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Effectiveness of an Aspiration Risk-Reduction Protocol

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Abstract

Background—Aspiration of gastric contents is a serious problem in critically ill, mechanically ventilated patients receiving tube feedings.

Objectives—To evaluate the effectiveness of a three-pronged intervention to reduce aspiration risk in a group of critically ill, mechanically ventilated patients receiving tube feedings.

Method—A two-group quasi-experimental design was used to compare outcomes of a usual care group (December 2002–September 2004) with those of an Aspiration Risk Reduction Protocol (ARRP) group (January 2007–April 2008). The incidence of aspiration and pneumonia were compared between the usual care group (n = 329) and the ARRP Group (n = 145). The ARRP had three components: maintaining head-of-bed elevation at 30 degrees or higher, unless contraindicated; inserting feeding tubes into distal small bowel, when indicated; and using an algorithmic approach for high gastric residual volumes.

Results—Two of the three ARRP components were implemented successfully. Almost 90% of the ARRP group had mean head-of-bed elevations of 30 degrees or higher as compared to 38% in the usual care group. Almost three-fourths of the ARRP group had feeding tubes placed in the small bowel, as compared to less than 50% in the usual care group. Only three patients met the criteria for the high gastric residual volume algorithm. Aspiration was much lower in the ARRP group than in the usual care group (39% versus 88%, respectively). Similarly, pneumonia was much lower in the ARRP group than in the usual care group (19% versus 48%, respectively).

Discussion—Findings from this study suggest that a combination of a head-of-bed position elevated to at least 30 degrees and use of a small-bowel feeding site can reduce the incidence of aspiration and aspiration-related pneumonia dramatically in critically ill, tube-fed patients.

Keywords

enteral nutrition; respiratory aspiration; preventive measures

Frequent aspiration of gastric contents predisposes tube-fed patients to pneumonia, especially those who are critically ill and mechanically ventilated. Airway protection from regurgitated gastric contents often is impaired in these patients by underlying illness, sedation, or both. A number of interventions have been proposed to minimize aspiration. For example, a research-based guideline issued by the Centers for Disease Control and Prevention recommends a head-

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of-bed position elevated to at least 30 degrees to reduce risk for aspiration-related pneumonia (Tablan et al., 2004). Further, a frequently cited study of aspiration in mechanically ventilated patients found that aspiration was significantly more likely when patients were supine; however, it also occurred when they were semirecumbent (Torres et al., 1992). Findings from the Torres et al. study are convincing in that the methods used to detect aspiration were scientifically sound (radiolabeled enteral formula and comparisons between organisms found in the subjects' stomachs and lungs). Other investigators have found that risk for pneumonia is increased by a low backrest elevated position (Grap et al., 2005). Investigators have shown that written medical orders for head-of-bed elevation are helpful in encouraging staff to maintain the appropriate backrest elevation (Helman, Sherner, Fitzpatrick, Callender, & Shorr, 2003). There is widespread agreement that an elevated head-of-bed position is helpful in reducing aspiration and pneumonia (Torres et al, 1992, Tablan et al, 2004; Grap et al., 2005).

A distal small-bowel feeding site has been also recommended to reduce aspiration risk, though it is less well-substantiated by research; presumably a small bowel feeding site reduces the likelihood of gastroesophageal reflux (Heyland, Drover, Dhaliwal, & Greenwood, 2002). Studies of the relationship between small-bowel feedings and aspiration have produced conflicting results. For example, in a study of 33 critically ill patients, Heyland et al. used radio-labeled formula to assess the extent of aspiration when feeding tubes were situated in various segments of the gastrointestinal tract (Heyland, Drover, MacDonald, Novak, & Lam, 2001). The rate of aspiration was 5.8% in the stomach (n = 21); 4.1% in the first portion of the duodenum (n = 8), 1.8% in the second portion of the duodenum (n = 3); and 0% in the fourth portion of the duodenum (n = 1). Overall, patients fed in the stomach tended to have more microaspiration than patients fed beyond the pylorus (7.5% vs. 3.9%, p = .22). When the logarithmic mean of the radioactivity count was compared across groups, there was also a trend toward increased microaspiration (1.9 vs.1.4 counts/g, p =.09) in patients fed into the stomach (Heyland et al., 2001). However, also using radio-labeled enteral formula, other investigators found no significant difference in aspiration in 27 patients fed in the stomach and 24 fed transpylorically (7% versus 13%, respectively; Esparza, Boivin, Hartshorne, & Levy, 2001). Although Heyland et al. (2001) and Esparza et al. (2001) used a reliable test for aspiration, both studies had relatively small sample sizes. Another problem with the Esparza et al. (2001) study was failure to provide information about the degree of aspiration encountered in patients fed in different portions of the small bowel. Despite the conflicting research findings regarding feeding tube location, many physicians prefer small-bowel feedings in patients at high risk for aspiration, provided the procedure can be performed at the bedside by bedside nurses (Heyland, Cook, & Dodek, 2002). There is evidence that bedside nurses can be taught how to successfully place feeding tubes into the distal small bowel (Welch, 1996).

