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A COMPARISON OF INCISIONAL INFILTRATION OF KETOROLAC WITH OR WITHOUT BUPIVACAINE VERSUS INTRAMUSCULAR KETOROLAC FOR POSTOPERATIVE ANALGESIA.

Anaesthesiology

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ABSTRACT

Background: The use of non-steroidal anti-inflammatory drugs (NSAIDs) for post-operative analgesia has become popular in surgeries ranging from minor outpatient procedures to major inpatient surgeries. In common with other NSAIDs, ketorolac has been advocated as an adjuvant to reduce post-operative pain and opioid requirements. Ketorolac is a NSAID that acts through inhibition of prostaglandin synthesis and is said to have analgesic efficacy comparable to morphine.

Aims: The study is aimed to assess and compare the effects of incisional infiltration of ketorolac with or without bupivacaine and intramuscular ketorolac for post-operative analgesia.

Methods and Material: The study was a prospective, randomized, controlled, double blinded study. 60 patients undergoing elective lower abdominal surgery were divided into three groups of 20 each. Group C (Control) received incisional infiltration with 20 ml normal saline and intramuscular ketorolac 60 mg, Group K received incisional infiltration with 20 ml normal saline with 30mg ketorolac added to it, Group KB received incisional infiltration with 20 ml of 0.25% bupivacaine with 30 mg ketorolac added to it.

Statistical analysis used: Microsoft Excel 2007 and statistical software plug-ins, Chi-square test and student t-test (Unpaired and One way ANOVA).Data are being represented as mean ± SD. A 'p' value of <0.05 was considered significant.

Results: Pain score (mean VAS score) at 2 hours postoperatively was comparable in Group C (2.40+0.50), Group K (2.20+0.41), and Group KB (2.10+0.31). Mean VAS scores at 4,6,12,24 hours respectively in postoperative period were significantly less in Group KB (2.12±0.35; 2.15±0.36; 2.85±0.74; 4.75±0.64), Group K (2.25+0.40; 2.40±0.50; 4.40±0.59; 5.50±0.51) as compared to Group C (3.25+0.85; 5.50±0.51; 6.35±0.489; 6.60±0.46). Duration of analgesia was significantly prolonged in Group KB (12.05±2.114 hours) as compared to Group K (6.8±0.834 hours) and Group C (4.10±0.641 hours).

Conclusions: Addition of ketorolac to bupivacaine for incisional infiltration produces early onset, better quality of intraoperative as well post – operative analgesia as compared to infiltration of ketorolac alone, while use of intramuscular ketorolac does not produce any significant difference in postoperative analgesia.

KEYWORDS

Ketorolac; Bupivacaine; Postoperative analgesia

INTRODUCTION

John Dyran (1631-1701)[1] said for all the happiness mankind can gain not in pleasure but in rest from pain. Pain is the most common symptom that brings patient to see a physician. Pain is not just a sensory modality but is an experience. The International Association for the study of pain defines pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. This definition recognizes the interplay between the objective, emotional & psychological components. The response to pain can be highly variable among persons as well as in the same person at different times.

Pain management especially in the post-operative period is an essential practice in the field of anaesthesiology. Providing purposeful and proper postoperative analgesia has become a popular practice for the sake of patient comfort. The pain relief during surgery is an important component of balanced anesthesia. This postoperative pain is a self-limiting phenomenon, it is severe on the 1st day after surgery & diminishes over the next 24 hours and is minimum after 3rd & 4th day. Not just because of the humanitarian aspect of pain relief but also postoperative pain causes reduction of pulmonary volume and capacities and can also causes inability to cough which may lead to areas of under ventilation & atelectasis. There may also be tachycardia and vasoconstriction.

