

Study to Compare the Effect of Oral Gabapentin with Oral Clonidine for Perioperative Analgesia and its Effect on Prevention of PONV

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Abstract

Background: Ideal pre-medication would be that, which can decrease preoperative anxiety of the patients, can effectively attenuate the hemodynamic stress response to laryngoscopy and intubation and also provide post-operative analgesia with easy availability and minimal side effects. **Subjects and Methods:** The study was conducted in fifty adult patients for laparoscopic cholecystectomy under general anaesthesia. The patients were randomly allocated into two groups of 25 each, Group-I Gabapentin group, received oral tablet Gabapentin (300 mg) and Group-II Clonidine group received oral tablet Clonidine (2 µg), 2 hours before surgery. The post operative variables studied were heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, VAS score, mean consumption of rescue analgesic, mean consumption of Ondansetron for post operative nausea and vomiting. **Results:** There was no statistically significant difference between the two groups in respect of HR, SBP, DBP, and MAP. There was significant difference in the VAS score between the 2 groups; lower scores in the Gabapentin group. There is statistically significant difference in mean consumption of opioids in Gabapentin group was (4 ± 13.84 mg) with P value 0.0108 and as well as mean Ondansetron consumption for PONV in Gabapentin group (0.16 ± 0.78 mg) with P = 0.0089. **Conclusion:** Both the drugs have similar effect over the intraoperative hemodynamics and promising role in maintenance of perioperative analgesia. Both drugs have a promising role in postoperative analgesia, though Gabapentin is found to have better analgesia compared to clonidine. Gabapentin has better effect on the control over PONV compared to Clonidine.

Keywords: Analgesia, Clonidine, Gabapentin, Haemodynamics.

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Introduction

According to the International Association for the Study of Pain (IASP) "pain is a sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage".^[1] This includes acute pain, cancer and chronic non-cancer pain. The term pre-emptive analgesia describes an "antinociceptive treatment that prevents establishment of altered processing of afferent input, which amplifies postoperative pain".^[2] The technique of pre-emptive analgesia involves giving predetermined analgesic before the noxious stimulus sets in so that nervous system sensitization that amplifies pain will be prevented. This protective potential on the nociceptive system gives pre-emptive analgesia is more effective than similar analgesic treatment post operatively.

Ideal pre-medication decreases not only the preoperative anxiety of the patients but also effectively attenuate the hemodynamic

stress response to laryngoscopy and intubation thus providing post-operative analgesia. Gabapentin or Clonidine as pre-medication can be easily administered, minimal side effects, easily available with low price, both of them have sedative effect that can decrease anxiety and they can blunt the stress response. More over both drugs have anti-nociceptive effects that may be beneficial for controlling post-operating pain. Hence, this study was designed to evaluate and compare the effects of oral premedication with Clonidine and Gabapentin in normotensive patients on perioperative analgesia and PONV in patients undergoing an elective surgery.

Gabapentin is an anticonvulsant that has anti-nociceptive and anti-hyperalgesic properties.^[3,4] In pain models it has shown antihyperalgesic properties, possibly by reducing central sensitization.^[5] Following single oral dose of 300 mg gabapentin the mean maximum plasma concentration attained in 2-3hr.^[6,7] Bio-availability of a single 300 mg oral dose

of gabapentin is 60% and decreases with increasing the dose. Elimination of gabapentin is through renal clearance and is about 5-7 hr following a single oral dose of 200 to 400 mg.^[8]

Clonidine is an imidazoline antihypertensive drug.^[9] It also has sedative, anxiolytic & analgesic properties.^[9,10] It is a selective partial agonist for α_2 -adrenoreceptors, with a ratio of approximately 200: 1 (α_2 to α_1). Clonidine stimulates pre-synaptic α_2 -receptors & inhibits norepinephrine release from both central and peripheral adrenergic terminals. α_2 -receptors are abundant in pontine locus coeruleus which is an important source of sympathetic nervous system innervations of the forebrain & a vital modulator of vigilance. The sedative effects evoked by clonidine most likely reflect the inhibition of this nucleus.^[11]

Subjects and Methods

This prospective study was conducted after the approval from the institutional ethics committee. Oral and written consent from the patients were also taken.

