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A Prospective Randomized Comparative Study of the Intraoperative Hemodynamic Parameters and Adverse Effects of Single Preemptive Dose of Oral Pregabalin Versus Oral Gabapentin on Sub Arachnoid Block in Patients Undergoing Elective Infra Umbilical Surgeries

G Pradeep,[1] Dr Tejanand K, [2] Dr Arjun Swaroop A S,[3*] Dr Lingaraju N[4]

[1] Senior Resident, Department of Anesthesiology, PES University Institute of Medical sciences and research, Bengaluru-560100

[2] Assistant Professor, Department of Anesthesiology, Chamarajanagar Institute of Medical sciences, Chamarajanagara-571313

[3] Registrar, Manipal Hospitals, Whitefield- 560066

[4] Assistant Professor, Department of ENT, Chamarajanagar Institute of Medical sciences, Chamarajanagara- 571313

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KEYWORDS

Pregabalin, Gabapentin, Sub arachnoid block

ABSTRACT:

Introduction: Preemptive analgesia is defined as an anti-nociceptive treatment that prevents the establishment of altered central processing of afferent input, which amplifies postoperative analgesia. Various drugs such as local anaesthetics, opiods, non-steroidal anti-inflammatory drug, cyclooxygenase-2 inhibitors, gabapentin, pregabalin, clonidine and dexmedetomidine have been used as preemptive analgesics.

Aims: This study aims to assess the intraoperative effects of single pre-emptive dose of oral Pregabalin versus oral Gabapentin on Sub arachnoid block in patients undergoing elective infra umbilical surgeries on hemodynamics (Systolic Blood Pressure, Diastolic Blood Pressure, Mean Arterial Pressure and Heart Rate). In addition, the adverse effects like postoperative nausea, vomiting, sedation and dizziness were also assessed in the study.

Methodology: Ninety cases were included, on whom the routine monitoring of heart rate, blood pressure, peripheral oxygen saturation and ECG was instituted intra-operatively.

Results: There was no statistically significant difference with respect to the hemodynamic parameters or adverse side effects included in the study.

Conclusion: The findings of the study suggests that the preemptive oral Pregabalin and Gabapentin on Sub arachnoid block in patients undergoing elective infra umbilical surgeries provide a safe intraoperative and post-operative analgesia with maintained hemodynamic parameters and minimal adverse side effects.

INTRODUCTION

Preemptive analgesia is defined as an anti-nociceptive treatment that prevents the establishment of altered central processing of afferent input, which amplifies postoperative analgesia. By decreasing the altered central sensory processing, preemptive analgesia is thought to consequently decrease the incidence of hyperalgesia and allodynia after surgery.[1] Various drugs such as local anaesthetics, opiods, non-steroidal anti-inflammatory drug, cyclooxygenase-2 inhibitors, gabapentin, pregabalin, clonidine and dexmedetomidine have been used as preemptive analgesics.

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Gabapentin was first described in 1975 by Satzinger and Hartenstein and was approved for treatment of epilepsy in May 1993 in United Kingdom, following which FDA approval was attained in December 1993. Subsequently it was approved in United States of America for treatment of postherpetic neuralgia.[2]

Pregabalin was invented and synthesized in 1990 as an anticonvulsant by Richard Bruce Silverman. FDA approval was received in December 2004 and was available in the markets by fall 2005 under the brand name 'Lyrica'. In 2017, pregabalin obtained FDA approval for management of neuropathic pain in post-herpetic neuralgia and diabetic peripheral neuropathy.[3]

Neuraxial blockade has a wide range of clinical applications for surgery, obstetrics, acute postoperative pain management, and chronic pain relief. Single-injection spinal or epidural anesthesia with local anesthetic is most commonly used for surgery to the lower abdomen, pelvic organs (e.g. prostate), and lower limbs, and for cesarean deliveries. Neuraxial blockade result in one or a combination of sympathetic blockade, sensory blockade, or motor blockade depending on the dose, concentration, or volume of local anesthetic administered. Spinal anesthesia requires a volume of drug that is almost devoid of systemic pharmacologic effects to produce rapid, profound, reproducible sensory analgesia.[4]

