Effectiveness of post-pyloric tube placement using magnetic guidance

Efetividade da sondagem pós-pilórica usando guia magnético

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This study was developed by the Service of Intensive Care Medicine of the Hospital do Servidor Público Estadual "Francisco Morato de Oliveira" – HSPE-FMO - São Paulo (SP), Brazil.

Conflicts of interest: The study device and electromagnetic tubes were donated by the manufacturer (VIASYS MedSystems).

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ABSTRACT

Objective: Appropriate nutritional support is important to the outcomes of critically ill patients. However, a significant portion of these patients experience intestinal motility problems. Administration of enteral nutrition by means of tubes placed in the post-pyloric position has been suggested to improve the nutrition tolerance. The aim of this study was to compare the rate of successful post-pyloric placement using a real-time electromagnetic positioning device to the success rate using the conventional placement method.

Methods: This was a prospective, randomized and controlled study, conducted in a tertiary hospital over a period of three months. The patients were randomized to one of two groups: electromagnetically guided system group, whose patients underwent real-time monitoring of post-pyloric tube placement; or the control group, whose patients underwent tube placment using to the conventional blinded technique. The rates of successful post-pyloric placement and the procedure times were assessed and compared between the groups.

Results: Thirty-seven patients were enrolled, 18 in the electromagnetic group and 19 in the control group. The final tube position was evaluated using radiography. The electromagnetic guided group showed better success rates and shorter procedure times when compared to the control group. Additionally, in the electromagnetic guided group, higher pH values were found in the fluids aspirated from the probe, suggesting successful post-pyloric placement.

Conclusion: The electromagnetically guided method provided better placement accuracy than did the conventional technique.

Keywords: Nutrition therapy; Enteral nutrition/instrumentation; Enteral nutrition/methods; Intubation, gastrointestinal

INTRODUCTION

Appropriate nutritional support is important to the outcomes of critically ill patients.[1] Early enteral feeding is beneficial and is recommended by important guidelines.[1-4] However, it is recognized that up to 60% of patients receiving an enteral diet are not able to achieve their scheduled energy values.[5] This is perhaps due to the significant portion of severely ill patients with intestinal motility issues, which lead to increased gastric residual volumes.[6]

Enteral post-pyloric diet administration has been suggested as an option to improve feeding tolerance, with lower associated aspiration and pneumonia rates.[3,7] However, there are serious complications related to the placement of this device, which are associated with higher costs and longer times and can delay the start of the diet infusion.[8-10]

Several techniques have been described for post-pyloric tube placement. Endoscopy and fluoroscopy have high success rates, but are limited by cost, availability and the need for transferring the patient out of the intensive care unit (ICU). Therefore, Heyland *et al.* recommeds routine post-pyloric diet infusion only in institutions where it can be conveniently and quickly achieved.[11]

This scenario provides a rationale for the evaluation of safe and cost-effective bedside post-pyloric tube placement techniques. Recently, a new technique was developed to ease the insertion of nasoenteral tubes; it utilizes an electromagnetic device in the tip of the tube that transmits the path of the tube to a monitor screen (Figure 1).

