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Safety of physical therapy interventions in critically ill patients:

A single center prospective evaluation of 1,110 ICU admissions

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Abstract

Purpose: Critical illness survivors commonly have impaired physical functioning. Physical therapy interventions delivered in the intensive care unit (ICU) can reduce these impairments, but the safety of such interventions within routine clinical practice requires greater investigation.

Materials and Methods: We conducted a prospective observational study of routine physical therapy from July 2009 through December 2011 in the Johns Hopkins Hospital Medical ICU in Baltimore, MD. The incidence of 12 types of physiological abnormalities and potential safety events associated with physical therapy were monitored and evaluated for any additional treatment, cost or length of stay (LOS).

Results: Of 1787 admissions of ≥24 hours, 1110 (62%) participated in 5267 physical therapy sessions conducted by 10 different physical therapists on 4580 patient-days. A total of 34 (0.6%) sessions had a physiological abnormality or potential safety event, with the most common being arrhythmia (10 occurrences, 0.2%) and mean arterial pressure >140 mmHg (8 occurrences, 0.2%) and <55 mmHg (5 occurrences, 0.1%). Only 4 occurrences (0.1%) required minimal additional treatment or cost, without additional LOS.

Conclusions: In this large, single-center study, routine care physical therapy interventions were safe for critically ill patients.

Key words: safety; physical therapy modalities; rehabilitation; critical illness; intensive care unit

1. Introduction

Critically ill patients are frequently exposed to prolonged periods of immobility [1-3], contributing to subsequent physical impairments [3-6]. Physical therapy interventions delivered during the intensive care unit (ICU) stay can reduce these impairments [7-11]. However, many perceived barriers prohibit the delivery of early ICU-based physical therapy as part of routine clinical practice. One such barrier is a concern for the safety of physical therapy interventions in critically ill patients [12-14].

The safety of early physical therapy in critically ill patients has been demonstrated in clinical trials [7, 11, 15-17] and related systematic reviews [18-20]. However, most existing studies evaluating the safety of ICU-based physical therapy as part of routine clinical care are relatively small (e.g., 19 - 166 patients) [9, 12, 13, 21-28]. Interventions that have been demonstrated as safe in clinical trials are not necessarily safe when introduced into routine clinical care. For example, the incidence of serious bleeding events associated with recombinant human activated protein C (rhAPC) in critically ill patients with sepsis was higher in observational studies of routine care (up to 10%) [29] than in the original randomized controlled trial of this therapy (3.5%) [30]. The safety profile of physical therapy in clinical trials may not apply to routine care because clinical trials may include additional highly trained staff, and have strict criteria for patient eligibility and for starting/stopping physical therapy sessions. Hence, the objective of this study is to conduct a larger-scale, single-site evaluation of the safety of routine physical therapy in medical ICU (MICU) patients.

2. Materials and Methods

Description of Delivery of Physical Therapy Interventions

During their clinical rotations in the MICU (lasting from a few weeks to a few months), physical therapists generally provided rehabilitation only to patients located in the MICU. The experience levels of physical therapists working in the MICU ranged from recent graduates to staff with many years of experience, with all physical therapists completing on-the-job training for working in the ICU setting. The 16-bed MICU typically had 2.25 full-time equivalents of physical therapy support spread over 6 days per week, with a typical nurse:patient ratio of 1:2. Physical therapy interventions were almost exclusively focused on patient mobilization/exercise rather than mechanical ventilation or other respiratory interventions (e.g., manual hyperinflation, chest percussion) that were performed, if ordered by a physician, by 2 full-time respiratory therapists working 24 hours per day, 7 days per week.

Each patient with a physical therapy order was individually evaluated on a daily basis (6 days per week) by a physical therapist working in the MICU. Therapists do not use an algorithm or protocol for delivering physical therapy interventions; delivery of such interventions are informed by the physical therapists' training/experience and general rehabilitation principles, as described herein and in prior publications [7, 27, 31-33]. More specifically, in their evaluations, physical therapists determine whether or not to perform rehabilitation interventions based on the patient's medical stability, in consultation with MICU nurses and/or physicians. Patients typically receive a progression of physical therapy interventions based on patient tolerance starting with exercises in bed (e.g., active range of motion, rolling), and then advancing through sitting in bed, sitting on the edge of bed, standing and transferring from bed to chair, marching on the spot with progression to ambulation activities. The decision to progress a patient to higher

level interventions is made by the physical therapist based on the patient's clinical status and vital signs, and on their performance and response during prior physical therapy sessions, as documented in physical therapy notes in the medical record. The estimated duration of a typical physical therapy session was 30 to 45 minutes [34]. Physical therapy interventions continue until patients return to their previous level of function or were discharged.

