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Research Article

Undetected Cortrak tube misplacements in the United Kingdom 2010–17: An audit of trace interpretation

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ABSTRACT

Objectives: Determine why Cortrak-guided, undetected tube misplacement may occur in relation to the system of trace interpretation used.
Methodology: From 2010 to 2017 we obtained seven of the eight Cortrak traces from the United Kingdom where misplacement was undetected and the patient received feed. Seven suffered serious harm. Each misplacement was interpreted by three systems: screen position, manufacturer guidance and gastrointestinal (GI) flexures.
Setting: National and local records.
Main outcome measures: Ability to identify misplacement.
Results: Traces that were later identified as misplacements, could not be differentiated from GI position when they wholly or partially: a) overlapped with the GI screen area plotted from historical records (57–71%) or b) met both manufacturer guidance criteria or were confused with receiver misplacement or unusual anatomy and reached the lower left quadrant (14–71%). Conversely, all lung misplacements were identified as unsafe using the GI flexure system. All three systems failed to detect the intraperitoneal trace. Traces were inconsistently stored by healthcare centres.
Conclusion: Trace file storage should be mandated by and accessible to relevant health authorisation bodies to improve safety research. Screen position alone and manufacturer guidance fail to consistently differentiate the shape of safe from unsafe traces. GI flexure interpretation appears safer but requires testing in larger studies.
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Implications for clinical practice

- Cortrak guided tube placement offers safety advantages over blind placement but inadequate training led to 62 undetected misplacements. Further misplacements may have been recognised, but too late to pre-empt complications.
- Manufacturer guidance can fail to differentiate undetected lung placements from safe traces. This occurs because midline trace deviation can be confused with receiver misplacement or unusual anatomy and four of six traces reached the lower left screen quadrant but were lung not gastric; we suggest this guidance appears to be unsafe and should be replaced.
- All UK lung events would have been correctly interpreted and prevented using the GI flexure system; this system appears to be safer.
- Where mucosal perforation is possible, tube position should be guided by radiological methods or direct vision.

Introduction

Approximately 6% of hospital patients in the United Kingdom (UK) require invasive nutritional support (Elia, 2015), predominantly nasogastric (NG) feeding. Blind (unguided) tube placements represent a major clinical risk because 1–2% enter the lung and

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0.25–4%, are associated with major complications (Krenitsky, 2011). Importantly, >90% of lung complications and deaths are associated with misplacement detected too late by an end-of-procedure X-ray or pH testing (Koopmann et al., 2011; Krenitsky, 2011, Sorokin and Gottlieb, 2006). In addition, using a pH threshold of 5.5 could result in 5% of tubes being oesophageal placements, thus risking aspiration (Ni et al, 2014).

In contrast, direct vision via endoscopy and fluoroscopy should pre-empt misplacement but is costly, delays feeding and incurs additional risk due to the invasive nature of the procedure and the requirement for the patient to be transported off the ward (Parmentier-Decrucq et al, 2013). More practical guidance systems for critical care include body impedance and IRIS™ version 2, that provides an endoscopic screen image (Mizzi et al, 2017; Wischmeyer et al, 2018), for both of which results are pending, and Cortrak™. Cortrak has been the most widely used system with over one million tubes sold worldwide (Medex, 2017) and is the subject of this paper.

Cortrak consists of a receiver unit placed on the xiphisternum parallel to the spine (Fig. 1). The receiver (a.) detects the position of the tube guide-wire's electromagnet (b.) inside the body. A computer-generated screen (c.) trace displays the tube path frontally (A), head at the top, from the side (B), head at the left and in cross-section (C). The screen's 'left and right' is from the patient's perspective. The electromagnet is seen as a green dot tracing a yellow path on the screen. Gastric placement would be seen as a yellow path following the vertical midline, indicated on the anterior (A) screen in white, then turning left close to the xiphisternum (Fig. 1, blue dot), usually following a clockwise path around the stomach before moving right into the intestine. The lateral screen path moves left to right, deep in the oesophagus, becoming shallow in the stomach, then deep again when entering the intestine. The cross-section screen shows depth from the abdominal surface and only traces a path once below the horizontal line and to the right of the vertical midline. Safe placement and congruence between Cortrak traces and X-ray is achievable (McCutcheon et al, 2018; Powers et al, 2018). However, resulting placements appear to be expertise-dependent. There have been 54 undetected misplacements in the United States of America (USA) and eight in the UK. In the UK these are defined as a 'NEVER event' (National Health Service Improvement: NHSI, 2016), with most resulting in severe complications or death (Bourgault et al, 2017; Metheny and Meert, 2017; 2014; Strategic Executive Information System: StEIS, 2018). In the UK Cortrak use is restricted to guidance (NHSI, 2016) but may also be used to confirm placement in the USA, despite concerns regarding Cortrak interpretation by the Food and Drug Administration (FDA, 2018). Failure to detect misplacement appears to be due to training issues (Bryant et al, 2015).

