

## COMPARISON OF SINGLE DOSE OF OMEPERPRAZOLE (20MG) VERSUS ESOMEPRAZOLE (40MG) ON GASTRIC ACIDITY

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### ABSTRACT

*Objective:* The objective of this study was to evaluate and compare the effectiveness of single dose of omeprazole 20mg and esomeprazole 40mg on stomach pH.

*Material and Methods:* In this study 50 patients, of ASA class  $p_1$  and  $p_2$  status, of age 15 to 60 years and body mass index (BMI) 20 to 35 kg/m<sup>2</sup> undergoing inguinal hernia surgery electively of both sexes were included. In group "O" 20 mg Omeprazole and in group "E" 40 mg Esomeprazole was given to all participants on the night before surgery at 10 pm and were asked to remain nothing per orum after midnight. In morning after induction of general anaesthesia a multiorifice nasogastric tube (16F) was passed in stomach and verified by auscultation over epigastrium with 10ml air. Gastric fluid was withdrawn in a sterile syringe and transferred to a sterile test tube. pH was determined by calibrated pH paper and was confirmed by pH meter. Nasogastric tube was then removed.

*Results:* In group "O" the median range of gastric fluid pH was 4.5 (1.5 – 7.0). In group "E" it was 7.0 (3.0 – 8.0). P value not significant.

*Conclusion:* Single oral dose of Esomeprazole 40 mg at bed time before surgery has same efficacy in increasing the intragastric pH like single oral dose of Omeprazole 20 mg.

*Key Words:* Gastric pH, Omeprazole, Esomeprazole.

### INTRODUCTION

Pulmonary aspiration of gastric contents is one of the most feared complications of general anaesthesia. Its severity depends both on pH and volume of gastric juice aspirated and the host's factors that predispose patient to aspirate.<sup>1,2</sup>

The risk of gastric aspiration may be reduced by identification of patients at risk, pre-operative fasting, adaptation of various anaesthetic maneuvers and pharmacological interventions. Gastric acidity may be at its peak after overnight fast when patient comes to operation room leading to greater danger of acidic juice aspiration.<sup>1</sup>

In 1946, Mendelson described an "asthma like" syndrome in obstetric patients aspirating gastric contents at induction of anaesthesia and reported 66 cases of airway obstruction.<sup>3</sup> Teabeaut demonstrated in rats that once the pH of inhaled material falls below 2.4 then typical syndrome develops.<sup>4</sup>

Proton pump inhibitors are drugs that provide gastric acid suppression and maintain pH of more than 4 for 18 – 24 hr/day.<sup>5</sup> Different drugs like rabeprazole, esomeprazole, lansoprazole, pantoprazole and omeprazole are used to decrease the gastric acid secretion and increase pH of gastric juice thus reducing the risk of aspiration.<sup>6-11</sup> This study was conducted to evaluate

and compare the effect of preoperative single oral dose of omeprazole 20 mg with esomeprazole 40mg on gastric pH, in patients undergoing elective inguinal hernia surgery under general anaesthesia.

### MATERIAL AND METHODS

After approval by hospital ethics committee and IRB of KEMU, this study was conducted in general surgery operation theatres of Mayo Hospital Lahore. 50 patients of ASA class  $P_1$  and  $P_2$  status, age 15 to 60 years, body mass index (BMI) of 20 to 35 kg/m<sup>2</sup>, of both sexes undergoing inguinal hernia surgery electively were included after written informed consent.

Two groups of 25 patients each were made by using random number table. In group "O" 20mg Omeprazole and in group "E" 40 mg Esomeprazole was given to participants on the night before surgery, at 10pm and were asked to remain nothing per orum after midnight. All patients were reassured and explained about the premedication and general anaesthesia management preoperatively.

In the operation theatre all patients were monitored (ECG, SPO<sub>2</sub>, NIBP, Temperature) and intravenous access was secured with 18G cannula. Ringer lactate was infused at body temperature @ 15 ml/kg.

All participants were pre oxygenated for 3 minu-

tes. Induction was performed with intravenous pentothal 5 mg/kg, nalbuphine 0.1 mg/kg and tracheal intubation facilitated with atracurium 0.5 mg/kg intravenously. Anaesthesia was maintained with 50% oxygen, N<sub>2</sub>O and isoflurane 1.5%. A multiorifice nasogastric tube of size 16 french gauge was passed into the stomach and verified by auscultation over the epigastrium with 10ml air. Gastric fluid was withdrawn in a sterile syringe and transferred to a sterile test tube. pH was determined by calibrated pH paper (Universal indicator pH 0 – 14 Merck) and confirmed by pH meter. Nasogastric tube was then removed. At the end of surgery patients were reversed by using atropine 20 µg/kg and neostigmine 35 µg/kg.