The use of non-steroidal anti-inflammatory drugs (NSAIDS) has become popular in operations ranging from minor outpatient procedures to major inpatient surgeries. In common with other NSAIDs, ketorolac has been advocated as an adjuvant to reduce postoperative pain and opioid analgesic requirements[2,3]. Ketorolac is an NSAID that acts through inhibition of prostaglandin synthesis, is said to have analgesic efficacy comparable to morphine[3-5]. The explanation for the effectiveness of ketorolac stems at least in part from inhibition of eicosanoid mediators of pain and tissue injury response[6]. Therefore, we investigated the possibility that ketorolac might have a more profound analgesic effect if present in high concentrations at the site of injury. We compared the analgesic efficacy of wound infiltration with ketorolac and intramuscularly administered ketorolac. We also investigated if wound infiltration with ketorolac has any additional analgesic effect beyond that of local anaesthetics (bupivacaine 0.5%) such that there would be benefit in combining them.

AIMS AND OBJECTIVE

The aim of this study is to compare the postoperative analgesia from infiltration of ketorolac combined with bupivacaine versus ketorolac infiltration alone and intramuscular ketorolac.

The objective of this study were:

1. To assess the efficacy of ketorolac wound infiltration for postoperative analgesia.
2. To assess the efficacy of ketorolac combined with bupivacaine as wound infiltration for postoperative analgesia.
3. To assess the efficacy of intramuscular ketorolac for postoperative analgesia.
4. To evaluate and compare the postoperative analgesic effect of incisional infiltration of ketorolac with or without bupivacaine versus intramuscular ketorolac.

MATERIAL AND METHODS

STUDY DESIGN: Randomised control prospective study

SAMPLE SIZE:

Sixty (60) patients of either sex between 25-60 years of age belonging to ASA Grade I & II were included in this study. The patients were randomly divided into three groups of 20 each. Randomisation was done using sequentially numbered opaque sealed envelopes (SNOSE).

Group C (Control): Patients received wound infiltration with normal saline 20 ml and injection ketorolac 60 mg intramuscular.

Group K: Patients received wound infiltration with normal saline 20 ml mixed with injection ketorolac 30mg.

Group KB: Patients received wound infiltration with 0.5% isobaric bupivacaine 20 ml mixed with injection ketorolac 30 mg.

The solution to be infiltrated was prepared by an independent anaesthesiologist. The infiltration was done by surgeon just before wound closure.

DURATION OF STUDY: One year
PLACE OF STUDY: Santosh Medical College & Hospital, Ghaziabad, UP

INCLUSION CRITERIA

1. ASA physical status I and II
2. Age between 15 to 60 years
3. Weight between 40 to 100 Kgs
4. Patients undergoing elective lower abdominal surgical procedures
5. Patient's written consent

EXCLUSION CRITERIA

1. Patient's refusal
2. Age less than 15 years
3. Inability to comply with the study procedure e.g. language barrier
4. Concurrent usage of either opioids or NSAIDS pre-operatively
5. Patient with significant hepatic, renal or cardiovascular disease
6. Patients having metabolic disorder
7. Hypersensitivity to any of the study medications
8. Bleeding diathesis or coagulopathy
9. Sepsis

METHODOLOGY

PRE-ANAESTHETIC CHECKUP

A thorough pre-anaesthetic evaluation was done for all patients. The anaesthetic procedure was explained to the patients and consent obtained. All patients received tablet alprazolam 0.5mg on the night before surgery. All the patients were kept nil per orally for at least 6 hours prior to surgery Routine investigations included haematological, biochemical and radiological investigations appropriate for the surgery.

On arrival in operating room, minimum mandatory monitoring instituted and preoperative vitals noted. Intravenous cannula was secured and intravenous fluid started. Routine premedication in the form of injection Ondansetron 4mg i.v. and injection fentanyl 1-2µg/kg i.v. was given to each patient in operation theatre.