This study aims to assess the intraoperative effects of single pre-emptive dose of oral Pregabalin versus oral Gabapentin on Sub arachnoid block in patients undergoing elective infra umbilical surgeries on hemodynamics (Systolic Blood Pressure, Diastolic Blood Pressure, Mean Arterial Pressure and Heart Rate). In addition, the adverse effects like postoperative nausea, vomiting, sedation and dizziness were also assessed in the study.

Methodology:

After obtaining hospital ethical committee approval and written informed consent, a thorough pre anesthetic evaluation (PAE) of the patients was done, on the previous day of surgery and, the concept of visual analog scale (VAS) was introduced to the patients and any doubts regarding the same was cleared. Patients were fasted for 8 hours before the surgery. On the day of surgery, in the preoperative room 2 hours before surgery, vital parameters like Pulse rate, Blood Pressure and peripheral oxygen saturation of all the patients was recorded and then the drug selected for the study was given with a sip of water. On entering the OT, an intravenous (IV) line was secured using an 18 Gauge cannula. All patients were pre-loaded with 15ml/kg of Ringer's Lactate fluid. All the basic monitoring (ECG, H.R, SPO_2, NIBP) were applied and baseline values were documented and Ramsay sedation score was also noted and no other pre-medications was given. Under strict aseptic precautions, in left lateral or sitting position, at the L3-L4 intervertebral space, lumbar puncture was done using a 27Gauge Quincke's Spinal needle and a volume of 3.0ml of Hyperbaric solution of 0.5% Bupivacaine was injected intrathecally. The patients were then placed in supine position with head end at lower level to ensure that a sensory block of atleast T6 was achieved. The level of sensory block was assessed and recorded as a loss of sensation to pin prick using a 26 gauge hypodermic needle, checking in a caudal to cranial direction. Subjects were divided into 3 groups- Group G – received 1200mg of Gabapentin capsule, Group P – received 300mg of Pregabalin capsule, and Group C – received identical placebo capsule.

Routine monitoring of heart rate, blood pressure, peripheral oxygen saturation and ECG was instituted intra-operatively. Fluid administration was continued intra- operatively and a decrease in mean arterial pressure greater than 15% below the pre- operative baseline value was considered as hypotension and was treated with incremental bolus doses of injection Mephentramine 3mg IV. A decrease in heart rate below 50 beats/min was considered as bradycardia and was treated with incremental doses of injection Atropine 0.6mg IV.

Hypotension was defined as decrease in mean arterial pressure greater than 15% below the pre-operative baseline value and will be treated with incremental doses of injection Mephentramine 3mg IV. Bradycardia was defined as decrease in heart rate below 50 beats/min and will be treated with incremental doses of injection Atropine 0.6mg IV.

Results:

The present study included a total number of 90 patients. Among them, 30 patients in Group G, 30 patients in Group P and 30 patients in Group C were distributed randomly. In our study, the mean age of group G is

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39.1±12 years, group C is 40.2±11 years and group C is 38.5±10.7 ears. There was no statistical difference, with respect to age of the patients, between the three groups (p value= 0.956). In our study, 53.3% were males and 46.7% were females in group G, 50.0% were males and 50.0% were females in group P and 53.3% were males and 46.7% were females in group C. There was no statistically significant difference in sex distribution amongst the three groups (p value = 0.95).

The mean body weights were 57.6±5.7 kg in group G, 55.4±5.0 kg in group P and 57.2±5.8 kg in group C respectively. There was no statistically significant difference in mean body weights between the three groups (p value=0.26).

