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Reducing Accidental Dislodgement of the Percutaneous Endoscopic Gastrostomy: A Prospective Trial of the “SafetyBreak” Device

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Abstract

Background—The percutaneous endoscopic gastrostomy (PEG) is a ubiquitous feeding tube with high rates of accidental dislodgement, with significant morbidity and health care costs. We hypothesized use of a decoupling device is a safe and effective mechanism to reduce dislodgements.

Study Design—We studied a prospective cohort of 100 patients from an academic center. Enrollment included patients requiring PEG tube placement with follow up extending through an individual’s lifetime use of their PEG tube. The primary endpoint was accidental dislodgement of the principally placed PEG tube. The secondary endpoint was time to accidental dislodgement of the PEG tube.

Results—All 100 patients received the SafetyBreak device and had complete follow-up. Half of the patients had at least a single episode of device decoupling, indicating prevention of dislodgement of the PEG. Eight patients ultimately had dislodgement, resulting in a significantly lower dislodgement rate when compared with a historical cohort ($P = .036$) and significantly

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Declaration of Conflicting Interests

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longer survival of the PEG (log rank = 0.005). When compared with a concurrent cohort (without the device) there was also significantly lower dislodgement rate ($P = .03$) and a trend toward longer survival of the PEG (log rank = 0.08).

Conclusions—When compared with both a historical and concurrent cohort of patients, the SafetyBreak device reduces accidental dislodgement of PEG tubes. As an increasing number of PEGs are being placed, an increasing number of patients are at risk for dislodgement. The SafetyBreak device is an innovative, economical solution to the problem of accidental dislodgement of the PEG tube.

Keywords

biomedical engineering; flexible endoscopy; gastric surgery; interventional endoscopy

Introduction

The percutaneous endoscopic gastrostomy, or the PEG, as it is now most commonly known, was first introduced in 1980 by Gauderer et al¹ for children who could not swallow as an alternative to open gastrostomy to provide long-term enteral access. This procedure described the technique of approximating the stomach with the abdominal wall without the need of a laparotomy.^{1,2} Placement of a PEG is now the second most common indication for upper endoscopy and has been shown to be an efficient method of gastrostomy placement with fewer complications than surgical gastrostomy.³ In 2001, greater than 215 000 PEGs were being placed annually and as the population continues to age, this number has continued to rise.⁴

The standard PEG tube provides direct access to the stomach and provides enteral nutrition via the long, flexible feeding tube with a soft internal bumper. Conveniently, the soft inner bumper of the PEG collapses and slides out through the tube tract, allowing the PEG to be removed with relatively minimal external traction. This feature allows easy, intentional removal in an outpatient, clinic setting without the need for an operation or sedation when the patient has recovered from their initial insult.

Consequently, because of this flexible inner bumper, a major complication is “premature removal” or accidental dislodgement, from which significant morbidity and mortality may occur.⁵ A number of adverse events may occur with premature removal as the gastrocutaneous fistula tract has not fully matured, which allows the stomach to separate from the anterior abdominal wall, and the open gastrostomy to leak gastric contents. Some of these reported complications include bacterial and fungal peritonitis requiring laparotomy, abdominal wall necrotizing fasciitis, and hemoperitoneum following gastrostomy tube reinsertion.^{6–9} Accidental dislodgement rates are well published and have been reported between 1% and 13.4% for early dislodgement and 12.8% when followed longitudinally for the lifetime of the originally placed PEG.^{12–20}

While early dislodgements can be clinically devastating, late dislodgements after gastrocutaneous fistula maturation are less detrimental, yet may still require expensive emergency department visits, surgical consultations, replacement tubes, and radiographic

confirmation of position.²⁰ To alleviate this clinical and financial burden we embarked on developing a solution to what has become the “Achilles heel” of the PEG tube; accidental dislodgement.

Objective

In light of the high rate of accidental dislodgements at our institution, we developed a novel decoupling device coined the “SafetyBreak,” to prevent collapsing of the internal bumper and dislodgement of the PEG with unintentional external traction of the tube. We hypothesized use of the SafetyBreak device, in continuity with the PEG tubing, would reduce the rate of accidental dislodgement by 75%.