ANAESTHESIA TECHNIQUE

A standard general anesthesia technique was used. Injection propofol 1-2.5 mg/kg i.v. was used for induction of anaesthesia. Tracheal intubation was facilitated by using injection vecuronium 0.1-0.15 mg/kg i.v. Anaesthesia was maintained using N_2O:O_2 (60:40) and sevoflurane. Surgical relaxation was maintained by boluses of injection vecuronium 0.01 mg/kg every 25-30 minutes.

At the end of the surgery patients received incisional wound infiltration by surgeon, with the solution prepared by an independent anaesthesiologist. The neuromuscular blockade was reversed with injection neostigmine 0.05 mg/kg i.v. and glycopyrrolate 0.005-0.01 mg/kg. i.v.

Patients in **Group C** (control) received wound infiltration with normal saline 20 ml and injection ketorolac 60 mg in the deltoid muscle immediately after infiltration.

Patients in **Group K** received wound infiltration with normal saline 20 ml mixed with ketorolac 30 mg.

Patients in **Group KB** received wound infiltration with 0.5% isobaric bupivacaine 20 ml mixed with ketorolac 30mg.

Wound infiltration was done in each case by the operating surgeon just before the closure of the incision and the observer was blinded to the nature of the drugs infiltrated.

After infiltration and intramuscular Injection of the drugs following parameters were noted. Pulse rate (PR), non-invasive blood pressure (NIBP) and oxygen saturation (SpO_2) were noted at 0 min (at the time of infiltration), 1 min, 2 min, 5 min, 10 min and thereafter every 15 min till patient was in the post anaesthesia recovery room. Same parameters were also recorded every hourly in the ward.

ASSESSMENT OF PAIN RELIEF

Pain score was reliably recorded by using the Visual Linear Analogue Method for assessing pain as described by Revill et al7. This method includes the use of 10 cm line on a piece of white paper on which a continuum of the patient's opinion on the severity of pain is represented. 10 was marked as the worst pain possible of 0 as no pain at all.

VISUAL LINEAR ANALOGUE SCALE

0-------1--------2--------3--------4--------6--------7--------8--------9--------10

Postoperative pain was evaluated by this 10 cm visual analogue scale at 2, 4, 6, 12 and 24 hrs and treated with rescue analgesic in form of injection tramadol 1-2 mg/kg i.v. on patients demand.

Duration of postoperative analgesia: Time interval from the end of surgery to the need of first dose of rescue analgesic.

Total cumulative dose of rescue analgesic used was also noted.
Any side effects: if present were noted.

a. Nausea
b. Vomiting
c. Rash
d. Peripheral edema
e. Bleeding disorders
f. Drowsiness
g. Any other

Results

The age, sex and weight distribution is given in Tables 1, 2 and 3 respectively. Results were analysed statistically using student's t-test, chi square test. The three groups in the present study are comparable in terms of age, sex and weight distribution.

Intraoperative hemodynamic parameters (HR, MAP) in the three groups is given in Table 4 & 5 respectively. There is no statistically significant difference in intraoperative heart rate and mean arterial pressure in the three groups ($p>0.05$).

