



A PROSPECTIVE AND RANDOMIZED DOUBLE BLIND STUDY TO COMPARE THE EFFECTIVENESS OF PROPHYLACTIC GRANISETRON VERSUS PETHIDINE FOR THE PREVENTION OF POSTOPERATIVE SHIVERING IN PATIENTS UNDERGOING ELECTIVE THYROID SURGERIES

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ABSTRACT

MATERIALS AND METHODS

90 Patients randomly allocated into three groups- group P, group G, group S in each group 30 patients were Selected Group P Patients were given Inj Pethidine 25 mg intravenously 5 minutes before induction of general anaesthesia. Group G Patients were given Inj Granisetron 40 microgram /Kg intravenously 5 minutes before induction of general anaesthesia. Group S Patients were given Saline intravenously 5 minutes before induction of general anaesthesia.

RESULTS

Postoperative shivering graded after extubation at 15 and 30 minutes interval no shivering in Pethidine group 83.3% {n= 25} Granisetron, group 73% {n=22} Placebo group 27% {n=8} P value not significant between P & G group but significant in Placebo group {P <0.05}. Shivering occurs at grade 3 in pethidine group 7% [n=2] Granisetron group 10% [n=3], Placebo group 60% [n=18] P value statistically not significant between P & G groups but significant in Placebo group {P <0.05}.

CONCLUSION

From this study prophylactic use of both Pethidine and Granisetron were equally effective for the prevention of postoperative shivering

KEYWORDS : Post operative shivering, Pethidine, Granisetron Temperature.

INTRODUCTION

Shivering after anaesthesia is the most frequent problem during the recovery period in both during general and neuroaxial anaesthesia. Incidence of Post operative shivering in general anaesthesia 40 to 60%. Post operative shivering was in 6th position of among 33 low morbidity clinical outcomes. Shivering following general and neuroaxial anaesthesia depends upon the gender, age, room ambient temperature, drugs used and the duration of the procedure. Shivering increase Post operative pain which causes extreme discomfort to the patients. which causes several physiological changes such as increased in sympathetic stimulation, oxygen consumption and carbon dioxide production which results in raised minute ventilation, increased metabolic oxygen demand and stress on the cardiopulmonary system. Cardiac output and also increased. Metabolic acidosis, oxygen saturation and hypoxemia may occur in elderly patients with limited cardiopulmonary reserve. The following drugs are used to treat shivering which are pethidine, tramadol, clonidine and ketamine. Among these pethidine found to be most effective in prevention of Post operative Shivering although its action is not completely understood. But may act through kappa opioid receptors (5) directly on the thermoregulatory centre. The study by Alfonsi et al (11) Al studies suggested the role of serotonergic system in control of postanesthetic shivering. Serotonin (5-HT) is generally present in the brain and spinal cord, which is biological amine in nature. 5-HT₃ receptor antagonist. Asif Iqbal (1) and his colleagues conducted a study comparing the prophylactic use of granisetron 40 microgram/kg body weight and pethidine for prevention of postoperative shivering in patients undergoing general anaesthesia. We designed a study in our hospital for the prevention of postanesthesia shivering following general anaesthesia by prophylactic use of intravenous injection pethidine and Granisetron to compare the effectiveness of these two drugs for the prevention of postoperative shivering.

MATERIALS & METHODS

This study was approved by institutional Ethical committee of Madras Medical College Chennai. The study was A Prospective Randomized Double Blind Study to Compare the Effectiveness of Prophylactic Granisetron versus Pethidine, for the Prevention of Post operative Shivering in Patients undergoing Elective Thyroid Surgeries. Informed consent obtained from patients regarding study.

INCLUSION CRITERIA

- Age : More than 18 years
- Weight: 40-70 Kg
- ASA : 1 and 2
- Surgery : Elective Thyroid Surgeries Who have given a valid informed consent.
- Duration: less than 3 hours Elective Thyroid Surgeries

EXCLUSION CRITERIA:

- Not satisfying the above said inclusion criteria
- Patients with cardiopulmonary diseases
- Psychiatric diseases
- Patients who require blood or blood products

MATERIALS AND METHODS

This study was approved by institutional Ethical committee of Madras Medical College Chennai. The study was A Prospective Randomized Double Blind Study to Compare the Effectiveness of Prophylactic Granisetron versus Pethidine, for the Prevention of postoperative Shivering in Patients undergoing Elective Thyroid Surgeries. Informed consent obtained from regarding study.

MATERIALS REQUIRED:

Nasopharyngeal Temperature probe,
Drugs: Inj pethidine, inj. Granisetron.,
Inj. Glycopyrrolate, Inj. Atracurium Besylate,
Normal Saline, Sevoflurane, and Emergency drugs.

MONITORS:

EKG, SPO₂, NIBP, ETCO₂ and Temperature Probes.

RANDOMIZATION:

90 patients were randomly allocated into three groups – group P, group G, group S in each groups thirty patients were selected **GROUP P** (n=30) patients were given Inj. Pethidine 25 mg intravenously 5 minutes before induction of general anaesthesia.

