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Accuracy of the combined method (auscultation and pH measurement) and ultrasonography for confirmation of gastric tube placement: a study protocol for a prospective study

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ABSTRACT

Introduction Patients using a nasogastric tube (NGT) are vulnerable to adverse events, therefore proper assessment of these patients, verification of the correct tube placement and constant monitoring by the nursing staff are strategies that can reduce adverse events and risks associated with the care. The aim of this study will be to assess the accuracy of the combined method (auscultation and pH measurement) and ultrasonography for confirmation of gastric tube placement compared with the X-ray method. A further aim will be to measure and provide evidence for the direct costs of each method of confirming NGT placement and to evaluate the impact of each method on the mean direct cost of the patient.

Methods and analysis This is a prospective, single-centre study of diagnostic accuracy. Data will be collected in the clinical and surgical wards, intensive care unit and coronary care unit of a Brazilian teaching hospital. The sample will consist of 385 assessments, performed in adult patients that agree to participate in the study and that receive an NGT. The combined method and the ultrasound will be the index tests and will be performed on all study participants for later comparison with an X-ray examination, considered the reference standard and the gold standard to distinguish between gastric and pulmonary placement. Sensitivity, specificity, positive predictive value and negative predictive value will be calculated to assess the diagnostic accuracy of the methods investigated in this study, with Cohen's kappa analysis used to evaluate the degree of concordance.

Ethics and dissemination The study was approved by the Research Ethics Committee of the University of São Paulo at Ribeirão Preto College of Nursing, registration number: 83087318.4.0000.5393. The findings will be reported through academic journals, seminars and conference presentations, social media, print media, the internet and community/stakeholder engagement activities.

Strengths and limitations of this study

► This study will demonstrate the accuracy and limitations of two methods used to confirm the positioning of the nasogastric tube (NGT) inserted blindly at the bedside.
► Intubation will be performed by nurses from the hospital sites, reflecting the current daily practice.
► Few exclusion criteria will be applied, resulting in increased generalisability.
► There has been no prior study evaluating the costs related to the methods employed in this study to confirm the positioning of the NGT inserted blindly at the bedside.
► A limitation of this study is that only one model of ultrasound equipment will be used to verify the NGT positioning in the patients.

INTRODUCTION

Nasogastric tubes (NGTs) are common in healthcare. In the USA, about 1.2 million NGTs are inserted in adults and children per year, for the purpose of enteral feeding.[1] According to the National Health Service (NHS) in 2015, approximately 790 000 fine-bore NGTs are purchased in the UK and used annually in patients, however, many more are probably used outside NHS hospitals.[2] In Brazil, although the use of NGTs seems to be frequent in hospitals and long-term care facilities,[3 4] there are few studies estimating the number of users of this tube in Brazilian health services.

Despite being common, NGTs are frequently associated with serious and fatal adverse events. According to a report published by the Food and Drug Administration, there were 51 reports of pneumothorax

associated with the insertion of NGTs in the USA from January 2012 to July 2017.[5] In the majority of the cases, there was need for urgent intervention, including needle decompression or the insertion of a chest tube. Several of these events were associated with cardiopulmonary arrest and death.[5]

In Brazil, it is the nurse's responsibility to insert the NGT, assure the safe maintenance of the tube in the patient throughout the time of use, ensure the correct enteral nutrition administration and define the nursing care regarding the safe manipulation of the tube.[6] The NGT is blindly inserted by the nurse at the bedside, with epigastric auscultation being the main method used to confirm the positioning of the tube in Brazilian health services. This method is, however, considered inconclusive and it is related to false positives, even when the tube is located in the oesophagus or in the trachea.[7] The most proficient professionals can have difficulty in recognising pulmonary intubation when inserting an NGT since the sound made by the insufflated air can be transmitted to the epigastrium, regardless of the tube being placed in the lungs, oesophagus, stomach, duodenum or jejunum.[8]

Among the other non-radiographic methods used, the measurement of pH is the first line test and the most sensitive. According to a recent review of international guidelines,[9] epigastric auscultation is the least desirable method, with pH measurement recommended by the UK National Patient Safety Agency (NPSA)[10] and American Association of Critical-Care Nurses.[7]

