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Effects of metoclopramide administration on gastric emptying in mechanically ventilated intensive care patients: A prospective randomized controlled trial

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Abstract

Background: Vitality of human body is dependent upon proper nutrition. The primary objective of this research is to evaluate metoclopramide impact on gastric emptying in mechanically ventilated individuals. Secondary outcomes include frequency of ventilator-associated pneumonia, hospital stay duration, and weaning time from mechanical ventilation.

Methods: Eighty ventilated intensive care head trauma patients of either gender aged 20-40 years were randomly allocated into either metoclopramide or control groups receiving 10mg intravenous metoclopramide or placebo respectively every eight hours for 5 days. We assessed gastric residual volume (GRV) every eight hours for 1st five days of enteral nutrition in semisitting and right lateral positions. Aspiration risk, feeding intolerance, diet volume ratio (DVR), pneumonia incidence, mechanical ventilation duration, and length of ICU & hospital stays were evaluated.

Results: GRV was significantly lower in metoclopramide group compared to control group starting from 2nd day till the 5th day ($P \leq 0.05$).

Aspiration risk significantly reduced in metoclopramide group compared to control group ($p < 0.05$). Enteral nutrition duration and DVR were greater in metoclopramide group compared to control group. ($p < 0.05$).

Aspiration pneumonia incidence was 2.5% and 10% in metoclopramide and placebo groups respectively ($p > 0.05$).

ICU length of stay and MV duration were significantly lower in metoclopramide group contrasted to control group ($p < 0.05$) without significant difference in hospital stay.

Conclusion: Intravenous 10mg metoclopramide every 8hrs for five days resulted in significant reduction of GRV, aspiration risk, FI complications, ICU stay and MV duration and increased DVR without effect on pneumonia incidence or hospital stay.

Keywords: Malnutrition, metoclopramide, aspiration, intensive care

Introduction

Enteral nutrition (EN) is crucial in the critical care treatment, particularly when there is a decrease in nutritional intake and intestinal dysfunction [1-2].

The presence of malnutrition in individuals admitted to ICUs has been related to unfavorable outcomes, including higher rates of illness, death, and longer hospital stays. Research indicates that in individuals with a well-functioning digestive system, it is advisable to provide nutrients through the enteral route. Parenteral feeding is particularly linked to heightened infectious problems [3].

The significance of nutrition assistance in critically ill individuals has garnered considerable attention, with studies concentrating on the nutrition route, type and timing of nutrition [4].

Provision of nutrients has progressed to encompass nutrition treatment. This therapy aims to reduce the body's metabolic reaction to stress, preventing damage to cells caused by oxidation, and positively influencing immunological responses [5].

Critically sick individuals in a condition of stress catabolism are most susceptible to malnutrition. Furthermore, the combination of insufficient or delayed nutrition provision will result in a further decline in nutritional well-being [6].

Providing nutrition assistance to critically sick patients encompass enhanced wound healing, less catabolic response to damage, and better structure & function of the gastrointestinal system [7-8].

The objective of this research was to evaluate the prokinetic impact of metoclopramide on gastric emptying in critically ill mechanically ventilated individuals. We hypothesized that the use of metoclopramide would improve feeding tolerance in critically ill individuals receiving enteral feeding.

Patients and Methods

After approval from Institutional Ethics Committee (22/2/35298), registration in the clinical trial registry (NCT05641051), and informed written consent from the patient guardians, this prospective randomized placebo-controlled research was performed on 80 patients admitted to postsurgical ICU, Tanta University Hospital. The research was conducted between February 2022 and March 2023.

Inclusion Criteria: Twenty to sixty-year-old male or female mechanically ventilated head trauma patients undergoing enteral nutrition through a nasogastric tube.

Exclusion Criteria: Individuals who had extrapyramidal manifestations, contraindications to enteral nutrition, a documented allergy to metoclopramide, seizures, renal or hepatic disease, or extrapyramidal manifestations.

The accurate antral placement of the gastric feeding tube was ascertained prior to enrollment. Enteral nutrition was initiated promptly for every individual once their hemodynamic stability was confirmed. The gastric EN protocol commenced at a rate of 20 mL/h & progressively raised by 20 mL/h every 8 hours until the desired rate was reached.

