

## EFFECTS OF PROTON PUMP INHIBITORS ON GASTRIC VOLUME AND GASTRIC PH IN ADULT PATIENTS POSTED FOR ELECTIVE OPERATIVE PROCEDURES

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### ABSTRACT

Under general anaesthesia even in elective operative procedure, there are chances of aspiration of gastric contents resulting in acid aspiration syndrome. H<sub>2</sub> antagonists Ranitidine and Proton Pump Inhibitors were evaluated to compare efficacy of the drugs in decreasing gastric volume and increasing gastric pH when administered orally overnight and early in the morning; 250 patients of ASA grade I and II of either sex were divided in 5 equal Groups of 50 patients each. Group I patients received Tab. Placebo, Group II received Tab. Ranitidine 150 mg, Group III received Tab. Omeprazole 20 mg, Group IV received Tab. Pantoprazole 40 mg and Group V patients received Tab. Esomeprazole 40 mg overnight at 10 pm and 6 am morning. Prior to induction of anaesthesia, gastric contents were aspirated after insertion of nasogastric tube (Ryles tube) with the help of syringe. The volume and pH of aspirated gastric contents was measured in all patients. It was observed that in proton pump inhibitors Groups (III, IV and V) and also in Group II (Ranitidine), the gastric volume was significantly less as compared to control Group I. Mean gastric volume in Group II was 13.38±3.3 mL, in Group III 10.7±3.6 mL, in Group IV 10.4±3.4 mL and in Group V 9.58±3.2 mL. There was no significant difference in gastric volume amongst Groups III, IV and V. There was significant difference in proton pump inhibitors Group and ranitidine Group as far as gastric volume was concerned. Mean gastric pH was 5.31±0.48 in Group II, 4.83±0.35 in Group III, 4.82±0.39 in Group IV and 5.17±0.44 in Group V. There was no significant difference in gastric pH in Group II, III, IV and V. Gastric pH and gastric volume were significantly above and below critical values in study Groups as compared to control Group. It is concluded that proton pump inhibitors, Omeprazole, Pantoprazole and Esomeprazole can be administered orally overnight and early morning to increase gastric pH and decrease gastric volume in patients posted for elective operative procedures under general anaesthesia. Proton pump inhibitors satisfactorily increases gastric pH and reduces gastric volume much above critical values. Esomeprazole was found to be superior to Omeprazole and Pantoprazole in this regards.

### KEYWORDS

Critical Gastric Volume Critical pH, Acid Aspiration Syndrome, H<sub>2</sub> Antagonist, Proton Pump Inhibitors.

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### INTRODUCTION

Aspiration of gastric contents into respiratory tract during induction of general anaesthesia and endotracheal intubation has been recognized as a serious complication and may be one of the important cause of death. James Simpson<sup>1</sup> in 1953, reported first anaesthesia death due to this complication and also by (Hamelberge and Bosomworth et al 1964.<sup>2</sup> Bannister and Sattirao 1962.<sup>3</sup> Mendelson (1946).<sup>4</sup> reported 66 deaths during inhalation of nitrous oxide, oxygen and ether in obstetric patients and described as syndrome with wheeze, signs of hypoxia and pulmonary oedema.

This is mainly a problem in obstetric patients in labour where due to altered physiology there is delay in emptying time of stomach. There is possibility of vomiting of stomach contents and possibility of regurgitation and aspiration. The oxyntic cells of stomach secretes, hydrochloric acid with pH 0.87 and concentration about 140 mmol/lit secondary to stimulation due to food particles (Solid and semisolid) in the

stomach. The critical pH of gastric contents responsible for pulmonary damage is 2.5 and critical volume 25 mL in adult patients (0.4 mL/kg).

This problem of aspiration of gastric contents can be minimized by preventing the contents reaching to respiratory tract and rendering the gastric contents less harmful by using various methods.

It is universally accepted that H<sub>2</sub> receptor antagonist are used to reduce the gastric acidity or increase alkalinity. Recently introduced Proton Pump Inhibitors (Omeprazole, Pantoprazole, newer agents Esomeprazole and Rabeprazole) can be tried to decrease gastric volume and increase gastric pH. The present study was undertaken to compare and evaluate efficacy of oral Ranitidine and proton pump inhibitors (Omeprazole, Pantoprazole, Esomeprazole) when given preoperatively in adult patients undergoing elective operative procedures.

