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A COMPARATIVE STUDY OF THE EFFECT OF CLONIDINE OR FENTANYL AS AN ADJUVANT TO INTRATHECAL BUPIVACAINE FOR POSTOPERATIVE ANALGESIA

Anaesthesiology

Dr. Aksha Khan — Postgraduate Resident, Department of anesthesiology and critical care, S.R.G. hospital & Jhalawar Medical College, Jhalawar, Rajasthan, India

Dr. Sukriti Bhardwaj — Postgraduate Resident, Department of anesthesiology and critical care, S.R.G. hospital & Jhalawar Medical College, Jhalawar, Rajasthan, India

Dr. Mohammed Mishal — Senior Resident, Department of anesthesiology and critical care, S.R.G. hospital & Jhalawar Medical College, Jhalawar, Rajasthan, India

Dr. Akil Hussain — Associate Professor, Department of anesthesiology and critical care, S.R.G. hospital & Jhalawar Medical College, Jhalawar, Rajasthan, India

Dr. Rajan Nanda — Senior professor and HOD, Department of anesthesiology and critical care, S.R.G. hospital & Jhalawar Medical College, Jhalawar, Rajasthan, India

ABSTRACT

Background- Spinal anaesthesia is the most commonly used technique but this usually associated with short duration. This study was to compare the effectiveness of clonidine and fentanyl used as adjuvant to 0.5 % hyperbaric bupivacaine for surgeries under spinal anaesthesia. **Methods-** After ethical committee approval and written informed consent from patients and/or attendant, this study was carried out in 50 adult patients of ASA grade I and II between the age of 20-60 year, undergoing major surgeries in which lower limb and lower abdominal surgeries. Patients were divided in two groups Group BC received Intrathecal Bupivacaine 12.5mg (2.5mL) +50mcg clonidine (0.5ml) and Group BF received Intrathecal Bupivacaine 12.5mg (2.5mL) +25mcg fentanyl (0.5ml). Anesthetic characteristics and vital parameters along with side effects were observed. **Results-** The time of onset of motor and sensory block in min found significantly earlier in group BC (2.83±0.44 and 1.89 ±0.49) than group BF (4.4 ± 0.72 and 3.62 ±0.65) respectively. Mean time to two segment regression was delayed in group BC (175.76±10.75 min) than group BF (135.72±7.9 min). (p-0.001) Duration of analgesia (minutes) was statistically longer in group BC (340.08 ±13.01) than Group BF (295.8 ± 15.66). (P-0.002) **Conclusion-** It is thus concluded from this study that combination of intrathecal clonidine as an adjuvant to hyperbaric bupivacaine provides early onset of sensory and motor block, as well increases the total duration of analgesia and first analgesic request time in comparison to intrathecal fentanyl without significant side effects.

KEYWORDS

Spinal anesthesia, Clonidine, fentanyl and bupivacaine

INTRODUCTION

Spinal anesthesia, defined, as 'the regional anaesthesia obtained by blocking nerves in the subarachnoid space' is a popular and common technique used worldwide. Spinal anaesthesia is the most commonly used technique for lower abdominal surgery, being simple to perform, economical and produces rapid onset of anaesthesia and complete muscle relaxation. It carries high efficiency, involves less drug doses. These advantages are sometimes offset by relatively short duration of action and uncomfortable postoperative period when its action wears off. In order to extend intraoperative analgesia into postoperative period a number of spinal adjuvants like opioids(fentanyl), clonidine, ketamine, morphine and buprenorphine and so on have been added to prolong intrathecal bupivacaine action. However each drug has its own limitations, and a need for alternative methods or drugs always exist.[1] The aim of using neuraxial opioids is to achieve as good analgesia as with systemic administration and to do it with smaller doses and systemic concentration and the risk of systemic side effects. This lead to the use of intrathecal Morphine but, was associated with side effects like respiratory depression, nausea, vomiting due to slower uptake and longer duration of action with higher CSF concentration with rostral spread of the narcotic . These considerations lead to the use of more lipophillic drugs such as Fentanyl, Sufentanil. Which are more potent and has the advantages over Morphine such as rapid uptake with short duration of action with low CSF concentration with limited rostral spread of narcotic and less respiratory depression and early motor recovery compared to Morphine.[2] Recently clonidine which is an α_2 adrenergic agonist has been tried as an adjuvant to prolong the action of local anesthetics. Intrathecal clonidine produces dose dependent analgesia and has been successfully used as a sole analgesic via the intrathecal route.[3] Hence, this study was aimed to evaluate the effectiveness of adding 50mcg clonidine and 25mcg fentanyl to bupivacaine 0.5% heavy for spinal anesthesia and to compare their anesthetic characteristics and associated complications.

