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An evaluation of the comparative efficacy of preoperative oral omeprazole, lansoprazole and dexrabeprazole on gastric fluid pH and volume in patients undergoing elective surgery under general anaesthesia

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ABSTRACT

Background and Aims: Aspiration of gastric contents in the lungs is one of the most feared complications of anaesthesia. Although the incidence of this complication is very low, it has high morbidity and mortality. The present study was carried out to evaluate and compare the efficacy of omeprazole, lansoprazole, and dexrabeprazole in reducing gastric volume and increasing the fasting pH in patients undergoing elective surgery. **Methods:** After obtaining institutional approval and written informed consent from the patients, 150 patients of ASA physical status 1 and 2, between age 18–55 years undergoing elective surgery under general anaesthesia were included in the study. The patients were randomly assigned to one of the three groups i.e. omeprazole (20 mg) group, lansoprazole (30 mg) group or dexrabeprazole (10 mg) group. Comparison of fasting interval, pH, volume and volume/weight of the aspirate was done using Kolmogorov-Smirnov test and Student Newman-Keuls test. A p-value <0.05 was considered statistically significant. **Results:** The mean pH was significantly lower in omeprazole group as compared to other two groups. The volume of gastric aspirate was significantly higher (p-value <0.005) in omeprazole group than in dexrabeprazole and lansoprazole group. There was no significant difference in the pH and volume of gastric contents in lansoprazole and dexrabeprazole group. **Conclusion:** Newer proton pump inhibitors like dexrabeprazole and lansoprazole are better than omeprazole in controlling gastric fluid environment.

Key words: Anaesthesia, aspiration, gastric pH, gastric volume

INTRODUCTION

Aspiration of gastric contents is a relatively rare but potentially devastating and most feared complication of anaesthesia[1,2]. Pulmonary aspiration is associated with high morbidity and mortality and is a preventable complication. Therefore, the prevention and identification of risk factors of pulmonary aspiration should be the major concern for anaesthetist during perioperative management of the patient. The incidence of pulmonary aspiration is increased in patients with higher ASA physical status, emergency surgeries and in pregnant patients[3].

The methods to prevent aspiration of gastric contents include preoperative fasting, gastric acidity and volume control and airway protection. The drugs used to decrease acid production and increase the pH of gastric contents include H2 receptor antagonists and proton pump inhibitors. Proton pump inhibitors (PPI's) are the most effective acid inhibitors currently available[4]. The PPI's commonly available for clinical use include omeprazole,

How to cite this article: Mehta S, Saroa R, Palta S, Mehta D. An evaluation of the comparative efficacy of preoperative oral omeprazole, lansoprazole and dexrabeprazole on gastric fluid pH and volume in patients undergoing elective surgery under general anaesthesia. Northern Journal of ISA 2016;1:54-57.

Table 1: Demographic Data

Group	N	Females	Males	Mean Age (yrs)	Mean weight (kg)	BMI (kg/m2)	Mean Height (cm)
Omeprazole	50	38	12	39.92±11.128	60.02±9.563	23.65±3.21	158.88±5.133
Lansoprazole	50	34	16	37.04±10.895	61.76±6.878	25.10±2.88	157.17±4.408
Dexrabeprazole	50	35	15	41.48±11.251	62.62±6.629	25.21±2.95	157.77±3.788

pantaprazole, omeprazole, lansaprazole, rabeprazole and dexrabeprazole.

Although a variety of proton pump inhibitors are available, yet studies comparing relative effects of older PPI's with newer PPI's on gastric fluid properties are limited. Hence, the present study was undertaken to evaluate the comparative efficacy of preoperative oral omeprazole, lansoprazole, and dexrabeprazole on gastric fluid pH and volume in patients undergoing elective surgery under general anaesthesia.

METHODS

After obtaining institutional approval and written informed consent, 150 patients of ASA physical status I and II of either gender, between age 18–55 years undergoing elective surgery under general anaesthesia were enrolled into the present study. The patients were randomly assigned to one of the three groups i.e. omeprazole (20 mg) group, lansoprazole (30 mg) group or dexrabeprazole (10 mg) group. Patients were given one of the three drugs (omeprazole, lansoprazole and dexrabeprazole) as per random table assignment along with alprazolam 0.25 mg on the night prior to surgery and two hours before the surgery. General anaesthesia was given to patient using standard technique with thiopentone (2-4 mg/kg) and vecuronium (0.1 mg/kg). Maintenance of anaesthesia was done with isoflurane, 60% N_2O and 40% oxygen.

After endotracheal intubation and fixation of the tube, 12–14 Fr Ryle's tube was inserted in the stomach and confirmed by aspiration of typical gastric juice or auscultation of injected air into stomach. With the patient in supine, both lateral and reverse trendelenberg positions, gastric fluid was aspirated through a 50 ml syringe. Repeated attempts were made to maximise the volume of aspiration. The volume of aspiration was measured directly from 50 ml syringe and pH measurement was done immediately with a digital electronic pH meter having range of 0-14 pH and accuracy of 0.01 pH (model 131 E, MS Electronics, India).

Comparison of fasting interval, pH, volume and Volume/weight of the aspirate was done using Kolmogorov-Smirnov test and Student Newman-Keuls test. A p-value <0.05 was considered statistically significant. Power analysis revealed that the sample size of current study (n=50) was sufficient to obtain differences in the above mentioned variables at a power of 0.8.

RESULTS

The demographic data including age, weight, sex, height and BMI were statistically insignificant in three groups as shown in Table 1. The fasting interval between three groups was comparable and was not statistically significant (Table 2).

