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Original Research Article

A Study to Determine the Efficacy of 0.3M Sodium Citrate as an Antacid Prophylaxis against Aspiration Pneumonitis in Obstetric Patients Undergoing Elective Caesarean Section under General Anesthesia

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Abstract:

Background: Aspiration pneumonitis is a syndrome resulting from the ingestion of gastric contents. The incidence in obstetric anesthesia has fallen, largely due to improved anesthetic techniques and the increased use of regional anesthesia at caesarean section. However, aspiration pneumonitis is still a cause of maternal morbidity and mortality, and it is important to use effective prophylaxis, 0.3M sodiumcitrate has been shown to elevate gastric pH when given as a single dose prior to induction and thereby minimizing the risk of aspiration**.**

Aims & Objectives: aim of this study was to determine the effectiveness of 0.3M sodium citrate, a non-particulate antacid, in neutralizing secreted gastric acid as prevention of aspiration pneumonia. To assess the ph of the gastric aspirate after induction and at the time of extubation in the study and control groups. To assess the change in gastric ph before and after giving 0.3M sodium citrate.

Materials and Methods: 50 patients selected and evaluated were randomized by simple random sampling into two groups of 25 patients each. Group A-25 received 30 mL of test solution A. Group B-25 received 30 mL of Control Solution B. Both solutions were stored in identical amber bottles. 25 patients who received 30 mL of 0.3M sodium citrate were categorized into group A or study group. The remaining 25 patients who received 30 ml of distilled water were categorized into groupB or control group.

Conclusion: We conclude that the non-particulate antacid 0.3M sodium citrate, givenorally about 20 min before induction of anesthesia, is an effective and safe antacid for prophylaxis against aspiration pneumonitis in all elective obstetric surgeries without producing any side effects.

Keywords: Aspiration Pneumonitis, Obstetric Anesthesia, Sodium Citrate Prophylaxis.

Introduction

Aspiration is one of the most common intraoperative complications in patients referred for surgery under general anesthesia. A subset of obstetric patients has a longer gastric emptying time and a reduced LES tone, resulting in a much higher risk of aspiration. They are therefore considered as full stomach patients. A recent maternal death study report from India found that most fatal events due to intra operative anesthesia were related to anesthesia induction time. This is due to two main causes- aspiration of stomach contents and cardiac arrest due to unsuccessful intubation.

Aspiration can occur in 1 in 3000 cases of anesthesia and accounts for 9% to 25% of anesthesia-related deaths. Micro particulate antacids such as aluminium hydroxide and magnesium trisilicate have been used to induce responses of lung injury in animal models. [1] Therefore, particulate antacids should be avoided in the perioperative setting. This has led to the use of non-particulate antacids.

Among all non-particulate antacids, 0.3M sodium citrate is the most popular. This drug is especially useful for neutralizing stomach acid during surgery. Gastric contents with pH less than 2.5 and a volume greater than 25 mL increase the risk of lung aspiration. 0.3M sodium citrate has been shown to elevate gastric pH when given as a single dose prior to induction and therebyminimizing the risk of aspiration. [2] There are few studies or reviews on the use and efficacy of sodium citrate as an antacid prophylaxis in the Indian scenario, conducted to facilitate the daily use of sodium phosphate. In this study, the pH of gastric content samples before and after administration of sodium citrate

is measured with a digital pH meter and is used to determine the efficacy of 0.3 Molar sodium citrate.

Methods to Reduce Risk of Regurgitation and Pulmonary Aspiration [3]

- Minimize intake: Adequate preoperative fasting, Clear liquids only if necessary, Increase gastric emptying
- Prokinetics (e.g., metoclopramide)
- Reduce gastric volume and acidity: Nasogastric tube aspiration, Nonparticulate antacid (e.g.,0.3.M sodium citrate) [4] H2-receptor antagonists (e.g., ranitidine) [5]
- Airway management and protection during anesthetic induction and intubation: Cricoid pressure (Sellick's manoeuvre) [6] Cuffed endotracheal intubation- provides better airway seal [7] ProSeal laryngeal mask airway has a gastric drainage port, and the cuffprovides a better seal when compared to classic LMA

Preoperative Fasting Guidelines for Elective Surgery- Asa-2011 [5], 2011 [8]:

Food Material	Minimum Fasting Period required
Clear liquids	**2hrs**
Breast milk	**4hrs**
Nonhuman milk, Infant formula, Light meal	**6hrs**
Fatty, heavy meals	**8hrs**

Pharmacology of Non-Particulate Antacid- 0.3 Molar Sodium Citrate: 4 Sodium citrate is considered to be one of the most effective medications used for the immediate neutralization of the acidic gastric contents.

Mechanism of action and dosage: Sodium citrate is the salt of a weak acid. When given orally, it gets mixed and combined in the stomach with hydrochloric acid, a strong acid. This reaction produces sodium chloride and citric acid, a weaker acid, which acts as a buffer increasing the intragastric pH.

