# Naso-enteric Tube Placement: A Review of Methods to Confirm Tip Location, Global Applicability and Requirements

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#### **SCIENTIFIC REVIEW**

### Naso-enteric Tube Placement: A Review of Methods to Confirm Tip Location, Global Applicability and Requirements

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#### **Abstract**

*Background* The insertion of a tube through the nose and into the stomach or beyond is a common clinical procedure for feeding and decompression. The safety, accuracy and reliability of tube insertion and methods used to confirm the location of the naso-enteric tube (NET) tip have not been systematically reviewed. The aim of this study is to review and compare these methods and determine their global applicability by end-user engagement.

*Methods* A systematic literature review of four major databases was performed to identify all relevant studies. The methods for NET tip localization were then compared for their accuracy with reference to a gold standard method (radiography or endoscopy). The global applicability of the different methods was analysed using a house of quality matrix.

Results After applying the inclusion and exclusion criteria, 76 articles were selected. Limitations were found to be associated with the 20 different methods described for NET tip localization. The method with the best combined sensitivity and specificity (where n > 1) was ultrasound/sonography, followed by external magnetic guidance, electromagnetic methods and then capnography/capnometry. The top three performance criteria that were considered most important for global applicability were cost per tube/disposable, success rate and cost for non-disposable components.

Conclusion There is no ideal method for confirming NET tip localisation. While radiography (the gold standard used for comparison) and ultrasound were the most accurate methods, they are costly and not universally available. There remains the need to develop a low-cost, easy-use, accurate and reliable method for NET tip localization.

**Electronic supplementary material** The online version of this article (doi:10.1007/s00268-015-3077-6) contains supplementary material, which is available to authorised users.

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#### Introduction

The insertion of a tube through the nose into the oesophagus or beyond is a common procedure in hospitals. The first recorded occasion was by Capivacceus in 1598 who used the tube to provide nutrients to the foregut [1]. During the seventeenth century, it became more common to feed liquid nutrients fed by a tube in the oesophagus [1]. It has become common practice to insert a tube into the stomach for decompression for gastric or intestinal ileus and obstruction [2, 3]. Today a naso-enteric tube (NET) is used in roughly 10 % of hospitalised patients to provide nutritional support [4, 5]. Patients that most commonly require a NET are in the surgical, intensive care, neonatal and paediatric settings [2, 6].

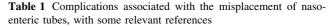
The insertion of a NET is not always successful. There are a range of complications from NET misplacement (Table 1) [2, 7]. It occurs in 13–20 % of adult and 39–55 % of paediatric patients [8]. It has also been suggested that it is associated with a higher morbidity and mortality rates than other misadventures such as retained sponges and wrong-site surgery [5]. The NHS Patient Safety Board has identified NET misplacement as a "never event", meaning that this routine task should be 100 % reliable, and has listed it as "one of a restricted list of serious avoidable events" [4]. This means that a safe, accurate and reliable method to insert and confirm the tip location of a NET is required [9].

Many different methods have been described, including those using radiation, acidity and sound, but none appear to be meet the requirements to ensure that misplacement is a 'never event' [9]. A formal review of the methods used to confirm the location of the NET tip has not been published. Further there has not been an attempt to formally appraise the appropriateness of the methods from the perspective of the end-users and stakeholders. The three aims of this study are to systematically review current and proposed methods to confirm the NET tip location, to compare these methods in regards to accuracy, reliability, cost and safety and to determine their global applicability.

#### **Methods**

#### Literature review

Four major biomedical databases (PubMed, Scopus, Web of Science and Embase) were used in an electronic literature search to find articles that reported on methods of placement or position verification of nasally inserted tubes for any purpose and intended for any destination in the gut. The search included articles published between 1985 and



Complications	References	
Aspiration	[2, 9, 14]	
Asphyxia		
Pneumonitis/pneumonia	[2, 9, 15–17]	
Pneumothorax	[2, 9, 15, 17]	
Respiratory failure	[2]	
Peritonitis	[2]	
Intracranial placement	[7, 18]	
Pulmonary haemorrhage	[17]	
Pleural effusion	[15–17]	
Empyema	[9, 15–17]	
Tracheal-esophageal fistula	[17]	
Enteric perforation	[9]	
Death	[9, 19]	

2012. Only articles in English were searched. The search string used was (enteral OR ryles OR nasogastric OR nasojejunal OR nasoduodenal OR feed OR feeding) AND tube AND (airway OR gastric OR oesophag\* OR stomach OR duoden\* OR jejun\* OR pyloric OR diaphragm\*) AND (confirm\* OR verif\* OR detect\* OR predict\* OR placement), NOT (percutaneous OR PEG OR \*ostomy).

