Prospective Randomised Control Study of Femoral Nerve Block -Suitability and Efficacy of 10cc of Bupivacaine 0.25% with or Without 25mceg Fentanyl for Post Operative Analgesia In Skin Grafting at Donor Site.

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Date of Submission: 19-07-2019 Date of acceptance: 05-08-2019

I. Introduction

Relieving pain is one of the fundamental responsibilities of anaesthesiologists and is frequently a primary goal for which patients are seeking care. Peripheral nerve block are becoming more popular due to minimal or no side effects . Femoral nerve block is also a method of anesthetizing the antero medial aspect of the thigh[1]. It can be used for skin graft harvesting, in addition to various surgeries on the thigh and knee. In painful skin grafting procedures, opioids may be needed to treat the patients with severe pain. So we carried out the study in sixty consecutive patients with femoral nerve block for post operative analgesia at donar site in skin grafting patient with 10cc of 0.25% bupivacaine alone and with 25ug of fentanyl.

II. Material And Methods

The study was performed as a randomized, prospective, double blind, clinical trial in 60 adult patients after getting approval from the hospital ethics committee. Inclusion criteria - Adult male or female patients between the age group of 14yrs to 70yrs posted for skin grafting from lower limb with ASA Grade I and II, those who gave written informed consent.

Exclusion criteria - Those with ASA Grade III, IV patients known to have or suspected to have Diabetics, Leprosy, femoral artery graft , Lower limb neurological deficit and patients with known or suspected allergy to local anesthetics and narcotics, or to other medications used under study . Patient were randomly assigned to either of the groups (30 patient per group) Group B received 10cc of injection bupivacaine 0.25%. Group BF received injection fentanyl 25ug and 10cc of injection bupivacaine 0.25%.

A detailed pre-anaesthetic evaluation including history of previous medical illness, previous surgeries, general examination and appropriate baseline investigations was carried out and recorded in the proforma. An informed written consent was obtained. All preoperative medications were continued until the morning of the surgery. All patients were premedicated only with IM inj. of glycopyrrolate 4microg/kg body wt, half an hour prior to surgery.

On the operation table, patients were re-examined. Intravenous access was obtained and a slow ringer lactate drip was started. Standard moniters like sphygmomanometer ,pulse oximeter(spo2), electrocardiogram (ECG), capnogram were attached to the patient .Also Baseline values of heart rate, blood pressure (systolic/diastolic, mean arterial pressure) were recorded by an observer who did not know which group the patient is assigned to. After baseline recordings, the patients received sedation with IV midazolam 0.03 mg/kg body wt and analgesia with IV fentanyl 2 mcg/kg body wt. 10 minutes after sedation and analgesia induction of general anaesthesia was started. All patients were pre-oxygenated with 100% oxygen by face mask for 3 minutes. Induction was done with propofol IV (2mg/kg body weight) after confirming ventilation pancuronium IV 2mg/kg body weight was given and patient was ventilated with O2:N20: Isoflurane 50:50:0.8% respectively.

Laryngoscopy was performed and intubation with appropriate size endotracheal tube was done. Patients was then maintained with 50:50 of oxygen and nitrousoxide and intermittent isoflurane 0.5% using a circle with absorber circuit, at a average rate of 10-12 breath/min and a tidal volume6 to 8 ml/kg.

At end of surgery before surgical anesthesia was reversed femoral nerve block was given with short bevel regional anesthesia needle or 22G needle at the point 1.5 cm lateral and 1.5 cm distal to the intersection of the inguinal ligament and the femoral artery. where the femoral nerve lies below two facial planes: the fascia lata and the fascia iliacus. By simply feeling two successive "pops" as a short bevel regional anesthesia needle passes through these fascial layers indicates placement of the needle in the perineural space.10cc of injection

bupivacine 0.25% alone or with 25ug injection fentanyl was given after piercing the deep fascia.by loss of resistance technique in that region. Anesthseia was completely reversed with neostigmine 0.05 mg/kg body weight and patient was extubated after fulfilling extubation criteria. Post operatively the base line hemodynamic parameters were recorded at this stage and only those patients without haemodynamic compromise were involved further in the study. The pain score was noted by visual analog scale(VAS).0 as no painand 10 asworst possible pain

VAS Scale											
0	1	2	3	4	5	6	7	8	9	10	

Visual Rating Prince Henry Scale (VRS)

- : no pain on coughing (score=0)
- : pain on coughing but not on deep breathing (score=1)
- :pain on deep breathing (score=2)
- : pain at rest ,but slight (score=3)
- :pain at rest severe (score=4)

This degree postoperative pain, and corresponding pulse rate, systolic and diastolic blood pressure was assessed on arrival to the recovery room at a interval of 15min, 1st hour ,3rd hour 5th hour and at 7th hour after giving femoral nerve block . Time interval between accomplishing of femoral nerve block at the donor site and requirement of first rescue analgesia was noted .Patient complaining of pain after giving femoral nerve block was given rescue analgesia with injection diclofenac 75mg intramuscular route when VAS score was 5 or more than 5 at appropriate interval. Side effect like nausea, vomiting, sweating, bleeding, intravascular injection of drug and anaphylaxis were noted in both the groups at different interval of time.

