Faecal diversion system usage in an adult intensive care unit

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ABSTRACT

Objective: To determine the frequency, indications and complications associated with the use of faecal diversion systems (rectal tubes) in critically ill patients.

Design: A single centre observational study over 15 months.

Setting: Intensive care unit (ICU).

Participants: Patients admitted during this period.

Main outcome measures: Frequency of rectal tubes utilisation in ICU, as well as associated adverse events, with major events defined as lower gastrointestinal bleeding associated with defined blood transfusion of two or more units of red cells or endoscopy or surgical intervention.

Results: Of 3418 admission episodes, there were 111 episodes of rectal tubes inserted in 99 patients. Rectal tubes remained indwelling for a median of 5 days (range, 1–23) for a total of 641 patient-days. The most frequent indication for insertion was excessive bowel motions. A major adverse event was observed in three patients (3%; 0.5 events per 100 device days). Two patients underwent laparotomy and one patient sigmoidoscopy. These patients received between two and 23 units of packed red blood cells. Patients who had a rectal tube inserted had a substantially greater duration of ICU admission (mean, 14 days [SD, 14] *v* 2.8 days [SD, 3.7]) and hospital mortality (15% *v* 7.7%; risk ratio, 2.0; 95% CI, 1.2–3.4) as well as an overall higher Australian and New Zealand Risk of Death (ANZROD) score (mean, 27 [SD, 22] *v* 12.6 [SD, 20]).

Conclusion: Rectal tubes appear to be frequently inserted and can lead to major adverse events in critically ill patients.

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Diarrhoea and faecal incontinence occur frequently in critically ill patients.[1-3] Caring for patients with faecal incontinence is time-consuming. Furthermore, incontinence is a risk factor for skin breakdown, pressure ulcers and nosocomial infection.[4-6] To mitigate the adverse effects of faecal incontinence, faecal diversion systems can be implemented. Proprietary intrarectal faecal diversion and collection devices, so called rectal tubes, have been adopted by many intensive care units (ICUs).[5,7]

Case reports have described major adverse effects, such as massive bleeding, perforation or fistulas that occur with rectal tube placement.[7-11] However, there are limited epidemiological data on the frequency, indications and adverse events associated with the use of rectal tubes during usual clinical practice in the context of a general adult ICU. Our aim was to describe the epidemiology, with a focus on major adverse events.

Methods

We conducted an observational cohort study between November 2016 and January 2018 of all patients admitted to a single ICU. The research protocol was approved as a quality assurance project, with the need for informed consent waived (Royal Melbourne Hospital Research Ethics Committee).

All patients admitted to ICU during the 15-month research period were screened daily for the presence of a rectal tube. The decision to insert a rectal tube was made by bedside health care practitioners guided by a local protocol. The protocol included relative contraindications to insertion; for example, local anatomical abnormalities and systemic anticoagulation. All rectal tubes (Flexi-Seal SIGNAL FMS; ConvaTec) were inserted by ICU nursing staff who had received training in this procedure. Once inserted, ongoing protocol management by the primary nurse aimed to mitigate pressure injury by balloon deflation and volume checks once per shift, and completion twice per day of a checklist designed to confirm that the rectal tube was still clinically warranted and there were no signs of bleeding or excoriation. However, the protocol did not mandate removal for certain post-insertion events, such as commencement of systemic anticoagulation or fall in platelet count.

Adverse events associated with rectal tubes were identified by a manual review of ICU and hospital discharge summaries for documentation of indication for insertion and any complications perceived to be related to rectal tube placement. Finally, we linked data with the International Classification of Diseases (ICD-10) coding for potential complications related to rectal tubes and an electronic

hospital-wide incident and complication management system (RiskMan; Datix Group, Melbourne, VIC, Australia) for complications related to rectal tubes. In particular, we conducted a key word and term search across all RiskMan submissions for the patient list during their ICU admission using "rectal", "flexiseal", "faecal" and "fecal".

We categorised complications as major if insertion was associated with an outcome that we believed would be important to patients.[12] We defined major complications as clinically important lower gastrointestinal bleeding, which was modified from the definition used to describe upper gastrointestinal bleeding by the Canadian Critical Care Trials Group and others;[13-15] rectal bleeding associated with anaemia (haemoglobin < 70 g/L) and transfusion of two or more units of packed red blood cells within 72 hours of first documentation of rectal bleeding; need for operation; or death.

We defined minor complications as reported dislodgement requiring repeat insertion, overinflation of the balloon without independently documented rectal pressure ulceration, or device dysfunction with skin or wound contamination. Identification of all complications required the agreement of two authors who had independently reviewed the clinical notes to clarify that the complication could be attributable to rectal device placement.