The reference pH values are typically distinct in the lungs, stomach and bowel. The gastric pH is acid, with values varying from 1 to 5.5.[9] Values equal to or higher than 6 are indicators of gut or respiratory aspiration, with the latter being more alkaline.[7] Accordingly, values that are lower than 6 indicate gastric positioning and exclude the possible displacement of the tube to the lungs.[9] Nevertheless, the possibility of the distal end of the tube being in the oesophagus is not excluded. It should be considered that some medications, such as proton pump inhibitors or H_2 receptor antagonists, as well as prolonged fasting and enteral feeding, may alter the pH of the stomach, limiting the use of this method.[11] It is highlighted that misplaced NGT is considered a never event in the UK, that is, a specific sentinel event related to patient safety that, when present, usually results in serious harm or death.[12] Therefore, this method should not be used in isolation.

Radiography is the diagnostic method adopted worldwide as the gold standard to distinguish between gastric and pulmonary placement.[13–17] However, it is associated with high costs, delayed enteral feeding administration and the exposure of the patient to radiation.[18 19] In addition, the costs related to radiographic examinations are significant. While a typical pH test strip costs less than 25 cents, a single chest or abdominal radiography may cost from \$100 to several hundred US dollars.[9] According to the NHS, the routine use of radiography to confirm NGT positioning is not recommended except for patients at high risk of tube displacement, such as newborns or patients in a critical condition.[10]

Ultrasonography is another diagnostic method currently used in the clinical practice to confirm NGT placement. The method was accurate in 34 of the 35 patients participating in a study conducted in an intensive care unit (ICU).[20] According to the researchers, ultrasound is a simple and reliable method, which is faster than conventional radiography and does not expose the patient to radiation.[20] The method was also useful to assess the correct positioning of the NGT in patients with reduced levels of consciousness in the context of emergencies. However, as a limitation of the study, the authors recognised the difficulty of directly analysing the accuracy of the ultrasound examinations due to the low number of cases of incorrectly placed tubes. For more accurate results, the authors recommended studies with a larger number of patients.[21]

A recent systematic review conducted to assess the diagnostic accuracy of ultrasound for gastric tube placement confirmation suggested that ultrasound does not have sufficient accuracy as a single method to confirm gastric tube placement, which supports the need for further study.[22] According to the authors, this method can be useful to detect misplaced gastric tubes in settings where X-ray is not readily available.[22]

It should be noted that the São Paulo Regional Nursing Council (*Conselho Regional de Enfermagem de São Paulo*, COREN-SP) published guidance (No. 028/2015) stating that nurses can use ultrasound as a replacement method for radiological examination to confirm the position of the NGT, as long as the equipment and professionals with adequate training are available.[23] The COREN-SP also recommended that, if radiological methods cannot be implemented to confirm NGT positioning, two non-radiological methods should be associated, namely the pH method and epigastric auscultation.[24]

There is an urgent need for this study considering that, in Brazil, NGTs are inserted by nurses blindly at the bedside and that COREN-SP provided guidance stating that the ultrasound can be used to verify the position of the NGT when the X-ray examination is unavailable, despite a lack of supporting evidence. In addition, there are no studies that measure and provide evidence of the direct costs of each method used to confirm the positioning of the NGT or to assess the impact of each method on the mean direct cost of the patient. This aspect also highlights the unprecedented nature of this study and the importance of this analysis, considering the economic crisis that Brazil has been experiencing. The results from this analysis will allow Brazilian health institutions to choose safer methods for patients using NGTs, with a more affordable cost.

