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Original Research Article

Comparison of intra-articular injection of local anaesthetic Ropivacaine versus Ropivacaine+Ketorolac and Ropivacaine+Tramadol for post-operative pain relief in knee and hip arthroplasty surgeries under spinal anaesthesia

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ABSTRACT

Context: Local anaesthetic infiltration in knee and hip arthroplasty is employed as a part of multi-model analgesia to reduce opiate consumption and help in early ambulation of elderly people It reduces post-operative pain effectively and thus reduces complications like Deep vein thrombosis, pulmonary embolism, pneumonia and even myocardial infection. Addition of ketorolac or Tramadol further prolongs the duration of analgesia.

Aims: To compare the local anaesthetic infiltration of Ropivacaine alone and Ropivacaine with Ketorolac and Ropivacaine with tramadol for postoperative pain relief in knee and hip arthroplasty.

Materials and Methods: Randomize double-blind study was conducted on 60 patients undergoing knee or hip arthroplasty under spinal anaesthesia. Group A patients received wound infiltration with Inj. Ropivacaine0.75% 50ml (5-7 mg/kg), Group B patients received Inj. Ropivacaine 0.75% 50 ml+1ml Inj. Ketorolac(30 mg) and Group C patients received Inj Ropivacaine 0.75% 50 ml+ Inj Tramadol 2ml (100mg), all diluted with NS to make 100 ml infiltration. Post-operative pain scores, time of first rescue analgesia (FRA), hemodynamic parameters and total rescue analgesic consumed in 24 hrs. as Inj Diclofenac and Tramadol was assessed and any untoward incidences like nausea, vomiting, knee swelling & Hypotension etc. were noted.

Results: The VA Score was significantly lower in Grp C as compared to Grp B and A in first 4-6 hrs. as tramadol and ketorolac significantly prolongs the duration of analgesia. VA score in Grp Cis 3.8+_0.52, as compared to 4.02 ± 1.58 in Grp B and 5.7 ± 1.014 in Grp A. which was statistically significant (P value 0.0141). The time of first rescue analgesia (FRA) was also prolonged by 2.2 hrs. in Grp C as compared to Grp B and C which is statistically significant. (P value 0.003). The total rescue analgesia in 24 hrs. given as Inj Diclofenac and Inj Tramadol was significantly lower in Grp C as compared to Grp B and A. No of pts requiring rescue analgesia was also less 45% in Grp C as compared to 50% and 95% in Grp B and A respectively. 25% pts in Grp C has excellent pain relief as compared to 20% in Grp B and 10% in Grp A. No untoward effect like nausea vomiting is noted in any patient, only 3 pts in Grp A and 2 pts in Grp B required bl transfusion.

Conclusion: Local infiltration of Ropivacaine provides good analgesia. Addition of tramadol or Ketorolac prolongs the analgesic effect of Ropivacaine and lowers the VAS significantly and improves patient satisfaction score. It also decreases post-operative 24hrs NSAID or opioid consumption.

1. Introduction

The last decade has seen growing use of enhanced recovery pathways (also known as “fast track” recovery

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and rehabilitation). Post-operative pain relief has shown both improved patient care and reduced length of hospital stay and thus has huge implications in terms of health care savings. Pt for total knee and hip surgery are usually elderly, with other associated co-morbidities and require early ambulation in order to reduce the complications like bed-sores, deep vein thrombosis, thrombo-embolism, respiratory complications like pneumonia and M.I. There has been a shift towards the use of regional anaesthesia over general anaesthesia in knee and hip surgeries. [1–4]

In order to optimize pain control in early post-operative period several adjuncts have been tried, these includes continuous epidural anaesthesia, peripheral nerve block and local anaesthetic infiltration in the joint (intra-articular and pari-articular space). Local anaesthetic infiltration in the joint is a safe and easy technique without much expertise and complications as compared to other techniques like continuous-epidural block, peripheral nerve block or systemic opioid administration which all require either expertise or are full of complications. Based on the principle of blocking the pain signal at the site of nociceptive stimulus. [5]

Most studies use a multimodal approach using either Bupivacaine or Bupiv plus analgesic or opioids. In our study we used Ropivacaine which is a long acting local anaesthetic agent with less Cardiac and C.N.S toxicity as compared to Bupiv and adding analgesic and anti-inflammatory agents (Ketorolac &/or Tramadol) further increases the duration of block.

