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Original Article / Özgün Araştırma

Comparison of Two Different Enteral Nutrition Protocol in Critically Ill Patients

Yoğun Bakım Hastalarında İki Farklı Enteral Beslenme Protokolünün Karşılaştırılması

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Abstract / Öz

Objective: In this study, two enteral nutrition protocols with different gastric residual volumes (GRVs) and different monitoring intervals were compared with respect to gastrointestinal intolerance findings in intensive care unit (ICU) patients.

Methods: The study was carried out prospectively in 60 patients in the anaesthesiology and reanimation ICU under mechanical ventilation support, who were scheduled to take enteral feeding. Patients were sequentially divided into two groups: Group 1, GRV threshold of 100 mL, and monitoring interval of 4 hours, and Group 2, GRV threshold of 200 mL, monitoring interval of 8 hours. To test the significant difference between the groups, Student's t test, chi-square text and Fisher exact test were used.

Results: In Group 1, 3.3% vomiting, 6.6% diarrhoea was observed; in Group 2, 16.6% vomiting, 10% diarrhoea. In terms of total intolerance (vomiting and/or diarrhoea) of the two groups, the incidence was significantly higher in Group 2 (33.3%) than in Group 1 (10%) (p=0.02).

Conclusion: According to the results of the study, a lower gastrointestinal intolerance rate was detected in the GRV threshold 100 mL, monitoring interval for 4 hours protocol (Group 1) than in GRV threshold 200 mL, monitoring interval for 8 hours protocol (Group 2); Group 1 may be preferred renovation.

Keywords: Enteral nutrition, gastric residual volume, intensive care unit, critical Ill patient

Amaç: Bu araştırmada yoğun bakım ünitesi (YBÜ) hastalarında gastrik residüel volüm (GRV) eşiği ve izlem aralığı farklı olan iki enteral beslenme protokolü gastrointestinal (GİS) intolerans açısından karşılaştırılmıştır.

Yöntemler: Prospektif olarak planlanan çalışma Anestezi ve Reanimasyon Yoğun Bakım Ünitesinde mekanik ventilasyon desteği altındaki enteral beslenme alması planlanan 60 hastada gerçekleştirilmiştir. Ardışık olarak 2 gruba ayrılan hastalardan birinci grubun enteral beslenmesi, GRV eşiği 100 mL, izlem aralığı 4 saat, ikinci grubun ise GRV eşiği 200 mL, izlem aralığı 8 saat olacak şekilde uygulanmıştır. Gruplar arası farkın anlamlılığını test etmek için student-t, Kikare ve Fisher's exact testleri kullanıldı.

Bulgular: Çalışmamızda Grup 1'deki olguların %3,3'ünün kustuğu, %6,6'sının diyare olduğu, Grup 2'deki olguların ise %16,6'sının kustuğu, %10'unun diyare olduğu görüldü. Toplam intolerans (kusma ve/veya diyare) açısından Grup 2'deki intolerans sıklığının (%33,3) Grup 1'den (%10) istatistiksel olarak anlamlı düzeyde yüksek olduğu saptandı (p=0,02).

Sonuç: Çalışmanın sonuçlarına göre GRV eşik değeri 200 mL, izlem aralığı 8 saat olan (Grup 2) protokole göre daha düşük oranda gastrointestinal intolerans saptanan GRV eşik değeri 100 mL, izlem aralığı 4 saat olan olan protokol tercih edilebilir.

Anahtar kelimeler: Enteral beslenme, gastrik residüel volüm, yoğun bakım ünitesi, yoğun bakım hastası

Introduction

Nutrition therapy is important in critically ill patients (1). In adequately nourished patients, wound healing and immune responses are improved. However, in undernourished patients, the rate of morbidity and mortality are increased (2-7). According to patients' clinical condition, enteral and/or parenteral routes can be chosen for nutrition. If no contraindication using the primarily physiological route is present, enteral nutrition (EN) is recommended (8-10).

