JOURNAL OF CLINICAL AND HEALTH SCIENCES

ORIGINAL ARTICLE

Efficacy of Prophylactic Dexamethasone on Postoperative Nausea and Vomiting in Laparoscopic Appendicectomy: A Randomized Controlled Trial

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Received
4th February 2024
Received in revised form
10th May 2024
Accepted
17th June 2024
Published
1st March 2025

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ABSTRACT

Introduction: Dexamethasone has been established as an effective prophylactic antiemetic in various studies done in elective surgery. However, its efficacy in emergency surgery specifically, laparoscopic appendicectomy is not well documented. This study was conducted to compare the efficacy of prophylactic intravenous (IV) dexamethasone 8mg in preventing postoperative nausea and vomiting (PONV) in this surgical population. **Methods:** A total of 84 participants were recruited for the study in Hospital Universiti Sains Malaysia and were randomly assigned in equal numbers to treatment group with prophylactic IV dexamethasone 8mg or placebo. The outcomes of both groups were taken at three-time intervals; first hour, 12th hour and 24th hour postoperatively which were proportion of PONV, PONV scores, pain scores and the need for rescue antiemetic. **Results:** The group receiving dexamethasone had significantly lower proportion of PONV compared to control group in the first hour postoperatively (dexamethasone vs Control; 16.7% vs 42.9%, P = 0.009) and at 24th hour postoperatively (0% vs 14.3%, P = 0.011). The dexamethasone group also required less rescue antiemetic at the first hour (14.3% vs 35.7%, P = 0.023) and 12th hour postoperatively (0% vs 11.9%, P = 0.021). No significant differences in pain scores or PONV scores were found in both groups. **Conclusion:** Prophylactic dexamethasone reduced postoperative nausea and vomiting (PONV) incidence in the first hour and 24 hours post-surgery, decreased the need for rescue antiemetics in the first hour and 12th hour, but did not significantly affect analgesia or PONV severity between groups.

KEYWORDS: postoperative nausea and vomiting, laparoscopic appendicectomy, antiemetic, pain scores, prophylactic dexamethasone

INTRODUCTION

Postoperative nausea and vomiting (PONV) is a debilitating side effect which increases medical burden worldwide. However, it may not be cost-effective to treat every patient with antiemetic prior to surgery. Thus, various scoring systems are available to stratify individuals at risk of PONV, notably the Simplified Apfel score [1], with four components, scoring one point for each; female, non-smoker, history of PONV or motion sickness, and the use of postoperative opioids. Some experts recommend that those at low risk (score of 0 to 1) may not require antiemetics at the expense of developing unwarranted side effects. Whereas, those with moderate or high risk (score of 2 or more) of developing PONV should be prophylactically treated with one or more interventions [2, 3].

However, most risk scores that stratify the risk of PONV do not include the type of surgery. Most studies on PONV tend to be conducted in elective surgeries such as gynaecological surgeries [4, 5] laparoscopic cholecystectomy [6-8] which are deemed high risk of developing PONV. Studies conducted on emergency surgery like laparoscopic appendicectomy is uncommon, but Kleif et al [9] conducted this study using prophylactic dexamethasone in preventing PONV in this population. It was reported that the incidence of PONV is as high as 63% in laparoscopic appendicectomy if untreated [9].

Vol 10(1) (2025) 49-57 | jchs-medicine.uitm.edu.my | eISSN 0127-984X
https://doi.org/10.24191/jchs.v10i1.5427

Most studies on the topic of prophylactic antiemetic have largely been confined to elective surgeries. There are only a handful of studies documenting the effects of antiemetic on PONV in emergency surgeries notably laparoscopic appendicectomy [5, 6]. A study by Kleif et al [5] studied the efficacy of intravenous (IV) dexamethasone 8mg vs placebo in this surgical population but found no significant difference in the proportion of PONV between these two groups. However, the non-significance inferred from the study could be due to confounding factor whereby both groups received prophylactic ondansetron prior to surgery. In another study by Lee et al [6] in the same surgical population (laparoscopic appendicectomy), one group was treated with IV esmolol infusion at a rate of 5-10μg/kg/min intraoperatively and an IV bolus of 1mg/kg prior to extubation vs placebo (normal saline). The study concluded that esmolol administration had significantly less PONV compared to the placebo group.

