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An Observational Study Comparing Prophylactic Pre - Operative Gabapentin Vs Granisetron for Prevention of Post Operative Nausea and Vomiting in Laparoscopic Abdominal Surgeries

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Abstract: ***Background: After laparoscopic abdominal surgeries under general anaesthesia, Postoperative nausea and vomiting (PONV) is a common complication. The study was done to evaluate the efficacy of preoperative oral tab. Gabapentin 300mg and Granisetron 0.04mg/kg, administered intravenously for prevention of PONV. Materials and Methods: a prospective, randomized, clinical controlled study was conducted for 1 and 1/2 years, on 60 ASA I & II patients of either sex, aged between 18 to 65 years, planned for laparoscopic abdominal surgery under general anaesthesia. Patients were randomly assigned to one of the two groups, group A (n=30), received oral tab. Gabapentin 300mg 1hour prior to surgery with sips of water and group B (n=30), received Inj. Granisetron 2mg I.V., 2min before induction of anaesthesia. Postoperatively, incidences of nausea, vomiting were noted and any need for rescue antiemetics over 24hrs after surgery were evaluated. Rescue antiemetic drug injection Metoclopramide 10mg IV was given in case of PONV score 2 or more. Results: Both the groups were comparable with respect to demographic features i.e. age, sex, weight, ASA grade, duration of surgery (p>0.05). There was no statistically significant difference between the two groups regarding overall incidence of nausea and vomiting in 24hrs. The incidence of vomiting once in 24hours was 3.33% in Granisetron group and 3.33% in Gabapentin group. The incidence of postoperative vomiting more than once in 24Hours (PONV score 3) is 3.33% in Group A and 3.33% in Group B. This difference is also statistically insignificant with (p-value =1). 73.3% in group A while 66.6% in group B showed complete response to the study drug. Haemodynamically there was no major changes observed in either group. Modified Ramsay sedation score was higher in Gabapentin group compared to Granisetron throughout the various time intervals in the study.***

Keywords: PONV, general anesthesia, nausea, vomiting

1. Introduction

Postoperative nausea and vomiting (PONV) is a common, unpleasant, and distressing adverse effect that may occur after surgery and can lead to increased recovery room time, potential hospital admission, and increased total health care costs. Postoperative nausea and vomiting (PONV) has serious side effects which may lead to dehydration, bleeding from the operative site, wound dehiscence and aspiration pneumonia up to death. It is estimated that one episode of vomiting prolongs postanaesthesia care unit stay by approximately 25 minutes.

The incidence of nausea vomiting is 30% in surgery under general anaesthesia when inhalational anaesthetics are used alone without prophylaxis.

Laparoscopic surgery is one condition, where risk of PONV is particularly pronounced due to pneumo-peritoneum causing stimulation of mechanoreceptors in the gut. Now, there has been a general trend towards a decrease in the incidence and intensity of the problem because of the use of less emetic anaesthetic agents, improved pre and post-operative medication (e.g. analgesics), refinement of operative techniques and identification of patient predictive factors. However, in spite of these advances, nausea and vomiting still occur with unacceptable frequency in association with surgery and anesthesia and the description of it as “the big little problem”.

Incidence of PONV increases with increase in duration of surgery with every 30 minute increase in duration, PONV risk increases by approximately 60% from baseline. Risk of PONV varies from one surgical procedure to another.

Gabapentin is a gamma γ -aminobutyric acid (GABA) analogue. Gabapentin was initially introduced and approved by the Food and Drug Administration in 1994in USA as an adjunctive medication to control partial seizures (effective when added to other antiseizure drugs).Gabapentin in past has shown effectiveness in suppression of nausea and vomiting in perioperative period in patients undergoing laparoscopic cholecystectomy. Gabapentin has also shown its effectiveness as an antiemetic to supress chemotherapy induced nausea and vomiting in patients of breast cancer.

Graninsetron is a selective 5-hydroxytryptamine3 (5-HT3) receptor antagonist and acts on the vagal afferent nerves of the gut, producing irreversible block of the 5-HT_3 receptors, and may account for the long duration of this drug. Granisetron can be used for both prophylactic and therapeutic drug for nausea and vomiting as it has a superior efficacy, safety and pharmacoeconomic profile compared with other groups of antiemetics, namely antidopaminergics, antihistamines and anticholinergics. Ondansetron is well tolerated and its side effects are mild.