The study was conducted in fifty adult patients of in ASA grade-I and II physical status scheduled for laparoscopic cholecystectomy under general anaesthesia, after exclusion criteria were met. The study was taken out only in surgeries lasting for not more than 75 minutes durations. Each patient was examined in the preanesthetic check-up clinic. A detailed history was taken and physical examination done for all patients. All patients underwent the following investigation namely complete urine analysis, hemogram, blood chemistry, X-ray chest and a preoperative ECG.

Exclusion criteria

- Age < 20, >50 years
- Known hypersensitivity to any of the study drugs.
- Known case of coronary artery disease, bronchial asthma, epilepsy, hypertension, any patients with thyroid disease.

The patients were randomly allocated into two groups, group-I and group-II (having 25 patients in each group).

- Group-I Gabapentin group: comprising of 25 patients, who received oral tablet Gabapentin (300 mg), 2 hours before surgery.
- Group-II Clonidine group: comprising of 25 patients, who received oral tablet Clonidine (2 μ gm), 2 hours before surgery.

The premedication, induction agent, and muscle relaxant to facilitate were standardized for both the groups. Intravenous cannulation was done with 18 G cannula after shifting the patient into the waiting area of the operation theatre, and connected to a drip of ringer lactate solution. Premedication with inj. Glycopyrrolate 5 μ gm/kg, inj. Fentanyl 2 μ gm/kg

were given slowly intravenously, 20 minutes before induction. Patients was connected to non-invasive blood pressure monitors, pulse oximeter probe and ECG leads (limb lead-II). All patients were preoxygenated.

The patient was induced by inj. propofol (2-3mg/kg body weight). Intubation was facilitated by using Vecuronium bromide 0.1mg/kg body wt. Intubation was achieved with an appropriate size oral cuffed endotracheal tube. Anaesthesia was maintained with Vecuronium bromide 0.08mg/kg top-up doses, time bound doses were given for every 20 minutes; and the patient's lungs were mechanically ventilated to maintain normocarbida (CO₂ between 36 and 44 mmHg). Isoflurane in the range of 0.5%–1% to maintain anaesthesia. Recording were done at pre-induction, post intubation and then for every regular interval of 15 minutes. The parameters were titrated within 10 % of baseline using additional bolus of fentanyl, propofol and isoflurane. The parameters recorded were heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure. Intraoperative fluid requirements were also given according to the protocols, blood loss and urine output. At the end of surgery, neuro muscular blockade was reversed with Neostigmine (0.05mg/kg), Glycopyrrolate (0.01mg/kg). All the patients were followed in the post operative period 0 to 6 hrs for hemodynamic, adequate analgesia, presence of any nausea and vomiting etc. Number incidence of any adverse effects of the Clonidine and Gabapentin were seen in the post operative period in the comparison of two groups.

The recording was noted at various intervals as detailed below from the study conducted:

- Preoperative i: e before induction
- After intubation
- Every 15 minutes till the surgery was completed
- At the time of extubation or 75minutes, whichever is earlier
- At the end of 90minutes of surgery and anaesthesia
- Post operatively at end of 0 hrs, 2nd hrs, 4th hrs, 6th hrs
- The parameters monitored in the post operative period were heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, VAS score, mean consumption of Tramadol as a rescue analgesic, mean consumption of Ondansetron as measure for post operative nausea and vomiting.
- If the VAS scores were more than 4, a dose of inj. Tramadol 50mg diluted and slow I.V was given Postoperative pain was assessed by visual analog scale and we have used Nurse controlled Analgesia (NCA). The nurse administered the drug based on VAS score >4.
- If there was any nausea and vomiting, then a dose of inj. Ondansetron 4mg I. V slowly was given. The comparison of hemodynamics both intraoperative and postoperative between the 2 groups is made. The postoperative analgesia, comparison of VAS scores, postoperative

nausea and vomiting, the mean dose of Tramadol for pain scores >4 , the mean dose of inj. Ondansetron for PONV is compared between the groups. Statistical analysis was done using Microsoft excel software version 2010 with unpaired student t test and with Graph pad instat version 3.00 for Windows 7, graph pad software, San Diego California USA. P value < 0.05 was considered as "significant" where as P value > 0.05 was considered as "not significant". P value < 0.001 was considered highly significant.