Finally, an algorithmic approach to deal with high gastric residual volumes (GRV) has been proposed (Bourgault, Ipe, Weaver, Swartz, & O'dea, 2007; Kattelmann et al., 2006). For example, it has been recommended that gastric feedings be interrupted when a residual volume of 500 ml or more is identified (McClave et al., 2002) and it has been suggested that prokinetic drugs be initiated when GRVs of 250 ml or greater are identified (Booth, Heyland, & Paterson, 2002; Nguyen et al., 2007). A drawback to the use of prokinetics is their potential to produce undesirable side effects, such as dystonic reactions (Dubow, Leikin, & Rezak, 2006; Kenney, Hunter, Davidson, & Jankovic, 2008; Pasricha, Pehlivanov, Sugumar, & Jankovic, 2006; van der Padt, van Schalk, & Sonneveld, 2006).

Although the effects of single risk factors for aspiration have been studied previously, no studies were identified in which the combined effect of postpyloric tube site, head-of-bed elevation, and gastric residual volume were evaluated. Because it is likely that a combination of aspiration-risk-reducing interventions will be more beneficial than a single intervention, the

study reported here was used to evaluate the effectiveness of a three-pronged intervention to reduce aspiration risk in a group of critically ill, mechanically ventilated tube-fed patients.

Method

Design

A two-group quasi-experimental design was used to compare outcomes of a usual care group with those of an Aspiration Risk Reduction Protocol (ARRP) group. Both groups included critically ill, mechanically ventilated tube-fed patients cared for in the same intensive care units (ICUs). The primary outcomes of interest were the frequency of aspiration and the incidence of pneumonia. A secondary outcome was the use of hospital resources (length of hospitalization, length of intensive care stay, and number of days of mechanical ventilation). The study was approved by the appropriate institutional review boards. A secondary data analysis was performed on the usual care group. Patients in the usual care group who had surgically or endoscopically placed tubes were eliminated from the analysis for the work reported here.

Setting

Both phases of the study took place in the same five ICUs at a Level I trauma center in the Midwest. Major services provided in the ICUs included neuromedicine/neurosurgery, trauma/surgery, and general medicine/pulmonary medicine.

Subjects

The usual care group (n = 329) was studied prospectively between December 2002 and September 2004 (Metheny et al., 2006). The ARRP Group (n = 145) was studied prospectively between January 2007 and April 2008. Inclusion criteria for the ARRP group were the same as for the usual care group: a) admitted to one of the five ICUs at the study site, (b) age ≥ 18 years; (c) informed consent of patient or legal guardian; (d) mechanical ventilation; and (e) medical order for blind insertion of feeding tube at bedside. Exclusion criteria were: (a) pneumonia present before tube feeding started; and (b) medical order for surgically or endoscopically placed feeding tube.

All patients who met the criteria were invited to participate for a 3-day period. While the ARRP was implemented for all tube-fed patients in the ICUs, data were collected only on those who gave informed consent. Registered nurse research assistants were present 16 hours a day, 7 days a week, to recruit patients, obtain informed consents, and collect data. The same measurements were made on the usual care group and ARRP group.

Independent Variable

The independent variable consisted of the two treatment conditions (usual care and the ARRP).

Usual care was defined as the absence of a systematic approach to minimize risk for aspiration. In 2002–2004, standing medical orders on the ICUs did not routinely include information about head-of-bed elevation and nurses did not chart head-of-bed angles on the patients' flow sheets. Further, no formal program was in place to teach ICU nurses how to place small-bowel feeding tubes. Finally, there was no standardized approach for dealing with high gastric residual volumes.