Individuals were divided into 2 groups of forty patients randomly, employing a computer-generated randomization sequence that was concealed within opaque sealed envelopes.

Group I: Metoclopramide group (M): patients received 10 mg intravenous (IV) metoclopramide / 8 hours. **Group II:** Control group (C): patients received the same volume of IV placebo / 8 hours.

The allocated drug administration continued during the first 5 days of EN.

The drugs were prepared by a dedicated anesthesiologist who was aware of the allocated group & had no subsequent role in the research.

IF the patient developed feed intolerance (FI), EN was discontinued for four hours, and then restarted at half the previous rate, increased by 10 mL/h every 8 hours as tolerated.

At least three out of five positive variables were required to define FI, with one variable of GRV being essential for this purpose. The variables consist of: absence of gastrointestinal sounds, diarrhea (characterized by loose stools passed more than three times daily), vomiting (visible regurgitation of gastric contents), bowel distension (confirmed via x-ray with a small bowel measuring more than three cm or a large bowel measuring more than five cm) & a large GRV of at least 500 ml.

A focused abdominal sonography (Mindray E-cube 8 - Korea) was executed while the case was in right lateral (RLP) & semi-sitting positions. A curved transducer at a frequency range of 2 to 5 MHz was swept from the left to right subcostal margins in order to locate the antrum within the epigastrium. The descending abdominal aorta and the

left liver lobe served as anterior & posterior landmarks, respectively, for this evaluation. A flat antrum characterized by anterior and posterior walls that were juxtaposed was deemed empty, while a distended antrum with hypochoic contents & thin walls was indicative of fluid content. A distended antrum with contents exhibiting mixed echogenicity was deemed to contain solids (Figure 1).

The antral cross-sectional area (CSA) was measured utilizing the equation

$$CSA = \pi (1) [D1 \times D2] / 4$$

(D1 & D2: two antral dimensions) ^[9]

Gastric residual volume (GRV) was calculated at an 8-h interval throughout the 1st 5 days of EN. Calculation was performed utilizing the following equations:

- Gastric residual volume (mL) = 215 + 57 log CSA (cm²) - 0.78 age (year) - 0.16 height (cm) - 0.25 weight (kg) - 0.80 ASA (Bouvet & colleagues' equation for semi-sitting position) ^[10].
- Gastric residual volume (mL) = 27.0 + (14.6 × right lateral CSA) - 1.28 × age (Perlas & colleagues' equation for RLP) ^[11].
Aspiration risk was classified utilizing the framework that Ven de Putte & Perlas proposed ^[12] as:
- Low risk individuals with an empty stomach and gastric residual volume of less than 1.5 mL/kg.
- Patients with gastric residual volume or solid contents exceeding 1.5 mL/kg are at a great risk.

Diet volume ratio (DVR): considered as an index of efficacy of nutrient delivery, was computed as follows:

$$\text{Diet VR (\%)} = (\text{diet volume administered} / \text{volume recommended}) \times 100$$

Pneumonia was diagnosed based on the ATS/IDSA clinical criteria (13) & was defined as the presence of a new or progressive radiographic infiltration together with at least two of the three clinical characteristics listed below. (1) temperature greater than 38 °C; (2) leukocytosis or leucopenia; & (3) purulent discharges. Pneumonia diagnosis did not require microbiological proof.

Primary outcome

Assessment of the risk of aspiration.

Secondary outcome

1. Ventilator associated pneumonia.
2. Time of weaning from mechanical ventilation
3. Duration of hospitalization

Sample size calculation

The sample size & power analysis were computed utilizing version 2002 of the Epi-Info software statistical application, which was developed by the Centers for Disease Control & Prevention of the World Health Organization in Atlanta, Georgia, USA.

The calculation of the sample size was based on the following criteria

- 95% percent confidence limit

- 80% power of the research
- The anticipated result was 85% in the treatment group & 55% in the control group.

In each group, the sample size determined by the aforementioned criteria was found to be $N > 37$. Forty patients were recruited in each group to compensate for dropped out cases.

