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Research Article

Effect of Esomeprazole and Pantoprazole on Gastric Ph and Volume in Patients Posted for Elective Abdominal Surgeries – a Comparative Clinical Study

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ABSTRACT
Background: Pulmonary aspiration during general anaesthesia is influenced by both gastric acidity and residual gastric volume. Proton pump inhibitors may improve these gastric characteristics before surgery.
Objective: To compare the effects of intravenous esomeprazole and pantoprazole on gastric pH and aspirate volume in patients undergoing elective abdominal surgery.
Methods: This prospective randomized comparative study included 60 ASA I–II adults, allocated equally to intravenous pantoprazole 40 mg or esomeprazole 40 mg administered 30 minutes before induction. Gastric aspirate pH and volume were measured after intubation and before extubation.
Results: Gastric volume decreased in both groups, with no significant between-group difference post-intubation (12.00 ± 3.23 vs 10.88 ± 3.75 mL; p=0.220) or pre-extubation (8.93 ± 3.03 vs 8.35 ± 3.92 mL; p=0.524). Gastric pH increased in both groups. Pre-extubation pH was significantly higher with esomeprazole than pantoprazole (6.05 ± 0.86 vs 5.27 ± 1.17; p=0.005). No drug-related adverse reactions were observed.
Conclusion: Esomeprazole provided greater perioperative acid suppression than pantoprazole, while both produced comparable effects on gastric aspirate volume.

Keywords: Esomeprazole, Pantoprazole, Gastric Ph, Gastric Volume, Aspiration Prophylaxis.

INTRODUCTION

Gastric aspiration is a significant risk during general anaesthesia. Clinically significant aspiration is rare in elective surgical practice but can have serious consequences, including transient hypoxaemia, chemical pneumonitis and respiratory failure. The presence of gastric contents is not the only factor that affects the likelihood and severity of pulmonary injury; the volume and acidity of the contents also play a role. Historically, a gastric pH < 2.5 and a relatively large residual gastric volume have been considered to be a combination that is linked to greater aspiration-related pulmonary injury, and these parameters remain useful practical surrogates for assessing strategies aimed at reducing the risk of aspiration. Even with good fasting, there may be residual gastric contents, which is why fasting alone is not a guarantee of an empty stomach.[1,2]

Various methods have been employed to alter the gastric contents prior to anaesthesia, such as the use of H_2-receptor antagonists, prokinetic agents, non-particulate antacids and proton pump inhibitors (PPIs). PPIs are especially potent inhibitors of gastric acid secretion because they block the last step in the production of acid by inhibiting the gastric H^+/K^+-ATPase. Evidence from perioperative studies suggests that acid-suppressive treatment can increase gastric pH and, depending on the drug, dose and timing of administration, may also reduce residual gastric volume. A meta-analysis of PPIs versus H_2-receptor antagonists for aspiration prophylaxis showed that the efficacy of these drugs was highly dependent on the route and timing of administration, and that intravenous PPIs were a reasonable alternative when rapid

acid suppression is needed in the perioperative period.[3]

One of the PPIs that has been studied specifically in the preanaesthetic setting is pantoprazole. When oral medication is not desired or feasible just prior to surgery, intravenous administration is convenient. In a randomized study of adults undergoing elective surgery, Memiş et al. showed that preoperatively, intravenous pantoprazole significantly changed the characteristics of gastric fluid, which is favourable for aspiration prophylaxis.[4] Other perioperative studies have also shown that proton pump inhibitors can improve preanaesthetic gastric pH profiles and decrease the number of patients with gastric characteristics traditionally associated with a higher aspiration risk.[5]

Esomeprazole is also a strong inhibitor of gastric acid secretion, the S-isomer of omeprazole. PPIs work on the same ultimate target, but they do not necessarily have the same onset, magnitude or duration of acid suppression. This is especially important in the peri-operative setting, where the therapeutic window between the time of administration of an acid-suppressive agent and induction of anaesthetic may be brief for some PPIs, such as pantoprazole.