In addition to that, appendicectomy is the commonest performed emergency abdominal operation [7]. The reported incidence of PONV in this particular surgical operation has been reported to be 56% [6] and 63% [5] in untreated patients. In view of the high frequency of PONV and performed procedure, it may be prudent to treat this population who are at high risk of developing PONV. However, scarce evidence exist concerning the efficacy of prophylactic antiemetics in this surgical population. Appendicectomy is the most commonly performed emergency abdominal operation. The reported lifetime risk of appendicectomy is 12.0% and 23.1% in males and females respectively [10].

Dexamethasone is an established antiemetic [1] and mostly recommended by consensus for the treatment of PONV. However, the arrival to this conclusion was mostly driven by many studies conducted in elective surgeries. With regards to the efficacy of dexamethasone as an antiemetic treatment, Apfel et al reported that it contributed to a 26% relative risk reduction in PONV [11]. A quantitative systematic review by Henzi et al favoured the use of dexamethasone in preventing PONV compared to placebo. The number needed to treat for its anti-nausea effect was 4.3 in adult patients [12]. Only one study so far, Kleif et al [5] focused on the effect of prophylactic dexamethasone on PONV in this selected surgical group and found that it did not affect the incidence of PONV significantly. However, delving into the details in the methods of the study found incongruence in the administration of prophylactic antiemetic in some patients. Thus, the result may inadvertently be affected. Thus, we would like to investigate if in fact, dexamethasone could potentially be a useful tool in preventing PONV in this surgical group.

MATERIALS AND METHODS

This double-blinded, randomised controlled trial was conducted in the operation theatre of Universiti Sains Malaysia, Kelantan from 31 October 2018 to 30 September 2019 after obtaining approval by the Human Research Ethics Committee of Universiti Sains Malaysia (JEPeM Code: USM/JEPeM/18060288). The study was conducted after obtaining written consent from the selected patients. A total of 84 American Society of Anaesthesiologists (ASA) physical status I-II patients, aged of 18 to 65 years, scheduled for laparoscopic appendicectomy for suspected acute appendicitis were included in the study. Patients with suspected perforated appendicitis clinically with evidence of rebound tenderness suggestive of peritonism, patients in sepsis (a score of ≥2 for Sequential Organ Failure Assessment Score [SOFA score]), patients with history of PONV or motion sickness, immunocompromised patients : patients with Human Immunodeficiency Virus (HIV) infection , Acquired Immunodeficiency syndrome (AIDS), and on immunosuppressant drugs, on long-term steroid therapy, patients with diabetes mellitus on insulin therapy were excluded from this study.

The patients were randomized into two groups, the Group C (Placebo) and Group D (Dexamethasone group), using computer-generated randomization. There will be two sets of 42 unique numbers per set, ranging from 1 to 84, sorted from the least to greatest. Once the patient has been recruited, the researcher will draw out 2ml (8mg) of dexamethasone or 2ml of normal saline (placebo) in a 3ml clear syringe closed with a stopper. Both drugs are clear, colourless, of equal volume of 2ml and appear identical. The syringe is then placed in blank envelope. This will be handed over to the doctor who is independent of the research and

Vol 10(1) (2025) 49-57 | jchs-medicine.uitm.edu.my | eISSN 0127-984X
https://doi.org/10.24191/jchs.v10i1.5427

unaware of the group the patient is in. The administration of the drug will be after the induction of general anaesthesia.

In the OT, an 18G or 20G intravenous (IV) cannula was inserted and standard monitoring in anaesthesia including non-invasive blood pressure (NIBP), SpO2, electrocardiogram (ECG) and end-tidal carbon dioxide $ETCO_2$ were put in place. General anaesthesia (GA) was performed in a standard procedure for the patients with IV fentanyl 2µg/kg, IV propofol 2mg/kg and IV suxamethonium 1mg/kg. Both groups will receive IV metoclopramide 10mg. Following induction, Group C will receive the placebo (2ml of normal saline) IV whereas group D will receive IV dexamethasone 8mg. Anaesthesia was then maintained with sevoflurane with targeted minimum alveolar concentration (MAC) of 1 to 1.2%. Muscle relaxation is achieved with IV rocuronium 0.6mg/kg. Analgesic requirement for both groups will be standard: IV morphine 0.05-0.1mg/kg at the start of surgery and local anaesthetic infiltration with bupivacaine 0.5% 10ml total at laparoscopic port sites at the end of surgery. Postoperatively, both groups will receive IV tramadol 50mg 8 hourly for three doses. For emergence from anaesthesia, residual muscle relaxation will be antagonized with IV neostigmine 2.5mg and IV atropine 1mg in both groups. In the event the surgery is converted to open surgery from laparoscopy, the patient will not be dropped from the study and will be continued in the same study group. The change of approach will be recorded in the data collection sheet