Visual analogue score (VAS) in the three groups at 2,4,6,12,24 hours respectively is given in Table 6(A). The comparison of mean VAS scores between three groups is given in Tables 6(B), 6(C), 6(D) respectively. There is no significant difference in mean VAS score between group C and group K at 2 hours but significant difference is seen at 4, 6, 12, 24 hours respectively. There is no significant difference in mean VAS score between group C and group KB at 2 hours but significant difference is seen at 4, 6, 12, 24 hours respectively. The comparison of duration of analgesia between three groups is given in Table 7. The duration of analgesia in group KB (12.05±2.114 hours) is significantly longer than group K (6.80±0.834 hours) and group C (4.10±0.641 hours) ($p<0.05$). The mean cumulative analgesic dose (C.A.D.) required in the three groups is given in Table 8. The mean cumulative analgesic dose in group KB (60±20.520 mg) is significantly lesser than group K (107.50±18.317 mg) and group C (200 mg) ($p<0.05$). The comparison of duration of surgery in three groups is given in Table 9. There is no significant difference in the duration of surgery in group KB (65±3.261 minutes) compared to group K (65±3.261 minutes) and group C (70.75±5.447 minutes) ($p>0.05$). The comparison of length of incision between the three groups is given in Table 10. There is no significant difference in the length of incision in group KB (9.10±2.404 centimetres) compared to group K (8.05±2.373 centimetres) and group C (9.60±1.930 centimetres) ($p>0.05$). The comparison of side effects in form of nausea, vomiting and shivering between three groups is given in Tables 11(A), 11(B) and 11(C) respectively. Only 15 % patients in group C and no patients in group K and KB experienced nausea. ($p>0.05$). Only 20 % patients in group C, 15 % patients each in group K and KB experienced mild vomiting ($p>0.05$). Mild shivering was experienced by 25 % patients in group C, 15 % patients in group K and none of the patients in group KB ($p>0.05$).

Table 1. Age distribution

	Age Groups			Mean ± SD	
	25-30 yrs	31-45 yrs	46-60 yrs		
GROUP C	0	10	10	45.80	6.56
GROUP K	8	5	7	37.50	10.30
GROUP KB	9	6	5	37.80	11.54

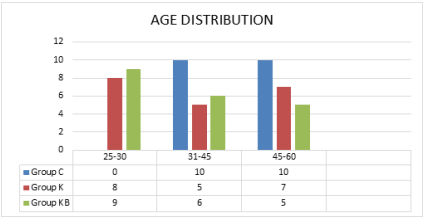


Table 2. Sex distribution

Sex	Group			Total
	Group C	Group K	Group KB	
Male	3	4	5	12
	15.0%	20.0%	25.0%	20.0%
Female	17	16	15	48
	85.0%	80.0%	75.0%	80.0%
Total	20	20	20	60
	100.0%	100.0%	100.0%	100.0%

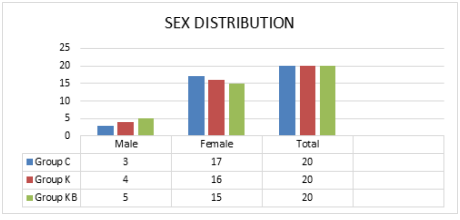


Table 3. Weight distribution

Groups	Weight		P-value
	Mean	SD	
GROUP C	58.15	5.11	P-value > 0.05
GROUP K	56.75	3.22	
GROUP KB	56.75	2.86	

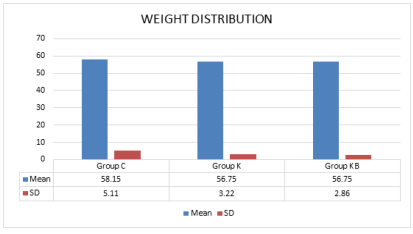


Table 4. Intraoperative changes in Heart Rate (HR)

	Change in PR		
Groups	Mean	SD	P-value
GROUP C	90.35	5.12	>0.05
GROUP K	86.60	4.00	
GROUP KB	86.30	4.34	

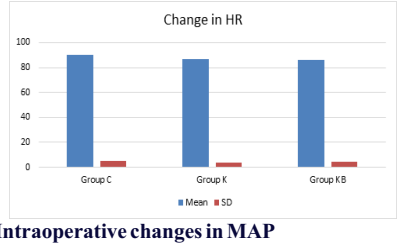


Table 5. Intraoperative changes in MAP

GROUPS	Mean	SD	p value
GROUP C	91.53	3.20	>0.05
GROUP K	86.24	2.29	
GROUP KB	85.10	2.02	