There are also differences in the early pharmacodynamic effects of esomeprazole and pantoprazole, as suggested by direct comparisons.[6,7] These results suggest that the same milligram doses of esomeprazole and pantoprazole may not result in the same intragastric pH profile in healthy volunteers. Most of the comparative literature, however, has been obtained from healthy volunteers or patients with acid-related gastrointestinal disease, and the clinical significance of these pharmacodynamic differences in the immediate perioperative period is less well established.

In addition, gastric acidity is just one part of the possible effects of aspiration; the volume of fluid in the stomach is also significant. Thus, a drug that could quickly raise the pH of the stomach while keeping the gastric residual volume unchanged or lowered would be desirable in patients under general anaesthesia. Comparative information on the effects of single preoperative intravenous doses of esomeprazole and pantoprazole on both gastric pH and aspirate volume during surgery is relatively limited.[8,9]

The present prospective randomized study was therefore conducted to compare the effect of intravenous esomeprazole 40 mg and intravenous pantoprazole 40 mg given 30 minutes prior to induction of general anaesthesia on the pH and volume of gastric aspirate in patients undergoing elective abdominal surgery. The two regimens were evaluated by measuring the gastric contents after tracheal intubation and before extubation.

MATERIALS AND METHODS

Study Design and Setting

This prospective, randomized, comparative clinical study was conducted in the Department of Anaesthesiology, Adichunchanagiri Institute of Medical Sciences and Research Centre, B.G. Nagara, Karnataka, between November 2015 and July 2017. The study compared the effects of intravenous esomeprazole and pantoprazole on gastric pH and gastric aspirate volume in patients undergoing elective abdominal surgery under general anaesthesia.

Study Population

Sixty adult patients of either sex, aged 20–50 years, belonging to American Society of Anesthesiologists (ASA) physical status I or II and scheduled for elective abdominal surgery under general anaesthesia were included. Eligible participants had a body mass index of 18–25 kg/m².

Patients with ASA physical status III or higher, emergency surgical procedures, bleeding disorders or anticoagulant therapy, acute respiratory infection, significant neurological, cardiovascular, renal, metabolic, or psychiatric disease, gastric outlet obstruction, pregnancy, known hypersensitivity to anaesthetic agents, or a history of acid-peptic symptoms requiring drugs that could alter gastrointestinal function were excluded.

Sample Size and Allocation

The prespecified sample-size calculation indicated a minimum requirement of 25 participants per treatment group. To allow for possible exclusions or attrition, 60 patients were enrolled, with 30 patients in each group.

Participants were allocated in a 1:1 ratio using a computer-generated random sequence to receive either:

- **Group P:** pantoprazole 40 mg intravenously
- **Group E:** esomeprazole 40 mg intravenously

The allocated study drug was administered 30 minutes before induction of general anaesthesia.

Preoperative Preparation and Anaesthesia Protocol

All patients underwent routine pre-anaesthetic evaluation on the day before surgery, including relevant history, physical examination, and investigations. Patients were instructed to remain nil per oral for 6–8 hours before surgery and received oral alprazolam 0.5 mg on the night before the procedure.

On arrival in the operating room, standard monitoring comprising electrocardiography, non-invasive blood pressure, pulse oximetry, and end-tidal carbon dioxide monitoring was instituted. Intravenous access was secured and Ringer lactate solution administered.

Premedication consisted of fentanyl 2 µg/kg, midazolam 0.02 mg/kg, and glycopyrrolate 0.01 mg/kg intravenously. Following preoxygenation with 100% oxygen for 3 minutes, anaesthesia was induced with thiopentone 5–7 mg/kg intravenously, titrated until loss of the eyelash reflex. Succinylcholine 1.5 mg/kg was administered to facilitate tracheal intubation.

After confirmation of correct endotracheal tube placement by auscultation and capnography, anaesthesia was maintained with oxygen, nitrous oxide, and sevoflurane with controlled ventilation. Vecuronium 0.05 mg/kg was used for neuromuscular blockade. At the completion of surgery, residual neuromuscular blockade was reversed with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg.