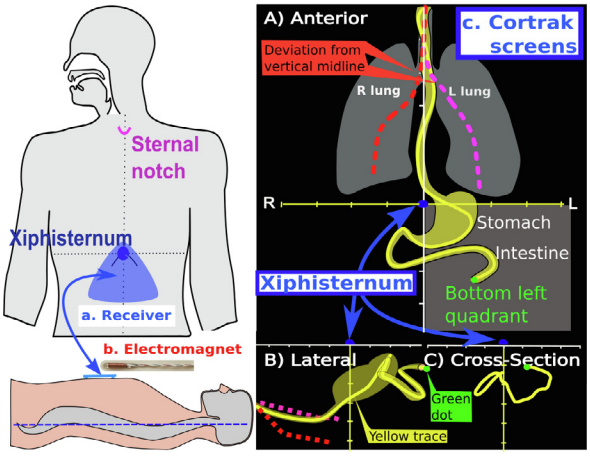

Fig. 1. Cortrak receiver position, electromagnet and screens showing traces superimposed on probable anatomical position. [Taylor, 2018 – with permission]

Study aim and objectives

Each Cortrak trace was examined to determine whether misplacement could be identified from each of three systems:

1. 'GI versus lung area' on the Cortrak screen as expected from previously confirmed traces,
2. Manufacturer guidance offering two criteria to differentiate lung from GI position or,
3. Trace characteristics at known GI flexures.

Methods

Study design and data collection

We observed the efficacy of Cortrak trace interpretation using Cortrak-related, mandated patient safety incident reports between January 2010 and December 2017 from NHSI and StEIS (equivalent to USA, Manufacturer and User Facility Device Experience [MAUDE]) and anonymised traces requested from NHS Trusts and the manufacturer (Avanos Medical Inc). Analysis was restricted to undetected misplacements where operators relied only on Cortrak to determine tube position.

Trace classification

Traces were classified as misplaced, uncertain or safe GI positions by authors KA and ST who have led a total of >1000 placements, replacements and re-traces. Each trace was classified as GI or not according to three systems of trace interpretation:

1. GI vs Lung screen area: We compared the screen position of 'misplacement traces' with the GI and lung areas covered by traces confirmed as GI (n = 402) and lung (n = 48) in a previous study (Taylor et al, 2017b). Trace coordinates are described in 'cm' left or right of the vertical screen line and above (+) or below (−) the horizontal line. The vertical-horizontal intersection should be over the xiphisternum.
2. Manufacture guidance: To ensure consistency with this guidance, the authors attended the 2-hour Cortrak training course (18/10/2017) and read the latest Trainee and Trainer booklets (Avanos Medical Inc., 2018; Avanos Medical Cotpak, 2017). This guidance encapsulates differentiation of lung from gastric position within the statements: "[a.] For a correct NG placement (in typical anatomy) the trace journey will progress straight down the vertical with no deviations above the horizontal midline" and [b.] "the green dot and yellow trace should be in the bottom left quadrant" (Fig. 1) (Avanos Medical Inc., 2018).
3. GI flexure system: Trace interpretation is based on knowing the characteristics of a GI trace path on the anterior and lateral screens at known flexures (Taylor, 2018; Taylor et al, 2017a, b). A GI trace will simultaneously become shallow and turn left (pre-gastro-oesophageal junction [pre-GOJ] flexure), continue shallowing and turn towards the sagittal midline (gastric body flexure), reach the shallowest point then deepen and continue towards the right (pyloric flexure).

Ethical approval

Ethical approval was not required for this audit. NHS Improvement granted permission to use anonymised data (24/01/18: Reference 050.DSA.16).