Duplicate articles were removed from a compiled title list from all database searches. Articles were included in the review if they used human subjects and if the test for confirming the tip location was compared with a gold standard, which was considered plain radiography and/or endoscopy. Studies that looked at markers or indicators of pulmonary misplacement of NET were also included as many were found to contain relevant techniques. Two reviewers (SM, HS) independently checked the article titles and abstracts for inclusion criteria and in the case of any differing results third party mediation was employed. Specific quantitative and qualitative data were extracted including: title of paper, author(s), date of publication, journal, type of hospital setting, type of study, total number of subjects, total number of valid observations, ratio of subject genders, subject age group, subject condition, intended site for tube placement, description of technique used, gold standard used for comparison, whether the method was being independently validated, duration of procedure, cost of procedure, positive and negative likelihood ratios, sensitivity, specificity, number of trials unable to determine result, number of pulmonary misplacements and specific issues reported associated with using the technique. For articles using a number of different techniques on the same subject population, the techniques were entered separately into the data extraction table. The PRISMA checklist was used for reporting the results [10].



The quality of the studies were assessed using the Newcastle Ottawa quality assessment scale [11]. The scale involves assessment for selection (including representativeness of exposed cohort, selection of the non-exposed cohort and ascertainment of exposure and demonstration that the outcome of interests was not present at the start of the study), comparability of cohorts (on basis of design or analysis) and the assessment of outcome. A 'star system' is used where each study is assessed and given a maximum of one star for each of the four items under 'selection', two stars for 'comparability' and one star for the three items listed under 'exposure'. The exposure was defined as the technique that was used for confirming NET placement. The outcome was defined as whether the placement of the tube was known i.e. by confirming with radiography. The nature of NET studies means that long-term follow-up is not required. As such, some of the scale criteria did not directly apply to the studies included in the review. Thus modifications had to be made to the original scale system, which included: (1) No stars being awarded for the following selection criteria: "demonstration that outcome of interest was not present at the start of the study", as it was not clear at the start of the study whether placement of the tube was correct or not. Thus selection had a maximum of three stars to be awarded, as oppose to four. (2) The 'comparability' section was also removed. It was determined that no major conditions favoured the use of one technique over another for confirming NET placement. For example, age and gender did not make a large difference to placement of the NET. (3) Due to the studies being investigated in a cross-sectional manner, the follow-up section of 'outcome' criteria meant all studies received a star for this section.

#### Comparison of methods to confirm NET tip location

The different identified methods used to confirm NET tip location were compared for accuracy. The number of studies reporting each method was recorded along with sensitivity and specificity. It was assumed that unless the true negative (TN) values and false negative (FN) values were directly stated, that they had not been included in calculations of specificity and sensitivity as it was assumed that the health care practitioner would simply re-insert the NET if they thought it was in the incorrect position. For example, if stated that the pH method agreed with the radiograph in 84 % of observations, then if the TN and FN values were not stated it would be assumed that the true positive value was 84 %. In some studies, in addition to stating the tip location as correct or incorrect when compared with the gold standard, there was the report of an indeterminate location and this was recorded where available.

## Determining global appropriateness of methods to confirm NET tip location

The global appropriateness and applicability of available methods to confirm NET tip location were also evaluated. To do this, the performance characteristics of each method were appraised against the needs and requirements of a representative 'global user base'. The methodology for identifying the 'global user base', the determination and weighting of the user requirements, the evaluation of the global appropriateness of the methods using the house of quality matrix [12, 13] and the schematic of this approach (Fig. S1) are included in the electronic supplementary material.

