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Feeding tube safety: National guidance ignores the 'elephant in the room'

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Abstract

Background: National guidance attempts to prevent tubes remaining undetected and being used when misplaced in the respiratory tract. The 'elephant in the room' is that this guidance detects misplacement too late to prevent most pneumothoraces and pneumonias.

Objective: Review risks of undetected and detected respiratory or oesophageal tube misplacements and how 'in-procedure' methods of determining tube position might reduce them.

Methods: Tube misplacement risk was compared for different methods of checking tube position. Data were obtained from UK NHS England (NHSE), a literature search between 1986 and 12/07/2024 using CINAHL, Embase, Medline and Emcare and from a local database.

Results: Post-procedure pH or X-ray checks on tube position have failed to prevent a rising incidence of undetected respiratory misplacements (NEVER events) (0.013%). Worse, current checks cannot prevent the 0.52% of placements that lead to in-procedure pneumothorax, constituting 97% of lung complications. In addition, pH may fail to prevent aspiration risk from oesophageal misplacement. Conversely, pneumothorax-risk would be reduced to 0.021% by using a supplementary mid-procedure CO_2 check or to 0.005% with expert guided tube placement (both $p < 0.0001$). Guided tube placement can additionally pre-empt oesophageal-related complications, but its safety is expert-dependent, with higher rates of undetected misplacement and pneumothorax in low-use Cortrak centres (0.10%) than expert centres (0%, $p < 0.009$).

Conclusion: The high health burden from feeding tube-related complications could be almost eliminated if regulatory authorities recommended a mid-procedure CO_2 check for respiratory placement or expert guided tube placement, alongside mandates for the necessary training.

Keywords

blind, capnography, capnometry, carbon dioxide (CO_2) detection, Cortrak, direct vision, electromagnetic, ENvue, guided tube placement, integrated real-time imaging system (IRIS tube), misplacement, nasogastric, tube, national guidance, NEVER event, oesophageal misplacement, pH, pneumonia, pneumothorax, respiratory misplacement, tube, undetected misplacement, X-ray

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Introduction

This paper aims to review the overall risks of feeding tube placement and recommend to regulatory bodies, the tube position checks best able to mitigate risk.

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Definitions

Tube-related complications arise from pneumothorax or bacterial contamination during respiratory misplacement or later infection caused by infusions. The latter is an 'undetected misplacement'. This occurs because tube position checks either failed or weren't done correctly and is often only found after clinical deterioration. Using a tube misplaced in the lung is a (UK) NEVER event (NE), defined as "incidents on the list should be avoidable if available preventative measures have been implemented."[1] Of 11.5 million European and USA feeding tubes used per year,[2,3] 0.015% result in NEVER event-related complications.[4] By NEVER event definition, nationally sanctioned post-procedure checks for safe tube position should eliminate even a low risk. Unfortunately, the 1st and 2nd-line checks, pH and X-ray, respectively,[5] are fallible, even when correctly applied, and cannot 100% guarantee that a tube is in a safe position.[6] Crucially, 'detected misplacements', where the tube is removed prior to use, are far more common and result in most tube-related pneumothorax, pneumonia and death.[4] In-procedure lung events and oesophageal misplacement, risking aspiration pneumonia,[7] are the 'elephant in the room' and cannot be prevented by current national guidelines.

Post-procedure checks

These checks warn of tube misplacement post-placement.

pH. Colourimetric pH sticks, probes or meters have been used to determine whether fluid from the tube is a pH of ≤4.0–5.5 and therefore 'gastric'. The method fails when fluid cannot be aspirated or there is idiopathic or iatrogenic hypochlorhydria, especially during use of proton-pump inhibitors,[8] which increases with age.[9] In addition, colour-misperception misclassified 12% of pH 6.0 (potentially lung) samples as pH 5.5 (safe).[10] Correctly calibrated pH readers or meters overcome this problem. However, a low pH indicates placement in acid and is therefore only a surrogate check for gastric position, since regurgitated fluid aspirated into the oesophagus or respiratory tract would falsely indicate safe placement, a mechanism that may explain the 16% (15 of 95 over 4.5 years) of UK, NEs associated with a pH of ≤5.5.[5] Ultimately, pH thresholds between 5.0 and 6.0 can fail to differentiate tube position because this pH is present in samples from the stomach (18.3%), small intestine (5.1%) and lung or pleural fluid (0.7%).[11] In addition, while a high threshold (5.5) may be more sensitive to detecting gastric position, specificity declines, risking undetected oesophageal or respiratory placement.

X-ray. Theoretically, the gold standard for determining NG tube position is an X-ray specifically taken to check tube position and checked by a radiologist trained to interpret its position using 4 criteria (1. Sagittal midline path, 2. Bisects the carina or bronchi, 3. Crosses the diaphragm in the midline, 4. The tip is below the left hemi-diaphragm).[5] Unfortunately, X-ray misinterpretation is consistently the single most common cause; 62.6% of known causes of undetected lung misplacement.[6] This may relate to 3 problems: 1. Failure to follow the criteria; 2. The X-ray being a static view of a tube versus anatomy so if either was partially obscured by chest opacity or equipment, interpretation could be complex; and 3. X-ray is often only done when pH checks have failed and so represents a higher proportion of patients with a misplaced tube.

