Original Article ISSN (O):2395-2822; ISSN (P):2395-2814

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

Obaid Ahmad Siddiqi[1], Manazir Athar[2], Shahna Ali[1], Sajad Hussain Najar[2]

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

Received: September 2016
Accepted: October 2016

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 perioperative 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.

Name & Address of Corresponding Author
Dr. Manazir Athar
Senior Resident,
Dept. of Anaesthesiology and Critical Care,
Jawaharlal Nehru Medical College,
Aligarh Muslim University, UP, India.

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.[6-9] 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 (Pulse rate, Blood pressure), quality of analgesia and

incidence of side effects as compared to local infiltration block.

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 before spinal anaesthesia. Upon arrival in the operating 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-guage 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, 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 ($p_{o=}$ 65%, p_1=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 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 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].

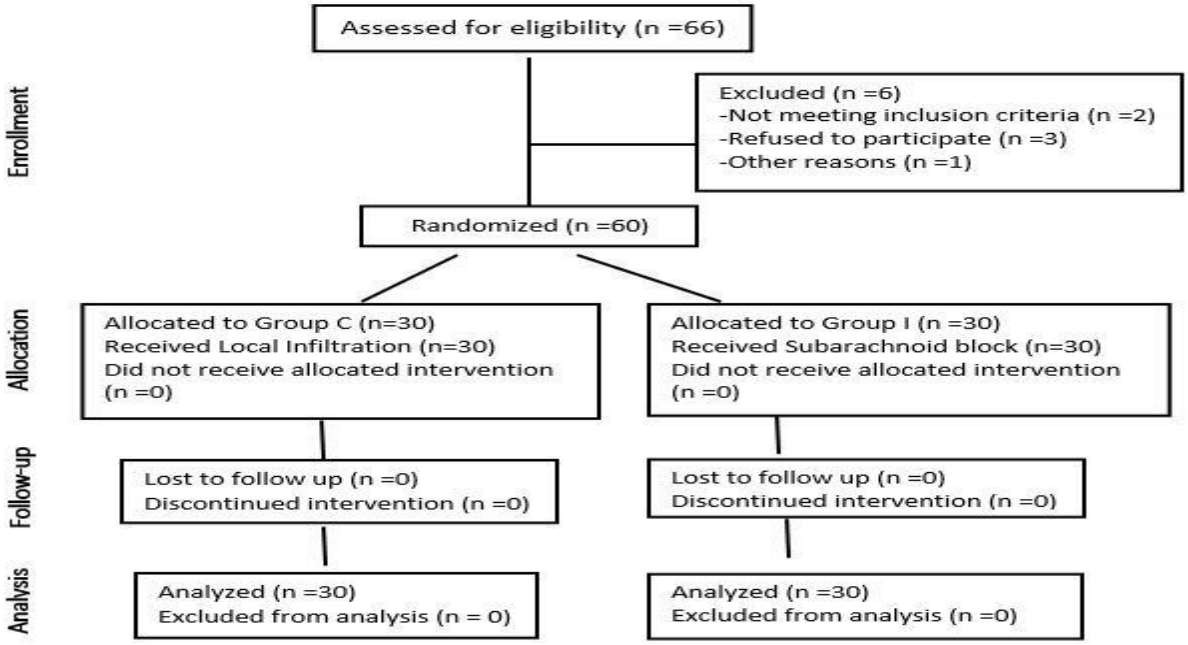

Figure 1: CONSORT diagram showing the flow of participants through each stage of a randomized trial.

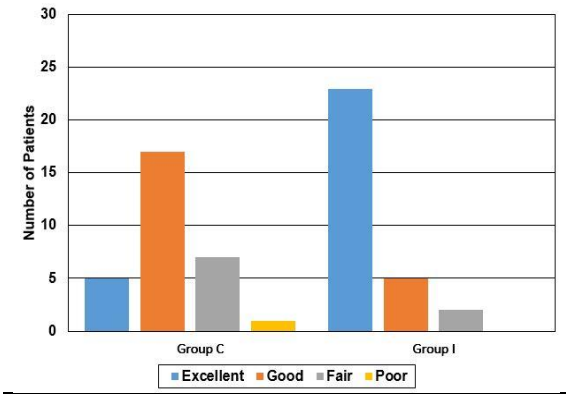

Figure 2: Shows quality of analgesia in different groups with majority of patients having excellent analgesia with subarachnoid block.

Table 1: Patient Characteristics.

Variable	Group C(n=30)	Group I (n=30)	P value
Age (year)	37.1±6.8	38.7±8.5	0.42
Height (cm)	164±6.8	162±7.5	0.28
Weight (kg)	54.3±7.9	57.7±7.6	0.09
Duration of surgery(minutes)	35.3±15.2	31.3±16.0	0.32

n=number, mean±SD, p≤0.05 statistically significant (Source: Authors)

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]

Table 2: Outcome variables and side effects.