Gastric Sampling and Measurement

Immediately after tracheal intubation, a 16-French nasogastric tube was inserted. Correct intragastric placement was confirmed by insufflation of air with auscultation over the epigastrium.

The first gastric aspirate was obtained immediately after intubation and designated Sample 1 (post-intubation). To maximize recovery of gastric contents, the nasogastric tube was rotated, withdrawn approximately 10 cm, and re-advanced with repeated aspiration.

A second gastric aspirate, designated Sample 2 (pre-extubation), was obtained near the completion of surgery before tracheal extubation.

Gastric aspirate volume was measured using a graduated syringe and recorded in millilitres. The aspirated fluid was transferred into sterile borosilicate containers, and gastric pH was measured immediately using a Chemiline digital pH meter.

Outcome Measures

The primary outcomes were:

1. gastric aspirate volume at post-intubation and pre-extubation sampling;
2. gastric pH at post-intubation and pre-extubation sampling; and
3. comparison of gastric volume and pH between the esomeprazole and pantoprazole groups.

Absolute and relative changes in gastric aspirate volume between the two sampling points and absolute change in gastric pH were also summarized.

The secondary outcome was the occurrence of adverse reactions attributable to either study drug during the perioperative observation period.

Statistical Analysis

Continuous variables were summarized as mean ± standard deviation, while categorical variables were presented as n (%).

Baseline continuous variables and gastric pH and volume measurements were compared between treatment groups using the independent-samples Student's *t* test. Categorical variables, including sex, age categories, weight categories, and type of surgery, were compared using the chi-square test, with an exact test used where appropriate for small expected frequencies.

For the principal efficacy outcomes, between-group mean differences were reported with 95% confidence intervals. Changes between post-intubation and pre-extubation measurements were summarized as absolute change, with percentage change additionally calculated for gastric volume.

All statistical tests were two-sided, and a p-value <0.05 was considered statistically significant.

Ethical Considerations

The study was conducted after obtaining approval from the institutional ethics committee. Written informed consent was obtained from all participants before enrollment, and confidentiality of participant information was maintained throughout the study.

RESULTS

A total of 60 patients undergoing elective laparoscopic abdominal surgery under general

anaesthesia were included in the analysis, with 30 patients allocated to intravenous pantoprazole 40 mg (Group P) and 30 to intravenous esomeprazole 40 mg (Group E). The groups were similar with respect to demographic and procedural characteristics, including sex, age distribution, body weight, type of surgery, and duration of surgery (Table 1).

Women constituted the majority in both treatment groups, accounting for 18 (60.0%) patients in Group P and 16 (53.3%) in Group E. The age profile was broadly comparable between groups, and mean body weight was also similar (61.36 ± 9.12 kg vs 60.33 ± 7.60 kg, respectively; p=0.636). Laparoscopic cholecystectomy and laparoscopic appendicectomy together accounted for most procedures in both groups. Mean operative duration was comparable between Group P and Group E (125.00 ± 19.38 vs 126.40 ± 20.77 minutes; p=0.788).