Accordingly, the primary aim of this study will be to assess the accuracy of the combined method (auscultation and pH measurement) and ultrasonography for confirmation of gastric tube placement compared with the X-ray method. The secondary aims are to compare
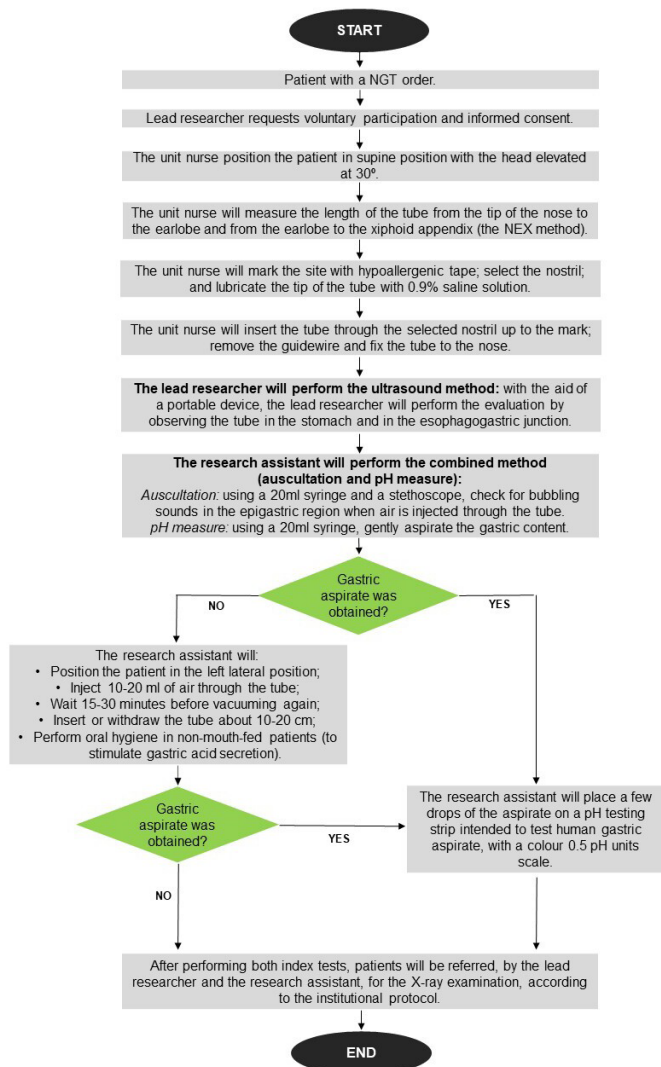
Figure 1 Study flowchart. NEX, Nose–Ear–Xiphoid; NGT, nasogastric tube.

the time required to perform the methods, considering the correct diagnosis, to measure and provide evidence regarding the direct costs of each method used to confirm NGT placement and to evaluate the impact of each method on the mean direct cost of the patient.

METHODS AND ANALYSIS
Study overview

A prospective, single-centre study of diagnostic accuracy will be conducted with adult patients undergoing NGT insertion. The Standards for Reporting of Diagnostic Accuracy Studies will be applied.[25]

The study will be carried out in a 922-bed Brazilian teaching hospital, which has approximately 35 400 annual admissions and is a high complexity centre in the northeast of São Paulo state. Data collection will take place in all the clinical and surgical wards, the ICU and coronary care unit of the hospital, from Monday to Friday, during business hours.

All NGTs will be prescribed by the attending physician (for full or additional tube feeding, water and/or medications). The same type and brand of NGT will be used in the patients. All tubes will be polyurethane, radiopaque, with a 10 French distal tungsten tip and guidewire. The NGT will be inserted into the patient by the unit nurse, according to the relevant institutional protocol, in order to reflect the clinical nursing practice in place. The NGT insertion protocol consists of the following: measuring the length of the tube from the tip of the nose to the earlobe and from the earlobe to the xiphoid appendix (the NEX method)[10]; marking the site with hypoallergenic tape; selecting the nostril; lubricating the tip of the tube with 0.9% saline solution; inserting the tube through the selected nostril up to the mark; removing the guidewire and fixing the tube to the nose. Figure 1 presents the study flowchart.

Sample size

In order to determine the number of assessments necessary to analyse the accuracy of the combined method (auscultation and pH measurement) and ultrasonography for confirmation of gastric tube placement compared with the X-ray method, the sample size calculation was based on Gwet's agreement coefficient.[26] The expression is given by:

$$AC1 = \frac{\pi_a - \pi_e}{1 - \pi_e}$$

where π_a is the observed agreement and π_e is the probability of agreement given by $\pi_e = 2P_1\left(1 - P_1\right)$, with the probability P_1 given by:

$$P_1 = \frac{d_{00} + d_{10} + d_{00} + d_{01}/2}{N}$$

with d_{00} representing the number of agreements in a category, and d_{10} and d_{01} representing amounts of discordant pairs.