The assessment of the PONV, pain score and need for rescue antiemetic at the first hour will be assessed by the nurses in the recovery area of OT and the 12th hour and 24th hour by the ward nurses. PONV scores is recorded using the PONV Impact Scale (score of 0 to 3), represented as ordinal data, whereby 0 is no presence of nausea, retching or vomiting, 1 is mild nausea (mild PONV), 2 is moderate nausea (moderate PONV), and 3 is severe nausea, retching or vomiting (severe PONV). Pain score is recorded using the Numerical Pain Rating Scale ranging from 0 to 10, whereby 0 is no pain, and with increasing number, the pain severity increases whereby 10 is the highest pain score. The need for rescue antiemetic is determined by patient's request or treating doctor's discretion is also documented (Figure 1).

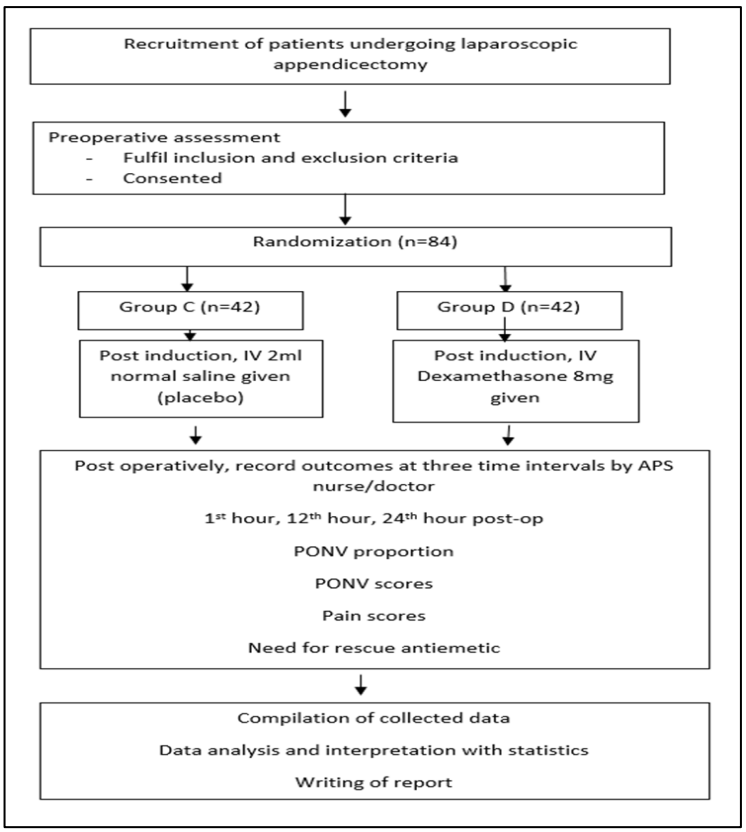

Figure 1 Consort flow diagram

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https://doi.org/10.24191/jchs.v10i1.5427

The sample size was calculated using Power and Sample Size Calculations software version 3.0 (January 2009, © 1997-2009 by William D. Dupont and Walton D. Plummer), and the data were based on a previous study by Kleif et al (9). To detect a 50% risk reduction, with alpha of 0.05 and beta of 0.2, the sample size needed for each limb would be 38. To account for a 10% dropout rate, the sample size needed would be (38 x 2) x 1.1 = 84. Thus, 42 participants for each limb. All data was recorded using Microsoft Excel and analysed via SPSS for Window. Numerical data was presented as median ± interquartile range (IQR); while categorical data was presented as frequency and percentage. The difference between numerical variables were determined using Mann Whitney test due to non-normal distribution of data. The difference in distribution of categorical variables were calculated via chi square test for homogeneity. The interaction between study variables (i.e. sex, smoking status, study group) and PONV was determined by Odds ratio. A statistically significant difference was determined if the P value was <0.05.

RESULTS

Demographic Details

The demographic details are represented in Table 1. In general, the median age of all subjects were 27±13 years old. Overall, there were 47 (56%) male and 37 (44%) female participants respectively. There were 23 (27.4%) smokers among the study participants. In terms of medical history, the ASA status of the participants were mostly ASA I (n = 45) and ASA II (n=39). When comparing patient demographics between the two groups, the randomization in recruitment resulted in no statistical significance in age, gender, body mass index (BMI), smoking status, ASA physical status.