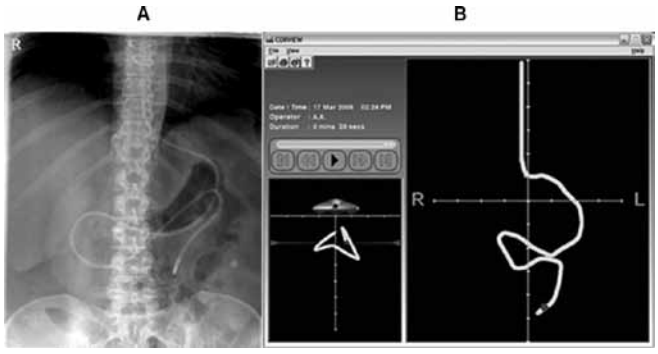


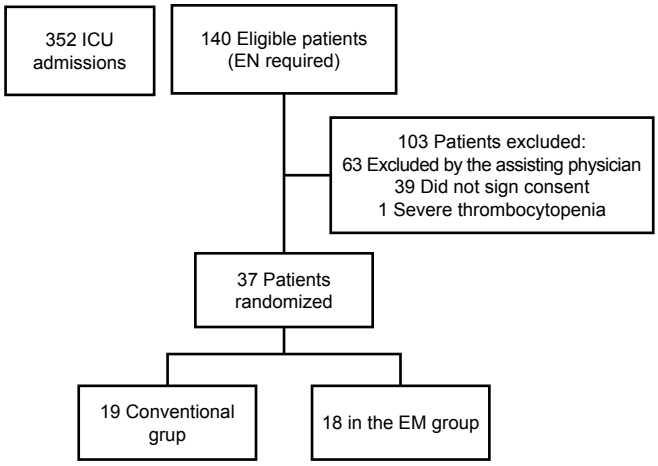
Figure 1 - A - Post-placement abdominal x-ray; B - Screenshot example of an electromagnetically guided tube.

The objective of the present study is, thus, to evaluate the success rate of post-pyloric placement using a technique that follows the probe's path using real-time electromagnetic positioning compared to the traditionally used method.

METHODS

This was a prospective, randomized and controlled trial that was conducted in a general ICU of a tertiary hospital. The monitoring device used in this study and the electromagnetic tip tubes were donated by the manufacturer (VIASYS MedSystems™). The manufacturer had no participation in this study design and/or analysis. Prior to the study, approval from the Institutional Ethics Committee was granted, and informed consent was signed by each patient or by the patient's legal representative.

The procedures were performed from September 1, 2008 to December 31, 2008. Inclusion criteria were age greater than 18 years old and at least one of the following criteria: requirement of a nasoenteral tube for enteral diet administration, indication for post-pyloric positioning, evidence of delayed gastric emptying, aspiration of large amounts of gastric content, repeated gastric aspirations, history of pulmonary aspiration of gastric contents, high-risk status, and severe acute pulmonary disease (Figure 2).



ICU – intensive care unit; EN – enteral nutrition; EM – electromagnetically guided

Figure 2- Patient inclusion flowchart.

Exclusion criteria were active gastrointestinal bleeding, history of esophageal or gastric varices, severe thrombocytopenia (<50,000), recent esophageal or stomach surgery, pharyngeal or laryngeal obstruction, psychomotor agitation, contraindications for >30º angle of the head of the bed, head or face trauma, and requirement of non-invasive mechanic ventilation (Figure 2).

Twenty-five patients were required for each group, considering a 5% alpha error, calculated for an 80% power assuming success rates of 55% and 20% for the intervention and control groups, respectively. However, due to shortness of device supplies, the study was stopped early.

Patients meeting the inclusion criteria were randomized by means of envelopes, with the group names distributed at a 1:1 rate. The two groups were the electromagnetically guided (EM) group, in which the patients underwent tube placement under real-time monitoring of the probe's tip via magnetic transmission (Cortrak™), and the control group, in which the conventional blinded nasoenteral tube placement technique was used.

The traditional enteral diet tube placement procedure was as follows: hand hygiene was followed, there was an explanation of the procedure to the patient, and then the patient was positioned at a semi-seated 45º incline. The tube was checked (to ensure it was patent and without ruptures), and personal protective equip-

ment including a mask, procedure gloves and protective goggles were donned. The tip of the tube was positioned by the tip of nose and mouth and was measured to the earlobe and then to the xiphoid process. Following injection of mineral water into the tube for lubrication purposes and application of nostril and tube tip lubrication with lidocaine gel, the tube was slowly introduced. After approximately 10 cm of introduction, the patient was asked to flex the neck and make swallowing movements to facilitate the introduction. The remaining portion of the tube was inserted continuously and delicately to the previously measured distance. The gastric position of the tube was assessed using two techniques: gastric contents aspiration and then epigastric auscultation for sounds following a small air injection (10 to 20 mL) through the tube. This was followed by post-pyloric placement, which consisted of lowering the head, positioning the patient on his/her right side, and then carefully introducing the tube an additional 10 to 15 cm. The guide wire was removed and discarded, and the probe position in the duodenum was checked using a 20-mL air injection with difficult return and less than 10 mL recovered, or measurement of pH ≥ 6.0. In all patients, abdominal radiography was performed to check the tube position. This procedure was performed in standardized fashion by one of five specially trained nurses, each of whom had at least three years of experience, in cooperation with other nursing team members.

For the electromagnetically guided tube placement, the steps were similar to the traditional method. However, in this method, the device transmitted the tube tip's path to a computer that showed it graphically on a screen (Figure 1).

