A Randomised Controlled Trial of Infiltration versus Low Dose Subarachnoid Block in Hydrocele Surgery.

Obaid Ahmad Siddiqi, Manazir Athar, Shahna Ali, Sajad Hussain Najar

1Assistant Professor, Department of Anaesthesiology and Critical Care, JNMCH, Aligarh Muslim University, UP, India.
2Senior Resident, Department of Anaesthesiology and Critical Care, JNMCH, Aligarh Muslim University, UP, India.

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ABSTRACT

Background: Hydrocele surgery is a short surgical procedure requiring an anaesthetic technique that allows good surgical anaesthesia, short recovery time and minimal side effects. This study was designed to compare the traditionally used technique of local infiltration block and subarachnoid block using 1% lidocaine with 25mcg of fentanyl in patients undergoing hydrocele surgery. Methods: Sixty ASA grade I and II patients of 18-60 years of age, scheduled for hydrocele surgery were randomly assigned to two groups of 30 patients each. Group C patients received local infiltration using 1% lidocaine (maximum upto 5mg /kg) while Group I patients received intrathecal injection of 1% lidocaine with 25 mcg of fentanyl (1.5 ml of 2% lidocaine + 1 ml of normal saline + 0.5 ml fentanyl). The subjects were assessed in terms of physiological variables, the quality of analgesia, and incidence of side effects as compared to local infiltration technique.

Results: Patients in group C required significantly more number of fentanyl boluses for pain as compared to patients in group I. The most common problem encountered in any group was backache with an incidence of 16.6% in group I and 6.6% in group C. Pruritus was reported to be 13.3% in group I but was absent in group C (P<0.05). However, it was mild and did not require any medication. 23 patients in group I regarded their experience of the periperooperative period as excellent as compared to only 5 patients in group C. Time to void and to meet discharge criteria was comparable in both the groups.

Conclusion: We conclude that the use of smaller dose lidocaine-fentanyl combination in spinal anaesthesia provides potent and excellent quality of analgesia with limited side effects without prolonging recovery as compared to 1% lidocaine infiltration in patients of hydrocele surgery.

Keywords: Hydrocele, Infiltration, Subarachnoid Block.

INTRODUCTION

Hydrocele surgery is a short surgical procedure, which is usually done on day care basis. It is usually carried under local infiltration anesthesia. This technique is simple to carry out, safe to administer and cost effective, but it has its own limitations. The manipulation in the patient usually turns out to be very difficult and cumbersome thereby causing uneasiness to the patient and problem to the operating surgeon. The experience may carry lifelong unpleasant memories for some of the patients. Therefore, it is necessary to adopt an anaesthetic technique which should allow good surgical analgesia along with a short recovery room stay.