In terms of operative details and events, the median duration of surgery across the board was 80 ± 61 minutes, while the morphine dosage was 3.00 ± 1.38mg/kg. Laparoscopic appendicectomy was the most commonly performed surgical procedure overall [75 (89.3%)]. When comparing operative details and events between both groups, no significance was detected in postoperative diagnosis, the type of surgery performed at the end, the duration of surgery and morphine doses given.

Table 1 Demographics of study subjects in control and dexamethasone groups

Variables	Control	Dexamethasone	P value
Age, years old	26±14	28±14	0.791[a]
Gender			
Male	22 (52%)	25 (60%)	0.510[b]
Female	20 (48%)	17 (40%)	
BMI, kgm^{-2}	23.5±8.2	22.7±6.4	0.295[a]
Smoker			
No	29 (69%)	32 (76%)	0.463[b]
Yes	13 (31%)	10 (24%)	
ASA			
I	21 (50%)	24 (57%)	0.512[b]
II	21 (50%)	18 (43%)	
Diagnosis			
Acute appendicitis	27 (65%)	29 (69%)	0.682[b]
Perforated appendix	14 (33%)	11 (26%)	
Others	1 (2%)	2 (5%)	
Operation Type			
Laparoscopic appendectomy	35 (83%)	40 (96%)	0.054[b]
Converted open	7 (17%)	1 (2%)	
Others	0 (0%)	1 (2%)	
Duration, minutes	78.0±61.0	82.5±64.0	0.785[a]
Morphine dose, mg/kg	3.00±1.25	3.50±2.00	0.118[a]

Note: [a]Mann Whitney test [b]Chi square test; Statistically significant at p<0.05; Data was presented as median ± interquartile range for age, Body Mass Index (BMI), duration, and morphine dose; categorical data was presented as frequency (percentage).

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https://doi.org/10.24191/jchs.v10i1.5427

Proportion of PONV

At the first hour postoperatively, there were significantly (P = 0.009) more cases of PONV in the control group [18 (42.9%)] as compared to the dexamethasone group [7 (16.7%)]. At the 12th hour postoperatively, eight participants had PONV in the control group while three developed PONV in the dexamethasone group but was statistically insignificant (19.1% vs 7.1%, P = 0.106). At the 24th hour postoperatively, there were significantly (P<0.011) more cases of PONV in the control group [6 (14.3%)] as compared to the treatment group [0 (0.0%)] (Table 2).

Table 2 Comparison of PONV proportion between control and dexamethasone group

Timepoint for the presence of PONV		Control	Dexamethasone	OR (95% CI)	P value
At first hour post-operation					
No		24 (57.1%)	35 (83.3%)	0.267 (0.097, 0.736)	0.009[b]*
Yes		18 (42.9%)	7 (16.7%)		
	Mild	9 (21.5%)	6 (14.3%)		
	Moderate	5 (11.9%)	1 (2.4%)		
	Severe	4 (9.5%)	0 (0.0%)		
At 12th hour post-operation					
No		34 (81.0%)	39 (92.9%)	0.327 (0.080, 1.331)	0.106[b]
Yes		8 (19.0%)	3 (7.1%)		
	Mild	2 (4.8%)	3 (7.1%)		
	Moderate	0 (0.0%)	0 (0.0%)		
	Severe	6 (14.2%)	0 (0.0%)		
At 24th hour post-operation					
No		36 (85.7%)	42 (100.0%)	-	0.011[b]*
Yes		6 (14.3%)	0 (0.0%)		
	Mild	4 (9.5%)	0 (0.0%)		
	Moderate	0 (0.0%)	0 (0.0%)		
	Severe	2 (4.8%)	0 (0.0%)		

Note: [b]Chi square test; *Statistically significant at P<0.05; Categorical data was presented as frequency (percentage). OR (95% CI): Odds ratio (95% Confidence Interval), PONV: postoperative nausea and vomiting. (PONV score of 0 designated as no PONV, 1 as mild PONV, 2 as moderate PONV and 3 as severe PONV).

Comparison of PONV Score

There was no statistical difference in PONV scores at the first hour (P = 0.168) and at the 12th hour postoperatively (P = 0.085). At the 24th hour, no participants reported severe PONV in the dexamethasone group (Table 3).

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Comparison of Pain Scores

At all three-time intervals, there were no significant difference in pain scores between both groups respectively (P = 0.768, P = 0.808 and P = 0.971), representing the first, 12th and 24th hour postoperatively (Table 4).