1.1 Aim

To evaluate the efficacy and potency of pre-operative Gabapentin and Granisetron for postoperative nausea and vomiting in patients undergoing laparoscopic abdominal surgeries.

1.2 Objectives

- To observe Incidence of postoperative nausea and vomiting in patients undergoing laparoscopic abdominal surgeries under General anaesthesia.
- To observe the requirement of rescue antiemetics in the postoperative period.
- To observe Intra and Postoperative hemodynamic changes (pulse rate, systolic blood pressure and diastolic blood pressure)
- To observe any side effects or complications during study period

2. Materials and Methods

This study was conducted in Dhiraj-hospital in Department of Anaesthesiology. We have included 60 patients of Grade-I and Grade-II of American Society of Anaesthesiologist's (ASA) classification who were admitted for Elective Laparoscopic Abdominal surgeries under general anaesthesia and were allocated randomly to two equal groups (by Chit Method).

Group A (*n* =30)	Received pre-operatively Tablet Gabapentin 300mg 1 hour prior to surgery.
Group B(*n* =30)	Received inj. Granisetron 0.04mg/kg I/V.

Study Population
Patients undergoing laparoscopic surgeries. Total subjects were 60 and equally divided into two groups A for Gabapentin and group B Granisetron.

Study Design
Prospective observational study.

Duration of Study
December 2016 to May 2018 (1 and half years).

Inclusion Criteria
1) Patients of either gender in the age group of 18 to 65 years, undergoing Elective Laparoscopic Abdominal surgeries under general anaesthesia.
2) ASA grades I and grade II.
3) Patients with no known history of allergy, sensitivity or other form of reaction to the drugs to be used.
4) Patient willing to sign informed consent.

Exclusion Criteria
1) Patient refusal
2) Patient with a history of PONV and motion sickness.
3) History of drug allergy to Gabapentin and Granisetron.
4) ASA III or more
5) 5.Pregnant and lactating mothers

3. Results and Observations

This study comprised of two groups – group A Gabapentin and group B Granisetron,30 patients in each group and subsequently observed for haemodynamic parameters, PONV score at different time intervals, requirement of rescue antiemetic, adverse effect and complications (if any) were studied.

The mean age of patients in Group A was 32 ± 11 and 31 ± 8.5 in Group B and was statistically insignificant.

It was observed that there were 16 male patients (53.33%) in Group A and 14 (46.66%) males in Group B respectively as compared to 14 females (46.66%) patients in Group A and 16 patients (53.33%) in Group B respectively. There was no statistically significant difference in sex ratio of the study group. (p=0.99).

The mean ASA grading of patients in Group A was 21 (70%) for Grade I and 9 (30%) for group II in Group A. while 20 (66.67%) for grade I and 10 (33.33%) for grade II in Group B. The p value was >0.99and was not statistically significant.

The mean duration of surgery in Group A was 98.8 ± 15.3 mins and 31 ± 96.4 mins in Group B and was statistically insignificant(p= 0.490).

In the above study it was observed that there was no statistically significant difference in diastolic blood pressure among groups seen at all time intervals during first 24hours.(p>0.05).

It was observed that the overall incidence of nausea postoperatively in 24 hrs is 26.6% in Group A and 33.3 % in Group B and statistically not significant with p-value > 0.05.

In the study the overall incidence of vomiting once only, in 24hrs, is 3.33% in Group A and 3.33% in Group B, with (p-value >0.05), which is statistically insignificant as shown in table.

It was observed that the incidence of postoperative vomiting more than once in 24Hours is 3.33% in Group A and 3.33% in Group B. This difference is statistically insignificant with (p-value =1) as shown in table.

In the study it was observed that there were 22 (73.3%) patients in Group A and 20 (66.6%) patients in Group B showed complete response (i.e. no nausea or vomiting) to prophylactic dose of the study drug. (p-value >0.05) which is statistically insignificant as shown in table.

In the study it was observed, in Group A 1(3.33%) patients and 1 (3.33%) patient in Group B received rescue antiemetic. This analysis was found to be statistically insignificant (p- value >0.05) as shown in table.

It was observed that in Group A 1 (3.33%) patients had developed headache and in Group B 2 (6.66%) patient had headache. In Group B 1 (3.33%) patients had developed

dizziness and in Group A 2 (6.66%) patient had dizziness and had no statistically significant difference.