In-procedure checks

This paper considers single-operator methods of bedside tube placement and position checks. The review excludes endoscopic and fluoroscopic tube placement because they cannot be done at the bedside and ultra-sound guided placement because it does not follow the entire tube path from pharynx to lung or stomach.[12] The most tested bedside methods to determine tube position and pre-empt complications are detecting high respiratory tract CO_2[13] and guided tube placement.[14] Cortrak™, ENvue® and integrated real-time imaging system (IRIS) Kangaroo® feeding tubes are the most commonly used guided bedside placement methods. Cortrak and ENvue equipment uses an electromagnetic (EM) field to produce a computer trace of the path of a feeding tube. IRIS tubes show an endoscope-like image of internal anatomy on a console. All three methods permit the operator to interpret tube position in real-time. To date, regulatory authorities, do not mandate any methods to pre-empt lung and oesophageal-associated complications despite their potential to reduce overall risk. Instead, these methods are only permitted as additional checks of tube position, not, as in the case of guided tube placement, as primary methods to determine tube position.[5]

While CO_2 detection can be applied with limited training, operators of guided tube placement require extended training.[14,15] Serious safety concerns regarding undetected lung misplacements using Cortrak[14–19] likely relate to inadequate training.[14,20] In particular, experts rated manufacturer operator guides, for guided tube placement, as inadequate[14] and, unlike X-ray, regulatory authorities have not set standards for training.

Methods

Ethics

This study, as a literature review, is exempt from Institutional Review Board approval and is registered with North Bristol NHS Trust as a Quality Improvement project: QI96397.

Objectives

The review determines:

1. Post-procedure risk from undetected respiratory misplacement,
2. Published risks from detected and undetected tube misplacement and which tube position checks prevent them and
3. Efficacy of X-ray versus guided tube placement.

Reviews

Several reviews were undertaken. The number and cause of undetected respiratory misplacements were obtained from the UK NHS Improvement (NHSE).[6] Detected and undetected lung misplacements, associated complications and use of blind or guided tube placement and CO_2 checks were reviewed in a search between 1986 and 11/07/2024 using CINAHL, Embase, Medline and Emcare (Appendix 1). Studies were excluded where they lacked information on the outcomes[21] or population or where both guided tube placement and post-procedure checks were used and it could not be discerned which influenced outcomes.[22] Direct comparison of first-time tube placements for Cortrak and IRIS (prospectively collected) and X-ray (retrospectively collated) was done using local data to determine risk of and from respiratory misplacement.

Risks reviewed include those directly associated with tube placement including lung trauma, pneumonia and damage to the alimentary mucosa. Indirect risks include transporting patients out of their clinical area for X-ray and its associated irradiation plus prolonged delays to confirm tube position precluding feed, fluid and medication.

Analysis

UK 'NEVER events' were plotted over time. Risk of detected and undetected respiratory misplacement was determined for blind (followed by X-ray) versus guided tube placements (Cortrak, IRIS). The proportion of misplacements, presented as percentages, were statistically compared using Fisher's exact test (R studio Version Version 2023.06.2 + 561). When comparing local data regarding the risk from Cortrak, IRIS and blind tube placement (followed by X-ray), continuous data were checked for normal distribution ('shapiro.test') and differences examined using the 'wilcox.test' or 'fisher.test' for binary data.

Results

Post-procedure risk

Failure to detect misplacement and subsequent infusion via the tube, a NEVER event (NE), was plotted by year (Figure 1). Despite regular alerts[5,23–28] the annual rate of NEs have increased. Data were inadequate to determine whether this is a true increase despite alerts, a reflection of increased tube placements or due to better reporting, and it does not preclude improved safety in individual hospitals.[28] However, of the 14 NHS Trusts with a full set of data (13% of 122; 92% acknowledged) responding to a 'Freedom of Information' questionnaire, 21% had not complied with mandatory alerts.[29] Therefore, ongoing NEs may be due both to the fallibility of pH checks and failure to comply with criteria for X-ray checks. Because X-ray is often done after failure of a pH check, comparison of risk by method is not possible. Nevertheless, X-ray checks failed to prevent 63% of all NEs.[6]

In-procedure risk

Blind placement. Of 16,304 blind tube placements having a post-procedure X-ray check, 1.8% of tubes entered the respiratory tract, 0.52% caused a major complication, mostly pneumothorax, and 0.08% died (Appendix 2). In contrast, pneumothorax from undetected misplacement only occurred in 0.013% and death in 0.006%. This means that post-procedure checks failed to prevent ~97% of complications and 92% of deaths from respiratory tube misplacement (Figure 2)

.52% x 16,304 = 84.8 pneumos, .08% x 16,304 = 13 deaths
.013% x 16,304 = 2.12 pneumos, .006% x 16,304 = .97 deaths
1-(2.12/84.8) = 97.5%, 1-(.97/13) = 92%