### MATERIAL AND METHODS

After approval of Ethical Committee of Medical College, present study was undertaken; 250 patients of either sex between age range of 15-60 years of ASA grade I and II posted for elective operative procedures were studied. These patients were divided into 5 equal groups of 50 patients according to the oral study drugs administered.

From every patient, written valid consent was obtained for anaesthesia and operative procedure and valid consent for insertion of Ryles tube was taken.

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**Group I:** Received Tab. Placebo.

**Group II:** Received Tab. Ranitidine 150 mg.

**Group III:** Received Tab. Omeprazole 20 mg.

**Group IV:** Received Tab. Pantoprazole 40 mg.

**Group V:** Received Tab. Esomeprazole 40 mg.

The patients with known acid peptic disease, gastro-oesophageal reflux, patients on medication like – NSAID, H<sub>2</sub> receptors antagonists or proton pump inhibitors were excluded from the study. All patients were administered the drugs according to Group allotments at 10 pm overnight and 6 am in the morning with sip of water.

On the day of surgery before administration of any premedication, 16-French G Ryles tube was introduced nasally into the stomach. Gastric fluid was aspirated with 20 mL syringe in different positions in order to aspirate the contents maximally to ensure gastric emptying. The volume of gastric content aspirated was measured and pH of gastric fluid was determined with pH meter.

Then all patients were pre-medicated with Inj. Midazolam 0.3 mg/kg, Inj. Pentazocine 0.5 mg/kg. Anaesthesia was induced with Inj. Thiopentone, Inj. Suxamethonium 1 mg/kg and endotracheal intubation. Anaesthesia was maintained on Gas + Oxygen intermittent doses of Inj. Rocuronium 1 mg/kg on controlled ventilation. Intraoperatively, all patients were monitored for vital parameters and at the end of surgery reversal was carried out with Inj. Neostigmine and Inj. Atropine. After complete reversal, all patients were extubated and shifted to recovery room and respective wards.

#### OBSERVATIONS

250 patients were divided into 5 equal Groups of 50 patients, each according to study drugs administered orally.

#### The Age Distribution was as shown in Table I

There were maximum number of patients about 80% in age range of 21-30, 31-40 and 41-50 years in all Groups. Mean age range was 37.02±11.50 years in Group I, 37.52±11.21 in Group II, 36.94±11.16 in Group III, 37.88±11.43 in Group IV and 38.14±11.48 years in Group V. There was no significant difference in age range in all Groups.

#### Sex Wise Distribution was as shown in Table II

There was almost identical sex distribution in all five Groups. There was not much difference in sex distribution.

#### Weight Wise Distribution was as shown in Table III

Maximum number of patients were in weight range of 51-55, 56-60 and 61-65 kg in all Groups. Mean weight in Group I patients was 59.22±5.68 kg, 58.92±5.72 in Group II, 59.00±5.96 in Group III, 58.44±6.08 in Group IV and 58.76±5.80 kg in Group V patients. There was no significant difference in weight range in any Group.

#### In all Patient's Height was Measured in cms and Distribution was as shown in Table IV

The maximum number of patients were having height range in between 151-155 cm, 156-160 cm and 161-165 cm in all Groups.

Mean height in Group I patients was 158.78±5.90 cm, 157.80±6.0 cm in Group II, 158.70±5.55 cm in Group III, 159.0±6.12 cm in Group IV and 158.64±5.93 cm in Group V patients. There was no significant difference in height range was concerned in all Groups.

#### All Patients were Evaluated Pre-anaesthesia for Fitness of Anaesthesia and were Graded as shown in Table No. V

Almost all patients were in ASA grade I to II in all 5 Groups. There was no difference in any Group.

After Ryles tube aspiration, the gastric volume was measured in all patients before induction of anaesthesia. The gastric content aspirated were noted as shown in Table No. VI.

Mean gastric volume in Group I patients was 25.6±3.99 mL in Group I, 13.38±3.66 mL in Group II, 10.77±3.6 mL in Group III, 10.48±3.47 mL in Group IV and 9.58±3.27 mL in Group V patients. Mean gastric volume was highly significantly more in Group I (Placebo Group) as compared to any other Group. There was no significant difference in mean gastric volume amongst Groups III, IV and V. In Group V, mean gastric volume was insignificantly less as compared to Groups III and IV. It was observed that preoperative medication with proton pump inhibitors (Omeprazole, Pantoprazole and Esomeprazole) significantly decreases gastric volume similar to Group II (Ranitidine) as compared to control Group.