Enteral nutrition can be limited by gastrointestinal intolerance or dysfunction (vomiting, gastric distention, high gastric residual volume [GRV] and diarrhoea) (9, 11, 12). The gastric liquid volume measured by aspiration through an enteric tube is termed GRV. The GRV values are used to decide whether to continue or stop the EN (1, 12-14); however, it has not been determined which GRV threshold is the most appropriate for maintaining or stopping EN (15). Although there are some

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studies in which GRV threshold is accepted as a minimum of 30 mL and a maximum of 500 mL (14, 15), Metheny et al. (15) suggested that this value must be less than 200 mL. There are limited number of studies on validity, limits and factors affecting the GRV threshold (2, 16, 17).

There are some practice differences in the GRV threshold value and the measurement interval. Frequent measurement of the GRV causes a delay in reaching the target calories (2, 3). If the monitoring interval is prolonged, gastrointestinal intolerance may be overlooked. In order to reach target calories without losing time while minimising gastrointestinal intolerance, the most appropriate GRV threshold and the most appropriate monitoring interval must be determined. The aim of this study is to compare two EN protocols with different GRVs and different monitoring intervals with respect to gastrointestinal intolerance findings in intensive care unit (ICU) patients.

Methods

After being approved by the Institutional Ethics Committee and informed consent being obtained by the patients/patients' relatives, 60 consecutive patients who had been followed up at Dokuz Eylül University School of Medicine Anaesthesiology and Reanimation Department Intensive Care Unit were enrolled into this prospective randomised clinical trial.

Adult patients over 18 years of age, who were planned to be under mechanical ventilation support and planned to be fed with EN at least following 3 days, were chosen. Mechanical bowel obstruction, paralytic ileus, generalised peritonitis, inflammatory bowel disease, fistula in distal duodenum (if its output is higher than 500 mL day^{-1}), gastrointestinal bleeding, short bowel syndrome, morbid obesity (body mass index (BMI) >40), having gastrostomy/jejunostomy process and drug use affecting gastrointestinal motility were determined as exclusion criteria.

Evaluating the difference of hours to reach the target rate of feeding with 95% CI and 80% power, in each group, 51 patients were found to be necessary in the planning process of the study. However, at the end of the study, 30 patients could be included in each group. In post-hoc analysis with 90% CI, power was found to be 74%. The patients were randomised into two groups in which there were sequential 30 patients in each group. Group 1 (n=30): In patients whose GRV threshold was determined as 100 mL, measurements were performed every 4 hours and rate of nutrition increase was 10 mL h^{-1} Group 2 (n=30): In patients whose GRV threshold was identified as 200 mL, measurements were conducted every 8 hours and rate of nutrition rise was 20 mL h^{-1}

The demographic data of the patients, previously used drugs, BMI, Sequential Organ Failure Assessment (SOFA), Acute Physiology and Chronic Health Evaluation II (APACHE II), Glasgow Coma Scale (GCS) scores, associated diseases and intraabdominal pressures (by indirect method in bladder with Foley catheter in terms of cmH_2O) were recorded.

Twelve-French nasogastric tubes were placed into all patients, and the positions of the tubes were monitored every day using chest X-rays. Tubes were ensured to be in stomach over the course of nutrition and measurement period.

The patients were continuously fed by the same polymerase formula (Osmolite, Abbot, Illinois, USA) by using Flexiflo Compannon Pump Set (Abbot, Illinois, USA), which was regularly calibrated. The energy need of patients was calculated by the Schofield formula. The average calculated daily energy target for the first group was 1598.6±262.0 kcal and 1588.2±284.5 kcal for the second. During nutrition period and GRV measurements, the bed head was kept at 30-45º. Ramsay sedation score was kept at 3-6 by ensuring its compatibility with patients' mechanical ventilator. Midazolam and fentanyl-remifentanyl continuous intravenous infusions were used to provide sedation. The sedation protocol was not standardised for all patients. The gastrointestinal intolerance findings (vomiting and diarrhoea) of the patients were monitored and registered. In each group,

1. Nutrition was initiated at the rate of 20 mL h^{-1}
2. In case of gastrointestinal intolerance observation, no EN was applied as long as findings continued to appear in patients during the nutrition intervals until the next control.
3. If gastrointestinal intolerance was not determined, planned increases were performed in the event of GRV being below the threshold value. The nutrition was continued at the latest decided rate without any rise if GRV exceeded the threshold value.
4. When the patients whose nutrition was discontinued due to gastrointestinal intolerance were re-evaluated, the nutrition was initiated again at the rate of 20 mL/h if there was no gastrointestinal intolerance finding, and the decision related to EN was made (18).