The ARRP had three components: (a) maintain head-of-bed elevation at 30 degrees or higher, unless medically contraindicated; (b) insert feeding tube into distal small bowel, when requested by the attending physician; and (c) initiate an algorithmic approach for high gastric residual volumes.

Prior to initiation of the study in 2007, the hospital nursing practice committee and the ICU medical directors approved the ARRP for use in the ICUs, and 2 months prior to data collection, an advanced practice nurse skilled in critical care and nasoenteral tube placement initiated an educational program to introduce the protocol to the ICU staff. This nurse was present 40 hours a week during the ARRP phase of the study to encourage adoption of the protocol in the ICUs involved. Coaching by the advanced practice nurse consisted of a combination of teaching, training, and counseling designed to promote diffusion of the ARRP components. The advanced practice nurse also provided monthly feedback about implementation of the interventions and reinforced desired behaviors by emphasizing successful aspects of the protocol delivery.

Maintain head-of-bed elevation at 30 degrees or higher, unless medically contraindicated—Attending physicians were encouraged to write orders for the desired head-of-bed elevation and this action promoted appropriate patient positioning. Also, bedside nurses were encouraged to record head-of-bed angles at hourly intervals on the patients' ICU flow sheets; this action reminded the nurses to check the bed position frequently and make corrections as necessary.

Insert feeding tube into distal small bowel, when requested by attending physician—Physicians were informed that the advanced practice nurse would assist ICU nurses with small-bowel tube insertions at the bedside. Thus, physicians were able to write orders more freely for bedside small-bowel tube insertions when they were deemed important for high-risk patients. The advanced practice nurse demonstrated small-bowel tube insertion to bedside nurses who were unskilled in this procedure and coached these nurses during small-bowel tube insertions until they gained proficiency in the procedure. To facilitate learning further, a videotape of a successful tube insertion was made available in all of the ICUs for nurses to view at their discretion.

The tube insertion procedure consisted of several steps. First, the patient's attending physician was contacted to obtain permission to administer metoclopramide, 10 mg, intravenously. If permission was obtained, the medication was administered 10 minutes prior to introduction of the feeding tube through the patient's mouth or right or left naris (whichever was most appropriate). Metoclopramide increases gastric and small intestinal motility and thus facilitates placement of a feeding tube into the small bowel (Rohm, Boldt, & Piper, 2009). The feeding tube was advanced to the 55 to 60 cm mark and an attempt was made to aspirate gastric contents. If an aspirate was obtained, its pH was measured with a pH test-strip and the appearance of the aspirate was observed. If the pH was 6 or higher, and the aspirate had the appearance of sputum, the tube was removed and a second attempt was made to insert the tube via the esophagus into the stomach. A pH less than 6 and as aspirate with a gastric appearance was used as an indication of tube placement in the stomach. The feeding tube was advanced gently with a rotating motion. When the 90 to 100 cm mark was reached, another attempt to aspirate fluid was made. This attempt was facilitated by injecting 30 ml of air through the tube to force the tube's ports away from the intestinal mucosa. An aspirate pH $\geq$ 6 with bile staining was used as an indication of tube placement past the pylorus. A confirmatory radiograph was obtained to determine actual tube location.

Detect and manage high gastric residual volumes—The algorithmic approach used to manage high GRVs during gastric feedings is depicted in Figure 1.

Measurements

Measurements performed on the usual care and ARRP groups are summarized in Table 2 and described below. All of the registered nurse data collectors were trained by the principal investigator and the project director on scoring of the measurements prior to data collection.

Pepsin assay to detect aspiration of gastric contents—Bedside nurses collected tracheal secretions in sputum traps during routine suctioning (between 0800 and 2400 hours) on Days 1, 2, and 3. The specimens were treated and frozen at minus 20 degrees Centigrade in a hospital laboratory prior to being transported to a research laboratory for pepsin analysis. The immunoassay used for pepsin analysis has been described previously (Metheny et al., 2006). In an animal model study, the assay was shown to have a sensitivity of 92.5% and a specificity of 100% (Metheny et al., 2004). The same biochemist, blinded to patients' clinical status, interpreted all of the assays and recorded the results as either *positive* or *negative*. A positive reading indicated that the specimen contained pepsin in a concentration ≥ 1 μg/ml. The percentage of pepsin-positive tracheal secretions was calculated for each patient. The mean number of tracheal secretions assayed per patient was 15.9 ± 4.7 in the usual care group and 13.1 ± 4.2 in the ARRP group.