Each patient record was further reviewed by manual search for documentation of rectal tube output daily, where available.

Data were then extracted from the Australian and New Zealand Intensive Care Society Adult Patient Database (ANZICS-APD) on all patients admitted to the ICU during the study period, to allow direct comparison of demographics and outcomes. These data were merged with the rectal tube dataset using, as key variables, each patient's unique identification number and ICU admission dates for those with more than one admission in the study period.

Statistical analyses

Data were merged within Stata version 16 (StataCorp, College Station, TX, USA) for further analyses. Day 1 was the first day of ICU admission and was therefore a partial day, with all others being full calendar days. Continuous data were summarised as mean with standard deviation (SD) for normally distributed variables. Data with skew distributions were otherwise summarised as median with interquartile range (IQR) or [range]. Binary data were summarised as proportions with associated 95% binomial confidence intervals, while comparisons of two proportions were reported as risk ratios (relative risks) with 95% confidence intervals (CIs). Proportions within levels of categorical data were compared using χ^2 tests.

Results

Data were available for a total of 3418 ICU admission episodes for 3074 individual patients.

There were 111 episodes of rectal tube placement in 99 patients; that is, 3.2% of patients had a rectal tube inserted. These comprised 90 patients with only one episode of a rectal tube being inserted, another seven patients with rectal tubes inserted on two occasions (within the same ICU admission [n = 5] and across separate ICU admissions [n = 2]), and one subject with three and one subject with four episodes of rectal tubes inserted. At the time of rectal tube insertion, 79 patients (78%) were mechanically ventilated.

The median day of ICU admission for first rectal tube insertion was Day 6 (IQR, 4–9), with the most frequent indications being diarrhoea or excessive bowel motions (94/111, 85%), diversion after peri-anal surgery (4/111, 4%), prone ventilation (3/111, 3%), and peri-anal excoriation (2/111, 2%), with no indication recorded for eight episodes (7%).

The median of rectal tube use across the 111 episodes was 5 days [range, 1–23], with a mean of 5.8 days (SD, 4.6) for a total of 641 patient-days of exposure to the intervention. Data regarding stool output collected within the rectal tube diversion system were available from 74 cases. The median stool output was 350 mL (IQR, 200–706) on Day 1 and 238 mL (IQR, 100–600) on Day 2.

Comparison between patients who did and did not have rectal tube inserted

Patients who had a rectal tube inserted shared about the same age and sex distribution as patients for whom rectal tubes were not placed (Table 1) but had a substantially greater severity of illness with accompanying risk of death, as summarised by the Australian and New Zealand Risk of Death (ANZROD) score.[16]

It was substantially more common for patients managed with rectal tubes to have a medical diagnosis (3.8%) rather than a trauma (3.0%) or surgical (1.8%) diagnosis (Table 2) (medical, trauma or surgical risk ratio, 1.7; 95% CI, 1.2–2.6).

There was also strong evidence for different proportions of rectal tube use across 20 Acute Physiology and Chronic Health Evaluation (APACHE) diagnostic groups (Table 2). In terms of absolute number of events, the most common ICU diagnostic categories of patients receiving rectal tubes in an episode of ICU care were cardiovascular medical (15/365, 4.1%), sepsis (13/322, 4%), cardiovascular surgical (15/609, 2.5%) and non-operative trauma (12/368, 3.3%). However, within ICU diagnostic groups, the highest proportional use of rectal tube devices was in 13% (5/39) of patients with medical haematological conditions and 12% (10/82) of medical gastrointestinal illness cases

Adverse events

There were 14/99 patients (14%) who had an adverse event attributable to rectal tube insertion or placement, corresponding to 2.2 events per 100 days of rectal tube insertion.

Three patients (3.0%) had a major adverse event, corresponding to an event rate of 0.5 per 100 days of rectal tube insertion (Table 3). In all three cases, patients were noted to have rectal bleeding and progressive anaemia, and subsequently found to have rectal mucosal ulceration causing blood loss clinically attributed to the rectal tube. These three patients received invasive surgical or endoscopic investigation as well as blood transfusion (Table 3).

Eleven patients (11%) had a minor adverse event (online Appendix, table S1). Minor adverse events included balloon failure requiring reinsertion (n = 4), tube bypassing causing contamination of wound or soiling (n = 4), and tube being unintentionally dislodged (n = 3).

Other outcomes

Patients who received rectal tubes stayed on average more than four times longer in the ICU (mean, 14 days [SD, 14] *v* 2.8 days [SD, 3.7]). These patients had about double the mortality rate of patients in whom those devices were not used (Table 1) (mortality, 15% *v* 7.7%; risk ratio, 2.0; 95% CI, 1.2–3.4).

