Please note: These studies may involve findings that exceed the claims currently cleared by the FDA for the product. Bravida Medical is not intending to make performance claims about its product. The intent is to disseminate the scientific literature on these products. We encourage you to read these studies to understand the strengths and limitations of the data. For some claims, Bravida is seeking to broaden the indications with the FDA in the future using data, such as these studies, to provide the substantiation.

PEG TUBE DISLODGEMENT: REDUCING HARM THROUGH INNOVATIVE PRODUCT AND PROCESS CHANGE

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BACKGROUND

- An unusual number of PEG tube dislodgements were recognized by an educator and clinical staff of the Intermediate Neuro Unit and Neuro Intensive Care Unit which resulted in peritonitis and additional surgery
- A task force was created to evaluate these occurrences and understand both current policy and clinical practice related to PEG tube management
- Percutaneous endoscopic gastronomy (PEG) tubes are the most common method for delivering long-term enteral nutrition
- Up to 5% of PEG tube have reportedly been dislodged prior to the maturation of the gastrocutaneous tract
- Dislodgement is associated with high risk of increased morbidity, mortality, hospital length of stay and cost of care

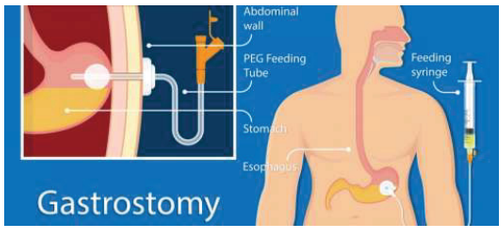

Figure 1: Depiction of gastrostomy anatomy (Maryland Bariatrics, 2019).

PURPOSE

The task force determined that an evidence-based solution was necessary to reduce risk of dislodgement for patients with PEG tubes. A new nurse-driven guideline was designed to improve PEG tube assessment and securement.

Inconsistencies identified:

- Variation in clinician knowledge:
  - Assessment (including tube length)
  - Care and maintenance
  - Securement of PEG tube
- Variation in expectations between physician, nurse and management regarding care and maintenance
- Variation in practice (Figure 2):
  - lack of or various securement tactics
  - placement of excess tubing (pulled through gown)
  - inconsistent assessments
  - differing site care and dressing practices (various cleaning solutions and various number of drain sponges)

Figure 2: Image of incorrect securement method used prior to intervention.

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METHOD

A multidisciplinary task force was created, including nursing, endoscopy, medical staff, quality/safety, hospital leadership and nursing education. The task force met to conduct chart reviews of the four most recent dislodgements to identify causes and potential opportunities to improve practice. Additionally, this task force reviewed the most current evidence for care and securement practices.

A simple guideline was developed:

- Standardized assessment of insertion site and tube position
- Use of colored tape to mark the external bumper position that would clearly stand out from other tape used for patient care (to assist with tube length)
- Standardized cleaning and dressing practices (soap and water with one drain sponge)
- Introduction of a skin friendly universal hydrocolloid-based tube securement device
- Development of audit tool to ensure standardized approach

Tools and products added to supply room:

- Colored tape (added to endoscopy carts)
- Securement devices
- Dressing maintenance supplies (drain sponge, cleaning solution)

A multimodal education strategy was implemented using presentations, staff huddles, visual aids, vendor rounds and just in time teaching of product usage. Supply availability was prioritized for necessary tools and products so that this was not a barrier to protocol adherence.

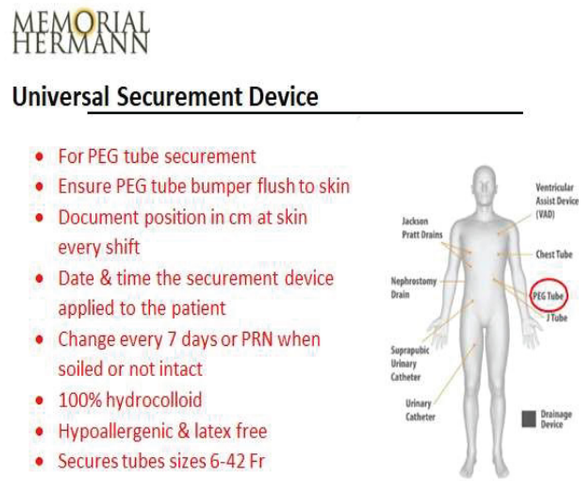

Figure 3: New Universal Securement device included in protocol and added to unit stocking (upper left); correct securement method with blue tape, securement device and single drain sponge (lower right).

RESULTS

Inpatient reports of PEG tube placements were retrieved for twelve months pre and post protocol implementation. Patient charts were manually reviewed for both original insertion documentation and any subsequent reports of additional PEG placements, fistula repairs, and abdominal wall repairs. The dislodgement rate pre-implementation was 6.6% and reduced to 4.4% post. While not statistically significant, there was a 32% decrease in dislodgement rate which is clinically relevant. Lack of statistical significance may be related to small sample size; more data collection is necessary to fully understand the impact of this practice change.

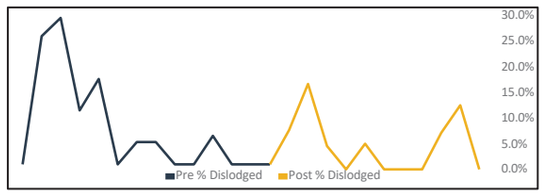

Figure 4: Dislodgement rate by month.

PRACTICE IMPLICATIONS

- Standardization of PEG dressing, site care, position marking, and the use of a skin friendly, effective securement device can reduce dislodgement
- Use standardized PEG tube assessment, dressing, site care and securement device for evidence-based harm reduction
- May be used for other lines and tubes such as chest tubes, jejunostomy tubes and left ventricular assist devices to reduce harm from dislodgement
- Clinical staff reports securement device is easy to use and feel confident PEG tube is more secure

LESSONS LEARNED

- Develop the business case to make a practice and product change
- Ensure that all pertinent stakeholders are involved
- Seek senior and local leadership support
- Have sufficient par levels to support the practice change at the unit level
- Ensure the location of supplies make sense to the flow of the clinicians' practice

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