



Trabajo Original

Nutrición artificial

Incidents and adverse events in enteral feeding tube users: warnings based on a cohort study

Incidentes y eventos adversos en usuarios de sonda enteral: alerta a partir de una cohorte

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Abstract

Introduction: few studies clearly describe incidents or adverse events that occur during the enteral nutrition process, which hinders the identification of critical points.

Objective: to describe breaches of protocol, incidents and adverse events, during the period beginning with indications until the use of enteral feeding tube in an Emergency Department.

Method: trained nurses prospectively monitored a cohort of adults in a Brazilian Emergency Department where use of enteral feeding tube was indicated and up to their use. The study sought to identify breaches of protocol, such as verbal orders to insert feeding tubes, or authorization of their use without X-rays to confirm the position of the feeding tubes. Incidents were characterized as events that could have caused harm to patients, while adverse events were those that did actually cause harm. The study was approved by the institution's Research Ethics Committee.

Results: in 150 feeding tube insertions, there were 169 breaches of protocol: verbal orders for feeding tube insertion (n = 59); no X-rays taken (n = 11); and no examination of the X-rays by physicians (n = 12). There were 30 incidents: unintentional removal of the feeding tube (n = 23); and administration of enteral nutrition after breach of preventive barriers. There was one adverse event: aspiration of enteral nutrition.

Conclusion: there was a high frequency of breaches of safety protocols; many developed into incidents, and one resulted in an adverse event.

Key words:

Enteral nutrition.
Emergency
Department. Hospital.
Patient safety.

Resumen

Introducción: pocos estudios describen claramente los incidentes o eventos adversos que suceden durante el proceso de nutrición enteral, dificultando la identificación de puntos críticos.

Objetivo: describir las rupturas de protocolo, los incidentes y los eventos adversos de la indicación para uso de sondas nasogástricas en un Servicio de Urgencias.

Método: enfermeras capacitadas siguieron prospectivamente a una cohorte de adultos de un Servicio de Urgencias brasileño, con indicación de uso de sonda enteral. Se buscó identificar las rupturas de protocolo, descritas como: "orden verbal" para inserción de la sonda o para aprobar su uso; y no realización de radiografía confirmatoria del posicionamiento de la sonda. Los incidentes fueron considerados eventos que podrían haber provocado daños al paciente, mientras que los eventos adversos, como incidentes que efectivamente los provocaron. Este proyecto fue aprobado por el Comité de Ética en Investigación de la institución.

Resultados: en 150 inserciones de sonda hubo 169 rupturas de protocolo: orden verbal para inserción de sonda (n = 59), no realización de radiografía (n = 11) y radiografía no evaluada por médico (n = 12). Ocurrieron 30 incidentes: retiro inadvertido de sonda (n = 23) y administración de dieta en vigencia de ruptura de barreras (n = 7). Hubo un evento adverso grave (aspiración de dieta).

Conclusión: hubo elevada frecuencia de ruptura de protocolo de seguridad; muchas evolucionaron a incidentes y uno de ellos resultó evento adverso.

Palabras clave:

Nutrición enteral.
Servicio de
Urgencias. Hospital.
Seguridad del
paciente.

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INTRODUCTION

Despite being frequent in Brazilian hospitals and other centers, the insertion, maintenance and administration of enteral feeding tube (EFT) are procedures with risks. Errors in the position of the distal tip of the feeding tube can result in serious complications (1), such as aspiration or infusion of enteral nutrition or medication in the respiratory tract (1,2). In a study (2) prompted by the occurrence of two events, 2,079 feeding tube insertions were reviewed. X-ray reports between 2001 and 2004 were examined, looking for combinations of feeding tube, lung, pneumothorax and bronchus. In 1.3% ($n = 50$) of the patients, the X-ray reports showed that the distal tip of the feeding tube was located in the bronchi or lung. Among these 50 patients, 10% developed pneumonia, 16% experienced a pneumothorax, and two deaths were directly associated with incorrect anatomical positioning of the feeding tube. These findings show that the frequency of serious adverse events (permanent damage or death) is low, albeit of high clinical relevance, which justifies the adoption of strategies to minimize such risks.