Following randomization, demographic, clinical and laboratory information were collected to verify a balanced distribution between the groups. After the tube was installed, distal fluid was aspirated for pH assessment, and then 15 mL contrast was given 15 minutes before the abdominal X-ray was performed to assess the nasoenteral tube position. The radiographic examination was conducted up to one hour after the tube placement. The duration of the entire procedure was recorded, including the time for tube passage, location, migration and fixation.

The ICU admission Acute Physiologic and Chronic Health Evaluation (APACHE II) and Sequential Organ Failure Assessment (SOFA) scores were calculated within the first 24 hours following admission.

No patient-appropriate therapy was refused due to study participation. Patients were withdrawn from the study if any medical necessity prevented compliance with the protocol. Medical necessity was defined as changes in hemodynamic or respiratory parameters that were life-threatening, such as gastrointestinal bleeds.

Statistical analysis

The two groups were compared in terms of demographic and clinical data and the APACHE II and SOFA scores. The data were expressed as mean ± standard deviation, median and 25-75 percentiles, or percentages, according to the variable's distribution. The continuous quantitative variables were analyzed via parametric testing (Student's *t*-test), if they were normally distributed, or via non-parametric testing (Mann-Whitney U test) if they were irregularly distributed. For nominal variables, the Fisher exact test was used, with confidence intervals based on a normal approximation of a binomial distribution.

The data were entered into an electronic databank and later analyzed using SPSS (version 13.0) software. Values of $p < 0.05$ were considered significant.

RESULTS

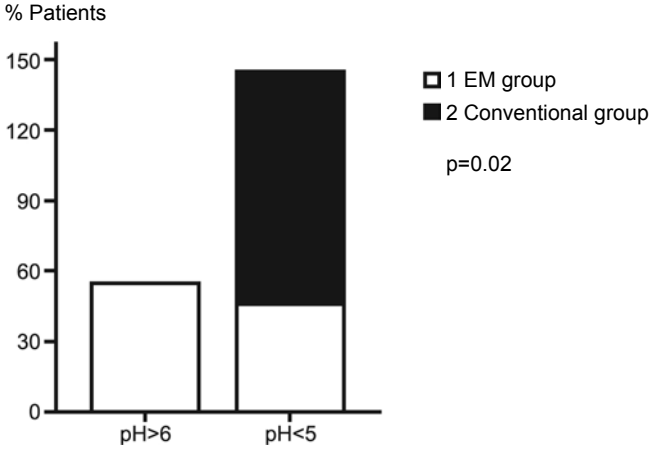
Thirty-eight patients were enrolled; one of them was subsequently excluded due to thrombocytopenia. A total of 18 patients were included in the EM group and 19 were included in the control group. The mean patient age was 67.3 years; the mean APACHE II and SOFA scores were 22.0 and 6.7, respectively. Pulmonary causes of respiratory failure were the diagnoses found in most of the medical patients (ten patients), followed by acute renal failure (three patients), heart failure (three patients), and stroke (one patient). In surgical patients, vascular surgery (eight patients) was most common, followed by heart surgery (three patients), neurosurgery (three patients), urologic surgery (three patients), gastric surgery (two patients) and orthopedic surgery (one patient). The comparison between the EM and control groups showed no statistically significant difference between the groups regarding demographics or clinical data (Table 1).

The EM group had higher pH values in the fluid aspirated from the tube as compared with the conventional group, in which 100% of the patients had pH values below 5.0 in the aspirated fluid, indicating gastric tube position (Figure 3). Additionally, the radiographic tube positioning showed that the EM group had more frequent post-pyloric placement than the control group (Figure 4). In addition, in the EM group, the time elapsed for the entire procedure was shorter than in the control group (Figure 5).