Results

A total of 79 Cortrak-related incidents were identified, 78 nationally (StEIS, 2018) and one from the authors' local database. Most incidents were delays to tube placement, not misplacements. The staff initially inserting these tubes, failed to detect 10 NG and two nasointestinal (NI) misplacements. Four of these misplacements were subsequently detected by X-ray prior to feeding; the one lung placement resulted in pneumothorax and three oesophageal misplacements caused no harm. Of the remaining eight tubes misplaced into the lung (n = 7) or peritoneum (n = 1) and used for feeding, six were NG and two NI. NHS Trusts provided four traces, one trace printout and one X-ray. Author (ST) identified NEVER event traces for two further patients in official guidance (Avanos Medical Inc., 2018). The seven traces (6 lung, 1 peritoneum), including the print-out, were analysed.

Screen area

The GI area shows that while GI traces rarely deviate >5 cm right (R) of midline, they can deviate >15 cm to the left (L) of the vertical midline (Fig. 2). This meant that all (n = 4) or a large part (n = 1) of most misplacement traces overlapped with the known GI and lung areas; tube position could not be differentiated by screen position alone.

Manufacturer guidance

The anterior traces from NG1 and NG5 deviate acutely right at +17 cm and +13.5 cm above the horizontal screen line, respectively, and descend below the level of the xiphisternum without returning to midline (Fig. 3). This means that both traces should have been classified non-GI because they do not meet the manufacturer criteria that they should follow a vertical midline path (criterion a.) and end in the lower left quadrant (b.); both patients died.

The left deviation from the midline of NG2.1a and NG4 may have been falsely interpreted as being in a 'high' gastric body as seen when a Receiver is placed too low. Both traces reached the lower left quadrant and therefore met manufacturer guidance criterion b. However, as denoted by NG2's anterior trace arrow (a.1), the receiver is mis-aligned to 11o'clock; when this was corrected to 12o'clock (a.2) the deviation was pronounced. In contrast, the replacement tube only deviated left after travelling >25 cm and probably reached the gastric fundus (b); the lateral trace was unavailable to confirm this. Both patients suffered aspiration pneumonia.

The anterior traces of NG6 and NI2 deviated left above +20 cm on the vertical scale and descended slanting right to left. This fails manufacturer criterion a. that the trace be vertical but, particularly NG6, may have been falsely interpreted as a trace artefact caused by clockwise receiver misalignment. Furthermore, the clockwise traces in the lower left quadrant (criterion b.) mimic the greater gastric curvature. One NG6 operator thought the trace print-out looked 'gastric'. Both NG6 and NI2 resulted in aspiration pneumonia and death, respectively.

The anterior trace of NI1 has a left-shift, due to the receiver being misplaced slightly right of the xiphisternum in the presence of

