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EVALUATION OF EFFICACY AND SAFETY OF PREOPERATIVE INTRAVENOUS LORNOXICAM AS AN ADJUNCT TO MULTIMODAL ANALGESIA FOR POST OPERATIVE PAIN RELIEF AFTER TOTAL ABDOMINAL HYSTERECTOMY

Anaesthesiology

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ABSTRACT

Background and objectives-In the present study we compared the evaluation and safety of preoperative intravenous lanoxicam as an adjunct to multimodal analgesia for post operative pain after total abdominal hysterectomy.

Methods-This was a randomized double blinded study conducted in 90 patients randomly, divided in three groups (B,B+F,B+F+L),30 patients in each.

Group A (30 patients, control group B):- In this group, the patients will receive subarachnoid analgesia with 20mg Bupivacaine HCL

Group B (30 Patients) (study group B+F) :- In this group, the patient will receive subarachnoid analgesia with 17.5 mg Bupivacaine HC1 +25µg Fentanyl (½ ml) having total volume of 4 ml.

Group C (30 Patients) (study group B + F+L) :- In this group, the patients will receive inj. Lornoxican 8 mg i.v., prior to administration of sub arachnoid analgesia with inj. Bupivacaine HCl 17.5 mg + 25µg Fentanyl having total volume 4 ml.

Conclusion- In present study has clearly demonstrated the preemptive use of IV lornoxicam 8 mg ,prior to the subarachnoid administration of bupivacaine heavy 17.5 mg and fentanyl 25µgm . This method effectively prolonged the post operative analgesia,reduced the total consumption of analgesic reuirement with better pain relief score without increasing untoward side effects. The addition of i.v. lornoxicam did not changed the character of spinal block and hemodynamics.

Hence, i.v. lornoxicam 8 mg can be safely and effectively used for prolonging postoperative analgesia.

KEYWORDS

lanoxicam,fentanyl,bupivacaine, spinal anaesthesia, multimodal analgesia, preemptive analgesia.

INTRODUCTION-

Uncontrolled perioperative pain may potentiate some of the perioperative pathophysioiogy and increase morbidity and mortility of patients. The detrimental effects of poor analgesia are now well documented and has many adverse physiological and psychological physical and financial burden on the patient.

Multimodal analgesia is technique of combining multiple modalities of pain relief to provide more effective analgesia and a lower incidence of adverse effects. The use of multi-drug therapy in neuraxial blocks is one common and effective example, and may also help in avoiding rapid tolerance to individual medications. Multimodal analgesia encompasses the combination of different classes of pain medications and different sites of analgesic administration to provide superior dynamic pain relief with reduced analgesic side effects. Published studies on multimodal approaches for postoperative pain scores and similar reductions in analgesic requirements

AIMS AND OBJECTIVES

Hence, the present study will be designed to evaluate the efficacy and safety of multimodal analgesia for postoperative pain relief after total abdominal hystrectomy. A combination of preoperative intravenous NSAID (Lonoxicam) and subarachnoid analgesia with local anesthetic agent and opioids will be used as constituent of multimodal analgesia and will be compared with subarachnoid analgesia, with only local anesthetic agent, with or without opioids. The study will also be designed to assess and compare the side effects amongst various groups and also to document the opioid requirement in postoperative period.

MATERIALS AND METHODS

The present prospective, randomized, double blinded study was conducted at the Department of Anaesthesiology at Umaid Zanana and Paedictric Hospital attached to Dr. S.N. Medical College, Jodhpur.

Total 90 female patients of ASA grade I and lI according to physical status supposed to undergo abdominal hysterectomy were selected. The patients were divided into 3 groups, each group will constitute of 30 patients.

Group A (30 patients, control group B):- In this group, the patients received subarachnoid analgesia with 20mg Bupivacaine HCL

Group B (30 Patients) (study group B+F) :- In this group, the patient receivedsubarachnoid analgesia with 17.5 mg Bupivacaine HC1 +25µg Fentanyl (½ ml) having total volume of 4 ml.