Table 1 compares, amongst the three groups, the mean of heart rate measured at various intervals preoperatively and intraoperatively. There was no statistically significant difference observed between the three groups with respect to mean heart rate. Figure 1 compares, amongst the three groups, the mean of systolic blood pressure measured at various intervals preoperatively and intraoperatively. There was no statistically significant difference observed between the three groups with respect to the systolic blood pressure. Figure 2 compares, amongst the three groups, the mean of diastolic blood pressure measured at various intervals preoperatively and intraoperatively. There was no statistically significant difference observed between the three groups with respect to the diastolic blood pressure. Figure 3 compares, amongst the three groups, the mean of mean arterial pressure measured at various intervals preoperatively and intraoperatively. There was no statistically significant difference observed between the three groups with respect to the mean arterial pressure. Table 2 compares the adverse effects like nausea, vomiting and dizziness observed in the three groups. Postoperative nausea was seen in 16.7% of patients in group G, in 16.7% of patients in group P and in 10.0% of patients in group C. On comparison, there was no statistically significant difference in the incidence of nausea between the three groups (p value between groups G and P, groups G and C, and groups P and C being 0.99, 0.68, and 0.68 respectively).

Postoperative dizziness was seen in 20.0% of patients in group G, in 6.7% of patients in group P and none in group C. On comparison, there was no statistically significant difference in the incidence of postoperative dizziness between group G and group P (p value=0.1). But, there was statistically significant difference in the incidence of postoperative dizziness between groups G and C, and groups P and C (p values being 0.01 and 0.04 respectively), with maximum number of patients complaining of dizziness in group G(6 patients) as compared to group P (2patients) and group C (0 patients).

Table 1: Heart Rate variations by groups

	Group G BPM(SD)	**Group P BPM(SD)**	**Group C BPM(SD)**	**G & P p value**	**G & C p value**	**P & C p value**
At baseline	91.2 (12.0)	90.9 (10.1)	90.7 (10.6)	0.99	0.99	0.99
Before SAB	88.7 (12.1)	88.5 (11.2)	88.1 (10.2)	0.99	0.99	0.99
At 1min	78.1 (12.7)	75.5 (13.9)	76.6 (11.2)	0.57	0.13	0.78
At 3mins	80.5 (9.9)	74 (11.2)	78.1 (8.6)	0.06	0.08	0.09
At 5mins	81.7 (11.1)	74.4 (13.2)	75.6 (11.6)	0.58	0.06	0.8
At 10mins	82.8 (10.6)	77.1 (10.2)	75.8 (11.5)	0.11	0.07	0.7
At 15mins	83.9 (11.6)	77.7 (18.5)	80.7 (11.2)	0.06	0.1	0.21
At 25mins	84.5 (7.9)	78.6 (11.6)	82.8 (10.6)	0.07	0.2	0.45

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At 35mins	86.6 (11.5)	78.6 (12.4)	84.2 (12.0)	0.09	0.07	0.06
At 45mins	87.2 (12.5)	79.3 (10.0)	85.8 (12.0)	0.1	0.12	0.56
At 60mins	87.3 (12.5)	79.9 (9.1)	86.2 (12.0)	0.16	0.08	0.07
At 75mins	88.5 (12.2)	85.4 (9.7)	86.7 (14.9)	0.21	0.66	0.71
At 90mins	89.5 (9.0)	82.5 (11.3)	90.6 (11.7)	0.2	0.81	0.12
At 105mins	89.6 (12.2)	82.9 (10.7)	91.6 (13.7)	0.12	0.78	0.11
At 120mins	90.0 (12.8)	84.1 (11.2)	91.9 (9.7)	0.4	0.79	0.34