In the study it was observed that the mean postoperative analgesia requirement in Group A was 160 ± 38.05 mg compared to Group B where it was 197 ± 74.95 mg in first 24hours post operatively. This analysis was found to be **statistically significant (p- value =0.01).**

Table 1

Comparison parameters	Group A	Group B	P value
Age (years)	32±11	31±8.5	1 Insignificant
Gender	Male 53.3 Female 46.66	Male 46.66 Female 53.3	1 Insignificant
Weight (kgs)	56.7±9.93	54.96±6.87	0.417 Insignificant
Duration (minutes)	98.8±15.3	96.4±11.14	0.480 Insignificant
Rescue emetic required	3.3%	3.3%	>0.05 Insignificant
PONV1	26.6%	33.3%	>0.05 Insignificant
PONV2	3.33%	3.33%	>0.05 Insignificant
PONV3	3.33%	3.33%	>0.05 Insignificant
Diclofenac requirement	160±38.05	197±74.95	0.01 Significant
ASA Grading	I - 70% II - 30%	I – 66.67% II – 33.33%	>0.99 Insignificant
Incidence of nausea			
0-2 hours	0%	0%	
2-8 hours	6.6%	10%	
8-16 hours	13.3%	13.3%	
16-24 hours	6.6%	10%	>0.05
Total	26.6%	33.3%	Insignificant
Complete response to prophylactic dose	Yes - 73.3% No - 26.67%	Yes - 66.6% No – 33.37%	>0.05 Insignificant
Adverse effect	Headache – 3.33 % Giddiness – 6.66%	Headache – 6.66% Giddiness - 3.33%	1 Insignificant

In the study it was observed that the mean postoperative sedation score in both the groups, it was found to be statistically insignificant with p- value =0.089 and p- value =0.321 respectively.

