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Reducing Enteral Feeding Related Aspiration Risk During the Provision of Nursing Care

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Reducing Enteral Feeding Related Aspiration Risk During the Provision of Nursing Care

Proper nutritional support of hospitalized patients has often proven a challenge for clinicians. Critically ill patients are even more challenging in that they require additional calories, special diets, and atypical feeding routes. In order to preserve or return to normal gastrointestinal function, enteral feedings are preferred to parenteral methods of providing nutritional support in this population. Enteral methods of feeding include various types of liquid diets instilled through tubes placed in the stomach or small bowel. If we are to meet the patients' caloric needs, frequent prolonged interruptions of enteral feeding should be avoided.

There are several barriers to providing consistent nutrition using an enteral feeding device. These include variations in practice patterns among clinicians, lack of conclusiveness of existing research findings, and the difficulty in reliably detecting complications. One of the more common and devastating complications of enteral feedings is aspiration, or the inhalation of gastric and contaminated oral secretions into the lungs. Nosocomial pneumonia, a result of aspirating contaminated oral and/or orogastric secretions, is the most common type of nosocomial infection, and is estimated to significantly extend the length of stay (by as much as 16 days) and increase the cost of care by \$30,000 to \$40,000 per case (Metheny, Chang, et al., 2002, p. 150; Rello et al., 2002, p. 2118). The human suffering that is associated with necessarily prolonged ventilator support is excessive.

Existing research into the prevention of aspiration has focused on proper feeding tube placement, tolerance of the feedings by measuring gastric residual volumes, and the early detection of aspiration episodes. Positioning of the patient with the head of the bed

at 30 – 45 degrees is often prescribed to decrease the risk of aspiration, however, patient-types commonly receiving enteral feedings are frequently placed supine for turning, transport, and diagnostic testing. No clear guidance exists as to the proper procedure for clinicians to follow when conducting this routine nursing care. The observed practice of turning off the enteral feeding just prior to placing the patient supine defies logic, as the rate of continuous feeding rarely exceeds 80 cc's an hour (1.3 cc's per minute that the patient is supine). This intervention would not take into account the existing gastric volume of food, which represents the real threat for aspiration.

The purpose of this study is to determine the effectiveness of a method of preventing aspiration of tube feeding during episodic supine periods while meeting the patients' nutritional requirements. Existing best practices will be followed with regards to verifying enteral tube placement and detecting episodes of aspiration, however it is noted that "Many of the nursing guidelines to facilitate the care of patients with enteral tubes have not been based on current research, but on ritual and opinion" (Williams & Leslie, 2004, p. 330).

Review of the Literature

A literature search was conducted using the terms gastric, enteral, aspiration, pneumonia, and tube feeding including PUBMED via Ovid, CINHALL via Ovid, and Google Scholar, a metasearch engine for scholarly material. Documents included are no more than 10 years old and in the English language. In addition to research studies, I included practice reviews and consensus statements as they give a clear picture of the current state of nursing clinical practice behaviors, and frame the importance of this study

in improving the practical application of nursing care of the enterally fed critically ill patient.

In order to realize the benefits that could be realized through a reduction of rates of aspiration, we must first understand the gravity of the problem. Rello, et al., (2002) described the impact of aspiration pneumonia as causing significant increases in length of stay, cost, and number of ventilator days, but found no difference in mortality in their sample (p. 2118). In another study identifying aspiration pneumonia as the major type of nosocomial infection in critically ill patients, significant increases in morbidity and mortality were noted (Esparza, Boivin, Hartshorne, & Levy, 2001, p. 661). Though mortality rates of patients with ARDS have declined since the 1980's, Hudson & Steinberg (1999) describe a 30 – 40 % mortality rate in patients whose aspiration pneumonia progresses to ARDS (p. 80).

The occurrence of aspiration is a source of much debate in the literature, with rates described from 0.8 – 95% of critically ill patients. Much of this variation has been attributed to the lack of a standardized definition of aspiration. Recent studies indicate a rate of 9.3 – 10% (Esparza et al., 2001, p. 663; Rello et al., 2002, p. 2117) of critically ill patients have episodes of aspiration. Rello et al. determined this rate using a highly specific and selective method of tagging tube feedings with the isotope technetium such that daily lung scans would conclusively demonstrate the rate of aspiration amongst this vulnerable population.