Table 2: Mean fasting interval in various groups

Group	Mean fasting interval (hours)	Standard deviation
Omeprazole	10.05	1.447
Lansoprazole	10.32	1.335
Dexrabeprazole	10.09	1.757

The mean pH of gastric aspirate in omeprazole group was 5.72±0.87 and was the lowest as compared to other two groups. The mean pH in lansoprazole group and dexrabeprazole was 6.35±0.81 and 6.15±0.70 respectively. The mean pH in omeprazole group was significantly lower than the other two groups, whereas, the mean pH was greater in lansoprazole group but it was statistically not significant in comparison to dexrabeprazole.

The mean volume of aspirate (in ml) of patients was 10.64±2.15 in omeprazole group, 9.96±2.48 in dexrabeprazole group and 10.03±2.35 in lansoprazole group. The volume analysis revealed significant difference in omeprazole group and the other two groups. However, there was no statistical correlation betweem dexrabeprazole and lansoprazole group.

The mean volume/weight of aspirate (ml/kg) of patients in omeprazole group was 0.18±0.05, while in lansoprazole group it was 0.16±0.49 and 0.16±0.46 in dexrabeprazole group (Table 3). The results in all the three groups were statistically insignificant.

Table 3: Showing mean pH , volume and volume/weight of gastric aspirate

Group	Mean pH	Mean volume (ml)	Volume/ weight(ml/kg)
Omeprazole	5.72±0.87	10.64±2.15	0.18±0.05
Lansoprazole	6.35±0.81	10.03±2.35	0.16±0.49
Dexrabeprazole	6.15±0.7	9.96±2.48	0.16±0.46

DISCUSSION

Aspiration of gastric contents is a life threatning and preventable complication of anaesthesia[1]. Though the incidence of pulmonary aspiration has steadily decined over past decades, the complications following acid aspiration still have major morbidity and mortality. Robert and Shirley postulated that a gastric pH of 2.5 or less and gastric volume of 0.4 ml/kg or more for an average adult was considered critical for pulmonary damage[5]. Proton pump inhibitors are the newest group of drugs that have shown the potential to decrease gastric volume and increase gastric pH.

The main finding of the present study was that lansoprazole and dexrabeprazole are more effective than omeprazole in decreasing the volume and improving the acidity of gastric contents. This can be explained by the pharmacodynamics of lansoprazole and dexrabeprazole. Proton pump inhibitors act on the gastric parietal cells and inhibit H^+K^+Atpase pump decreasing acid secretion in its final step[6]. Omeprazole and lansoprazole binds irreversibly to the pump whereas rabeprazole binds reversibly to the receptors and dissociates more rapidly leading to its shorter duration of action[7]. Rabeprazole has greater antisecretory properties than omeprazole. A study by Bruley *et al*. showed that a low dose of Rabeprazole results in stronger and more rapid anti secretory activity than low dose of omeprazole (10 mg). Dexrabeprazole is R(+) enantiomer of rabeprazole that is more effective than racemic mixture in inhibiting acid related gastric lesions[8].

The results of our study are in line with the results of the study done by Nishina *et al*. in 2000 comparing lansoprazole, rabeprazole and ranitidine[9]. A single dose of ranitidine was most effective in controlling gastric fluid environment. Administration of two consecutive doses of rabeprazole was the second most effective regimen followed by two consecutive doses of lansoprazole. Our study has also demontrated equal efficacy of lansoprazole and dexrabeprazole.

The present study demonstrated that dexrabeprazole 10mg was better than omeprazole 20 mg in controlling pH and volume of gasric aspirate. The results are in accordance with study done by Prakash and Faulds, the difference being only that the study drug in this study was rabeprazole 10 mg compared to dexrabeprazole 10 mg in the present study[7]. In a recent study by Pai *et al.* in 2007, dexrabeprazole (10 mg) was reported to be more effective than rabeprazole (20 mg). This basically highlights the difference in potency between rabeprazole and dexrabeprazole[10].

The results of this study are in contrast with the results of the study done by Miner etal in 2010[11]. Miner *et al*. compared omeprazole 20 mg with lansoprazole 15mg for increasing gastric pH and decreasing gastric volume. Omeprazole was better than lansoprazole in controlling pH and volume of the gastric contents. The difference in results of present study with respect to this study may be in the use of 30 mg lansoprazole as compared to 15 mg in the study done by Miner.

The major limitation of the present study was that it was done in patients with ASA physical status I and II undergoing elective surgery. Whereas, the risk of aspiration is higher in patients with greater ASA physical status III and IV and patients undergoing emergency surgery. Also, this is a single center study and to get more unbiased results multicentric studies are required for comparing the efficacy of these drugs in patients at higher risk. The other limiting factor in our study was the use of a syringe for gastric aspiration, which may not completely aspirate the gastric volume, therefore possibly underestimating the volume of gastric aspiration. Visually guided gastroscope or dye dilution techniques are the alternative methods that can measure gastric volume more accurately[12]. The only disadvantage of newer PPI's is the non availability of parenteral formulations of these drugs, which potentially limit the use of these agents for prophylaxis of aspiration pneumonia in unconscious patients.

Although all these drugs have shown to reduce gastric volume and increase gastric pH thus improving the gastric environment before the surgery, but still there is no evidence to support the routine use of these drugs to prevent aspiration because of the infrequent incidence of this complication[2]. However, the newer studies have challanged the concept of critical volume (0.4 ml/kg) and pH of less than 2.5 for pulmonary damage[4]. The recent guidelines by American Society Of Anaesthesiolgists do not recommend the routine use of gastric anti secretory drugs in patients with ASA physical status I and II except in the high risk patients[13].

CONCLUSION

Our study clearly shows that lansoprazole and dexrabeprazole are better than omeprazole for improving the gastric acidity and decreasing the volume of aspirate. However, the use of proton pump inhibitors for reducing

the risk of aspiration is not routinely recommended except in high risk cases.

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