Original Article

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Blood Glucose Concentration Profile After Prophylactic Administration of Intravenous Dexamethasone for Prevention of Postoperative Nausea and Vomiting in Patients Undergoing Laparoscopic Cholecystectomy Under General Anesthesia

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Abstract

Dexamethasone has been shown to reduce nausea and vomiting after surgery (PONV), but it can also raise blood glucose levels. The effect of two doses of 2 mg and 4 mg dexamethasone on blood glucose levels, PONV, and analgesia in the first 24 hours after laparoscopic cholecystectomy was investigated in this study. At the time of anesthesia induction, 90 patients were enrolled and randomized to receive either saline (control group) or 2 mg or 4 mg dexamethasone in three groups. At baseline and 1, 2, 4, 6, and 24 hours after induction, blood glucose concentrations were measured. PONV and pain scores score were assessed following extubation at 0, 4, 8, 12, and 24 hours. Blood glucose levels rose dramatically in both the control and dexamethasone classes over time (from a median baseline of 87, 87, and 89.5 mg/dL to a final median of 148.5, 168, and 151 mg/dL. ($P < 0.001$). For every time, there was no significant change in blood glucose concentration between the groups receiving dexamethasone (2 or 4 mg) and those receiving saline. Groups of Dexamethasone showed lower pain score and PONV levels. Dexamethasone administration (2 and 4 mg) did not change blood glucose levels, but it decreased PONV and pain scores that were significantly low at all times. Dexamethasone prophylactic administration can easily be used for nausea and vomiting without hyperglycemia-related issues.

Keywords: PONV prophylaxis, dexamethasone, hyperglycemia, laparoscopic cholecystectomy

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Introduction

Postoperative nausea and vomiting (PONV) is one of the most common postoperative complications in patients undergoing surgical procedures under general anesthesia, and it is distressing for both the patient and the anaesthesiologist, particularly in laparoscopic cholecystectomy.[1–4]

Dexamethasone is an anti-inflammatory corticosteroid with a proven role in the reduction of postoperative nausea and vomiting.[5] It has anti-inflammatory, immunomodulatory, analgesic, and antiemetic properties. It is mostly used in the perioperative setting to prevent nausea and vomiting.[6] Corticosteroids can also improve clinical rehabilitation in the postoperative period by modulating the neuroendocrine and inflammatory stress response induced by surgery. Clinical studies have shown that a single low dose of dexamethasone lowered pain scores and analgesic uses, improved mood, decreased sleep scores, and improved quality of recovery after surgery.[7,8] Although the benefits of dexamethasone therapy have been well reported, glucocorticoid-related adverse events have not been well documented.

The administration of a single low-dose dexamethasone at the time of anesthesia induction will result in intraoperative and postoperative hyperglycemia. A small number of recent studies have shown that dexamethasone administration causes an increase in blood glucose levels. The findings of the analysis were hampered by research design limitations, such as the lack of a test group in small study groups,[9–11] the lack of randomization and standardization of anesthetic and surgical management, and inadequate follow-up time for hyperglycemic cases.

Acute hyperglycemia may have a number of negative physiological effects, including osmotic diuresis and hypovolemia, decreased immune function, elevated systemic inflammatory cytokine concentrations and molecule expression adhesion, endothelial disturbance, electrolyte and acid-base imbalances.[12,13] Although optimal glucose targets have not been identified, it has been determined that shooting hyperglycemia can be avoided. For doctors to reliably determine the risk-benefit ratio of corticosteroids in the surgical environment, the influence of dexamethasone on blood glucose concentrations should be measured.

The primary goal was to assess the effect of two prophylactic doses of dexamethasone (2 mg and 4 mg at the time of anesthesia induction) recommended for PONV safety within the first 24 hours on blood glucose concentrations. Primary targets included comparing pain and PONV scores 24 hours after surgery.

