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Role of postoperative continuous subfascial bupivacaine infusion after posterior cervical laminectomy: Randomized control study

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KEYWORDS

Postoperative pain; Posterior cervical fixation; Local bupivacaine infusion; PCA

Abstract Introduction: One of the major drawbacks of posterior cervical decompression and rigid internal fixation is the severe postoperative neck pain created by extensive soft tissue and muscular dissection. The usual management of acute postsurgical pain consists of systemic opioids or nonsteroidal anti-inflammatory drugs. Another satisfying method of postoperative pain relief is continuous local infusion of analgesic agents in posterior subfascial paravertebral space on both sides of the wound using epidural catheters.

Methods: Sixty patients scheduled for cervical laminectomy with fixation surgery via the posterior midline approach with postoperative epidural catheters placed subfascially on both sides of the wound. They were randomly divided into two groups, bupivacaine group with local infiltration of 0.5% bupivacaine at the rate 2 ml/h, and control group with saline infusion at a rate 2 ml/h. The patient controlled analgesia device (PCA) was given to all patients and set to deliver IV morphine in 1 mg boluses with a lock out at 10 min and a 4 h maximum 10 mg.

Results: The visual analog score was statistically significant lower in bupivacaine group compared to control group during the first 60 h postoperatively. While in 66 and 72 h postoperatively there was no statistical significant difference was observed between the two groups. The total doses of morphine delivered by PCA in the three postoperative days were statistically significantly higher

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in control group than bupivacaine group. The incidence of side effects related to narcotics was higher in control than bupivacaine group.

Conclusion: Bilateral subfascial continuous 0.5% bupivacaine infiltration through an ordinary epidural catheter at the rate 2 ml/h for three successive postoperative days is associated with better pain control, reduced narcotics, early ambulation and no serious side effects in the postoperative period in patients undergoing posterior cervical fixation.

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1. Introduction

Decompression and rigid internal fixation of the cervical spine is a well-accepted treatment for patients with spastic intractable symptoms related to degenerative disc disease [1]. It allows early patient mobilization with reduced need for external immobilization [2]. However, one of the major drawbacks of posterior cervical instrumentation is the severe neck pain created by extensive soft tissue and muscular dissection which is necessary to expose the appropriate anatomy. Prolonged muscle retraction intra-operatively leads to tissue ischemia and muscle denervation and lead to high incidence of new axial neck pain, which can be debilitating to the patients [3]. Delayed mobilization contributes to increased risk of medical complications such as pneumonia, deep vein thrombosis, urinary tract infections and psychological distress [4].

Most patients complain of severe pain at rest during the first 12 h after surgery. This pain increases considerably with mobilization because of the reflex spasm of paraspinal muscles that is triggered by the primary wound pain. During the following 48–72 h, postoperative back pain is generally moderate at rest, whereas it remains severe on movement and produces discomfort that can interfere with patient mobilization and, possibly, with discharge time [5].

The usual management of acute postsurgical pain consists of systemic opioids which can be administered parenterally (intramuscularly and intravenously), subcutaneously and epidurally. It can be provided continuously when needed or via patientcontrolled analgesia (PCA). The other choice was non-steroidal anti-inflammatory drugs (NSAIDs) which may contribute to cardiovascular toxicity and impaired bone healing. Neither opiates nor NSAIDs are completely effective alone, and they carry a lot of side effects, particularly with prolonged or repeated doses [6].

Epidural analgesia with local anesthetics or opioids is performed routinely after major thoracic, abdominal and orthopedic surgery, and proven to be superior to conventional intravenous analgesia providing the same or better pain control with fewer side effects [7]. Cervical epidural anesthetic is not an easily performed technique, and it is difficult to limit the anesthesia to the brachial dermatomes, thus it can lead to phrenic or intercostals nerve paralysis [8].

Local anesthetic infiltration of the surgical wound is a useful method in the treatment of postoperative pain after various surgical procedures [9–12]. Postoperative bolus injection of local anesthetic into the local environment alleviates pain at its source. However, the duration of therapeutic benefit is limited by the biological half-life of the analgesic agent, with loss of effect once the drug is cleared. Continuous local infusion of analgesic agents for postoperative pain relief has been previously described with significant beneficial results [13,14].