#### **Results**

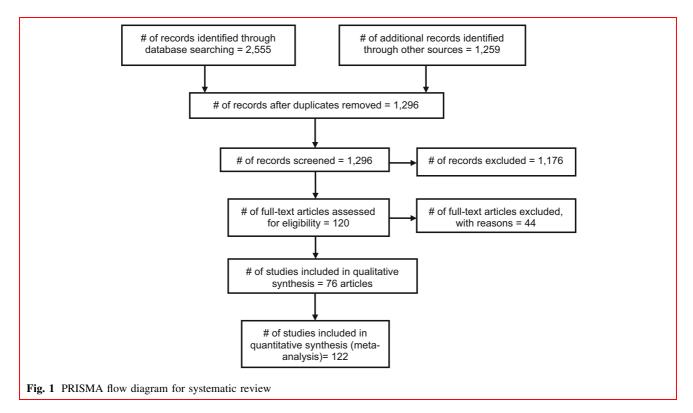
#### Literature review

The literature review identified 2555 articles from the initial database search (Scopus 862, Web of Science 669, Embase 617, PubMed 407). Duplications (n = 1176) were eliminated. Of the 120 articles that appeared to meet the inclusion criteria on first review, 44 were excluded on a detailed reading. This left 76 articles available for qualitative analysis and these contained 122 studies available for quantitative analysis (Fig. 1). The comprehensive assessment of the quality of the studies was performed [11]. A threshold score was developed for the quality assessment results (Table S1 in electronic supplementary material) distinguishing between good and poor quality articles. Those articles with five stars and above were classed as being 'good quality' (37 articles), whereas those with four stars and below were classed as 'poor quality' (34 articles).

The included articles covered a wide range of study designs. The majority were prospective studies and included randomised and blinded studies, observational studies, descriptive clinical studies, with a minority of retrospective studies and case series. The studies were performed in a variety of settings, with the majority coming from critical care units and tertiary hospitals. There was a large spread in the subject characteristics of the studies. The number of subjects in each study ranged from 4 to 1239, with an average of 137 subjects per study. The ages of subjects also ranged from 3 days to 92 years. The female to male ratio was 50:50.

There were two 'gold standard' methods used to confirm the intended placement of a NET tip: radiographic (fluoroscopic) or endoscopic. These methods allowed immediate and accurate NET tip localization and were excluded from analysis as it was against them that the other





methods were usually compared. Table 2 lists the ten other methods described to confirm NET tip location that have been or still are in clinical use. A brief description of each method is included along with any significant problems associated with the method. Table 3 lists the seven methods that have been proposed for NET tip localization and those that remain experimental.

#### Comparison of methods to confirm NET tip location

Table 4 provides a summary table of the 122 studies from which sensitivity and specificity could be calculated for the different methods and combination of methods. Of the methods with more than one study, it can be seen that the highest sensitivities are obtained with the combined method of pH and enzyme testing of the NET aspirate, ultrasonography and ECG. The methods with the highest specificities are capnography/capnometry, ultrasonography, visual inspection of aspirate and electromagnetism. Overall, ultrasonography delivers the best combination of sensitivity and specificity. Specificity (or true negative rate) is the more important of these two because of the desire for absolute certainty in identifying when the NET tube tip is misplaced.

# Determining global appropriateness of methods to confirm NET tip location

The list of stakeholder requirements and the ranking of importance by the participating stakeholders are reported in Table S3, ranked from the highest to the lowest average importance (in electronic supplementary material). There are three sets of results from the House of Quality approach to the assessment of the global appropriateness. The first are the results of the 'top of house' interaction matrix that reveal the five most interrelated performance criteria are success rate, market size, lifetime of disposable (time before required maintenance/ disposal), size and cost per tube for disposables (Table S4). The second are the results of the 'inside of house' matrix that show the level of interrelation between the performance criteria and the user requirements. The five criteria that are most dependent on other criteria are cost per tube/disposable, lifetime of nondisposable portion, success rate, cost for non-disposable components and market size (Table S5). The third set is the results of the performance criteria ranked by the average importance to the stakeholders (Table S6). The five performance criteria considered to be the most important for a 'globally appropriate' solution are cost per tube/disposables, success rate, cost for non-disposables, lifetime of non-disposable portion and lifetime of disposable. While a comprehensive evaluation of each method identified in the review was beyond the scope of this study, it was evident that none of the current methods meet all of the most important criteria laid down by all of the stakeholders, largely due to a positive relationship between cost/complexity and accuracy of a device.