Evaluation of the data statistically

The computation was performed utilizing IBM SPSS software program version 20.0 on the inputted data (IBM Corp., Armonk, New York). The Shapiro-Wilk test and histogram observation were employed to ascertain the distribution's normality. Qualitative data were described in terms of percentages & numbers.

The normally distributed quantitative parameters were calculated using the independent sample t-test & were expressed as mean \pm standard deviation.

The parameters that did not conform to the normal distribution were statistically examined using the Mann-Whitney test, & they were reported as the median with the interquartile range.

Categorical data were supplied in the form of the number of patients or the frequency of occurrence (in percentages), and those data were evaluated using χ^2 test or the Fisher's exact test, depending on the circumstances.

A P-value that was less than 0.05 was deemed to be statistically significant. Testing the hypothesis was conducted in a manner that was two-sided.

Results

After assessing the eligibility of 110 individuals, it was determined that 25 individuals did not fulfill the inclusion criteria and 5 patients' relatives declined to take part in the research. Forty patients comprised the two categories to which the remaining eighty were assigned at random. All patients were statistically analyzed and followed up with until the conclusion of the investigation. Figure (2)

Demographic data were comparable among the both examined groups ($p > 0.05$). (Table 1)

Before EN beginning, the mean value (\pm SD) of APACHE II score was (13.65 \pm 2.05) and (13.45 \pm 2.34) in metoclopramide and control groups respectively. After EN, the mean value (\pm SD) of APACHE II score was (7.53 \pm 1.81) and (8.15 \pm 1.87) in metoclopramide and control groups respectively. APACHE II score was significantly lower in 2 groups after EN duration with APACHE II score significantly lower in metoclopramide group contrasted to the control group. ($p < 0.05$).

GRV in the semisetting and right lateral positions in the first five days of enteral nutrition is illustrated in (table 2).

The GRV was significantly lower in the metoclopramide group compared to the control group from the 2nd till the 5th day at P. value ≤ 0.05 . (Table 3)

In day 1 and day 2, 7 patients had high risk for aspiration in metoclopramide group contrasted to 16 cases in the control group ($P = 0.026$). The number of patients with high risk for aspiration significantly reduced in metoclopramide group by day 3 to become 6 cases contrasted to 14 cases in control group ($P = 0.039$). In the last two days the number of cases with high risk for aspiration in metoclopramide group significantly decreased to 1 patient compared to 13 patients

in the 4th day and 12 patients in the 5th day in the control group at P. value (< 0.05)

Enteral nutrition duration ranged from 5-11 days in metoclopramide group and 5-9 days in placebo group with a mean (\pm SD) of (7.08 \pm 1.69) days and (6.15 \pm 0.95) days in metoclopramide group and placebo group respectively. Metoclopramide group was associated with significantly higher EN duration contrasted to the control group.

The frequency of aspiration pneumonia was 2.5% and 10% in metoclopramide and placebo groups respectively ($p > 0.05$).

Feeding intolerance complications were illustrated in Table (4)

The mean DVR% increases gradually from day 1 to day 5 during the first five days of enteral nutrition in metoclopramide group.

The DVR% was significantly greater in metoclopramide group contrasted to control group ($p < 0.05$).

The length of ICU stay was significantly lower in metoclopramide group contrasted to control group ($P = 0.007$). The duration of hospitalization did not differ significantly among both groups ($P = 0.428$). MV duration was significantly lower in metoclopramide group contrasted to control group ($P = 0.034$). Table (3)

Discussion

The use of IV metoclopramide 8hrs for 5 days resulted in significant reduction of gastric residual volume, aspiration risk, FI complications, ICU and stay and MV duration, and resulted in increased the DVR% with no effect on the incidence of aspiration pneumonia or hospital stay.

