Evaluation of Gastric Emptying by Ultrasonography after Recommended Fasting Period and Administration of Prokinetic in End-stage Renal Disease Patients

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Abstract

Background: Delayed gastric emptying is observed in end-stage renal disease (ESRD). Aims: Evaluation of gastric emptying after recommended fasting period and on oral administration of prokinetic in ESRD patients using ultrasonography (USG). Settings and Design: Randomized, double-blind, prospective, controlled study. Materials and Methods: After institutional ethics committee approval, 200 patients were divided randomly into two equal groups. Three sessions of USG evaluation of gastric antrum were done in supine and right lateral position for assessing gastric emptying, first at 8 am, second after the light meal at 8.30 am, and third after 6 h of light meal. Group A received placebo (sugar-coated pill) and Group B received tablet metoclopramide hydrochloride 10 mg after second session of USG. In each session, measurement of anteroposterior and craniocaudal diameters of gastric antrum was done, and then cross-sectional area was estimated. Three-point grading system (Perlas) was used to perform qualitative evaluation. Statistical Analysis: Comparison of normally distributed continuous variables was performed using Student’s t-test. Nominal categorical data were compared using Chi-squared test. Nonnormal distribution continuous variables were compared using Mann–Whitney U-test. Results: 6 h of fasting after light meal showed that Group A only had 14% incidence of complete gastric emptying, whereas Group B had 71% as compared by Perlas grading. Gastric antral cross-sectional area measured both in supine (480.89 ± 84.92) and right lateral (575.40 ± 92.62) position of Group A was more than Group B supine (394.15 ± 62.80) and right lateral (470.25 ± 73.63) position (P < 0.05). Conclusion: USG of ESRD patients preoperatively can evaluate gastric contents to assess risk of pulmonary aspiration and guide anesthetic management. Metoclopramide is a good drug to enhance gastric emptying in ESRD patients within the recommended fasting period.

Keywords: End-stage renal disease, gastric antrum, metoclopramide hydrochloride, stomach, ultrasound imaging

Introduction

Until the advent of ultrasonography (USG), there was no point-of-care device for the assessment of gastric volume and content.[1] Recently published studies have shown the use of ultrasound for the assessment of gastric volume and content in healthy controls, children, obese patients, women in labor, and surgical patients.[2-6]

In end-stage renal disease (ESRD) patients, the most common gastrointestinal disorder is dyspepsia with a prevalence of 48%–70%.[7] It is characterized by bloating, upper abdominal pain or discomfort, early satiety, postprandial fullness, nausea with or without vomiting, anorexia, regurgitation, and belching.[8] A study conducted by Strid et al. observed an association between delayed gastric emptying and gastrointestinal symptoms, showing gastric emptying delay in chronic renal failure (CRF) patients.[9] In ESRD patients who are either managed conservatively or undergoing
hemodialysis, gastric emptying is delayed.\[^7\] Gastric emptying time is significantly prolonged in about one-third of ESRD patients having hemodialysis.\[^1\] Due to gastric emptying delay in CRF patients, anesthetists often prefer rapid sequence induction to prevent pulmonary aspiration. However, there is no well-defined method to identify patients showing gastric emptying delay.

Guidelines have been developed by anesthesiology societies for preoperative fasting.\[^10\] Pulmonary aspiration risk and the management is closely related to the current recommendations of fasting guidelines. It is not clear that the current preoperative fasting guidelines apply on the patients with renal failure, which is recommended by anesthesia societies.\[^7\]

This study was designed to evaluate gastric emptying in ESRD patients after following universal fasting guidelines and to compare and evaluate the effect of prokinetic and placebo on gastric emptying in ESRD patients by comparing USG assessment of gastric antrum.

**Materials and Methods**

The study was conducted in the department of anesthesiology along with the department of radiology, over a period of 12 months. Participants were recruited from patients presenting in the department of urology posted for elective surgery. After obtaining permission from the institutional ethics committee (SRHU/HIMS/ETHICS/2019/92), written informed consent was taken from the participants included in the study.

We have taken a total of 200 patients of either sex with age between 18 and 60 years having the American Society of Anesthesiologists (ASA) physical status classes II and III. Patients having body mass index (BMI) <40 kg/m\(^2\) and receiving regular hemodialysis treatment were included in the study. We have taken fasting duration >2 h for transparent liquids and duration of fasting >6 h for nontransparent liquids and solids in the study. Patients having diabetes mellitus, history of disease of gastrointestinal tract, and previous history of surgery of the gastrointestinal tract and allergic to metoclopramide were excluded from the study [Figure 1].