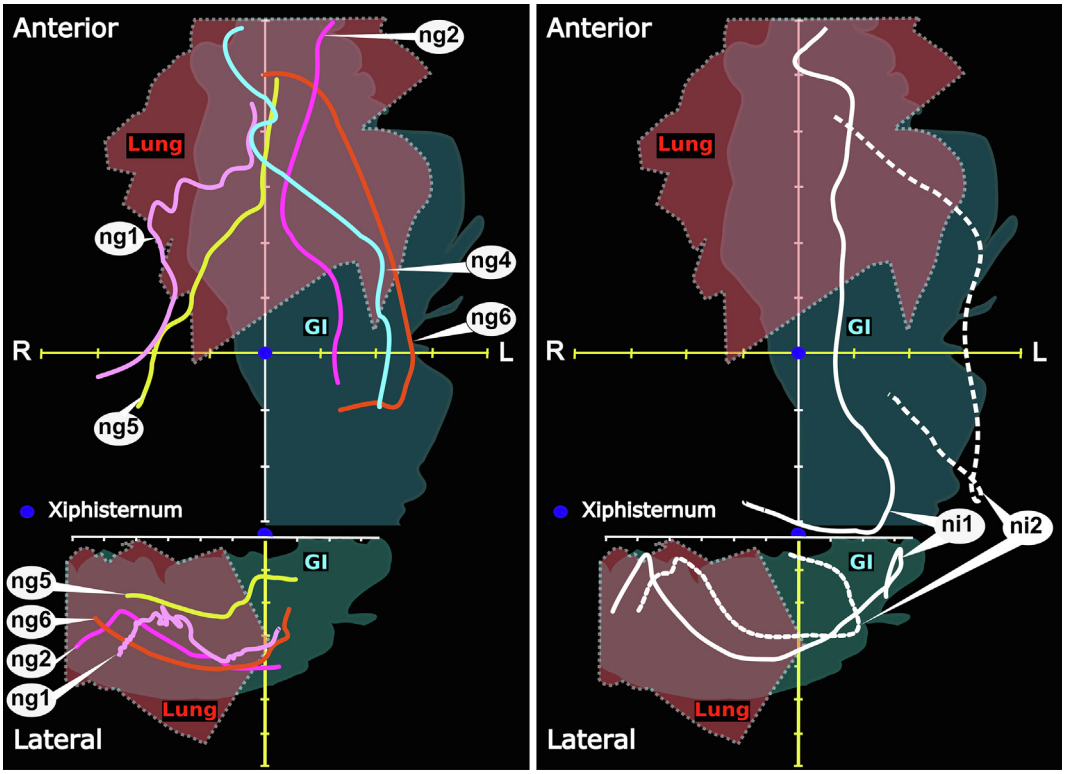

Fig. 2. Misplacement traces superimposed on known GI and lung areas (adapted from Taylor, 2018 with permission).

ascites. Otherwise, the trace is parallel to the midline and passes through the lower left quadrant, thereby meeting both manufacturer criteria a. and b. However, the tube was actually intra-peritoneal.

GI flexure system

The following lung misplacements were all correctly identified by the absence of pre-GOJ and/ or gastric body flexures (Fig. 3). In particular, traces for NG1, 5 and 6 and NI2 do not turn left close to the midline at the pre-GOJ flexure; NG1's lateral trace shallows where an oesophageal trace would deepen and NG2's anterior and lateral traces don't turn towards the midline and become shallow, respectively. The high left deviation of NG4 without a return towards midline suggests lung placement unless later parts of the trace permitted identification of the pyloric or intestinal flexures. The authors interpretation of NG4 was from a screen printout only, therefore the absence of the lateral trace view precludes a definite interpretation.

Aside from the left-shift, NI1's anterior and lateral traces were vertical then clockwise and deep-shallow-deep, respectively. This typifies a path from oesophagus to stomach to duodenum part-1. Medical staff incorrectly confirmed this from an X-ray. The trace mimicked the pre-GOJ, gastric body and pyloric flexures and was similar to a previous jejunal trace and subsequent gastric trace (not illustrated). Following a CT-scan with radio-contrast, it was identified that the tube exited the lower oesophagus and followed the *external* gastric greater curvature before it abutted duodenum part-2.

Systems compared

Trace misplacement rating agreement was 100% between authors for each system. Interpretation by screen position or manufacturer guidance falsely identified GI position in 57% and 14% of tube placements, respectively; both methods left uncertainty in up to 71% (n = 5) (Table 1) of which 80% suffered aspiration pneumonia or death. Uncertainty stemmed from misplacement traces having approximately 90–100% overlap with a normal GI trace area (NG2, NG4, NG6, NI1, NI2). For manufacturer guidance NG2, NG4, NG6 and NI2 all reached the lower left quadrant (criterion b.) and lack of a vertical trace (criterion a.) may have been wrongly attributed to receiver misalignment. The GI flexure system mis-identified the intra-peritoneal placement (n = 1) as duodenal. Whilst it did not cause serious harm, it had the potential to do so. Conversely, the GI flexure system correctly identified all lung misplacements by the absence of the pre-GOJ and/ or gastric body flexures.

Discussion

Primary finding

This is the first study to examine the reasons for Cortrak trace misinterpretation. Failure to detect the seven misplacements analysed was not equipment failure but operator misinterpretation due to:

- Lung and oesophageal traces having overlapping deviations.
- Lower left screen quadrant traces not being gastric.
- Peritoneal trace mimicking GI flexures.

