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Original Research Article

Prophylactic Use of Pre-Operative Dexamethasone for Prevention of Post-Operative Nausea, Vomiting and Pain in Patients of Laparoscopic Cholecystectomy

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ABSTRACT

Context: Laparoscopic cholecystectomy is the gold standard treatment for symptomatic cholelithiasis and there are many factors which can cause nausea, vomiting and pain after laparoscopic cholecystectomy.

Aims: To assess the incidence of postoperative nausea, vomiting and pain as well as efficacy and safety of preoperative dexamethasone in preventing postoperative nausea, vomiting and pain in laparoscopic cholecystectomy.

Settings and Design: Randomized double blind trial.

Methods and Materials: Sixty patients undergoing lap cholecystectomy were randomly allocated into two groups of 30 each to receive either 8mg dexamethasone intravenously 90 minutes preoperatively(group A) or 2ml saline as placebo 90 minutes preoperatively (group B).

Results: Incidence of nausea and vomiting was 23.3% in group A whereas in group B it was 60.0%.Similarly, in group A 3 (10%) patients needed rescue antiemetic in the form of ondansetron while in Group B 10 (33.3%) patients needed it. Incidence of post-operative pain at 1hr, 4hr and 8 hr time intervals, was less in group A as compared to group B. However, at 24hr and 48 hr interval, the statistical analysis shows a p value of >0.05 implying statistically insignificant effect of dexamethasone at these time intervals. However no difference in analgesic requirement was noted amongst the two groups.

Conclusion: Prophylactic intravenous administration of single dose of Inj. dexamethasone 8mg 90 minutes prior to surgery is effective in reducing PONV and antiemetic requirement after laparoscopic cholecystectomy. It is also associated with statistically significant reduction in post-operative pain in the first 12hrs.

Key words: Dexamethasone, Laparoscopic, Cholecystectomy.

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INTRODUCTION

Although laparoscopic cholecystectomy has lot of benefits, still there are some complications like postoperative nausea, vomiting (PONV) and pain. PONV can lead to serious complications such as aspiration, dehydration, electrolyte disturbances and disruption of incision site.[1] Recently, dexamethasone has been reported to be effective in preventing PONV.[2] Also, the analgesic effects of glucocorticoids are provided through inhibition of the phospholipase enzyme and accordingly blockage of both the cyclooxygenase and the lipoxygenase pathway in the inflammatory chain reaction.[3] So the present study was undertaken to evaluate the efficacy of dexamethasone in preventing PONV and decreasing the incidence of postoperative pain in lapraroscopic cholecystectomy patients.

MATERIALS AND METHODS

After approval from the hospital ethical committee, a randomized double blind study was conducted on 60 cases of age group 20-65 years undergoing elective cholecystectomy. Patients having acute cholecystitis, already taking drugs with analgesics and antiemetic effects pre-operatively, suffering from motion sickness, with gastrointestinal dysfunction, with previous allergic reaction to any drug pregnant patients were excluded from the study. Also patients in which laparoscopic cholecystectomy was converted to open cholecystectomy and in which surgery lasted for >3 hours were excluded from the study. After obtaining a written informed consent from the patients, they were randomly divided by computer generated numbers into 2 groups of 30 each. Group A

received injection dexamethasone 8mg intravenous 90 minutes pre-operatively whereas group B patients was given placebo as intravenous 2ml normal saline 90 minutes pre-operatively. All operations were performed with a four port technique under general anaesthesia. After surgery the incidence and severity of nausea and vomiting experienced by each patient was recorded based on a 3-point whole number linear scale by the resident double blinded to the study in each of the following assessment periods i.e. 1 hr, 4 hrs, 8 hrs, 24 hrs and 48 hrs after the recovery from anaesthesia. The following scale was used for nausea and vomiting according to method adopted from Uppington et al.[4]

- 0: No nausea or vomiting
- 1: Mild nausea (feeling nauseated but not severe enough to want an antiemetic.
- 2: Severe nausea (wanting an antiemetic)
- 3: Vomiting

The highest score recorded during each assessment period was recorded. Vomiting was recorded as either present or absent. If the patient vomited, the time to the first episode was noted. Retching was not considered as separate entity and both vomiting and retching was considered as emetic events. Rescue antiemetic was allowed if the patient had severe nausea or emetic episode with the injection ondansetron 4 mg.

