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AN OBSERVATIONAL STUDY OF THE EFFECT OF DEXAMETHASONE PROPHYLAXIS ON POST-OPERATIVE NAUSEA AND VOMITING IN PATIENTS FOLLOWING TOTAL ABDOMINAL HYSTERECTOMY UNDER COMBINED SPINAL EPIDURAL BLOCK

DR. SADIA UMMER, DR. S. KAMALUDEEN, AND DR. K. CHERAN
Corresponding author - DR. S. Kamaludeen
Email - dr.kamalrms@gmail.com

Introduction
Postoperative vomiting or retching (POV) can lead to rare but serious medical complications, such as wound dehiscence, bleeding, electrolyte imbalance, dehydration and pulmonary aspiration of gastric contents. Hence the present study was planned to find out the effect of prophylactic dexamethasone for prevention of postoperative nausea and vomiting in patients undergoing total abdominal hysterectomy under combined spinal epidural block. Influences of dexamethasone on patient satisfaction and postoperative analgesia were also observed as secondary objectives.

Methods: 110 female patients who are undergoing total abdominal hysterectomy were included in this observational study. Patients were divided into two groups. 54 patients in group A and 56 patients in group B. Group A received 8mg dexamethasone i.v along with premedication The primary outcome variable was to compare post-operative nausea and vomiting using numerical rating scale (NRS). Secondary outcome variable was visual analogue scale of post-operative pain and overall patient satisfaction.

Results: Age, height, weight, ASA and hemodynamic parameters were compared between the2 groups but were statistically insignificant. The PONV scores were significantly lower in group receiving dexamethasone during 0.5, 6, 12, 24h postoperatively. The VAS score for post-operative pain was also significantly lower in group receiving dexamethasone. Over all patient satisfaction was much better in those receiving dexamethasone as part of premedication, the total analgesic requirement was also significantly lower. There were no complications.

Keywords:-
Post-operative nausea and vomiting, total abdominal hysterectomy, combined spinal epidural block, dexamethasone, premedication, post op analgesia

Introduction
Postoperative nausea and vomiting (PONV) is a common, troublesome and potentially hazardous complication of anaesthesia and surgery. The reported incidence of PONV with regional anaesthesia are lower compared to general anaesthesia, but its deleterious effects to the individual patient is same. Among various associated risk factors, gynaecological surgeries have been identified as an independent risk factor for PONV. All these causes significant

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morbidity, delay in nutrition, increase in the hospital stay, increased health care cost. Following surgical intervention, patients view PONV as a very undesirable outcome, even more unpleasant than pain[1]. Therefore, the prevention and treatment of PONV is an important responsibility of anaesthesia care provider.

Various prophylactic anti-emetics have been used for prevention and control of PONV. In this study we aims to infer the effectiveness of dexamethasone, a glucocorticoid in the prevention of PONV. Glucocorticoids have been used to reduce inflammation and tissue damage in a variety of conditions, including inflammatory bowel disease, rheumatoid arthritis, and some malignancies[2].

Dexamethasone is found to be effective as prophylactic antiemetic with limited side effects during peri-operative period. Further, it has got an additional advantage of reducing postoperative fatigue, pain and total analgesic requirement. This study aims to find out the effect of dexamethasone prophylaxis on post-operative nausea and vomiting in patients following total abdominal hysterectomy under combined spinal-epidural blockade.

The ongoing need to improve understanding, prevention and treatment of PONV is reflected in the literature: approximately 3000 randomized controlled trials of PONV have been published in peer-reviewed journals, and almost 300 new studies are published each year.[14] The present study was designed primarily to evaluate the effects of dexamethasone as a prophylactic antiemetic in patients undergoing total abdominal hysterectomy under combinedspinal epidural block[3]. Influences of dexamethasone prophylaxis on patient satisfaction and post-operative analgesia were also observed and documented as secondary objectives.