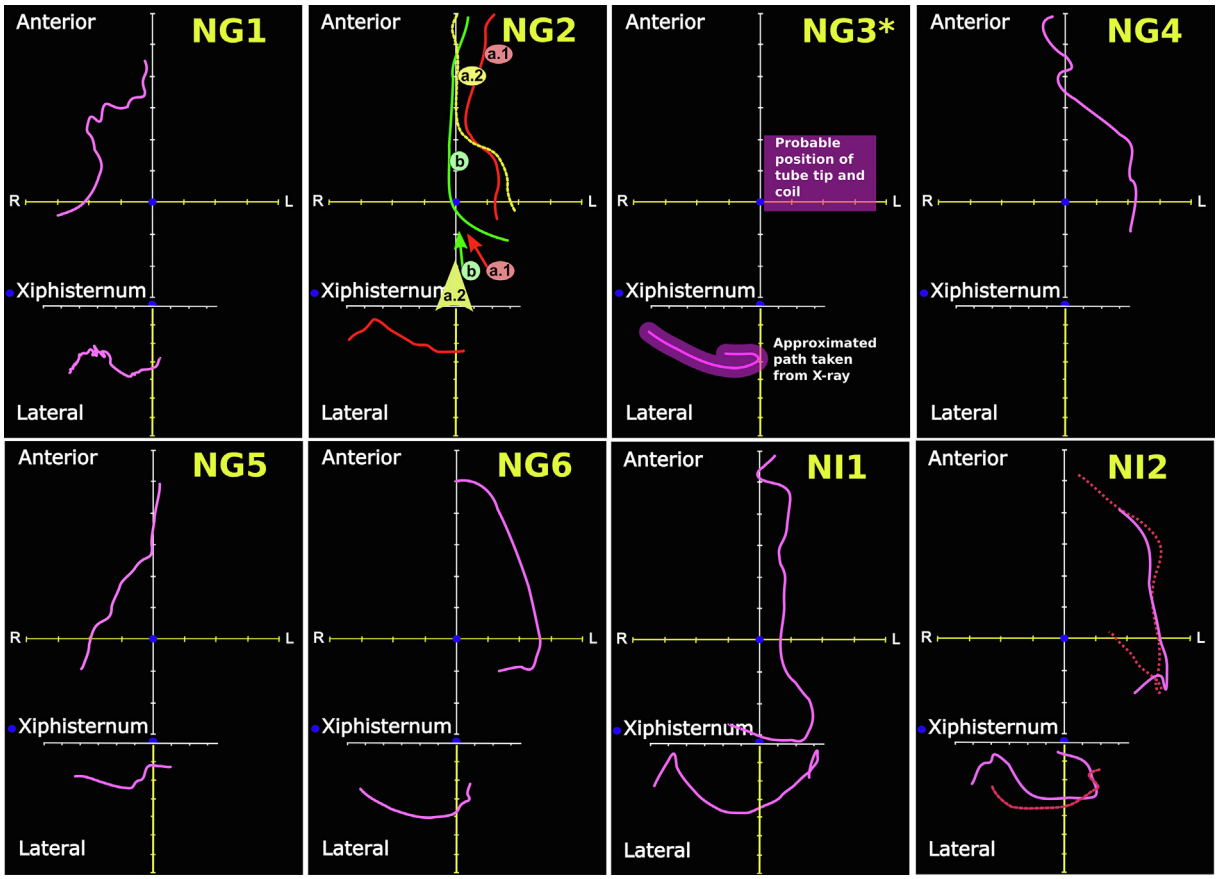

Fig. 3. Traces from undetected NG and NI misplacements.

Table 1
System of interpretation: Incorrect identification of GI position.

System:		a) GI screen position	b) Official guidance		c) GI flexure			Actual position	Severity of harm^
Tube			Trace Vertical	Tip in lower left quadrant	Pre-GOJ	Gastric body	Pyloric		
NG	1	0	0	0	0	0	–	Lung	Death
	2	1	?	1	0	0	–		Aspiration pneumonia (AP)
	3*	–	–	–	–	–	–		
	4	1	?	1	0	0	–		
	5	0	0	0	0	0	–		Death
	6	1	?	1	0	0	–		AP
NI	1	1	1	1	1	1	1	Intra-peritoneal	↑ monitoring only
	2	??	?	1	0	0	0	Lung	Death

?? = Most of the misplacement trace overlapped the GI area. ^ Data from StEIS (2018).
0 = correctly identified as not GI, 1 = false GI, ? = possible confusion with receiver misplacement.
*No trace, X-ray only.
ST did consultancy for Cortrak in 2008. ST and KA worked on a study in 2013–14 sponsored by Cortrak through North Bristol NHS Trust in which Cortrak played no part in planning, execution or publication of the work.

Rates of trace misinterpretation varied by system: Screen position (57–71%); manufacturer guidance (14–71%) and GI flexures (14%). The GI flexure system detected all six lung misplacements.