In Group I, maximum number of patients (84%) had gastric volume in the range of 21-30 mL. In Group II, 80% of patients had gastric volume in the range of 11-25 mL. In Groups III, IV and V there were maximum number of patients who had gastric volume less than 20 mL, i.e. below critical volume limit of 25 mL.

#### Pre-operatively, Gastric Aspirate was Subjected to Estimation pH with Portable pH Meter and the Readings of Gastric pH in all Groups was noted as shown in Table VII

Mean gastric pH was 3.04±0.4 in Group I patients, 5.31±0.48 in Group II, 4.83±0.35 in Group III, 4.82±0.35 in Group IV and 5.17±0.44 in Group V patients. Gastric pH was significantly acidic in control Group (Placebo) in all patients of Group I. Gastric pH was significantly more alkaline in Group II patients followed by Groups V, IV and III. In Groups II and V, gastric pH was insignificantly more as compared to Groups III and IV. Overall, gastric pH was above critical pH i.e. 2.5 in patients of proton pump inhibitors and H<sub>2</sub> receptor antagonist.

In Group I, more than 76% of patients had gastric pH above critical pH 2.5 in the range of 2.1 to 3.5. In Group II, 92% of patients had gastric pH in range of 4.6-6.0. In Group III and IV, 96% of patients had gastric pH in the range of 4.1-5.5. In Group V, 88% of patients had gastric pH in the range of 4.6-6.0. Thus, in all study Group patients 80-90% of patients had gastric pH in the range of 4.6-6.0, i.e. much higher than critical pH 2.5.

It was observed that 80-90% of patients in Group II (Ranitidine) and Groups III, IV and V (Proton pump inhibitors – Omeprazole, Pantoprazole and Esomeprazole) had gastric volume less than 25 mL and gastric pH more than 2.5, i.e. above critical values.

Age in Years	Group I		Group II		Group III		Group IV		Group V	
	No.	%	No.	%	No.	%	No.	%	No.	%
15-20	3	6	2	4	3	6	3	6	2	4
21-30	13	26	14	28	14	28	12	24	14	28
31-40	15	30	13	26	14	28	15	30	13	26
41-50	12	24	13	26	12	24	13	26	13	26
51-60	7	14	8	16	7	14	7	14	8	16
<b>Total</b>	<b>50</b>		<b>50</b>		<b>50</b>		<b>50</b>		<b>50</b>	
<b>Mean</b>	<b>37.02±11.56</b>		<b>37.82±11.21</b>		<b>36.94±11.16</b>		<b>37.88±11.43</b>		<b>38.14±11.48</b>	

Table I: Showing Age Wise Distribution

Gender	Group I		Group II		Group III		Group IV		Group V	
	No.	%	No.	%	No.	%	No.	%	No.	%
Male	30	60	28	56	31	62	32	64	28	56
Female	20	40	22	44	19	38	18	36	22	44
<b>Total</b>	<b>50</b>		<b>50</b>		<b>50</b>		<b>50</b>		<b>50</b>	

Table II: Showing Sex Distribution

Weight Range in Kg	Group I		Group II		Group III		Group IV		Group V	
	No.	%	No.	%	No.	%	No.	%	No.	%
45-50	2	4	3	6	3	6	2	4	2	4
51-55	14	28	12	24	13	26	14	28	13	26
56-60	14	28	15	30	15	30	14	28	15	30
61-65	12	24	13	26	12	24	12	24	13	26
66-70	8	16	7	14	7	14	8	16	7	14
<b>Total</b>	<b>50</b>		<b>50</b>		<b>50</b>		<b>50</b>		<b>50</b>	
<b>Mean</b>	<b>59.22±5.68</b>		<b>58.92±5.72</b>		<b>59.00±5.96</b>		<b>58.44±6.08</b>		<b>58.76±5.80</b>	

Table III: Showing Weight Wise Distribution

Height in Cms	Group I		Group II		Group III		Group IV		Group V	
	No.	%	No.	%	No.	%	No.	%	No.	%
145-150	3	6	4	8	2	4	3	6	3	6
151-155	13	26	14	28	13	26	13	26	13	26
156-160	15	30	14	28	15	30	14	28	15	30
161-165	12	24	12	24	13	26	13	26	12	24
166-170	7	14	6	12	7	14	7	14	7	14
<b>Total</b>	<b>50</b>		<b>50</b>		<b>50</b>		<b>50</b>		<b>50</b>	
<b>Mean</b>	<b>37.02±11.56</b>		<b>37.82±11.21</b>		<b>36.94±11.16</b>		<b>37.88±11.43</b>		<b>38.14±11.48</b>	