Materials and Methods

Study design

The study was conducted at Vinayaka Mission's Medical College and Hospital. Karaikal. An observational study of the effect of dexamethasone prophylaxis in post operative nausea and vomiting in patients following total abdominal hysterectomy under combined spinal epidural block. Ethical committee clearance was obtained and all the patients gave their written informed consent for participation in the study.

Study Population

This study involves patients undergoing total abdominal hysterectomy under combined spinal epidural block.

Inclusion criteria

American Society of Anaesthesiologist Physical Status I&II patients undergoing total abdominal hysterectomy under combined spinal epidural block.

Exclusion criteria

Patients receiving anti emetics and with history of hypersensitivity to steroid will be excluded.

Sample size

110 patients were studied. 54 in group A and 56 in group B.

Group A received 8mg dexamethasone i.v along with premedication The primary outcome variable was to compare post-operative nausea and vomiting using numerical rating scale

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(NRS). Secondary outcome variable was visual analogue scale of post-operative pain and overall patient satisfaction. The data was analysed with SPSS version 20.0

Statistical Analysis

Data were analysed using computer software, Statistical Package for Social Sciences (SPSS) version 16. To elucidate the associations and comparisons between different parameters, chi square test was used as nonparametric test. Student's t test was used to compare mean values between two groups, including general characteristics of the two groups. For all statistical evaluations, a two-tailed probability of value, $P<0.05$ was considered significant.

Results

110 female patients who were undergoing total abdominal hysterectomy under combinedspinal epidural block were observed. Among 110 patients 54 patients who received dexamethasone 8 mg pre-operatively were included in group A and 56 patients who did not receive dexamethasone pre-operatively were included in group B.

PONV was graded using a 11 point numeric rating scale (NRS), for which the patient wasasked to rate the severity of his or her nausea between 0 and 10, with 0 corresponding to no symptoms and 10 corresponding to worst possible symptoms .NRS was calculated at 30 min, 6H, 12H, and 24H. Any episode of PONV more than score 5 was treated with ondansetron 4 mg intravenously as a rescue antiemetic. Postoperative pain is being assessed using 10 cm visual analogue scale (VAS) (0= no pain, 10= worst pain imaginable), at 30 min post op and at 6H ,12H, and 24H. Overall patient satisfaction was also assessed after 24 hours.

General characteristics of the two groups

General characteristics such as age, height and weight were compared between two groups. Mean age (yrs) was 44.7 in group A and 44.9 in group B. This data was analyzed by t- test and was found to yield a p value of 0.859 which is >0.05. This shows that there is no significant difference in the age between two patient groups. Mean height (cm) was
148.59 in group A and 151.68 in group B. This data was analysed by t- test and was foundto yield a p value of 0.186 which is >0.05. This shows that there is no significant differencein the height between two patient groups.

ASA based on groups

The American Society of Anesthesiologists physical status scores (ASA) across the two groups is shown in figure 4.2 and table 2. 48.1% of patients in group A were of ASA classI and 55.4% patients were of ASA class II. In group B 51.9% patients were of ASA class I and 44.6% patients were of class ASA II.

Comparison of Risk of nausea and vomiting based on the groups

In group A 48.1% of patients and in group B 50% of patients had any one or more of risk factors for nausea and vomiting. 51.90% patients in group A and 50% in group B had no risk factors for nausea and vomiting. Chi- square test was done to find the association between risk factors and groups. Chi- square value was 0.38 and with a p value 0.846, which is not statistically significant

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Comparison of heart rate at different interval of time between two groups

Heart rate of the patients were recorded in the pre-operative period, and compared with HR at half hour after the surgery, and 12 hr after the surgery. There was not much difference in mean heart rate (pre-operative heart rate, heart rate at 0.5 hr and heart rate at 12 hr) between two groups. Here p value greater than 0.05 so it was not statistically significant.