Since incidents can occur at different times throughout the process in the period between indication and clinical use of EFT, the Brazilian Ministry of Health has established rules for the care of patients on enteral nutrition (EN) (3). The proposed actions are based on national (4) and international (5) guidelines and require the implementation of preventive measures when administering EN. These measures include confirming the prescription information on the enteral nutrition label, correct patient identification and composition of the therapy, and checking the entire access line to the gastrointestinal tract, with special attention to the anatomical position of the distal tip of the feeding tube, confirmed through X-rays (3-5).

In certain situations, the risk of incidents and adverse events can be even greater, such as in Emergency Departments, since they are characterized by overcrowding, high circulation of professionals, complex work processes and miscommunication, which can contribute to mistakes during the provision of care, such as in the EN process (6-8). Furthermore, most feeding tube insertions in hospitals are indicated in Emergency Departments (9). Especially in the Brazilian Health System, this data is corroborated by the fact that almost all hospital admissions take place through Emergency Departments. It is also worth noting that, in Brazil, short-term devices (Levin tube - Dobhoff type) are widely used for long periods, when long-term devices are indicated (10,11). The use of long-term devices for EN is still not a reality in Brazil.

Therefore, given the shortage of publications describing incidents or adverse events that occur during the enteral nutrition process, which hinders identifying critical points, especially in Emergency Departments, the objective of the present study was to describe breaches of protocol, incidents and adverse events related to the insertion and maintenance of EFT in an Emergency Department.

METHODS

In the first half of 2015, a cohort of adults (> 18) who needed the placement of enteral feeding tubes to administer therapy

(nutrition, water and/or medication) was prospectively monitored during the care they received in an Emergency Department. This Emergency Department is part of a 795-bed tertiary university hospital which is a reference for clinical patients in the south of Brazil. The institution where the study was conducted is certified by the Joint Commission International (JCI) and has a protocol that outlines the EN process: a) the physician prescribes the placement of the feeding tube and informs the nurse responsible for the patient; b) the nurse blindly inserts the EFT at the bedside, performing clinical tests, such as auscultation; c) the patient must be X-rayed to determine the position of the distal tip of the feeding tube; d) the attending physician examines the X-ray image and expresses an opinion on the patient's medical record, authorizing use of the feeding tube for administration of therapy, or requesting that the feeding tube be repositioned; and e) administration of therapy via the feeding tube, which should only be done after completing all the previous steps.

The selection of patients was based on a list generated when physicians prescribed feeding tubes. The sample was consecutive, by convenience. Patients whose EFT were inserted using endoscopy or during surgery; who had previously undergone gastrointestinal tract surgery or surgery in the region of the head and neck; or for whom there were contraindications for blind insertion of EFT were not included. It is worth noting that all patients used the same type of radiopaque feeding tube, with a tungsten distal tip and 10 Fr steel guidewire.

Previously trained nurses monitored the patients during every stage of the EN protocol (from indication to actual use of EFT), every day of the week, 24 hours a day, using a standardized instrument for data collection. Clinical data, as well as data on the patients' treatment and data related to the work process, were examined. The electronic patient records were also consulted daily in search of additional data.

Failures to comply with any of the steps of the institution's protocol were considered as breaches of protocol, including verbal orders to insert enteral feedings tube or authorize their use, considering that EN is not an emergency procedure. A guideline from the Brazilian Ministry of Health was used (12), based on definitions from the World Health Organization (13) that defines incidents as events or circumstances that could have resulted in unnecessary harm to patients, such as: unintentional removal of the EFT; obstruction of the feeding tube; administration of therapy/EN without having taken an X-ray; administration of therapy/EN without medical authorization to use the feeding tube; and administration of therapy with the EFT in a risk position for aspiration. In the same reference, adverse events are deemed to be any incidents that result in harm to patients.