Table IV: Showing Height Wise Distribution

ASA Grade	Group I		Group II		Group III		Group IV		Group V	
	No.	%	No.	%	No.	%	No.	%	No.	%
I	29	58	30	60	31	62	32	64	30	60
II	21	42	20	40	19	38	18	36	20	40
<b>Total</b>	<b>50</b>		<b>50</b>		<b>50</b>		<b>50</b>		<b>50</b>	

Table V: Showing ASA Grade Distribution

Gastric Volume in mL	Group I		Group II		Group III		Group IV		Group V	
	No.	%	No.	%	No.	%	No.	%	No.	%
5 - 10	0	0	10	20	30	60	32	64	35	70
11 - 15	0	0	30	60	11	22	10	20	10	20
16 - 20	8	16	8	16	9	18	8	16	5	10
21 - 25	10	20	2	4	0	0	0	0	0	0
26 - 30	29	58	0	0	0	0	0	0	0	0
31 - 35	3	6	0	0	0	0	0	0	0	0
<b>Total</b>	<b>50</b>		<b>50</b>		<b>50</b>		<b>50</b>		<b>50</b>	
<b>Mean</b>	<b>25.6±3.99</b>		<b>13.38±3.66</b>		<b>10.70±3.64</b>		<b>10.48±3.47</b>		<b>9.58±3.27</b>	

Table VI: Showing Preoperative Gastric Volume

Gastric pH	Group I		Group II		Group III		Group IV		Group V	
	No.	%	No.	%	No.	%	No.	%	No.	%
1.5 – 2.0	2	4	0	0	0	0	0	0	0	0
2.1 – 2.5	6	12	0	0	0	0	0	0	0	0
2.6 – 3.0	12	24	0	0	0	0	0	0	0	0
3.1 – 3.5	26	52	0	0	0	0	0	0	0	0
3.6 – 4.0	3	6	0	0	0	0	2	4	1	2
4.1 – 4.5	1	2	2	4	9	18	12	24	3	6
4.6 – 5.0	0	0	12	24	26	52	24	48	14	28
5.1 – 5.5	0	0	24	48	13	26	10	20	20	40
5.6 – 6.0	0	0	10	20	2	4	2	4	10	20
6.1 – 6.5	0	0	2	4	0	0	0	0	2	4
<b>Total</b>	<b>50</b>		<b>50</b>		<b>50</b>		<b>50</b>		<b>50</b>	
<b>Mean pH</b>	<b>3.04±0.4</b>		<b>5.31±0.48</b>		<b>4.83±0.35</b>		<b>4.82±0.39</b>		<b>5.17±0.44</b>	

**Table VII: Showing Preoperative Gastric pH**

## DISCUSSION

Perioperative morbidity and mortality secondary to aspiration of gastric contents is avoidable complication during induction of general anaesthesia reported by Meril and Hingson et al (1951).<sup>5</sup> 33% by Hall et al (1940).<sup>6</sup> 10-34% by Hamelberg et al (1964).<sup>2</sup> Lunn and Mushin et al (1982).<sup>7</sup> found pulmonary aspiration of gastric contents to be leading cause of death directly related to general anaesthesia.

In 1946, Mandelson.<sup>4</sup> an American Cardiologist reported that obstetric patients who inhaled gastric contents during administration of nitrous oxide, oxygen and ether anaesthesia developed signs of pulmonary oedema. He described the symptoms of acute pulmonary oedema as bronchospasm, hypoxia and secretions. The basis of aspiration was the presence of liquid and semisolid material in the stomach, triggered the emesis and loss of protective reflexes under general anaesthesia disabled the aspirate to travel into respiratory tract.

Borson and Adriani et al (1954).<sup>8</sup>, Hall et al (1950).<sup>6</sup>, Mendelson et al (1948).<sup>4</sup>, Teabeaut et al (1952).<sup>9</sup> Roberts and Shirley et al (1974).<sup>10</sup> and Davidson et al (1970).<sup>11</sup> and many others have worked on gastric volume, gastric pH under general anaesthesia and also on critical volume and critical pH for occurrence of acid aspiration syndrome. They also worked on measures to prevent aspiration of gastric contents into respiratory tract.