Table 1. Baseline and Procedural Characteristics by Treatment Group

Characteristic	Category	Pantoprazole (N=30)	Esomeprazole (N=30)	Test Statistic; P-Value
Sex	Male	12 (40.0)	14 (46.7)	X^2=0.27; P=0.602
	Female	18 (60.0)	16 (53.3)	
Age, Years	20–30	9 (30.0)	13 (43.3)	X^2=1.25; P=0.534
	31–40	10 (33.3)	9 (30.0)	
	41–50	11 (36.7)	8 (26.7)	
Weight, Kg	Mean ± SD	61.36 ± 9.12	60.33 ± 7.60	T=0.48; P=0.636
	35–44	2 (6.7)	0 (0.0)	X^2=5.72; P=0.221
	45–54	3 (10.0)	7 (23.3)	
	55–64	15 (50.0)	14 (46.7)	
	65–74	6 (20.0)	8 (26.7)	
	75–84	4 (13.3)	1 (3.3)	
Surgery	Laparoscopic Cholecystectomy	13 (43.3)	15 (50.0)	X^2=0.84; P=0.839
	Laparoscopic Appendicectomy	13 (43.3)	11 (36.7)	
	Laparoscopic Mesh Repair	2 (6.7)	3 (10.0)	
	Laparoscopic Cholecystectomy + Appendicectomy	2 (6.7)	1 (3.3)	
Duration Of Surgery, Min	Mean ± SD	125.00 ± 19.38	126.40 ± 20.77	T=-0.27; P=0.788

Values are n (%) unless otherwise stated. χ^2 values are from Pearson chi-square tests; t values are from independent-samples comparisons.

Gastric Volume

Mean gastric aspirate volume decreased between the post-intubation and pre-extubation sampling points in both treatment groups. In Group P, the mean volume decreased from 12.00 ± 3.23 mL to 8.93 ± 3.03 mL, corresponding to an absolute mean reduction of 3.07 mL. In Group E, it decreased from 10.88 ± 3.75 mL to 8.35 ± 3.92 mL, an absolute mean reduction of 2.53 mL. The two groups did not differ significantly in gastric volume at either sampling point (Table 2 and Figure 1).

At the post-intubation assessment, the mean difference between groups was 1.12 mL, with a 95% confidence interval spanning zero. A similarly small between-group difference was present before extubation. Thus, although gastric volume decreased over the intraoperative period in each group, the comparative data did not demonstrate a meaningful separation between esomeprazole and pantoprazole for this outcome.

Table 2. Gastric Volume at Post-Intubation and Pre-Extubation Sampling

Sampling Time	Pantoprazole (N=30), Mean ± SD	Esomeprazole (N=30), Mean ± SD	Mean Difference (E−P)	95% CI	Test Statistic; P-Value
Post-Intubation Sample	12.00 ± 3.23	10.88 ± 3.75	-1.12 Ml	-2.93 To 0.69	T=1.24; P=0.220
Pre-Extubation Sample	8.93 ± 3.03	8.35 ± 3.92	-0.58 Ml	-2.39 To 1.23	T=0.64; P=0.524

