Feeding tube securement in critical illness: Implications for safety.

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8 Abstract

9 Background: Over 50% of tape secured feeding tubes are inadvertently lost.

10 Aims: Determine the impact of nasal bridle securement on tube loss, outcome and duration of use and

- 11 potential complications.
- 12 Methods: Observing the effect of nasal bridle securement on nasogastric (NG) and nasointestinal (NI) tube
- 13 loss from 01.10.2014 (NG) and 01.01.2010 (NI), respectively, to 31.12.2017.
- 14 Findings: Use of nasal bridles was independently associated with reduced NI (and NG) tube loss 36.9% to
- 15 11.8% (odds ratio, [OR]: 95% confidence interval [CI]: 0.2: 0.12-0.33, p< 0.0001), increased duration of
- 16 tube use (OR: 2.2 days, 95%CI: 0.8-2.9, p = 0.004) and increased likelihood of tubes being used until no
- 17 Ionger needed (18.1% to 33.8%, OR: 2.3, 95%CI: 1.6-3.3, p < 0.0001). In a single-room ICU, tube loss
- 18 dropped from 53% to 9% and tube redundancy (no longer required) rose from 20% to 64%.
- 19 Conclusions: UK-wide bridle securement could reduce premature tube loss need for replacement by 40%
- and could be associated with 1422 fewer pneumonias or pneumothoraces and 768 fewer deaths.

21	
22	Running title
23 24	Tube securement: Safety implications.
25	Keywords
26 27	Nasal bridle; feeding tube; inadvertent, loss, safety; securement.
28	What is already known
29	Most feeding tubes are lost to inadvertent patient removal or slippage.
30	 Nasal bridles reduce tubes loss and increase delivery of goal nutrition.
31	
32	What this paper adds
33 34	 Use of nasal bridles is independently associated with reduction of inadvertent tube loss and this appears to increase the number of tubes reaching redundancy.
<u> </u>	
35	 By obviating the need for tube replacement, nasal bridle use may reduce risk of tube-related
36	complications by 40%; this potentially translates into more than 1400 fewer major complications
37	and deaths in the UK.

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40 Conflict of interest

- 41 ST: Involved in developing a new nasal bridle with no commercial connection to the one used in the
- 42 current study.
- 43 Other authors: None.
- 44 **Ethics**
- 45 The study observed standard practice and therefore did not require ethical approval.
- 46 Financial support
- 47 None.

48 Authorship contributions

- 49 Conception and design of the study (ST), the acquisition of data (ST, KA), or the analysis (DT, ST)
- 50 and interpretation of the data (All).
- 51 Drafted or provided critical revision of the article (All).
- 52 Provided final approval of the version submitted for publication (All).

53 Introduction

In the UK 790,000 naso-enteral tubes are purchased each year [NHSI. 2016]. However, in ICU 54% of tubes are lost to inadvertent patient removal and slippage with at least 44% requiring replacement [Taylor et al. 2014a]. Risk from tube loss and replacement depends on how accurate tube guidance and confirmation are and the frequency of misplacement.

58

59 X-ray and pH are the most common methods to confirm feeding tube position, but both methods often fail. X-60 ray misinterpretation is the single most common cause of serious harm (45-47%) resulting from feeding 61 through a misplaced tube [NPSA. 2011; NHSI. 2016]. Similarly, using colorimetric strips, 12% of pH 6.0 62 samples are mis-identified as reaching the UK critical pH of 5.5 [Clemente and Taylor. 2016]. In rare cases, 63 such as tonsillar squamous cell carcinoma, lung aspirates of pH 4.5-5.5 occur [Sellers. 2012]. In addition, 64 using a threshold of 5.5 carries a 50% risk of identifying tube position as gastric when it is oesophageal [Ni et 65 al. 2014]; oesophageal placement occurs in 20% of blind placements, so using a pH threshold of 5.5 would 66 result in 10% being fed into the oesophagus. Undetected tube misplacements result in approximately 20 67 cases of serious harm, including 4 deaths, per year in the UK [NHSI. 2016]. However, 1.5% of blindly placed 68 tubes are misplaced into the respiratory tract, 0.5% resulting in pneumonia or pneumothorax [Taylor. 2018]. 69 Harm from oesophageal misplacement is unknown. These much more common complications cannot be 70 prevented by an end-of-procedure pH test or X-ray [Taylor. 2013].