Significant work has been done in the area of confirming placement of feeding tubes. While radiographs remain the gold standard (Cirgin Ellett, 2004, p. 253), other techniques are commonly described. These include the insufflation of air while

ascultating over the stomach (Metheny, Wehrle, Wiersema, & Clark, 1998), checking the pH of secretions (Ellett, 2004; Metheny et al., 1999, p. 253), checking for the presence of pepsin, trypsin, and/or bilirubin (Metheny et al., 2004; Metheny et al.) and visual confirmation using endoscope-guided placement (O'Keefe, Foody, & Gill, 2003).

In order to prevent overexposure to radiation, we must limit radiographic placement to initial confirmation and episodes when non-radiographic findings are inconclusive in the face of adverse symptoms. Traditionally, intubated patients receive a daily chest x-ray, and careful placement of the film would facilitate the confirmation of nasogastric tube location without additional exposure.

The commonly used technique of insufflation of air to listen for a gurgling sound has been proven to be unreliable and ineffective alone in determining gastric versus pulmonary placement (Williams & Leslie, 2005). Similarly, checking the gastric pH is problematic because common medications and enteral feedings are known to raise the gastric pH to levels that are indistinguishable from those of pulmonary secretions. Use of pH in the confirmation of new feeding tube placements is accepted if consideration is given to the fact that 70% of gastric secretions are a pH of 0 – 5, while most respiratory secretions are 7 or above (Metheny, Aud, & Ignatavicius, 1998; Williams & Leslie). Consequently, the lower the pH of secretions, the greater the likelihood the tube is in the stomach. Small-bore feeding tubes placed in the duodenum or jejunum cannot be reliably placed or evaluated this way due to the rise in pH once secretions enter the bowel. Conversely, suctioning of tracheal secretions to reveal aspiration is unreliable unless the gastric pH is low enough to contrast amongst the pulmonary secretions – a condition that is unlikely after the patient has received continuous tube feedings and medications.

Bedside testing for pepsin, trypsin, and bilirubin are not widely available at this time. Several studies have concluded that pepsin would be useful in bedside monitoring for tube placement and aspiration detection. This is due to the high selectivity and specificity of the test (Metheny et al., 2002; Ufberg et al., 2004, p. 151), though the lack of availability of a bedside method of testing requires the sample to be frozen and sent to an outside lab. Consequently, the results would not be available in a timely fashion such that confirmation of placement or treatment for aspiration could be initiated. In addition, Ufberg, et al. stated that pepsin activity decreases over time and therefore would likely limit the usefulness of the assay in detecting acute aspiration episodes. Bilirubin testing, when available, is useful in predicting the correct placement of a nasogastric tube in the small bowel when the visual bilirubin scale is used (Metheny, Smith, & Stewart, 2000).

The final, and most invasive method described in the literature (short of surgical placement) is placement of small bore feeding tubes using an endoscope (O'Keefe et al., 2003). They describe the benefits of endoscopic placement as the visual confirmation of proper placement, ability to visualize the upper GI tract to observe for undiagnosed pathology, and the decreased risk of trauma to the nasal and oral mucosa.

Blue food coloring (Cosmetic Blue No. 1) had been widely used for many years to color enteral feedings. It was believed that observing blue coloring in sputum conclusively indicated aspiration, though this method of detection is known to have poor specificity (McClave et al., 2005). Unfortunately, it has been associated with serious adverse events, including the death of several patients (Lucarelli, Shirk, Julian, & Crouser, 2004, p. 793). Its use has subsequently declined. Other types of dyes, such as methylene blue, have long been out of use for similar reasons. The frequent similarity of

gastric and pulmonary secretions made coloration of gastric fluids a particularly well embraced way of detecting aspiration, however the benefits do not outweigh the risks.

Though not useful for detecting gastric placement, the use of glucose test strips for the detection of aspiration is common. By measuring pulmonary secretions for the presence of glucose, one may suspect that gastric contents have entered the pulmonary space. The difficulty that exists with this technique relates to the impact bloody or blood-tinged secretions have on findings, possibly resulting in false positive readings when blood is present in the pulmonary tree.

Once inserted, placement of the enteral feeding tube should be confirmed on a regular basis using a combination of the available techniques and in conjunction with organizational policies. Placement confirmation is usually performed every 8 hours, but a more frequent assessment may be required for restless or combative patients to assure the tube has not been dislodged. Frequent assessment of residual volumes must occur during initiation of feedings, when the rate of feedings has increased, or when the patient has gastrointestinal pathology. Many institutions check residual volumes every four hours, and more frequently when indicated. The literature, however, does not support the validity of checking gastric volumes to determine aspiration risk (McClave et al., 2005, p. 329).