Group C (30 Patients) (study group B + F+L) :- In this group, the patients received inj. Lornoxican 8 mg i.v., prior to administration of sub arachnoid analgesia with inj. Bupivacaine HCl 17.5 mg + 25µg Fentanyl half ml having total volume of 4 ml. Pre Anaesthetic Checkup:- Each and every patient will be thoroughly assessed and examined in pre anaesthetic clinic one day prior to surgery for detailed general physical and systemic examinations.

A note of characteristics of spinal analgesia (onset of sensory analgesia, maximum height of block achieved, the degree of motor blockage according to bromage score and the regression time of 2 dermatomes) will be recorded. All the vitals will be observed throughout intraoperative period continuously or at a specific time (1,3,5,10, 15 minutes).

Any intraoperative complication i.e. hypotension, brady cardia, arrythmia, respiratory depression and the amount of bleeding as assessed by the surgeon etc., will be noted and will be treated accordingly.

In postoperative period, the intensity of pain and the degree of pain relief will be assessed by a visual analogue scale on 0 to 10 cm -/scale, where O will indicate no-pain and 10 cms will indicate maximum pain. The intensity of pain and the degree of pain relief will also be assessed using a 5 character verbal rating scale.

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Pain score (verbal rating scale)
0= None
1= Slight
2= Moderate
3= Severe
4= Uncomfortable

Pain Relief (verbal rating scale)
0= None
1= Slight
2= Moderate 3= A lot
4= Complete

The assessment will be done at 15,30; 45minutes and then at 1,2,3,4,5,6,8,10,12,18,20 & 24 hours postoperatively. Whenever the patient has VAS score of > 4 or pain intensity of grade II (moderate), an injection of Fentanyl 100 pg will be given.

The assessment of pain relief will also be done accordingly.

To assess analgesic efficacy, the following variables will be calculated as

- Time of demand for first rescue analgesia.
- Demand for top up doses of rescue analgesics, in first 24. ~ hours .

Tolerability assessment will be based on patient's reports of adverse event (itching, nausea, vomiting, retentions of urine etc,), measurement of vital signs up to 24 hours post operatively and results of physical examination and clinical laboratory tests after 24 hours of treatment.

TABLE 1 VAS SCORE

Time	B		B+F		B+F+L		P. Value
	Mean ±SD	SEM	Mean ±SD	SEM	Mean ±SD	SEM	
15 Min	.66 ±0.2537	.04632	.10 ±3051	.5571	0.00 ±0.00	0.00	.2329
30 Min	.20 ±66.44	.1213	0.4 ±8550	.1561	0.00 ±0.00	0.00	0.1515
45 Min	.933 ±1.048	0.1914	1.26 ±1.112	0.2030	0.034 ±0.1857	0.03448	<.0001 extremely significant
1 Hr	2.76 ±1.331	0.2430	2.26 ±0.827	0.1511	1.76 ±0.8584	0.1567	.0015 Very Significant
2 Hr	4.033 ±1.426	0.2603	2.53 ±0.8996	0.1642	2.4 ±0.894	0.1633	<.0001
4 Hr	4.76 ±1.54	0.2824	3.5 ±1.227	0.2236	2.9 ±1.725	0.2054	<.0001 Extremely significant
8 Hr	5 ±1.287	0.2349	3.633 ±1.402	0.2559	3.5 ±1.042	0.1903	<.0001 Extremely significant
12 Hr	4.66 ±1.768	0.3228	4.16 ±1.020	0.1862	3.73 ±1.285	0.2346	.0388 Significant
24 Hr	5.6 ±1.868	0.341	4.56 ±1.431	0.2612	5.533 ±1.408	0.2570	.0217

The above table is showing distribution of VAS score at diff intervals among three groups.One way analysis test was performed on the above and mean value was calculated at diff time intervals among three groups.The p value <0.05 was considered as stastically significant.The p vlue at the postop time intervals of 45 min,1hr,2hr,4hr,8hr,12hr,24hr were significant.