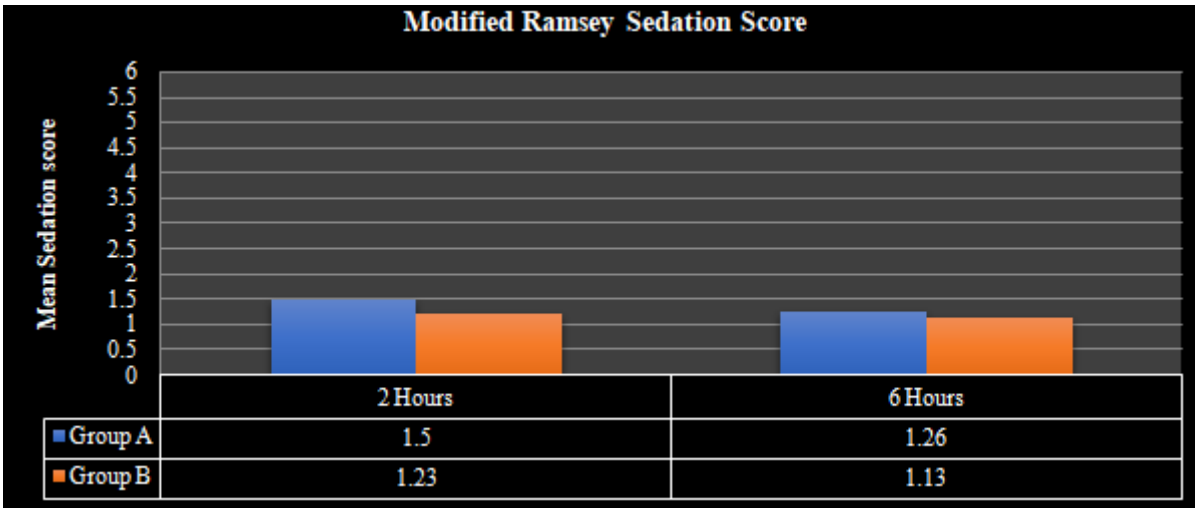


Figure 2: Modified ramsey sedation score among groups

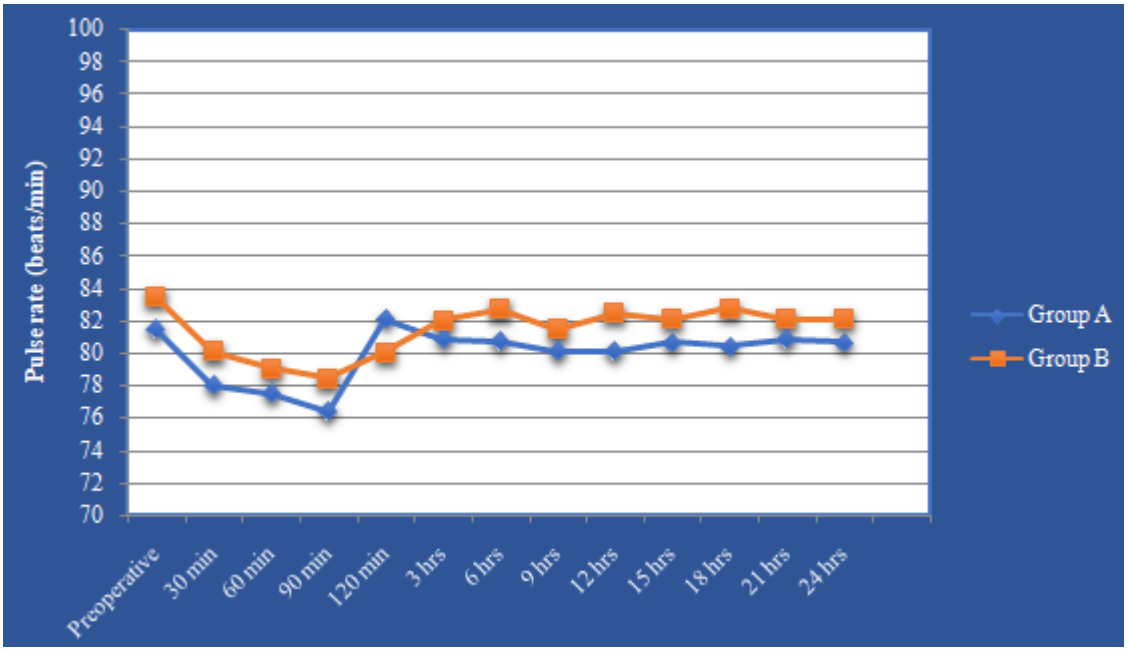


Figure 3: Comparison of pulse rate (beats/min) in study groups at different time intervals

In the above study it was observed that there was no statistically significant difference in pulse rate among groups seen at all time intervals during first 24hours.($p>0.05$).