The choice of the technique depends on several factors, including patient and surgeon preferences, feasibility of the technique, pain relief in the perioperative period and the time to discharge from the hospital. In this context, there has been an increasing popularity of low dose neuraxial anesthesia, particularly in daycare surgeries.[1-4] Traditionally local anesthetics alone have been used for providing perioperative pain relief, however the sole use of local anesthetic agent delays the discharge of the patient from the hospital due to greater amount of dosage. In recent years efforts have been made to improve the spinal anaesthetic technique for day care surgeries by reducing the dose of local anaesthetics and the addition of small doses of opioids to obtain satisfactory pain relief.[5-9] This combination utilizes the advantage of synergistic action of local anaesthetics with opiates thereby producing adequate analgesia and lesser intensity of motor blockade leading to early discharge of the patients from the hospital. Therefore, this study was conducted to compare the technique of local infiltration block with spinal anesthesia using 1% lidocaine (isobaric) in combination with 25mcg of fentanyl in patients undergoing day care hydrocele surgery. The present study was designed to evaluate the effect of this combination on the patients’ physiological variables.
incidence of side effects as compared to local
and subcutaneous tissue were infiltrated with 4-5 m l
avoid any intravenous injection of local anaesthetic.
injecting, the plunger of needle was aspirated to
slowly at different angles with 3ml at each place
start when the level of block reached L1. In Group C
loss of sensation to pinprick. Surgery was allowed to
as ‘zero’. The level of sensory block was assessed
of the spinal medication, the patients were placed
was blinded to the study groups. After the injectio n
[Figure 1]. Patients were assigned to two groups of
30 patients each on the basis of computer generated
randomization (www.randomization.com). Patients
in group C (Control) received local infiltration using
1% lidocaine (maximum up to 5mg/kg) while group
(20 mcg of fentanyl (1.5 ml of 2% lidocaine + 1 ml of normal saline + 0.5 ml fentanyl) intrathecally)
using 25 guage Quincke-Babcock spinal needle (Becton Dickinson, Madrid, Spain).
All the patients received 10 ml/kg of crystalloids
before spinal anaesthesia. Upon arrival in the
opening room, standard monitors including
Electrocardiography (ECG), Pulse oximeter, and
Noninvasive blood pressure (NIBP) were applied.
The vitals were recorded by a research associate who
was blinded to the study groups. After the injection
of the spinal medication, the patients were placed
supine immediately, the time of which was recorded
as ‘zero’. The level of sensory block was assessed
using 22-gauge hypodermic needle with 2mm
protrusion through guard, every 5 minutes till the
loss of sensation to pinprick. Surgery was allowed to
start when the level of block reached L1. In Group C
patients, local analgesia was given by 1% lidocaine
injected both at inguinoscrotal junctions and just
above the scrotum in order to anaesthetize the
spermatic cord with the help of an assistant holding
the cord in between his thumb and forefinger. The
injection was given over a period of two minute,
slowly at different angles with 3ml at each place
without withdrawing the needle completely. Before
injecting, the plunger of needle was aspirated to
avoid any intravenous injection of local anaesthetic.
After 5 mins, the skin of scrotum was kept taught
over the anterior surface of testicle and whole skin
and subcutaneous tissue were infiltrated with 4-5 ml
of lignocaine. Maximum 20 ml of 1% lidocaine was
used to perform this technique. Inadequate
anaesthesia (complaint of pain) was treated with a
bolus dose of fentanyl (25mcg) and repeated up to a
maximum of 100 mcg.
The vitals were recorded every 5 mins during
surgery and common complications like nausea and
vomiting, pruritus, respiratory depression,
hypotension and inadequate analgesia were recoded.
After surgery, the patients were shifted to PACU for
monitoring till there was a complete resolution of
sensory and motor block. Level of discomfort of the
patients was assessed as mild, moderate or severe.
The time to meet discharge criteria was also noted
by the research associate blinded to the study group.
Discharge criteria were stable vital signs, haemostasis, proprioception of great toe, adequate
pain control, complete motor and sensory control
and ambulation. After these criteria were met, the
patients were discharged when they had voided and
were in no discomfort from the surgical procedure.
Global evaluation of study medication was assessed
by interviewing the patients 24 hours after the
surgery to get the information regarding their
experiences of perioperative period in terms of the
following four options; poor, fair, good and
excellent.

Statistical Analysis:
Data were analyzed using t-test and chi-square test
and p<0.05 was taken as significant. All the values
were expressed as Mean±SD. Assuming α error of
0.05 and 30% decrease in proportion of patients with
discomfort (p=65%, p=25%), it was found that a
minimum of 21 patients were needed to obtain a
power of 80%. Considering 10% drop-out, a total of
24 patients were required. So, we recruited 30
patients in each group.

RESULTS
Patients in both the groups were comparable with
regard to demographic variables [Table 1]. There
was no significant difference in the mean duration of
surgery (mins) in both the groups (31.3±5.0 in
Group I vs 35.3±5.2 in Group C). Patients in group C
required significantly more number of fentanyl
boluses(1.33±0.95) for pain as compared to patients
in group I (0.33±0.06) with a p value of 0.0001, but
none of the patients required conversion to the
general anaesthesia. In group I, 76% of patients had
do no discomfort as compared to 17% of patients in
group C. Vitals were maintained throughout the
procedure in all the cases. None of the patient in any
group had significant hypotension (BP<20 % of
baseline) or bradycardia (HR<60/min) during the
perioperative period. The most common
complication encountered in any group was
backache with an incidence of 16.6% in group I and
6.6% in group C (p=0.24). Mean duration of the
backache was 2.4±1.3 days. Another common
adverse effect observed in group I was pruritus. It
was reported to be 13.3% in group I but was absent
in group C (p=0.04). Pruritus was mild in all cases
and did not require any medication. There was no
significant difference in the incidence of nausea and
vomiting in both the groups (10% in group I vs 6.6%
in group C). Post spinal headache was observed in
3% of the patients in group I, it was mild in nature

MATERIALS AND METHODS
Following approval from the institutional ethical
committee and written informed consent, sixty
American Society of Anesthesiologist (ASA) grade I
and II patients of 18-60 years of age, schedule for
hydrocele surgery were enrolled in the study.
Patients with neurological and neuromuscular
disease, infection at the intended site of needle
insertion or hypersensitivity to amide local
anaesthetic or fentanyl were excluded from the study
[Figure 1]. Patients were assigned to two groups of
30 patients each on the basis of computer generated
randomization (www.randomization.com). Patients
in group C (Control) received local infiltration using
1% lidocaine (maximum up to 5mg/kg) while group
I (Intervention) patients received 3 ml of 1% lidocaine with 25 mcg of fentanyl (1.5 ml of 2% lidocaine + 1 ml of normal saline + 0.5 ml fentanyl) intrathecally using 25 guage Quincke-Babcock spinal needle (Becton Dickinson, Madrid, Spain).
All the patients received 10 ml/kg of crystalloids
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operating room, standard monitors including
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Noninvasive blood pressure (NIBP) were applied.
The vitals were recorded every 5 mins during
surgery and common complications like nausea and
vomiting, pruritus, respiratory depression,
and responded to oral analgesics [Table 2]. Time to void and to meet discharge criteria was comparable in both the groups. The overall global evaluation of the study medication was excellent in most of the patients [Figure 2].