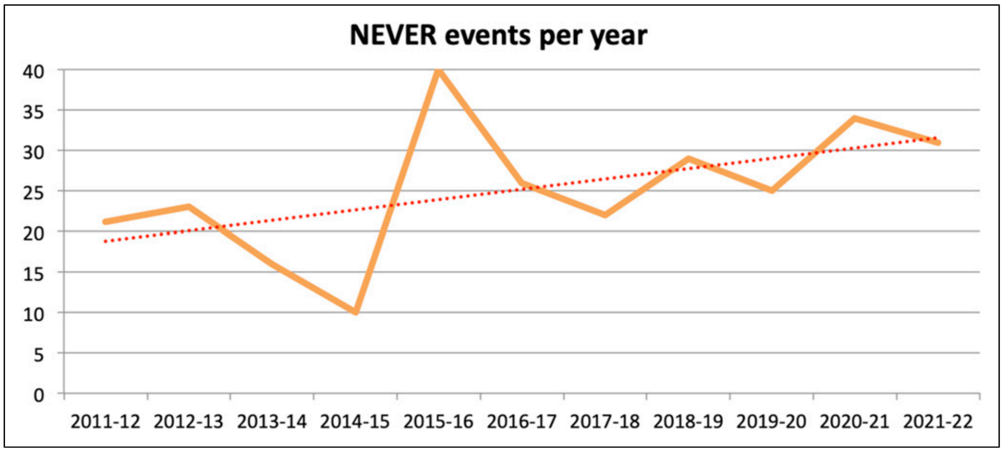

Figure 1. UK undetected respiratory misplacements (NEVER events). *The low 2014–15 figures may be due to late reporting during 2015–16.

and that for every NEVER event there were approximately 40.5 non-NE complications, including 11 deaths, from respiratory tube misplacement per se. This is an underestimate, because few studies examined pneumonia risk which nearly doubles when a tube enters the lung.[30]

Mid-procedure checks

CO_2 detection. The higher CO_2 level detected as a capnogram waveform or colourimetric capnometry in the respiratory tract can differentiate it from the GI tract.[31] Some studies compared CO_2 detection versus auscultation to determine gastric position, something neither can reliably confirm.[9,32] It is important to emphasise that CO_2 checks alone can screen for respiratory misplacement, but do not inform on tube position outside the respiratory tract[9]; end-of-procedure tube position must be checked by pH or X-ray prior to use. In addition, while differentiating CO_2 levels from correctly placed gastric and endotracheal tubes proves the concept,[33] practical testing necessitates that gas be obtained from a misplaced feeding tube. Practicalities of CO_2 checks include:

1. CO_2-testing at a 'tube depth' that could have entered the trachea, but not beyond the carina, risking pneumonia and pneumothorax, for example, measuring from the nose to tragus of the ear to sternal notch. This may improve upon a set 30–40 cm length as the distance from nose to carina, and therefore potential pneumothorax risk, varies.[34]
2. Awareness that certain drugs, food and carbonated drinks may produce CO_2.
3. The tube must be flushed to clear it of fluid and check it is not kinked, the measuring device must attach with an air-tight seal and testing last a sufficient time to register a high CO_2 level if present.
4. The CO_2 threshold indicating respiratory placement must be validated for a specific device.

Combining data from 16 studies in a systematic review[13] and a subsequent publication,[9] showed that of 1801 NG tube placements 148 (8.2%) entered the respiratory tract. CO_2 detected 142 (95.9%) and failed in 6 (4.1%). Overall, CO_2 failed to detect the 0.3% of tubes placed which entered the lung compared with 1.83% where the 'blind' operator did not detect respiratory misplacement ($p < 0.0001$) until post-procedure X-ray. CO_2 checks correctly determined that 1573 (87.3%) of tubes were not in the respiratory tract, but incorrectly indicated that 80 (4.4%) were. Where the CO_2 check failed to warn of respiratory misplacement, follow-up X-ray pre-empted tube advancement.[35,36] Because CO_2 checks warn of all but 4.1% of respiratory misplacements, this would reduce the blind placement risk of pneumothorax from 0.52% to 0.021% ($p < 0.0001$) and pneumothorax from undetected misplacement from 0.013% to 0.0005%.

While not 100% accurate, CO_2 checks could prevent 96% (sensitivity, specificity 95%) of respiratory misplacements progressing to cause a pneumothorax, and, potentially, pneumonia or requirement for an X-ray. By comparison, a policy of mid-procedure X-ray only reduced pneumothorax risk from 0.38% to 0.09%, a 76% reduction, due to non-adherence to the policy.[37] The cheaper, simpler CO_2 check may, by being easier to use, prevent more complications and reduce risk from irradiation, moving the patient off their clinical area[38] and cumulative delays to drug, fluid and nutritional treatment.[39] Where CO_2 checks are easily repeatable and combine with pH testing, this would further reduce costs and delays to tube use.[40] Further testing in mixed hospital settings is planned.[31]