The formulation used in this study is AmbNPA® - available as a 30ml solution containing sodium citrate IP 500mg, and citric acid monohydrate IP 334mg per 5ml of solution. It is given as a single dose of 30ml just 10-20 minutes before induction of anesthesia and is effective in increasing the gastric fluid pH above 2.5.

There is no lag time in the onset of action of sodium citrate as seen with H2 blockers. [9] This drug mainly exerts its effect by acting on the fluid already present in the stomach.

Aims & Objectives of the Study

Aim: The purpose of this study was to determine the effectiveness of 0.3 M sodium citrate, a non-particulate antacid, in neutralizing secreted gastric acid as prevention of aspiration pneumonia in obstetric patients undergoing elective lower caesarean section under general anesthesia.

Objectives:

- To assess the pH of the gastric aspirate after induction and at the time of extubation in the study and control groups.
- To assess the change in gastric pH before and after giving 0.3 M sodium citrate.
- To determine the efficacy of 0.3M sodium citrate in neutralizing gastric acid secretion

Materials and Methods

After getting approval from the institutional ethical committee of Govt Medical College, Kadapa, and informed, written consent, fifty pregnant patients with term gestation having an American society of anesthesiologist grade I & II undergoing lower segment caesarean section electively under general anesthesia were enrolled in the study.

This study was conducted in government general hospital, Kadapa.

Study Design: Our study was a double-blinded, prospective randomized controlled study

Study Groups: 50 patients selected and evaluated were randomized by simple random sampling into two groups of 25 patients each.

Group A-25 received 30 mL of test solution A. Group B-25 received 30 mL of Control Solution B. Both solutions were stored in identical amberbottles. Therefore neither the patient who received it nor the person who gave it knew what was in the bottle.

The analyzer then separated them into two groups. 25 patients who received 30 mL of 0.3 M sodium citrate were categorized into group A or study group.

The remaining 25 patients who received 30 ml of distilled water were categorized into group B or control group.

At the end of surgery, all patients in both groups received Inj Ranitidine 50 mg IV to protect against the risk of aspiration. After removal of the gastric aspirate prior to extubation.

Inclusion Criteria:

- Patients undergoing elective Lower segment caesarean section under generalanesthesia.
- Patients fasting for more than or equal to 8hrs
- Particulate antacids were not used

preoperatively

Exclusion Criteria:

- Patients with Body mass index > 30
- Patients with any anticipated difficult airway
- Patients undergoing emergency surgery
- History of any drug use or disease which alters the gastric secretion
- History of any drug allergy
- Patient's refusal for general anesthesia

Parameters Observed in the Study:

- Baseline vital parameters- PR, BP, SpO2
- Baseline pH of the aspirate.
- A pH of gastric aspirate – at 30 min following induction
- pH of gastric aspirate – before extubation.
- Incidence of nausea and vomiting
- Incidence of pulmonary aspiration in the post-op period
- Post-op vital parameters.

The following parameters are measured, analyzed, and compared during the study periodin the test and control groups. The pH of gastric aspirate –

1. Baseline (before induction of anesthesia)
2. The pH of gastric aspirate – at 5 min after induction
3. The pH of gastric aspirate – at 30 min following induction
4. The pH of gastric aspirate – during extubation
5. The number of patients at high risk of aspiration (based on baseline pH of gastric aspirate.

Statistical Analysis: (Done by using SPSS software version 29.0.0.0 (241)

- It is a randomized, double-blind clinical study
- all Variables were analyzed with the student t test and Mann and Whitney U test
- Sample size obtained according to previous background study.
- p value < 0.05 was taken as significant

Observation & Results

Table 1: Distribution of Age-Group among Groups

Age – Groups (in year)	Group – A No. of patients (%)	Group – B No. of patients (%)
20 – 22	4 (16 %)	8 (32%)
23 – 25	13 (52 %)	12 (48%)
26 - 28	8(32 %)	5 (20%)
>28	0 (0)	0 (0)
Total	25 (100.0	25(100.00)

The age group distribution shows more patients in 23-25 age in both the study (groupA) and control (group B) groups.

Table 2: Fasting Duration in Study and Control Groups

Group	No of patient	Mean (Hrs)	Standarddeviation	'P' Value
Group A(study)	25	9.40	0.816	0.163
Group B(control)	25	9.04	0.888	

This table compares the fasting duration (in hours) in the pre-operative period, which is almost the same – 9 hours in both the groups.

Table 3: Mean pH Values at Various Intervals in the Study and Control Groups

Variables	Group A(study)		Group B(control)	
Baseline pH	2.	0.89	2.	0.65
pH after 5 min	4.	1.12	2.	0.70
pH after 30 min	4.	1.11	2.	0.73
pH before extubation	4.	1.13	2.	0.68

The values are expressed in mean ± SD. The mean baseline pHs in study and control groups are 2.94 and 2.80 respectively and there is no statistical difference in baseline pHvalues in both. After administration of the test solution, the pH values in the study groupat 5min, 30min and extubation are all at a higher range than that of control group, signifying the acid neutralizing effect of0.3M sodium citrate in the study group.