Gastric residual volume measurements of the patients included in the study were recorded by project coordinators by assessing their latest conditions every 4 hours in Group 1 and every 8 hours in Group 2. Runny stool was considered as diarrhoea when it was seen in patients three or more times in 24 hours (19).

Gastric residual volume measurements were measured in mL by aspiring from nasogastric tube with a 50-mL injector. The volume obtained from the patient was not returned but emptied. The time required to reach target EN rate, the interval periods and their causes were noted. All patients received EN for 72 hours. The patients excluded from the study were those who were discharged from ICU before the 72nd hour of EN and those whose EN was stopped indefinitely. There was no intervention to treatment procedure applied to the patients; only 10 mg metoclopramide was given 3 times per day intravenously to diabetic patients.

Statistical analysis

Statistical analysis was performed using Statistical Package for the Social Sciences software (IBM SPSS Statistics, Armonk, NY, USA). The data were presented as mean±standard deviation. In terms of independent variables, the differences

Table 1. Patients and enteral nutrition characteristics

	Group 1 (n=30) GRV: 100 Interval 4 hours Increase rate: 20 mL h^{-1}	Group 2 (n=30) GRV: 200 Interval 8 hours Increase rate: 20 mL h^{-1}	p*
Age (years)	54.8±22.2	54.1±22.8	0.900
Weight; kg	74.3±13.2	73.4±15.0	0.807
Body mass index (kg m^{2-1})	26.2±4.25	26.0±5.2	0.830
APACHE II	19.6±9.2	17.8±8.0	0.432
SOFA 1st day	5.0±2.9	6.5±3.7	0.098
SOFA 2nd day	5.2±2.9	6.9±4.0	0.080
SOFA 3rd day	5.1±2.9	7.0±4.1	0.054
Time to reach the target calories (hours)	21.3±6.3	22.1±9.5	0.44

*Student- t test

Table 2. Glasgow coma scores of patients

	Group 1 (n=30) n (%)*	Group 2 (n=30) n (%)*	Total n	Chi-square	p
3–8	25 (52.1)	23 (47.9)	48	0.75	0.687
9–12	3 (50.0)	3 (50.0)	6		
13–15	2 (33.3)	4 (66.7)	6		
Total	30	30	60		

*line percentage

Table 3. Patients diagnosis

Diagnosis	Group 1 (n=30) n (%)	Group 2 (n=30) n (%)	p*
Head trauma	6 (46.2)	7 (43.8)	0.175
After brain surgery	9 (75.0)	3 (25.0)	
Trauma /surgery	8 (53.3)	7 (46.7)	
Medical	7 (35.0)	13 (65.0)	

*Chi-Square test

between groups were evaluated through the statistical point of view; p<0.05 was regarded as statistically significant. Student's t test was used for significant differences between the groups in measurements. For evaluation of countable data, chi square test and Fisher's exact test were used.

Results

No significant differences were determined in terms of patients' age, sex, body weight, BMI, causes for admission to ICU and their associated diseases, APACHE II, SOFA (Table 1), Glasgow Coma Scales (Table 2), and diagnosis (Table 3).