Pain was registered postoperatively at 1hr, 4 hr, 8hrs, 24hrs and 48 hrs, using a VAS, which range from:

- 1: Absence of pain
- 2: Tolerable pain with moments when patient does not remember it or with low intensity. In both cases, there is no need for medication
- 3: Pain with moments when the patient does not remember it, but there is a need for analgesic drugs.
- 4: Unforgettable pain, need for analgesic drugs control symptoms.
- 5: Persistent pain, even with use of analgesic drugs; there is no significant improvement.[5]

Diclofenac sodium 75mg was used as rescue analgesic if the condition of patient warranted. Post-operative assessment regarding pulse, blood pressure, consumption of analgesics and antiemetics were noted. All the post-operative findings were recorded by a resident doctor who didn't know about the group allocation. The groups and the findings were compared at the end of study and results evaluated.

Table 1: Demographic Variables

		Group A	Group B	p value
AGE		43.53 ± 12.50	43.10 ± 7.64	0.87
SEX	**Males**	3	2	0.64
	Females	27	28	

Table 2: Incidence of Nausea and Vomiting in Both Groups

N&V	**Group**		**p value**
	A (1+2+3)	**B (1+2+3)**	
Present	7 (23.3%)	18 (60.0%)	0.004*
Absent	23 (76.7%)	12 (40.0%)	

Table 3: Use of Rescue Anti-Emetic in Both Groups

GROUP	**Yes = 1**	**Percent (%)**	**P value**
A	3	10.0%	0.029*
B	10	33.3%	

RESULTS

Descriptive statistics were done for all data and were reported in terms of mean values and percentages. Continuous variables were analysed with the unpaired t test. Categorical variables were analysed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as $P < 0.05$. The data was analysed using SPSS version 16 and Microsoft Excel 2007.

Demographic characteristics of the patients were similar in the two groups (Table 1). None of the laparoscopic cholecystectomies performed in both groups were converted to open cholecystectomy. Therefore the conversion rate was 0% in both the groups. Both groups were comparable with respect to operating time. In Group A mean operating time was 38.40±5.28 minutes, while in Group B mean operating time was 39.07±5.50 minutes. Hemodynamic variables were comparable in both the groups. Incidence of PONV was decreased in group A with only 7 (23.3%) patients of group A had PONV (Post-Operative Nausea and Vomiting) while in Group B 18 (60.0%) patients had PONV(Table 2).

Also need for antiemetics was reduced in group A with only 3 patients needed rescue antiemetics in group A while in group B 10 patients needed it.(Table 3) Incidence of pain was also decreased in group A. Statistical analysis showed a p value of <0.05 at 1hr, 4hr and 8 hr time intervals, which implies that the results are statistically significant at these intervals.(Table 4) However, at 24hr and 48 hr interval, the statistical analysis shows a p value of >0.05 implying statistically insignificant effect of dexamethasone at these time intervals. But the need for rescue analgesic was comparable in both the groups.(Table 5)

Table 4: Showing Comparison of Incidence of Pain Amongst Patients of Two Groups; Post-Operatively At Various Time Intervals

Time Interval	Group	Pain					P value#
		No Pain (1)	Tolerable pain (2)	Pain needing analgesic (3)	Unfor. Pain (4)	Persistent pain (5)	
		No. (%age)	No. (%age)	No. (%age)	No. (%age)	No. (%age)	
1 hr	Group A	19 (63.3%)	8 (26.7%)	3 (10%)	0	0	0.030*
	Group B	11 (36.7%)	12 (40%)	4 (13.3%)	3 (10%)	0	
4 hr	Group A	24 (80.0%)	5 (16.7%)	1 (3.3%)	0	0	0.007*
	Group B	14 (46.7%)	12 (40.0%)	3 (10.0%)	1 (3.3%)	0	
8 hr	Group A	26 (86.7%)	4 (63.3%)	0	0	0	0.033*
	Group B	19 (63.3%)	9 (30.0%)	1 (3.3%)	1 (3.3%)	0	
24 hr	Group A	28 (93.3%)	2 (6.7%)	0	0	0	0.126
	Group B	24 (80.0%)	5 (16.7%)	1 (3.3%)	0	0	
48 hr	Group A	30 (100%)	0	0	0	0	0.078
	Group B	27 (90.0)	3 (10.0%)	0	0	0	