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72 Reducing the pH threshold from 5.5 to 4.0 would reduce placement errors from 9.4% to 0.6% and but 73 increase the need for X-ray confirmation from 24% to 34% [Ni et al. 2014]. This, the restriction of X-ray 74 interpretation to senior Radiologists and a ban on overnight placement [NPSA. 2011] was associated with an 75 8-9h delay to feed and drugs [Brazier et al. 2017]. These changes also increased the delay before feeding 76 after nasogastric (NG) tube (re-)placement (median: 5.3h [IQR: 2-9] to 10 [6-16], p = 0.028), increased the 77 energy deficit per NGT (re-)placement (Kcal: 402 to 768, p = 0.04) and per enteral nutrition episode (Kcal: 78 2423 to 5660, p = 0.00024) and reduced the nutrition goal delivered (84% to 71%, p = 0.018) [Segaran et al. 79 2015]. Finally, placement-associated complications are related to placement frequency, therefore if tube 80 securement reduces preventable loss there could be a proportionate reduction in risk.

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We determined associations between bridle use and inadvertent (patient or slippage) feeding tube loss and, for NI tubes, all causes of tube loss and the likelihood of tubes reaching redundancy. Based on these findings and published tube placement risk, we estimated the safety implications of bridle placement.

85 Methods

86 Study design

Nasogastric tube loss data was collected, prospectively, as part of a 'device loss' audit from 1.10.2014 to 31.12.2017 and compared per patient admission and ventilated day. Nasointestinal tube loss, reason for loss and duration of use were collected prospectively from 1.1.2010 to 31.12.2017 from the 'bedside NI tube placement service' audit.

91

92 1.1 Bridle use

93 In May 2014 two predominantly open ward ICUs were merged into an ICU with single-patient rooms. From 94 01.11.2014, a policy of fitting AMT[™] nasal bridles to NG tubes was gradually introduced, as staff were 95 trained, if one tube had been inadvertently removed by a patient, the tube was difficult to place or was a vital 96 feed and/ or drug route. For NI tubes, all were fitted with bridles immediately after tube placement from 97 01.1.2015.

98

99 Analysis

We determined the effect of bridle securement on NG and NI tube loss and the potential impact on UK-wide safety. Parameters did not have normal distribution (Shapiro-Wilk test) therefore univariate analysis was carried out using Mann-Whitney signed-rank and Fisher's exact test using 'R Studio' v1.1.383. Because groups were dis-similar, age, acute physiology and chronic health evaluation (APACHE) 2 score, height, weight, disease category, conscious state, airway and days from ICU admission were entered into linear or logistic regression models. Independent variables with a p-value < 0.1 were retained and associations retested including 'bridle use'.

108 Findings

109

110 **NG tube loss**

During October 2014, 45 NG tubes were lost. From 01.11.014 nasal bridles began to be fitted to NG tubes but the policy only became established over several months as staff trained in bridle use. Although NG tube and bridle use were not audited, compared with October 2014, one year from 'bridle introduction' NG tube loss (Figure 1) or tube loss per ICU admission or per ventilated days fell by more than 50%, using data from 648 tube losses.

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Figure 1: NG tube loss per month.



119 NI tube loss

Reasons for tube loss was documented in all 710 NI tube placements from 01.1.10 to 31.12.17. Unbridled versus bridled patients were similar in age, APACHE 2 score, height, weight, sex and the proportion sedated or unconscious (Table 1.1). However, in the new ICU it became practice to place a tracheostomy later so a higher proportion of bridled patients retained an endotracheal tube, patient mix included more non-trauma neurosurgical and fewer trauma patients and NI tubes were placed earlier during ICU admission.

Table 1 Patient demography and clinical state.