Metoclopramide exerts its antiemetic effects through the activation of serotonin 5-HT₃ receptors and the inhibition of D₂ receptors in the chemoreceptor trigger zone (CTZ) situated in the region postrema of the brain. Additionally, it inhibits presynaptic and postsynaptic D₂ receptors, agonism of presynaptic excitatory serotonin 5-HT₄ receptors, & presynaptic inhibition of the muscarinic receptor in the gastrointestinal tract. ⁽¹⁴⁾

This process facilitates the liberation of acetylcholine, subsequently resulting in enhanced gastric emptying, improved antroduodenal coordination, & increased intragastric pressure, as well as tone in the lower esophageal sphincter (LES) & gastric region. ⁽¹⁵⁾

Consistent with our research, Lewis *et al.* ⁽¹⁶⁾ conducted a meta-analysis which demonstrated that prokinetic agents effectively diminished feeding intolerance (RR 0.73, 95% CI 0.55, 0.97; $P = 0.03$; moderate certainty). This equivalented an absolute reduction in feeding intolerance of 17.3% (95% CI 5, 26.8 percent). The risk of developing elevated gastric residual volumes was also diminished by prokinetics (RR 0.69; 95 percent CI 0.52, 0.91; $P = 0.009$; moderate quality).

Our findings were consistent with those of Baradari *et al.* ⁽¹⁷⁾, who examined the effect of metoclopramide and neostigmine on GRV & found that 96.7 percent of patients in the group that received both metoclopramide and neostigmine experienced an improvement in GRV (GRV below 120 cc). Specifically, fifty percent & 43.3 percent of the cases in the metoclopramide & neostigmine groups, respectively, achieved an improvement in GRV (p below 0.001).

Our study also revealed that usage of metoclopramide led to

significant reduction in aspiration risk in metochlopramide group contrasted to control group with no statistically significant variance in incidence of aspiration pneumonia between both groups.

Our research adhered to the most recent guidelines set forth by the American Society of Parenteral and Enteral Nutrition (ASPEN), which recommend the administration of erythromycin or metoclopramide to patients who are at a heightened risk of aspiration [18].

The comparison among both studied groups according to APACHE II severity score showed that there was no statistically significant difference among examined groups with respect to pre-initiation of the enteral feeding. However, APACHEI II score was significantly reduced in 2 groups after initiation of the feeding but more in the metochlopramide group.

This is consistent with the findings of Hu *et al.*'s [19] multicenter study, which examined whether metoclopramide or domperidone could improve the success rate of spiral nasojejunal tube post-pyloric implantation. The study enrolled three well-matched groups, metoclopramide, domperidone and control group, the three groups were similar in baseline APACHE II score, but post-pyloric placement of the nasojejunal tube, the APACHE II score was significantly greater in control group contrasted to other groups.

Furthermore, the objective of the study conducted by Amin *et al.* [20] was to determine whether consistent metoclopramide therapy could reduce the incidence of aspiration pneumonia in stroke patients who were managed with nasogastric tubes. The baseline data and APACHE II score did not differ significantly among the control & metoclopramide groups. The research revealed that individuals treated with metoclopramide have significantly lower APACHE II score compared to placebo group In our study, the comparison among 2 examined groups In accordance with feeding intolerance (FI) complication, showed that vomiting occurred in 15% in metoclopramide group in comparison to 35% in placebo group with statistically significant difference value at p. value of 0.039, distention occurred in 7.5 percent of patients receiving metochlopramide in comparison to 12.5% in control group,

diarrhea occurred in 7.5% & 2.5% of cases in metochlopramide & control groups respectively and diminished peristalsis occurred in 2.5% of patients in both groups.

Consistent with our research, Lewis *et al.* [16] found evidence of moderate quality indicating that prokinetic agents effectively mitigated nutrition intolerance in critically ill patients when compared to placebo or no intervention.

Contrary to the findings of our research, Nursal *et al.* [21] reported that feeding intolerance (FI) complications did not differ significantly among the control group & the group treated with metoclopramide.

The disagreement may be due to the different definition of feeding intolerance as they considered the gastric residual volume to be high and hence as a sign of feeding intolerance if it was greater than 150 ml, however we considered it high if it was higher than 500

In current research the comparison among 2 studies groups according to DVR%, revealed that DVR% was significantly greater in metoclopramide group in contrast to control group along the five days.

Research indicates that providing extensive nutritional assistance to critically sick patients might enhance their chances of survival and decrease the time required for recovery. Consequently, this leads to a shorter hospital stay & lower total hospital expenses [17]. The present study demonstrated a statistically significant reduction in the duration of ICU stay in the metoclopramide group compared to the placebo group, with a p-value of 0.007.