Subjects and Methods

This prospective randomized controlled double-blind pilot study was performed on 90 patients with ASA physical status I & II, aged 18-60 years, scheduled for elective laparoscopic cholecystectomy, and was accepted by the professional ethics board holding EC/NIMS/1545/2014 on 22 August 2014 with CTRI/2017/06/008769 and written informed consent of the patient. Exclusion conditions include ASA III & IV, open-label laparoscopic cholecystectomy, patients with unregulated diabetes mellitus, pancreatic tumors, adrenal tumors, related migraine, BMI > 30 kg/m2, with known drug allergy patients were randomly divided into three categories based on random numbers produced by the machine and sealed envelope methods. Group-A is the monitoring group and Group-B is the 2 mg group of dexamethasone; Group-C is the 4 mg group of dexamethasone.

Anesthetic management: All the patients were pre-premedicated with 0.5 mg oral alprazolam and 150 mg ranitidine the night before and the morning of the surgery. For all the patients, a standard general anesthesia protocol was adopted. Baseline HR, SBP, DBP, and SpO2 were tracked in the operating room and the finger prick blood glucometer was used to measure the baseline blood glucose. After establishing venous access with an 18G cannula, 0.1 mg Inj.Glycopyrrolate was administered intravenously 5 minutes until induction. Fentanyl 2g/kg intravenous injection was used to provide analgesia. For 3 minutes, both patients were pre-oxygenated with 100 percent oxygen. Injection thiopentone 4mg/kg intravenously or before failure of eyelash reflex and injection atracurium 0.5 mg/kg intravenously for muscle relaxation is part of the standard anesthesia induction protocol. Immediately after anesthesia infusion, both patients got the research drug based on their randomization. Group A received 1 ml of normal saline intravenously; Group B received 2 mg of dexamethasone in 1 ml solution (saline reconstituted); and Group C received 4 mg of dexamethasone in 1 ml. The anaesthesiologist who gave the injection was unaware of the medication being examined. Patients were intubated using a cuffed endotracheal tube of the required height. Sevoflurane and oxygen were used to maintain anesthesia, along with occasional doses of atracurium. Both patients got a 15 mg/kg IV paracetamol infusion. Capillary blood glucose levels were measured at baseline, as well as the first, second, fourth, sixth, and twenty-fourth hours following anesthesia induction. Both blood capillary blood glucose readings were taken with the Freestyle Optium H Glucometer. Both patients received glucose-free IV fluids intraoperatively and postoperatively for 24 hours, and 20 ml of 0.25 percent bupivacaine was infiltrated into laparoscopic port sites. Following effective recovery and fulfilling the extubation criteria, the residual neuromuscular blockade was reversed and extubated with 0.04-0.07 mg/kg of neostigmine and 0.4 mg of glycopyrrolate. The immediate postoperative pain score was calculated using the visual analog pain scoring scale (VAS), with a score of ’0’ representing ’no pain’ and a score of ’10’ representing’severe pain.’ Following surgery, both patients were tracked for 24 hours. Any episode of nausea, retching, or vomiting was reported, analysed, and graded as 0-none, 1-nausea, 2-stretching, 3-vomiting, and 4-vomiting severity on a five-point PONV ordinal scale. It was discovered in cases of nausea and vomiting, and IV Ondansetron 4 mg was administered as a rescue drug.

Statistical Analysis

With 10 patients in each group, a pilot study was performed. Considering a magnitude of the margin of equivalence of blood glucose levels, i.e the largest difference that is not of practical significance to be 15 and with true difference between the means to be 8.00. Group sample sizes of 25each achieve 83% power with alpha error 0.10 to detect non-inferiority using a one-sided, two-sample t-test.

For the analysis of the results, Statistical Program SPSS 15.0 was used. Continuous measurement results were presented as mean $\pm$ SD and categorical measurement results were presented in no (percent) or median and interquartile range. The analysis of variance (ANOVA) method was used to determine the importance of research parameters between groups. Fisher/Chi-square The exact test was used to determine the importance of research parameters on a categorical basis when comparing two or more categories. Statistical significance was defined as a p value of 0.05.