Davidson et al (1970).<sup>11</sup> stated that the gastric emptying time is prolonged by 50% from 34 weeks of pregnancy onwards. The contributing factors are pain, anxiety, administration of narcotics and belladonna alkaloids. Crawford et al (1970).<sup>12</sup> and Virginia Bond et al (1979).<sup>13</sup> quoted that critical pH 2.5 is responsible for the symptoms of acid aspiration syndrome, but gastric pH more than 2.5 up to 3.5 may also cause some symptoms of aspiration.

Alkaline mixture of magnesium trisilicate were tried to increase gastric pH, but due to increased gastric volume may not avoid aspiration of gastric contents (Keith Maliniak et al (1979).<sup>14</sup> Schwartz et al (1980).<sup>15</sup> have shown that antacid aspiration to be more harmful than acid aspiration. H<sub>2</sub> receptors present in the stomach are responsible for gastric acid secretion in response to histamine stimulation. H<sub>2</sub> receptor antagonist Cimetidine, Ranitidine, Famotidine counter act release of gastric acid, thereby increases gastric pH.

J Moore et al (1989).<sup>16</sup> observed that proton pump inhibitor Omeprazole increases gastric pH and reduces gastric volume.

In the present study, proton pump inhibitors Omeprazole, Pantoprazole and Esomeprazole were compared with Ranitidine to evaluate efficacy to increase gastric pH and decrease gastric volume when orally administered in elective patients posted for operative procedures. Our demographic data coincides with other authors (F Escolano et al 1992.<sup>17</sup> D. Menis et al 2003.<sup>18</sup> A Hussein et al 2008.<sup>19</sup> and S Sadawarte et al 2009.<sup>20</sup>).

Prior to induction of anaesthesia, gastric contents were aspirated with syringe and measured. Mean volume of gastric aspirate was Group I (Control) 25.6 mL, Group II 13.3 mL, Group III 10.7 mL, Group IV 10.4 mL and in Group V 9.5 mL. The mean gastric volume was significantly less in proton pump inhibitors Groups III, IV and V as compared to Group I. In Group II, mean gastric volume was highly significantly least as compared to control Group and insignificantly more than III, IV and V Groups. Gastric volume was lowest in Esomeprazole Group. Our observations coincides with F Escolano et al (1992).<sup>17</sup>, D. Menis et al (2003).<sup>18</sup> A Hussein et al (2008).<sup>19</sup> and S Sadawarte et al (2009).<sup>20</sup>

In the present study, gastric pH was estimated with portable pH meter after aspiration of gastric contents. Mean gastric pH in Group I was 3.0, in Group II 5.3, in Group III 4.8, in Group IV 4.8 and in Group V was 5.1. It was observed that gastric pH was significantly more in all study Groups as compared to control Group. In Group II, gastric pH was significantly more as compared to proton pump inhibitors.

There was no significant difference in gastric pH among proton pump inhibitors, but pH was significantly more than control Group. Esomeprazole was found to be more efficient (Equivalent to Ranitidine) than Omeprazole and Pantoprazole as far as increase in gastric pH was concerned. Our observations were similar with those of Davil Morison et al (1982).<sup>21</sup> T Gin et al (1999).<sup>22</sup> Escolano et al (1992).<sup>17</sup>, Anand Sagar et al (1996).<sup>23</sup>, K. Nishina et al (1999).<sup>24</sup> A Hussein et al (2008).<sup>19</sup> all have observed proton pump inhibitors significantly increases gastric pH as compared to control Group.

**CONCLUSIONS**

All the time there are every chance of aspiration of gastric contents at the time of induction of anaesthesia and endotracheal intubation even in elective operative procedures. H<sub>2</sub> receptor antagonist Ranitidine is known to increase gastric pH and reduce gastric volume below critical values. Proton pump inhibitors when administered orally (overnight and early in morning) significantly increases gastric pH and decreases gastric volume. So proton pump inhibitors Omeprazole, Pantoprazole and Esomeprazole can be tried to avoid chances of acid aspiration syndrome under general anaesthesia even in elective operative procedures. Esomeprazole was found to be superior to Pantoprazole and Omeprazole in this regard.

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