Comparison of Need for Rescue Antiemetics

At the first hour postoperatively, there were significantly (P = 0.023) more participants who received rescue antiemetic in control group [15 (35.7%)] as compared to the dexamethasone group [6

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https://doi.org/10.24191/jchs.v10i1.5427

(14.3%)]. Similarly, at the 12th hour postoperatively, there were significantly (P = 0.021) more participants who received rescue drugs in control group [5 (11.9%)] as compared to the dexamethasone group [0 (0.0%)]. No difference was detected in the need for rescue antiemetic at the 24th hour between both groups (P = 0.152) (Table 5).

Table 3 Comparison of PONV scores between control and dexamethasone group

Median PONV Score	Control	Dexamethasone	P value
At first hour post-operation	1.5±1.0	1.0±2.0	0.168[a]
At 12th hour post operation	3.0±2.0	1.0±0.0	0.085[a]
At 24th hour post operation	3.0±2.0	-	-

Note: [a]Mann Whitney test; *Statistically significant at P<0.05; Data was presented as median ± interquartile range. PONV: postoperative nausea and vomiting. (PONV score ranges from 0 to 3)

Table 4 Comparison of pain scores between control and dexamethasone group

Pain Score at different timepoint	Control	Dexamethasone	P value
At first hour post operation	4.0±3.0	4.0±2.0	0.768[a]
At 12th hour post operation	3.0±2.0	3.5±1.0	0.808[a]
At 24th hour post operation	3.0±2	2.5±2	0.971[a]

Note: [a]Mann Whitney test; *Statistically significant at P<0.05; Data was presented as median ± interquartile. (Pain score ranges from 0 to 10).

Table 5 Comparison for the need of rescue anti-emetic drug between control and dexamethasone group

The need of rescue anti-emetic drug at different timepoint	Control	Dexamethasone	P value
At first hour post operation	15 (35.7%)	6 (14.3%)	0.023[b]*
At 12th hour post operation	5 (11.9%)	0 (0.0%)	0.021[b]*
At 24th hour post operations	2 (4.8%)	0 (0.0%)	0.152[b]

Note: [b]Chi square test; *Statistically significant at P<0.05; Categorical data was presented as frequency (percentage)

DISCUSSION

The mechanism by which dexamethasone prevents postoperative nausea and vomiting (PONV) is not completely understood at present. Dexamethasone is a synthetic form of adrenocorticoid, and acts mainly as a glucocorticoid receptor with almost no mineralocorticoid receptor functions [13]. Certain glucocorticoid receptors are associated with the physiological pathways involved in vomiting [14, 15]. Glucocorticoid receptors are located in the brain stem, specifically in the area where the nucleus of the solitary tract and area postrema are situated [16]. Other potential reasons for dexamethasone's ability to prevent postoperative nausea and vomiting (PONV) include its central inhibition of prostaglandin synthesis, reduction in central serotonin activity, and alteration of the permeability of the blood-brain barrier to plasma proteins [17].

The efficacy of dexamethasone in preventing PONV in the immediate to early postoperative period, frequently described as up to six hours postoperatively

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https://doi.org/10.24191/jchs.v10i1.5427

have been documented widely for elective surgeries [3, 7, 18-20]. Dexamethasone itself has grade A1 evidence in the prevention of PONV in elective surgeries [1]. It appears that this antiemetic effect of dexamethasone in the immediate postoperative period is also demonstrable in our patients.

It is worth noting that the efficacy of dexamethasone in the prevention of PONV was not significant in the intermediate time period in our study at 12th hour postoperatively. These similar results were also reported by Celik et al [20]. In his study, the use of dexamethasone reduced PONV in the early postoperative period significantly up to 6 hours (P = 0.007). However, at the intermediate time period of the study, described as 6-12 hours postoperatively, dexamethasone did not show significant effect in preventing PONV (P = 0.06). Conversely, at the later periods, 12-24 hours postoperatively, patients treated with dexamethasone had significantly less PONV than untreated group (P = 0.02). In our study, we found similar efficacy of dexamethasone in the immediate and late postoperative time periods and not the intermediate time-frame. However, the similarity in the prevention of PONV in the early period (< 6 hours post-operatively) and late period (up to 24 hours) was not explained by Celik et al [20].