Results

Discussion

Balanced anaesthesia includes four components adequate analgesia, adequate amnesia, loss of reflexes (reversibly), and muscle paralysis (reversibly). Maintenance of good analgesia is one of the key components of balanced anaesthesia. The chief modalities of analgesia include non-opioid based techniques and Opioid based techniques, no doubt opioids are one of the mainstay drugs for Perioperative analgesia but they have their own ill effects. Regional analgesic techniques like nerve blocks and central neuraxial technique is one more promising option but patient's co-operation and its ill effects and contraindications in certain conditions are some drawbacks. Adjuvant drugs like Gabapentin, which belongs to newer antiepileptic group and traditionally used for epilepsies and neuropathic pain has promising role in anaesthesia. It forms one of the key modalities in multimodal analgesic techniques whereby we can reduce the consumption of Opioids and thus reduce the side effects due to Opioids. Also, due to its synergistic activity on Opioids, it reduces the dosage requirements of Opioids. Oral Clonidine is also a promising drug with less side effect profile and tolerated well by majority of the patients. It is a very cost-effective drug in the oral form. It has properties like sedation, anxiolysis, reduced analgesic requirements etc due its action on α_2 -receptors. The study was done to know the efficacy of non-opioid based oral drugs; oral Clonidine $200\mu\text{g}$ and oral Gabapentin 300mg given preoperatively 2 hours before surgery and to know their efficacy in maintaining the analgesia perioperatively and prevention of PONV. Peak action of both the study drugs was known to be 1-2 hours after oral administration as per study conducted by Seib R K, Paul J E et al.^[12] So we gave the study drugs 120 minutes before induction of anaesthesia. In the present study 25 patients were selected in each group having ASA Gr-I and II, 20-50 years of age, weighing between 40-75 Kg. All investigation was under normal limits. The duration of surgery was also standardized and duration exceeding 75 minutes was excluded from the study. Informed consent was taken from the patients, both written and oral. Both the study drugs were given 2 hours prior to surgery, oral

Clonidine $200\mu\text{g}$ and oral Gabapentin 300mg. Verma A et al,^[13] studied the effect of Gabapentin 300mg in decreasing postoperative pain. Oral clonidine was used in the range of 100-300 μg m. We used 200 μg m Clonidine because this was the dose used by many authors, like Ghafari M H et al,^[14] Chung C S et al.^[15] Tramadol consumption on VAS score > 3 , the post operative mean Ondansetron consumption were compared in both the groups and statistical analysis was done. P value < 0.05 was considered as significant. There was no statistical difference pertaining to the age group, the mean body weight, the duration of surgery etc. which was similar to the study conducted by Ghafari MH et al.

Intraoperative period:

In our study there was slight elevation of SBP, DBP, MAP, and HR after intubation but all parameter trended towards normalization after 15 minutes of intubation. All the above findings were similar to the study conducted by Ghafari M H et al. Kiran S et al,^[16] has studied the effects of gabapentin 800 mg in attenuation of hemodynamic response to direct laryngoscopy and tracheal intubation in elective surgery. SBP, DBP, and MAP was significantly lower in the gabapentin group as compared to control group at 0, 1, 3, 5, and 10 minutes after intubation but tachycardia response was not completely eliminated.

Post operatively:

Mean Systolic blood pressure values did not show any statistical significant in all the reading taken at the end of 0 hr, 2 hr, 4 hr and 6 hr. There was no statistical difference in the Mean Diastolic pressure value and also the mean of MAP. All the above finding are similar to the study conducted by Ghafari M H et al.

VAS score:

There was significant difference in the VAS score between the 2 groups; lower scores in the Gabapentin group. The total rescue mean analgesic dose of Tramadol was also significantly less in the Gabapentin group compared to the Clonidine group which was found to be statistically significant. Mohammadi SS et al,^[17] conducted the study and found out that the least consumption was observed in the Gabapentin group. In our study mean consumption of opioids i.e. Tramadol, in Gabapentin group was 4 ± 13.84 mg as compared to Clonidine group of 18 ± 22.49 mg, the P value being 0.0108 which indicates a significant difference between the groups.