This randomized placebo control double blinded study aims to determine the efficacy and safety of continuous infusion of local anesthetic (bupivacaine 0.5%) through epidural catheter placed subfascially on both sides of the wound after posterior cervical laminectomy and fixation surgery.

2. Patients and methods

After approval of the ethical committee and written consent, 60 patients in Kasr Aini hospital proved to suffer from cervical spinal instability and scheduled for cervical laminectomy with fixation surgery via the posterior midline approach which was performed by the same surgical team. They were randomly divided according to computer randomization list into two groups, 30 patients in each group (control group and bupivacaine group) the patients selected between 20 and 60 years old with American Society of Anesthesiologists (ASA) I & II and Malanpatti 1&2.

The patient's exclusion criteria included (ASA) physical status III and IV, morbid obesity, coagulation disorders and drug abuse.

The patients, surgical team and data collector were blinded to the randomization. The day before surgery, patients were trained to use the 0–10 cm visual analog scale (VAS) on which 0 = "no pain" and 10 = "the worst imaginable pain ". Patients were also instructed how to use patient control analgesia system (PCA).

All patients received midazolam 2–3 mg IV as a premedication 20–30 min before surgery. For stabilization of the neck, all patients wear a neck collar. General anesthesia was induced with fentanyl 2 μ g/kg, propofol 1–2 mg/kg and atracurium 0.5 mg/kg for intubation using fibro-optic technique to avoid any movements of the neck and subsequent increments doses of muscle relaxant every 20 min, then maintained with isoflurane 1.5% inspired concentration. Monitors included electrocardiography (ECG), pulse oximetry, non-invasive arterial blood pressure and end tidal CO₂ analyzer. All patients were operated on prone position with 20° head up, the neck in flexed position and the face resting in cotton padded Mayfield (horseshoe) headrest.

After wound closure and insertion of suction drains, all patients remained in the prone position for placement of paravertebral multiport epidural catheters. Under complete aseptic technique, the anesthesiologist inserts a 17 gauge Touhy needle into the paraspinal muscle under the cervico-dorsal fascia parallel to the wound. The bevel of Touhy needle was directed toward the wound; the point of entry was 2 cm inferior and 2 cm lateral to the wound. The needle was inserted 2–4 cm deep from the skin according to subcutaneous fat. The trochar was removed and the 19 gauge catheter (with three lateral holes and closed end) was inserted in place. The same

technique was done on the other side of the incision with another set of epidural. Five milliliter of 0.5% bupivacaine was infused via each catheter before turning the patient supine as an initial bolus dose to the wound. The catheter was covered with sterile dressing and plastic tape which was separated from the wound dressing to avoid dislodgement of the catheters. The correct placement of the catheters was checked with portable image at the end of the procedure. Those catheters were fixed in place for 72 h post-operatively; they are connected to two infusion pumps. The infusion rate was 2 ml/h of 0.5% bupivacaine per catheter for the total 48 ml/day for 3 days only in bupivacaine group while the control group had 2 ml/h normal saline with the same total volume per day for the three successive days. The catheters were not inserted in the wound itself because of the presence of suction drains which would likely remove much of the infused anesthetic drugs.

In the recovery room, the patient controlled analgesia device (PCA) was given to all patients and set to deliver IV morphine in 1 mg boluses with a lock out at 10 min and a 4 h maximum 10 mg. For patients with persistent pain despite these measures, ketorolac 15 mg IV was administered.

Pain data were collected using the visual analog scale (VAS). Neck pain score and narcotic usage were documented by a nurse 2 and 4 h postoperatively then every 6 h for 72 h for all patients. The ability of the patients to move their neck was recorded on scale from 0 to 4 while 0 = inability to move the neck, 1 = mild movements of the neck with sever limitation, 2 = moderate movements of the neck, 4 = free movements of the neck in all direction. Pruritus and postoperative nausea and vomiting were assessed every 6 h. every episode of postoperative nausea and vomiting was treated with 4–8 mg IV ondansetron (Zofran).