Other clinicians may also participate with the MICU physical therapist in delivering rehabilitation interventions, depending on the need for additional staff and their availability. For instance, at least 2 other staff (e.g., a respiratory therapist, rehabilitation technician and/or MICU nurse) are present for ambulation of a mechanically ventilated patient, as described in prior literature [35, 36]. For each physical therapy session, patients' vital signs were monitored, immediately before/after and throughout each session, to ensure stability and tolerance of activities. Specifically, patients were on continuous telemetry and pulse oximetry throughout physical therapy sessions. Blood pressure was measured before and after sessions, and during activities, particularly with any change in patients' clinical status. In those patients with an arterial catheter (a minority of physical therapy sessions), blood pressure was monitored continuously throughout the physical therapy sessions.

Patient Population and Patient Data

Using the Johns Hopkins Critical Care Physical Medicine and Rehabilitation Program (the "Program") registry, we identified all consecutive patients receiving physical therapy interventions while admitted to the Johns Hopkins Hospital MICU for ≥24 hours between July 1, 2009 and December 31, 2011. The following patient data, obtained from medical records, were available for this evaluation: age, sex, weight, height, ambulation status prior to hospitalization, MICU admission source (hospital ward, emergency department, outside hospital, or other ICU

within Johns Hopkins Hospital), MICU admission diagnosis category, mechanical ventilation status (ever vs. never during MICU admission, excluding non-invasive ventilation), and MICU and hospital length of stay (LOS). On a daily basis, the treating physical therapists prospectively recorded patients' highest daily level of activity during physical therapy treatment, using a 6-level ordinal scale (in-bed exercise, in-bed cycling, sitting, transfer from bed to chair, standing, walking).

Outcome Measures: Physiological Abnormalities and Potential Safety Events

Based on prior studies [7, 9-11, 13, 14, 26, 27, 37, 38], 12 types of physiological abnormalities and potential safety events were defined. On a daily basis, treating physical therapists prospectively evaluated and recorded any occurrence of these abnormalities and events with their therapy treatment sessions. These events are as follows: cardiac arrhythmia; hypertension (mean arterial pressure >140 mm Hg); hypotension (mean arterial pressure <55 mm Hg); desaturation (oxygen saturation <85% for >3 minutes); fall; removal of medical device (separately recorded for each of the following: feeding tube; chest tube; arterial, central venous or dialysis/pheresis catheter; artificial airway (endotracheal or tracheostomy tube)); and cardiorespiratory arrest. Arrhythmia events excluded sinus tachycardia, premature ventricular contractions, and pre-existing arrhythmia that did not worsen during treatment (e.g., atrial fibrillation). Fall was defined according to published guidelines, which included a controlled lowering of the patient to the ground by a physical therapist and a fall without any patient injury [39]. To ensure accuracy and completeness of recording physiological abnormalities and potential safety events, a weekly meeting was held with the physical therapists working in the MICU, the Program's Medical Director (DMN), and Program Coordinator (AN), during which

potential events and any related questions were discussed. Moreover, these events were also formally reviewed, on a monthly basis, as part of a report presented to this same group.

For patients with any pre-defined event, additional data on the day of the event were obtained from the Program registry and review of medical records, including: sedation and delirium status using the Richmond Agitation-Sedation Scale [RASS] [40] and Confusion Assessment Method for the ICU [CAM-ICU] [41], respectively; benzodiazepine, narcotic or propofol infusion; mechanical ventilation status and associated airway type (oral endotracheal or tracheostomy tube); and other medical devices *in situ*, including catheters (urinary and intravascular (central venous, dialysis/pheresis, arterial, and peripheral)) and tubes (chest, feeding, abdominal drainage, and rectal).

