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STUDY ON INTRATHECAL FENTANYL AND BUTORPHANOL AS AN ADJUVANT TO INTRATHECAL BUPIVACAINE IN INFRA- UMBILICAL SURGERIES – RANDOMIZED, DOUBLE BLIND STUDY

Anaesthesiology

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ABSTRACT

The aim of the study was to compare the effectiveness of intrathecal fentanyl andbutorphanol in infraumbilical surgeries.
Present study was conducted in the department of Anaesthesiology in MGM medical college ,Kishanganj. 110 patients were selected using above defined criteria.
GROUP A (F)- 55 patients who were received intrathecal 0.5% hyperbaric bupivacaine 3ml with fentanyl 25 microgram (0.5 ml) total 3.5ml [n=55]..
GROUP B (B)- 55 patients who were received receive intrathecal 0.5%hyperbaric bupivacaine 3 ml with butorphanol 250 microgram(0.25 ml) by insulin syringe and normal saline 0.25 ml (total 3.5 ml) [n=55].
We showed the mean values of HR, SBP, DBP, RR and SpO2 at different time interval were comparable among the groups.We found that in two groups no patients had sedation, bradycardia respiratory depression, Shivering and hypotension. In Group-A (F), 4(7.3%) patients had pruritis. In Group-B (B), 2(3.6%) patients had pruritis. Association of pruritisin two groups was not statistically significant (p=0.4010).In Group-A (F), 5(9.1%) patients had nausea& vomiting. In Group-B (B), 2(3.6%) patients had nausea& vomiting. Association of nausea& vomitingin two groups was not statistically significant (p=0.2412).Difference of mean consumption of rescue analgesiain two groups was statistically significant (p<0.0001).In two groups all patients had ramsay sedation scale 2.
Addition of butorphanol to bupivacaine in infra- umbilical surgeries significantly prolongs the duration of analgesia and motor block and is a remarkably safe and less side effect method of providing post-operative analgesia.

KEYWORDS

INTRODUCTION

Spinal anaesthesia is the fastest, most predictable and reliable form of regional anaesthesia. By adding a small dose of narcotics to local anaesthetic solution the duration of anaesthesia can be significantly prolonged. [1]

Fentanyl is a commonly used adjuvant with local anaesthetic as it is a potent, synthetic opioid analgesic with a rapid onset and short duration of action.[2]But it having problems of pruritus, postoperative nausea, vomiting, respiratory depression and urinary retention due to mu agonism.

Butorphanol is a partial agonist and antagonist having the mu opioid receptor competitive antagonist activity and partial agonist activity at the kappa opioid receptor. [3] Butorphenol when administer intrathecally it binds to kappa receptor in the brain and spinal cord areas which is involved in nociception producing analgesia and sedation without side effect associated with mu receptors. For this butorphanol is widely available without restriction as compared to fentanyl and other potent opioids .Butorphanol is also quite effective at reducing post-operative shivering.

Till date only few studies done so far that compared the effectiveness of fentanyl with butorphenol as adjuvant to local anaesthetic in subarachnoid block. Also there is a controversy regarding the dose of intrathecal butorphenol used in various studies. [4,5]

Neuraxial opioids are widely used in conjunction with local anesthetics [LA] as they permit the use of lower dose of LA while providing adequate anesthesia and analgesia.[6]Neuraxial opioids also allow prolonged analgesia in the postoperative period and faster recovery from spinal anesthesia. [7-8]

It has been observed from various studies conducted previously that equivalent efficacy of butorphenol to fentanyl is obtained with 10 times intravenous dosage of butorphenol as compred to fentanyl. [9]

The present study is being undertaken to compare the safety and efficacy of anesthesia and analgesia of intrathecal bupivacaine-fentanyl mixture with intrathecal bupivacaine- butorphanol mixture for infraumbilical surgeries. This study is being conducted as only a limited number of studies have explored the use of intrathecal butorphanol in human subjects previously.

The aim of the study was to compare the effectiveness of intrathecal fentanyl andbutorphanol in infraumbilical surgeries.

MATERIALS AND METHODS

Our present study was conducted in the department of Anaesthesiology in MGM medical college ,Kishanganj from July 2018 to June 2019. 110 patients were selected using above defined criteria, 55 patients had in Group-A (F) and 55 patients had in Group-B (B). Present study was conducted from July 2017 to June 2018. Using computer generated random numbers, patients were allocated into 2 groups:- GROUP A (F)- 55 patients who were received intrathecal 0.5% hyperbaric bupivacaine 3ml with fentanyl 25 microgram (0.5 ml) total 3.5ml [n=55]. GROUP B (B)- 55 patients who were received receive intrathecal 0.5%hyperbaric bupivacaine 3 ml with butorphanol 250 microgram(0.25 ml) by insulin syringe and normal saline 0.25 ml (total 3.5 ml) [n=55].

Statistical Analysis:

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS 24.0. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate. p-value ≤ 0.05 was considered for statistically significant.