Table 2 Methods currently used in clinical practice for confirming NET tip location

Method	Explanation of method	Limitations of method	References	
Visual inspection of aspirate	Looking at the colour and consistency of the aspirate. The aspiration can be compared with a set of known location aspirate for visual characteristics (e.g. yellowness and cloudiness)	Visual appearances of aspirate can be highly variable. Aspirates from respiratory system can appear similar, especially if aspiration has occurred	[20–25]	
pH analysis of aspirate	Aspirate is applied to pH indicator (litmus paper) which turns from blue to red if acidic	False positive if gastro-oesophageal reflux disease and tip is in the oesophagus.  Medication (e.g. antacids), the buffering effect of food and partial gastrectomy can alter pH of stomach. The pH of trachea and duodenum can be similar. Frequently equivocal	[16, 20, 21, 26–35]	
Enzymatic analysis of aspirate	The detection of pepsin and/or trypsin can indicate if the tube is in the stomach. Pepsin concentration less than 100 µg/ml and trypsin concentration less than 30 µg/ml is often used to infer respiratory placement	Not a true bedside test as it requires an enzyme assay, with delays in laboratory analysis. Evidence reveals difficulty in distinguishing location in lungs versus stomach. Presence of gastro-oesophageal reflux a problem	[22, 24]	
Bilirubin analysis of aspirate	The detection of bilirubin concentration less than 5 mg/dl has been used to deduce that placement of the NET is the lungs	If dipstick method then could be a bedside test, but cannot distinguish between gastric and small bowel location. Low sensitivity assay and therefore not accurate in determining respiratory placement	[22, 36]	
Auscultation	Air is insufflated down the NET using a syringe and a stethoscope is placed in the epigastrium. A "whooshing" sound is used to confirm placement in the stomach. The lack of a sound, or muffling, might indicate respiratory placement	Widely used method with poor localisation. The sound can be heard even if the tube is misplaced. Pseudoconfirmatory bowel 'gurgling' sounds (as in bowel obstruction for which NET are used to decompress) can be mistaken. This technique requires some experience	[16, 37–39]	
Blind placement	Placement of a nasogastric tube without the use of any aids to confirm the tip location, relying on experience and clinical judgment	Highest risk of misplacement	[40, 41]	
Palpation	Air is insufflated through the NET and the point of maximum intensity of air bubbling is determined by palpation of the epigastric area	A high level of expertise is required to detect on palpation the effect of air insufflation. Obesity precludes this technique	[42]	
Radiological	The gold standard. Radio markers are embedded within the NET allowing confirmation of tip location	Exposes the patient to radiation, expensive (\$140–\$400), time consuming and can be inconvenient for patients. Mobile fluoroscopy allows this to be done at the bedside, but with radiation exposure to those in proximity. Equipment may not be available in timely manner or at all. Images can be misinterpreted	[21]	
Bubbling	The external end of the NET is placed under water, if bubbles are observed this can indicate respiratory misplacement	Bubbling can also occur when the NET is in the gastrointestinal tract. The lack of bubbles with respiratory misplacement may indicate blockage of the NET with mucous	[9]	
Endoscopy	The tip of the NET is placed in the stomach or advanced into the duodenum	Invasive procedure and may require sedation or general anaesthetic. NET might be dislodged on the removal of the endoscope	[43, 44]	

#### **Discussion**

The review of current and proposed methods of confirming NET tip location has revealed that there are limitations with all methods used and none are  $100\,\%$  reliable. From the stakeholder analysis, the most important requirement was the rate of successful placement, as NET misplacement is considered an event that should

never occur. Another important requirement was the need for it to be of low risk to patients, jointly followed by universal language suitability and minimal training requirement. Even before using the HOQ to translate these requirements to measurable performance characteristics, there is a clear need for a new method for more reliable confirmation of NET tip location that meets stakeholder requirements.



