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ORIGINAL ARTICLE

Efficacy of dexamethasone in prevention of postoperative nausea and vomiting in laparoscopic cholecystectomy.

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ABSTRACT... Objective: To evaluate the efficacy of intravenous dexamethasone in comparison with control group for the prevention of po3stoperative nausea and vomiting in patients undergoing laparoscopic cholecystectomy. **Study Design:** Randomized controlled study. **Setting:** Department of Surgery, Dr. Akbar Niazi Teaching Hospital, Islamabad, Pakistan. **Period:** 1st November 2022 to 31st April 2023. **Material & Methods:** A total of 120 patients of prospective laparoscopic cholecystectomy from both genders in ages between 18-60 years were randomized into two equal groups A and B. Group A subjects were administered with 4 mg IV dexamethasone preoperatively while group B patients were control subjects. The primary outcome was set as the reduced PONV after surgery. It was assessed through VAS scores and recorded at different time intervals. The final outcome was measured at 24th hour. Rescue antiemetic was administered whenever VAS score became > 5. **Results:** At 24 hours after surgery, VAS score was 0.57 ± 1.42 SD in group A and in group B it was 1.67 ± 2.10 SD (p=0.001). Efficacy of treatment (no PONV up to 24 hours) was present in 81.7% patients in group A (dexamethasone) and in 56.7% of patients in group B (control). The difference was statistically significant (P=0.003). **Conclusion:** Preoperative intravenous administration of dexamethasone was found effective in controlling PONV in patients undergoing laparoscopic cholecystectomy. Moreover, prophylactic dexamethasone administration also resulted in lesser consumption of rescue antiemetics when compared with controlled group.

Key words: Dexamethasone, Laparoscopic Cholecystectomy, Postoperative Nausea and Vomiting, Randomized Controlled Trial.

INTRODUCTION

Nausea is a condition of discomfort, which usually occurs without vomiting[1] where as vomiting is an involuntary expulsion of gastrointestinal content from the mouth.[2] Postoperative nausea and vomiting (PONV) remains a common complication for patients undergoing laparoscopic cholecystectomy (LC).[3] Laparoscopic cholecystectomy is the most preferred form of surgery for the removal of gall bladder.[4]

Patients with PONV may experience gastric content aspiration, a raised intraocular pressure, delays in recovery and discharge time along with significant psychological distress and an increase in cost of care.[5] Control of PONV is an essential criterion for discharge of patients from the Post-anesthesia-care-unit (PACU).[6] Without prophylaxis, PONV occurs in about 30-50% of adults and children after anesthesia. For an individual patient, the risk of PONV varies. It may be up to 70-80% in high risk individuals like females, patients with history of prior PONV or motion sickness, negative smoking history and in those receiving opioids before or during the surgery.[7]

A meta-analysis conducted in 2019, provides strong evidence of dexamethasone and few other drugs being the prophylactic antiemetics preventing PONV in patients undergoing LC.[8] In a randomized trial study, administration of 8mg of dexamethasone was reported to lower

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the PONV severity in patients undergoing non-acute surgery.[9] In another study, intraperitoneal dexamethasone administration reduced post-LC severity of nausea and pain, but not PONV.[10]

PONV remains a huge problem in patients undergoing LC. It makes them uneasy and makes them go through discomfort after the surgery. To overcome this problem, this study has been designed to evaluate the efficacy of dexamethasone in our local population undergoing LC.

MATERIAL & METHODS

This randomized controlled study was conducted at the department of surgery, Dr. Akbar Niazi Teaching Hospital, Islamabad, Pakistan. The duration of study was six months from 1st November 2022 to 31st April 2023. The study proceeded after the approval from the ethical review committee (letter number 66/IMDC/IRB-2022) and written consent from all patients.

A sample of 120 patients was collected as per WHO sample size calculator (2.2b) using non-probability consecutive sampling technique. Inclusion criteria involved patients undergoing elective laparoscopic cholecystectomy from both genders in ages between 18-60 years. They were randomized into two equal groups A and B. In group A, there were 20.0% males and 80.0% females and in group B there were 25.0% males and 75.0% females. In group A, 76.7% of subjects were categorized as ASA grade I and 23.3% as ASA grade II. Whereas in group B, there were 78.3% of patients with ASA grade I and 21.7% with ASA grade II. VAS score was estimated in the form of mean ± SD.

Exclusion criteria included those patients with established gastrointestinal disease, intraoperative hypotension (mean blood pressure less than 60) or excessive blood loss (more than 500ml), cholecystectomy lasting for more than 2 hours, patients taking antiemetic drugs, and patients with known diabetes mellitus.