Positioning is widely described in the literature as being the primary way to decrease the incidence of aspiration. “For ventilated patients receiving enteral feeding, the supine position has been shown to be a risk factor for gastric aspiration and pneumonia compared with the semirecumbent position” (Scolapio, 2002, p. 58).

Drakulovic, et al., (1999) found in their study that the incidence of pneumonia in supine

patients is significantly higher than those cared for in a semirecumbent position. The rate of aspiration pneumonia in supine patients was 50%; consequently, the study was stopped.

Current nursing practice guidelines reflect the above literature findings in that they recommend a radiograph to confirm initial placement of an enteral feeding tube and frequent reassessment of placement using a combination of methods (insufflation, pH, bilirubin levels, and/or glucose levels). Pepsin assays look very promising in confirming placement and identifying acute episodes of aspiration, however the absence of a readily available bedside test makes this method unwieldy. Nurses must combine protective interventions such as positioning at a 30 – 45 degree angle (if not medically contraindicated), diligent monitoring of tube feeding placement, and assessment of risk factors for aspiration. Examples of risk factors include nausea, vomiting, frequent coughing, or loss of airway reflexes. Positioning during the provision of regular nursing care must be done with the consideration that it may make the patient vulnerable to aspiration.

Despite evidence supporting positioning interventions to prevent aspiration, no mention is made in the literature of the best practice to use when placing the patient supine for turning, transporting, or performing diagnostic procedures. Patients prone to aspiration would be at great risk during these evolutions, and strategies need to be developed to help guide the clinician when caring for their patients.

This study will inquire as to whether there is any benefit to aspirating gastric contents prior to placing a patient supine and then returning the contents when the patient is placed back in a semirecumbent position. This technique will be compared to the

incidence of aspiration observed using the traditional technique of turning off the feeding immediately prior to and during the supine episode and the restarting after the patient is no longer supine.

Funding for this study will be obtained through the NINR and/or the NIH who have supported this type of research in the past. Expected expenses include the cost of conducting the bedside pH testing, pepsin analysis, and the preparation and analysis of the instruments. A cellular phone will be purchased to provide a contact point in case of questions by those collecting the data.

Methods

Design

Hypothesis 1: Patients who have their gastric contents withdrawn prior to being placed supine have a lower incidence of aspiration pneumonia than those who retain their gastric contents while supine.

Hypothesis 2: Patients who have their gastric contents withdrawn prior to being placed supine have a lower incidence of aspiration than the organizations documented rates of aspiration.

This study is an experimental design utilizing a convenience sample of 30 patients at each of three Midwest ICU's (n=90). Patients studied will include those mechanically ventilated with whom nasogastric or orogastric feeding tubes are placed to initiate feeding. The gastric tube placement will be confirmed by radiograph, and a gastric pH reading will be obtained and recorded. The patients will then be randomly assigned to one of two groups, and assigned a code number which will be placed on their bedside instrument and any lab work: One group will receive the experimental intervention of

having their gastric contents withdrawn prior to leaving the semirecumbent position of 30-45 degrees and returned when they resume that position. The second group will experience the current practice of turning off the tube feeding just prior to leaving the semirecumbent position and restarting it once they have returned to the semirecumbent position.

Utilizing the best available indicators of aspiration, both groups will have their tracheal secretions tested for pepsin and pH each morning at 0600 (all pepsin samples will be frozen and sent to same outside laboratory). The bedside clinician will note the sample collection times and record the pH on the provided form. The data will be collected for 3 consecutive days for each patient not including the day of insertion of the tube. The clinicians will be encouraged to provide typical care aside from that described above.

Data collected will be compared to previous rates of aspiration pneumonia maintained by each respective hospital, and then combined to compare with the intervention/non-intervention groups from all facilities.

Setting

Three Midwest ICU's will participate in this experiment following the approval of the respective IRB's and with the unit directors' consent. The units have similar patient populations, including pulmonary, non-cardiac surgical, trauma, and medical illnesses and consist of 15, 18, and 20 beds respectively. Typical demographics tend toward the elderly (>70 yrs of age), and all units have high concentrations of mechanically ventilated and enterally fed patients at any given time.

The staff are amenable to research projects, and are obligated to participate as a function of their job descriptions. None of the units has a formal policy on the management of tube feedings when repositioning the patients, and is open to suggestions in improving their procedures for caring for this patient population.