Table 3 Proposed or experimental methods to confirm NET tip location

Method	Explanation of method	Limitations of method	References	
Capnography/capnometry	In-line monitoring of CO <sub>2</sub> concentration in the NET with a sensor that charts CO <sub>2</sub> content and/ or a wave pattern can indicate respiratory misplacement	Poor evidence base for use with NET. Requires a capnograph monitor. Unable to differentiate between NET placement in oesophagus and oral cavity	[41, 45– 51]	
Colourmetric capnography/capnometry	In-line monitoring of CO <sub>2</sub> concentration in the NET with a sensor that displays above expected CO <sub>2</sub> content with a colour indicator	Expensive technology not usually available outside of theatre and intensive care units. Not easily bedside test	[35–42]	
	change, too detect respiratory misplacement or pneumothorax	Air, mucus and refluxed gastric secretions as well as confusing colour changes have been noted		
ECG guidance	A patient is fitted with two skin electrodes in epigastric area, each lateral to the midline and above the umbilicus. Readings are taken from these two electrodes and a change in the QRS wave is taken to indicate the passage of the tip across the midline and into the duodenum	Not reliable. Potential interference. Substantial amount of training would be required for effective operation	[52, 53]	
Electromagnetic field detection	A permanent magnet placed in the tip of the NET is detected by an external sensor that can locate tip position in order to indicate its tracking pathway	Lack of easily accessible equipment and its associated cost. Substantial amount of training would be required for effective operation. There are associated problems with malfunctioning and calibration	[5, 54–58]	
External magnet guidance	A permanent magnet is incorporated into the tip of a NET and an external magnet is used to drag the tube into its proper position	Expensive indicators of tip location.  Cumbersome external device with problems with unreliable movement of NET.	[59–62]	
		Determining exact location of NET tip often not possible		
Illumination	A flexible cable with a cold light source is inserted into the NET which is then advanced normally while fully illuminated. The light passing through to the abdominal wall in the epigastric area can be visually tracked in a darkened room	Equipment is expensive and readily available. Appropriate illumination is not always seen, therefore limiting its use. Obesity is a problem	[63]	
Ultrasonography	Following placement of the NET, a bedside trans-abdominal ultrasound is used to determine the position of the tip. The basic ultrasound can be enhanced by the insufflation of air into the tube, forming bubbles at the tip and by filling the stomach with water	Expensive equipment that is not readily available. There is limited data currently available for its use to confirm the tip location	[40, 64– 66]	

An important aim of this study was to identify and describe current and proposed methods for confirmation of NET placement. The study revealed a 20 different methods. A majority of the techniques commonly used are traditional methods that have been available, with little modification, for many years. In discussions with stakeholders who use these methods on a regular basis, there was often a belief that these traditional techniques are the most reliable, but this is not supported by the data from this review. It is possible that familiarity with a particular method may influence the perception of how accurate it is. Additional evaluation of the accuracy of these methods, in both high and low resource environments, should be undertaken.

A number of methods on the market or in early stage development (e.g. electromagnetic or external magnet guidance systems) have yet to implemented. From discussions with stakeholders, it appears that that the initial capital outlay is the primary reason for not investing in these new technologies when other cheaper and more familiar tests are available, e.g. aspiration techniques. However, a full cost-benefit analysis is required as the frequent use of X-rays for secondary confirmation needs to be included in the real cost of the various techniques available.

The results generated from the HOQ provide a useful way to evaluate the global appropriateness and applicability of the different methods for NET tip localization. Considering only those methods with 3 or more studies, so



Table 4 Comparison of the different methods used to confirm NET tip location from studies that used radiography for comparison

Method	Total studies (n)	Sensitivity (mean ± SD, %)	$(n)^{a}$	Specificity (mean ± SD, %)	$(n)^{b}$
Electromagnetic methods	23	86 ± 13	23	91 ± 18	9
Auscultation/insufflation	12	$66 \pm 36$	12	$68 \pm 40$	8
Aspirate: visual inspection	12	$70 \pm 23$	12	$93 \pm 16$	12
Aspirate: pH testing	25	$81 \pm 21$	25	$84 \pm 16$	18
Aspirate: bilirubin testing	2	$40 \pm 56$	2	98	1
Aspirate: enzyme testing (pepsin, trypsin)	4	$87 \pm 12$	4	$83 \pm 13$	4
External magnet guidance	7	$78 \pm 24$	7	100	3
Illumination using fibre optic	1	100	1	100	1
Magnet detector	2	$100 \pm 0$	2	NA	2
Blind insertion	1	26	1	100	1
Ultrasonography	4	$90 \pm 6$	4	$92 \pm 17$	4
Capnography/capnometry	11	$80 \pm 40$	11	$94 \pm 15$	11
ECG/EMG	2	$90 \pm 14$	2	75	1
Other <sup>c</sup>	4	$95 \pm 3$	4	$79 \pm 34$	4
Combined: ultrasound and insufflation	1	96	1	50	1
Combined: capnography/capnography/capnometry and insufflation	1	88	1	100	1
Combined aspirate: pH and visual inspection	1	70	1	100	1
Combined: palpation and insufflation	1	92	1	100	1
Combined aspirate: pH and enzyme testing (pepsin, trypsin)	4	$94 \pm 4$	4	$100 \pm 0$	3
Combined aspirate: bilirubin and pH	3	$80 \pm 18$	3	$90 \pm 13$	3