For purposes of this study, for every event identified, the entire medical record was reviewed for a 7-day period after the event to determine if it was associated with any additional treatment, cost or hospital LOS, as done in a prior safety evaluation of ICU rehabilitation [27]. This review was conducted by a pulmonary and critical care medicine physician (TS) with each decision confirmed by the Program's Medical Director (DMN).

Statistical analysis

Descriptive statistics were performed, including count and proportion for binary or categorical variables, and median and interquartile range (IQR) for continuous variables. Comparisons of patient data between admissions with and without physiological abnormalities or potential safety events were done using Chi-square test for binary or categorical data, and Wilcoxon rank-sum test for continuous data. Statistical significance was defined as a two-sided p-value <0.05. All analyses were performed using Stata 12.1 software (Stata Corporation,

College Station, TX). The Institutional Review Board at Johns Hopkins University approved this study.

3. Results

Over the 30-month study period, there were 1787 consecutive MICU admissions of ≥24 hours duration, with 1110 (62%) receiving physical therapy in the MICU. Of the MICU admissions not receiving physical therapy, 179 (26%) died in the MICU and the majority of the remaining admissions did not receive physical therapy due to severe medical instability. For the 1110 patient admissions receiving physical therapy, a total of 5267 physical therapy sessions were performed by 10 different physical therapists on 4580 MICU patient-days. The initiation of physical therapy occurred at a median (IQR) of 2 (1-3) days after MICU admission. Of the 1110 MICU patient admissions, 553 (50%) were male, with a median (interquartile range, IQR) age of 57 (45-68) years, and 87% were ambulatory prior to hospitalization. The majority of patients (60%) received mechanical ventilation (Table 1).

A total of 34 physiological abnormalities and potential safety events occurred in 25 MICU patient admissions, representing 0.6% of all 5267 physical therapy sessions (i.e., 6 per 1000 physical therapy sessions) and 2% of all 1110 MICU admissions. The abnormalities and events occurred at a median (IQR) of 6 (2-11) days after MICU admission. A single event occurred in each of 18 patients, whereas 2 events occurred in 6 patients, and the remaining 4 events occurred in 1 patient. The patient who experienced 4 events (3 reports of arrhythmia and 1 report of hypotension), had an underlying cardiac conduction defect, which gave rise to arrhythmias that occurred frequently even outside of physical therapy sessions (e.g., during routine nursing care). The majority of these 34 physiological abnormalities and events occurred

while patients were mechanically ventilated (53%), alert and calm (68%), not delirious (65%) and not receiving an infusion of benzodiazepine (91%), narcotic (88%) or propofol (97%) on the day of treatment. Patients admissions with, versus without, any physiological abnormality or potential safety event had a significantly longer MICU and hospital LOS, and significant differences in MICU admission source, while other baseline and hospitalization data were similar between these two groups (Table 1). The most frequent medical devices *in situ* at the time of potential safety events are described in Table 2.

Across all ICU days with physical therapy, the most common highest daily activity level with physical therapy was ambulation (24%) with the frequency of the remaining 5 pre-defined activity levels ranging from 10% (transfer from bed to chair) to 21% (in-bed exercise) (Table 3). Approximately two-thirds of ICU days with physical therapy treatment involved mobilizing the patient to sitting at the edge of the bed or a higher level of activity. Of all the activity levels (including ambulation), sitting was associated with the highest event rate (2.0% vs. 0.4%, $p < 0.001$; Table 3), with cardiovascular-related physiological changes representing 16 (89%) of the 18 events that occurred during sitting.

Analysis of the 34 physiological abnormalities and potential safety events demonstrated that there were no cardiorespiratory arrests and no removal of central venous or dialysis catheters, or endotracheal or tracheostomy tubes (Table 4). The 3 most common potential safety events recorded were all associated with the cardiovascular system: arrhythmia (10 occurrences, 29% of the 34 occurrences, 1.9 per 1000 physical therapy sessions), mean arterial pressure >140 mmHg (8 occurrences, 24%, 1.5 per 1000 physical therapy sessions), and mean arterial pressure < 55 mmHg (5 occurrences, 15%, 0.9 per 1000 physical therapy sessions) (Table 4). These cardiovascular events, along with oxygen desaturation (4 occurrences, 12%, 0.8 per 1000

physical therapy sessions), were transient physiological derangements that tended to resolve relatively quickly when the physical therapy intervention was temporarily paused or stopped, and never required any additional therapy, cost or LOS.

