabs	4 [3–5] tabs
NSAID (ibuprofen mg)	3036 ± 516	2415 ± 499*	2050 ± 413*,†

Duration of analgesia is the time reported in hours from discharge to the time that patient first experienced incisional pain of 3 or greater. Data for analgesic consumption are presented as the median [range], and were analyzed using nonparametric analysis of variance (MANOVA). Other continuous data are presented as the mean ± SD

L low-dose dexamethasone 4 mg was added to the local anesthetic; *H* high-dose dexamethasone 8 mg was added to the local anesthetic; *POD3* third postoperative day; *A + C tablet* acetaminophen 325 mg + hydrocodone 7.5 mg; *NSAID* nonsteroidal anti-inflammatory drug: the total amount of ibuprofen used by the patient within 72 h after surgery, in milligrams

* Signify statistical significance with a p value < 0.05 when compared to the control group

† Statistical significance when comparing Group H to Group L

bupivacaine prolongs the duration of the motor block and improves the quality of interscalene block. Our findings also indicated that both 4 and 8 mg doses of dexamethasone were equally effective at prolonging the duration of analgesia and improving the quality of pain relief when mixed with bupivacaine. Interestingly, the duration of the motor block was also increased when dexamethasone was added to the local anesthetic mixture.

Our finding that dexamethasone can be used to increase the duration of regional analgesia from a peripheral nerve block correlates well with other recently published investigations [8]. A single dose of dexamethasone added to bupivacaine has been used successfully to produce a preemptive analgesia following podiatric surgery [13]. These patients received local infiltration of the local anesthetic in addition to mid-metatarsal nerve blocks. An independent group of investigators observed similar effects when a longer-acting glucocorticoid was added to plain bupivacaine. These patients experienced prolonged sensory anesthesia (24 h) following a single bolus axillary approach brachial plexus block [14]. In a preliminary work by Iyers et al. on 13 patients, adding 4 mg of dexamethasone to 0.5% ropivacaine (similar to Group L in this study) increased the duration of sensory block from 12.7 to 22.2 h after interscalene nerve block. These authors report a similar effect upon adding dexamethasone 4 mg to both bupivacaine and ropivacaine after femoral blocks.

The precise mechanism by which dexamethasone prolongs the duration sensory block is not completely understood. Although the mechanism of action for dexamethasone was not examined by this study, direct antinociceptive effects have been described following the local administration of steroids. Johansson et al. [15] demonstrated that locally administered steroids inhibit the signal transmission of nociceptive C-fibers and by modifying the membrane lipid phase equilibrium. Interestingly, myelinated nerve fibers were spared from these changes. The biologic half-life of dexamethasone is between 36 to 54 h, and its effects are most apparent in the first 48 h [16]. Our results showed that dexamethasone prolonged the duration of analgesia for approximately 24 h. Opioid-sparing effects of dexamethasone were apparent only on the first and the second postoperative days.

Dexamethasone alone lacks any analgesic property in thermal injury and secondary hyperalgesia [17]. Inclusion of dexamethasone in bupivacaine microspheres injected in animal experiments results in prolonged duration of analgesia. In a study done by Kohane et al. [18], coencapsulation of tetrodotoxin (TTX) in controlled-release devices containing bupivacaine and dexamethasone resulted in exceedingly prolonged nerve blocks. Kopacz et al. found similar clinical effects following the addition of dexamethasone in bupivacaine microcapsules used for intercostal blocks in healthy volunteers. These investigators found an increase of at least 96 h in the duration of intercostal block [19].

The safety of the perineural administration of dexamethasone may raise some concerns, especially when it contains benzyl alcohol. It is important to note that a small fraction of this additive is given and that it is diluted in a volume of 40 mL, so the chance of causing nerve damage under this circumstance is low [20]. In an animal study, dexamethasone reduced blood flow to the normal nerves for 4 h after topical application [21]. However, the reduction is generally below the threshold for developing ischemic changes in peripheral nerve fibers. Rare reports of nerve injury associated with dexamethasone injection are generally due to direct needle trauma [22]. Intrafascicular injection of dexamethasone produces minimal injury, while methyl prednisolone has shown to cause intermediate damage [23]. Intrafascicular steroid injections produced a harmful effect on nerve fibers; however, there were no reports of long-term local effects on peripheral nerves. We continue to follow our patients through periodic phone calls, and have established a self-reporting mechanism that allows the patients to report any untoward reaction that can remotely mimic late-onset neuropathy for a period of 1 year.

We understand that the terms of the sensory and motor blockade used in this study may not correlate well with other investigations in which these variables were examined by a health professional. The source of information for our results was the survey questionnaires collected from the patients. Assessment of pain can potentially be affected by the time and pattern of sleep, unless the severity of the pain arouses the patient from sleep. Although these patients were educated preoperatively by an anesthesiologist and a study nurse, and coached through the postoperative period over the phone by the study nurse, almost all of the sensory block assessments were subjective. This issue will remain a significant limitation for any human study in the outpatient setting, due to the operational logistics of outpatient surgery centers. It is therefore acceptable to use the time to report surgical pain as a surrogate marker for the duration of sensory block. Our results indicated that the addition of dexamethasone to bupivacaine prolonged motor weakness following interscalene block. Since the duration of the motor block is a semi-objective measure, it was recorded from the time of block as the reference time point. As for the duration of analgesia (a purely subjective measure), we used the time of discharge as our reference point. As there was no difference in the length of hospital stay among the groups, our results for the duration of analgesia were not affected. Only one patient was dissatisfied from prolonged motor weakness postoperatively. We should note that the reported motor block considered only abduction of the arm

(deltoid muscle) in this study. The majority of the patients were able to use their fingers while arm abduction was still blocked.

We conclude that adding dexamethasone to the bupivacaine/epinephrine mixture significantly prolonged the duration of analgesia and motor blockade, and reduced opioid consumption for 48 h postoperatively. Although there was no report of adverse events related directly to the dexamethasone–bupivacaine mixture interscalene block in our case mix during the four-week follow-up period, we are unable to comment on the safety of this therapeutic approach due to the relatively small sizes of our study groups. Overall, patients were satisfied with the postoperative analgesic control. As a result of this study, we believe that this technique may be a good alternative to the continuous perineural block if technical and logistic issues are of concern. Future studies may need to examine the effectiveness of dexamethasone when it is added to ropivacaine, and to determine whether the duration of sensory blockade is comparable to bupivacaine with a shorter motor blockade.

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