Discussion

Key findings

Based on observations at our centre, a considerable proportion of patients have a rectal tube inserted during their ICU admission. We recorded 111 insertions in 99 patients across a 15-month period. Most rectal tubes were inserted because the patient had diarrhoea or faecal incontinence, and we observed three major adverse events at a rate of 0.5 per 100 days of rectal tube insertion.

Moreover, the events we identified highlight the life-threatening nature of complications rectal tubes cause. All three cases of major rectal haemorrhage required transfusion of packed red blood cells and an invasive procedure. The frequency of rectal tube insertion and complication rate, and the magnitude of morbidity when a complication occurs, is concerning for a device that, to the best of our knowledge, has never been rigorously evaluated as to whether it has patient benefits. Our observations, if representative of other sites, suggest that rigorous evaluation of the benefits and harms of rectal tube placement is warranted.

Relationship to previous studies

To our knowledge, our observational study represents the first independent systematic study to provide epidemiological data on the frequency, indications and adverse events associated with the use of rectal tubes during usual clinical practice in ICU. Pre-existing data in this area are available either as manufacturer-supported research, analysis of an older generation of rectal tubes no longer used in ICU, or case reports.[7,8,10,11] While the case series and case reports highlight the substantial harm that may occur with rectal tube use, they offer limited perspective on the frequency of these events. Our data suggest that adverse patient-centred outcomes may be more frequent than previously considered.

Limitations and strengths

Our study had a number of strengths. The use of thorough, multistep, manual review as well as database (RiskMan) analysis allowed greater detection of harm. It should also be

Table 1. Characteristics of patients with and without rectal tube placed at some time during intensive care unit (ICU) admission*

	Rectal tube		
	Absent	**Present**	**Total**
Female	1102/2975 (37.0%)	38/98 (38.8%)	1140/3073 (37.1%)
Age (years)			
Mean (SD)	57 ± 19	58 ± 16	57 ± 19
Median (IQR) [range]	61 (44–72) [16–108]	61 (45–69) [18–86]	61 (44–72) [16–108]
ICU LOS (days)			
Mean (SD)	2.8 ± 3.7	14 ± 14	3.1 ± 4.8
Median (IQR) [range]	1.7 (0.9–3.1) [0–56]	10 (7–18) [0.6–78]	1.7 (0.9–3.4) [0–78]
ANZROD risk of death (%)			
Mean (SD)	12.6% ± 20.0%	27% ± 22%	13.0% ± 20.2%
Median (IQR) [range]	3.2% (0.9–14%) [0–99.9%]	23% (9–36%) [1.2–98.5%]	3.5% (1–15%) [0–99.9%]
Died in ICU	230/2975 (7.7%)	15/98† (15%)	245/3073† (8.0%)

ANZROD = Australian and New Zealand Risk of Death; IQR = interquartile range; LOS = length of stay; SD = standard deviation. * Summary statistics are calculated for the first ICU admission episode to prevent double counting. † Missing data for one patient.

Table 2. Acute Physiology and Chronic Health Evaluation (APACHE) III diagnosis categories according to the presence or absence of rectal tube in each intensive care unit admission episode

APACHE category	Faecal diversion device: Absent *n* (%)	Faecal diversion device: Present *n* (%)	Total *N* (%)
Non-operative (medical) diagnoses			
Cardiovascular	350 (10.6%)	15 (13.6%)	365 (10.7%)
Sepsis	309 (9.4%)	13 (11.8%)	322 (9.4%)
Respiratory	310 (9.4%)	12 (10.9%)	322 (9.4%)
Gastrointestinal	72 (2.2%)	10 (9.1%)	82 (2.4%)
Neurological	303 (9.2%)	7 (6.4%)	310 (9.1%)
Metabolic	221 (6.7%)	5 (4.6%)	226 (6.6%)
Haematological	34 (1.0%)	5 (4.6%)	39 (1.1%)
Renal/genitourinary	45 (1.4%)	1 (0.9%)	46 (1.4%)
Musculoskeletal/skin	6 (0.2%)	0 (0%)	6 (0.2%)
Other	6 (0.2%)	0 (0%)	6 (0.2%)
Post-operative (surgical) diagnoses			
Cardiovascular	594 (18.0%)	15 (13.6%)	609 (17.8%)
Neurological	88 (2.7%)	5 (4.6%)	93 (2.7%)
Musculoskeletal/skin	24 (0.7%)	3 (2.7%)	27 (0.8%)
Gastrointestinal	246 (7.4%)	2 (1.8%)	248 7.3%)
Respiratory	105 (3.2%)	1 (0.9%)	106 (3.1%)
Renal/genitourinary	56 (1.7%)	0 (0%)	56 (1.6%)
Gynaecological	17 (0.5%)	0 (0%)	17 (0.5%)
Metabolic	8 (0.2%)	0 (0%)	8 (0.2%)
Trauma (non-operative)	356 (10.8%)	12 (10.9%)	368 (10.8%)
Trauma (operative)	155 (4.7%)	4 (3.6%)	159 (4.7%)
Total	**3305* (100%)**	**110* (100%)**	**3415 (100%)**