On that note, the late efficacy of dexamethasone in preventing PONV is not an isolated incident. However, the reasons behind them are still unknown [7]. The half-life of dexamethasone is 36 to 72 hours [7], and it is known to have a slow onset and long duration of action [21]. However, there are no studies currently exploring the extent of the actual duration of action of dexamethasone [22]. In fact, it has been widely accepted that the anti-emetic effects of dexamethasone can last till 24 hours postoperatively [2, 7, 21]. Thus, we are unsure if the late effect seen in reducing PONV is indeed attributed to the long half-life of dexamethasone. Perhaps in the future, the duration of action of dexamethasone in PONV prophylaxis can be studied and decided if an additional top-up dose is necessary in the postoperative period.

For secondary outcomes, when interpreting the PONV scores, among those who suffered PONV, there was a tendency for higher PONV scores in the control group compared to the dexamethasone group. However, this difference was not significant. Perhaps, the sample size was not big enough to detect such a difference.

The median pain scores in both groups did not differ significantly (P > 0.05) at all three-time intervals (0, 12th and 24th hours postoperatively). Similarly, Jokela et al also found that the analgesic effect of dexamethasone has not been proven to be significant when compared to placebo post-operatively in the immediate postoperative period up to 72 hours post-operatively. However, a study [23] showed that dexamethasone has the ability to reduce pain scores at the second hour and at the 24th hour postoperative significantly. The conflicting results from various studies could perhaps be due to the differences in methodology, patient demography or types of surgery. In our study, all participants received multi-modal analgesia in the form of local anaesthetic (LA) infiltration into operative sites and opioid analgesia intra and postoperatively. Perhaps, the significance in detecting a difference could be explained by these confounding factors.

With regards to the use of rescue anti-emetics, the control group required more rescue anti-emetics than the group treated with dexamethasone [15 (35.7%) vs 6 (14.3%), P =0.023] at the first hour and 12th hour postoperatively [5 (11.9%) vs 0 (0.00%) P = 0.021]. This similar result was also reported in a study [9] which found that rescue anti-emetics were significantly found more in the control group than treated groups with dexamethasone. The need for rescue anti-emetic could be explained by the increased incidence of PONV in control groups. However, the decision to administer rescue anti-emetic was left to the treating clinician and the logical clinical explanation would be that as the severity of PONV increased, the need for rescue anti-emetic increased.

However, the decision on the optimal dose has not been decided. A low-dose of IV dexamethasone 2.5mg has been reported to be effective in preventing PONV by Liu et al for gynaecological surgeries [18]. On the contrary, the use of higher dose of 8mg in many studies have reported additional benefits such as analgesia, less fatigue, with an improvement in the quality of recovery. The extent of the effects at this dose include a reduction in sore throat, nausea, myalgia, reduced opioid use, albeit at the expense of difficulty in

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https://doi.org/10.24191/jchs.v10i1.5427

falling asleep [2]. Although the optimal dose has yet to be defined, the consensus for PONV management recommends that 4 to 5mg is the minimum effective dose for its antiemetic effects [1].

The strength of this study is that both groups were adequately randomized such that there were no significant differences ($p > 0.05$) that separated them in demographics and intraoperative events. Thus, confounding factors that could potentially affect the development of PONV such as smoking status and gender have been evenly distributed between both groups. The limitations of the study are absence of a criteria for the administration of rescue anti-emetics, and there were possibly confounding factors (additional analgesia and local anaesthetic infiltrations) in the methodology which may make the detection in pain score differences insignificant. However, dexamethasone per se is not an established analgesic drug and withholding analgesia solely for the purpose of detecting significance in pain scores would seem unethical.

CONCLUSION

We surmise that prophylactic dexamethasone is effective in preventing PONV at the first and 24th hour postoperatively in those undergoing laparoscopic surgery for suspected appendicitis. It also resulted in fewer use of rescue anti-emetics in the first hour and 12th hours postoperatively. It did not improve pain scores or affect the severity of PONV at any time postoperatively. Given the high occurrence rate of PONV following emergency laparoscopic appendectomy procedures, it would be beneficial to establish a standardized protocol for managing this issue in the future.

Conflict of interest

Authors declare none.

Authors' Contribution

1. NSA: Conception, design, execution, analysis, interpretation of the data, drafting and final approval of manuscript

2. PS: Critical revision of article, statistical analysis, final approval of article

3. MHH: Critical revision of article, statistical analysis, final approval of article

4. MZM: Critical revision of article, statistical analysis, final approval of article

5. SCO: Conception, design, execution, analysis, interpretation of the data, drafting and final approval of manuscript

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Vol 10(1) (2025) 49-57 | jchs-medicine.uitm.edu.my | eISSN 0127-984X
https://doi.org/10.24191/jchs.v10i1.5427