TABLE NO. 2 PAIN RELIEF SCORE

Time	B		B+F		B+F+L		P. Value
	Mean ±SD	SEM	Mean ±SD	SEM	Mean ±SD	SEM	
15 Min	4.00 ±0.00	0.00	4.0 ±0.00	0.00	4.0 ±0.00	0.00	0.00
30 Min	3.96 ±.1826	0.033	4.0 ±0.00	0.00	4.00 ±0.00	.3721	.3721
45 Min	3.133 ±1.137	.2075	3.333 ±0.7581	0.1384	4.00 ±0.00	0.00	<.0001
1 Hr	1.8 ±1.095	0.200	2.533 ±0.8604	0.1571	3.066 ±0.944	0.1724	<.0001
2 Hr	0.76 ±0.9353	0.1708	2.44 ±0.7739	0.1413	2.23 ±0.9714	0.1744	<.0001
4 Hr	0.60 ±.8137	0.1486	1.33 ±1.028	0.1877	1.633 ±1.217	0.22	<0.0007
8 Hr	0.7666±0.8584	0.1567	1.6 ±1.037	0.1894	1.6 ±0.9685	0.1788	.0009
12 Hr	1 ±0.9829	0.1794	1.233 ±0.8172	0.1492	1.533 ±0.7303	0.1333	0.0566 not significant
24 Hr	0.666 ±0.8841	0.1614	1.666 ±0.8277	0.1511	1.1 ±0.9595	0.1752	0.1178 not significant

The above table is showing distribution of pain relief score among three groups. the mean value of pain relief score was calculated among three groups at different time intervals,postoperatively.P value at<.05 was considered stastically significant.Postoperatively at time interval of 45 min.,1hr,2hr,4hr,8hr,12 hr were proved to be significant.

Table No 3 Total No. Of Doses Of Rescue Analgesia

	GP B	GP B+F	GP B+F+L
mean±s.d.	3.4±0.8193	2.466±0.5713	2.3±0.5960
S.E.M	0.146	0.5713	0.5960
P value	<0.0001		

Above table is showing distribution of total doses between three groups of our study. One way analysis test of difference was performred and P value was calculated which was <0.0001 ,which is extremely significant.

DISCUSSION

Multi modal analgesia involves selective use of specific drugs in combinations. The most most commonly combined medications groups include local anaesthetics, opioids, NSAIDS, acetaminophens and alpha-2 agonists.

Multimodal analgesia is now a proven modality for pain relief and effective in reducing the consumption of opiods with lesser incidence of side effects ,provided the tolerability of the drugs are accepted.

Most of these studies however, are documented with GA , only lesser nu. of studies are awailable with regional analgesia. The uses of opioids, Mg, clonidine, neostigmine are frequently in neuraxial blocks. The most commonly used opioid in neuraxial blocks along with LA agents have been found to be effective but produces unpleasant side effects.

However these drugs don't act on the peripheral mechanism of pain.

The present study has demonstrated preemptive use of NSAIDS (lornoxicam) along with intrathecal lipophillic opioids (fentanyl) not only provided the reduction in VAS score upto 12 hours ,postoperatively but it also reduced the total consumption of opioids in postoperatively period, without increasing the side effects significantly.

PREEMPTIVE ANALGESIA-Preemptive analgesia can be defined as antinociceptive treatment that prevents establishment of altered central prcessing of afferent inputs from the site of injury.it should establish effective antinociceptive before injury and ensure the combination of this effective analgesic level well in the post injury period to prevent central sensitisation during the inflammatory phase.
The use of fentanyl (25µg) along with LA (Bupivacaine heavy 17.5mg)intrathecally,did not significantly affect the characteristics of spinal blocks (onset of sensory block, modified motor bromage scale, time to two segment regression) in the present study.

The use of fentanyl 25µg intrathecally produced the reduction in VAS score,pain intensity difference, better pain relief score and TOTPAR, upto 12 hrs, postoperatively In our study.

However the incidence of prititus was more in GP B+F and GP B+F+L. As a protocol in our our study the rescue analgesic in the form of

fentanyl 100µg i.v. was administered, whenever the VAS score reached 4 or >4 or whenever the patients pts demanded for analgesia.

Our study results are in accordance with other studies in which the authors did not find any significant changes in haemodynamics and side effects. Intraoperative and postoperative analgesia was better.

Charecteristics Of Spinal Analgesia-

1.-time To Onset Of Sensory Block-Mean time to onset of sensory block in our study was 2.74±0.62 ,2.68±0.659 and 2.69±0.672 minutes ,in three groups B,B+F,B+F+L respectively.