Table 4. Gastrointestinal intolerance results of the patients

	Group 1 (n=30) n (%)	Group 2 (n=30) n (%)	Total (n=60) n	p
Patient with vomiting only	1 (3.3)	5 (16.6)	6	0.211*
Patient with diarrhoea only	2 (6.6)	3 (10.0)	5	0.305*
Patient with vomiting and diarrhoea	0	2 (6.6)	2	-
Patients with gastrointestinal intolerance	3 (10.0)	10 (33.3)	13	0.028**

*Fisher-Exact test, **Chi Square test

Table 5. Outcome variables

	Group 1 (n=30)	Group 2 (n=30)	p*
ICU stay (days)	12.7±12.4	17.8±14.1	0.143*
ICU mortality	12 (40%)	10 (33%)	NS**

*Student's t test **chi square test. ICU: intensive care unit

The mechanical ventilation modes of the patients, their time limit and applied PEEP ratios were similar (p>0.05). In view of the average daily intraabdominal pressure measurements of the patients, no statistically significant difference was observed over a 3-day period (p>0.05). There was no statistically significant difference in the target calorie values averages between the groups (p>0.05). Targeted calorie could never be reached in two patients in group I. No statistically significant difference was determined in terms of hours to reach the goal rate of feeding in two groups. It was 24.5±14.2 hours for Group 1 and 22.1±9.5 hours for Group 2 (p>0.05).

The gastrointestinal intolerance results of the patients are given in Table 4. Both groups were reviewed for their vomiting and diarrhoea conditions. It was observed that one patient vomited and two patients had diarrhoea in Group 1 and that five patients vomited, three patients had diarrhoea and two patients had both vomiting and diarrhoea in Group 2. When all gastrointestinal intolerance observed cases were evaluated (diarrhoea and/or vomiting), it was seen that there was a statistically significant difference between the groups (p<0.05), but no statistically significant difference was established in terms of only vomiting or only diarrhoea between the groups (p>0.05).

There was no significant difference between the groups for the drugs used (p>0.05). Metoclopramide use, known to increase gastrointestinal motility, was needed at 16.6% in Group 1 and 20% in Group 2 (p>0.05).

The average hospital stay of patients in ICU was 12.7±12.4 days in Group 1, whereas it was 17.8±14.1 days in Group 2; there was no statistical difference between the groups

(p>0.05). No significant difference was established between the groups in mortality rate (p>0.05) (Table 5).

Discussion

In this clinical study, we found that there was no significant difference for reaching target calories and the hours to reach the goal rate of feeding between the two groups, but the frequency of vomiting and diarrhoea in Group 2 (GRV: 200 interval 8 hours, increase rate: 20 mL h^{-1}) was found to be higher than in Group 1 (GRV: 100, interval 4 hours, increase rate: 10 mL h^{-1}). This result supports the studies which suggest 4-hour monitoring interval for GRV (2, 3).

One of the most substantial parameters of EN protocols used as guideline in EN applications is informed as GRV measurement. Spain et al. (3) stated monitoring interval as 4 hours and GRV as 200 mL, whereas Bochicchio et al. (20) reported monitoring interval as 6 hours and GRV as 150 mL. Until reaching to a consensus on this subject, further studies are needed.

Targeted calorie in EN can usually be reached in 3 days, but in some studies, periods of 3 days to 6 weeks can be observed (2, 21). Bochicchio et al. (20) who evaluated EN tolerance in 57 patients with head trauma established that target calorie could be reached in more than 3 days only in four patients. The patients in our study group reached target daily calorie intake within 3 days, and no significant difference was identified in terms of reaching target calorie period between the two groups in our study. These results are similar to the studies of Flesher et al. (22) and Pinilla et al. (2).

In ICU patients, gastrointestinal motility is affected by multiple factors besides nutrition. Undergoing GIS surgery is one of the most important factors (23). Therefore, the patients who underwent a GIS surgery were excluded from this study. Other factors known to affect GIS motility are diabetes mellitus and used pharmacological agents that change colonic flora and colon motility (24, 25). Head trauma was also known to increase GIS intolerance (26). In our study, two groups were similar in terms of these features; the results consequently showed that GIS intolerance is strongly associated with nutrition.