Table 1- Group comparison

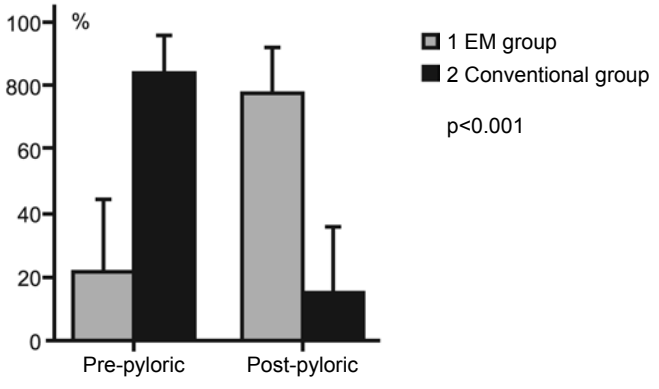
Variables	All (N=37)	EM group (N=18)	Control group (N=19)	*p* value
Age (years)	67.3 ± 14.2 67.0 (68.0-78.0)	65.8 ± 11.3 65.5 (57.0- 74.0)	68.7 ± 16.7 68.0 (63.2- 81.5)	0.54 0.41
Female gender	54.1	55.6	52.6	0.56
Weight (kg)	78.6 ± 19.9 75.0 (65.0-87.2)	84.3 ± 22.5 80.0 (70.0- 92.5)	73.5 ± 16.2 70.0 (63.5- 83.7)	0.10 0.12
Height (cm)	165.2 ± 8.6 165.0 (160.0-170.0)	167.4 ± 8.8 168.0 (160.0 - 171.2)	163.2 ± 8.1 164.0 (156.2 - 170.0)	0.14 0.16
APACHE II	22.0 ± 5.9 23.0 (18.0-26.0)	21.2 ± 5.8 22.5 (17.0-25.0)	22.9 ± 6.1 23.0 (18.0-27.5)	0.38 0.49
SOFA	6.7 ± 2.7 7.0 (4.5-9.0)	6.2 ± 2.7 6.0 (4.0- 9.0)	7.2 ± 2.8 7.0 (5.2- 8.7)	0.31 0.23
Clinical patients	45.9	38.9	52.6	0.48
Elective surgery patients	29.7	38.9	21.1	0.48
Emergency surgery patients	24.3	22.2	26.3	0.48
Invasive mechanical ventilation patients	90.0	92.3	88.2	0.60
Use of vasopressors	38.9	29.4	47.4	0.22
Use of gastric protectors	50.0	44.5	55.6	0.75
Fluid from digestive tube aspiration	47.2	58.8	36.8	0.16
Tube replacement required	5.4	5.6	5.3	0.97

APACHE – Acute Physiologic Chronic Health Evaluation; SOFA – Sequential Organ Failure Assessment; EM - electromagnetically guided. The values expressed are mean ± standard deviation, median (25-75 percentiles), or percentages.



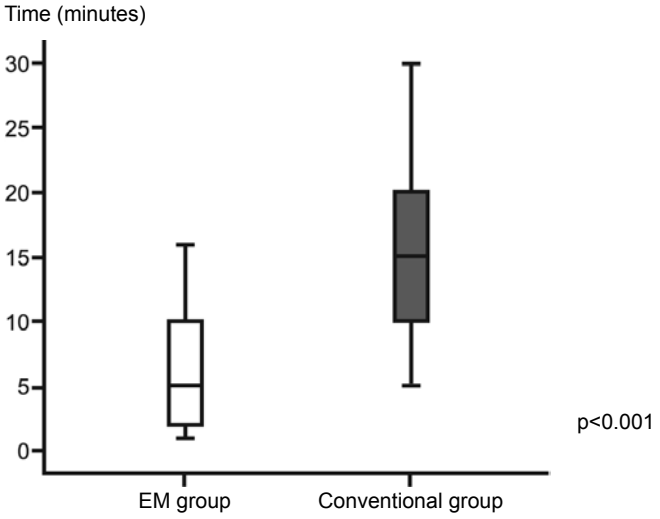
The dark column shows the Conventional group percentage, and the pale column the EM group. No Conventinal group patient had pH>6. EM - electromagnetically guided.

Figure 3 – Group comparison for the percentage of patients with >6 and <5 pH values in the aspired fluids.



EM - Electromagnetically guided

Figure 4 – Group comparison of tube tip position according to abdominal radiography.



EM - Electromagnetically guided

Figure 5 – Group comparison of time required to perform the procedure.

DISCUSSION

Comparing groups with similar characteristics, post-pyloric tube placement using the real-time electromagnetic monitoring system showed higher success rates relative to placement using the conventional technique, as assessed by means of the measured pH of the fluid aspirated from the tube and by abdominal radiography.