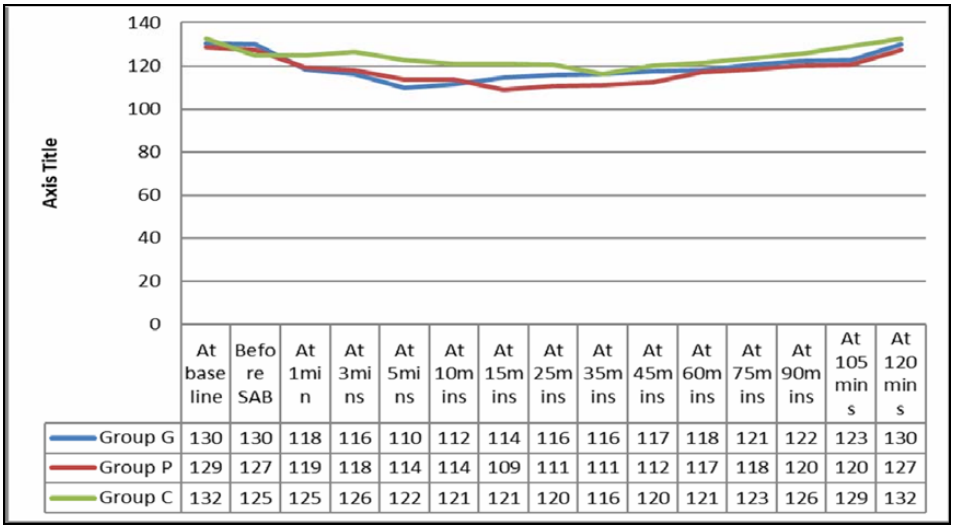

Figure 1: Systolic Blood Pressure variation by groups

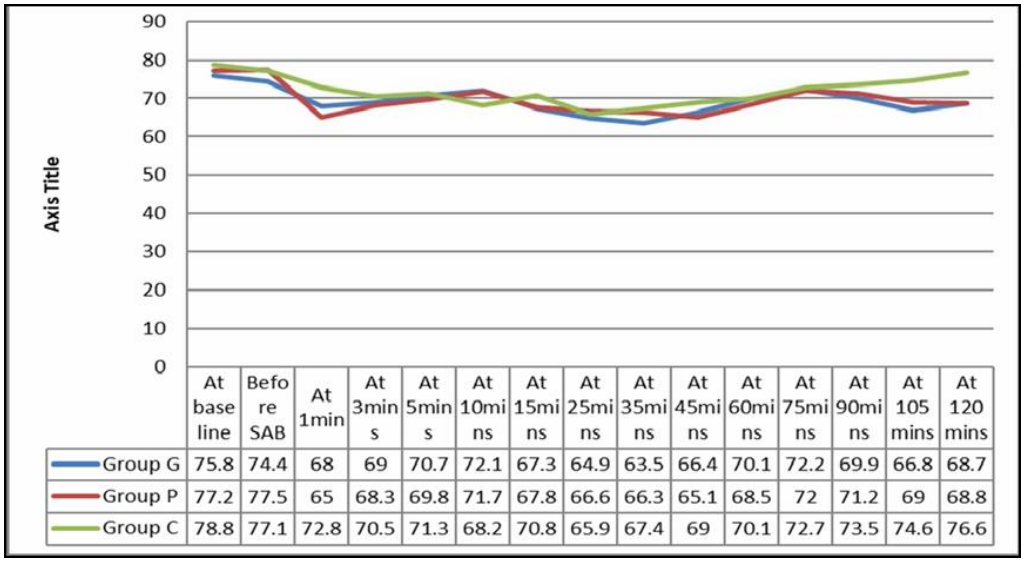

Figure 2: Diastolic Blood Pressure Variation by groups

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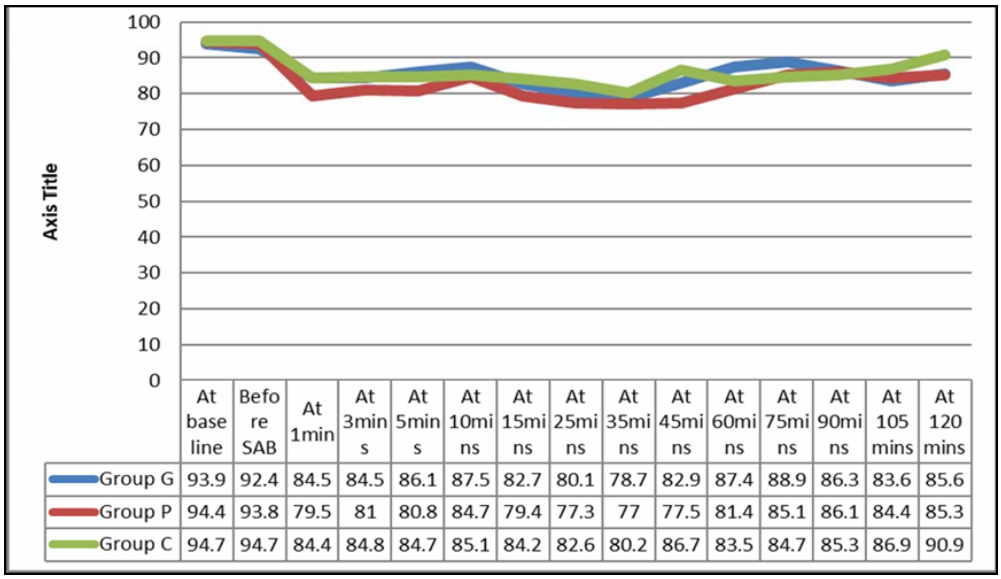

Figure 3: Mean Arterial Pressure variation by groups

Table 2: Incidence of Adverse effects by groups

	Group G Number (%)	Group P Number (%)	Group C Number (%)	G & P p value	G & C p value	P & C p value
Nausea	5 (16.7)	5 (16.7)	3 (10.0)	0.99	0.68	0.68
Vomiting	3 (10.0)	3 (10.0)	2 (6.7)	0.99	0.78	0.78
Dizziness	6 (20.0)	2 (6.7)	0 (0.0)	0.1	**0.01**	**0.04**

DISCUSSION

In our study, the heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure were measured to be assessed as hemodynamic parameters at baseline, before SAB, and at 1,3,5,10,15,25,35,45,60,75,90,105 and 120 min after SAB intraoperatively. It was observed that there was no statistically significant difference in any of the hemodynamic parameters (heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure) between the three groups (P>0.05). The studies conducted by Usha Bafna et al,[5] Saraswat V et al,[6] Anita Kumari et al,[7] and Upasana Bhatia et al,[1] all reported that there was no significant changes in the hemodynamic parameters between the pregabalin or gabapentin or placebo group intraoperatively, which correlates with our study. Although, in studies conducted by Alireza et al[8] and Monica Kholi et al,[9] there was significant reduction in the heart rate and mean arterial pressures in the pregabalin group than in the placebo group, in the intraoperative period, compared to the preoperative values, which doesn't correlate with our study.