METHODOLOGY

After ethical committee approval and written informed consent from patients, the study was carried out in 50 adult patients of American Society of Anesthesiologist (ASA) grade I and II between the age of 20-60 year, undergoing major surgeries in which lower limb and lower abdominal surgeries included, under subarachnoid block. Patients belonging to ASA grade III, IV or V & emergency cases, pregnant or lactating females, patients having cardio respiratory dysfunction or any other systematic illness were excluded from this study.

All patients in this study were subjected to detailed pre anaesthetic evaluation which included complete medical and surgical history of past and present illness, general physical examination and systemic examination including CVS, respiratory system, CNS and vital parameters like BP, pulse, temperature and respiratory rate. All baseline routine investigation were evaluated.

Each patient after pre anaesthetic check-up was kept on overnight fasting after midnight for surgery. Patient's written informed consent and PAC was checked. All patients were premedicated with Tab. Ranitidine 150mg and Tab. Ondansetron 8mg orally on the night before surgery. Intravenous access with 18 gauge IV cannula was secured at forearm level. Baseline vital parameters like blood pressure, pulse rate, SpO2, respiratory rate were documented. All 50 patient were randomly divided into 2 group, each group were consisted of 25 patients (n=25). Group BC received Intrathecal Bupivacaine 12.5mg (2.5mL) +50mcg clonidine (0.5ml) and Group BF received Intrathecal Bupivacaine 12.5mg (2.5mL) +25mcg fentanyl (0.5ml).

Patients were preloaded with lactated Ringer's solution as a bolus of 10 ml/kg before subarachnoid block to all patients. Spinal anaesthesia was performed at L3-L4 interspace with the patient in sitting position by using a 25 Gauge Quincke needle under strict aseptic conditions. Free flow of cerebrospinal fluid was verified before injection of the anaesthetic solution 3.0 ml volume, which was be administered over 30 seconds. The direction of the needle aperture was kept cranially during the injection. All patients were immediately placed in a supine position. Monitoring was done using continous electrocardiography, heart rate, non-invasive blood pressure and continous pulse oximetry and patients were given 4.0 L/min of oxygen by venti-mask. Vitals were checked every 5 minutes for first 30 minutes then every 10 minutes till surgery and then every 30 minutes for 6 hours

postoperatively. When adequate spinal block was achieved, the time from the end of intrathecal injection to readiness for surgery was recorded. Then the patient was positioned for planned surgery. Patients were monitored and different time intervals were noted to calculate the onset and duration of sensory and motor blockade. After completions of surgery patient were shifted to post-operative ward for monitoring and observation.

Monitoring of vital parameters like pluse, BP (SBP, DBP & MAP) and oxygen saturation (SpO_2) was done throughout procedure and was noted at preoperative, intraoperative and postoperatively. Sensory block was assessed by pinprick test at each minute after completion of intrathecal drug injection at L3-L4 interspace to the time taken to achieve T11-T12 level of sensory block. Onset of motor blockade and duration of motor blockade were recorded. The highest level of the block and the time to achieve the same was noted. Regression of sensory block was defined as the time taken for the sensory block to regress upto 2 segments of dermatome from the heighest level achieved. Sedation was assessed with Ramsay sedation scale and recorded. Score of 4 and above is considered as sedated. Analgesia in post-operative period was assessed using a standard 10 cm visual analog scale(VAS). Time for the first request of postoperative analgesic when VAS >3 (duration of analgesia) was noted and rescue analgesic intramuscular Tramadol 50mg or intramuscular Diclofenac 75mg was given. Complications and associated side effects like h ypotension (systolic blood pressure more than 20% fall from baseline), bradycardia (heart rate <50/min), sedation, pruritis, respiratory depression were noted and managed as a standard protocol.