Results

The clinical trial enrolled ninety patients. Due to loss of follow-up, one patient was excluded and 3 patients were required open procedures [Figure 1]. Data were obtained from 86 patients. In Groups A, B & C, 29, 31, and 26 patients, respectively. There was no statistical significance between the categories in terms of patient characteristics [Table 1]. The average length of surgery did not vary between classes.

There was no disparity between the groups in baseline glucose concentrations (median baseline 87.90±15.15; 89.32±17.67; 90.15±15.51). At all-time points in all the cohorts, blood glucose levels were elevated from baseline but displayed no statistical significance.

At 4 hours postoperatively, PONV scores were statistically significant [Table 3] and the percent of patients with PONV score according to the PONV scale [Table 4]. Ten patients (34.48%) in group A, six patients (19.35%) in group B, and seven patients (26.92%) in group C administered 4 mg of ondansetron IV as a PONV rescue drug.

Pain scores were significantly lower in dexamethasone groups at 8, 12, 24 hours postoperatively in comparision to control group. However, the pain scores in the 4 mg group were significantly lower than in the 2 mg group at 12 and 24 hours after surgery [Table 5].

In the postoperative period, none of the patient received insulin for. There is no incidence of hypoglycemic episodes was reported.

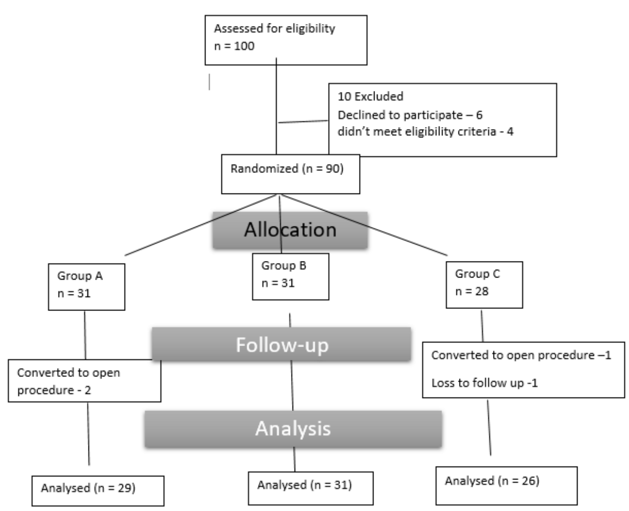

Figure 1: Participant flow chart

Discussion

This randomized, double-blind, placebo-controlled analysis looked at the impact of two different doses of dexamethasone (2 and 4 mg) on intraoperative and postoperative blood glucose concentrations, as well as PONV and pain ratings. The increase of perioperative blood glucose concentrations after a single low dose of dexamethasone (peak blood glucose 165.2339.64 Group - B and 162.1258.15 Group - C) did not vary from the placebo group (153.6934.07), but blood glucose concentrations increased significantly from baseline in both groups. The median increase in blood glucose levels in group B was 13.971 and 5.176 in group C. These findings suggest that, while blood glucose levels in dexamethasone patients were slightly elevated, the clinical significance of this effect is likely to be small. The Freestyle Optium H Glucometer is used to calculate all capillary blood glucose readings.