RESULT AND ANALYSIS

In our study showed that difference of mean age in two groups was not statistically significant (p=0.9846). In Group-A (F), 18(32.7%) patients had female and 37(67.3%) patients had male. In Group-B (B), 15(27.3%) patients had female and 40(72.7%) patients had male. Association of sexin two groups was not statistically significant (p=0.5325). Difference of mean BMI in two groups was not statistically significant (p=0.7282).

In Group-A (F), the mean of time spinal drugs to sensory level (mean±s.d.) of patients was 1.5091 ± .5045 mints. In Group-B (B), the mean of time spinal drugs to sensory level (mean±s.d.) of patients was 1.4727 ± .5039 mints. Difference of mean time spinal drugs to sensory

level in two groups was not statistically significant (p=0.1306).In Group-A (F), the mean of segment sensory level (mean±s.d.) of patients was 41.9455 ± 1.7365 mints. In Group-B (B), the mean of segment sensory level (mean±s.d.) of patients was 50.5636 ± 4.4379 mints. Difference of mean segment sensory level in two groups was statistically significant (p<0.0001).

Our study showed all patients had maximum motor block achieved (modified borage scale) 1.In Group-A (F), the mean of time spinal drugs to maximum motor block (mean±s.d.) of patients was 5.2745 ± .3233 mints. In Group-B (B), the mean of time spinal drugs to maximum motor block (mean±s.d.) of patients was 5.2727 ± .3217 mints. Difference of mean time spinal drugs to maximum motor block in two groups was not statistically significant (p=0.9765).In Group-A (F), the mean of time modified borage scale of 3 (mean±s.d.) of patients was 81.2364 ± 4.8799. In Group-B (B), the mean of time modified borage scale of 3 (mean±s.d.) of patients was 109.8364 ± 2.6159. Difference of mean time modified borage scale of 3in two groups was statistically significant (p<0.0001). Difference of mean duration of the operationin two groups was statistically significant (p=0.4393).

We showed the mean values of HR, SBP, DBP, RR and SpO2 at different time interval were comparable among the groups.

In our study showed group-A (F), 5(9.1%) patients had nausea& vomiting. In Group-B (B), 2(3.6%) patients had nausea& vomiting. Association of nausea & vomiting in two groups was not statistically significant (p=0.2412).In Group-A (F), the mean of consumption of rescue analgesia (mean±s.d.) of patients was 287.2727 ± 7.3723. In Group-B (B), the mean of consumption of rescue analgesia (mean±s.d.) of patients was 377.4182 ± 10.2536. Difference of mean consumption of rescue analgesiain two groups was statistically significant (p<0.0001).

DISCUSSION

We found that difference of mean age in two groups was not statistically significant (p=0.9846). Association of sex in two groups was not statistically significant (p=0.5325). Difference of mean BMI in two groups was not statistically significant (p=0.7282).

Dr. Rajkumar N Jaisinghani et al [10] the mean age (mean± s.d.) of patients was 36.51 yrs. ± 10.21years in group-A and 38.70yrs. ± 11.54 years in group-B. Nama NagarjunaChakravarthy et al [11] the mean age (mean± s.d.) of patients was 38.43 ± 9.56 years in group-A and 39.06 ± 9.83 years in group-B. In group A, 8 patients had female and 22 patients had male. In group B, 7 patients had female and 23 patients had male.

Kumar B et al [12] found that The two groups were comparable with regards to age, gender, weight, height and duration of surgery. The mean baseline values of HR, SBP, DBP, RR and SpO2 were comparable among the groups.

Kumar B et al [12] found that the median highest sensory level achieved and the times to reach peak sensory level were comparable among the two groups. Significantly slower block regression to S 2 level was observed in the group receiving butorphanol as compared to fentanyl (P=0.0230).

TuhinVashishth et al [13] found that the mean time to achieve sensory block up to T8 level was 4.78±2.16 minutes in Group I, 3.58±1.33 minutes in Group II and 3.24±1.04 minutes in Group III. Statistically, there was a significant intergroup difference In Group I, there was 1 and in Group II there were 2 patients who could not achieve the sensory block up to T8 level till 15 minutes.

Kumar B et al [12] found that a higher number of patients in the fentanyl group requested for rescue analgesia during the postoperative study period than the butorphanol group (9 versus 2; P=0.0238). The patients in the fentanyl group requested rescue analgesia earlier than patients in the butorphanol group as the average times to first request for rescue analgesia were 308.6±14.9 and 365.9±12.3 minutes, respectively (P=0.0254).

Prabhakaraiah UN et al [14] found that onset of motor block in Group BN was 2.53 ± 1.28 min, whereas in Group BF, it was 2.40 ± 1.22 min which was found to be statistically nonsignificant (P = 0.688).