Clinical pulmonary infection score—The Clinical Pulmonary Infection Score (CPIS) described in Table 3 was used to assess for pneumonia at the end of Days 1, 2, 3, and 4 (Luna et al., 2006). Data on infiltrates were obtained from radiographic reports. The first blood gas of the day was used to calculate the oxygenation PaO_2/FiO_2 ratio. Bedside nurses estimated the volume and appearance of tracheal secretions at the time of routine suctioning. Blood leukocyte data were obtained from laboratory reports, and temperature data were obtained from the medical records. When an infiltrate was present, a CPIS score ≥ 6 was used as a proxy for pneumonia. The same individual, blinded to the pepsin assay results, calculated all of the CPIS scores. In an earlier study, investigators found significant agreement (r = .96) between the simplified CPIS results and 34 bronchoalveolar lavages (p < .001; Metheny et al., 2006). Another group of investigators compared postmortem examinations of 38 patients who had died after at least 72 hours of mechanical ventilation and compared their CPIS scores with bronchoscopic and histological techniques; according to their findings, the CPIS had a sensitivity of 72% and a specificity of 85% for pneumonia (Papazian et al., 1995).

Use of hospital resources—Information needed to calculate hospital length of stay, ICU length of stay and ventilator days was obtained through chart review.

Angle of head-of-bed—During both phases of the study, registered nurse data collectors determined hourly backrest angles from digital readouts available on the patients' beds (Stryker Medical, Kalamazoo, MI). During the ARRP phase of the study, the bedside nurses were encouraged to use the beds' digital readouts to determine hourly backrest elevations and to record their findings on the patients' flow sheets. The same beds were in use during both phases of the study. In a previous study, investigators compared 1,002 readings made between digital readouts on the Stryker Apex or Stryker EPIC II Critical Care beds and those obtained from a handheld angle reader; the Pearson correlation was .87, p < .001. However, the mean bed readouts tended to be higher than the mean readings obtained from the handheld device (21.3 ± 13.3 vs. 18.9 ± 11.7; Metheny et al., 2006).

Feeding tube site—Radiographic confirmation of tube location was obtained immediately after tube insertion; also at this time, the length of tubing extending from the exit site was measured with a centimeter tape. This measure was repeated at 4-hour intervals between 0800 and 2400 on Days 1, 2, and 3; also assessed at these times were the pH and appearance of fluid

aspirated from the feeding tubes. The efficacy of these measures in detecting tube dislocation has been described previously (Metheny et al., 2005).

When there was concern about possible tube dislocation, the need for a radiograph was discussed with the patient's attending physician. In addition, reports of radiographic studies performed on Days 1, 2, and 3 were reviewed to observe for radiographic evidence of tube movement. Most patients had at least one treatment-related x-ray during the study period that included information about the feeding tube's location.

Residual volumes from feeding tubes—Research nurses used 60 ml syringes to measure volumes from feeding tubes every 4 hours. Approximately 30 ml of air was injected into the feeding tube prior to each attempt to withdraw fluid from the tube; then slow and steady negative pressure was applied with the plunger. The procedure was repeated until no more fluid could be withdrawn. The total volume of fluid removed from the feeding tube was reported in milliliters. Policy at the data collection site called for returning a gastric residual volume of 200 ml or less to the patient and discarding of any amount greater than 200 ml.

Level of consciousness—The Glasgow Coma Scale (GCS), adjusted for use with intubated patients, was used by the research nurses to assess patients' level of consciousness at 4-hour intervals from 0800 through 2400. Scoring of the GCS is based on three components (best eye response, best motor response, and best verbal response). The worst possible total score is 3 and the best possible total score is 15. Because all of the patients were intubated tracheally, the verbal response was scored as *generally unresponsive, ability to converse is in question*, or *appears able to converse*. In a prospective, observational study, two observers determined the GCS of 39 poisoned patients; the weighted kappa score for the total GCS was .85; weighted kappa scores for individual components of the GCS ranged between .63 and .78 (Heard & Bebarta, 2004). In a review of published studies in which GCS was used, the tool was found to have good reliability (intraclass correlation coefficient, .8 to 1.0 for trained users); further, it was found to have well-established cross-sectional construct validity (Prasad, 1996).