The primary outcome was set as the reduced PONV after surgery. It was assessed through VAS scores and recorded at different time intervals. The final outcome was measured at 24th hour. Rescue antiemetic was administered whenever VAS score became > 5.

Statistical Package for the Social Sciences (SPSS) version 20 was used to analyze and describe the gathered data. All the continuous variables like age, BMI, VAS score were noted at different time intervals and number of rescue antiemetic injections used in 24 hours were presented as mean ± standard deviation data. For the categorical variable like gender, ASA grades and efficacy, frequency and percentage was calculated. Efficacy was compared in both groups by using chi square test in both groups. A P-value less than equal to 0.05 was considered statistically significant. Confounding variables like age, gender, ASA grades and BMI were further stratified. Chi-square test was used post stratification and a P-value less than equal to 0.05 was considered significant.

RESULTS

In group A, there were 20.0% (n=12/60) males and 80.0% (n=48/60) females. Mean age was 43.9 years ± 12.1 SD and BMI was 29.4 Kg/m^2 ± 2.9 SD. There were 36.7% (n=22/60) and 63.3% (n=38/60) subjects who were aged between 18-40 years and 41-60 years, respectively.

There were 63.3% (n=38/60) of subjects having BMI ≤ 30 Kg/m^2 and 36.7% (n=22/60) belonged to BMI group > 30 Kg/m^2, there were 76.7% (n=46/60) of subjects were categorized as ASA grade I and 23.3% (n=14/60) categorized as ASA grade II. In group B there were 25.0% (n=15/60) males and 75.0% (n=45/60) females.2 Kg/m^2 ± 3.5 SD, there were 28.3% (n=17/60) of subjects who had age between 18-40 years and 71.7% (n=43/60) had age between 41-60 years, 58.3% (n=35/60) of patients belonged to BMI group ≤ 30 Kg/m^2 and 41.7% (n=25/60) belonged to BMI group > 30 Kg/m^2 (table 1), 78.3% (n=47/60) of patients with ASA grade I and 21.7% (n=13/60) with ASA grade II in group B (Table-I).

VAS score was estimated in the form of mean ± SD at different time intervals of both groups

(Table-I).

Efficacy of treatment (no PONV up to 24 hours) was present in 81.7% (n=49/60) patients in group A (dexamethasone) and it was present in 56.7% (n=34/60) of patients in group B (control). The difference was statistically significant (P=0.003, Table-II)

Efficacy data was stratified with respect to gender and age (Table-III), ASA grades and BMI (Table-IV). Similar trends were noted across all groups and efficacy was found better in patients who received IV dexamethasone preoperatively when compared with the control group (P<0.05 in all cases).

Variables	Groups	Mean	Std. Deviation	P-Value t-test
VAS 1hr	Dexamethasone	0.65	1.42	0.001
	control	1.95	2.51	
VAS 6hrs	Dexamethasone	0.60	1.49	0.001
	control	1.67	2.10	
VAS 12hrs	Dexamethasone	0.63	1.58	0.002
	control	1.58	1.92	
VAS 18hrs	Dexamethasone	0.53	1.31	0.001
	control	1.70	2.13	
VAS 24hrs	Dexamethasone	0.57	1.24	0.001
	control	1.67	2.10	
Rescue injections	Dexamethasone	0.10	0.25	0.005
	control	0.40	0.87	

Table-I. Mean VAS at different time intervals

Efficacy	Group		Total	P-Value Chi-Square
	Dexamethasone	Control		
Present	49	34	83	0.003
	81.7%	56.7%	69.2%	
Absent	11	26	37	
	18.3%	43.3%	30.8%	
Total	60	60	120	
	100.0%	100.0%	100.0%	

Table-II. Efficacy of treatment in both groups

Variable		Efficacy	Group		Total	P-Value
			Dexamethasone	Control		
Gender	Males	Present	9 (75.0%)	10 (66.7%)	19 (70.4%	0.046
		Present	3 (25.0%)	5 (33.3%)	8 (29.6%)	
	Females	Present	40 (83.3%)	24 (53.3%)	64 (68.8%	0.002
		Present	8 (16.7%)	21 (46.7%)	29 (31.2%)	
Age groups	18-40 Years	Present	17 (77.3%)	8 (47.1%)	25 (64.1%)	0.041
		Present	5 (22.7%)	9 (52.9%)	14 (35.9%)	
	41-60 Years	Present	32 (84.2%)	26 (60.5%)	58 (71.6%)	0.018
		Absent	6 (15.8%)	17 (39.5%)	23 (28.4%)	

Table-III. Efficacy of treatment in both groups (stratification w.r.t gender and age)