III. Observation And Result

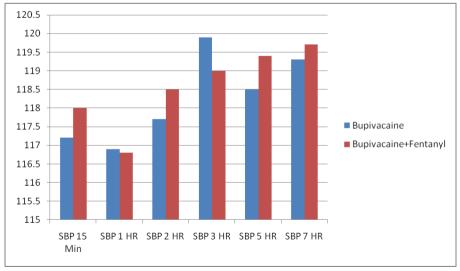
Patients in both the groups were comparable with respect to demographic characters of age and gender. The groups were also comparable with respect to haemodynamic parameters of pulse rate (PR), systolic blood pressure (SBP), diastolic blood pressure (DBP), at baseline.

TABLE 1: Comparison of sex wise distribution of two groups

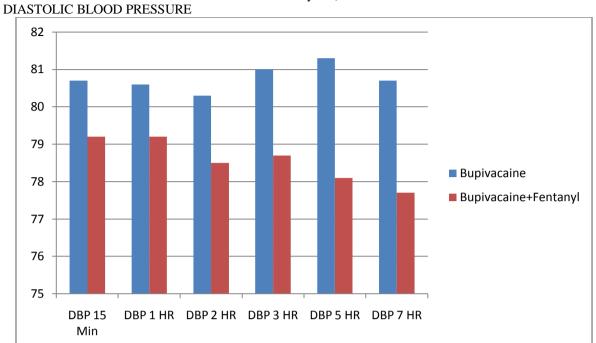
Sex	В	upivacaine	Bupivacaine+Fentanyl		
	n	%	n	%	
Male	12	40	11	36.7	
Female	18	60	19	63.3	
Total	30	100	30	100	

GRAPH 1: Comparison of mean systolic blood pressure between two groups (Result are presented by Mann-Whitney test)

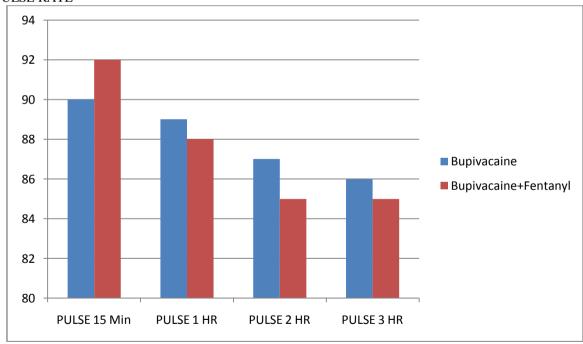
SYSTOLIC BLOOD PRESSURE



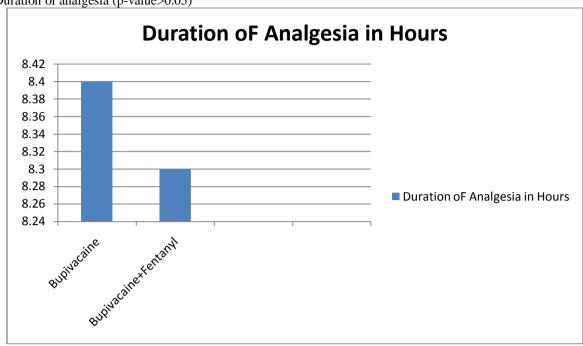
GRAPH 2: Comparison of mean diastolic blood pressure between two groups (Result are presented by Mann-Whitney test)



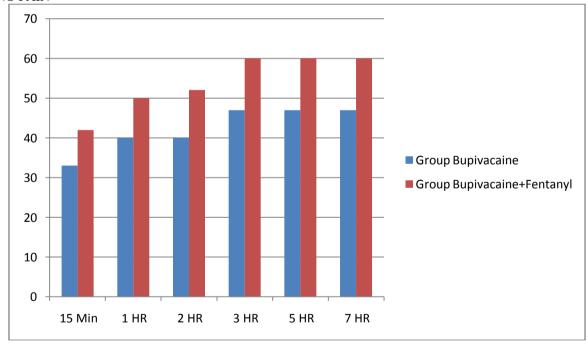
GRAPH 3: Comparison of mean pulse rate between two groups (Result are presented by Mann-Whitney test) PULSE RATE