Materials and Methods

This study was approved by the Institutional Review Board for Health Sciences Research (IRB-HSR) at the University of Virginia (UVA IRB-HSR # 15618). While not commercially available at this time, the SafetyBreak device is patent pending (US Patent Application Serial No. 14/365,272) and we anticipate it becoming commercially available in the future. The device was determined to be of nonsignificant risk and Investigational Device Exemption approval from the US Food and Drug Administration was not required. All subjects provided consent or surrogate consent was obtained prior to enrollment and participation. This study was also followed by a Data Safety Monitoring Officer who had open access to our data, was provided an interim safety report halfway through expected enrollment, and had the authority to modify or suspend the study at any time.

Study Design

This study was designed as a single institution pilot study where the total number of PEG tubes placed (and devices available) would be able to provide evidence in support of or against our primary hypothesis and provide proof of principle. The primary objective of the study was to determine whether there was a significant reduction in the rate of accidental dislodgements with use of the SafetyBreak device compared with a well-defined, published, historical cohort.²⁰ The primary endpoint was a binary measure (yes/no) of accidental dislodgement of the principally placed PEG tube. The secondary endpoint was time to accidental dislodgement of the PEG tube. This study was designed as a prospective longitudinal cohort for comparison against the historical cohort.²⁰ Based on the current estimate of accidental dislodgement at our institution (12.8% as published), we were 95% confident that the actual accidental dislodgement rate in this population is between approximately 10% and 15.5%. Using the lower bound of 10%, in order to detect a 60% reduction (to 4%) in accidental dislodgements, at the 10% significance level and 90% power, we would need to enroll approximately 104 patients. Detection of larger reduction percentages (75% as hypothesized) would require fewer patients and thus a sample size of 100 patients was deemed adequate.

Patients

All participants were adult patients admitted to our institution in whom a surgical endoscopy consultation for PEG tube placement was initiated. Patients were consented and enrolled

prior to PEG placement, be receiving their first PEG, and have an anticipated local discharge from the hospital. Patients were excluded if they previously had a PEG placed or residence was too distant to allow follow-up at the University of Virginia Medical Center.

Variables recorded for each patient included age, sex, race, height, weight, body mass index, admitting diagnosis, admitting service, restraint status, capacity to consent, comorbidities, trauma status, postoperative status, and the primary indication for PEG placement. We recorded the location of PEG placement (intensive care unit, endoscopy suite, operating room, “other”), thickness of the patient’s abdominal wall, decoupling force of the device (as tested prior to placement), total hospital duration of stay, discharge type (rehabilitation facility, skilled nursing facility, home, or another acute care hospital), and ultimate outcome of the original PEG (accidental dislodgement, intentional discontinuation, gastrostomy replacement/exchange, or death). Each participant was followed from the time of enrollment (day of PEG and device placement) through accidental dislodgement, intentional removal or replacement of the PEG, or patient death (whichever occurred first).

Patients enrolled into the study were examined by research personnel daily for the first week following placement of their PEG and SafetyBreak device. For the remainder of the hospital stay, patients were assessed daily by nursing staff and primary clinical team with communication of any adverse events or unanticipated problems to the research team. A bedside data collection sheet was used to record events of SafetyBreak disconnections, reason for disconnection (ie, rolling patient, working with physical therapy, patient pulled on tubing, etc), and any complication of the disconnection (ie, tube feed spillage, bed saturation, etc). Following inpatient discharge individuals were tracked by the electronic medical record for emergency department visits, readmissions, clinic visits, and mortality. Finally, patients, families, or transfer facilities were contacted every 2 to 4 weeks to determine the status of the PEG and SafetyBreak device, and to identify any additional episodes of disconnections, any need for removal or replacement, and any feedback or comments about the device.

Nonenrolled Cohort

During the open enrollment period for the SafetyBreak trial, we also identified a cohort of patients who received a PEG tube by our faculty surgeons but did not enroll in the trial, despite meeting inclusion criteria. These patients were identified by our Clinical Data Repository using the CPT code 43246 (upper gastrointestinal endoscopy, including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with directed placement of percutaneous gastrostomy tube). The majority of these patients received their PEG during a time in which we were open to enrollment but were awaiting additional devices from the manufacturer, precluding inclusion into the trial due to a lack of available devices. We retrospectively analyzed this group of patients, during the concurrent time period, for accidental dislodgement as a comparative cohort during the same time period to adjust for the limitations associated with a solely historical cohort.