**DISCUSSION**

Effective pain control is essential for optimal care of surgical patients. Administration of lipophilic opioids along with local anaesthetics has been found to have agonistic and synergistic actions during the perioperative period. Intrathecal opioids greatly enhance sub therapeutic doses of local anaesthetic\[10,11\] and make it possible to achieve successful spinal anaesthesia by using low doses of local anaesthetic.\[12\]

Lidocaine has a short duration of action, making it an excellent choice for a short operative procedure. The use of lidocaine along with fentanyl has been shown to have synergistic effect at intrathecal receptors potentiating the effects and hence leading to reduction in the doses of both drugs individually. In our study, we demonstrated the benefit of fentanyl- lidocaine spinal anaesthesia over the use of local infiltration of lidocaine in patients undergoing...
hydrocele surgery. The combination of low dose intrathecal fentanyl (25mcg) in combination with 1% lidocaine has a significantly improved analgesia without affecting the duration of motor and sensory block, and hence reducing the duration of hospital stay. Lesser number of fentanyl boluses along with greater degree of comfort was observed in patients that received low dose intrathecal block. This is due to the more intense and excellent quality of analgesia produced by a combination of local anaesthetic and an opioid. Liu et al.[13] made a similar observation by adding 20 ug of fentanyl to lidocaine. Apart from the advantage of an excellent quality of analgesia the small dose local anesthetic – fentanyl combination has been shown to provide a more stable hemodynamic course.[14-16] None of the patients had any episode of hypotension at any point of time which concur with previous reports. Respiratory depression was not evident in any of our patient at any point of time. It has been shown that a small dose of fentanyl (25mcg) administered intrathecally causes a decrease in respiratory rate which does not last for more than 40 minutes.[17] However the definition of respiratory depression (respiratory rate < 8 breaths per minute) used in our study was not very sensitive. The incidence of subclinical respiratory depression may have been much higher had arterial CO₂ tension or the CO₂ response curve been used to evaluate ventilation. Moreover severe respiratory depression 25 minutes after intrathecal fentanyl has been described and is due to rapid rostral spread into the cerebral cerebrospinal fluid.[18] There was an increased incidence of pruritus in patients receiving subarachnoid block. Although the pruritus was troublesome but was self-limiting in all the patients. The exact mechanism of neuraxial opioid induced pruritus remains unclear. Pruritus induced by neuraxial opioids is likely due to cephalad migration of the opioid in CSF and subsequent interaction with opioid receptors in the trigeminal nucleus.[19] The incidence of nausea and vomiting was similar in both the groups and was not significant. The most common problem encountered was mild backache with a incidence of 16.6% and 6.6% in spinal and local infiltration respectively. This was acceptable as all the symptoms were mild and none of the patients required any treatment for it. The incidence of backache after spinal anaesthesia has been reported to vary from 2% to 25%.[20,21] However it is an important side effect after all types of anaesthesia.[21] Though the exact etiology is not known but several factors other than spinal injection, such as trauma from ligament and stretching of the muscles in the lithotomy position are probably involved. Even though the use of smaller guage Quincke needles or pencil point needles such as the 25 guage Whitacre may result in less post dural puncture headache, we observed a 3% incidence of postspinal headache in our study. The headache was mild in nature and was relieved with oral analgesics. Ben-David et al[6] also found a 1.8% incidence of spinal headache with 25G or 26G pencil point needles. Time to void and to meet discharge criteria was comparable in both the groups. We used a dilute solution of spinal lidocaine, which allowed for a more accurate dosing and a rapid recovery of motor and sensory functions resulting in early discharge of the patients. Ben-David et al[8] reported the use of intrathecal fentanyl with a dilute solution of bupivacaine and observed better anaesthesia without prolonging recovery.[12] Addition of fentanyl will not prolong recovery because combination of fentanyl and lidocaine is known to improve sensory blockade without prolonging recovery.[13] Patient discharge could have been speeded by eliminating the requirement that patients void before discharge.

CONCLUSION

We conclude that the use of smaller dose lidocaine-fentanyl combination in spinal anaesthesia provides potent and excellent quality of analgesia for short duration outpatient hydrocele surgery. The technique had a satisfactory rate of side effects and high patient acceptance without a significant change in the time to discharge as compared to 1% lidocaine infiltration in patients of hydrocele surgery.

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