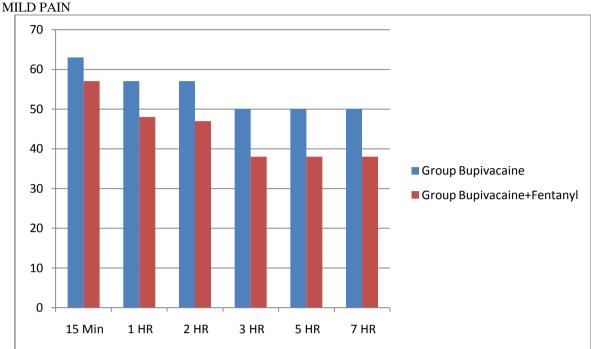


GRAPH 4: Comparison of Duration of analgesia in two groups (Result are presented by unpaired t test) Duration of analgesia (p-value>0.05)

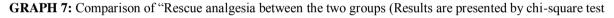


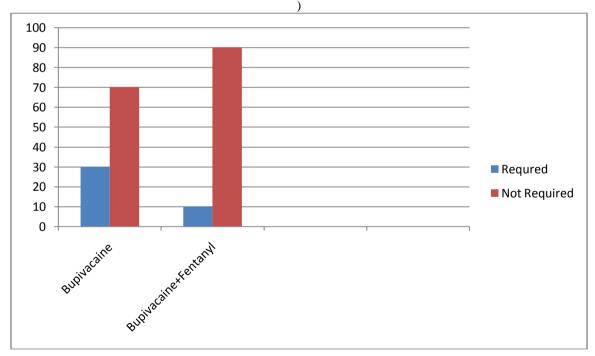
GRAPH 5 : Comparison of VAS Score in two groups (Result are presented by MannWhitney test) NO PAIN





GRAPH 6: Comparison of VAS Score in two groups (Result are presented by Mann- Whitney test)





Duration of post operative analgesia with group B was 8.43(+1.90) hours and with group . BF was 8.33(£1.70) hours. In this study the mean pulse rate at 15minn in group B was 2:89.6(£12.4) per min. while that of group BF was 91.5(£11.5) min. At 2hr mean pulse rateWY was 86.8(+10.8) in group B and 84.5(+9.5) per minutes in group BF while at 7th hour 82.1(+7.5) in group B and 80.7(+7.2)in group BF per minutes.Graph(3) The mean systolic blood pressure at 15 min was 117.3(£10.9) mm of Hg in group B and 118.0(+10.0) in group BF while at Shr 117.7(+9.9) in group B and 118.5(£9.7) in group BF and 7th hour 119.0(+6.8) in group B and 119.7(£8.9) mm of Hg in group BF. while mean diastolic pressure at 15 min in group D was 80.7(+6.9) mmHg and in group BF 79(+7.0) mm Hg at 5" hour 81.3(47.7)mm Hg in group B and 78.1(+7.7)mm Hg lin group BF while at 7 hour 80.7(+6.8)in group B and 77.7(+6.6) mm of Hg in group BF. While by Mann-Whitney test the

VAS score at ISmin shows 63 % of patient had mild pain in group B and 57% of patient in group BF had no pain after taking detail history. while at 5" and 7" hour 50% of patient in group B and 38% patient in group BF had mild pain .while at 15min 42% of patients in group BF and 33% in group B had no pain while at 5" and 7" hour 60% of patients in group BF and 47% in group had no pain there was no statistically significant difference in VAS score at |"and 2TM hour. Nine patient in group B and three patient in group BF was given rescue analgesia when VAS score was showing moderate pain aftercomplain of discomfort by the patient within 12 hour of giving femoral nerve block. No complications related to the infiltration of the local anesthetic were observed during study.

IV. Discussion

The optimal postoperative pain control for ambulatory surgery should be effective and safe, produce minimal side effects, facilitate early recovery and can be easily managed by patients after discharge. Postoperative pain is one of the main barriers to increasing the _range of ambulatory procedures.

Persistent pain has been shown to lead to postoperative nausea and vomiting (Anderson et al. 1996), delayed discharge (Chung 1995c), contact with medical facility after discharge (Fortier et al. 1996) and unanticipated admissions (Gold et al. 1989, Fortier et al 1996). Under treatment of pain is common in outpatients (Beauregard et al. 1998). Beauregard et al. reported that 40% of discharged outpatients suffered from moderate to severe pain during the first 24 hours. Management of postoperative pain in patients undergoing skin grafting has used several techniques but use of peripheral nerve block has been main recommendation. Postoperative pain can be managed by pharmacological methods like opiods, NSAIDS, local anesthetics (Infilteration, peripheral nerve block ,continous infusion) and non pharmalogical methods like acupuncture, Cryoanalgesia, Hypnosis and relaxation and Transcutaneous electric nerve stimulation (TENS).