**Data Analysis**

Data analysis was done using SPSS version 15. Patient characteristics were presented as Mean ± SD. Gastric pH was compared by student t-test. P < 0.05 was taken significant.

**RESULTS**

The physical characteristics of the two groups were presented as mean ± SD and did not differ in groups significantly (Table 1 and 2).

Median range of gastric fluid pH was 4.5 (1.5 – 7.0) in group “O” and 7.0 (3.0 – 8.0) in group “E” (Table 3) p value was not significant.

Figure 1 represent number and percentage of patients at risk i.e. four patients out of 25 were at risk in group “O” and no patient was found to be at risk in group “E”. Figure 2 denotes the relationship of premedication period to the pH metery of group “O”.

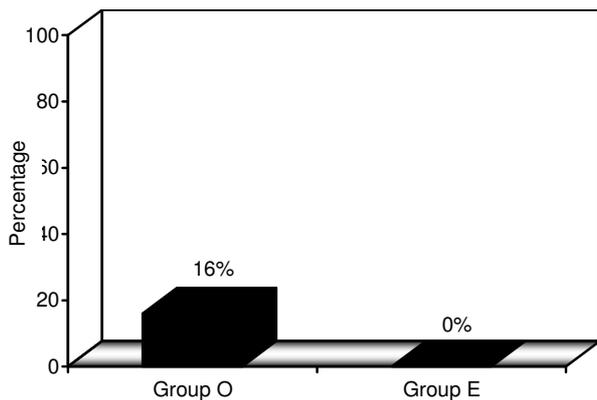


Figure 1: Percentage of Patients at Risk.

No corresponding changes in intragastric pH are seen with increase in premedication time. So results remain quite variable. Figure 3 shows as premedication period was increased the intragastric pH remain well above 2.5 in all cases.

Table 1: Physical Characteristic of Patients (Group “O”).

Characteristic	Median	Mean	SD	Range
Age (yrs)	30	32.8	12.75	16 – 60
Weight (kg)	68	66.32	6.95	55 – 72
Height (cm)	154	156.68	4.81	148 – 170
NPO period (hrs)	12	12.28	1.72	10 – 15
BMI kg/m <sup>2</sup>	28.67	27.02	3.06	24.91 – 32.87

Table 2: Group “E”.

Characteristic	Median	Mean	SD	Range
Age (yrs)	28	29.88	9.11	16 – 46
Weight (kg)	70	69.56	5.75	55 – 76
Height (cm)	165	163.08	10.64	148 – 180
NPO period (hrs)	12	12.08	1.38	10 – 15
BMI kg/m <sup>2</sup>	25.71	25.92	3.21	23.45 – 34.69

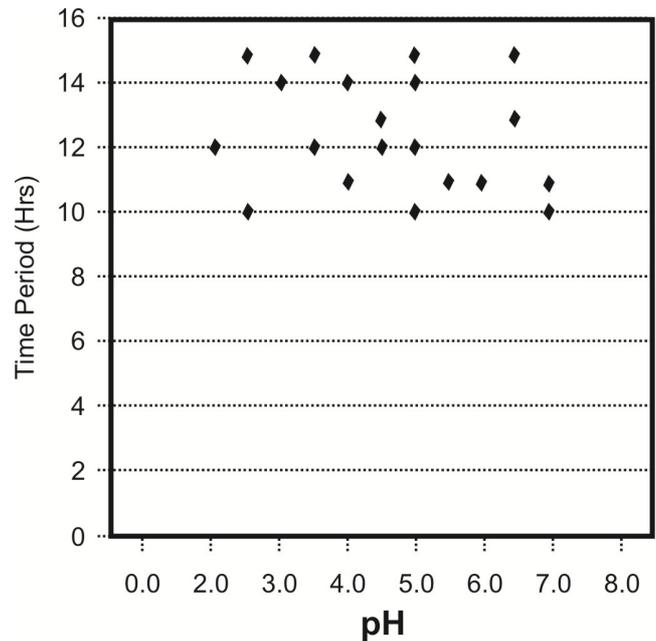


Figure 2: Premedication Period to Time of pH Metry Relationship (Group O).