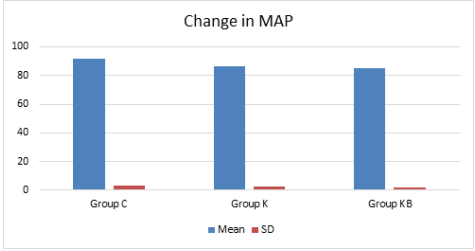


Table 6(A). Visual Analogue Score (VAS)

Variable	Group C	Group K	Group KB
VAS – 2 hours	2.40±0.50	2.20±0.41	2.10±0.31
VAS – 4 hours	3.25±0.85	2.20±0.41	2.10±0.31
VAS – 6 hours	5.50±0.51	2.40±0.50	2.15±0.36
VAS - 12 hours	6.35±0.48	4.40±0.59	2.85±0.74
VAS – 24 hours	6.00±0.46	5.50±0.51	4.75±0.64

Table 6(B). Visual Analogue Score (VAS) Group C vs Group K

Variable	Group C	Group K	p value
VAS – 2 hours	2.40±0.50	2.20±0.41	>0.05
VAS – 4 hours	3.25±0.85	2.20±0.41	<0.05
VAS – 6 hours	5.50±0.51	2.40±0.50	<0.05
VAS - 12 hours	6.35±0.48	4.40±0.59	<0.05
VAS – 24 hours	6.00±0.46	5.50±0.51	<0.05

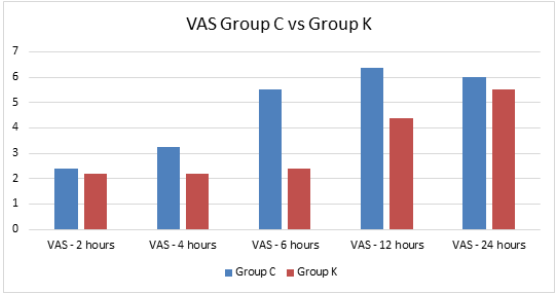


Table 6(C). VAS Group C vs Group KB

Variable	Group C	Group KB	p value
VAS – 2 hours	2.40±0.50	2.10±0.31	>0.05
VAS – 4 hours	3.25±0.85	2.10±0.31	<0.05
VAS – 6 hours	5.50±0.51	2.15±0.36	<0.05
VAS – 12 hours	6.35±0.48	2.85±0.74	<0.05
VAS – 24 hours	6.00±0.46	4.75±0.64	<0.05

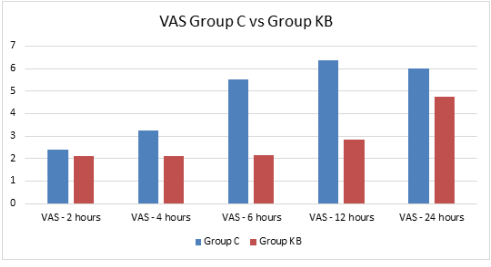


Table 6(D). VAS Group K vs Group KB

Variable	Group K	Group KB	p value
VAS – 2 hours	2.20±0.41	2.10±0.31	>0.05
VAS – 4 hours	2.20±0.41	2.10±0.31	>0.05
VAS – 6 hours	2.40±0.50	2.15±0.36	>0.05
VAS – 12 hours	4.40±0.59	2.85±0.74	<0.05
VAS – 24 hours	5.50±0.51	4.75±0.64	<0.05

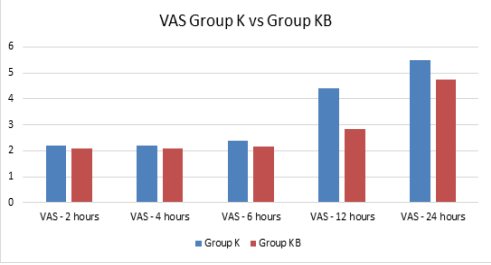


Table 7. Duration of analgesia

Groups		Mean	Std. Deviation	p value
Pair 1	Group C	4.10	.641	>0.05
	Group K	6.80	.834	
Pair 2	Group C	4.10	.641	<0.05
	Group KB	12.05	2.114	
Pair 3	Group K	6.80	.834	<0.05
	Group KB	12.05	2.114	