Statistical analysis-

The presentation of the Categorical variables was done in the form of number and percentage (%). On the other hand, the presentation of the continuous variables was done as mean ± SD and median values. The data normality was checked by using Kolmogorov-Smirnov test. The cases in which the data was not normal, we used non parametric tests. The comparison of the variables which were quantitative in nature were analysed using ANOVA (for normally distributed data) and Kruskal Wallis test (for not normally distributed data). For all normally distributed data, a Post Hoc test (Bonferroni correction) was applied.For all not normally distributed data, a Post Hoc analysis by Dunn's multiple pairwise comparison test was carried out. The comparison of the variables which were qualitative in nature was analysed using Chi-Square test. If any cell had an expected value of less than 5 then Fisher's exact test was used. The data entry was done in the Microsoft EXCEL spreadsheet and the final analysis was done with the use of Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, ver 25.0.For statistical significance, p value of less than 0.05 was considered statistically significant.

RESULT

All the study parameters were observed and result noted.

Table 1:-Comparison of demographic parameters.

Variable	Group BC (n-25)	Group BF (n-25)	P value
Age in years (mean±SD)	38.12 ± 2.45	37.96 ± 2.65	0.807
Female:Male	9:16	4:21	0.196
Weight in kg	68.44 ± 11.03	66 ± 8.95	0.379
Height in cm	162.12 ± 6.66	161.6 ± 6.84	1.000
Total duration of surgery in minutes	111.6 ± 4.08	112 ±4.09	0.735

Table 2:-Comparison of anesthetic characteristics.

Variable	BC(n=25)	BF(n=25)	P value
Sensory block time of onset (min utes)	1.89 ±0.49	3.62 ±0.65	0.001
Motor block of time of onset (minutes)	2.83 ± 0.44	4.4 ± 0.72	0.001
Mean time to two segment regression (minutes)	175.76 ±10.57	135.72 ±7.9	0.001
Duration of motor block (minutes)	201.12 ±14.75	199.2 ± 14.41	0.717
Mean time of analgesic request (minutes)	361.8 ± 12.56	312.52 ±16.01	0.003
Duration of analgesia(minutes)	340.08 ±13.01	295.8 ± 15.66	0.002

Table 3:-Comparison of adverse effect between groups.

Adverse effect	BC(n=25)	BF(n=25)	P value
No adverse effect	22 (91%)	21 (84%)	0.667
Sedation	3 (9%)	2 (8%)	1.000
Pruritis	0 (0%)	2 (8%)	0.490

Nausea, vomiting, hypotension and bradycardia was not observed in any case of either groups.

Table 4:-Comparison of VAS score between groups.

VAS score	BC(n=25)	BF(n=25)	P value
At 01 hr (Mean ± SD)	0.6 ± 0.65	0.92 ± 0.81	0.224
At 03 hours (Mean ± SD)	3.2 ± 0.76	3.24 ± 0.83	0.832
At 06 hr (Mean ± SD)	4.76 ± 0.97	5.12 ± 0.88	0.217

DISCUSSION

Neuraxial adjuvants have been used to improve or prolong analgesia, decrese the adverse effect associated with high doses of a single local anesthetic agent to increase the speed of onset of neural blockade (reduce latency), improve the quality and prolong the duration of neural blockade many drugs (Fentanyl, morphine and phenylephrine, α2 agonist) have been used as an additive to local anesthetics.[4]

The demographic characteristics such as age, gender, height and weight were similar between the groups and hence the role of confounding by these factors can be eliminated. **Bajwa BS et al** [5] Where they found that there was no significant difference in the demographic profile between the two groups studied.

In our study the mean onset of sensory block in group BC and group BF was (1.89±.49) and (3.62±0.65) in minutes respectively thus onset of sensory block was significantly earlier in group BC than group BF (p-0.001).Similarly onset of motor block was 2.83±0.44 minutes in group BC and 4.4±0.72 minutes in group BF and this difference was statistically significant (p-0.001). In our study results were similar to **Singh R et al**[6] found that the addition of clonidine in dose of 75µg and 37.5µg to low dose bupivacaine and bupivacaine fentanyl produced earlier onset of both sensory and motor block.