The practice of postoperative pain control counts little unless patient satisfaction is elevated and patient outcomesare improved. The use of regional anesthesia and analgesia techniques in skin grafting patients is gaining favor (8) The most common local anesthetics used is bupivacaine (0.0625%, 0.125%.0.25% 0.5%)Ropivacaine is an alternative (0.05%, 0.075% | 0.1%, 0.2%).[15]Use of opiods in petipheral nerve block after general anaesthesia reduces '| postoperative pain and analgesic requirements more effectively and at a lower average | patient cost than bupivacaine alone The most common opioids are:

- 1) Morphine—bolus 1-4 mg and infusion 25-50 g/mLat 5-15 mL/h
- 2) Fentanyl—bolus 25-100 ug and infusion 1-10 g/mL at 5-15 mL/h
- 3) Dilaudid—bolus 0.1-0.3 mg and infusion 3-12 g/mL at 5-15 mL/h [15]

Peripheral administration of an opioid agonist could theoretically inhibit the propagation of action potential or release of excitatory transmitters in primary afferent fibres, since opioid receptors have been demonstrated on primary afferent neurons (17,16)

Femoral nerve damage after femoral nerve block is unreported, and the use of a femoral nerve block in an anaesthetized patient without using a peripheral nerve stimulator has been described in previous studies .(7):

In this study the peripheral nerve stimulator was not used to signify a successful femoral nerve block with bupivacaine, as we felt it might unblind the anaesthetist, although it has been documented that a normal saline can also abolish the twitch response(6).

The most impressive differences between the two groups was their differing one of analgesic requirements during their stay in observation ward. Patients who receive a bupivacaine 0.25% alone had larger requirement of rescue analgesia after the effect of block ended. The number of analgesic administrations over the first 12 hour postoperatively demonstrated that the analgesic requirement of the bupivacaine and fentanyl group tended to decrease, whereas the requirement of the bupivacaine group increased with time. From the seventh to the twelfth hours, the number of analgesic administrations to the bupivacaine group was greater than that of the bupivacine and fentanyl group.

Visual analogue scale (VAS) is one of the most widely accepted methods to evaluate pain in the perioperative period. The VAS comprises a line (usually 10 cm long) representing the

spectrum of pain ranging from no pain at all to the worst pain imaginable.we will refer to the excellent study by iled to dem. (2001). who had 3 treatment groups receiving only single-injection femoral nerve block (25 mL of bupivacaine 0.25%, versus 0.5%, versus sham block consisting of assembled equipment and sterile skin preparation, with palpation and shaking of the quadriceps femoris muscle).

The pain scores in their sham treatment group gradually increased over the 8 postoperative days to a visual analog pain score of 5 out of 10 by day 8, versus Scores of 3 in the bupivacaine groups.1 Although the small patient sample precluded statistical conformation of this trend, this may have reflected the gradual onset of pain after the analgesic effects of the block ended the bupivacine

Indeed, the pain relief in the bupivacaine and fentanyl group may have not lasted much longer than with alone during stay in observation ward. The addition of fentanyl to the bupivacaine, to prolong analgesia,

may warrant future study. Kardash and colleague [16] who failed to demonstrate clinically relevant effect of adding opiods to local anesthetics such as mepivacaine in supraclacvicular block due to different pharmokinetics profile of the drugs .Nishikawa and colleague [17] reported improved success rate of sensory blockade but delayed onset of analgesia of adding fentanyl 0.IImg to lidocaine 15mg/ml which was explained with decreased pH of local anesthetics soloution caused by fentanyl addition

V. Conclusion

Femoral nerve block with 10cc of 0.25% bupivacaine alone or with fentanyl 25mcg at the donar site for skin grafting provides analgesia for 7-8hr .However suitability of adding fentany! 25ug to bupivacaine is questionable as it does not prolong the analgesia althoughimprove the quality of analgesia.

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Dr Priyanka moon. "Prospective Randomised Control Study of Femoral Nerve Block - Suitability and Efficacy of 10cc of Bupivacaine 0.25% with or Without 25mceg Fentanyl for Post Operative Analgesia In Skin Grafting at Donor Site.." IOSR Journal of Dental and Medical Sciences (IOSR-JDMS), vol. 18, no. 8, 2019, pp 23-39.