Procedures

All PEG procedures, and the SafetyBreak device placements, were performed by a UVA faculty surgeon in conjunction with the surgical endoscopy service to ensure reliability and consistency of insertion technique. Commercially available, 24-Fr PEG tube insertion kits were used and subsequently a single SafetyBreak device was placed in continuity with the PEG tubing. All SafetyBreak devices were placed on the same day as the PEG placement.

The SafetyBreak 2-piece decoupling device was placed in continuity within the PEG tubing. The male and female coupling mechanism permits the united pieces to provide continuity of the internal conduit, allowing tube feeds to pass directly through the device (Figure 1). Following standard PEG placement, the SafetyBreak device was placed in close proximity to the patient's abdominal wall. The PEG tubing was cut transversely approximately 2 cm above the top of the external bumper to allow insertion of the device (Figure 1). All SafetyBreak devices were individually tested prior to use by using a force gauge for a mean and range decoupling force.

Statistical Analysis

Demographics and comorbidities were tabulated and reported for the prospective cohort. Statistical analyses were performed using R v3.0.1 statistical programming language (R Development Core 2008). The proportion of patients who experienced accidental dislodgement of the PEG tube was tabulated. Differences in dislodgement rates between the prospective cohort and the historical cohort were assessed using Fisher's exact test at the 5% level of significance. Survival of the PEG tube in place (in days) was defined as the duration of time the original PEG tube was in place, with an "event" being defined as accidental dislodgement, while patients were "censored" when they no longer contributed days of their original PEG in place (eg, death, intentional PEG removal, tube exchange). The Kaplan-Meier method was used to estimate survival curves for the current prospective cohort with the SafetyBreak device and the historical cohort without the device. Differences in survival between the 2 cohorts were assessed using a log-rank test at the 5% level of significance. Similar analyses as described above were also used to compare the nonenrolled, concurrent cohort of patients to the SafetyBreak study cohort.

Results

Patients

From March 25, 2012 through December 1, 2012 we approached a total of 107 patients identified as eligible for enrollment. Six patients declined participation into the trial primarily due to a lack of perceived need for the safety decoupling device, all of whom were able to provide consent for themselves. In contradistinction, all medical decision makers approached for surrogate consent granted consent. One patient was enrolled but died prior to PEG placement, and, therefore never received the investigational device. A total of 100 patients enrolled in the prospective cohort, all of whom had successful placement of their PEG tube and the SafetyBreak device. There were no device-related complications during initial placement or subsequently throughout the trial. All 100 patients completed the trial without any patient lost to follow-up or discontinuation of participation.

Patients' demographics, comorbidities, and outcomes for the study cohort are shown in Table 1. Our study population consisted of primarily older adults with the vast majority being on the trauma, neurology, and neurosurgical services. Most patients had either dysphagia or had prolonged mechanical ventilation as their indication for PEG placement, predominantly required surrogate consent and were ultimately discharged to a rehabilitation or nursing facility.

Percutaneous Endoscopic Gastrostomy Outcomes

All 100 patients completed the trial. Two patients were excluded from the analysis due to taping over the device, defunctionalizing the decoupling mechanism and thus allowing dislodgement. Both of these patients presented to our institution's emergency department with their PEG tube in a plastic bag with the SafetyBreak device in place and taped together, confirming non-functionality. Both of these taped devices had prior episodes of decoupling, indicating prior function. Of the 98 patients with functioning devices included in the analysis, 6 patients had accidental PEG dislodgement, 60 in intentional removal of the PEG due to improvement in swallowing function, 7 with exchange of their original PEG for a replacement balloon gastrostomy tube (primarily due to PEG deterioration), and 25 died with the device in place (due to their primary disease process with none related to the PEG or experimental device).

In the historical control cohort of 563 patients, 72 patients experienced accidental dislodgement. Fisher's exact test revealed a significant reduction in the accidental dislodgement rate in the prospective SafetyBreak cohort compared with the historical cohort (6.1% vs 12.8%, $P = .036$). Kaplan-Meier estimates of survival, defined by time-to-accidental PEG dislodgement, clearly showed a longer survival in the SafetyBreak device cohort compared with the historical cohort (Figure 2). The log-rank test revealed a significant difference in survival between the 2 cohorts ($P = .005$).