The data was assessed according to its characteristics and distribution. When possible, associations between the categorical variables were tested using the Chi-squared test or Fisher's exact test. For all the analyses, the Statistical Package for the Social Sciences (SPSS) Version 20.0 was used.

All the outcomes were witnessed by the researchers during the monitoring of the cohort and communicated to the care team so that the applicable care and administrative measures could be

carried out. The methodological and ethical aspects of the study were approved by the institution’s Ethics Committee for Research (protocol no. 150028).

RESULTS

A total of 150 EFT placement procedures were monitored. There was a high number of breaches of protocol (n = 169) and incidents (n = 30) during one or more steps of the process (from indication of the EFT to its actual use). There was one serious adverse event. The characteristics of the patients who used an EFT are described in table I.

Among the breaches of protocol, verbal orders, rather than written, for insertion (39.3%) and authorization to use feeding tubes (58%) were the most frequent. In 7.3% of the placements X-rays were not performed or the attending physicians failed to issue written or verbal opinions on the position of the EFT after the X-rays (8%).

As for incidents, there was a large number of cases where feedings tubes were accidentally displaced (traction) or unintentionally removed by patients (15.3%), resulting in another insertion procedure. In some patients, the procedure (feeding tube reinsertion) needed to be repeated twice (16.2%) or three times (5.6%). When the association between the condition of patients at the time of feeding tube insertion and the proportion of unintentional removals was examined, it was noted that those who were alert or agitated removed the device the most (78.3% versus 50.4%; p = 0.014). There were no cases of obstructions of feeding tubes (Table II).

Among the eleven insertions where X-rays were not taken, there was direct administration of enteral nutrition via feeding tubes in three. In addition, among the 12 insertions where there was no record of medical authorization to use feeding tubes, administration of nutrition occurred in two. In one case, the three first steps of the protocol were performed (written prescription for the

Table I. Characteristics of the patients who used an enteral feeding tube at an Emergency Department in the south of Brazil

Characteristics	n (%)
Age (±SD)	65 ± 17.2
Male gender	60 (52.7)
<i>Reason for admission to the ED</i>	
Neurological problems	56 (48.7)
Respiratory problems	26 (22.6)
Gastrointestinal problems	22 (19.1)
Other	11 (9.6)
<i>Reason for indication of EFT*</i>	
Lower sensory functions	60 (40)
Lack of appetite or dysphagia	57 (38)
Invasive or noninvasive mechanical ventilation	22 (14.7)
Malnutrition	6 (4)
Other	5 (3.3)
<i>Previous diseases</i>	
Stroke (ischemic or hemorrhagic)	19 (16.5)
Parkinson or Alzheimer	14 (12.2)
Cerebral palsy or epilepsy	12 (10.4)
Systemic arterial hypertension	59 (51.3)

Source: research data, 2017. *The reasons for indication of the enteral tube were calculated using the total number of insertions (n = 150), since some patients who needed reinsertion had, as described in their charts, different reasons from the initial indication. The other values refer to the number of patients (n=115), since some patients required reinsertion of the enteral tube. ED: Emergency Department; EFT: enteral feeding tube.

Table II. Breaches of protocol, incidents and adverse events related to the insertion, maintenance and administration of therapy by EFT in an Emergency Department. The data is presented in absolute numbers and proportions

Outcome	Risk condition	n (%)
Breaches of protocol	Prescription to insert tube only by verbal order	59 (39.3)
	Authorization to use tube only by verbal order	87 (58)
	No X-ray taken	11 (7.3)
	No record of medical authorization to use the tube	12 (8)
Incidents	Accidental removal of the EFT	23 (15.3)
	Obstruction of the EFT	0 (0)
	Administration of therapy without an X-ray	3 (2)
	Administration of therapy with no record of medical authorization to use the tube	2 (1.3)
	Administration of therapy with the EFT in a bronchoaspiration risk position	2 (1.3)
Adverse event	Bronchoaspiration	1 (0.6)