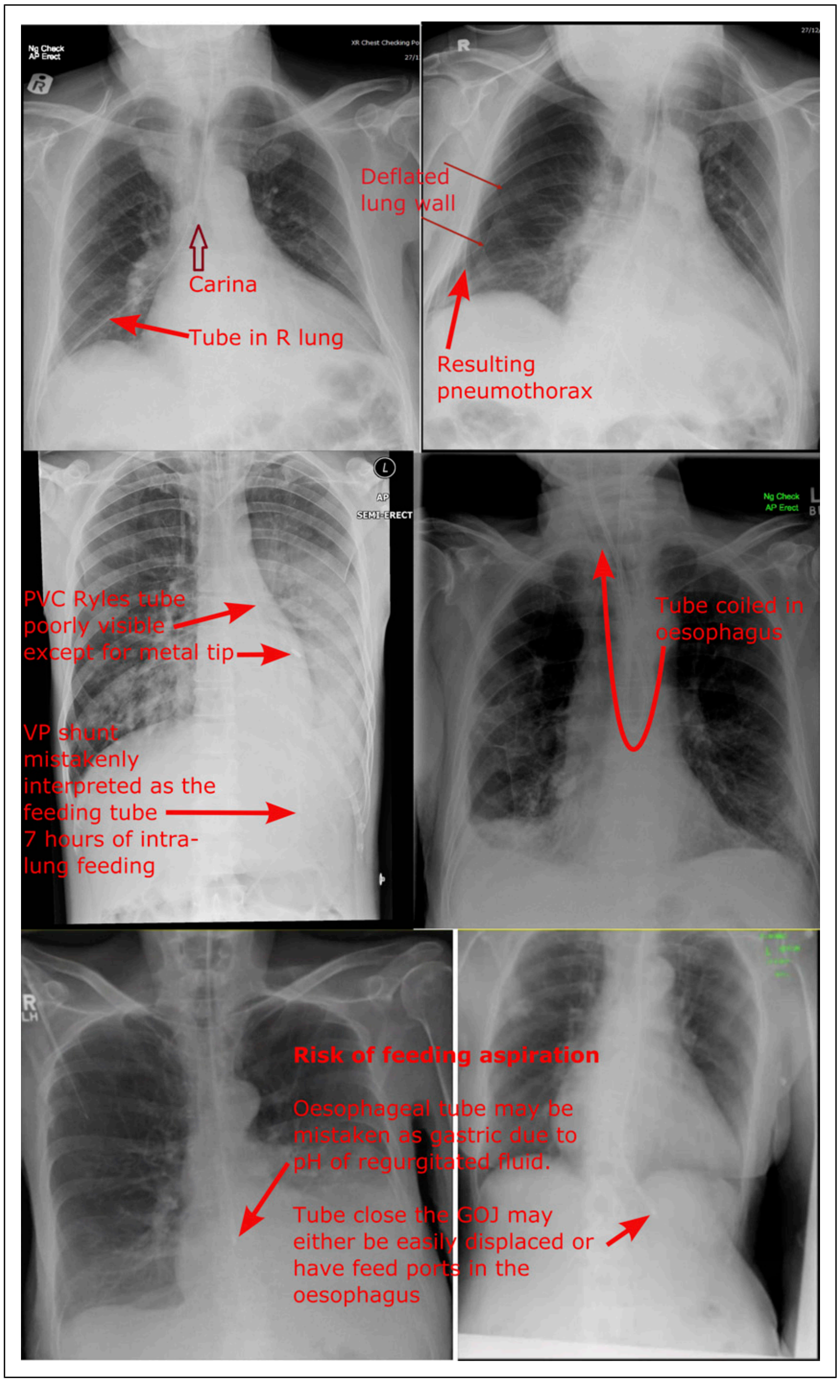

Figure 2. X-ray: Too late to prevent pneumothorax, misinterpreted and requiring tube re-positioning.

Real-time guided tube placement

These methods track tube position throughout placement.

Electromagnetic (EM) guidance. The one small cohort of ENvue placements precludes review.[41] In contrast, 21,401 Cortrak placements were reviewed (Appendix 3). Compared to blind placement, low-use Cortrak centres (<500 Cortrak tubes placed per centre) had higher rates of respiratory misplacement (1.8% vs 2.8%, $p = 0.03$) and pneumothorax associated undetected misplacement (0.013% vs 0.10, $p = 0.001$) whereas high-use Cortrak centres had lower risk of both misplacement (1.4%, $p = 0.01$) and pneumothorax (0%, $p = 0.2$). However, because most risk of pneumothorax occurs during placement, overall, EM methods of guided placement result in lower risk (Blind: 0.52% vs low-use Cortrak: 0.10% [$p = 0.001$], high-use Cortrak: 0.005% [$p < 0.0001$]) but high-use Cortrak centres are safer than low-use centres for both undetected misplacement ($p < 0.0001$) and all-cause pneumothorax ($p = 0.002$). High-use centres may have higher expertise, including, in one centre, the use of a validated guide to interpret EM traces (Figure 3).[4] Of note, the 7 high-use centres contributed 86% of published placements, which, if disproportionate to overall usage, may understate the overall risk.