However, the overall hospital stay duration was comparable in the two studied groups. This may be due to other factors affecting hospital stay like rehabilitation requirements post TBI and follow up of associated surgeries concomitantly present in those patients.

This was supported by the recent meta-analysis by Peng *et al.*, [22] who involved 10 RCTs and revealed that in critically ill adults receiving gastric feeding, prokinetic agents may decrease Duration of stay in ICU (MD -2.03, 95 percent CI - 3.96, -0.10; P = 0.04; low certainty) however in contrary to our study, it may reduce Duration of hospitalization (MD - 3.21, 95 percent CI -5.35, -1.06; P = 0.003; low certainty).

Table 1: Demographic data & cause of mechanical ventilation in the examined groups.

	Metoclopramide group	Control group	Test of Sig.	p
Gender				
M/F	18/22	16/24	$\chi^2= 0.205$	0.651
Age (years)	39.67±11.53	38.35±9.90	t=0.551	0.583
Weight (kg)	79.35±10.14	80.18±9.81	t=0.370	0.713
Height (cm)	165.4±3.18	166.5±2.86	t=1.626	0.108
MV cause [DCL]	40	40		

Data represented as Mean ± SD, patient number

DCL: Disturbed conscious level.

t: Student t-test

χ^2 : Chi square test

Table 2: Daily GRV in each position in the two studied groups

GRV	Metoclopramide group (n = 40)		Control group (n = 40)		Test of Sig.	P
	N	Median (Q1 – Q3)	N	Median (Q1 – Q3)		
Semi sitting position						
Day one	10	143.84 (135.56 – 155.55)	16	163.56 (150.92– 169.03)	t=3.309	0.073*
Day two	7	144.3 (133.82 – 156.51)	15	160.25 (144.49 – 171.53)	t=2.712	0.013*
Day three	4	143.2 (134.47 – 147.43)	13	161.9 (145.1– 169.65)	t=4.000	0.001*

Day four	4	143.2 (147.4 – 147.43)	12	161.25 (144.01 – 169.32)	t=2.214	0.047*
Day five	0	EMPTY	12	158.71 (141.96 – 170.75)	t=2.725	0.018*
RT lateral position						
Day one	40	82.85 (67.95 – 159.01)	40	85.45 (68.1 – 177.55)	U=615.0	0.075
Day two	40	75.09(65.22 – 152.2)	40	80.12 (68.12 – 171.71)	U=492.0*	0.003*
Day three	40	70.69 (63.63 – 139.43)	40	78.56 (70.34 – 169.07)	U=425.0*	<0.001*
Day four	40	72.36 (63.36 – 119.95)	40	79.55 (70.45 – 163.23)	U=403.0*	<0.001*
Day five	40	77.1 (65.12 – 115.84)	40	83.0 (76.51 – 161.52)	U=308.0*	<0.001*

Data presented as median and IQR(Q1-Q3).

U: Mann Whitney test

p: p value for comparing among 2 examined groups

*: Statistically significant at $p \leq 0.05$

Table 3: ICU stay, hospital stay and MV duration

	Metoclopramide group	Control group	U	P
ICU stay (Days)	9.38±2.17	10.23±1.42	523.0*	0.007*
Hospital stay (Days)	12.73±2.68	12.98±2.02	718.50	0.428
MV duration(Days)	6.15±2.24	7.30±2.44	584.50*	0.034*

Data represented as Mean ± SD.

Table 4: Feeding intolerance complication in the two studied groups:

FI complication	Metoclopramide group		Control group		χ^2	P
	No.	%	No.	%		
Vomiting	6	15.0	14	35.0	4.267*	0.039*
Distension	3	7.5	5	12.5	0.556	FE _p =0.712
Diarrhea	3	7.5	1	2.5	1.053	FE _p =0.615
Diminished peristalsis	1	2.5	1	2.5	0.721	FE _p =0.675

Data presented as number and percentage(%)