Source: research data, 2017.

feeding tube placement, insertion of the feeding tube by the nurse, and taking of the X-ray). However, one patient received enteral nutrition before the X-ray had been checked by the attending physician. In this particular case, the X-ray showed that the tip of the EFT was inserted in the distal third of the esophagus. This patient suffered bronchoaspiration of the enteral nutrition and the feeding tube was removed. The same patient required the feeding tube to be reinserted, due to needing intensive care. During the reinsertion, the X-ray indicated that it was in the middle third of the esophagus. Once again, the patient received nutrition via the feeding tube in a risk position.

DISCUSSION

This is the first study that prospectively evaluated incidents and adverse events related to EN in an Emergency Department. There was a large number of breaches of protocol throughout the EN process (from indication to actual use of feeding tubes) and, despite the low number of monitored enteral feeding tube placements, there was one adverse event.

There are strikingly high numbers of verbal orders for EFT insertions and authorizations for their use. Although verbal orders are accepted in Emergency Departments, they should be restricted to clearly urgent situations (14), where there are specific routines to repeat them, since verbal orders have the potential to lead to incidents or adverse events (14,15). Despite these warnings, verbal orders to modify enteral nutrition, request tests, infuse blood components or administer medication, among others, were frequently documented in care practices, even outside Emergency Departments (15).

Less frequent, but equally alarming, were situations where patients were not X-rayed to check the anatomical position of EFT. There were also cases where X-rays were taken but there were no opinions from physicians on the position of feeding tubes or authorizations for their use. It bears noting that X-rays were first suggested as a test to confirm the anatomical location of feeding tubes in the 1940s (16). This is currently the standard test for checking the anatomical position of the distal tip of EFT (inserted blindly), and is indicated for all insertions or reinsertions (3,5).

In fact, the entire process, from indication to use of feeding tubes, should be documented in patient medical records, so that the information can be safely utilized by members of care teams (5). Although there appear to be well-established routines for EFT insertion and maintenance in the institution of the present study, it is possible that overcrowding in the Emergency Department, miscommunication, and non-prioritization of therapies such as enteral nutrition may account for these findings. For this reason, compliance with institutional protocols or checklists (17) has proven to be effective in ensuring that all the steps of a procedure are performed, thereby avoiding forgetting or failing to comply with steps or preventive safety measures.

To minimize risks related to the steps of the EN process, the Brazilian Society of Parenteral and Enteral Nutrition (BRASPEN/SBNPE) (4), based on international guidelines (5), has recom-

mended the adoption of indicators such as rates of tube obstruction, unintentional feeding tube removal, differences between the volume of nutrition prescribed and administered, and the percentage of patients where nutritional assessment was performed within the first 24 hours of admission, among others (4). In the current study, the percentage of unintentional tube removal was high (15.3%) compared to another university hospital, also in the south of Brazil, which examined the incidence of unintentional tube removal or obstruction and the difference between the volume of nutrition prescribed and administered to inpatients (18).

In that study (18), among the 46 patients monitored, unintentional removal was observed in 4.6%. However, the study assessed intensive care patients and those from another inpatient unit, environments where the variables related to overcrowding and the bustling atmosphere of Emergency Departments are not present.

More unintentional removals of care devices, including EFT, were identified in a study that assessed 49 intensive care units in 39 different hospitals in the United States. The records of 49,482 patients per day were observed, indicating 1,097 cases of removal, where the frequency of patient-initiated tube removal was 28.9%. In around two-thirds of the patients who removed their feeding tubes, there were indications for reinsertion of the devices (19). Differences in design, number of observations and profile of critical patients, where more than one-half (58%) of those who removed care devices were agitated or anxious at the time of the incident and 27% were lethargic, according to the definitions of the study (19), may explain the higher rates of feeding tube removal than those found in the current study.