Fentanyl have a rapid onset of action because of its lipophillic nature .Time to onset of sensory block was slightly shorter in gp B+F and B+F+L in comparison to GP B. Although statistically the value of P was not significant.

In context with time to onset of sensory block ,our study results are similar with previous studies done by dr. B.N. BISWAS et al (2006) [and] dr. LEE et al (1996) and dr.DURAHEM et al (2007)

They have also observed a short onset of action when fentanyl 30 microgm was administered along with bupivacaine heavy 17.50 mg, Intrathecally.Although it was statistically insignificant.

2.maximum Height Of Sensory Block-The addition of intrathecal opioids and i.v.infusion lornoxicam didnot produce any significant difference in the maximum height of sensory block among the three group.

The results of our study matches with studies done by dr. B.N.BISWAS et al (2006)[35]and dr. LEE et al(1996)and dr.Yesiki Yen et al(2008) They also observed no significant change in maximum height of sensory block after intrthecal use of fentanyl use .

3.quality Of Motor Block By Bromage Scale-the mean value of bromage scale was 3.0±0.0,2.8±0.34,2.9±.034 for gp B,B+F,B+F+L respectively in our study.

P value was not significant.

Our study results are in accordance with other studies done by Bruce Ben David et al (2005) and Yesiki Yen et al (2008) They also have concluded that after addition of 30 micro gm fentanyl to bupivacaine in spinal anaesthesia with bupivacaine and iv lornoxicam did not increase the intensity of motor blockadge or prolonged the recovery in our study. We have added only 25 micro gm fentanyl.

Our results are comparative in regards to onset of sensory block and quality of motor block in all three groups with the studies done by Yesiki Yen et al (2007)and Noreitz et al (2005)

The comparative results are shown in following tables.

Haemodynamics- Regarding the hemodynamic changes there were no singnificant changes among three gps of our study.The addition of intrathecal fentanyl 25 microgram and i.v. infusion of 8 mg lornoxicam did not cause significant changes in comparison to bupivacaine group. In previous studies done by LEE et al (2003)and YESIKI YEN et al (2008),Bruce Ben David et al (2005)also concluded that the use of fentanyl 30 microgram and i.v. lornoxicam did not alter SBP,DBP,MEAN BP,HR,SPO2 significantly.

VAS SCORE- The value of vas score differ significantly from 45 minutes to 12 hours postoperatively.

At 45 minute ,the mean value of VAS score in gp B,B,+F,B+F+L was 0.933±1.048,1.26±1.112 and 0.034±0.1857 respectively.

At 1 hr the mean value of vas score was 2.76±1.3 ,2.26±0.82 and 1.76±0.85 respectively.

At 2 hr the mean value of vas score for gp B was 4.033±1.5 for gp B+F was 2.4±0.89 and for At 2 hr the mean value of vas score for gp B was 4.033±1.5 for gp B+F was 2.4±0.89 and for gp B+F+L was 2.4±0.894.

So diff among b/w gp B+F and B was 1.6 and b/w B+F and B+F+L was 0.

At 8 hr the mean value of vas score for gp B was 4.46±1.54for gp B+F was 3.63±1.4 and for gp B+F+L was 3.5±1.04.

At 12 hr the mean value of vas score for gp B was 4.66±1.769 for gp B+F 4.16±1.02was and for gp B+F+L was 3.73±1.28.p value was significant.

At 24 hrs p.o. there were no significant differences among three gps ,regarding the mean value of vas score.

The mean value of 4 or more than 4 has reached at 2 hrs in gp b and at at 12 hrs in gp b+f while it took 24 hrs in gp b+f+1.

Thus the addition of intrathecal fentanyl 25 microgm reduced the vas score p.o. and the addition of lornoxicam further reduced the vas sore through different mechanism.intrathecal opioids can greatly enhance analgesia from the subtherapeutic doses of local anaesthetics.

The explanation of the different synergism is from the drug's separate mechanism of action ,wherein inhibition of nociceptive transmission of occurs at sequential stages of that signal transmission .

Intrathecal opioids inhibits nociceptive efferent synaptic transmission via A-delta and C- fibres by opening presynaptic k+ channels to inhibit transmitter release and thus reduce calcium ions influx.