The cortisol level in the blood was measured preoperatively and once daily postoperatively for the three consecutive days of the study.

2.1. Statistical analysis

Values were expressed as means \pm standard deviation or ratio as appropriate. Comparison between groups was performed using one way analysis of variance (ANOVA) with post hoc Newman–Keul's test. VAS score were compared between the two groups using Kruskal–Wallis ANOVA test, with post hoc Mann–Whitney U test. P values <0.05 were considered significant.

3. Results

No significant differences existed in preoperative planning, surgical technique, or postoperative care during the time frame studied. All demographic data for patients included in this

Table 1	Demographic da	ata in both groups.
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	Bupivacaine group	Control group
Age (years)	48 ± 9	51 ± 8
Male:female	16:13	15:14
Weight (kg)	72 ± 5	69 ± 6
Duration of surgery (min)	103 ± 20	$109~\pm~16$

Data is represents as mean \pm SD. Number of patients = 29 in each group.

study are presented in (Table 1), variables such as age, sex, weight and time of surgery were similar between groups. In one patient in bupivacaine group the catheters was accidentally removed during changing the wound dressing in the 2nd post-operative day, while in the control group a unilateral catheter was accidentally slipped in one patient; both patients were excluded from the study so the total number of the patients were 29 in each group.

As regard VAS, it was statistically significantly lower in bupivacaine group compared to control group during the first 60 h postoperatively. While in 66 and 72 h postoperatively there was no statistical significant difference was observed between the two groups as presented in (Table 2). Most of the patients were satisfied and comfort with analgesia which did not interfere with the early daily ambulation.

The total level of morphine delivered by PCA was recorded each postoperative day and represented in (Table 3). It was

Table 2Visual analog pain (in the neck) score (VAS) in bothgroups.

Postoperative days	Bupivacaine group	Control group
1st day		
2 h	3.42 ± 1.77	$4.73 \pm 1.82^{*}$
4 h	3.41 ± 1.67	$4.62 \pm 1.71^{*}$
6 h	3.32 ± 1.47	$4.45 \pm 1.62^{*}$
12 h	3.29 ± 1.30	$4.41 \pm 1.56^{*}$
18 h	3.35 ± 0.92	$4.39 \pm 1.59^{*}$
24 h	3.24 ± 1.22	$4.23 \pm 1.42^{*}$
2nd day		
30 h	2.98 ± 1.21	$4.17 \pm 1.53^{*}$
36 h	2.96 ± 1.50	$4.12 \pm 1.41^{*}$
42 h	3.10 ± 1.32	$4.07 \pm 1.35^{*}$
48 h	$2.82~\pm~1.60$	$3.67 \pm 1.44^{*}$
3rd day		
54 h	2.61 ± 1.33	$3.42 \pm 1.40^{*}$
60 h	2.51 ± 1.12	$3.29 \pm 1.56^{*}$
66 h	2.26 ± 1.51	2.52 ± 1.37
72 h	2.17 ± 1.29	2.49 ± 1.23

Data is represents as mean \pm SD. Number of patients = 29 in each group.

P < 0.05 is considered statistically significant.

Significant difference from the other group.

Table 5	A margestes administration in both grou	*P ³ ·
	Bupivacaine	Control

Table 3 Analogoias administration in both groups

	group	group
The total dose of morphine (mg)/day		
1st postoperative day	12.9 ± 2.3	$23.6 \pm 3.1^{*}$
2nd	9.2 ± 2.5	$16.3 \pm 4.8^{*}$
3rd	6.9 ± 1.6	$9.5 \pm 2.4^{*}$
The number of patients need additional analgesics:	0 (0%)	4(13.7%)

Data is represents as mean \pm SD. Number of patients = 29 in each group.

P < 0.05 is considered statistically significant.

* Significant difference from the other group.

Table 4 Cc	rtisol level	(Microgram/dl)	in	both	groups.	
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	Bupivacaine group (Microgram/dl)	Control group (Microgram/dl)
Preoperative	18.3 ± 1.4	$18.5~\pm~1.35$
Postoperative 1st day 2nd day 3rd day	$21.4 \pm 1.3^{*}$ $20.2 \pm 0.9^{*}$ $19.3 \pm 0.6^{*}$	$26.4 \pm 1.8^{*,**}$ 25.8 \pm 1.3^{*,**} 22.3 \pm 1.1^{*,**}

Data is represents as mean \pm SD. Number of patients is 29 in each group.