Furthermore, we identified 139 patients during the period of enrollment who received a PEG tube by our surgical endoscopy service but were not enrolled into our clinical trial for reasons stated above. Of these, 20 had accidental dislodgement of their original PEG tube resulting in a rate of 14.4%. As expected, there is not a significant difference in the accidental dislodgement rates between the historical cohort and the nonenrolled cohort without the device (12.8% vs 14.4%, $P = .67$) based on Fisher's exact test. This test also revealed that the rate in the prospective SafetyBreak device cohort is significantly lower than the rate in the nonenrolled cohort without the device (6.1% vs 14.4%, $P = .03$). Kaplan-Meier estimates of survival again demonstrated a longer survival in the SafetyBreak device cohort compared with the nonenrolled, nondevice, concurrent cohort.

Device Decoupling

A total of 51 patients had at least a single episode of device decoupling (disconnection). Rates of device disconnection ranged from a single episode (20 patients) to 12 separate events of recorded disconnection in a single patient. In this series there were also 6 patients who required 12-Fr jejunal tube extensions for distal enteral nutrition and this was successfully placed through the SafetyBreak device itself. Two of these patients with jejunal

tubes in place had functional decoupling of their device, successfully preventing PEG and jejunal tube dislodgement. In total, 9 patients had an exchange of their SafetyBreak device without exchange of their original PEG tube. Each patient or provider requested an exchange due to a perceived need based on too frequent decoupling of the device.

Discussion

Percutaneous endoscopic gastrostomy has become ubiquitous for enteral feeding among all medical specialties. It is the preferred method for gastrostomy placement in many patient populations, including trauma, and greater than 250 000 are placed annually in the United States, with similar numbers in other developed countries, including Japan, Germany, and the United Kingdom.^{4,21} If the approximate annual rate of accidental dislodgement is 10%, lower than our institution's rate, this complication affects about 25 000 patients per year. Using a conservative estimate of \$3000 in additional hospital costs, this complication results in a \$75 million annual problem in the United States. This fiscal assessment does not begin to account for the clinical catastrophes or family frustrations associated with early dislodgement and recurrent inadvertent removal of these tubes.

The SafetyBreak device decreased the rate of tube loss in our treatment cohort compared to both historic controls and patients who received PEG tubes during the study period but without the device. While the decreased accidental dislodgement during this pilot study was not quite the 75% reduction as predicted, our results are still fairly dramatic in patient and end-user satisfaction with clear proof of concept. We believe there are a few factors that contributed to a less than predicted rate of dislodgement. First, our device study population may have been at higher risk for dislodgement when compared with the average population receiving PEG tubes, as indicated by the high rate of surrogate consent and need for restraints at the time of PEG placement. As described above, a number of self-consenting patients declined participation due to a perceived lack of need for the device, and one of these patients suffered accidental dislodgement of their PEG tube, highlighting the potential benefit of the device even in neurologically intact individuals.

Second, there is a learning curve with any new device for both patients and providers. For this device we believe a number of tubes likely dislodged due to their decoupling mechanism being taped together. Presumably, devices that would separate too easily were taped together by family, nursing staff, or other care providers because of too frequent disconnections. With the device taped, a force placed on the tube understandably allowed accidental dislodgement rather than device decoupling. Devices that were not completely dry prior to recoupling would potentially have moisture in the coupling mechanism, allowing the device to decouple at a much lower force; a hypothesis why devices may have been taped together. We believe with better education and mainstream use of the device, this alteration by taping would cease and patients would instead be referred for device exchange. With these 2 factors, we believe the actual performance of the SafetyBreak device is better than shown in this small cohort study.

We found a significant percent (51%) of patients had at least a single episode of device decoupling. This indicates that for roughly half of our patients, there was some force placed

along the length of the PEG tube resulting in the device separating. Bimonthly phone calls were quite enlightening with descriptions of how tubes got wrapped in belts and bedrails, “hands getting busy,” and confused elderly patients who seemingly just want to pull them out. Each event of decoupling had a clear force placed along the length of the PEG tubing with a resulting separation of the SafetyBreak device, and an easy reconnection for the patient or family. There were no episodes of tube loss into the gastric lumen after decoupling, as the external bumper has significant friction on the PEG tube prohibiting its internal migration.