Direct vision. To date, there are data on 400 placements (Appendix 4), too few to compare with other methods. However, there have been no instances of pneumothorax, possibly because direct vision permits earlier, tracheal-level, detection of respiratory placement.[42,43] In addition, direct vision shows a clear demarcation between the oesophagus and stomach to avoid risk from tube ports staying within the oesophagus and leading to aspiration (Figure 4).

X-ray versus Cortrak and IRIS checks. Local data permitted direct comparison of Cortrak, IRIS and X-ray checked tube placement placements. However, these were collected over different time periods and groups. When comparing X-ray versus combined guided placement and Cortrak versus IRIS placement, patient groups were statistically different for ward versus ICU, age, sex and disease (Appendix 5). Respiratory tube misplacement was detected in the order: X-ray for blind placement < Cortrak traces < IRIS direct vision (1.7% vs 11.1%, $p < 0.0001$ vs 18.5%, $p = 0.003$). However, the median depth of placement beyond the carina was less for IRIS (0 cm) than Cortrak (10 cm [$p < 0.0001$]) or guided versus blind placement (17 cm [$p < 0.0001$]).

Risk of oesophageal misplacement

Studies directly measuring risk of aspiration pneumonia associated with oesophageal tube placement are lacking therefore risk cannot be analysed. Oesophageal placement occurs in ~20% of X-rayed tubes.[39,44] While prior failure of pH checks may exaggerate X-ray findings, an upper estimate of risk may be made. Of the 20% of tubes in the oesophagus, ~50% may be checked using pH,[45] 10% overall, and, using a pH threshold of 5.5, 50% may be incorrectly classed as gastric.[7] That is, 5% of overall tubes could be used for feeding whilst within the oesophagus. If tubes are advanced a validated nose-stomach distance, xiphisternum-ear-nose (XEN) +10 cm or nose-ear-xiphisternum × 0.38696 + 30.37 + 6 cm, there is a higher likelihood of reaching the stomach; 97.4% and 99.0%, respectively.[46] However, tubes may still coil or retroflex into the oesophagus. Local data showed that compared to blind placement followed by X-ray, guided-tube placement left fewer tube in the oesophagus (7.5% vs 0%, $p < 0.0001$) (Appendix 5).

Other risks

Serious mucosal damage is relatively rare, with no datasets to analyse. Datasets were also lacking regarding irradiation from X-ray checks and risk from moving patients off-ward and delays to feed, fluid and medication; all of these may present clinically significant risks. For example, stroke patients lost 18% of feeding time.[47] This was mostly awaiting X-ray checks, where 59% of patients needed 3 or more tube placements and in 16.6% the tube had to be repositioned, increasing delay from 2.1 to 4.8 h.[39]

Collating risk

When pneumothorax or pneumonia per respiratory misplacement or percentage risk of pneumothorax or oesophageal misplacement are collated, post-procedure pH or X-ray represent the highest risk in all categories (Figure 5).

Discussion

Main outcomes

Current post-procedure methods, pH or X-ray, have not reduced undetected lung misplacement in the UK and cannot prevent 97% of feeding tube-related lung complications, particularly pneumothorax. Most (95.9%) of these complications could be prevented by a CO_2 check at the level of the sternal notch, which is easier to apply than a mid-procedure X-ray. Cortrak and IRIS-guided tube placement could similarly reduce overall risk of lung complications, but also avoid oesophageal misplacement and confirm gastric or small intestinal placement without delays. To achieve risk reduction, the lower training burden and equipment cost for CO_2 checks makes mass-use possible, with guided placement used by specialist teams.