There is also a direct postsynaptic effect with hyperpolarisation and reduced neuronal activity.LA act primarily by causing blockadge of voltage gated sodium channels in the axonal membrane and possibly a further effect on presynaptic inhibition of calcium channels.

Lornoxicam (NSAIDS) further acts through a different mechanism of action by inhibiting PGs synthesis through selectively selectively blockadge COX-2 inhibition.

In respect to VAS score our results are similar with the results of Jaishree Bogrea et al (2007) Durahem et al (2007) dr. Yesiki Yen et al (2008) and Norwittz et al (2005) Lee Perritz (et al 2003) used 30 micro gm intrathecal along with bupivacaine 17.50 mg bupivacaine and i v NSAIDS .They also have concluded that Preemptive use of IV lornoxicam in regional analgesia produced with bupivacaine and fentanyl lessens VAS score upto 6 to 12 hours.

PAIN RELIEF SCORE-The value of PRS differ significantly among three gps of our study from 45 mins to 8 hrs.

The mean value of PRS at 45 min in gp B was 3.133±1.37 and for gp B+F was 3.3±0.75 and for gp B+F+L was 4.00±0.00. p value was significant.

The mean value of PRS at 1 hr is gp B was 1.8±1.09 and for gp B+F was 2.5±0.85 and for gp B+F+Lwas 3.06±0.96. p value was significant.

At 2 hr , the mean value of PRS for gp B,B+F,B+F+L was 0.76±0.93,2.44±0.77,2.33±0.97 respectively. P value was significant.

At 8hr , the mean value of PRS for gp B,B+F,B+F+L was 0.76±0.83,1.64±1.037,1.6±0.97 respectively. P value was significant.

At 12 hr , the mean value of PRS for gp B,B+F,B+F+L was 1.00±0.93,1.233±0.81,1.53±0.7 respectively. P value was significant.

At 12 hrs the p value was not significant.So there was significant differences in PRS among three study groups of our study from 45 min. to 8 hrs postoperatively.

The results of our study correlate well with other studies done by Norwitz et al(2005)and Lee perritz et al (2003) They used 30 microgm intrathecal fentanyl along with bupivacaine 17.5 mg and observed significant difference in p value of PRS upto 6 hrs.

Dr. Jaishree bogra et al (2007) Durahem et al (2008)and dr Berrin etal (2008)used additional iv NSAID (lornoxicam or piroxicam) with itrathecal fentanyl 30 microgm and they observed significant difference in value of PRS upto 8 hrs postoperatively.

Total No. Of Rescue Analgesia-The mean value value of total no. of

rescue analgesia was 3.4±.65,2.466±.245,2.3±.44 for the gps B, B+F,B+F+L respectively.

The p value was significant for upto 8 hrs.So in our study the addition of intrathecal fentanyl helped in reducing the analgesic requirement for p.o. pain. The addition of iv lornoxicam further helped in reducing the analgesic requirement in comparison to plain bupivacaine group.

The results of our study correlate well with other studies done by Norwitz et al (2005)[31] and Lee Perritz et al (2003)[32].They used 30 microgm intrathecal fentanyl along with bupivacaine 17.5 mg and observed significant difference in total analgesic requirement in 24 hrs p.o.

Dr. Jaishree Bogra et al (2007)dr Durahem et al (2008)and dr Berrin etal (2008) ,Yesiki Yen et al (2008)used additional iv NSAID (lornoxicam or piroxicam) and they observed significant difference in the consumption of analgesic requirement postoperatively.

Side Effects- Although intrathecal opiods confers improved inraop and postop analgesic profiles, concern remains that benefits may be tempered by an increased incidence of side effects. Sedation ,nausea,respiratory depression , is associated with increased doses of opioids.

Bradycardia- The incidence of bradycardia among three study groups of our study was 5% 3%, 4% per among gps B,B+F,B+F+L respectively.Stastically the results were not significant.

Weijiech Wegi et al (2003),Yesiki Yen et al (2008)studied the effects of intrathecal opioids and NSAIDS .In their study they also did not notice any difference regarding bradycardia.

Norwitz et al (2005)and Lee Perritz et al (2003), used 30 micro gm fentanyl along with bupivacaine 17.5 gm .Regarding bradycardia their their results were not significant.