Ketorolac-A non-steroidal anti-inflammatory drug (NSAID), works by blocking synthesis of P.G in the body tissue by inhibiting 2-cyclooxygenaes isoenzyme COX1 AND COX2, thus decreasing pro-inflammatory cytokinin activity and inhibit neutrophil aggregation.

Tramadol- An opium related pain reliever, 10 times less potent than Morphine and acts by binding to u–opioid receptors. Also, a serotonin-norepinephrine re-uptake inhibitor causes less respiratory depression and other side effect as compared to Morphine.

2. Materials and Methods

This study was conducted after obtaining institutional ethical committee approval, as randomized double-blind controlled study. An informed written consent was obtained from all the patients. Sixty patients of ASA Group I, II and III (as our patients are elderly and HT and DM are common finding) are included in the study. Patients with uncontrolled HT, DM, those with h/o MI, Bronchial Asthma, Anaphylaxis to L.A, Anemia, and body weight above 100 kg were excluded from the study. Also, patients who were unable to understand VAS score were excluded from the study.

Patients were randomized into three Groups (n=20 each), according to computer generated random numbers and kept in separate sealed envelopes.

GRP A- Patients received inj. Ropivacaine 0.75% 50 ml (5-7.5mg/kg or 375 mg as max safe dose)+ 0.1 ml Adrenaline (1c.c diluted in 10ml, 1;10,000) +50 ml of NS, to make it 100 ml, infiltrated at the time of wound closure intra &/or periarticular by the surgeon who is blind to the drugs used.

GRP B - Patients received Inj. Ropivacaine 0.75% 50 ml + Inj. Ketorolac 30 mg(1ml) (safe dose of Ketorolac is 30 mg iv as single dose +0.1ml (1;10,000) Adrenalin+49 ml of NS to make it 100ml

GRP C– Patients received Inj. Ropivacaine 0.75% 50 ml + Inj. Tramadol 100 mg (2 ml) (Safe dose of Tramadol is 100 to 200 mg or2-4 mg/kg) +0.1ml(1;10,000)Adrenalin +48 ml of NS to make it 100 ml.

An Anaesthetist not involved in the conduct of anaesthesia and post-operative management prepared the study drugs and handed over to the surgeon for Intra and Peri articular injection at the time of closure of the wound. A blind observer assessed the patients for post-operative pain relief up to24 hours after surgery.

A thorough pre-anaesthetic checkup was conducted before surgery which Includes history taking, GPE (general physical examination), SE (systemic examination), and routine investigations which includes a complete hemogram, coagulation profile, fasting blood-sugar, ECG and X-ray chest. Any special investigation needed prior to surgery was done. VAS scoring system was explained to all patients thoroughly before surgery.

After shifting the patient in O.T, monitoring of HR, NIBP, SPO_2, and ECG started. These parameters were recorded thorough out the surgery. All patients were pre-loaded with 500 ml of RL and then given SAB in sitting position. Only 2 patients were given combined spinal epidural block (catheter placement) as surgeon planned for bilateral surgery. A27 G Quincke's needle was introduced in L2-L3 /L3-L4 vertebral space after painting and draping and with all aseptic precautions. A dose of 0.5% Bupivacaine heavy 3 to 3.5 ml was given. All patients were given Inj. Mephentermine 6mg in drip in order to prevent hypotension, with additional doses of 6mg given as bolus if patient had BP<90mmof HG. Patients who had incomplete blockade (not up to T6 level) or where surgery was prolonged and hence converted to GA, were excluded from the study.

At the end of surgery all patients received IA & PA infiltration of the study drugs by the surgeon on a random basis taken from a sealed envelope of which surgeon was blinded. All patients were shifted to the post-operative ward and were monitored for HR, BP, SPO_2. Post-operative pain scores were recorded at 0hrs., 30min, 1,2,4,6,12 and 24hrs. in the post-operative period. All patients received post-operative infusion of Inj. Neomol 1gmBD as slow infusion repeated every 12 hours for baseline analgesia and anti-inflammatory effect. Patients with VAS score4 and above

were given rescue analgesic, Inj. Diclofenac 1ml (75mg) iv diluted in 10 ml NS and if not relieved a further dose of Inj. Tramadol 50 mg iv was given. Time of first rescue analgesic (FRA) and the total dose of rescue analgesic given in 24 hrs. were noted. All patients who received rescue analgesic were then given Inj. Diclofenac every 8 hour and Inj. Tramadol (50-100mg) as and when required.