There are studies in which EN was initiated at infusion rates of 10, 20, 25, 30 and 40 mL h^{-1} in adults and 10-25 mL h^{-1}rate of rise was utilised (27). In this study, 20 mL h^{-1} rate infusion was started and 10 mL h^{-1} in Group 1 and in Group 2 20 mL h^{-1} increase rates were preferred. Twenty-four-hour volume that went into stomach was decided to be equal in two groups to provide standardisation when comparing in terms of groups' gastrointestinal intolerance. Therefore, the increase in infusion rate was not equal in two groups.

Williams et al. (27) suggested that gastric aspirate be returned to patient and this is proof level three. In addition, aspired GRV was not given back to the patient in order to avoid negative results regarding bolus implementation in our study.

Consistency with mechanical ventilation of ICU patients included in the study was provided with sedatives and sedation levels were followed by Ramsay sedation score. Since sedation is known to affect gastric discharge (15), sedatives implemented during the study were documented, and no significant difference was determined between the two groups in terms of Ramsay sedation score.

In the evaluation of gastrointestinal intolerance in patients fed by enteral method, there are studies concerning GRV, abdominal distention, nausea/vomiting and defecation changes as well as papers stating that bowel sounds must be monitored (11, 12, 15, 27). Nausea and vomiting develop in 20% of the patients fed by the enteral method. Vomiting is the most severe complication increasing the risk of pneumonia. Delayed gastric discharge is one of the most commonly encountered causes for vomiting, even though it is multi-factorial.

In a study by Elpern et al. (28) in which GRV threshold value was 150 mL and monitoring interval was 8 hours, nausea and vomiting rate was 9.2%, whereas it was determined as 16.5% and 29.5%, respectively, in a study in which two groups were used by Pinilla et al. (2). In our study, however, 3.3% vomiting and 6.6% diarrhoea complaints were seen in Group 1 and 16.6% of the patients vomited, 10% of the patients had diarrhoea in Group 2. Patient ratios for total intolerance (nausea and/or diarrhoea) were 10% in Group 1 and 33.3% in Group 2. It was observed that there was a major statistical significance difference in terms of total cases seen to have gastrointestinal intolerance between the two groups.

Two groups having different threshold values (100 mL/250 mL) were compared by Pinilla et al. (2), and vomiting, diarrhoea and high GRV were considered as total intolerance. On the other hand, in our study, we did not add high GRV to total intolerance since standardisation of two groups may be affected. Because records of GRV thresholds were different for the groups (100 mL/200 mL).

According to GRV values obtained from EN cases, it was decided either to continue or to pause the nutrition. A threshold value regarded as limit should be determined in order to take such a decision. The plan of continous EN based on GRV threshold, has not been clearly defined yet.

Edwards et al. (14) stated that GRV monitoring should be carried out, monitoring period should be performed every 4 hours and GRV threshold value should be kept at 200 mL. In our study, less gastrointestinal intolerance was observed to be determined in Group 1 compared to Group 2. In this case, a protocol in which there must be a monitoring process in every 4 hours and GRV threshold value is 100 mL could be proposed instead of a protocol in which there is a monitoring process in every 8 hours and GRV threshold value is 100 mL.

Conclusion

According to the results of this clinical study, we have decided that a protocol in which GRV threshold value is 100 mL and monitoring interval is 4 hours is a preferable guideline instead of a protocol in which GRV threshold value is 200 mL and monitoring interval is 8 hours for patients receiving EN in ICU.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Dokuz Eylül University Medicine Faculty Clinical and Laborotory Research Ethics Committee.

Informed Consent: Written informed consent was obtained from patients and the parents of the patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - M.A., S.B.; Design - S.B., M.A., U.K., Ö.M.; Supervision - U.K., Ö.M.; Resources - S.B., M.A.; Data Collection and/or Processing - S.B., M.Y.E.; Analysis and/or Interpretation - S.B., M.Ç.; Literature Search - S.B., M.A., M.Ç.; Writing Manuscript - S.B., M.A., U.K., M.Y.E.; Critical Review - Ö.M., M.Ç.

Conflict of Interest: First four and last authors (S.B., M.A., U.K., M.Y.E., Ö.M) was working in the Anaesthesiolgy ICU of Dokuz Eylül University Medicine Faculty Hospital during the study period.

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