The lab personnel at each institution have given their preliminary support for handling the pepsin tests, and all have the facilities to do so without additional cost.

Sample

A convenience sample of 90 patients who are mechanically ventilated and undergo the initial insertion of a nasogastric feeding tube (NGT) will be selected to join the study (30 at each facility), provided they do not meet any of the exclusion criteria. Subjects must be 18 or older and be able to give informed consent. Exclusion criteria include current or previous gastrointestinal surgery (excluding cholecystectomy and appendectomy), known gastrointestinal pathology, or diagnosed/suspected of pneumonia. This number is selected to provide an adequate comparison of the experimental versus control group without incurring excessive costs in processing lab work or creating an excessive administrative burden for the staff. The study should take no longer than one month based on patient populations and the size of each unit.

Patients will be randomly assigned to either the intervention group or the control group by means of a sealed envelope process. Inside the envelope will be the directions for one of the two groups. In order to blind the researchers and clinicians from the envelope's contents, the envelopes will be filled and sealed, mixed up, and then coded on the outside. The clinician will select an envelope once they identify an eligible candidate and obtain informed consent. The clinician will be advised to write the code from the

envelope on the instrument once it is opened. This code will then be used for all study documentation and lab work for that patient.

Interventions

Patients in the experimental group will have their gastric contents aspirated prior to being placed in a supine position. The contents will be saved until the patient is replaced in a semirecumbent position and then will be returned. Patients in the experimental group who must remain supine for more than 15 minutes should have their NGT placed to LCS until returned to the recumbent position, at which time the gastric secretions originally withdrawn will be returned. Patients in the control group will experience typical care with the exception of the daily pepsin and pH studies of tracheal secretions, which the staff will be trained in performing. This process will occur for 3 days following the day of insertion of the NGT. All other care provisions are to remain unchanged such that they do not influence the outcome of either group. The purpose of the control group is to identify if there is truly a difference in the rates of aspiration when the gastric contents are removed prior to placing a patient supine. Results of the study will be provided to each institution for their review and action, if indicated.

Variables

The primary variable measured in this study is aspiration. The instruments used to measure this variable are the results of the daily pepsin immunoassay and pH tests. The pepsin immunoassay is highly selective and specific as described earlier in this document. The gastric pH measurement is weakly selective in that it is impacted by medications and tube feedings which raise the gastric pH to levels that are similar to the pulmonary pH. The secondary variable that will be documented is whether the patient

had gastric fluid withdrawn or not. These two variables will be compared at the conclusion of the data collection to determine if the intervention influenced the rates of aspiration pneumonia.

Mortality and instrumentation are the only significant threat to internal validity that is apparent. Patients in this category may improve or expire during the course of the study and therefore be disenrolled. Clinicians may place a patient supine without aspirating the stomach contents thereby impacting the internal validity of the measurement. The likelihood of this is reduced by the short duration of the data collection for each patient. Conducting the study at three separate institutions positively influences external validity. The data will only be generalizable to adults with mechanical ventilation and nasogastric or orogastric tube feedings. Findings may not apply to patients with small-bore or j-tube feedings.

Instruments

Two instruments have been developed (Appendices A and B) which are from the experimental and control groups respectively. The experimental form contains a box to place the patient's code number, a table with the spaces for four pH measurements, and the three pepsin check-off boxes to indicate they were sent. Directions are included for aspirating the contents of the stomach prior to repositioning the patient, and obtaining and handling the pepsin and pH tests. A contact phone number is provided to answer any questions that may arise during the course of the study. The control form is identical with the exception of excluding the directions about aspiration of gastric contents. Instead, a message tells the staff to care for the patient as is normally done with the exception of the lab work daily at 0600.

Research Procedures/Informed Consent

The three institutions have provided initial approval for my study pending IRB review and acceptance. I expect that all three IRB's will respond within 6 months. Once IRB approval is obtained, I will arrange to visit each unit and meet with the manager and/or director to explain the procedures and establish a window of action. I will meet with the lab director to clarify the procedures for completing the pepsin tests and arrange for payment of the fees associated with the pepsin and gastric pH tests. I will distribute informational flyers at that time, explaining both the reason for the study and procedural information. Then, I will arrange a meeting with the intensivist at each facility to initiate the study. A box with 30 envelopes, each containing a code number that identifies both the facility and the random patient number will be placed at the nurses station such that nurses can randomly choose an envelope and initiate the indicated activities. The envelope box will have the cellular number for technical support, the inclusion and exclusion criteria, and a letter of support from the intensivist at each respective facility.