Pearson $\chi^2_{19} = 54.1$; $P < 0.0005$. * APACHE III category missing for one device event and two control admissions, reducing the total admission episodes from 3418 to 3415.

noted that the minor complications detected by this study also represent a potential mechanism for genuine injury — dislodgement with balloon inflated causing tears, and cuff overinflation causing mucosal pressure injury.

Our study has a number of limitations. Despite being the largest study in the literature, there were still a relatively small number of rectal tubes inserted (n = 111) and the event rate of major complications was only three. Accordingly, our estimates of frequency of major complications are presented with considerable uncertainty. The identification of patients with tubes inserted, as well as complications, relied heavily on clinician documentation, and it is therefore possible that cases of rectal tube insertion and complications may have been underestimated. Our study was conducted as a single site and, during this study period, we did not document or audit compliance with the rectal tube protocol. Therefore, we cannot exclude the possibility that complications represent clinical practice rather than the device per se. Nonetheless, this is the first observational cohort study of the documented rates of rectal tube insertion, and subsequent injury or complication.

Clinical implications

During the study period, we observed that patients who have a rectal tube placed remain in ICU for much longer periods and have double the mortality rate than the overall ICU population. While severity of illness, as evident with higher ANZROD scores, is a confounding variable, these associations highlight that patients who have rectal tubes placed are a vulnerable population with poorer outcomes. We also observed that more than 80% of placements occurred because of diarrhoea, which remains a subjective diagnosis in critically ill patients, with prevalence varying widely depending on the definition used.[2,3,17] Diarrhoea and repetitive soiling are unpleasant, are likely to have an adverse impact on patient dignity, and are associated with local complications such as skin breakdown.[18] However, in the absence of risk of contamination of an existing wound, whether repetitive soiling is more unpleasant or more undignified than placement of a rectal tube remains a matter of opinion. Given the adverse outcomes with treatment of diarrhoea (ie, rectal tube placement) we observed, strategies to limit the frequency and magnitude of diarrhoea have merit.[19] Such strategies include delaying the commencement of laxative bowel regimens,[20-22] and possibly, manipulation of enteral nutrition formulae.[23,24] Moreover, because of the outcomes associated with their use, it seems that

Table 3. Demographic data and outcomes associated with patients who had a major adverse event associated with rectal tube placement

Patient	Age (years)	Sex	Admission diagnosis category	Reason for insertion	Platelet count (x 10^9/L) on day of insertion	APTT (seconds) on day of insertion	INR on day of insertion	Number of days rectal tube indwelling before complication	Complication	Intervention	PRBC transfusion*	Haemoglobin nadir	Platelets (x 10^9/L) on day of bleeding†	Coagulation status on day of bleeding†	ICU LOS	Hospital LOS	Outcome of admission
1	63	Male	Traumatic injury	Loose bowels	142	35	1.1	13	Rectal bleeding and mucosal ischaemia	Laparotomy and flexible sigmoidoscopy and mechanical haemostasis	2 units	64	160–200	Normal	38	267	Died
2	51	Female	Cardiac surgery	Loose bowels	75	49	1.2	6	Rectal bleeding and anal wall tear	Laparotomy and mechanical haemostasis	23 units	57	40–60	Therapeutic anticoagulation (heparin)	62	62	Died
3	43	Male	Septic shock	Loose bowels	182	37	1.1	3	Rectal bleeding and mucosa ulceration	Flexible sigmoidoscopy	3 units	69	110–130	Prophylactic anticoagulation (heparin)	17	94	Discharged home

APPT = activated partial thromboplastin time; INR = international normalised ratio; ICU = intensive care unit; LOS = length of stay; PRBC = packed read blood cells. *Within 72 hours of initial blood loss. † Information from within 24 hours of bleeding event.

clinicians should carefully balance the risk–benefit of rectal tube placement for each individual patient, and institutions should have systems to audit the placement, compliance with protocols, and outcomes with these devices.

Conclusion

Our prospective observational study suggests that, at least at our centre, a relatively large number of rectal tubes are inserted each year, and that complications resulting in adverse patient-centred outcomes occurred. Our observations support the concept that rigorous evaluation of these devices is required.

Competing interests

None declared.

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