The quality of pain relief was assessed by Patients satisfaction score (PSS). All patients were observed for any untoward effect like N&V, Hypotension, Blood transfusion requirement etc. VAS and PSS were assessed as follows

2.1. *VAS score (0-10)*

0-4 mild, 4-6 moderate, 6-8 severe, > 8 extreme.

2.2. *PS score*

4-excellent, 3-good, 2-moderate, 1-poor.

2.3. *Sample size calculation*

We followed the study by L.O Anderson et al." High volume infiltration analgesia "Acta Anaesthesiologica Scandinavica", vol 52 no 10, pp1331-1335 2008 in which a sample size of 12 pts was used. This sample size was considered very small for a biomedical study. Based on the central limit theorem we decided to include 20 pts in each grp to study the difference of score of 2 in VAS with 95% confidence interval, power of 80% and an alpha error of 5%.

2.4. *Statistical analysis*

SPSS software (version 16 Chicago IL) has been used for statistical analysis. Data was presented as mean, SD, Median(range) or percentage as applicable. Analysis of variance (ANOVA) was used to find the significance between three groups for continuous variables and paired t-test was used for inter-group comparison. Categorical data were presented as numbers (proportion) and compared with Chi- Square test. 'P' value of < 0.05 % was considered statistically significant.

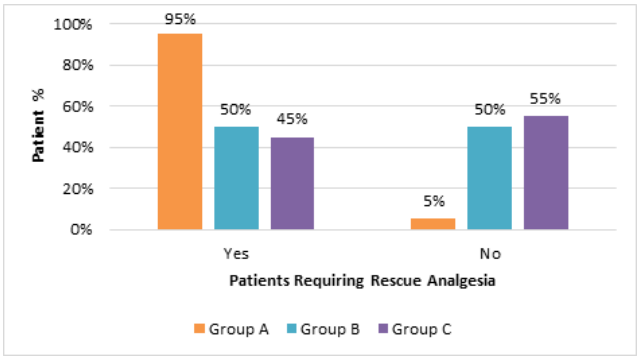

Fig. 1: Patients requiring rescue Analgesia (FRA)

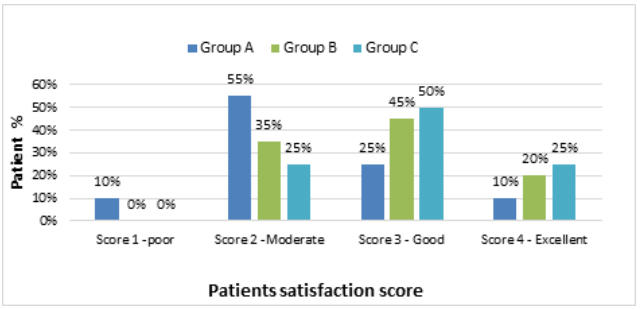

Fig. 2: Patients satisfaction score

3. Observation and Results

All three groups were comparable in respect to demographic data, (age, sex, weight) and pre-operative vitals HR, BP and Hb levels are all comparable in all the three Groups and are statistically insignificant (Table 1, P value>0.05).

Post-operative baseline HR at 0 hr. were comparable in all the three Groups and are statistically insignificant (P value>0.05). Mean HR was higher in Group A as compared to Group B and C at 4hrs. and 6hrs. post-operatively, which was related to higher Vas Score in Grp A and Grp B and is statistically significant (P value<0.025,0.026)

At 0hr. 1hr, 2hr & 4hr VAS Score were comparable in all three Groups and are not statistically significant. Vas Score was significantly higher in Group A as compared to Group B and Group C.at 6hrs,8hrs and so on It was statistically significant (P value 0.003,0.006 and so)) at - 6, 8, 12, 16 and 24 hrs. post-operatively. The mean time for first rescue analgesic (FRA) was 3.13 ±2.07hrs. in Group A,4.8 ± 2.24 hrs.in Group B and in Group C it was 5.2 ± 2.4hrs. This difference is statistically significant (P value<0003). Patient in Group B & Group C had later onset of pain, (Group A 180 ± 115 min, Group B 290 ± 130min and Group C has 310 ± 120min.) by 110 min in Group B and 130 min in Group C which was statistically significant (P value 0.003).