After explaining the procedure in detail, written informed consent was taken from all the patients. Thorough preanesthetic assessment and routine laboratory investigation as applicable were performed and all the eligible patients were enrolled. All participants were kept fasting overnight before the procedure. Ultrasound examinations were performed in three sessions.

The first session of USG was performed in morning at 8 am after overnight fasting. Thereafter, patients were provided with light meal comprising 150 ml of black coffee or black tea or clear apple juice with one bowl of oatmeal (166 calories), two brown toast (65 calories), and bowl of fruits (69 calories), which had to be eaten over 15–30 min. The meal provided was same to all the patients. The second session of USG was performed 15–30 min after the light meal at around 8.30 a.m.

| ASSESSED FOR ELIGIBILITY (n = 240) |
|-----------------------------------|
| Included in the study (n = 200)   |
| Age - 18–60 years                 |
| Either sex                       |
| Regular hemodialysis             |
| BMI <40kg/m²                     |
| ASA physical status II, III.     |
| Excluded from the study (n = 40) |
| Patient did not give consent - 20|
| History of diabetes - 10         |
| Patients allergic to metoclopramide - 5 |
| H/o of gastrointestinal disease -5 |

Figure 1: Consort diagram

The patients were divided randomly into two equal groups of 100 patients each by computer-generated table of random numbers. The drug was handed over to the nurse in charge of the patients in similar looking thick opaque envelope mark A or B to be administered as per the instruction. The nature of the drug was not known to the nurse.

Group A (n = 100): Patients received placebo (sugar-coated pill).

Group B (n = 100): Patients received tablet metoclopramide hydrochloride 10 mg (Perinorm™, IPCA Laboratories, Mumbai, Maharashtra, India).

The patients, the radiologist, and anesthesiologist recording the data were blind to the group allocated to the patients. Anesthesiologists were unaware of the sonographic findings. Anesthetic and surgical team proceeded according to the institutional guidance. Participants were permitted to have clear fluids (fluids which are transparent, easily digestible, and have no undigested residue in intestinal tract such as water, black coffee, apple juice, and pulp free orange juice) up to 2 h before performing the third session, but not allowed to take solids. The third session was performed after 6 h of light meal which was around 14:30 h.

A focused gastric USG was performed by the same experienced senior radiologist in supine [Figure 2] and right lateral decubitus [Figure 3] positions. A curvilinear low-frequency 1–5 MHz probe was used (Model number: EPIQ – 7G, serial number: US514B0146, probe number: C5-1: BIZQJV ultrasound system). The gastric contents had two estimations, quantitative and qualitative, which were performed in the supine and the right lateral decubitus positions.\[^11\] A characteristic multilayered wall present in the gastric antrum
Antral cross-sectional area = Anterior posterior × craniocaudal diameter × π/4

The three-point grading system which is described by Perlas et al. was used to perform qualitative evaluation. The procedure to perform the mentioned three-point grading system was as follows: if the antrum was flattened and empty in both supine and right lateral positions, Grade 0 was assigned; if fluid was seen in the antrum only in the right lateral positions, Grade 1 was assigned; and if fluid or food was observed in the antrum in both positions, Grade 2 was assigned.\[6\]

Statistical analysis

Study design

Type of the study: Randomized, double-blind, prospective, controlled study.

Sample size and sampling methods: The sample size for the study was calculated by the formula:

\[
n = \frac{(\sigma_1^2 + \sigma_2^2) (Z_{1-\alpha/2} + Z_{1-\beta})^2}{(M_1 - M_2)^2}
\]

where \(n\) is the required sample size, \(Z_{1-\alpha/2}\) is the critical value of the normal distribution at \(\alpha/2\), \(Z_{1-\beta}\) is the critical value of the normal distribution at \(\beta\), \(\sigma_1\) and \(\sigma_2\) are the standard deviations (SDs) of the two groups, \(M_1\) and \(M_2\) are the means of two groups.

For a confidence level of 95%, \(\alpha\) is 0.05 and the critical value is 1.96. For a power of 90%, \(\beta\) is 0.1 and its critical value is 1.282.