Parameter		No Bridle		Bridle		P value
		Median	IQR	Median	IQR	
Age		55.4	38.3-69.2	53.6	37.6-69.5	0.75
APACHE 2 score		15	8-22	15	10-20.5	0.76
Height		174	166-180	175	166-180	0.38
Weight		77.4	68-88	80	70-90	0.15
		Ν	%	Ν	%	
Sex (male)		211	72.5	160	69.3	0.44
Disease category	Medical	86	29.6	47	20.3	< 0.0001
	Neurosurgical (non-trauma)	21	7.2	46	19.9	
	Surgery (non-neurosurgery)	75	25.8	69	29.9	
	Trauma	109	37.5	69	29.9	
Consciousness	Awake	47	22	48	21	0.82
	Sedated or unconscious	167	78	181	79	-
Artificial airway	None	43	15.5	27	11.8	< 0.0001
	Endotracheal	153	55	176	76.9	_
	Tracheostomy	82	29.5	26	11.4	

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127 From 2010-2014, 67-77 tubes were placed per year except for 2013 when only 47 were placed; 25 patients 128 were randomised to a prokinetic drug study instead of NI feeding. Following the combining of two hospitals 129 and preferential use of NI feeding over erythromycin when metoclopramide fails, annual NI tube use rose to 130 between 95-101.

131

147

The predominant reason for NI tube loss, prior to bridle use was inadvertent patient removal or slippage. On Figure 2: Cause of inadvertent NI tube loss. 132

133 an open ICU, 2010-2013, this occurred in a % 134 before, during and after ICU patients were approximately 9% once all NI tubes were brid 135 136 risk reduction (OR: 0.2, 95%CI: 0.12-0.33, p < 137 risk of loss. Apart from tubes being lost to bloc 40 138 losses (spontaneous or endoscopic displace) 30 139 term feeding routes, clinical procedures or vor 140 20 Reduced tube loss was paralleled by an inder Figure 3: Reason for NI tube removal due to redundancy. 141 142 0.7-3.7, p = 0.004); age was negative %

143 nearly 3-fold increase in planned tra 60 0.0001) (weight, male gender negativ $_{40}$ 144 145 redundant at its removal (OR: 2.3, 95 146 and male gender were positively and n 10





Effect on potential risk 148

Table 2 represents the potential current complication rates associated with 'blind', that is unguided, NG and NI tube placement. This assumes 90% of UK-purchased tubes are placed, current misplacement rates and estimates the risk reduction if bridle securement, as in the current study, achieved a 40% reduction in premature tube loss and replacement.

Table 2 UK tube use, complication rates and potential effect of bridles.

Tube use and complications	N or %	Таре	Bridle	
		90% placed*	40% reduction	
Tubes per y UK	790000	711000	284400	
Complication rate**:	%			
■ Lung	1.5	10665	4266	
Pneumothorax,	0.5	3555	1422	

patient

pneumonia			
■ Death	0.27	1920	768
Oesophageal: placement	20	***142200	56880
undetected**		35550	14220

149 *90% of UK purchased tubes are placed to a length approximating the gastric or lung positions.

** Summarised from [Taylor. 2018 from Sorokin and Gottlieb. 2006; Kooperman et al. 2011; Krenitsky. 2011;

Rayner. 2013; Rollins et al. 2012].

*** Assumption: 50% detected by X-ray; 50% of the remainder (25%) detected by pH \leq 5.5.

151 Discussion

152 **Primary findings**

Most NG and NI tubes secured with tape are lost before they are no longer required. For NI tubes approximately 35% were lost to inadvertent patient removal and slippage on an open ICU ward. This increased to 53% when combining two ICUs and nursing patients in single rooms, then fell to 9% after bridle securement. Bridle securement was independently associated with this reduction in inadvertent tube loss. Bridle securement was associated with a more gradual increase in the proportion of patients progressing to alternative feeding routes; it is unclear why this lagged behind the decline in tube loss.

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160 Inadvertent tube loss

161 Inadvertent tube removal or slippage occurs in up to 73% of tubes when using tape securement [Brazier et 162 al. 2017]. Patients with neurological disease appear most prone to patient removal [Taylor et al. 2015], 163 occurring in 82% of stroke patients [Brazier et al. 2017]. In a hospital-wide population although risk of patient 164 tube removal increases with each removal (0: 61%, 1: 66%, 2: 70%) it was not confined to specific patient 165 groups [Taylor et al. 2015]. And, the rapidity of changes in sedation, level of consciousness and tape 166 adherence make patient tube removal or slippage unpredictable.

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In contrast, because about 6% of hospitalised patients require NG or NI feeding [Elia. 2015] the need for 30-50% of tubes to require replacement represents a significant healthcare risk and cost [Taylor et al. 2014a]. National alerts and extra radiological training have failed to prevent undetected misplacements [NHSI. 2016]. Many patients require several tube replacements (\geq 3: 28-59% [Brazier et al. 2017; Taylor et al. 2015] and misplacement risk increases from an average of 2.1% to 32% when there has been previous misplacement and risk of pneumothorax increases from 5% after the first misplacement to 36% after \geq 3 [Marderstein et al. 2004].