Hyperglycemia is a known risk of steroid administration, but the effects on blood glucose concentrations of single low-dose therapy have not been well defined. Tappy and colleagues found that short-term dexamethasone therapy induces reversible immunity to extrahepatic insulin and increased endogenous glucose development in healthy volunteers.[14] However, the role of single-dose dexamethasone therapy on glucose control in surgical patients has received little attention. It is further complicated in the perioperative cycle by the trauma reaction to surgery, which results in physiological changes that increase blood glucose concentrations. Surgical trauma also causes the release of glucagon, epinephrine, and cortisol, which increases hepatic gluconeogenesis and glycogenolysis.[12,13]

On the one hand, a single dose of dexamethasone at the time of induction will accelerate the metabolic changes caused by surgical tissue damage (increased endogenous glucose production and insulin resistance), but on the other hand, the attenuated surgical stress response to a single dose of corticosteroids can have a beneficial effect on perioperative glucose homeostasis by decreasing the releasability (epinephrine, cortisol, and glucagon). Our 24-hour examination revealed that the prevalence of perioperative hyperglycemia did not differ significantly between saline patients or between 2 and 4 mg of dexamethasone.

In the current research, a single dose of dexamethasone administered at the start of anesthesia reduced the incidence of PONV while increasing postoperative pain ratings. Even a moderate dose of 2 mg dexamethasone significantly reduced postoperative morbidity by decreasing the level of PONV and pain ratings.

Many experiments have been conducted to assess the effectiveness of dexamethasone on PONV and discomfort after laparoscopic surgery. However, a small number of patients were always used and standardized anesthetic procedures and

Table 1: Demographic data

Demographic Data	Group A	Group B	Group C	P value
Number of patients	29	31	26	-
Age (yrs)	37.41±13.03	35.35±12.44	38.62±10.56	0.588
Gender (M : F)	10 : 19	9 : 22	9 : 17	0.872
Duration of surgery (min)	96.21±35.12	91.45±25.17	97.69±36.78	0.110

Table 2: Blood glucose levels at various time points

Blood glucose	Group A (n-29) Mean ±SD	Group B(n-31) Mean ±SD	Group C(n-26) Mean ±SD	P
Baseline 0 hour	87.90±15.150	89.32±17.668	90.15±15.507	0.871
1hour	133.21±22.868	147.61±26.538	136.62±22.783	0.061
2 hours	151.69±34.066	165.23±39.636	158.00±39.076	0.383
4 hours	150.48±35.436	168.13±49.092	162.12±58.154	0.360
6 hours	135.17±31.296	158.97±46.581	148.50±60.160	0.152
24 hours	126.97±26.447	128.61±31.751	122.92±37.367	0.793

P0.05 is statistically significant

Table 3: PONV at different point of times

PONV	Group A (n-29) Median[IQR]	Group B (n-31) Median [IQR]	Group C (n-26) Median[IQR]	p
0 hours	0.00 [0.00-0.05]	0.00 [0.00-0.00]	0.00 [0.00-0.00]	0.475
4 hours	0.00 [0.00-2.00]	0.00 [0.00-0.00]	0.00 [0.00-0.00]	0.016*
8 hours	0.00 [0.00-2.00]	0.00 [0.00-2.00]	0.00 [0.00-0.25]	0.241
12 hours	0.00 [0.00-0.50]	0.00 [0.00-0.00]	0.00 [0.00-1.00]	0.754
24 hours	0.00 [0.00-0.00]	0.00 [0.00-0.00]	0.00 [0.00-0.00]	0.177

P 0.05 is statistically significant

protocols for rescue therapy were not followed.[7,15–19] The results of the few randomized placebo-controlled studies that tested the efficacy of a single IV corticosteroid administration, on the other hand, are contradictory and debatable. A statistically important improvement in the PONV score at 4 hours postoperatively was observed with the probability of peak activity of dexamethasone.[20,21] Dexamethasone's anti-emetic properties are well founded, but the mechanisms behind this anti-emetic action are largely unknown. Direct inhibition of prostaglandin, serotonin, or endorphin output has been proposed as one of the potential pathways.