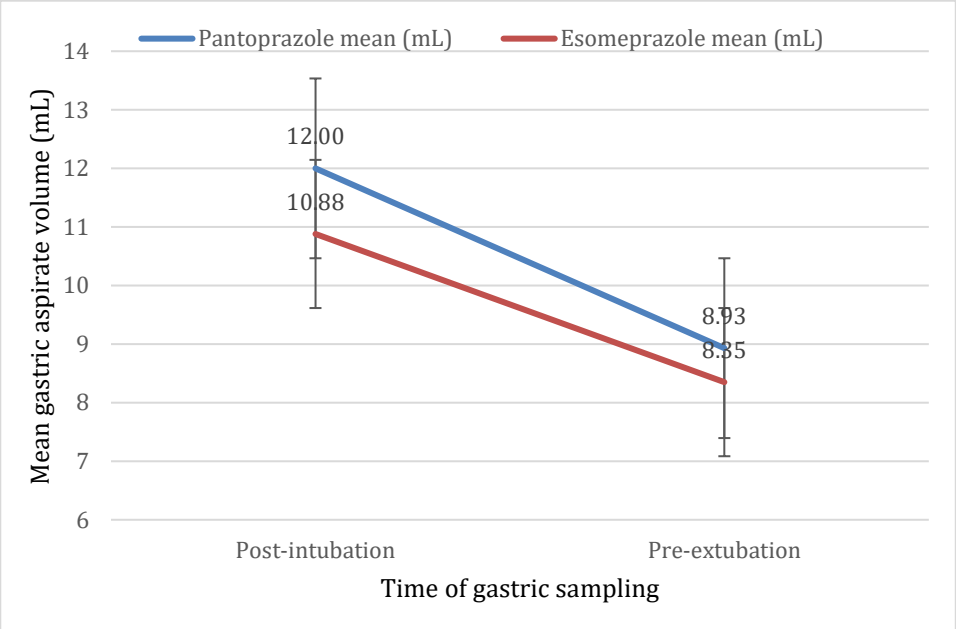

Figure 1. Mean Gastric Aspirate Volume In the Pantoprazole and Esomeprazole Groups at Post-Intubation and Pre-Extubation Sampling. Error Bars Represent Standard Deviation

Gastric Ph

Gastric pH increased from the post-intubation to the pre-extubation sample in both groups. Group P showed an increase from 3.96 ± 1.61 to 5.27 ± 1.17, while Group E showed an increase from 4.08 ± 1.39 to 6.05 ± 0.86. The corresponding absolute increases in mean pH were 1.31 and 1.97 units, respectively. Post-intubation pH was comparable between groups; however, by the pre-extubation assessment, mean gastric pH was significantly higher in the esomeprazole group (Table 3 and Figure 2).

The pre-extubation between-group mean difference was 0.78 pH units (95% CI 0.25 to 1.31; t=-2.94, p=0.005), favoring esomeprazole. This difference was not apparent at the earlier post-intubation sampling point, where the mean pH values were closely comparable (p=0.758).

Table 3. Gastric Ph at Post-Intubation and Pre-Extubation Sampling

Sampling Time	Pantoprazole (N=30), Mean ± SD	Esomeprazole (N=30), Mean ± SD	Mean Difference (E−P)	95% CI	Test Statistic; P-Value
Post-Intubation Sample	3.96 ± 1.61	4.08 ± 1.39	0.12	-0.66 To 0.90	T=-0.31; P=0.758
Pre-Extubation Sample	5.27 ± 1.17	6.05 ± 0.86	0.78	0.25 To 1.31	T=-2.94; P=0.005