Gwet's AC_1 is not affected by prevalence, sensitivity and specificity values and has better performance results.[27] The expression to determine the sample size[28 29] is given by:

$$n = \frac{1}{r^2\left(\pi_a - \pi_e\right)^2}$$

where r denotes the relative error. The correction for finite populations is given by:

$$nc = \frac{n}{1 + \frac{n}{N}}$$

with N denoting the size of the population. Considering a relative error of 25%, the difference between agreements of 20% ($(\pi_a - \pi_e)$=0.2) and a very large population (N=10 000), the minimum number of assessments was 385.

Inclusion criteria

Patients over 18 years of age that require NGT insertion will be eligible for inclusion.

Exclusion criteria

► Patients requiring NGT for drainage.

► Patients with enteral tube via ostomy.
► Patients undergoing surgical intervention in the gastrointestinal tract and thoraco-abdominal surgery.
► Pregnant women.

Identification of participants

The lead researcher and the research assistant will remain available at the hospital to identify the patients that require NGTs during hospitalisation and that fulfil the inclusion criteria proposed for the study. The lead researcher may also be informed by the institution's administrative team about the need for NGT insertion in a patient. A mobile phone number using WhatsApp Messenger and the email address of the lead researcher will be used to facilitate communication.

Assessing capacity and obtaining informed consent

The lead researcher will explain the research objectives to the patients and request their voluntary participation in the study. On consent, the participant will sign a consent form. In the case of patients unable to answer for themselves as a result of being in an advanced stage of disease, the lead researcher will request written authorisation from the legal guardian. Participants will be informed that the research results will be destined for possible publications and that their confidentiality and anonymity will be guaranteed.

Instruments

Data will be entered into an electronic form hosted on a secure platform (Survey Monkey) by the lead researcher. Demographic, clinical and therapeutic variables will consist of the following:

Demographic: date of admission to the unit; registration number; date of birth; gender; state/country; origin; race; marital status; degree of education and profession/occupation.

Clinical: primary and secondary medical diagnoses (according to the International Classification of Diseases (ICD-10)); Glasgow Coma Scale score; patient care complexity; disease severity; weight and height.

Therapeutic: NGT-related data (reason for use); data related to the prescribed medications (name, presentation, dose, schedule, pharmaceutical form, route and frequency of administration).

Methods: time taken (in seconds) to perform each method (combined method and ultrasound) and correct/incorrect positioning of the NGT.

Patient complexity will be assessed by the lead researcher before performing the combined method and the ultrasound to confirm NGT placement. The Patient Classification System (PCS) proposed by Fugulin[30] will be used for this. The PCS allows the determination of a patient's degree of dependence on the nursing staff to establish the time spent in care, as well as the number of staff needed to fulfil the patient's biopsychosocial and spiritual needs. The PCS is recommended by the Federal Nursing Council (Conselho Federal de Enfermagem)

through Resolution No. 543/2017, which establishes official parameters for the number of the nursing staff and indicates the minimum hours of care.[31] The instrument was developed for the purpose of classifying patients according to degree of dependence on the nursing staff and has nine critical indicators: mental state, oxygenation, vital signs, mobility, ambulation, diet, body care, elimination and therapy. The scores are distributed into five categories that correspond to the complexity of care: minimum, intermediate, high dependency, semi-intensive and intensive.[32]

The severity of the patients will be assessed by the lead researcher using the Charlson Comorbidity Index (CCI),[33] a method for categorising patient comorbidities according to the ICD-10. For this, data will be collected from the patient's medical record on admission, by the lead researcher. The CCI measures the severity of the disease regardless of the main diagnosis: it evaluates the prediction of the risk of death. The final CCI score is obtained by totalling the weights attributed to the comorbidities recorded as secondary diagnoses, with higher scores equating to a greater risk of the patient dying. Based on the final CCI score, the patients will be stratified into three groups: mild risk (scores 1–2); moderate risk (scores 3–4) and high risk (score ≥5).[34]

Methods to confirm NGT placement

The methods to confirm NGT placement (index tests) will be performed in the ward at the bedside, and in the following order: (1) ultrasound followed by (2) combined method (epigastric auscultation and pH measurement). This sequencing is necessary because the low transmission of ultrasonic waves through the air, due to its high acoustic impedance, limits the use of ultrasound as a method to check the position of the NGT after air injection by the same device.[35]