In our study the heart rate,SBP,DBP and spo2 distribution over time were comparable in all the groups and this difference were not statistically significant (p>0.05) The result of our study were coincides with studies by **Singh R et al**[6] **and Chopra P et al**[7]**.**

In our study the duration of two segment regression was longer in group BC (175.76±10.57 min) than group BF (135.72 ±7.9 min) and this difference was statistically significant (p-0.001). Our study result was similar to the findings of **Ahmed F et al** [8]**.** They observed that the time interval from intrathecal injection to two segment regression was statistically significant in group BC. **Chopra P et al**[7] found that mean time till two segment regressions was significantly longer in group BCF as compared to group BC (P-.002) and in group BC as compared to group BF (P-.01) which coincides with our study.

In our study analgesic request time was earlier in group BF (312.52 ±16.01 min) as compared to BC (361.8 ± 12.56 min) and this difference was stastically significant (p-0.003). In a study by **Singh R et al** [6] found that the time of requirement of supplement analgesia was longer in group BC and BF which was statistically significant and similar with our study.

In this study duration of analgesia in group BC and group BF was 340.08±13.01 in min and 295.8±15.66 in min respectively and thus duration of analgesia was significantly longer in group BC than Group BF(p-0.002). **Ahmed F et al** [8] also found that combination of intrathecal clonidine and fentanyl along with bupivacaine increase the duration of analgesia, which was similar to our study. **Chopra P et al**[7] observed that the low dose clonidine (30µg) when added to bupivacaine fentanyl mixture increased the duration of analgesia which was in agreement with our study.

Side effects in group BC and BF no significant side effect found. Only mild sedation observed in group BC and pruritis was observed in group BF and difference was not significant.

CONCLUSION

It is thus concluded from this study that combination of intrathecal clonidine as an adjuvant to hyperbaric bupivacaine provides early

onset of sensory and motor block, as well increases the total duration of analgesia and first analgesic request time in comparison to intrathecal fentanyl without significant side effects.

REFERENCES

1. Ghodki PS, Sardesai SP, Thombre SK. Evaluation of the effect of intrathecal clonidine to decrease shoulder tip pain in laparoscopy under spinal anaesthesia. Ind J Anaesth. 2010 May;54(3):231.
2. Quirion R. Pain, nociception and spinal opioid receptors. Progress in Neuro-Psychopharmacology and Biological Psychiatry. 1984 Jan 1;8(4- 6):571-9.
3. Eisenach JC, De Kock M, Klimscha W. α2-Adrenergic agonists for regional anesthesia: a clinical review of clonidine (1984-1995). The J American Soci Anesthesiol. 1996 Sep 1;85(3):655-74.
4. Pettinger WA. Pharmacology of clonidine. Journal of Cardiovascular Pharmacology. 1980 Jan 1;2:S21-28.
5. Bajwa BS, Singh AP, Rekhi AK. Comparison of intrathecal clonidine and fentanyl in hyperbaric bupivacaine for spinal anesthesia and postoperative analgesia in patients undergoing lower abdominal surgeries. Saudi journal of anaesthesia. 2017 Jan;11(1):37.
6. Singh R, Kundra S, Gupta S, Grewal A, Tewari A. Effect of clonidine and/or fentanyl in combination with intrathecal bupivacaine for lower limb surgery. Journal of anaesthesiology, clinical pharmacology. 2015 Oct;31(4):485.
7. Chopra P, Talwar V. Low dose intrathecal clonidine and fentanyl added to hyperbaric bupivacaine prolongs analgesia in gynecological surgery. Journal of Anaesthesiology Clinical Pharmacology. 2014 Apr 1;30(2):233-7.
8. Ahmed F, Khandelwal M, Sharma A. A comparative study of the effect of clonidine, fentanyl, and the combination of both as adjuvant to intrathecal bupivacaine for postoperative analgesia in total abdominal hysterectomy. Journal of anaesthesiology, clinical pharmacology. 2017 Jan;33(1):102.