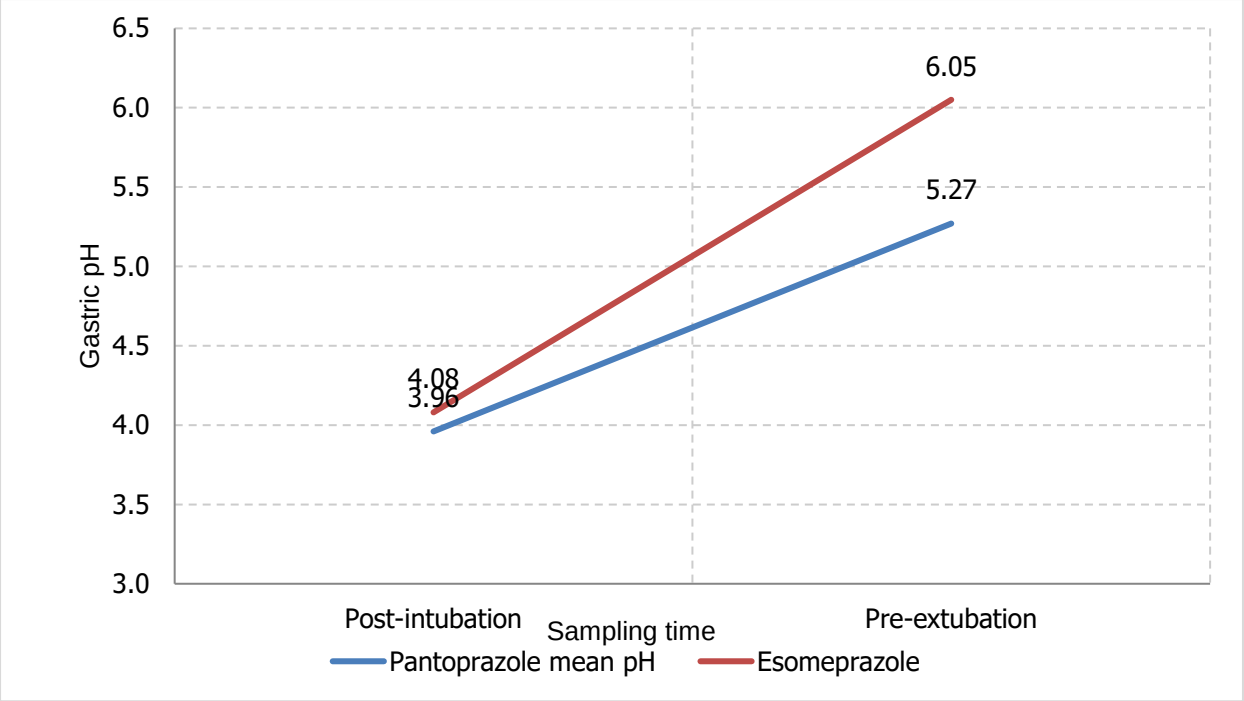

Figure 2. Mean Gastric Ph In the Pantoprazole and Esomeprazole Groups at Post-Intubation and Pre-Extubation Sampling. Error Bars Represent Standard Deviation

Taken together, both regimens were associated with lower gastric aspirate volumes and higher gastric pH at the pre-extubation assessment compared with the earlier post-intubation measurement. The principal between-group distinction was observed for gastric pH, with esomeprazole producing a higher mean pre-extubation pH, while gastric-volume measurements remained comparable between the two treatments.

Adverse Effects

No immediate allergic or other drug-related adverse reaction was recorded in either treatment group during the perioperative observation period. No treatment discontinuation attributable to the study medication was reported.

DISCUSSION

In the present study, the efficacy of a single preoperative intravenous dose of esomeprazole 40 mg and pantoprazole 40 mg was compared in patients undergoing elective abdominal surgery. Both treatments resulted in a decrease in gastric aspirate volume and an increase in gastric pH from post-intubation to pre-extubation sampling. The only difference was in acid suppression, with the mean gastric pH being significantly higher with esomeprazole than with pantoprazole (6.05 ± 0.86 vs 5.27 ± 1.17; mean difference 0.78, 95% CI 0.25–1.31; p=0.005), but gastric volumes were similar. These results indicate that esomeprazole is more effective in suppressing acid during the perioperative period at the same 40-mg intravenous dose, but without a significant effect on residual gastric volume.

This difference is in line with the pharmacodynamic comparison of the two PPIs. Armstrong et al. compared 30 healthy subjects who received esomeprazole 40 mg with 30 who received intravenous pantoprazole 40 mg and found that esomeprazole maintained intragastric pH >4 for 43.4% of the first day, while pantoprazole maintained pH >4 for 25.0% of the first day; on day 5, esomeprazole maintained pH >4 for 59.2% of the day, and pantoprazole maintained pH >4 for 33.9% of the day [10]. Miehlke et al. also reported that esomeprazole had a higher median 24-hour intragastric pH than pantoprazole (6.4 vs 5.1) and that 96.7% of the subjects receiving esomeprazole had pH >4 for >16 hours compared with 56.7% of those receiving pantoprazole (pH >4 for >16 hours) [11]. These studies employed different dosing regimens than the current perioperative regimen, but the direction of effect is similar to our results of increased acid suppression with esomeprazole.

More directly comparable evidence is provided by Piccoli et al., who gave 36 healthy volunteers intravenous esomeprazole 40 mg and intravenous pantoprazole 40 mg.

Intragastric pH was >4 for 47.8% of the time during the first 4 hours after dosing with esomeprazole and 18.9% of the time with pantoprazole. The proportions were 38.8% vs. 23.7% on day 1 and 55.0% vs. 35.2% on day 3 over 24 hours, and the median pH was significantly higher under esomeprazole [12]. This early separation is especially relevant to the present study, since both agents were given 30 minutes prior to induction, and the difference was observed at the later pre-extubation measurement, not immediately after intubation.