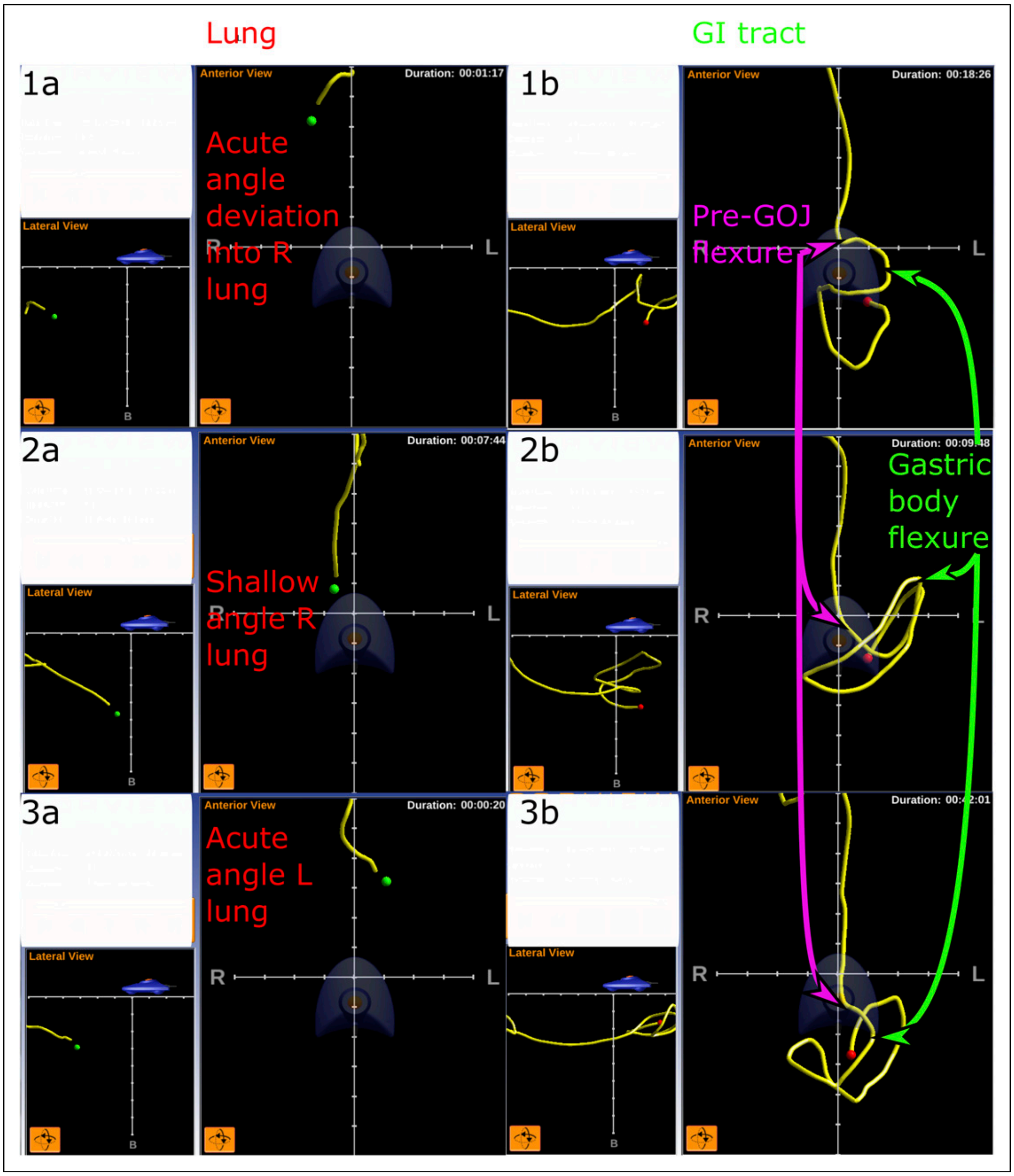

Figure 3. Interpretation of EM traces.

Most studies did not screen for pneumonia and therefore underestimates the advantages of CO_2 checks or guided placement. In particular, CO_2 checks and IRIS tube guidance are able to detect respiratory misplacement at the tracheal level. This reduces the tube-bacterial contamination depth and therefore pneumonia risk compared to when tube misplacement is only detected at a deeper level, for example, using Cortrak (10 cm post-carina) or blind placement plus post-procedure X-ray (17 cm). The higher rates of detecting respiratory misplacement (IRIS > Cortrak > Blind) may be partly due to IRIS to always detecting misplacement in the trachea whereas clinical symptoms may prompt EM or blind tube withdrawal prior to confirming misplacement beyond the carina. A limitation to the local data is that groups were different for demography and disease, largely because the Cortrak group was 'nasointestinal', not nasogastric. However, it is not clear that this would change the incidence or depth of respiratory placement.

Low-use Cortrak centres have higher rates of undetected misplacement than blind placement. This suggests poor training, potentially combined with the inadequate and inaccurate manufacturer guidance.[4,14,48–51] This guidance lacks an objective description of lung and stomach placement, how to interpret and solve receiver-related artefacts,[4,14] has two