P < 0.05 is considered statistically significant.

* Significant difference compared to the other group.

** Significant difference compared to the baseline in the same group.

Table 5 Post-operative data in both groups.				
	Bupivacaine	Control		
	group	group		
Postoperative complications				
(number of patients)				
Nausea and vomiting	3 (10.3%)	7 (24.1%)		
Respiratory distress	0 (0%)	1 (3.4%)		
Numbness	0 (0%)	0 (0%)		
Seizures	0 (0%)	0 (0%)		
pruritus	0 (0%)	1 (3.4%)		
Neck movements	3–4	1–3		
Data is represents as mean \pm SD. Number of patients is 29 in each				

statistically significantly higher in control group than bupivacaine group during the three postoperative days. Only four patients (13.7%) in control group needed additional doses of ketorolac in the 1st postoperative day while the patients in bupivacaine group were satisfied with the level of analgesia.

Three patients (10.3%) in bupivacaine group needed antiemetic drugs due to episodes of nausea and vomiting compared to seven patients (24.1%) in control group.

The level of cortisol was significantly elevated in both groups during the postoperative than the preoperative period. It was also statistically significantly higher in control group than bupivacaine group in the three postoperative days of the study (Table 4).

The incidence of complications and number of patients who suffered from postoperative side effects related to anesthesia were presented in (Table 5). The patient's ability to move their necks range from 3–4 in bupivacaine group compared to 1–3 in control group as they did not suffer from pain while they did not move their necks but had pain in trying to move it (Table 5).

4. Discussion

group.

In this prospective randomized control study, bilateral paravertebral epidural catheters were used for continuous infusion of bupivacaine 0.5% after posterior cervical laminectomy with fixation. Their use significantly lowered VAS score and the need for parental narcotics in the first three consecutive postoperative days. Posterior cervical laminectomy with rigid internal fixation surgery is a common spinal procedure. It is usually done with a midline dissection and extensive cutting of posterior muscle tissue which accompanied by prolonged retraction resulting in tissue ischemia and denervation which increase significantly postoperative pain [15–18]. This pain delays postoperative neck mobilization, increases length of hospitalization and leads to prolonged use of high doses of narcotics [14]. Persistence of pain may increase the post-surgical complications such as pulmonary embolism, deep venous thrombosis and pneumonia [19].

Narcotics and NSAIDs are considered the standard treatment of postsurgical pain but their side effects limit their prolonged use. Negative effects of narcotics include nausea, vomiting, pruritus, urine retention, altered mental status, sedation and respiratory depression [20–22]. Also the use of NSAIDS leads to several side effects such as renal failure, bleeding, anemia and gastrointestinal irritation [23]. And it had inhibitory effect on new bone formation which makes it contraindicated in fusion operations [23–25].

Local anesthetic infiltration in the surgical wound shows good results in controlling the postoperative pain [26,27]. But the usages of single intraoperative dose of local anesthetic only provide analgesia for 4–6 h which is not sufficient for the patient's satisfaction. That is why there is increased demand to use continuous infusion techniques of local anesthetic for providing a longer control of postoperative pain. Infusion techniques have the capacity to reduce complications associated with inadequate pain relief and excessive narcotics use [28].

The use of epidural set in inducing cervical epidural infiltration of bolus injection of bupivacaine was studied by many authors and they had a great debate about its effects and side effects. Capdevile et al. showed that epidural catheter in epidural space for local anesthetic infusion lead to control of perioperative and postoperative pain. But side effects such as impaired diaphragmatic excursion and decreased maximal inspiratory forced vital capacity and tidal volume secondary to phrenic nerve paralysis caused by regional anesthetic delivery to cervical spinal cord are not uncommon [8]. Many recent studies demonstrated the safe use of cervical epidural analgesia with excellent pain control and without evidence of respiratory impairment. In these studies authors suggested that respiratory dysfunction is more theoretical than clinically happened [29– 33].