PONV

In Gabapentin group Ondansetron requirement was lesser than Clonidine group which was statistically significant. The above finding co-relates well with the study under taken by Marashi S M et al,^[18] and Pandey et al.^[19] In their study they conducted a prospective, randomized double blind study on selected 22 patients in each group with one controlled group and evaluated

Table 1: Demographic data of the patients

Patient Factors	Group-I		Group-II		P value	S/NS/ HS
	Mean	SD	Mean	SD		
Mean Age	36.56	9.81	35.36	9.97	0.67	NS
SEX(M/F)	9(36%) / 16(64%)		11(44%) / 14(56%)			
Wt in Kg	57.56	6.23	55.36	6.34	0.22	NS
Surgery duration in minutes	61.76	8.67	60.40	8.99	0.58	NS

Table 2: Intraoperative heart rate

Time	Group-I		Group-II		P value	S/NS/HS
	Mean HR ± SD		Mean HR ± SD			
Pre-Intubation	86.12 ± 11.72		82.52 ± 10.65		0.261	NS
After Intubation	92.76 ± 12.21		88.72 ± 10.58		0.007	NS
15 Min	86.36 ± 10.18		85.72 ± 9.82		0.730	NS
30 Min	85.02 ± 10.40		84.72 ± 9.52		0.665	NS
45 Min	84.64 ± 10.09		83.92 ± 9.33		0.892	NS
60 Min	84.76 ± 9.79		83.00 ± 8.94		0.829	NS
75Min/ Extubation	85.24 ± 10.16		82.92 ± 9.41		0.617	NS
90 Min	84.56 ± 10.03		82.92 ± 9.72		0.636	NS

Table 3: Intra Operative Mean Systolic Blood Pressure (mmHg):

Time	Group-I		Group-II		P value	S/NS/HS
	Mean SBP ± SD		Mean SBP ± SD			
Pre-Intubation	124.96 ± 9.02		121.48 ± 11.37		0.236	NS
After Intubation	131.04 ± 8.49		126.52 ± 11.21		0.222	NS
15 Min	125.56 ± 7.58		124.12 ± 11.50		0.603	NS
30 Min	124.00 ± 8.34		121.96 ± 11.82		0.484	NS
45 Min	123.68 ± 8.10		119.96 ± 11.92		0.203	NS
60 Min	123.60 ± 8.06		120.52 ± 11.40		0.275	NS
75Min/Extubation	123.08 ± 7.66		121.24 ± 10.86		0.492	NS
90 Min	123.00 ± 7.47		120.60 ± 11.03		0.372	NS

Table 4: Intra Operative Mean Diastolic Blood Pressure(mmHg):

Time	Group-I		Group-II		P value	S/NS/ HS
	Mean DBP ± SD		Mean DBP ± SD			
Pre-Intubation	77.72 ± 6.40		75.64 ± 6.99		0.278	NS
After Intubation	79.68 ± 6.98		78.36 ± 6.88		0.242	NS
15 Min	78.80 ± 7.15		77.56 ± 6.98		0.537	NS
30 Min	78.52 ± 7.54		76.88 ± 7.01		0.429	NS
45 Min	78.52 ± 7.00		76.32 ± 6.79		0.264	NS
60 Min	78.84 ± 6.54		76.00 ± 6.73		0.136	NS
75Min/Extubation	78.92 ± 6.27		75.76 ± 7.03		0.100	NS
90 Min	79.08 ± 6.46		76.12 ± 6.77		0.120	NS

Table 5: Intra Operative Mean Arterial Pressure(mmHg):

Time	Group-I Mean MAP ± SD	Group-II Mean MAP ± SD	P value	S/NS/ HS
Pre Intubation	93.46 ± 6.59	90.92 ± 7.39	0.205	NS
After Intubation	97.18 ± 6.81	94.48 ± 7.21	0.179	NS
15 Min	94.38 ± 6.79	93.08 ± 7.36	0.818	NS
30 Min	93.67 ± 7.10	91.91 ± 7.45	0.396	NS
45 Min	93.57 ± 6.73	90.87 ± 7.41	0.183	NS
60 Min	93.75 ± 6.27	90.84 ± 7.25	0.135	NS
75Min/Extubation	93.64 ± 6.03	90.92 ± 7.17	0.153	NS
90 Min	93.71 ± 5.97	90.95 ± 7.23	0.147	NS