We anticipated a mean difference of 50 in the volume of gastric contents between the control and renal failure using USG as being clinically meaningful. Hence, we calculated that 100 patients were required in Group A and B for a type I error of 0.05 and a type II error of 0.2 with an effect size of 0.50. We increased the recruitment by 20% to compensate unexpected loss.

Interpretation and analysis of obtained results was carried out using Microsoft Excel. The data were analyzed for statistical analysis using Microsoft Excel 2010 and SPSS IBM version 22, IBM SPSS Statistics base (SPSS South Asia Pvt., Ltd., Bengaluru, Karnataka, India). Continuous variables were presented as mean ± SD and categorical variables were presented as absolute numbers and percentages. The comparison of normally distributed continuous variables between the groups was performed using Student’s \(t\)-test. Nominal categorical data between the groups were compared using Chi-squared test. Nonnormally distributed continuous variables were compared using Mann–Whitney U-test. For all statistical tests, \(P < 0.05\) was taken as a reference of significance and the results are interpreted as follows:

- \(P > 0.05\): Nonsignificant
- \(P < 0.05\): Significant
- \(P < 0.001\): Highly significant.

Results

A total of 200 patients completed this study. Demographic data (age, sex, weight, and height), BMI, and duration of hemodialysis in both the groups were comparable and observed no statistical significance [Table 1]. On comparing biochemical markers, we found that there was no statistically significant difference in both the groups [Table 2].
Antral cross-sectional area in supine and right lateral positions in both the groups after overnight fasting and after 30 min of light meal was found to be statistically nonsignificant [Tables 3-6].

In supine position, 6 h after light meal, it was observed that there was statistically significant difference in the mean anteroposterior and craniocaudal diameters between the two groups (P < 0.001: Student's t-test). The mean ± SD of antral cross-sectional area was 480.89 ± 84.92 mm² in Group A and was 394.15 ± 62.80 mm² in Group B, showing statistically significant difference in supine position 6 h after meal (P < 0.001, degree of freedom 198, mean difference 86.74, 95% confidence interval from 65.91 to 107.56, and standard error difference 10.562: Student's t-test) [Table 7].

6 h after light meal, on USG, in right lateral position, it was observed that there was significant difference in the mean anteroposterior and craniocaudal diameters between the two groups (P < 0.001: Student's t-test). The mean ± SD of antral cross-sectional area 6 h after meal in right lateral position was 575.40 ± 92.62 mm² in Group A and was 470.25 ± 73.63 mm² in Group B, showing statistically significant difference (P < 0.001, degree of freedom 198, mean difference 105.15, 95% confidence interval from 81.81 to 128.48, and standard error difference 11.832: Student's t-test) [Table 8].

On estimation and comparison of Perlas grading in both the Groups, 6 h after meal, we found that only 14 (14%) patients had Perlas Grade 0 in Group A, whereas in Group B, 71 (71%) patients had Perlas Grade 0. There was statistically significant difference present in both the groups having Perlas Grade 0, 1, and 2 after 6 h of having light meal (P < 0.001, Chi-squared equals 423.727 with 2 degrees of freedom: Chi-square test) [Table 9].

On intragroup comparison of anteroposterior and craniocaudal diameters, and antral cross-sectional area of gastric antrum in supine and right lateral position after overnight fasting and 6 h after having light meal in Group A, we found statistically significant difference in all the three measurement parameters of gastric antrum (P < 0.001, degree of freedom 198 and 95% confidence interval: Student's t-test) [Tables 10 and 11].

Similarly, we did intragroup comparison in Group B after overnight fasting and 6 h after having light meal in supine and right lateral position and found there was no statistically significant difference among all the three gastric antrum measurement parameters (P ≥ 0.05, degree of freedom 198 and 95% confidence interval: Student's t-test) [Tables 12 and 13].

**Discussion**

The ASA fasting guidelines have failed to provide clarity on whether they are equally applicable in all comorbidities such as diabetes mellitus, chronic kidney disease, gastroesophageal reflux disease, and obesity. These patients have higher risk of aspiration as compared to healthy patients. Using ultrasound to predict gastric contents may allow an anesthesiologist to improve care and safety.

Fasting guidelines are not applicable in the urgent or emergent surgical patient and certain physiologic states (e.g., pregnancy) and medical conditions (e.g., diabetes, trauma, renal, or liver dysfunction) which may result in delayed gastric emptying and significant residual gastric volume despite recommended fasting times.