The sensitivity and specificity (expressed as average percentage) are given

NA not applicable

that specificity and sensitivity could be calculated, the five methods with the highest average sensitivity and specificity score were combined aspirate testing (pH and enzyme), ultrasonography, external magnet guidance, electromagnetic guidance and capnography/capnometry. All of these methods largely satisfy the performance requirements for success rates, but the standard deviations for sensitivity and specificity are high, reflecting a wide variation in success rates within and between studies. These methods also have significant initial capital outlay and on-going cost because of disposable components. Aspirate tests for enzymes and capnographic tests require expensive testing equipment. While there has been some attempt to develop cheap, disposable, bedside tests based on these methods, the short shelf life of enzyme tests means that they are not a globally applicable solution. It appears from the available data that amongst the current methods there is a strong correlation between success rate and increasing cost.

There are a number of limitations with this review. There is considerable variation amongst the included studies, both in terms of study design, method of evaluation and the need for and provision of training. There were also variations in the medical condition of the subjects (e.g. mechanical ventilation, intensive care/critically ill, gastroenteritis, respiratory failure and burns), but this was not thought to have been a significant influence in the success rate of different methods. The intention of this review was to be inclusive and comprehensive, and in depth comparison of different promising methods have not been considered. However, the review has detailed the current 'state of play' and highlighted the need for more accurate and reliable methods that meet the requirements of global applicability.

In some studies, in addition to the outcomes of 'correct' or 'incorrect' position, there was a third possible outcome where the operator was unable to determine the location of the NET tip. In this review, we interpreted this third outcome as a failed result, since positive identification of the NET tip location was required. It is acknowledged that it is not possible to distinguish whether this represented a



<sup>&</sup>lt;sup>a</sup> Number of studies with sensitivity data

<sup>&</sup>lt;sup>b</sup> Number of studies with specificity data

<sup>&</sup>lt;sup>c</sup> Other refers to erythromycin, vacuum effect and paracetamol methods

failure of the method or the failure of the operator to carry out the method.

The small size of the stakeholder sample might be criticised in this study for the HOQ analysis to evaluate the global appropriateness and applicability of the different methods. The stakeholder sample consisted of six groups that were considered representative; a nurse, two dieticians, two manufacturer/designers and a surgeon. Given the importance placed on global applicability, it would have been helpful if the stakeholder sample could have been more representative of low resource environments. A further study could be undertaken with wider stakeholder representation; especially in developing nation settings where the gold standards of radiology and endoscopy are not readily available. Another way to increase the value of the HOQ analysis would be to include tests that allow extraction of additional end-points, including cost, duration of procedure, language suitability and training requirements. It is not known whether prior knowledge of, experience with or preference for different methods by the stakeholders might have confounded this evaluation. Our experience with HOQ analysis indicates that this approach has considerable merit and should be considered more widely in the evaluation of medical devices in the clinical setting.

This study has provided a comprehensive review of current and experimental methods available for confirming NET tip location. The review highlights that no ideal method exists for this common clinical procedure, and that misplacement remains an important clinical consequence. Further studies will provide more information about the relative merits of the different methods especially in relation to the gold standard methods (radiography and endoscopy). This review highlights the need for the development of new methods. The results of the HOQ analysis help to define the performance criteria required for any new method to address the problem of achieving accurate and reliable NET tip localisation. There is still the need to develop a low-cost, safe, intuitive, reliable and accurate method to confirm the intended NET tip location, to reduce the morbidity and mortality associated with misplacement.

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