GROUP G (n=30) patients were given Inj. Granisetron 40 µg/mg intravenously 5 minutes before induction of general anaesthesia.

GROUP S Placebo (n=30) patients were given Normal Saline intravenously 5 minutes before induction of general anaesthesia.

PRIMARY OUTCOME MEASURES:

- Post operative shivering score
- Temperature, (Core and Peripheral)
- Systolic blood pressure,
- Diastolic blood pressure,
- Mean Arterial Pressure,
- Heart rate and
- SPO2

Changes during intra operative and post operative period.

SECONDARY OUTCOME MEASURES:

- Post operative Pethidine requirement,
- Nausea and Vomiting
- Tachycardia / Bradycardia
- Hypotension and Desaturation

METHODOLOGY OF STUDY

The patients satisfying inclusive criteria were explained in detailed manner about the study and procedures and expected side effects after that informed consent obtained from the patients. They were clinically reassessed age, sex, height, and weight were noted. Baseline vitals like pulse, blood pressure were noted blood sugar complete count, blood urea, serum creatinine, bleeding time, clotting time, ECG and chest X-ray were checked.

PROCEDURE:

After the nil per oral confirmed, Monitors ECG, NIBP, Pulse oximetry are connected, Nasopharyngeal Temperature probes, Surface Temperature probes were applied after application of lignocaine gel. Base line parameters were noted. Patients were started with crystalloids after intravenous line secured with appropriate intravenous cannula. Heart rate, Temperature (Core and Peripheral, OT), Noninvasive blood pressure (SBP, DBP, MAP) and SPO2 were noted. Then study drug were given intravenously 5 minutes before Induction of anaesthesia all the patients were monitored intra operatively and after extubation in the recovery room, for 30 minutes patients received oxygen through facemask. The patients were observed for shivering, pain, nausea and vomiting of the study drug. Heart rate, non-invasive blood pressure, oxygen saturation and nasopharyngeal temperature were measured and recorded on admission to the recovery room 15 and 30 minute interval. The shivering was graded and side effects were recorded.

Patient with nausea and vomiting were treated with Metoclopramide 10mg slow IV. Shivering grade 3 or more treated with Pethidine 25mg intravenously.

Grading shivering was done by scale validated by Tsai and Chu

GRADES:

- 0- No shivering,
- 1- Piloerection, no visible shivering,
- 2- Muscular activity in only one group,
- 3- Muscular activity in more than one group but not generalised
- 4- Shivering is generalised involving whole body.

STATISTICAL ANALYSIS

All parameters were analysed using SPSS 20.0 for windows. These data were compared among three groups using one way ANOVA. The incidence of shivering and side effects were compared using Chi-Square test. The data comparison within the groups were analysed using Bonferroni's post-hoc testing. The data was expressed as mean ± standard deviation,

AP value < 0.05 was considered statistically significant.
AP value > 0.05 was considered statistically insignificant.

OBSERVATION AND RESULTS

A Prospective, Randomized Double Blind Study to compare the Effectiveness of Prophylactic Granisetron versus Pethidine, for the Prevention of Postoperative Shivering in Patients undergoing Elective Thyroid Surgeries. The study was conducted in 90 patients.

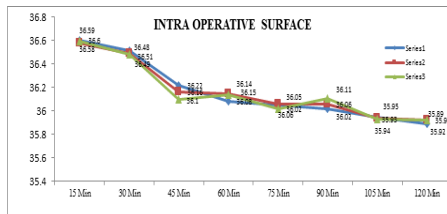
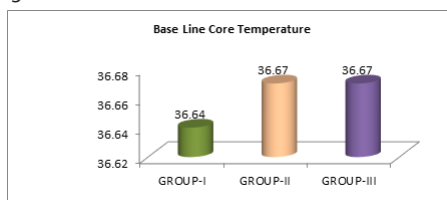
All were female. All the patients completed the study. There was no difference between the three groups with respect to age, sex, height, weight and procedure. The P value was insignificant.

For age (P-0.83), for height (P-0.47), for weight (0.16). these values shown in following tables.

BASE LINE TEMPERATURES

Group	Mean	Standard Deviation
GROUP-I	55.73	5.36
GROUP-II	54.23	3.72
GROUP-III	56.67	5.47
F-Value	1.87	
p-value	0.16- Not Significant	

of core, surface, and OT were recorded. Statically the P- values were insignificant between three groups. These values were shown in the following tables

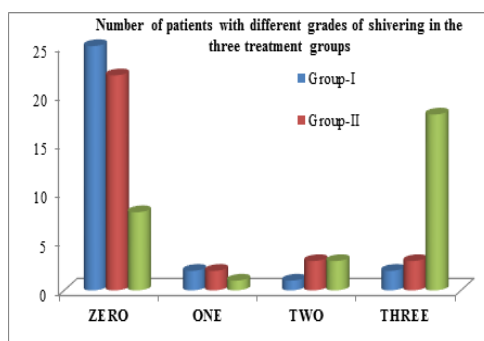


	Group-I	Group-II	Group-III	p-value	Significant
Pre-operative	36.64±0.12	36.67±0.12	36.67±0.11	0.48	NS
Post-operative(30 min)	36.64±0.10	36.64±0.10	36.59±0.11	0.30	NS
Operative Difference	0.00±0.02	0.03±0.02	0.08±0.00	0.53	NS

**** ANOVA Test**

Intraoperative and post operative temperature changes of P-value were not significant for three groups.