Variable		Efficacy	Group		Total	P-Value Chi-Square
			Dexamethasone	Control		
ASA Grades	Grades	Present	39 (84.8%)	30 (63.8%)	69 (74.2%)	0.021
		Absent	7 (15.2%)	17 (36.2%)	24 (25.8%)	
	Grades	Present	10 (71.4%)	4 (30.8%)	14 (51.9%)	0.035
		Absent	4 (28.6%)	9 (69.2%)	13 (48.1%)	
BMI Groups	≤30 Kg/m^2	Present	29 (76.3%)	21 (60.0%)	50 (68.5%)	0.034
		Absent	9 (23.7%)	14 (40.0%)	23 (31.5%)	
	>30 Kg/m^2	Present	20 (90.9%)	13 (52.0%)	33 (70.2%)	0.004
		Absent	2 (9.1%)	12 (48.0%)	14 (29.8%)	

Table-IV. Efficacy of treatment in both groups (stratification w.r.t ASA grades and BMI)

DISCUSSION

Postoperative nausea and vomiting (PONV) remains a common complication after surgery, particularly after abdominal surgeries.[11] PONV have also been observed as one of the several postoperative factors which were associated with a longer duration of hospital stay after laparoscopic cholecystectomy (LC).[12] Several strategies, both prophylactic and treatment, are available for PONV. The present study was designed to evaluate the efficacy of intravenous steroids in our local population undergoing LC. Our results showed that efficacy of treatment (no PONV up to 24 hours) was present in 81.7% patients in group A (dexamethasone) and it was present in 56.7% of patients in group B (control). The difference was statistically significant (P=0.003).

In another study, Azeem et al evaluated the effectiveness of preoperative dexamethasone in controlling PONV among LC patients. A dose of 8mg dexamethasone resulted in a significantly lower incidence of PONV when compared with placebo.[12] Wakasugi et al assessed the efficacy of dexamethasone in Japanese population. They reported 22% PONV in the dexamethasone group, compared to 18.3% incidence in our study.[13]

In a meta-analysis lower dose (4-5mg) of dexamethasone administration compared with control in the preoperative period resulted in a significant reduction in the incidence of PONV when compared with placebo. Moreover, no additional clinical benefit on the incidence of PONV was observed with higher doses (8-10mg).[14] These findings are quite similar to our study as we have used 4mg dose of dexamethasone. We, however, in the present study did not use combination therapy and higher doses of dexamethasone. Similarly, a large multicenter trial among forty five hospitals in UK reported that administration of dexamethasone prior to the surgery resulted in significantly lower incidence of PONV (P = 0.003).[15] In another study Wakamiya et al reported administration of IV dexamethasone resulted in significant reduction in the incidence of PONV when compared with placebo at 72-h after the surgery (P = 0.02).[16] In a similar study, Ismail et al also reported reduced PONV incidence upon use of dexamethasone.[17]

Yang Q et al in a pooled analysis of randomized controlled trials in patients undergoing primary total hip arthroplasty demonstrated the efficacy of preoperative dexamethasone against PONV.[18]

Several studies among local population demonstrated the efficacy of dexamethasone in preventing PONV. Laiq et al reported PONV to be 26% in women undergoing laparoscopic surgeries in comparison with 54% of controlled group ($P < 0.01$).[19] Ahsan et al in a study reported that combination of dexamethasone plus ondansetron resulted in 28% incidence of PONV, compared to 12% in patients receiving ondansetron alone ($p < 0.046$).[20] Their results in the dexamethasone groups are similar to the present study results. We, however, did not use ondansetron in our study.

In summary, current study results and numerous other studies present in the literature demonstrated that preoperative intravenous administration of dexamethasone is an effective therapy for preventing PONV in patients underwent laparoscopic cholecystectomy and other surgeries. Future areas for research are to determine the optimal dose of dexamethasone, comparison of dexamethasone alone with dexamethasone plus other antiemetic agents and comparison of intravenous versus intraperitoneal administration of dexamethasone.

Limitations of our study is that it was restricted to single center design, the findings may not be the representative of larger population of the patients. The potential benefits of combining other antiemetic interventions with dexamethasone for managing PONV was not studied in this trial. Moreover, the long term adverse effects of dexamethasone might not have been thoroughly evaluated in patients undergoing LC. In addition, more sample size can be another limiting factor.

CONCLUSION

In the present study, preoperative intravenous administration of dexamethasone was found to be effective in controlling postoperative nausea

and vomiting in patients undergoing laparoscopic cholecystectomy. The incidence of PONV was significantly less than observed in the control group. Moreover, prophylactic dexamethasone administration also resulted in lesser consumption of rescue antiemetics when compared with the controlled group.

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