A total of 3 falls occurred (9% of the 34 occurrences, 0.1% of all physical therapy sessions, 0.6 per 1000 physical therapy sessions) (Table 4). Two of these occurrences were assisted falls (i.e., a controlled lowering to the ground by the physical therapist) without any injury or additional treatment, cost or LOS. The third occurrence was an unassisted fall resulting in a lacerated wound at the patient's supraorbital rim, requiring debridement and suturing, but no other additional treatment, cost or LOS.

Finally, two orogastric feeding tubes and one radial arterial catheter (which was partially displaced prior to starting the physical therapy session) were removed, each of which required replacement, but did not require any other additional treatment, cost or LOS. One chest tube was removed but did not require replacement or any additional treatment, cost or LOS.

4. Discussion

This prospective observational study evaluated the safety of physical therapy, delivered by 10 different physical therapists as a part of routine care, in a single MICU over a 2.5-year period with >1100 patient admissions and >5200 physical therapy treatment sessions. Approximately two-thirds of ICU days with physical therapy treatment involved mobilizing the patient to sitting at the edge of the bed or a higher level of activity, with 24% involving ambulation. The 12 pre-defined and prospectively evaluated types of physiological abnormalities and potential safety events were rare, occurring in 0.6% (i.e., 6 per 1,000) of physical therapy sessions, with only 4 reported occurrences (i.e., 1 fall with small laceration and suturing, and 2

feeding tubes and 1 radial arterial catheter removed and replaced) requiring minimal additional treatment and cost, without additional LOS. These findings help support that physical therapy in the ICU is a safe intervention.

The potential safety events evaluated in this study are consistent with those evaluated in previous studies [7, 9-14, 17, 23, 25-27, 37, 38, 42-48]. Prior studies have demonstrated that physical rehabilitation in critically ill patients is safe in a wide variety of ICUs, including medical [7, 9, 10, 13, 26, 37, 43], respiratory [15, 16, 27], surgical [21-25, 28, 47, 49], and medical-surgical ICUs [11, 12, 17, 44, 48]. Our potential safety event rate (0.6% of total physical therapy sessions) was relatively low compared to safety event rates in 20 prior publications, which varied from 0% to 22% of total physical therapy sessions [7, 9-11, 13, 14, 16, 17, 22, 24-26, 28, 37, 42-44, 46-48]. With the exception of 4 studies [14, 37, 42, 46], event rates in these prior studies were <5%; higher event rates were attributable to much more sensitive measures (i.e., lower thresholds and/or more extensive definitions) of physiological abnormalities and potential safety events. The 34 occurrences identified in our study resulted in little or no additional therapy or cost, and no additional LOS, consistent with prior studies [9, 10, 12, 13, 16, 17, 21, 22, 24, 25, 27, 43, 44, 47, 48]. Event rates vary across prior studies likely due to differences in patient inclusion criteria, physical therapy treatment protocol, and types and definitions of physiological abnormalities and potential safety events evaluated. Notably, our study was a prospective evaluation of routine care, by 10 different physical therapists in a large academic MICU, rather than part of a research protocol which may be associated with lower safety event rates due to strict criteria for patient eligibility and starting/stopping of physical therapy interventions.

The majority of our potential safety events were cardiovascular-related physiological abnormalities (23 of 5267 physical therapy sessions, 0.4%), comparable to other studies reporting cardiovascular issues in 0.2% - 1.9% of physical therapy sessions [11, 28]. Our most frequent cardiovascular event was arrhythmia which was rare (10 of 5267 physical therapy sessions, 0.2%), similar to 10 prior studies monitoring cardiac rhythm or heart rate that reported a 0% event rate [9-11, 13, 14, 16, 17, 24, 44, 47] of 13 [9-11, 13, 14, 16, 17, 24, 37, 42, 44, 46, 47]. Event rates were highest with sitting activities, with most (89%) of these events being cardiovascular-related physiological abnormalities, similar to one prior study [42]. This finding is not unexpected since sitting is the first mobility activity, within the ordinal scale used in this study, that requires a change in position from supine; therefore, creating the potential for cardiovascular changes and potentially limiting further advancement of activity level during that physical therapy session. Similar to prior studies [7, 9-17, 21, 22, 24-27, 37, 42-49], with >3506 patients receiving >4075 physical therapy sessions, no cardiorespiratory arrest occurred during any of the 5267 physical therapy sessions in our study.