The no of patients requiring rescue analgesic were 95 % in Group A, as compared to50% in Group B and 45% in Group C.

The total dose of rescue analgesia required was Inj.Diclofenac 96.56 ± 37.52 mg and Inj. Tramadol123.33 ± 32.50 mg in Group A, as compared to 54.85 ± 22.56 mg & 80.56 ± 21.95mg in Grp B and 46.89 ± 21.92 mg & 63.56 ± 22.20mg in Group C, which is statistically significant(P value 0.0047 & 0.0007). Thus, patients in Group B&C had better pain relief with Mean VAS Score of 5.7 ± 1.01in Group A, 4.02+_3.58 in Group B and 3.8 ± 0.52 in Group C which is statistically significant (P value 0,0141)).

4. Discussions

Subcutaneous wound infiltration with local anaesthetic is effective, safe, inexpensive and without the need of

Table 1: Pre-operative demography

Particulars	Group A		Group B		Group C		P value
	Mean	Std	Mean	Std	Mean	Std	
Weight	56.15	13.5	57.56	121.8	55.59	13.87	0.8917
Age	60.15	7.6	58.46	9.3	59.25	10.2	0.8417
M/F Ratio	18:02	-	19:01	-	17:03	-	-
Heart Rate	90.36	5.35	91.46	4.38	90.59	4.35	0.7395
B.P(Sys)	96.55	25.6	98.23	24.9	99.45	12.3	0.9148
B.P(Dias)	80.35	13.56	78.22	12.56	81.59	14.93	0.7355

Table 2: Comparison of post-operative heart rate in groups

Hr.	Group A		Group B		Group C		P value
	Mean	SD	Mean	SD	Mean	SD	
0	91.8	11.8	90.07	12.85	91.05	12.21	0.905
30min	91.98	11.8	91.05	12.9	91.03	12.2	0.963
1h	92.46	12.01	91.35	12.98	91.22	12.26	0.943
2h	92.78	12.56	91.9	12.99	91.35	12.58	0.935
4h	98.8	14.21	93.85	12.9	92.06	12.56	0.0257
6h	100.5	15.94	95.08	13.56	93.32	12.85	0.0256
8h	92	12.22	90.98	12.01	90.56	11.85	0.927
12h	88.2	13.56	84.28	12.68	83.95	10.55	0.516
16h	84.12	12.01	84.5	12.06	83.15	10.56	0.925
20h	84.52	12.56	82.56	12.66	84.26	11.53	0.894
24h	82.17	11.59	82.98	12.84	82.96	12.01	0.96

Table 3: VAS score

Hr.	Group A		Group B		Group C		P value
	Mean	SD	Mean	SD	Mean	SD	
0h	2.03	1.21	2.05	1.01	1.35	1.56	0.677
30 min	2.33	1.23	1.76	1.32	1.86	1.63	0.396
1h	2.65	1.67	1.78	1.33	1.94	1.7	0.188
2h	3.05	1.95	2.63	2.35	2.03	1.86	0.299
4h	3.15	2.18	2.66	2.35	2.16	1.89	0.0309
6h	3.08	2.05	1.88	1.85	1.8	1.7	0.003
8h	2.88	1.63	1.51	1.55	1.5	1.36	0.0064
12h	2.56	1.53	1.02	1.5	1.32	1.26	0.003
16h	2.56	1.48	1.02	1.5	1.3	1.2	0.0021
20h	1.3	0.58	0.91	0.56	0.68	0.59	0.0035
24h	1.3	0.56	0.9	0.55	0.66	0.56	0.0023

Table 4: Time for first rescue analgesic(FRA)

	Group A		Group B		Group C		p value
	Mean	SD	Mean	SD	Mean	SD	
Time for first rescue analgesic given (hrs.)	3	1.9	4.8	2.24	5.2	2.04	0.003
VAS Score	5.7	1.01	4.02	3.58	3.81	0.52	0.0141

Table 5: Total rescue analgesic given in 24hours (in mg)