Final confirmation of the NGT placement will be obtained by X-ray examination (reference standard), which is considered the gold standard method to distinguish between gastric and pulmonary placement.[13–17]

Ultrasound method

After NGT insertion by a nurse of the hospital site, the ultrasound method (the index test), will be performed by the lead researcher, a registered nurse previously trained by a specialist physician. The method will be performed at the bedside with the aid of a portable device containing a Sectorial Transducer, with a frequency of 1.7–3.8 MHz, and a Linear Transducer, with a frequency of 3.4–8 MHz. The evaluation will be performed by observing the tube in the stomach and the esophagogastric junction (EGJ), which is the area that extends from the terminal portion of the oesophagus to the cardia. Two results can be obtained from the evaluation: (1) presence or absence of the NGT in the EGJ; (2) presence or absence of the NGT in the stomach. We will not record the precise gastric location of NGT tip in this study, only whether there is proper positioning in the stomach. The examination

time will be limited to 15 minutes to avoid any delays. The examination will be considered positive when the NGT is identified in the stomach by demonstrating a fine, long and slightly hyperechoic structure.[36] In addition, the lead researcher will be blind to the results of the combined method and the X-ray.

To record the time taken to confirm NGT placement by the ultrasound method, a trained research assistant will be using a stopwatch and the time will be recorded in seconds.

Combined method (auscultation and pH measure)

After performing the ultrasound, the combined method (auscultation and pH measure) (the index test), will be performed by a research assistant, a nurse previously trained by the lead researcher. The auscultation will be conducted according to the hospital protocol: using a 20 mL syringe and a stethoscope, the presence of bubbling sounds in the epigastric region will be listened for when air is injected through the tube. If a whooshing sound can be heard, it will be assumed that the NGT is placed in the stomach.

For the pH measurement, patient will have to have gone at least 4 hours without using proton pump inhibitors or H_2 receptor antagonists, 4 hours without eating solid foods and 2 hours without ingesting liquids. The method will be performed according to the flowchart proposed by the NPSA[10]: using a 20 mL syringe, the gastric contents will be gently aspirated; a few drops of the aspirate will be placed on a pH testing strip intended to test human gastric aspirate, with a colour 0.5 pH units scale. When the pH is found to be ≤5.5, it will be assumed that the end of the NGT is correctly placed in the stomach.

If aspiration is not obtained, one of these auxiliary techniques will be used: positioning the patient in the left lateral position; injecting 10–20 mL of air through the tube; waiting 15 to 30 minutes before vacuuming again; inserting or withdrawing the tube about 10–20 cm; performing oral hygiene in non-mouth-fed patients (to stimulate gastric acid secretion); without washing the tube with water.[10] The research assistant will be blind to the results of the ultrasound and the X-ray.

To ensure the reliability of data, the time taken to perform the combined method will be recorded, in seconds, by a trained research assistant using a stopwatch, considering the time from testing the aspirate to reading the pH testing strip. If any readings fall within the pH range of 5–6, a second experienced nurse, a member of the research team, will check the result.

Reference standard (X-ray)

After performing both index tests, patients will be referred for the X-ray examination, considered the gold standard for checking NGT placement, by the lead researcher and the research assistant. Patients will be moved with the aid of a stretcher or wheelchair, depending on their care complexity and severity of their disease. If it is impossible to move the patient to the examination site, the examination will be performed on the ward, at the bedside.

Considering the risk of radiation exposure arising from the X-ray examination, the basic principle of radiological protection will be adopted, with the justification that the X-ray examination will produce enough benefit for the patient, offsetting the risk of the radiation exposure. In addition, the three main radiation exposure control factors will be adopted, namely: exposure time, distance from the source and shielding for the purpose of safety and radiological protection.

Regarding the X-ray examination in the ward, in addition to the requirements for the protection of the study patient, other patients who cannot be removed from the ward will be shielded from the radiation by a protective lead barrier and placed in a safe position so that no part of their bodies is within 2 m of the radiological source.[37 38]

Chest X-rays will be interpreted by a specialist who will be blind to the results both of the other assessments (combined method and ultrasonography). Once the radiologist's examination report is available, the lead researcher will inform the nurse responsible for providing the enteral nutrition.