While dexamethasone's anti-inflammatory effects are well known, its effects on postoperative pain remain controversial. It was observed the effect on pain was only at 8^{th} and 12hrs postoperatively but not in the immediate postoperative period. Based on the pharmacokinetic profile of dexamethasone, anti-inflammatory symptoms are likely to occur a few hours after administration.[20,21] As a result, it is not shocking that the influence of dexamethasone on postoperative pain was not detected until 8 hours later. This may also explain why several trials found no substantial pain relief with dexamethasone in the immediate postoperative phase.

It has also been proposed that short-term steroid therapy can improve mood through a direct central nervous system effect or by attenuation of perioperative inflammatory mediator release, 7 reduce shivering through inhibition of the release of vasoconstrictor and pyrogenic cytokines,[22] and reduce the severity of postoperative fatigue18, both of which contribute to the beneficial effects. The current study found that dexamethasone, without causing a noticeable increase in blood glucose levels, decreased morbidity during laparoscopic cholecystectomy by decreasing PONV and postoperative discomfort within the first 24 hours. While there was no substantial difference in blood glucose and PONV increase between 2mg and 4mg dexamethasone levels, pain ratings were slightly lower for 4mg dexamethasone relative to 2mg.

Table 4: Comparison of PONV

PONV	0 hours	4 hours	8 hours	12 hours	24 hours
Group A (n=29)					
• 0	22 (75.9%)	16 (55.2%)	16 (55.2%)	22 (75.9%)	27 (93.1%)
• 1	2 (6.9%)	3 (10.3%)	3 (10.3%)	3 (10.3%)	1 (3.4%)
• 2	3 (10.3%)	7 (24.1%)	6 (20.7%)	2 (6.9%)	1 (3.4%)
• 3	2 (6.9%)	2 (6.9%)	4 (13.8%)	2 (6.9%)	0 (0%)
• 4	0 (0%)	1 (3.4%)	0 (0%)	0 (0%)	0 (0%)
Group B (n=31)					
• 0	27 (87.1%)	25 (80.6%)	22 (71%)	25 (80.6%)	31 (100%)
• 1	1 (3.2%)	3 (9.7%)	1 (3.2%)	5 (16.1%)	0 (0%)
• 2	3 (9.7%)	1 (3.2%)	4 (12.9%)	1 (3.2%)	0 (0%)
• 3	0 (0%)	2 (6.5%)	4 (12.9%)	0 (0%)	0 (0%)
• 4	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Group C (n=26)					
• 0	22 (84.6%)	22 (84.6%)	20 (76.9%)	19 (73.1%)	23 (88.5%)
• 1	2 (7.7%)	3 (11.5%)	3 (11.5%)	6 (23.1%)	2 (7.7%)
• 2	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (3.8%)
• 3	2 (7.7%)	1 (3.8%)	3 (11.5%)	1 (3.8%)	0 (0%)
• 4	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Table 5: Pain scores at different time points

Pain score	Group A (n-29) Median[IQR]	Group B (n-31) Median [IQR]	Group C (n-26) Median[IQR]	p
0 hours	0.00 [0.00-4.00]	0.00 [0.00-0.00]	0.00 [0.00-0.12]	0.000*
4 hours	2.00 [2.00-3.50]	0.00 [0.00-2.00]	1.00 [0.00-2.25]	0.001*
8 hours	2.00 [0.15-5.00]	0.00 [0.00-2.00]	0.50 [0.00-2.00]	0.001*
12 hours	1.00 [0.00-2.50]	1.00 [0.00-2.00]	1.00 [0.00-2.25]	0.703
24 hours	0.00 [0.00-2.00]	0.00 [0.00-0.00]	0.00 [0.00-2.00]	0.068

P* 0.05 statistically significant

Conclusion

A low dose of dexamethasone may not raise blood glucose levels, but it may reduce morbidity in the first 24 hours after laparoscopic cholecystectomy by decreasing PONV and post-operative pain. A single low dose of 2 mg dexamethasone after laparoscopic cholecystectomy will greatly reduce PONV without concern for blood glucose levels, but 4 mg dexamethasone can also provide enhanced analgesia.

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