We included ESRD patients in our study. We did not take healthy volunteer to compare gastric emptying with CRF patients as it is an established fact that normal healthy individuals have faster gastric emptying as compared to their counterparts suffering from CRF. We used metoclopramide as a prokinetic agent in our patients because metoclopramide

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**Table 1: Statistical evaluation of demographic profile of Group A and Group B (mean±standard deviation, frequency (n=100))**

|                          | Group A | Group B | P      |
|--------------------------|---------|---------|--------|
| Age (years)              | 54.22±15.61 | 52.44±14.91 | 0.411  |
| Sex: Male:female         | 47:53   | 36:64   | 0.114  |
| Weight (kg)              | 45.81±6.02 | 45.36±4.92 | 0.559  |
| Height (cm)              | 156.07±9.13 | 156.52±4.92 | 0.748  |
| BMI (kg.m⁻²)             | 18.88±2.93 | 18.59±1.89 | 0.401  |
| Duration of hemodialysis (months) | 13.95±11.38 | 11.67±6.22 | 0.735  |

SD=Standard deviation, BMI=Body mass index

**Table 2: Statistical evaluation of biochemical markers in Group A and Group B (n=100)**

|                          | Group A | Group B | P      |
|--------------------------|---------|---------|--------|
| Hb (g/dL)                | 7.73±1.68 | 5.00-12.00 | 7.50 (6.53-8.58) | 7.68±1.64 | 5.20-13.00 | 7.50 (6.23-8.50) | 0.999  |
| Na (mmol/L)              | 133.26±3.61 | 127-146 | 132 (131-135) | 133.96±4.48 | 122-147 | 134 (132-136.75) | 0.219  |
| K (mmol/L)               | 4.57±0.77 | 3.00-5.90 | 4.63 (3.96-5.15) | 4.67±0.79 | 3.11-6.40 | 4.51 (4.07-5.30) | 0.430  |
| BUN (mg/dL)              | 59.39±24.9 | 11.8-127.0 | 60.47 (37.25-79.75) | 58.92±32.57 | 16.0-179.0 | 51.5 (35.25-73.75) | 0.362  |
| Ca (mg/dL)               | 7.82±0.81 | 4-9 | 8 (7.40-8.40) | 7.75±0.86 | 5-10 | 7.80 (7.40-8.40) | 0.447  |
| PO₄ (g/dL)               | 5.20±2.19 | 2.60-11.00 | 4.30 (4.00-5.80) | 5.49±2.26 | 2.80-15.00 | 4.95 (4.20-5.58) | 0.078  |
| Parathyroid hormone (pg/dL) | 72.15±24.39 | 24-123 | 69 (55-90) | 81.56±32.25 | 30-170 | 78.5 (55.25-99.75) | 0.069  |
| Albumin (g/dL)           | 2.79±0.51 | 1.2-3.8 | 2.87 (2.25-3.10) | 2.71±0.57 | 1.2-3.8 | 2.87 (2.25-3.10) | 0.287  |

SD=Standard deviation, IQR=Interquartile range, Hb=Hemoglobin, Na=Sodium, K=Potassium, BUN=Blood urea nitrogen, Ca=Calcium, PO₄=Phosphate
is a combined serotonin (5-hydroxytryptamine4) agonist and dopamine D2 antagonist. It stimulates esophageal, stomach, and small intestinal contractions and enhances gastric emptying. Metoclopramide is presently used as the first-line agent for the management of gastroparesis.\[^{14}\] It is the only FDA-approved medication for the treatment of gastroparesis.\[^{15}\] There are many drugs such as domperidone, cisapride, and erythromycin, which increases gastric motility.\[^{16-18}\] We decided to use only metoclopramide because domperidone, a well-known antidopaminergic antiemetic drug, had its over-the-counter status withdrawn in many European countries after the European Medicines Agency recommended restriction of its use because of potentially life-threatening cardiac effects.\[^{16}\] Cisapride causes QT prolongation and may lead to *torsades de pointes*, and erythromycin, a macrolide antibiotic, has cardiac side effect such as QT prolongation and may result in potentially fatal cardiac arrhythmias.\[^{17,18}\] Gastrointestinal side effects such as nausea and diarrhea are common with erythromycin. Erythromycin has limitations due to its marked ability to inhibit cytochrome P450 resulting in interaction with drugs, which are metabolized by this enzyme system such as warfarin, carbamazepine, and theophylline.\[^{19}\]

Majority of the patients with ESRD in the study belonged to the age group of 41–50 years (but there was no significant difference in the proportion of men and women in the group), which is in accordance with the study conducted by Strid *et al.*\[^{10}\] They also did not observe any gender difference.