Level of sedation—The Vancouver Interaction and Calmness Scale (VICS) was used to assess patients' level of sedation (de Lemos, Tweeddale, & Chittock, 2000). This scale was developed for use with adult, critically ill, mechanically ventilated patients and it consists of two 5-item subscales quantifying interaction along a continuum from 5 to 30 points; the scores may range from 10 to 60. A low score indicates a high level of sedation. The tool's developers report interrater reliability for the two scales as .89 and .90, and internal consistency as .95 for both subscales (de Lemos et al., 2000).

Severity of disease—The Acute Physiology and Chronic Health Evaluation II (APACHE II) score was calculated at the time of the patient's admission to the ICU. This tool is designed to measure the severity of disease for adult patients admitted to ICUs. The tool has three components: the acute physiology score (APS), age, and chronic health. Overall, an integer score from 0 to 71 is computed on the basis of temperature, mean arterial pressure, heart rate, respiration rate, oxygenation, serum sodium, serum potassium, serum creatinine, hematocrit, white blood count, Glasgow Coma Score, age, and chronic health points (Knaus, Draper, Wagner & Zimmerman, 1985). Higher scores imply more severe disease state and greater risk for death. The APS component of the APACHE II instrument is highly reproducible (intraclass correlation coefficient = .90), and the age component of the instrument has an even higher reproducibility (intraclass correlation coefficient = .998). The chronic health component of the instrument does not fare as well (kappa = .66; Damiano, Bergner, Draper, Knaus, & Wagner, 1992).

Other observations—Demographic information was obtained by chart review. The number of vomiting episodes was determined by interviewing bedside nurses and by chart review.

Data Analysis

Simple descriptive statistics were used to describe the sample. To determine the effect of the ARRP on frequency of aspiration, a t-test for independent groups was used to compare patients in the usual care and ARRP groups on the mean percentage of pepsin-positive tracheal secretions. To determine the effect of the ARRP on the incidence of pneumonia, a z-test for comparing proportions in independent groups was used to compare the proportion of usual care patients with the proportion of ARRP patients with a positive CPIS for pneumonia on Day 4. Significant baseline differences between the two groups were controlled for in the analyses. To evaluate the effect of the ARRP on hospital resources, usual care and ARRP groups were compared using a z-test from the Mann Whitney U procedure, because the secondary outcomes of hospital length of stay, ICU length of stay, and days of ventilator use had skewed distributions.

Results

Descriptive Data

Descriptive data on both groups are provided in Table 1. As shown in Table 1, the ARRP and usual care groups did not differ in gender, level of consciousness, and the service that provided care. However, the ARRP group was younger, had a lower mean APACHE II score, and was less sedated than the usual care group.

The mean head-of-bed elevation was significantly higher in the ARRP group than in the usual care group (37.8 ± 9.1 versus 23.7 ± 12.4 degrees, respectively, $p < .001$). Further, a mean head-of-bed elevation ≥ 30 degrees was achieved in 88% of the ARRP group as opposed to 38% of the usual care group ($p < .001$; Figure 2). Physicians included orders for the desired head-of-bed angle in 90% ($n = 130$) of the 145 ARRP patients. Bedside nurses charted the head-of-bed angle in 44% of the possible observations.

As shown in Figure 3, a small-bowel feeding site was achieved in 72.4% of the ARRP group, compared to 48.3% of the usual care group ($p < .001$). Further, tube placement past the proximal duodenum was achieved in 53.1% of the ARRP group, compared to 18.2%, of the usual care group ($p < .001$).

Three patients in the ARRP group met the criteria for implementation of the high GRV algorithm depicted in Figure 1. One patient had nine high GRVs (ranging between 300 ml and 700 ml), a second had two high GRVs (both 350 ml), and a third had one GRV of 325 ml. However, physicians chose not to implement the algorithm in any of the cases.