Tube and catheter removal were rare (i.e., 0.06% and 0.02%, respectively) in our study, similar to prior studies evaluating these events (0.0% - 1.2% [7, 9, 10, 13, 26, 37, 47, 48] and 0.0% - 0.5% [7, 9, 10, 13, 22, 28, 37, 43, 44, 47], respectively). No airway device was removed in our study, consistent with prior literature reporting only 1 endotracheal tube removal [26] among 8 publications [7, 9, 13, 26, 27, 37, 47, 48] that monitored and reported on this event, representing 2491 patients receiving physical therapy in the ICU.

In our study, MICU patient admissions with potential safety events had a longer MICU and hospital LOS than those without potential safety events. As per our detailed chart review, this longer LOS was not associated with the physiological abnormalities and potential safety

events identified. This finding is more likely because those patients with a longer MICU LOS have a greater opportunity to receive more physical therapy sessions, and thus, be at higher risk for an event. Moreover, such patients may also have a greater severity of illness and medical instability that may give rise to more frequent physiological abnormalities during physical therapy interventions.

This study has potential limitations. First, there may be unrecognized potential safety events or incomplete reporting leading to an understatement of event rates. However, potential events were prospectively recorded, on a daily basis, with a full-time Program Coordinator available at all times for consultation on event reporting, and weekly multidisciplinary in-person meetings (and monthly summaries and review of all event reporting) to clarify any questions and prevent missing or inaccurate safety reports. Therefore, we believe that reasonable means were used to help ensure that all physiological abnormalities and potential safety events were recognized and reported. Second, the generalizability of the results may be limited because the study was conducted in a single hospital MICU and only reports on interventions performed by physical therapists, rather than other types of clinicians. However, the documented rehabilitation sessions were performed by 10 different physical therapists as part of routine care which is an important addition to the existing literature. Third, because the data reported in this study come from a MICU registry that captures all admissions, detailed descriptive data, such as specific diagnosis, severity of illness score, and daily mechanical ventilation and vasopressor status, are not available for each admission. Moreover, detailed data regarding the potential safety events are not available, such as the type of arrhythmias reported. Such detailed data were not feasible for collection given that all admissions, from a large MICU, were included in the registry.

5. Conclusions

Based on prior publications and our 2.5 year prospective evaluation of more than 5200 physical therapy sessions for more than 1100 consecutive MICU patient admissions, physical therapy intervention in critically ill patients has a strong safety profile, in addition to the established benefits of improving patients' physical outcomes. Continued prospective safety monitoring of physical therapy in critically ill patients will be important to expand the generalizability of these findings to other types of patients, ICUs and hospital sites.

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Table 1. Characteristics of MICU admissions receiving physical therapy, by event status[a]

Characteristics	All MICU admissions receiving PT (N=1110)	Admissions with physiological abnormalities or potential safety events (n=25)[b]	Admissions without physiological abnormalities or potential safety events (n=1085)	P-value[c]
Baseline data				
Age, median (IQR)	57 (45-68)	59 (49-66)	57 (45-68)	0.623
Male, n (%)	553 (50)	13 (52)	540 (50)	0.825
BMI[d], median (IQR) kg/m^2	27 (22-33)	29 (22-34)	27 (22-33)	0.344
Ambulatory prior to admission[d], n (%)	961 (87)	21 (88)	940 (87)	0.965
Hospitalization data				
ICU Admission Source[d], n (%)				0.010
Hospital ward	406 (37)	8 (32)	398 (37)	
Emergency department	380 (34)	6 (24)	374 (35)	
Outside hospital	260 (24)	6 (24)	254 (24)	
Other ICU within hospital	59 (5)	5 (20)	54 (5)	
ICU Admission Diagnosis, n (%)				0.355
Respiratory failure	476 (43)	15 (60)	461 (42)	
Sepsis (non-pulmonary)	162 (15)	4 (16)	158 (15)	
Gastrointestinal	154 (14)	2 (8)	152 (14)	
Cardiovascular	89 (8)	2 (8)	87 (8)	
Other	229 (21)	2 (8)	227 (21)	
Ever received ventilation[d], n (%)	669 (60)	18 (72)	651 (60)	0.232
ICU LOS, median (IQR)	6 (3-11)	17 (9-36)	5 (3-10)	<0.001
Hospital LOS, median (IQR)	14 (8-26)	31 (21-48)	14 (8-25)	<0.001