Screen position and manufacturer guidance

Current findings confirm that screen position failed to differentiate GI from non-GI placement (Bryant et al, 2015; FDA, 2018) because the GI and lung screen areas widely overlap (Taylor, 2018). Similarly, lung placements were not detected despite traces deviating significantly from the manufacturer criterion a. that the trace should move "*straight down the vertical with no deviations above the horizontal midline*" (Avanos Medical Inc., 2018). However, four of the current chest level trace deviations mimic those from receiver misplacement or unusual anatomy and could be confused with the 38% of GI traces that deviate ≥5 cm from the midline (Taylor et al, 2017b). All these traces reached the lower left quadrant, indicating gastric placement (manufacturer Cortrak criterion b.) and two turned clockwise, further mimicking gastric placement at the abdominal level. Unfortunately 'criterion b.' appears to be inaccurate and may confuse interpretation as 12% of tubes reach the gastric body in the upper left quadrant, before meeting 'criterion b.', and 49% of tubes meet criterion b. when still oesophageal (Taylor et al, 2017a) or are even in the right lung (Bryant et al, 2015). Current results confirm that while predicting position by quadrant was 70% accurate, identifying the absence of pre-GOJ junction and/ or gastric body flexures was 100% accurate in differentiating lung misplacements (Taylor et al, 2017a). Specifically, receiver misplacement, which occurs in 19% of placements and causes trace artefacts (Taylor et al, 2017a), likely contributed to the current NG2 misinterpretation as gastric, when the tube was in the lung. This confirms that tube position should not be interpreted from final location or quadrant position alone (FDA, 2018). Lastly, although the trachea is shallower than the oesophagus it cannot be used to differentiate position because the actual trace depth (Fig. 2) can only be known when the tube has been positioned in both tracts and compared in the same patient. In this study, manufacturer guidance did not consistently differentiate safe from unsafe traces because its criteria do not account for variation in typical or unusual anatomy or the inability to precisely align the receiver with internal anatomy.

GI flexure guidance

In the current study, the GI flexure system identified the absence of the pre-GOJ and/ or gastric body flexures and correctly classified all lung traces as unsafe. It has been used in patients with widely variable body mass index, including patients with hiatus hernia and achalasia (Taylor et al, 2017a) but requires wider testing. Where anatomy is radically altered by surgery or there is risk of GI perforation, as in the trace of NI1, Cortrak and plain X-ray can fail to detect misplacement and the use of direct vision or radiocontrast methods may be necessary (Taylor et al, 2014).

Training

Insufficient training may explain a higher rate of undetected misplacement using Cortrak than blind placement (Bryant et al, 2015; Krenitsky, 2011). In the cases we present there was no equipment failure, therefore, while unproven, it is probable that deficits in training and experience resulted in failure to detect misplacements. It has been suggested that the minimum of three supervised tube placements and trace interpretations (Avanos Medical Inc., 2018) should be increased to 75–100 and for device use to be restricted to or supervised by experts (McCutcheon et al, 2018). Indeed, while operators new to Cortrak reported feeling confident after 8–10 placements, 30% continued to utilise auscultation to confirm tube position, indicating a lack of confidence (Bourgault et al, 2019). More importantly, expertise can only be proven if based on an objective system of interpretation that is transferable between units.

Limitations

Risk comparison to blind placement was not possible because of the small numbers of events in the UK, incomplete trace acquisition, despite mandated event reporting, and because wider Cortrak use is not reported. Worldwide, misplacement rates are likely to be underestimated as publications are largely from expert centres or based on voluntary reporting to national databases.

To address these problems, we recommend extending analysis to the larger USA dataset; that healthcare centres are required to store traces and refer event-related files to statutory bodies (i.e. NHSI or FDA) as a mandatory condition of Cortrak use; and the manufacturer be required to publish tube use data. These data should be released to authorised researchers for prospective studies over a broad range of centres to establish the incidence and type of events and potential solutions through improved methods of interpretation.

Conclusion

Undetected Cortrak tube misplacements were due to trace misinterpretation. Most traces reached the lower left quadrant incorrectly suggesting gastric placement (manufacturer criterion b.) but deviation from the sagittal midline (manufacturer criterion

a.) failed to warn of misplacement possibly because safe traces often deviate. The GI flexure system of interpretation appears to reduce risk of undetected lung placement. Trace and incident reporting should be improved. Trace printouts are small, lack a depth view and are therefore inadequate for either interpretation or a permanent record.

This study suggests that current manufacturer guidance is inadequate, potentially unsafe and should be revised. Wider testing of the GI flexure or other objective system of interpretation is required.

Declaration of Competing Interest

ST did consultancy for Cortrak in 2008. ST and KA worked on a study in 2013-14 sponsored by Cortrak through North Bristol NHS Trust in which Cortrak played no part in planning, execution or publication of the work.

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