The presence of agitation at the time of feeding tube insertion was associated with its removal by patients in the present study. Therefore, agitation at the time of insertion should serve as a warning of increased risk of removal of the device, since this condition is characterized as a risk for unintentional removal of care devices (5,20,21). The high incidence of accidental removal of devices is worth noting, since the need for reinsertion increases the risk of incidents and adverse events, in addition to treatment-related costs (5).

Other incidents, such as administration of therapy via feeding tubes without all the steps of the protocol having been completed, demonstrate the weaknesses in this work procedure. Problems in care processes have been studied, and theories about their causes, trajectories and results seek to shed light on this complex theme (22,23). In their review of care safety and quality (23), Reis et al. point out that conditions related to the infrastructure or work environment, education/training and supervision, work overload, communication failures, and process failures are the main causes of breaches of protocol that result in incidents and adverse events in hospitals. In this context, incidents and adverse events would be the result of multiple factors.

In the present study, one serious adverse event was documented, resulting from aspiration of enteral nutrition due to the position of the feeding tube, even though the X-ray had indicated this problem. From a clinical point of view, esophageal topography

of the tip of the feeding tube stimulates gastroesophageal reflux, increasing the chances of reflux of gastric content and consequent aspiration (24). Aspiration pneumonia is considered as the main consequence of improper positioning of the EFT (25).

The frequency of incidents and adverse events, as determined in this study, is difficult to ascertain, primarily due to non-disclosure of data. The literature is limited to reports (26,27) or case studies (28) that describe serious adverse events in general, retrospective studies (25), or studies that assess the topography of the distal tip of the feeding tube and the relationship with bronchoaspiration (29). There appears to be an incorrect assumption that the problem is of low relevance, due to the apparent small number of people affected. However, given the potential harm, in terms of morbidity and mortality, it is worth the effort to alert professionals to the risks related to the EN process, so that safety measures can be adopted.

In regard to this theme, it is very difficult to make comparisons between the findings of the present study and others. As previously mentioned, the literature lacks studies with more comprehensive design, apart from the fact that the culture of reporting incidents and adverse events is still not well-established, not only in Brazil, but also elsewhere. Reporting enables cases to be studied and represents an important strategy for creating mechanisms to prevent further events (30,31). In a Portuguese study (31), the author asserts: "That which is not recorded, does not exist." Without reporting, it is impossible to identify the frequency of incidents and adverse events and the factors that contribute to their occurrence. In addition, the culture of recording through reporting helps debunk the punitive tradition that underlies the safety culture (30,32).

Thus, the main result to pursue involves researching actions that improve patient safety, with respect to procedures such as feeding tube insertion and maintenance. Knowing, through indicators, the frequency of incidents or adverse events and their characteristics, as well as systematically studying cases and identifying their determinants, apart from building an historical record, also enables earlier adoption of corrective actions, in order to reduce the risk of new cases. Initiatives such as these have already been undertaken in other categories of events, such as patient falls, medication errors, healthcare-associated infections and pressure sores (33).

Finally, the results of the present study prompted immediate changes in the Emergency Department in question. A panel composed of professionals from the institution working in care, nutritional therapy process management and safety, in addition to the Ethics Committee, formulated an improvement plan. In the area of research, researchers became responsible for reporting incidents or adverse events identified during the conducting of observational studies, along the lines of experimental studies.

The small number of insertions and the fact that the observations occurred in only one center may limit generalization of the results. However, the lack of studies aimed at investigating breaches of protocol, incidents and adverse events, at every stage (from indication to use of EFT) justifies the dissemination of these findings.

CONCLUSION

Breaches of protocol and incidents were frequent in the process for indication and use of EFT. Adverse events were less frequent, but with major clinical impact. The measurement of care quality indicators and the recording of near misses, incidents and adverse events enable early identification of unexpected deviations, investigation of root causes and, especially, ways to ensure safe practices, particularly in complex environments, such as Emergency Departments. Further research is needed to demonstrate the implications and negative effects of incidents involving the insertion of EFT, the administration of enteral nutrition, and its potential harm.

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