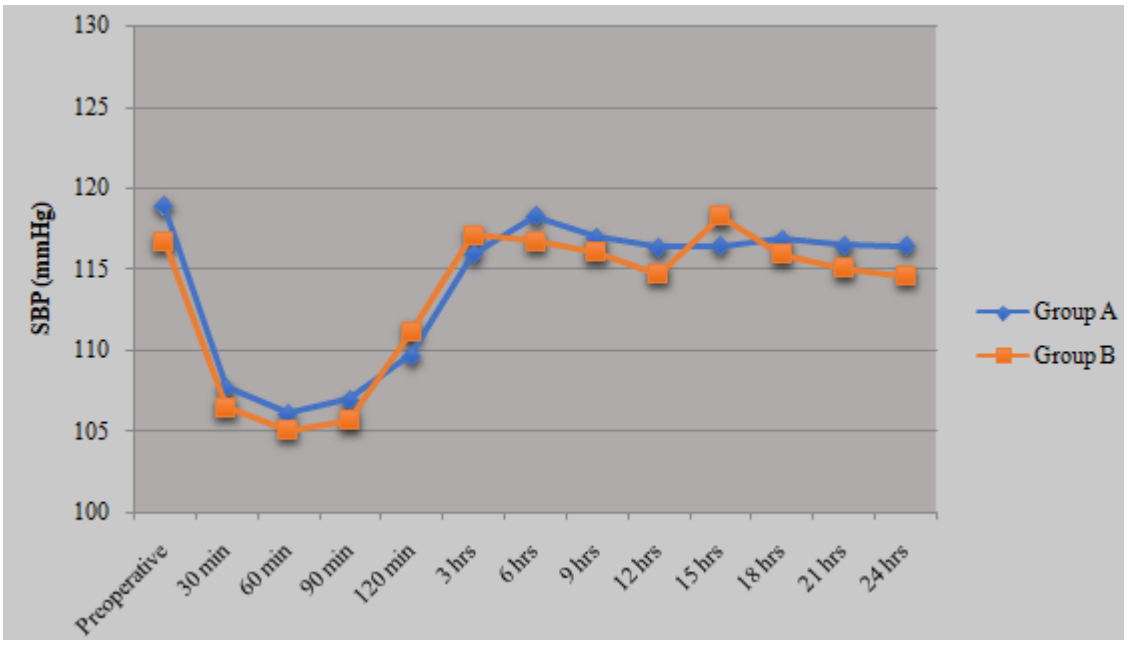
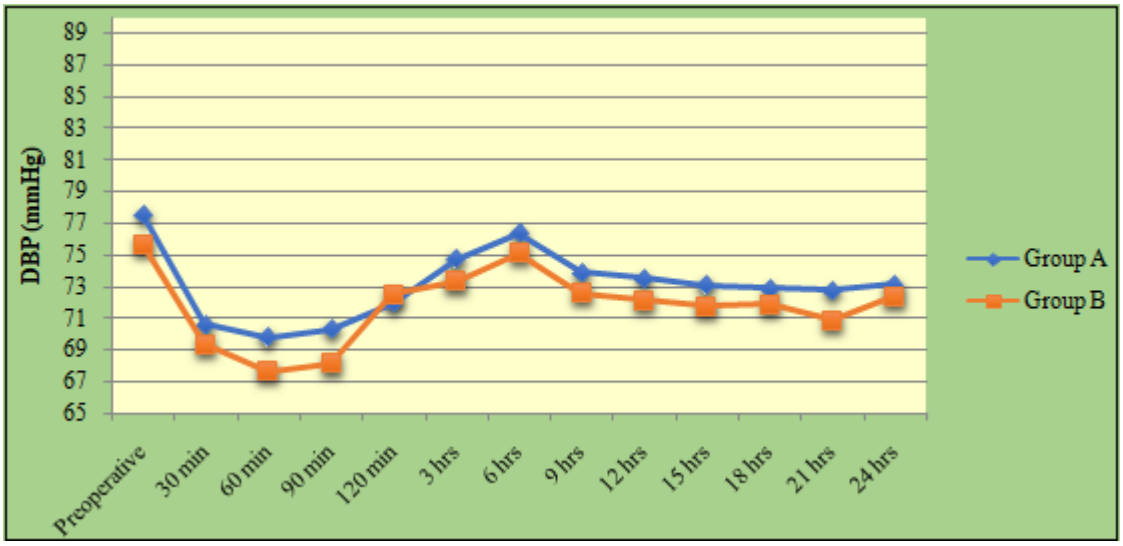


Figure 4: Comparison of SBP (mmHg) in study Groups at different time intervals

In the above study it was observed that there was no statistically significant difference in systolic blood pressure among groups seen at all time intervals during first 24hours.($p>0.05$FIGURE5.**:Comparison of DBP (in mmHg) in study Groups at different time intervals**



In the above study it was observed that there was no statistically significant difference in diastolic blood pressure among groups seen at all time intervals during first 24hours.(p>0.05) as shown in figure 8.

4. Discussion

The mean age in Group A is 32 ± 11 yrs and in Group B 31 ± 8.5 yrs. According to age both the groups are comparable (p=1). (Table No.1).

In the study there were 16 male (53.3%) patients in group A and 14 male (46.6%) group B respectively as compared to 14 females (46.6%) patients in group A and 16 females (53.3%) in group B respectively and was statistically insignificant. (p=0.99)

With respect to body weight both the groups were comparable and were statistically insignificant (p=0.417)

70% of the patients of Gabapentin group were of ASA grade I and 30% were of ASA grade II, and in Granisetron group 66.33% and 33.33% respectively (Table No.1) and did not have any statistical significance (p >0.99).

The mean duration of surgery in group A was 98.8 ± 15.3 mins compared to 96.4 ± 11.14 mins in group B and were statistically insignificant.

In present study, no major haemodynamic changes were observed, heart rate and blood pressure preoperatively, after premedication and postoperatively had no significant difference observed in group A and group B, with p-value > 0.05.(Table No.6, 7, 8).

In our study, (Table no. 1) the overall incidence of postoperative **nausea** (PONV Score 1) in first 24 hrs was 26.6% in patients among group A and 33.3% in patients of group B. This was in accordance in Group A with the studies done by Saeed et al , wherein it was 36.6%, in C k pandey et al , wherein it was 40% and Farhana et al , wherein it was 40%. Whereas Group B was in accordance to the studies done by Heidari et al , wherein it was 36.6%, Anuradha et al[84] wherein it was 30% and Bhattacharjee DP et al[85] wherein it was 26%. The incidence of nausea in our study which was statistically not significant with P value > 0.05 among both groups.