Post operative shivering graded after extubation at 15 and 30 minutes interval. No shivering occurs in Pethidine group 83.3% (n=25), Granisetron 73% (n=22), placebo group 27% (n=8) P-value statistically not significant between Granisetron and Pethidine groups but significant (P<0.05) in placebo group. Shivering occurs at grade 3 in Pethidine group 7% (n=2), Granisetron 10% (n=3), placebo group 60% (n=18) P-value statistically not significant between Granisetron and Pethidine groups But significant in placebo group (P<0.05).



TIME	0(%)	1(%)	2(%)	3(%)		Chis- quar e	p- value	Significa nt Significa nt
15	Grou p-I	25(83.33)	2(6.6 7)	1(3.3 3)	2(6.67)	31.48	0.000	Significa nt Significa nt
	Grou p-II	22(73.33)	2(6.6 7)	3(10. 00)	3(10.00)			
	Grou p-III	8(26.67)	1(3.3 3)	3(10. 00)	18(60.00)			
30	Grou p-I	25(83.33)	2(6.6 7)	1(3.3 3)	2(6.67)	31.48	0.000	Significa nt
	Grou p-II	22(73.33)	2(6.6 7)	3(10. 00)	3(10.00)			
	Grou p-III	8(26.67)	1(3.3 3)	3(10. 00)	18(60.00)			

DISCUSSION

The incidence of shivering in general anaesthesia is about 40% to 60%(23) which depends upon the age, sex, drugs used and the duration of the surgery. The shivering can increase metabolic rate 600% above the basal value Postanaesthetic shivering is not only causing discomfort to the patients also increasing postoperative pain, also causes several physiological changes such as increased the tissue oxygen consumption and carbondioxide production and Lactic acidosis, mixed venous oxygen desaturation and hypoxemia. Which increase in minute ventilation, cardiac output and metabolic oxygen demand which results in increased stress on the patients with limited cardiopulmonary reserve and old age. Shivering is one of the low morbidity clinical outcomes among 33 causes was ranked as the sixth most important problem. During general anaesthesia onset of core hypothermia contributed by three factors which includes central thermoregulatory impairment, redistribution of heat from central to periphery, heat loss to the environment. The interthreshold range increased for shivering and vasoconstriction. The cool ambient temperature environment in operation theatre and cold intravenous fluids further decrease the temperature and cause shivering. In our study use of Granisetron 40µgm, and Pethidine 25mg intravenously 5 minutes before induction of anaesthesia in patients undergoing general anaesthesia. Granisetron is 5HT receptor antagonist which used as an antiemetic clinically. Serotonergic pathways play a significant role in the regulation of postoperative shivering. In our study no shivering occurs in Pethidine group 83.3% (n=25), Granisetron 73% (n=22), placebo group 27% (n=8) P-value statistically not significant between Granisetron and Pethidine groups but significant (P<0.05) in placebo group. Shivering occurs at grade 3 in Pethidine group 7% (n=2), Granisetron 10% (n=3), placebo group 60% (n=18) P-value statistically not significant between Granisetron and Pethidine groups but significant in placebo group (P<0.05). similar results were derived by Asif Iqbal et al(1). In Asif Iqbal and his colleagues study 2 patients in Pethidine group, 6 patients in Granisetron group had shivering they found that both drugs are equally effective for the prevention of postoperative shivering. Powell and Buggy studied Ondansetron, a 5-HT3 antagonist and found that an intravenous dose of 8 mg a just prior to the induction of general anaesthesia significantly reduced the incidence of postoperative shivering. This effect is probably due to a central inhibitory mechanism, given that there was no measurable effect on heat redistribution. These observations suggest that the serotonergic pathways play a significant role in the regulation of postoperative shivering. Operation theatre temperature no significant change in preoperative and postoperative in all three groups. Compare to placebo group shivering was significantly reduced in both Granisetron and Pethidine group. Between study drug Granisetron and control group Pethidine equally effective.

SUMMARY

From this Prospective Randomized Double Blind Study we compared the Prophylactic Granisetron 40 µgm per Kg body weight versus Pethidine 25 mg, for the Prevention of Postoperative Shivering in patients undergoing Elective Thyroid Surgeries. During study and statistical analysis the following points were noted. The

demographic profile like age, sex, weight and height were compatible between three groups and statistically not significant. From our study we found that Granisetron and Pethidine were equally effective in preventing postoperative shivering when compared to placebo group.

CONCLUSION

From this study prophylactic use of both Granisetron and Pethidine were equally effective for the prevention of postoperative shivering.

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