Assessment of the direct costs of each method used to confirm NGT placement

The costs related to the methods employed to confirm NGT placement will be allocated according to the absorption costing methodology, which will require the final score obtained by the PCS and the time (in seconds) needed to perform each method. The time taken to perform each method will serve as the basis for indicating the direct labour cost of the nurse (lead researcher). It will also serve as a criterion (apportionment basis) of the associated indirect costs, following the absorption costing method.[39]

Absorption costing has, as its main goal, the allocation of costs to services and procedures. They absorb the costs in a process and through sequential allocation, which, in theory, would initially be grouped to a cost centre.[40 41] In general, absorption costing, like every method, has advantages and disadvantages arising from its use.[39] The advantages include, aggregation of all the costs, both fixed and variable and cheaper implementation, as it does not require separation of the manufacturing costs into fixed and variable components. Regarding the disadvantages, it should be considered that the costs that are not objectively related to the services or procedures are almost always distributed using apportionment criteria, many of them arbitrary or subjective.

Absorption costing promotes the distribution of inputs that are essential to the procedures. For this, the method follows certain steps,[42] including separation between costs and expenses, followed by the appropriation of direct costs to the procedures and the attribution of indirect costs to the procedures, according to previously established apportionment bases (apportionment criteria).

The methodology for measuring costs related to the methods used to confirm NGT placement will consist of four steps:

► Step 1: the costs of the hospital's clinical and surgical wards will be determined, including, personnel (salaries and charges), consumable goods and medicine, electricity, depreciation and maintenance of equipment and facilities, and rental of devices.

► Step 2: these costs will be attributed to the beds, the indirect ones being through established apportionment criteria. The hospital already has a system for this allocation: known as bar code medication administration technology.[43]

► Step 3: the bed costs, which are indirect to the procedures, will be transferred to all procedures performed on the patient via proportional apportionment for the execution time. The same will happen with the methods used to confirm NGT placement, which will receive the indirect bed costs proportional to their execution time.

► Step 4: for each of the methods used to confirm the NGT placement, the direct costs of execution indicated by the lead researcher will be grouped with the indirect bed costs—measured as proportional to their time of execution. Therefore, the total costs related to each of the methods used to confirm the positioning of NGT will be measured.

Data analysis

Continuous variables will be expressed as means±SD for the parametric variables and as medians with quartile intervals for the non-parametric variables (time taken for each method). The time determined by each method will be compared using the Mann-Whitney test.

Sensitivity, specificity, positive predictive value and negative predictive value will be calculated to assess the diagnostic accuracy of the methods studied in this research project, and Cohen's kappa will be calculated to evaluate the degree of concordance. The SPSS for Windows (V.25.0) software will be used to perform the statistical analysis. P values less than 0.05 will be considered statistically significant.

Data protection

Survey Monkey will be used for data collection and management. This platform hosts the questionnaires and, in accordance with its privacy policy, the questionnaires/forms/applications and responses collected are private by default. Only the main researcher and the project coordinator will have access to the platform, which is password protected.

Patient and public involvement

There was no patient or public involvement in the development of the research question, study design and planning. However, the findings, recommendations and implications of the project will be disseminated in accessible formats suitable for the relevant patient community.

ETHICS AND DISSEMINATION

The project has been approved by the Research Ethics Committee of the University of São Paulo at Ribeirão Preto College of Nursing, under authorisation number (CAAE) 83087318.4.0000.5393. The project will be developed in accordance with Resolution No. 466 of 12 December 2012, of the National Research Ethics Council of the Ministry of Health, which addresses ethics in research with human subjects.[44 45]

The results will be reported to the hospital and the findings may contribute to the hospital's policies and procedures for confirming the correct positioning of the NGT and improving the quality of care and patient safety. The results will also be reported through peer-reviewed academic journals and conference presentations, social media (eg, Facebook, Twitter), print media (eg, Patient Safety Alert), the internet (eg, links to study reports on the Patient Safety Research Group website) and community/stakeholder engagement activities (eg, community forums, stakeholder meetings). The project team includes academic researchers, hospital clinicians and experts involved in patient safety. This provides the project with access to a range of other conduits through which to disseminate results, for example, to policymakers and system implementers.

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