The main indication for enteral diet is the high incidence of gastroparesis in the ICU population (50% in mechanically ventilated patients and 80% in head trauma patients).[12-17] There are several causes of gastroparesis, such as abdominal surgery, hemodynamic instability, severe burns, electrolytic disorders, volume overload and use of vasoactive or sedative drugs. An enteral diet may improve these patients' tolerance.[18,19] One of the obstacles to starting enteral nutrition is difficulty in tube installation. Thus, there is a need for this new system, given its bedside feasibility.

Evidence of the benefits of an enteral diet is favorable, as reported Hsu *et al.*[20] Nasoduodenal tubes allow for better nutritional support and less vomiting and pneumonia. Additionally, Heyland et al. showed in a systematic review that an enteral diet provides better nutrition, reduces the time to nutritional target achievement and reduces the incidence of mechanical ventilation-associated pneumonia.[7]

On the other hand, Heyland states that a post-pyloric enteral diet is only recommended in institutions where the tube can be conveniently and quickly placed, considering the technical difficulties and the possible delay related to nasoenteral tube installation when compared with nasogastric tubes.[11]

In this context, the results of this trial, which tested the technique of nasoenteral tube placement monitored by magnetic transmission, suggest that this method may allow more institutions to be able to routinely place post-pyloric tubes.

The time elapsed in the EM group for the entire procedure was shorter than that for the control group. Also, when using the conventional technique, the correct probe position always has to be checked using radiographic testing, which causes additional delays in starting the diet infusion; this delay is not trivial, as there is evidence that early diet is beneficial.[1-3]

Several studies have shown the effectiveness of this electromagnetically guided system.[21-24] One study evaluated post-pyloric tube placement in 50 severely ill patients using the electromagnetically guided system and showed that the method is easily performed and has high success rates.[21] Another study conducted on 107 children found that the electromagnetic method is safe, effective and has low hospital costs.[22] Recently, a study in burn patients showed that the technique reduced energy deficit, X-ray exposure and costs of placement.[23] In another study, a multicenter trial, this new technique was shown to be effective and fast in ICU patients.[24]

This trial has some limitations. The main limitation is the sample size, which was limited, as the study was discontinued due to supply shortage. However, the study was shown to have sufficient statistical power to confirm the study hypothesis. The second limitation of this study is that no comparisons were made regarding the amount of diet infused, presence of vomiting or pneumonia and cost, which would have been useful for a better evaluation of its clinical impact. Additional studies with larger samples are necessary to provide more definitive conclusions.

CONCLUSION

The bedside electromagnetically monitored method was faster and more effective than the traditionally used technique for post-pyloric nasoenteral tube placement.

RESUMO

Objetivos: Suporte nutricional adequado tem papel importante na evolução de pacientes graves. Entretanto, significativa porcentagem destes pacientes evolui com dismotilidade intestinal, provocando alto volume gástrico residual. A administração de dieta enteral através de sonda em posição pós-pilórica tem sido sugerida como método para melhorar a tolerância. Objetivo deste estudo foi comparar a taxa de sucesso no posicionamento pós-pilórico da sonda nasoenteral por utilização de equipamento, que permite acompanhar a progressão da sonda através da visualização por transmissão eletromagnética em tempo real, em comparação com o método tradicional.

Métodos: Estudo prospectivo, randomizado, controlado, realizado em um hospital terciário durante três meses. Os pacientes foram randomizados para dois grupos: grupo com guia eletromagnético, pacientes submetidos à passagem de sonda nasoenteral sob auxilio do aparelho com visualização em tempo real e transmissão magnética e grupo convencional, passagem de sonda nasoenteral às cegas. O sucesso no posicionamento pós-pilórico e o tempo de duração do procedimento foram avaliados entre os grupos.

Resultados: Foram incluídos no estudo 37 pacientes, sendo 18 do grupo com guia eletromagnético e 19 do grupo convencional. A localização da sonda por meio da radiografia mostrou que o grupo com guia eletromagnético apresentou mais posicionamento pós-pilorico do que o grupo convencional, com menor tempo para realização do procedimento, com maior valor do pH do líquido aspirado pela sonda.

Conclusões: O método de passagem e visualização a beira leito por transmissão eletromagnética garante de forma segura a monitorização e acurácia frente à sondagem nasoenteral.

Descritores: Terapia nutricional; Nutrição enteral/ instrumentação; Nutrição enteral/métodos; Intubação nasogástrica

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