Total rescue analgesic given in 24 hrs. in mg	Group A		Group B		Group C		P Value
	Mean	SD	Mean	SD	Mean	SD	
Inj. Diclofenac (mg)	76.56	37.52	54.85	22.56	46.89	21.92	0.0047
Inj. Tramadol (mg)	96.33	32.5	80.56	21.95	63.56	20.28	0.0007

any expertise. Several studies used local infiltration using multi-model approach.[6,7] A systemic review and meta-analysis substantiated the analgesic efficacy of local anaesthetic wound infiltration using inj. Bupivacaine in knee arthroplasty and Bupivacaine+Ketorolac and they found statistically significant reduction in post-operative pain and total opioid consumption in 24 hrs.[8,9] We used inj. Ropivacaine as it is less cardiotoxic than Bupivacaine and is long acting. L.J Anderson & Poulsen used Ropivacaine and Ropivacaine + ketorolac and found significant post-operative pain relief after wound infiltration, they used 300mg of Ropivacaine as safe upper limit and we used slightly higher dose of 375 mg as safe upper limit and found that in 4hrs post-operatively only 2 pts required rescue analgesic.[10]

Our study portrays that wound infiltration with L.A provides adequate analgesia and addition of Inj. Ketorolac and Inj. Tramadol further prolongs the pain free period significantly(Pvalue0.003).The time of FRA was prolonged in Group B&C as compared to Group A(P value0.003)and mean VAS Score at FRA was also low in Group B& C as compared to Group A (P value 0.0141). The total dose of RA required in terms of Inj. Diclofenac and Inj. Tramadol was also less in Group C as compared to Group B which in turn was also less as compared to Group A, which implies that addition of Tramadol provides significant prolongation of FRA and reduction in total RA & VAS Score as compared to Inj. Ketorolac, which in turn gives better results (P value 0.003 and 0.0141) as compared to Inj. Ropivacaine alone.

VAS Score at 1,2,3 hrs. were comparable in all the three groups and were statistically insignificant(P value >0.05) and so the Heart Rate at 1,2,3 hrs. Whereas at 4 and 6 hrs. VAS Score were significantly low in Group C as compared to Group B&A (P value 0.0309 and 0.0030) and so was the Heart Rate(P value 0.0257 and 0.0256). After that HR was comparable in all three Groups and was statistically insignificant as rescue analgesic was started. In Group C 25% patients have excellent pain relief (PSS 4) as compared to 20% in Group B and 10% in Group C, whereas 50% patients in Group C had good pain relief (PSS 3), compared to 45% in Group B and 25% in Group A. Two patients in Group A had poor pain relief (PSS 1) i.e. 10% and 11 patients had moderate pain relief (PSS 2) i.e. 55%, as compared to seven pts i.e. 35% in Grp B and five pts i.e. 25% in Grp C. which again shows that Inj. Ropivacaine infiltration locally in knee joint (IA/PA) provides good pain relief and addition of Ketorolac and Tramadol prolongs the pain relief significantly.

Several studies have been conducted using Inj. bupivacaine 0.5% for local infiltration,[8,9] single shot Vs continuous infiltration of L.A using catheter tech[11,12] using Inj. Ropivacaine alone[11] and all has shown significant pain relief but none has compared Ropivacaine with Ropiv + Ketorolac and /or Tramadol as has been done in this study and has shown significant prolongation of pain free period and lesser doses of rescue analgesic drugs in 24hrs.

5. Conclusion

It is now almost established that local infiltration of wound by local anaesthetic is an established method of pain relief. It is safe, effective and without much expertise and with minimum risk of complications. It is based on the mechanism of pre-emptive analgesia as it blocks the nociceptive pain impulses at its very point of origin and before pain establishes. Addition of adjuvants like Opioids, NSAIDS, or alpha-adrenergic blockers like Daxmetomidine further prolongs the analgesic effect without much complications.

5.1. Drawbacks

Our study has certain draw backs as patients were initially given spinal anaesthesia and time taken to finish the surgery was not taken into consideration. Also, different patients have different pain perception hence initial low pain score can be due to effect of spinal anaesthesia. Further different surgeons gave local infiltration hence some variation could be there which has not been taken into consideration. With infiltration of 50 ml of L.A, there are chances of infection and may require proper aseptic precautions.

6. Source of Funding

Nil

7. Conflict of Interest

Nil.

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