0	Group C (n=30)	Group I (n=30)	P value
Pain level (%)			
No	5(16.7%)	23(76.7%)	-
Mild	17(56.7%)	5(16.7%)	-
Moderate	7(23.3%)	2(6.7%)	-
Severe	1(3.3%)	0	-
No. of fentanyl boluses (n)	1.33±0.95	0.33±0.66	0.0001
Hypotension	0	0	0.00
Pruritus	0	4(13.3%)	0.04
Nausea and Vomiting	2(6.6%)	3(10%)	0.64
Backache	2(6.6%)	5(16.6%)	0.23
Headache	0	1(3%)	0.31
Time to meet discharge criteria(mins)	134±20.08	138±19.05	>0.05

n=number, mean±SD, p≤0.05 statistically significant (Source: Authors)

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 CO_2 tension or the CO_2 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 cervical 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 punctre 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[6] reported the use of intrathecal fentanyl with a dilute solution of bupivacaine and observed better anesthesia 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.

REFERENCES

1. Liam BL, Yim CF, Chong JL. Dose response study of lidocaine 1% for spinal anaesthesia for lower limb and perineal surgery. Can J Anaesth 1998; 45(7): 645-50.
2. Akhtar N, Quadir A, Athar M, Singh N. Recovery profile of intrathecal ropivacaine with or without fentanyl: A randomized double-blind controlled trial in equivalent doses. Int J Health Allied Sci 2016;5:158-63.
3. Athar M, Ahmed SM, Ali S, Doley K, Varshney A, Siddiqi MMH. Levobupivacaína o ropivacaína: un ensayo aleatorio doble ciego controlado con dosis equipotentes en la anestesia espinal. Rev Colomb Anestesiol. 2016;44:97–104.
4. Athar M, Ahmed SM, Ali S, Siddiqi OA. Levobupivacaine: A safer alternative. J Curr Res Sci Med 2016;2:3-9.
5. Cousins MJ, Mather LE. Intrathecal and epidural administration of opioids. Anesthesiology 1984; 61: 276-310.
6. Ben-David B, Maryanovsky M, Gurevitch A, et al. A comparison of minidose lidocaine – fentanyl and conventional dose lidocaine spinal anesthesia. Anesth Analg 2000; 91: 865-70.
7. Vaghadia H, Mcleod DH, Mitchell GW, et al. Small dose hypobaric lidocaine – fentanyl spinal anesthesia for short duration outpatient laparoscopy. A randomized comparison with conventional dose hyperbaric lidocaine. Anesth Analg 1997; 84(1): 59-64.
8. Berlin Y, Zahn J, Abramovitz S, et al. Subarachnoid small dose bupivacaine versus lidocaine for cervical cerclage. Anesth Analg 2003; 97: 56-61.
9. Martin R, Tsen LC, Tzeng G, Hornstein MD, Datta S. Anesthesia for in vitro fertilization: The addition of fentanyl to 1.5% lidocaine. Anesth Analg 1999; 88: 523-26.
10. Wang C, Chakrabarti MK, Whitwam JG. Specific enhancement by fentanyl of the effects of intrathecal bupivacaine on nociceptive afferent but not on sympathetic efferent pathways in dogs. Anesthesiology 1993; 79: 766-73.

11. Penning JP, Yaksh TL. Interaction of intrathecal morphine with bupivacaine and lidocaine in the rat. Anesthesiology 1992; 77: 1186-200.
12. Ben- David B, Solomon F, Levin H, et al. Intrathecal fentanyl with small dose dilute bupivacaine: better anesthesia without prolonging recovery. Anesth Analg 1997; 85: 560-65.
13. Liu S, Chiu AA, Carpenter RL, et al. Fentanyl prolongs lidocaine spinal anesthesia without prolonging recovery. Anesth Analg 1995; 80: 730-34.
14. Ben- David B, Miller G, Gavriel R, Gurevitch A. Low dose bupivacaine fentanyl spinal anesthesia for cesarean delievery. Reg Anesth Pain Med 2000; 25: 235-39.
15. Ben- David B, Solomon F, Levin H, et al. Low dose diluted spinal bupivacaine for ambulatory surgery. Anesth Analg 1996; 83: 716-20.
16. Ben- David B, Frankel R, Arzumonov T, et al. Minidose bupivacaine-fentanyl spinal anesthesia for surgical repair of hip fracture in the aged. Anesthesiology 2000; 92: 6-10.
17. Belzarena SD. Clinical effects of intrathecally administered fentanyl in patients undergoing cesarean section. Anesth Analg 1992; 74: 653-57.
18. Palmer CM. Early respiratory depression following intrathecal fentanyl-morphine combination. Anesthesiology 1991 ; 74: 1153-55.
19. Cheney MA. Side effects of intrathecal and epidural opiates. Can J Anaesth 1995; 42: 891-903.
20. Moore DJ. Complications of regional anesthesia. In: Bonica JJ, ed. Regional anesthesia. Philadelphia: FA Davis, 1969: 218-51.
21. Brown EM, Elman DS. Postoperative backache. Anesth Analg 1961; 40: 683-85.

How to cite this article: Siddiqi OA, Athar M, Ali S, Najar SN. A Randomized Controlled Trial of Infiltration versus Low Dose Subarachnoid Block in Hydrocele Surgery. Ann. Int. Med. Den. Res. 2016; 2(6):AN33:AN37.

Source of Support: Nil, **Conflict of Interest:** None declared