During the course of the study, nurses will approach patients who meet the inclusion criteria as they are identified to seek consent for enrollment in the study. Patients who give understand their rights as a research subject and give informed consent will be enrolled in the study and randomly assigned via the envelope selection process. They must be aware that participation is voluntary, that they may disenroll at any time without fear of repercussion, and that their personal data will not be shared or released in any way. They will be advised of the anonymous code that they will be assigned and that their lab work will be labeled as such. They will be further advised that participation in

this study will not obligate them in any financial way because study's funding pays for the lab work.

This study will not expose the patient to any painful procedures or increase any risk factors surrounding their health. In fact, the experimental group may benefit from decreased gastric residual volumes during supine positioning. The only intervention patients experience involves the temporary removal and replacement of gastric secretions. Removal of gastric secretions is commonplace in nursing practice and, in most situations has no impact on the patients' fluid status or electrolyte balance. All other healthcare interventions will occur as if the patient is not a subject of the study.

Strengths and Limitations

Strengths of this study include a diverse population from which the sample is drawn, the proven quality of pepsin as a specific and selective marker of pulmonary aspiration of gastric contents, and the short duration of the study that helps to avoid a loss of subjects and loss of interest by the administrators of the instruments. Weaknesses of the study include the potential loss of data encountered by sending the pepsin lab work to an outside lab, the lack of conclusive data that supports gastric residual volumes as contributing to aspiration, and the reliance on individual nurses to consistently perform the intervention in the experimental group when it may be viewed as tedious or cumbersome. Inconsistency in performing the intervention would undermine the entire experiment.

Timeline

The completed proposal will be submitted to the three IRB's by May 1st. Responses are expected within 6 months. Meetings will occur with the

managers/directors of the ICU's in early December and include the distributing of flyers explaining the inclusion and exclusion criteria as well as the aim of the study. The second week of January will consist of meetings with each institution's intensivist. This will signal the start of the study. The study will continue until each facility enrolls 30 patients and completes the data collection process. It is estimated that this process will take between four and six weeks to finish. Data collected will be analyzed against each hospital's historical aspiration rates and then collectively compare the experimental and control groups from each facility. Finally, experimental groups will be combined and compared with the composite control groups. This data will be prepared and presented to the participating organizations and units for review and action if indicated. The exact date of presentation depends on the turn-around time on the pepsin samples and the length of time to complete the study at each facility.

ID No:

Appendix A

Experimental Group

Congratulations! You have been selected as a subject in the experimental group. Ensure that the patient’s HOB is kept at 30 – 45 degrees at all times. If the patient is lowered below this range, please withdraw all gastric contents until they are returned to the semirecumbent position. If you are leaving the patient supine for more than 15 minutes, please connect the NGT/OGT to low continuous suction for the duration. It is very important that this procedure is followed every time the patient is placed below 30 – 45 degrees.

Lab studies

Gastric pH Results
On NGT/OGT insertion:
0600:
0600:
0600:

Pepsin Immunoassay Completed
XXXXXXXXXXXXXXXXXXXXXXXXXXXX
0600:
0600:
0600:

Aside from the above activities, please perform all other nursing interventions as you normally would aside from collecting the above-mentioned labs each morning. If you have any questions about this study, please call 555-555-1212 and someone will assist you.

ID No:

Appendix B

Control Group

Congratulations! You have been selected as part of the control group. Please continue to provide your typical nursing care for this patient with the exception of adding the following lab tests each morning for 3 days.

Gastric pH Results
On NGT/OGT insertion:
0600:
0600:
0600:

Pepsin Immunoassay Completed
XXXXXXXXXXXXXXXXXXXXXXXXXXXX
0600:
0600:
0600:

If you have any questions about this study, please call 555-555-1212 and someone will assist you.

Appendix C

Timeline

| | |
|--|-------------------------|
| Submit Completed Proposal to IRBx3 | May 1 st |
| Receive Response and arrange meetings with Manager/Director ICU'sx3 | December 1st |
| Distribute Flyers regarding Study | December 15th |
| Meet with Intensivist/Project Kick Off | January 15th |
| Conclude Data Collection | No later than March 1st |
| Analyze Data | Complete by April 15th |
| Submit Results to Participating Facilities | May 1st |

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