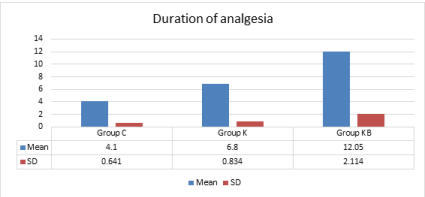


Table 8. Mean cumulative analgesic dose (CAD)

Groups		Mean (milligrams)	Std. Deviation	p value
Pair 1	Group C	200.00	.000	>0.05
	Group K	107.50	18.317	
Pair 2	Group C	200.00	.000	<0.05
	Group KB	60.00	20.520	
Pair 3	Group K	107.50	18.317	<0.05
	Group KB	60.00	20.520	

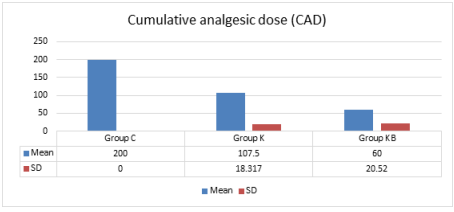


Table 9. Operative time

GROUPS	Operative Time (Minutes)		p value
	Mean	SD	
GROUP C	70.75	5.447	>0.05
GROUP K	65.00	3.261	
GROUP KB	65.00	3.261	

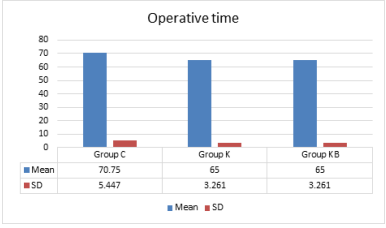


Table 10. Length of incision

Groups	Length of Incision (Centimeters)		p value
	Mean	SD	
GROUP C	9.60	1.930	>0.05
GROUP K	8.05	2.373	
GROUP KB	9.10	2.404	

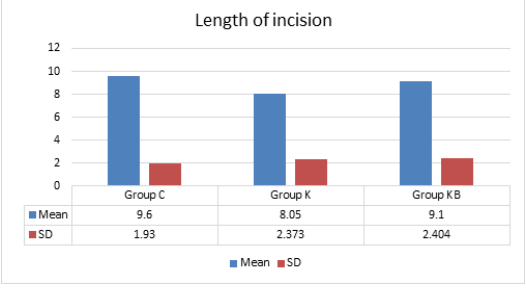


Table 11(A). Side effect: Nausea

Nausea	Groups			Total	p-value
	Group C	Group K	Group KB		
No	17	20	20	57	> 0.05
	85.0%	100.0%	100.0%	95.0%	
Mild	3	0	0	3	
	15.0%	0.0%	00.0%	5.0%	
Total	20	20	20	60	
	100.0%	100.0%	100.0%	100.0%	

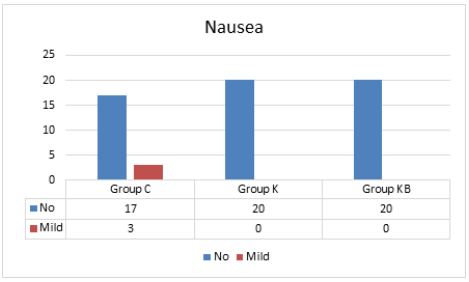


Table 11(B). Side effect: Vomiting

Vomiting	Groups			Total	p-value
	Group C	Group K	Group KB		
No	16	17	17	50	> 0.05
	80.0%	85.0%	85.0%	83.33%	
Mild	4	3	3	10	
	20.0%	15.0%	15.0%	16.66%	
Total	20	20	20	60	
	100.0%	100.0%	100.0%	100.0%	