Table 4: Comparison of pH at 5min of Induction between Two Groups

Groups	Ph at 5min	Mean Rank	Sum of rank	Mann- Whitney U test value & - value
Group A(study)	4.58	34.92	873.00	**77.00**
Group B(control)	2.87	16.08	402.00	**0.0000024** **Highly Statistically Significant**

The table 4 shown compares the pH values at 5 min after induction, after the test drug is given inthe study and control groups. A highly statistical difference was observed in between the groups. This implies that sodium citrate increases the pH of the gastric contents well above than the pH in control group.

Table 5: Comparison of pH at 30 Min of Induction between Two Groups

Groups	an Ph at30mi	Mean Rank	Sum of rank	Mann- WhitneU test value &p - value
Group A(study)	4.58	35.80	895.00	**55.00** **0.00000029** **Highly Statistically Significant**
Group B(control)	2.87	15.20	380.00	

In table 5, the pH in the study group is higher than in the control group, as seen by the difference in mean ranks in both the groups. A p value of <0.001 is observed in this table,implying high statistical difference in pH between the groups.

Table 6: Patients at High Risk (pH < 2.5) at Various Intervals

Sampling intervals	p A(study)N= 25	B(control)N=25
Baseline	11 (44 %)	11 (44%)
5 minutes after induction	0 (0)	10 (40%)
30 minutes after induction	0 (0)	9 (36%)
Extubation	0 (0)	11 (44%)

Table 6 shows the number patients who are having a pH of less than 2.5 in both the groups at various time intervals after induction and at extubation. They in turn fall under the high risk category for pulmonary damage if aspiration occurs, as per criteria. From this table, it is evidentthat, no patient in the study group came under high risk.

Discussion

Based on the observation and results obtained in our study, 25 patients in each group are discussed in detail by comparing them with the available evidence in the literature. In our study comparing the efficacy of 0.3 molar sodium citrate, anon-particulate antacid, with the control group, the mean age, weight, and Body Mass Index were comparable among the two groups (Tables 1,2,3,4).

Our results show that 0.3M sodium citrate is effective as a form of anti- aspiration prevention by increasing the pH of gastric contents than that of the control group. In turn, it lessens the damage to pulmonary mucosa. If aspiration of this less acidic gastric content occurs, 0.3 molar sodium citrate, 30ml when given in 20min before induction, raises the pH of gastric contents to above 2.5, in the protective range. The study group chosen was pregnant women undergoing elective LSCS. This type of patient is considered full stomach even after they are allowed adequate fasting time in the preoperative period. Hence, they are always at a greater risk of aspiration during the peripartum period. Procedures under general anesthesia in this group carry even higher risk, especially during intubation and extubation.

The dosage of sodium citrate was 30ml. In his study, Lahiri et al [10]. Found that 5 ml of 0.3 molar sodium citrate increased the gastric pH above 3.0 in 21 of 22 parturient. Later, Heath and Hester analyzed the same volume and dosage of sodium citrate and found no difference between the treated and untreated groups. In the subsequent related studies, they increased the volume of sodium citrate twice and the buffering capacity of the antacid administered and successfully brought the gastric content ph to above 2.5. In our study also, 30ml was used to increase the pH.

Curtis Lester Mendelson [11] analyzed and described the remarkable article, Aspiration of gastric contents into the lungs under obstetric anesthesia. He found aspiration in 66 cases out of 43,000 pregnancies. This equals a noticeable incidence of about 1 in 660 pregnancies. Nowadays, occurrence is much lesser, but it still represents the most common cause of anesthetic death in pregnant women.

Roberts et al [12]. Did an advanced study on the using sodium citrate as antacid prophylaxis in an obstetric subset of patients and concluded that it could be an effective regimen when compared with existing pharmacological interventions for aspiration. Based on their studies, they formulated that Volumes of gastric aspirates above 0.3 to 0.4 ml/kg (or) 20 to 25 millilitres maybe dangerous and causes aspiration pneumonitis if inhaled.

Warner et al [13]. From July 1985 to June 1991 he had undergone 215,488 general anesthesia surgeries in all surgical specialties, and his 172,334 consecutive patient laps over the age of 18. The perioperative course was retrospectively reviewed. Pulmonary aspiration may be associated with the presence of bile secretions or particles in the tracheobronchial tree or on postoperative chest radiographs not identified on preoperative radiographs in patients in whom the tracheobronchial airway was not directly examined

after regurgitation and was defined as the presence of infiltration on Physical examination.

Conclusion

We conclude that the non-particulate antacid 0.3M sodium citrate, given orally about 20 min before induction of anesthesia, is an effective and safe antacid for prophylaxis against aspiration pneumonitis in all elective obstetric surgeries without producing any side effects.

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