Maximum number of patients (100; 50%) enrolled in the study were underweight (BMI ≤ 18.5), whereas in a study by Chen *et al.*, the patients had an average BMI of 21.6 kg·m\(^{-2}\).\[^{1,20}\] This could be due to difference in the ethnic origin. Our patients were of Indian origin, whereas their participants belonged to mandarin (Chinese) population. There was no statistical
There was no statistically significant difference ($P \geq 0.05$) in biochemical data with regard to hemoglobin, sodium, potassium, calcium, phosphate, albumin, and parathormone in the study groups and control group. Chen et al. in their pioneer work did not observe any significant difference in biochemical profile.\[1\]

According to the study conducted by Chen et al., there was significant difference present in the antral cross-sectional area after overnight fasting in supine position, but no significant difference in the right lateral position.\[1\] This was due to the fact that they compared ESRD patients with healthy individuals. Whereas, in our study, there was no significant difference in the mean anteroposterior diameter, craniocaudal diameter, and antral cross-sectional area in supine and right lateral position as our study comprised only ESRD patients.

The observational study done by Chen et al. compared the gastric emptying potentials between ESRD and healthy patients. The results show that ESRD patients had delayed gastric emptying as compared to the control group.\[1\] In our study, it was observed that there was significant difference in the mean anteroposterior diameter, craniocaudal diameter, and antral cross-sectional area in supine position 6 h after meal between Group A and B. This suggested that metoclopramide administration after giving meal was successful in augmenting gastric emptying in patients of ESRD.

According to Chen et al., 6 h after light meal, 19 out of 30 patients had Perlas Grade 0, whereas in our placebo group, after 6 h of light meal, only 14 out of 100 had Perlas Grade 0. As the patients in the study conducted by Chen et al. were subjected to hemodialysis between the second session (just after giving light meal) and third session (6 h after the light meal), there was complete gastric emptying in more percentage of patients.\[1,\] In our study, the patients did not undergo hemodialysis resulting in prolonged gastric emptying. This indicates that hemodialysis via improvement of electrolyte imbalance and metabolic acidosis affect the autonomous nervous system and ultimately leads to improvement of impaired gastric motility in patients with chronic renal failure. Adachi et al., also showed in their study that most CRF patients on hemodialysis had no or less gastrointestinal symptoms, and more than half of these patients had normal gastric motility.\[21\] GI symptoms associated with disturbed motility reported by patients with CRF may improve by treatment with hemodialysis. Strid et al. also found in their study that dialytic status might have an impact on gastric emptying in patients with CRF.\[9\]

Van de Putte and Perlas also found, in their pioneer study, high aspiration risk when gastric ultrasound demonstrates the presence of (a) solid gastric contents, (b) an estimated total gastric fluid volume $>1.5$ ml.kg$^{-1}$ in the right lateral decubitus position, and (c) the ultrasonographic presence of clear fluids in both the supine and lateral decubitus positions (Perlas Grade 2).\[10\]

Our study showed that all ESRD patients within Group A and Group B had empty stomach after overnight fasting. Also,
most patients in Group B who received metoclopramide after light meal had empty stomach after 6 h of fasting. Majority of patients who did not receive metoclopramide (Group A) had significant residual gastric contents after the same time period. We also carried out intragroup comparison and found that increasing the fasting time [Tables 10 and 11] or introducing a novel prokinetic such as metoclopramide [Tables 7-9] can enhance gastric emptying in a group of patients who have renal failure. On comparing gastric emptying after overnight fasting with administration of prokinetic after light meal, we did not find significant difference [Tables 12 and 13], justifying our hypothesis that either increasing the fasting time period or administrating oral metoclopramide in ESRD patients can lead to optimal gastric emptying with least risk of pulmonary aspiration.

**Conclusion**

The fasting guidelines given by various societies need to be modified to include high-risk patients such as ESRD patients. USG is a new point of care system which can be used preoperatively to evaluate gastric contents and volume to assess risk of pulmonary aspiration and guide anesthetic management in patients with slow gastric emptying, and metoclopramide is a good drug to enhance gastric emptying in ESRD patients within the recommended fasting period.

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**Conflicts of interest**
There are no conflicts of interest.

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