Pruritus-Pruritus occurs frequently following opioids use, particularly after neuraxial administration. Although not life threatening pruritus is discomforting and may decrease the pts satisfaction. Even though the mechanism of opioids induced pruritus is not fully understood, there is increasing role of played by μ receptors. Serotonine receptors D2 receptors,PGs and spinal pathway also be involved.

The incidence of pruritus was 0 %among gp B,among B+F , 4%,among B+F+L 4%.

Thus Intrathecal opioids are associated with increased incidence of pruritus.

In respect to pruritus ,our results are similar with the study done by Weigeich Weiget et al (2003)and Yesiki Yen (2008) and Norwitz et al (2005) .They also observed slightly increased incidence of pruritus inthe pts who were administered intrathecal fentanyl.

NAUSEA AND vomiting -incidence of nausea and vomiting was 6%,3%,2% in our three groups of study respectively.Increasing dose of opioids is associated with nausea and vomiting because they effect of stimulation chenotactic trigger zone.

Our results are in accordance to studies done dr. Berring et al (2007)and Yesiki Yen et al and Durahem et al (2008)They observed that incidence of nausea and vomiting was not significant after intrathecal fentanyl and NSAIDS.

Norwitz et al (2005)and Lee Perritz et al (2003)used 30 microgm intrathecally fentanyl along with bupivacine 17.5 mg.Likewise our study they also did not notice any significant value regarding to nausea and vomiting.

Respiratory Depression-None of the patients of our study gps suffered from respiratory depression.Increasing doses of opioids are associated with depressant effect on respiratory system.The depressant action is dose dependant .Lornoxicam have no effect on respiratory system.

Due to low intrathecal opioids dose used in our study(25μg),none of the our patients suffered from respiratory depression.

Dr.Berring David et al (2007) ,Yesiki Yen (2008)' Durahem et al (2007)[30]used itrathecal fentanyl 30 μgm along with B upivacaine 17.5 mg and iv NSAID.They did not notice any of the patient suffering from respiratory depression.

Norwitz et al (2005)and Lee Perritz et al (2003)used 30 microgm fentanyl along with Bupivacaine.Likewise our results none of their pt. suffered from respiratory depression.

RESULTS

Characteristics of spinal block-

1. Time to onset of sensory block-The mean value was2.74min.,2.68min.,2.69min. in GP B,B+F,B+F+L respectively.
2. maximum height of sensory block-results were statistically not significant.
3. quality of motor blockadge by bromadge scale-The mean value was3.0,2.8,2.9 in GPS B,B+F,B+F+L respectively.
4 Time to two segment regression –The mean value of time to two segment regression was

Haemodynamics- There were no signigicant changes among three gps intraop and postop regarding the haemodynamics.

VAS Score-the p value was significant from 45 mi to 12 hrs p.o.In gp B the value reached upto 4 at 2hr,while it took 12 hrs in gp B+F and 24 hrs in GP B+F+L.

Pain Relief Score-The value of P value among three gps was significant from 45 mins upto 12 hrs p.o.

Total No . Of Rescue Analgesia-The mean value of rescue analgesia was 3.4,2.46,2.3 in gp B,B+F,B+F+L respectively.

Side Effects-The incidence of bradycardia in GP B,B+F,B+F+L was 5%,3%,4% respectively.

The incidence of pruritus in GP B,B+F,B+F,B+F+L was 0%,4%,4 %respectively.

The incidence of nausea ,vomiting was 6%,3%,2% among gp B,B+F,B+F+L respectively.

None of the our study gps pt developed respiratory depression.

SUMMARY AND CONCLUSION

Hence the present study has clearly demonstrated the preemptive use of IV lornoxicam 8 mg ,prior to the subarachnoid administration of bupivacaine heavy 17.5 mg and fentanyl 25μgm . This method effectively prolonged the post operative analgesia,reduced the total consumption of analgesic reuirement with better pain relief score without increasing untoward side effects.The addition of i.v. lornoxicam did not changed the character of spinal block and hemodynamics.

Hence, i.v. lornoxicam 8 mg can be safely and effectively used for prolonging postoperative analgesia.

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