Other methods to protect accidental tube loss include the use of endoscopically placed gastrointestinal anchors that function by maintaining gastric apposition to the anterior abdominal wall prior to a mature gastrocutaneous fistula, frequently used in patients at high risk for inadvertently removing their PEG tubes. Although these anchors do aid in successful intubation of the gastrostomy with a replacement tube once a PEG is dislodged, they do not decrease the likelihood of accidental removal by themselves. None of the patients in our trial had anchors placed at the time of PEG, and all patients with the device who had inadvertent PEG removal were able to have a balloon replacement tube successfully placed at the bedside in to the stomach, indicating the device had functioned long enough for a mature tract to form.

Other current methods of prevention consistently include less than desirable restraint of the patient, either with soft hand mitts, wrist restraints, abdominal binders, or pharmacological sedation. None of these interventions are ideal, and although the SafetyBreak device does not completely eliminate the need for these since a patient can still pull the PEG proximal to the device, a significant reduction in restraint use may be possible with device insertion.

From a practical standpoint, the device is also a better solution than suturing the PEG in place. Should a significant force be placed on a PEG that is stitched into the abdominal wall like a drain, it would possibly pull the stitch through the skin and is not supported by the authors. Other clinical rejections to suturing PEGs is that the tube should be rotated or spun daily to aid in tract maturation and that they remain in place far longer than standard drains or other tubes.

Our study solidly confirms the feasibility and initial safety profile of this entirely novel device with no adverse events discovered. While we did not randomize our study due to cost and time, we did compare with both a robust recent historical cohort of patients and a concurrent cohort during the same trial period, eliminating changes in practice as responsible for the reduction in dislodgement. The data presented further suggest that sufficient efficacy has been demonstrated to allow the consistent use of this device, particularly in patients felt to be at especially high risk of accidental tube dislodgement. The authors acknowledge that the benefit of this device may be limited to those tubes designed to be removed by external traction, and not those that have a rigid internal bumper or a balloon gastrostomy.

Conclusion

When compared with both a historical cohort and a concurrent cohort of patients, the SafetyBreak device reduces accidental dislodgement of the PEG tube. As the population continues to age, an increasing number of PEGs are being placed, which comes with an increasing number of patients at risk for dislodgement, especially in the nursing and rehabilitation facilities. As health care dollars become tighter, we must continue to refine current methods of practice and improve quality without significantly increasing cost. The SafetyBreak device is an innovative, economical solution to the problem of accidental dislodgement of the PEG tube.

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Figure 1. Male and female pieces of the SafetyBreak device in the coupled (A) and decoupled (B) positions.

Figure 2.
Kaplan-Meier survival analysis comparing current prospective cohort and historical cohort.

Table 1

Demographics and Outcomes of the Prospective SafetyBreak Device Cohort.

Demographics and Outcomes ^a	All Patients
Age, years	62.5 ± 1.8, 64
Sex, Male	56 (56)
Race	
Caucasian	84 (84)
African American	14 (14)
Hispanic	0 (0)
Other	2 (2)
BMI, kg/m ²	27.8 ± 0.7, 27
Admitting service	
Neurology	22 (22)
Neurosurgery	20 (20)
Trauma	18 (18)
Other medical specialties	16 (16)
Other surgical specialties	14 (14)
Oncology	10 (10)
Indication for PEG placement	
Dysphagia	54 (54)
Ventilator dependence	31 (31)
Malnutrition	11 (11)
Gastric decompression	4 (4)
Surgery within 30 days prior to PEG	45 (45)
Admission following trauma	21 (21)
Surrogate consent needed	63 (63)
Restraints in place at time of PEG	33 (33)
Location of PEG Placement	
Intensive care unit	42 (42)
Endoscopy suite	48 (48)
Operating room	10 (10)
Jejun extension tube placement	6 (6)
Duration of stay, days	20.3 ± 1.7, 18
Discharge type	
Rehabilitation facility	41 (41)
Home	19 (19)
Hospital transfer	17 (17)
Skilled nursing facility	15 (15)
Inpatient death	7 (7)
Prison	1 (1)
SafetyBreak device decoupling	51 (51)
Accidental dislodgement (n = 98)	6 (6)

Demographics and Outcomes ^a	All Patients
Mortality, 30-day, all-cause	10 (10)

Abbreviations: BMI, body mass index; PEG, percutaneous endoscopic gastrostomy.

^aContinuous data are displayed as mean $\pm$ standard error of the mean, median. Categorical data are displayed as: the number, (percentage of the total).