**DISCUSSION**

Aspiration of gastric contents is one of the major cause of general anaesthesia related morbidity and mortality.<sup>12</sup> Prophylaxis against aspiration may be considered in certain surgeries such as cesarean section.<sup>13,14</sup> Many different pharmacological agents have been used to decrease the intragastric fluid volume and to in-

Table 3: PH of Gastric Contents.

Group	Median	Mean	SD	Range
O	4.5	4.32	1.56	1.5 – 7.00
E	7.0	6.40	1.60	3.00 – 8.00

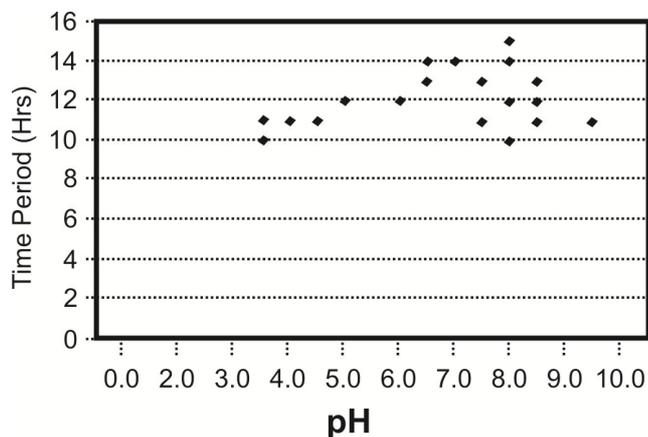


Figure 3: Premedication Period to Time of pH Metry Relationship (Group E).

crease the pH of intragastric fluid.

This trial was aimed to improve the quality of anaesthesia care and to reduce the complications related to acidic gastric pH in pulmonary aspiration of gastric contents. In our study we did not find significant difference regarding increase in pH of gastric fluid with use of esomeprazole and omeprazole. Only one patient was dropped out of study due to occurrence of skin rash that is a common complication of PPI.

The results of our study are in accordance with the study conducted by Miehke S et al. They also did not find statistically significant difference in intragastric pH with the use of omeprazole and esomeprazole.<sup>15</sup> Our results are in consistence with Cruickshank RH et al who concluded that omeprazole has a role in prophylaxis against acid aspiration syndrome when given intravenously 1 hour before surgery as it increased pH of gastric content.<sup>16</sup> Similarly in the study of Gouda BB et al, preoperative oral administration of omeprazole (60 mg) decreased the gastric content volume and increased pH more than 2.5, possibly reducing the effects of pulmonary aspiration of gastric contents.<sup>17</sup> Tripathi et al also found greater increase in gastric pH with omeprazole as compared to ranitidine when given in emergency caesarian section.<sup>18</sup> The results of our study are comparable to study done by Bunno M et al. They used both omeprazole and esomeprazole and found safety and efficacy profiles of esomeprazole plus rebamipide and omeprazole and rebamipide similar for the treatment of endoscopic sub-mucosal dissection induced ulcers.<sup>19</sup> Levack ID, et al, compared effects of oral omeprazole with oral ranitidine on gastric pH and volume

in patients undergoing elective surgery and found that there were no statistically significant difference between two groups.<sup>20</sup> Their results also indirectly support the result of my study regarding efficacy of both groups of drugs.

The results of our study are not supported by Chen CY et al who compared esomeprazole 40 mg with 20 mg omeprazole and found esomeprazole to be better than omeprazole.<sup>21</sup> This could be due to the different methodology as Chen used the drugs for healing of erosive esophagitis for 8 weeks and we assessed the effects of drugs on gastric pH when given the night before surgery.

Contrary to our results, many studies have found greater elevation of gastric pH and better acid control with esomeprazole as compared to other drugs. In a review article Dent J reported superior effect of esomeprazole (40 mg) as compared to omeprazole (20 mg) in achieving a pH of 4.<sup>22</sup> Armstrong D, et al, compared esomeprazole with pantoprazole 40 mg and found that esomeprazole was better than pantoprazole.<sup>23</sup> Wilder – smith C et al, found greater elevation of gastric pH and better acid control with esomeprazole when compared to Lansoprazole.<sup>24</sup> Limited comparability of these studies with ours could be because of discrepancy in patient selection and time of administration of drugs. We suggest need of further large sample size studies to find out more accurate results regarding gastric acid aspiration prophylaxis.

In **conclusion**, a single oral dose of esomeprazole 40mg administered the night before surgery increases the intragastric pH similar to omeprazole 20mg. Thus both drugs have a role in premedication for prevention of acid aspiration at the time of induction of general anaesthesia and have approximately same efficacy.

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