Comparison of DBP at different interval of time between two groups

DBP of the patients were recorded pre-operatively and at various time intervals. SBP is shown in table 5.6 and represented in figure 5.6. In group A the mean DBP at pre-op, at 0.5h post op, at 12h post op were 65, 63, and 76 mmHg respectively. In group B it was 66,66 and 75mmHg. There was not much difference in mean DBP (pre-operative DBP, DBP at 0.5 hr and DBP at 12 hr) between two groups. Here p value greater than 0.05 so itwas not statistically significant.

Mean NRS at 0.5h

Group A patients the mean NRS was 1.48 and in Group B patients mean NRS was 2.77 with a p value of < 0.000, which showed that the difference in nausea and vomiting was statistically significant.

Mean NRS at 6h

Group A patients the mean NRS was 2.37 and in Group B patients mean NRS was 4.43 with a p value of < 0.000, which showed that the difference in nausea and vomiting was statistically significant.

Mean NRS at 12h

Group A patients the mean NRS was1.78 and in Group B patients mean NRS was 5.07 with a p value of < 0.000, which showed that the difference in nausea and vomiting was statistically significant.

Mean NRS at 24h

Group A patients the mean NRS was1.52 and in Group B patients mean NRS was 4.04 with a p value of < 0.000, which showed that the difference in nausea and vomiting was statistically significant.

Chi-square test was used as the non-parametric test. The resultant p value for nausea and vomiting at different interval of time between two groups were significant ($p<0.001$). This indicated that dexamethasone is effective in preventing nausea and vomiting with a statistically significant p value.

Association between emetic episodes among the study subjects

Of the total 83 patients who experienced no nausea 63.9% belonged to group A and 36.1% belonged to group B. In the group of patients who experienced nausea once 4.5% belonged to group A and 95.5% belonged to group B. No patient in group A experienced nausea and vomiting, but 5 patients in group B experienced nausea and vomiting. Chi square test wasused as the non-parametric test and the chi square value Chi square value: 29.529 p value: 0.000, it was statistically significant.

Association between Patient satisfaction among the study subjects

Patient satisfaction among the two study groups is depicted. After 24 hrs of surgery, of the 85 patients who expressed satisfaction, 53(62.4%) patients expressed satisfaction in group A as compared to 32(37.6%) in group B (P=0.000).

Table 1 – Basic parameters distribution

Parameters	**Group A (n=54)**		**Group B(n=56)**	
	Mean	**SD**	**Mean**	**SD**
Age(yrs)	44.70	6.483	44.93	6.750
Height(cm)	148.59	12.171	151.68	12.128
Weight (Kgs)	59.85	9.139	60.29	9.141
ASA physical status	**Group A (n=54)**		**Group B (n=56)**	
	No	**%**	**No**	**%**
ASA physical status 1	26	48.1	31	55.4
ASA physical status 2	28	51.9	25	44.6
Risk of nausea and vomiting	**Group A (n=54)**		**Group B (n=56)**	
	No	**%**	**No**	**%**
Risk present	26	48.1	28	50.0
Risk absents	28	51.9	28	50.0
Heart rate	**Group A (n=54)**		**Group B (n=56)**	
	Mean	**SD**		**Mean**
Pre operative Hr	71.96	11.464	70.09	12.583
Hr at 0.5hr	74.70	11.029	74.86	9.660
Hr at 12hr	81.57	7.733	81.54	7.471
Systolic blood pressure	**Group A (n=54)**		**Group B (n=56)**	
	Mean	**SD**	**Mean**	SD
Pre-operative SBP	123.54	9.819	123.88	12.799
SBP at 0.5hrs	110.39	9.908	112.29	9.796
SBP at 12hrs	123.48	10.685	124.59	10.106
Diastolic blood pressure	**Group A (n=54)**		**Group B (n=56)**	

	Mean	SD	Mean	SD
Pre-operative DBP	65.72	10.333	66.34	12.863
DBP at 0.5hrs	63.00	10.544	66.11	11.533
DBP at 12hrs	76.20	8.568	75.84	8.883