Table 6: Heart Rate Comparison

Time	Group-I Mean HR ± SD	Group-II Mean HR ± SD	P value	S/NS/HS
0 Hr	86.12 ± 9.71	84.88 ± 8.86	0.639	NS
2 Hr	86.00 ± 10.85	85.52 ± 8.50	0.862	NS
4 Hr	85.60 ± 10.14	86.36 ± 8.14	0.717	NS
6 Hr	84.80 ± 9.60	86.04 ± 7.32	0.609	NS

Table 7: Post Operative Mean Systolic Blood Pressure(mmHg):

Time	Group-I Mean SBP ± SD	Group-II Mean SBP ± SD	P value	S/NS/HS
0 Hr	123.00 ± 7.71	121.00 ± 10.59	0.449	NS
2 Hr	122.76 ± 7.47	121.56 ± 10.16	0.636	NS
4 Hr	123.28 ± 7.19	122.00 ± 10.02	0.606	NS
6 Hr	123.36 ± 7.19	121.92 ± 10.21	0.570	NS

Table 8: Post Operative Mean Diastolic Blood Pressure(mmHg)

Time	Group-I Mean DBP ± SD	Group-II Mean DBP ± SD	P value	S/NS/HS
0 Hr	79.16 ± 6.47	76.00 ± 6.63	0.094	NS
2 Hr	79.40 ± 6.70	76.28 ± 6.78	0.108	NS
4 Hr	79.76 ± 6.67	76.72 ± 6.64	0.112	NS
6 Hr	79.76 ± 6.86	76.08 ± 6.85	0.063	NS

Table 9: Post Operative Mean Arterial Pressure(mmHg)

Time	Group-I Mean MAP ± SD	Group-II Mean MAP ± SD	P value	S/NS/ HS
0 hr	93.77 ± 6.01	90.49 ± 7.00	0.080	NS
2 hr	93.85 ± 6.07	91.37 ± 6.91	0.183	NS
4 hr	94.26 ± 6.04	91.81 ± 6.85	0.186	NS
6 hr	94.29 ± 6.33	91.35 ± 6.96	0.124	NS

Table 10: Post Operative Mean VAS:

Time	Group-I Mean VAS ± SD	Group-II Mean VAS ± SD	P value	S/NS/HS
0 Hr	0.64 ± 0.48	2.28 ± 0.73	0.0001	HS
2 Hr	1.00 ± 0.81	2.44 ± 0.76	0.0001	HS
4 Hr	2.08 ± 0.75	2.76 ± 0.77	0.0027	S
6 Hr	2.48 ± 0.82	3.16 ± 0.74	0.0034	S

Table 11: Post Operative Mean Tramadol consumption (in mg).

	Group-I Mean ± SD	Group-II Mean ± SD	P value	S/NS/HS
Tramadol consumption in mg	4 ± 13.84	18 ± 22.49	0.03	S

Table 12: Post Operative Mean Ondansetron consumption (in mg).

	Group-I Mean ± SD	Group-II Mean ± SD	P value	S/NS/HS
Ondansetron consumption in mg	0.16 ± 0.78	1.28 ± 1.90	0.004	S

the effect of Clonidine and Gabapentin premedication on postoperative pain intensity, morphine consumption, PONV. They found that PONV was significant in Clonidine group and Control group as compare to the Gabapentin group.

Conclusion

This study was undertaken to assess the effectiveness of oral adjuvant analgesic drugs and their effect over perioperative analgesia which was assessed based on the hemodynamics. Both the drugs have similar effect over the intraoperative hemodynamics. Gabapentin and Clonidine have a promising role in maintenance of perioperative analgesia. Onset and peak action of the drugs under study is almost similar. Both Gabapentin and Clonidine have a promising role in postoperative analgesia, though Gabapentin is found to have better analgesia compared to clonidine. Gabapentin has better effect on the control over PONV compared to Clonidine.

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