In our study, incidence of adverse effects in the first 24 hour postoperative period was assessed. It was observed that there was no statistically significant difference between the three groups with respect to the incidence of nausea and vomiting. This observation is comparable to the studies done by Induja R et al,[10] and Monica Kholi et al,[9] Alireza et al,[8] Saraswat V et al,[6] Amany F et al[11] and Upasana Bhatia et al,[1] which had similar observations.

The incidence of dizziness was found to significantly higher in the gabapentin and pregabalin group as compared to the control group in our study. Similar observations was reported by Monica Kholi et al[9] and Alireza et al,[8] in their studies, while Mihye Park et al[12]

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reported no difference in the incidence of dizziness in between the pregabalin and placebo group.

Our study showed no statistically significant difference between the pregabalin and gabapentin group(P=0.1) with respect to postoperative incidence of dizziness, which is comparable with the study by Saraswat V et al,[6] who reported similar findings (P>0.05). But, the study by Swarup Pal et al [13] showed that the incidence of dizziness is significantly lesser in the pregabalin group compared to the gabapentin group.

CONCLUSION

The findings of the study suggests that the preemptive oral Pregabalin and Gabapentin on Sub arachnoid block in patients undergoing elective infra umbilical surgeries provide a safe intraoperative and post-operative analgesia with maintained hemodynamic parameters and minimal adverse side effects.

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