Table – 2 – Distribution of clinical parameters

NRS	**Group A (n=54)**		**Group B (n=56)**	
	Mean	**SD**	**Mean**	**SD**
0.5hr	1.48	0.926	2.77	1.027
6hr	2.37	0.808	4.43	1.399
12hr	1.78	0.718	5.07	1.798
24hr	1.52	0.966	4.04	2.199
VAS	**Group A (n=54)**		**Group B (n=56)**	
	Mean	**SD**	**Mean**	**SD**
0.5hr	2.509	0.8270	3.455	1.1090
6hr	2.769	1.0034	3.732	1.1869
12hr	2.259	0.8509	3.777	1.2095
24hr	1.574	0.7673	2.536	0.8886
No of rescue doses given first24 hrs post Operatively	**No**	**%**	**No**	**%**
Zero times	51	94.4	4	7.1
One times	3	5.5	31	55
Two times	0	0	21	37
No of emetic episodes 24 hrs post operatively	**No**	**%**	**No**	**%**
Zero times	53	63.9	30	36.1
One times	1	4.5	21	95.5
Two times	0	0	5	100
Patient satisfaction	**No**	**%**	**No**	**%**
Yes	53	62.4	32	37.6
No	1	4.0	24	96.0

DISCUSSION

The effect of timing of dexamethasone administration on its efficacy as a prophylactic antiemetic for postoperative nausea and vomiting was studied by Wang JJ et al. One hundred twenty women (n = 40 in each of three groups) undergoing abdominal total hysterectomy under general anaesthesia were enrolled in this randomized, double-blinded, placebo-controlled study. Group 1 received dexamethasone before the induction of anaesthesia, Group 2 received dexamethasone at the end of anaesthesia, and Group 3 received placebo (saline)[4,5,6].

The incidence of PONV was evaluated. During the postoperative period of 0-2 h, patients in Group 1 reported a less frequent incidence of PONV (15%) than those in Groups 2 and 3 (45% and 53%, respectively). Patients in Group 1 also requested less rescue antiemetic (8%) than those in Groups 2 and 3 (30% and 35%, respectively). During the postoperative period of 2-24 h, patients in both Groups 1 and 2 reported less frequent incidences of PONV (25% and 28%) and requested fewer rescue antiemetics (13% and 15%) than those in Group 3 (55% and 38%, respectively). They concluded that that dexamethasone, when given immediately before the induction of anaesthesia, was more effective than when given at the end of anaesthesia. These findings were consistent with our results.

The main limitations of the study, is the small population, the relatively short period of follow-up, and only females are included in the study. A longer period (36 hours) of follow up may have shown a significant statistical difference between the groups, as Dexamethasone has a high anti-inflammatory potency, with peak anti-inflammatory effect at 12-24 hours and duration of action of 36-54 hours[5,7]
. The study is limited to patients who are undergoing total abdominal hysterectomy, a larger trial including other surgeries under regional anaesthesia is required to further evaluate the effectiveness of single dose dexamethasone in the prevention of PONV in such patients. Onlya single dose of dexamethasone is studied, also the side effect profile of glucocorticoids is not included in the study.

CONCLUSION

Dexamethasone 8mg i.v given as part of pre-medication to patients who are undergoing total abdominal hysterectomy under combined spinal epidural blockade reduced the incidence of post-operative nausea and vomiting in the 24 h post operative period. It also reduced the need for rescue antiemetic. Dexamethasone significantly reduced the post operative analgesic requirement in a statistically significant manner. Over all patient satisfaction was much better with those who received dexamethasone than not received. All other variables studied were comparable in both groups. None of the patients developed any complications in this study.

Competing Interests
Authors do not have any competing interestConflict of interest
The author declare that they have no conflict of interest.

Informed consent
Informed consent was obtained for all interventions from the participant included in thestudy.

Funding
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Ethical approval
All procedures in the study were in accordance with the ethical standards of the institutional research committee.

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