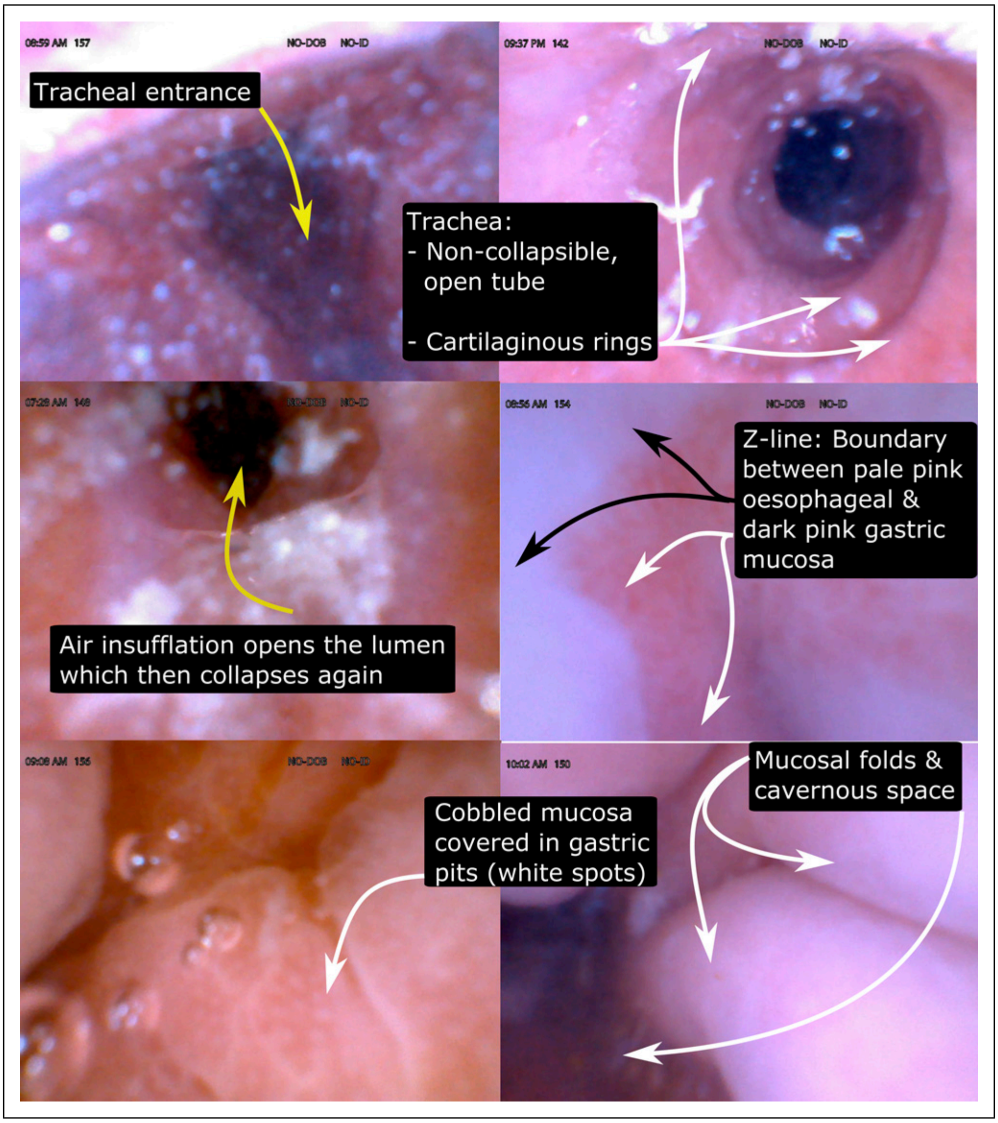

Figure 4. Interpretation of IRIS images.

incorrectly interpreted example traces[51] and lacks proof that its use leads to accurate interpretation.[4,14] To date Avanos have declined to use the prospectively validated 'GI flexure system',[52] and make incorrect safety claims[53] which have been rebutted.[54]

Again, IRIS manufacturer guidance,[55] though accurate, is not comprehensive or evidence-based.[14] Cardinal Health have undertaken to incorporate into their written guidance elements of the validated operator guide[42,43]; this includes description of anatomical characteristics alongside images that enable identification of anatomy during IRIS tube placement.

Regulating to attain lower risk

Regulatory bodies permit only post-procedure pH or X-ray as checks for tube position, failing to recognise that neither prevents most lung complications and pH may not detect oesophageal misplacement.[5,16] This dis-incentivises use of CO_2 checks or guided placement. The current stance may be partly due to 139 (known) undetected Cortrak tube misplacements.[4,17–19] However, evidence suggests poor training[20] and manufacturer guidance as potential causes of these 'guided failures'.[4,52] Conversely, if proven methods of interpretation and training for guided placement[4,14,42,43,52] were authorised, as they have been for X-ray interpretation,[5] then both Cortrak or IRIS guided tube placement is, overall, the safest method of tube placement and confirming position.[4] Where tube dislodgement is suspected, a CO_2 check for