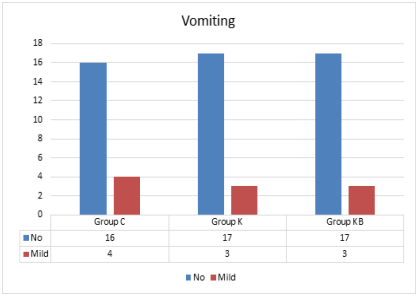
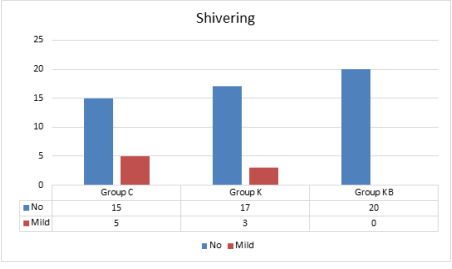


Table 11(C). Side effect: Shivering

Shivering	Group			Total	p-value
	Group C	Group K	Group KB		
No	15	17	20	52	> 0.05
	75.0%	85.0%	100.0%	86.66%	
Mild	5	3	0	08	
	25.0%	15.0%	0.0%	13.33%	
Total	20	20	20	60	
	100.0%	100.0%	100.0%	100.0%	



Discussion

Pain is a highly subjective phenomenon and a variety of receptors mediate pain perception. To extend analgesia beyond operation theatre along with minimal requirements of systemic analgesics in form of opioids and NSAIDs has always been a fascinating and challenging arena for health care providers since it directly adds to cost of medical care by virtue of longer stay in hospital and risk of side effects and complications of systemic medications.

The use of wound infiltration with local anaesthetics for postoperative pain relief is an attractive method because of its simplicity, safety and low cost. Despite widespread use, the method is still inconsistently used by surgeons and anesthetists[8] probably due to fear of infection, delayed healing, short duration of action[9] and lack of consensus on when and after which surgical procedure would it be more effective.

The present study is being carried out with the aim to assess the efficacy of ketorolac wound infiltration, to assess the efficacy of ketorolac combined with bupivacaine as wound infiltration, to assess the efficacy of intramuscular ketorolac for post-operative analgesia and to evaluate & compare the post-operative analgesic effect of

incisional infiltration of ketorolac with or without bupivacaine versus intramuscular ketorolac.

Kumar et al.[10] in their study found significant differences in pain scores in three such similar groups postoperatively.

They found that VAS at 2 hrs in control group (similar to group C in our study) as 4.92±2.41, for group II (similar to group K in our study) as 2.96±1.06 & in group III (similar to group KB in our study) as 3.06±0.99. VAS at 4 hrs for control group was 6.70±3.60, group II as 3.29±2.20 & group III as 3.28±3.12. VAS at 6 hrs for control group as 5.71±4.54, group II as 4.54±3.72, group III as 2.91±2.14. VAS at 12 hrs in control group as 6.04±3.44, group II as 4.88±2.70, group III as 2.92±1.93. VAS at 24 hrs in control group as 7.88±2.31, group II as 3.98±2.86, group III as 3.90±1.85. Pain scores were higher at all times of observation in control group(I) compared to study groups(II & III).There was no difference in pain scores between the two study groups at 2,4 & 6 hrs postoperatively. However the difference in pain scores was observed at 12 hours ($p<0.05$).

As regards the time to demand of first analgesic (rescue analgesic) which is also the duration of analgesia afforded by the particular drugs in each group, we observed significant differences in the three groups. In addition to significant differences between the two study groups, there are significant differences between each study group compared to the control group.

We found that the mean duration of analgesia in Group C is 4.10±0.64 hours, in Group K is 6.80±0.83 hours whereas in Group it is 12.05±2.11hours, which is statistically significant ($p<0.05$). Hence mean duration of analgesia was more in KB group as compared to K group. Also mean duration of analgesia was more in either study group as compared to the control group.