175

176 Implications for safety

pH or X-ray confirmation do not prevent tube misplacement which represents more than 90% of the burden of misplacement morbidity and mortality [NPSA. 2011; NHSI. 2016] (Table 2). The number of complications from undetected oesophageal misplacements is unknown. Because most misplacements are detected and the tube correctly repositioned, clinicians often fail to realise that misplacement was the cause of complications. The reduction in complications when nasal bridles are placed pre-emptively is based on the 182 reduction in inadvertent patient removal and slippage in this study, in single patient rooms, obviating the

183 need for tube replacement.

184

Actual placements, and thus misplacements and complications, will depend upon the patient population. Patients with impaired neurology, including critically ill and stroke patients, are prone to inadvertent tube loss but also form a large proportion of tube fed populations [Taylor et al. 2014a; 2015; Brazier et al. 2017]. If the UK tube-fed population were similar to our ICU NI tube-fed patients, pre-emptive bridle placement is predicted to prevent 1422 major complications and 768 deaths. Bridle securement could also reduce delays to feed and drug delivery [Segaran et al. 2015; Brazier et al. 2017] thereby improving clinical outcome and reducing healthcare staff burden.

192 Cautions

This study was observational so un-measured confounders may partly explain findings. For example, after introducing nasal bridles, there was a progressive, rather than single-step, reduction in tube loss and increase in patients no longer needing their tube prior to 'loss'. However, improved training in positioning of the bridle clip could explain the decremental reduction in tube loss after introduction of bridles. Equally, increased retention of tubes until redundant might lag behind reduction in tube loss, because only once tubes are secured would there be an imperative to improve tube maintenance, such as flushing. Lastly, the effects of bridle introduction were large after accounting for most potential confounders.

200

201 Conclusions

202 On moving from tape to bridle securement, inadvertent tube loss fell from 53% to 9% while the number of 203 patient's tube's that reached redundancy increased from 20% to 64%. While this study is retrospective and 204 single-centre the independent associations appear very strong. A similar effect UK-wide should achieve 205 major reductions in misplacement-associated complications and death. Further investigation, including 206 randomised controlled trials, is required to determine whether these changes affect hospital length of stay 207 and holistic treatment cost.

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212 Appendix Regression models including bridle securement adjusted for potential confounding factors.

Model	Independent variable	*	95% (CI	P value
Inadvertent		OR	2.5%	97.5%	
tube loss	(Intercept)	0.51	0.21	1.15	0.11
	bridle	0.20	0.12	0.33	< 0.0001
	disease_neurosurgical (non-trauma)	1.60	0.68	3.68	0.27
	disease_surgery (general)	1.03	0.50	2.12	0.93
	disease_trauma	2.57	1.42	4.76	0.002
	sedated_unconsciousness (vs awake)	1.53	0.69	3.55	0.31
	airway_endotracheal	0.58	0.22	1.49	0.26
	airway_tracheostomy	0.71	0.27	1.82	0.48
Tube duration		Days	2.5%	97.5%	
of use	(Intercept)	9.63	6.19	13.06	< 0.0001
	bridle	2.21	0.70	3.72	0.004
	age	-0.06	-0.09	9 -0.02	0.005
	kg	0.03	-0.02	1 0.06	0.13
Planned		OR	2.5%	97.5%	
transfer to	(Intercept)	0.41	0.15	1.10	0.08
alternative	bridle	2.83	1.86	4.34	< 0.0001
nutrition	APACHE 2 score	0.94	0.91	0.97	< 0.0001
	age	1.00	0.99	1.01	0.90
	sex	0.58	0.36	0.94	0.03
	kg	1.01	1.00	1.02	0.13
Tube no longer		OR	2.5%	97.5%	
needed	(Intercept)	0.48	0.25	0.91	0.03
	bridle	2.26	1.55	3.31	< 0.0001
	sex	0.55	0.36	0.82	0.004
	airway_endotracheal	2.04	1.15	3.73	0.017
	airway_tracheostomy	2.24	1.14	4.51	0.021
	NJ tube_ICU day of placement	0.98	0.94	1.00	0.165

*95% confidence interval of OR or estimate.