This trend is supported by other pharmacodynamic studies. Hunfeld et al. showed that esomeprazole was more acid inhibitory than pantoprazole and explored the relationship of these differences with drug exposure and CYP2C19 polymorphism [13]. These observations suggest that the reason for the similar gastric pH in our groups shortly after induction (4.08 vs 3.96; p=0.758) and then diverged during the intraoperative period is plausible. The results also highlight the need to not assume that equal doses of milligrams of various PPIs will have the same acid suppression effect.

The results of the gastric volume measurements are of a different nature and should be discussed separately. In our study, volume was reduced from 12.00 ± 3.23 to 8.93 ± 3.03 mL with pantoprazole and from 10.88 ± 3.75 to 8.35 ± 3.92 mL with esomeprazole, but there was no significant difference between the post-intubation and pre-extubation values in either group. Previous peri-operative research indicates that acid suppression and gastric-volume reduction are not always correlated. In 87 surgical patients, Cruickshank et al. demonstrated that intravenous omeprazole raised the pH and decreased the number of patients with the traditionally high-risk combination of pH <2.5 and volume ≥25 mL; curiously, one hour before surgery resulted in a higher pH and smaller gastric volume than three hours before surgery [14]. This illustrates the need for timing when interpreting the effects of PPIs perioperatively.

Escolano et al. compared 110 elective surgical patients who were given omeprazole, ranitidine, famotidine or placebo 3 hours prior to surgery. All three active treatments significantly raised gastric pH and lowered gastric volume compared with placebo, but omeprazole was not as effective as the H_2 blockers in increasing pH. In the omeprazole group, 15% had a combined high-risk profile of low pH and high volume, while 23% of the placebo group had a combined high-risk profile, but none of the ranitidine or famotidine groups had a combined high-risk profile [15]. Similarly, in 222 elective surgical patients, Levack et al. found successful gastric characteristics (pH ≥2.5 and volume <25 mL) in 84% of those who received two doses of omeprazole, 84% who received ranitidine, and 73% who received a single 80-mg dose of omeprazole in the morning [16]. These results collectively indicate that the dose schedule and timing can significantly affect the peri-operative gastric characteristics.

Additional support is provided by Nishina et al., who compared the efficacy of rabeprazole, lansoprazole and ranitidine in adults undergoing elective surgery and found that antisecretory therapy before surgery can have a favourable effect on the characteristics of gastric fluid [17]. Their findings, along with the present results, suggest that pH and volume are not necessarily linked endpoints and that increased acid suppression does not necessarily lead to a corresponding decrease in gastric volume.

In the present study, there were no immediate adverse reactions or treatment discontinuations related to the drug in either group. This is in line with the overall good tolerability observed in comparative PPI trials. However, the study was not intended to measure clinical pulmonary aspiration, which is a rare occurrence and would require much larger sample sizes to assess directly. The small sample size, single centre design, limited age range (ASA I–II adults aged 20–50 years) and lack of placebo group reduce the generalizability. Furthermore, the volume of the stomach may not be recovered by nasogastric aspiration, and the two sampling points do not give a continuous picture of the time course of acid suppression.

In general, both PPIs had positive effects on the gastric characteristics during the perioperative period, with esomeprazole having a significantly higher gastric pH at the end of surgery, but similar gastric volumes. This is reinforced by the agreement with pharmacodynamic studies demonstrating more rapid and durable acid suppression with esomeprazole. The observed benefit, however, should be viewed as a superiority in the surrogate endpoint of gastric acid suppression, not as a proven decrease in clinical aspiration events.

CONCLUSION

Both intravenous esomeprazole and pantoprazole improved perioperative gastric characteristics, but esomeprazole produced a significantly higher pre-extubation gastric pH, while gastric aspirate volumes were comparable. These findings suggest superior acid suppression with esomeprazole at equivalent 40-mg dosing, although larger studies are needed to determine whether this translates into a clinically meaningful reduction in aspiration risk.

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