OR: Odd's ratio C.I: Confidence interval LL: Lower limit UL: Upper Limit



Fig 1: Gastric antrum ultrasound image A: empty gastric antrum with GA-gastric antrum, Liver- liver, SMA- superior mesenteric artery, AO-aorta B: gastric antrum containing clear fluid with 1-D1,2- D2

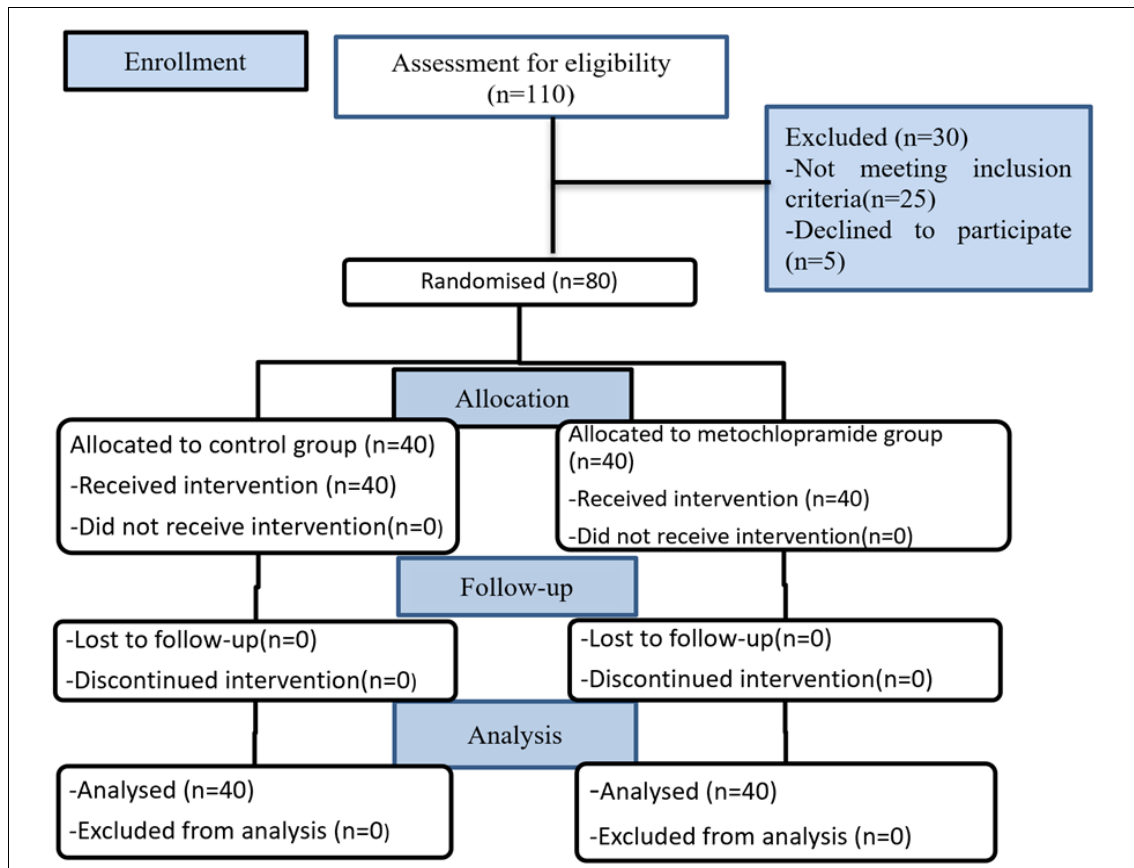


Fig 2: The CONSORT flow diagram, including enrollment, intervention, allocation, and analysis.

Conclusion

Administration of 10mg IV metoclopramide/ 8 hours for 5 days effectively improved gastric emptying in critically ill patient that received early enteral nutrition. There was significant reduction of gastric residual volumes, aspiration risk, FI complications, ICU stay and MV duration upon metoclopramide administration with an increase in the DVR% and no effect on incidence of pneumonia or hospital stay.

Limitations

The present investigation was constrained by being a single center design, a comparatively small sample size, and a relatively brief follow-up period. We require additional well-controlled investigations with extended follow-up periods & larger sample sizes to validate our findings and identify risk factors for adverse events.

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Conflict of Interest: Nil

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