Kumar et al.[10] found that the mean duration of analgesia (hours) in control group is 2.38±0.38, in group II 7.40±4.15, group III 14.3±7.93. The time to first demand of analgesic (which is the same as duration of analgesia of the drugs used in each case) was longer in patients of group II ($p<0.05$) & group III ($p<0.05$) compared to group I.

As regards the cumulative dose of rescue analgesic (tramadol in our study) in 24 hrs, we found significant differences between the three groups. Mean cumulative analgesic dose (C.A.D) in Group C is 200±0.00 mg, in Group K 107.50±18.31 mg & in the KB group it is 60.00±20.52 mg, which is significant statistically ($p<0.05$).Therefore mean cumulative analgesic dose was higher in control group compared to either study group (Groups K & KB). Furthermore the mean cumulative analgesic dose was higher in K group compared to KB group.

Kumar et al.[10] also concluded significant differences in cumulative dose of analgesic in 24 hrs in three such similar groups. They found that the cumulative analgesic dose given in first 24 hrs postoperatively in control group was 260.70±56.48 milligrams, in group II 150.06±41.00 milligrams and in group III it was 50.86±30.24 milligrams. This difference was statistically significant ($P<0.05$).

Ben-David et al.[11] concluded that the wound infiltration with ketorolac in saline or combined with bupivacaine afforded analgesia superior to intramuscular ketorolac given alone.

It has been observed that differing absorptions between the intramuscular and wound infiltration resulting in higher tissue concentration of ketorolac at the site of surgery yielded more effective & longer duration of analgesia than afforded by larger intramuscular dose. The effect of ketorolac locally at the surgical site exceeded the systemic effect indicating some prostaglandin independent effect in the periphery.

This can be compared with the study done by **J. Romsing et al**.[12] in which peripheral analgesic effect of local infiltration with non-steroidal anti-inflammatory drugs (NSAIDs) in postoperative pain was observed.

We also found that incisional ketorolac plus bupivacaine prolonged the analgesia beyond that of incisional ketorolac alone. Although difficult to explain for this analgesic effect outlasting the pharmacological effects of both the drugs, some unknown synergistic drug interaction could be possible. Other workers[13,14] have reported similar results. They also stated that this combination regimen was also able to diminish or delay the peripheral hypersensitivity response. The mean VAS score at the time of request of analgesia were also lower in study groups. The analgesic advantage of wound infiltration with ketorolac persisted throughout the study period after surgery in-spite of greater analgesic use by control patients as also reported by Ben-David B Katz et al.[11]

There is conflicting evidence from the previous studies as to the benefits of incisional infiltration of local anaesthetics after abdominal operations. Some investigators[9,15,16] failed to reveal good analgesic action of infiltration of bupivacaine and stated that it neither reduced postoperative morphine consumption nor pain scores in first 48 hrs after operation.

Kleim et al.[16] were of the opinion that deeper structures were responsible for much of the painful stimuli i.e. visceral pain predominates in first 24 hrs. Whereas **Colbert et al**.[17] found subcutaneous infiltration along with peritoneal instillation of bupivacaine superior to that of former alone for post-appedicectomy pain.

Conclusion

Addition of bupivacaine to ketorolac wound infiltration can prolong the duration of analgesia in postoperative period. In our study incisional infiltration of 30 mg of ketorolac alone produced lower VAS scores and longer duration of analgesia as compared to incisional infiltration of saline combined with intramuscular injection of 60 mg of ketorolac, which was statistically significant. Addition of 0.5 % bupivacaine to incisional infiltration of 30 mg of ketorolac produced even better quality of post-operative analgesia as observed by even lower postoperative VAS scores and longer duration of analgesia and lower requirement of mean cumulative analgesic dose, without increasing the side effects or complications. Thus adequate relief of pain in patients undergoing lower abdominal operations can be done by wound infiltration with 30 mg of ketorolac along with 0.5% bupivacaine, as it is a safe, simple and cost effective technique.

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