We compared incidence of nausea in relation to different time intervals i.e. at 0-2 hours, 2-8 hours, 8-16 hours and 16-24 hours among both groups and there was no statistical significance difference noted among both the groups. The incidence of nausea at 0-2 hours, 2-8 hours, 8-16 hours and 16-24 hours were 0%, 6.6%, 13.3% and 6.6% in Gabapentin group. (Table no. 9) Which was in accordance to Various studies which support our result.

In our study, (Table no. 1) the overall incidence of postoperative **vomiting** (PONV Score 2) in first 24 hrs was 3.33% in patients among group A and 3.33% in patients of group B. This was in accordance in Group A with the studies done Saeed et al, C K Pandey et al and Farhana et al. Whereas Group B was in accordance to the studies done by Heidari et al. The incidence of nausea in our study which was statistically not significant with P value > 0.05 among Group A and Group B.

The overall incidence of **vomiting more than once** (PONV Score 3) in 24hours was 3.3% in Gabapentin group and was 3.3% in Granisetron group. Though the result were statistically insignificant with (p-value = 1) (Table no.1). In both the group results were similar and various studies also support our results.

There was no significant difference between the two groups regarding the percentage of patients showing complete response (patients who had no nausea and vomiting and no need for rescue antiemetic during 24 hrs observation period) (p-value >0.05) (Table no 1). 73.3% in group A and 66.6% in group B showed complete response to the study drug. This is comparable to other studies.

In our study 1 patient in group A had emesis in the first 24 hours compared to group B wherein it was also 1 patient in first 24hours. The requirement of rescue antiemetic was 3.33% in group A and 3.33% in group B, which was not statistically significant (Table no 1) in present study. In both the groups, results were in accordance to various studies.

There was significant statistical difference between the two groups regarding the postoperative analgesia requirement (per patient in mg required) with (p value = 0.0001). Inj Diclofenac75 mg i/v was given on slight discomfort to the patient. In the study the mean Diclofenac required in Group A was 160 ± 38.05 mg and 197.5 ± 74.95 mg in Granisetron group in first 24hours. The requirement of Inj. Diclofenac is higher in group B and the difference between two groups was statistically significant (p=0.01). This was in accordance with the studies by Uma srivastava et alwherein it was 375.8-83.5 mg in control group and 253.9-44.8 mg in Gabapentin group with p-value <0.05, M. Paul Wilson et al wherein it was 363.3 mg in control group and 270 mg in Gabapentin group with p-value <0.05 and C k pandey et alwherein it was 505.9±82.0 µg Inj Fentanyl in control group and 221.2±92.40 µg Inj Fentanyl in Gabapentin group with (p-value = 0.01). Our results suggest that 300mg gabapentin given preoperatively 1 h before surgery had a definite role in management of pain after laparoscopic abdominal surgeries as it reduced postoperative pain and Inj. Diclofenac consumption.

Both Gabapentin and Granisetron are known to have non-serious adverse effects like short duration headache, constipation, dizziness and prolongation of QTc interval. one patient in groups A complained of headache, and two patients in group B. two patient in group A complained of dizziness whereas 1 patient had dizziness in group B. This result was non-significant statistically (Table No.1). Apart from this no side effects were observed in patients of both the groups in our study.

Modified Ramsay's sedation score was used to assess the postoperative sedation. Throughout the observation period Mean sedation scores were higher in the gabapentin group as compared to that of the granisetron group. Gabapentin group patients showed higher levels of sedation but none of the patients had episodes of desaturation (SpO2 <98%) and no further management was required. Our results were in accordance to study done by Shailendra Deochandra Modak et al. That vital parameters SBP,DBP and pulse rate had no statistical significance in the study.

5. Conclusion

In Our study, results have demonstrated that incidence of PONV is comparable in prophylactic preoperative oral gabapentin 300mg when compared to inj. Granisetron 2mg I.V. for prevention of postoperative nausea and vomiting in patients undergoing laparoscopic abdominal surgeries under general anaesthesia which was statistically insignificant. Both the drugs have statistically non-significant effect on haemodynamics. Sedation is one of the side effect in Gabapentin group which is however statistically non-significant.

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