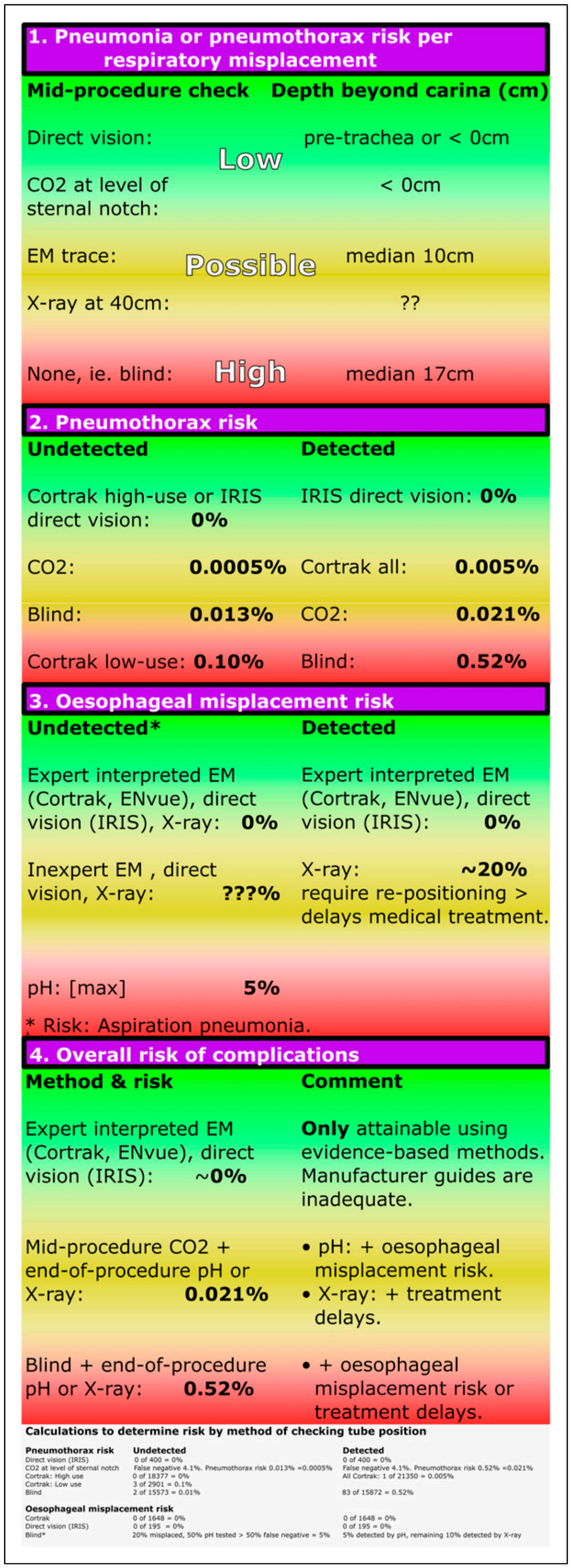

Figure 5. Summary of tube placement risk.*

respiratory displacement or Cortrak or IRIS checks for tube position can all be done at the bedside. Lastly, the mandated checks by regulatory bodies do not take into account overall patient risk from delays to drugs, fluid and nutrition incurred by post-procedure X-ray[39] or that effective tube securement can pre-empt placement risk by reducing the need for placement (replacement) by 40%.[47,56]

Limitations

Despite relatively large samples, these are small compared to annual tube placements. More studies are required to validate the accuracy of CO_2 check devices and ENvue and IRIS guided tube placement systems. In addition, only 7 centres are responsible for 86% of published Cortrak placements; this may understate risk in low-use, less expert centres who had 5 undetected misplacements compared to the 139 that are known.[14] The risk of pneumonia from tube placement per se, aspiration pneumonia secondary to undetected oesophageal misplacement and indirect risks are all under-studied but would increase the advantages of using a mid-procedure CO_2 check or guided tube placement. Finally, there is not yet the data to determine risk reduction versus cost. CO_2 checks are low cost, whereas guided tube placement is high cost for equipment and per tube, but, if replacing X-ray, could be lower.

Conclusion

Based on a 1.83% misplacement rate at post-placement X-ray, 18.3 respiratory misplacements occur per 1000 blind tube placements. Whilst currently recommended checks will be detect most prior to tube use, they will still cause, on average, 5 pneumothoraces, 1 death and an unknown number of pneumonias. Assuming use of pH as the 1st-line check, with a threshold of 5.5, there could also be up to 50 undetected oesophageal misplacements with associated aspiration risk. Post-procedure pH or X-ray checks of tube position fail to prevent >97% of tube-related lung complications and 92% of deaths and represents the highest risk approach reviewed. With millions of tube placements worldwide, the current policy represents a major health risk. Effectively restricting risk prevention to only undetected respiratory misplacement, by using post-procedure pH and X-ray checks, may make in-procedure CO_2 checks and guided tube placement appear to be wasted time and expense, ignoring their ability to lower overall risk.

Regulatory authorities should consider overall tube placement risk. For maximum risk reduction at minimal cost and delay, a mid-procedure CO_2 check should be recommended as standard followed by post-procedure pH or X-ray checks.[57] The training of small, expert teams for bedside guided tube placement should be encouraged to reduce both respiratory and oesophageal misplacement risk and further reduce delays to tube use, particularly for high-risk placements. However, to ensure safety, regulatory authorities must mandate that manufacturers produce evidence-based operator guides and their training should be independently accredited. These changes would eliminate most risk from tube placement, delays to tube use and potentially reduce burden to Radiology services.

Statements and declarations

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Literature Search: Intrapulmonary Feeding Tube Placement - complications. Katie Barnard and Jo Hooper (11/07/2024). UK: North Bristol NHS Trust Library and Knowledge Service.

Author contributions

ST conceived the study, analyzed the data and wrote the manuscript.

Conflicting interests

The author declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: ST has done consultancy for Cortrak (2007). Studies were sponsored by Cortrak (now Avanos Medical Inc, 2013–14) and IRIS (Cardinal Health, 2020–23) through North Bristol NHS Trust in which Cortrak/Avanos and Cardinal played no part in planning, execution or publication of the work. ST co-owns a nasal bridle patent. ST is part of BAPEN's NG-Special Interest Group and co-chair of the BDA's CCSG NJ team.

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Ethical approval

This study, as a literature review, is exempt from Institutional Review Board approval and is registered with North Bristol NHS Trust as a Quality Improvement project: QI96397.

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Supplemental material

Supplemental material for this article is available online.

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