Table 5: Use of Rescue Analgesic in Both Groups

	Yes = 1	Percent (%)	p Value
A	4	13.3%	0.253*
B	7	23.3%	

DISCUSSION

Combined incidence of post-operative nausea and vomiting in patients of laparoscopic cholecystectomy in both groups showed that 7 (23.3%) patients had PONV (Post-Operative Nausea and Vomiting) in study group (Group A) as compared to 18 (60.0%) in Group B. On statistical analysis result was significant with a *P* value of 0.04.similar results were obtained by various authors. Bhutta et al[1] reported the incidence of PONV of 21% in dexamethasone (study) group as compared to 51% in control group. Wang et al[6] reported incidence of 23% PONV in study group as compared to 63% in control group. Feo et al[7] in their study reported PONV in 14% patients of study group while 46% in control group.

Rescue antiemetic requirement was decreased in study group as compared to control group. In a study conducted by Feo et al[7] the rescue antiemetic requirement was 10% in dexamethasone group and 44% in control group patients. Bhutta et al[1] reported use of rescue antiemetic in 17% patients of study group as compared to 50% in control group. So the present study was in concordance with other studies.

The mechanism by which glucocorticoids alleviate nausea and vomiting is not fully understood, but the effects are probably centrally mediated via inhibition of prostaglandin synthesis or inhibition of the release of endogenous opioids. Others have suggested that the usefulness of dexamethasone in the control of chemotherapy-related emesis may be caused by the release of endorphins, resulting in mood elevation, a sense of well-being, and appetite stimulation.[8]

Pain is still considered as one of the most common complaint after LC and the reason of prolonged hospitalization, increased morbidity, and delayed functional recovery.[9] Thus effective analgesia is mandatory. Acute inflammation induced by tissue damage has a major role in development of post-operative pain. Therefore, dexamethasone should be useful in lowering pain, due to its potential anti- inflammatory effect. Various studies have been cited in literature, which report the use of prophylactic dexamethasone to reduce post-operative pain in patients of laparoscopic cholecystectomy. In the present study, pain was measured on a VAS at 1hr, 4hr, 8hr, 24hr and 48 hr intervals post-operatively in both the groups and compared. Statistical analysis of the results was done. The results of present study revealed a p value of <0.05 at 1hr, 4hr and 8 hr time intervals, which implies that the effect of dexamethasone on post-operative pain is statistically significant at these intervals. However, at 24hr and 48

hr interval, the statistical analysis showed a p value of >0.05 implying insignificant effect of dexamethasone at these time intervals. Our results are in accordance to Mohtadi et al.[10] They conducted a study on LC patients using dexamethasone 8mg as prophylaxis for post-operative pain and reported that that intravenous single-dose of dexamethasone can reduce post-operative pain at first 12 hours in comparison with placebo. However at and after 24hrs, the difference between two groups was insignificant. Similar results were obtained by Lim et al[11] and Fukami et al[12] who also found that 8 mg of intravenous dexamethasone has significantly reduced post-operative pain and fatigue after laparoscopic cholecystectomy. However our results are in contrast to Feo et al[7], Miranda et al[13] and Elhakim et al.[14] They reported no difference in post-operative pain in dexamethasone group and control group. Also, a meta-analysis conducted by Waldron et al[15] stated that the outcome measures regarding analgesic effect of dexamethasone were not uniform across studies.

This difference in rescue analgesic requirement is not significant with a p value of 0.253. Feo et al[7] stated in their study that no difference in analgesic requirement was noted among two groups. Wang et al[6] also reported no significant reduction in the use of rescue analgesic (morphine) in their study. Waldron et al[15] conducted a meta-analysis and stated that reduction in pooled opioid consumption with dexamethasone were modest and possibly not clinically relevant. Thus the results of present study are in accordance with results of other similar studies.

No significant adverse effects were reported in the study group, notably variations in the haemodynamic parameters such as pulse rate, systolic and diastolic blood pressure, delayed wound healing and wound infection. Bhutta et al[1], Henzi et al[11] and Waldrom et al[15] in their study showed that single dose of dexamethasone to prevent PONV and post-operative pain is not associated with any apparent adverse effects.

CONCLUSION

Prophylactic intravenous administration of single dose of Inj. dexamethasone 8mg 90 minutes prior to surgery is effective in reducing PONV and antiemetic requirement after laparoscopic cholecystectomy. It is associated with statistically significant reduction in post-operative pain in the first 12hrs. It is freely available, economical and the single dose is not associated with any significant side effects.

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