We found that in Group-A (F), 34(61.8%) patients had highest sensory level T6 and 21(38.2%) patients had highest sensory level T8. In Group-B (B), 15(27.3%) patients had female and 40(72.7%) patients had male. 35(63.6%) patients had highest sensory level T6 and 20(36.4%) patients had highest sensory level T8. Association of sexin two groups was not statistically significant (p=0.8436).We found that in Group-A (F), the mean of time spinal drugs to sensory level (mean±s.d.) of patients was 1.5091 ± .5045 mints. In Group-B (B), the mean of time spinal drugs to sensory level (mean±s.d.) of patients was 1.4727 ± .5039 mints. Difference of mean time spinal drugs to sensory level in two groups was not statistically significant (p=0.1306).We found that in Group-A (F), the mean of segment sensory level (mean±s.d.) of patients was 41.9455 ± 1.7365 mints. In Group-B (B), the mean of segment sensory level (mean±s.d.) of patients was 50.5636 ± 4.4379 mints. Difference of mean segment sensory level in two groups was statistically significant (p<0.0001). All patients had maximum motor block achieved (modified borage scale) 1.In Group-A (F), the mean of time spinal drugs to maximum motor block (mean±s.d.) of patients was 5.2745 ± .3233 mints. In Group-B (B), the mean of time spinal drugs to maximum motor block (mean±s.d.) of patients was 5.2727 ± .3217 mints. Difference of mean time spinal drugs to maximum motor block in two groups was not statistically significant (p=0.9765).In Group-A (F), the mean of time modified borage scale of 3 (mean±s.d.) of patients was 81.2364 ± 4.8799. In Group-B (B), the mean of time modified borage scale of 3 (mean±s.d.) of patients was 109.8364 ± 2.6159. Difference of mean time modified borage scale of 3in two groups was statistically significant (p<0.0001). TuhinVashishth et al [13] found that the mean time to achieve Grade III motor block was 8.87±3.68 minutes in Group I, 5.64±2.60 minutes in Group II and 6.08±3.23 minutes in Group III. The mean time to achieve Grade III motor blockade was minimum in Group II and maximum in Group I showing a significant intergroup difference (p value < 0.001). There were 3 patients in Group I who did not achieve Grade III motor block till 15 minutes. It means that Grade III motor block was achieved earliest in the patients receiving Nalbuphine followed by the patients receiving Fentanyl.

It was found that difference of mean duration of the operationin two groups was statistically significant (p=0.4393).We showed the mean values of HR, SBP, DBP, RR and SpO2 at different time interval were comparable among the groups.

TuhinVashishth et al [13] found that the mean duration of complete analgesia was found to be 129.3±10.2, 183.4±20.1 and 190.9±30.3 min. in Groups I, II and III respectively. The mean duration of effective analgesia was found to be 151.3±40.1, 242.4±41.4 and 280.3±45.1 min. in Groups I, II and III respectively. Group I had significantly shorter duration of complete as well as effective analgesia as compared to Groups II and III (p value < 0.001). A significant difference was observed between Groups II and III for the mean duration of effective analgesia (p value < 0.001) with Group III showing significantly longer duration as compared to Group II.

The principal findings of this study are that intrathecal butorphanol-bupivacaine mixture provides longer duration of sensory blockade and superior analgesia (with lesser requirement for rescue analgesia) as compared to intrathecal fentanyl-bupivacaine mixture.

The use of opioids in conjunction with local anesthetic for spinal anesthesia has been associated with decreased pain scores and reduced analgesic requirement in the post-operative period. [15,16] Results of previous studies have demonstrated that intrathecal opioids not only enhance analgesia when added to subtherapeutic doses of local anesthetics but also do not prolong recovery. [16-17]

Kumar B et al[12] found that Seven patients in the fentanyl-treated group and two patients in the butorphanol-treated group had hypotension in the peri-operative period (P=0.0771). Bradycardia, responsive to a single dose of intravenous atropine was seen in two patients in the group receiving fentanyl as compared to none in the butorphanol group (P=0.2468). Pruritis was observed in five patients receiving fentanyl as compared to none of the patients who received butorphanol (P=0.0273). Although six patients in the butorphanol group had sedation compared to none in the fentanyl group (P=0.0127); none of the patients developed respiratory depression. Four patients in the fentanyl group and three in the butorphanol group required urinary catheterisation due to difficulty in voiding. Nausea and vomiting were not reported by any of the patients.

CONCLUSION

From our study found that addition of fentanyl as an adjuvant to bupivacaine (0.5%) for single injection infra- umbilical surgeries prolongs the duration of sensory block, needs less time of rescue analgesics in the post-operative period. It was found that significant change in onset of sensory block, time Modified borage scale of 3 and rescue of analgesia was observed in two groups.

In conclusion, both fentanyl and butorphanol given intrathecally with 3 mg of hyperbaric bupivacaine provide effective and safe anesthesia for infra- umbilical surgeries with minor side effects. Intrathecal bupivacaine-butorphanol mixture provides longer duration of sensory and motor blockade and better quality of analgesia than intrathecal fentanyl-bupivacaine mixture.

Table: Distribution of adverse effect in two Groups

		Group-A (F)	Group-B (B)	p-value
Sedation	**NO**	55	55	
Bradycardia	**NO**	55	55	
Hypotension	**NO**	55	55	
Pruritis	**NO**	51	53	0.4010
	YES	4	2	
Respiratory depression	**NO**	55	55	
Nausea& vomiting	**NO**	50	53	0.2412
	YES	5	2	
Shivering	**NO**	55	55	
Ramsay sedation scale	**2**	55	55	

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