The use of epidural cervical space infusion need close monitoring and adjustment by nurses as well as there is high risk of catheter migration with unwanted side effects [34–36]. These side effects were not reported in the present study, as the epidural catheters were placed in the subfascial compartment and the local anesthetic was diffused into the surrounding paravertebral muscles, and not in the epidural space. Also the presence of suction drain in the wound during surgery in all patients of both groups could remove any local anesthetic drug present in epidural space as a result of extravasations or direct delivery.

In the present study, patients were suffering from posterior cervical instability and relatively the same preoperative neurological symptoms. The results of this study demonstrated significant low VAS in bupivacaine group in the first 60 h postoperatively compared to control group, while there was no significant difference in VAS in both groups after the first 60 h till the end of the study. The peak level of pain occur usually in the first two postoperative days, but later on the pain

threshold decrease to become more acceptable in the 4th postoperative day [13]. That is why we limited our study in the first three postoperative days. The total doses of morphine delivered by PCA were $(12.9 \pm 2.3, 9.2 \pm 2.5 \text{ and } 6.9 \pm 1.6)$ respectively in the first three postoperative days in bupivacaine group, which was significantly lower than control group $(23.6 \pm 3.1, 16.3 \pm 4.8 \text{ and } 9.5 \pm 2.4)$ which proved the effect of infusion of bupivacaine as local anesthetics in the wound area in improving the analgesia. No patient in bupivacaine group needed an extra analgesic in the postoperative days, while in the control group four patients (21%) needed an extra analgesic during the first postoperative day due to severe pain. As a result of excessive use of morphine in control group, nine patients suffered from nausea and vomiting which needed medical interference and one patient had pruritus. One patient in control group had respiratory distress and hypoxemia with a decrease in O₂ saturation to 90% on pulse oximetry 6 h postoperatively. The patient improved on oxygen therapy and he needed no further interference.

Bianconi et al. reported that postoperative pain control in posterior lumber stabilization surgery (at rest and on mobilization) was better after 0.5% ropivacaine wound infiltration followed by continuous wound perfusion with ropivacaine 0.2% at a flow rate 5 ml/h than with systemic analgesia. In this study the wound infiltration was done using a multihole 16 gauge catheter which was placed between the muscle fascia and subcutaneous tissue all along the wound. They found that the largest total plasma concentration (C_{max}) of ropivacaine always remained less than the toxic threshold and it reached the maximum peak in the first 24 h in most of the patients [37]. But this technique was not suitable in presence of the drain in the wound, as most of the local anesthetic would be drained outside.

In the postoperative period, level of cortisol is usually elevated compared to the preoperative level due to stress of surgery and postoperative pain. In this study the cortisol level increased in both groups in the postoperative period compared to the preoperative period but this increase was significantly higher in control group compared to the bupivacaine group, this could be explained by the fact that the pain was higher in the control group in spite of the use of narcotics. The Patients also showed earlier normalization of bowel habits and ambulation in bupivacaine group.

In the present study the use of the epidural set had a great economic benefit as the cost of epidural set was about \$20 (approximately 100 LE). In the control group of our study, patients had two catheters at the paravertebral sites of the wound with infiltration of placebo (saline), which made their response to pain score, narcotics usage or early ambulation not affected by absence of the psychological support of presence of the infusion catheters. In a case controlled nonrandomized study, James et al. investigated the use of continuous infusion of bupivacaine via two paravertebral catheters using ON-Q Pain-Buster device for pain control in patients undergoing posterior cervical spine surgery. This study had many limitations as the cost of the device for each patient was approximately \$350 (approximately 2000 LE) so the device was not used in control patients and they were not treated with a continuous infusion of a placebo which could have theoretically affected their reported pain scores or other outcome measures [13].

In conclusion, Bilateral subfascial continuous 0.5% bupivacaine infiltration through an ordinary epidural catheter at the rate 2 ml/h for three successive postoperative days is associated with better pain control, reduced narcotics, early ambulation and no serious side effects in the postoperative period in patients undergoing posterior cervical fixation.

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