BMI, body mass index; ICU, intensive care unit; IQR, interquartile range; MICU, medical intensive care unit; N, number of all admissions; PT, physical therapy; LOS, length of stay

[a] Proportions in Table may not add to 100% due to rounding.
[b] The 34 physiological abnormalities or potential safety events reported in this study occurred in 25 unique MICU patient admissions.
[c] Calculated using Chi-square or Wilcoxon rank-sum, test, as appropriate.
[d] Missing data for all admissions: 198 for BMI, 8 for ambulatory status prior to admission, 5 for ICU admission source, and 3 for ever received ventilation.

Table 2. Medical devices *in situ* during 34 physical therapy sessions with physiological abnormalities or potential safety events

Medical devices at time of event	Number (%) of occurrences (n=34)
Artificial airway	
Oral endotracheal tube[a]	18 (53)
Tracheostomy tube[b]	2 (6)
Catheter, any	33 (97)
Urinary catheter	29 (85)
Central venous catheter	23 (68)
Peripheral intravenous catheter	23 (68)
Arterial catheter	6 (18)
Dialysis/pheresis catheter	0 (0)
Tubes, any	25(74)
Feeding tube	23 (68)
Rectal tube	5 (15)
Chest tube	3 (9)
Abdominal drainage tube	3 (9)

[a] All endotracheally intubated patients were mechanically ventilated.
[b] Both tracheostomized patients received oxygen via a mask, rather than a mechanical ventilator.

Table 3. Physiological abnormalities or potential safety events, by highest daily level of activity with physical therapy treatment

Highest daily level of activity with PT treatment	Number (%) of all PT treatment days (n=4580)[a]	Number (%) of physiological abnormalities or potential safety events (n=34)	Event rate per 1000 PT treatment days
In-bed exercise	941 (21)	1 (3)	1.1
In-bed cycling	628 (14)	1 (3)	1.6
Sitting[b]	885 (19)	18 (53)	20.3[c]
Transfer from bed to chair	467 (10)	5 (15)	10.7
Standing	569 (12)	5 (15)	8.8
Walking[d]	1090 (24)	4 (11)	3.7

PT, physical therapy

[a] A total of 5267 PT treatment sessions occurred on 4580 ICU days, with level of activity being recorded as the highest level for each ICU day with PT treatment.
[b] Patients sat at the edge of bed in 97% of all sitting activities, while 3% were sitting in bed.
[c] Rate of physiological abnormalities or potential safety events per 1000 PT treatment days was 20.3 (2.0%) with sitting versus 4.3 (0.4%) with all other activities ($p<0.001$).
[d] Walking tasks required patients to take steps away from the bed or chair, rather than marching in place or take steps solely for the purpose of transfer from bed to chair.

Table 4. Types and rates of physiological abnormalities or potential safety events (n=34)

Type of physiological abnormality or potential safety event	Number (%) of events[a] (n=34)	Event rate per 1000 PT treatment sessions[b]
Arrhythmia	10 (29)	1.9
Mean arterial pressure >140 mmHg	8 (24)	1.5
Mean arterial pressure <55 mmHg	5 (15)	0.9
Oxygen saturation <85% for >3 minutes	4 (12)	0.8
Fall	3 (9)	0.6
Removal of feeding tube	2 (6)	0.4
Removal of chest tube	1 (3)	0.2
Removal of arterial catheter	1 (3)	0.2
Removal of central venous catheter	0 (0)	0.0
Removal of dialysis/pheresis catheter	0 (0)	0.0
Removal of artificial airway[c]	0 (0)	0.0
Cardiorespiratory arrest	0 (0)	0.0

PT, physical therapy

[a] Proportions may not add to 100% due to rounding.
[b] Across all 1110 patient admissions included in the study, there were a total of 5267 PT treatment sessions.
[c] Defined as endotracheal or tracheostomy tube.