Effect of the ARRP on Aspiration, Pneumonia, and Use of Hospital Resources

Aspiration was significantly lower in patients in the ARRP group than in usual care group, as evidenced by a lower mean percentage of pepsin-positive tracheal secretions (12.4 ± 21.8% versus 30.9 ± 24.2%, $p < .001$). Aspirating at least once was half as likely in the ARRP group as in the usual care group (39.3% versus 88.4%, $p < .001$). Further, pneumonia occurred in less than one-fifth of the ARRP group but in nearly half of the usual care group (19.3% versus 48.2%, $p < .001$; Figure 4). The ARRP patients were hospitalized on average 2.2 fewer days than usual care patients (25.1 ± 14.9 versus 27.3 ± 13.4, z from Mann Whitney U = −2.39, $p = .017$), and the average ICU length of stay for ARRP patients was 1.9 fewer days than for usual care patients (21.3 ± 10.5 versus 19.4 ± 12.1, z from Mann Whitney U = −2.46, $p = .014$). Finally, ARRP patients averaged 1.5 fewer days of mechanical ventilation than the usual care

patients (16.2 ± 9.7 versus 17.7 ± 9.8, respectively, z from Mann Whitney U = −1.46, p = .14; Figure 5). When the usual care and ARRP groups were compared on the outcome variables using age, APACHE II, and sedation as covariates, the results were nearly identical.

Discussion

Success in Delivery of the ARRP

Two of the three components of the ARRP were implemented successfully. That is, almost 90% of the ARRP group had mean head-of-bed elevations of 30 degrees or higher and almost three-fourths had feeding tubes placed in the small bowel (most beyond the proximal duodenum).

Successful implementation of a head-of-bed elevated position probably was influenced by a number of factors. Written medical orders regarding the desired backrest angle eliminated the possibility of elevating the backrest inappropriately and reminded staff of the importance of proper positioning. Frequent documentation of the backrest angle ensured corrections as needed. Also, the documentation probably enhanced the nurses' sense of responsibility for appropriate patient positioning. A factor that also may have had a significant effect on the greater use of an elevated head-of-bed position in the ARRP group, as compared to the usual care group, was the growing number of publications emphasizing the need for an elevated head-of-bed position to prevent pneumonia (Tablan et al, 2004; Grap et al., 2005).

Successful implementation of small-bowel feeding tube insertions also probably was influenced by several factors. Many physicians prefer small-bowel feedings in patients at high risk for aspiration, provided the procedure can be performed at the bedside by bedside nurses; and in this study the educational program provided by the advanced practice nurse allowed a cadre of bedside nurses in the five ICUs to significantly improve their success in placing small-bowel feeding tubes.

Poor use of the algorithm was due to reluctance of the attending physicians to prescribe prokinetic agents for the three patients who met the criteria in the algorithm depicted in Figure 1. In all three cases, the physicians expressed concern about recent published reports of possible undesirable effects associated with prokinetic agents (Dubow et al, 2006;Kenney et al, 2008;Pasricha et al, 2006;van der Padt et al, 2006).

Improvement in Outcomes

To determine if younger age, better APACHE II score, and lower level of sedation had a significant effect on outcomes (aspiration and pneumonia), these factors were entered as covariates in the analyses. These factors had no significant effect on outcomes when the two groups were compared.

The combination of an elevated head-of-bed position and a mid-to-distal small-bowel feeding site probably contributed to the significantly less aspiration and pneumonia in the ARRP group than in the usual care group. The shorter hospital and ICU lengths of stay in the ARRP group were modest and doubtless influenced by the lower incidence of pneumonia.

Head-of-bed elevation—The supine position is a well-recognized risk factor for aspiration. As indicated earlier, there is widespread agreement that an elevated head-of-bed position is helpful in reducing aspiration and pneumonia (Torres et al, 1992, Tablan et al, 2004; Grap et al., 2005).

Small-bowel feeding site—Findings from the study reported here support those of other investigators who used a sensitive and specific test for aspiration of gastric contents (Heyland et al, 2001).

Gastric residual volume—Because the algorithm for high GRVs during gastric feedings was not implemented in the three ARRP patients with one or more GRVs ≥ 250 ml, it was not possible to determine what effect it might have had on their rates of aspiration (which ranged between 50% and 100%).

The study reported here adds to the evidence that an elevated head-of-bed position is helpful in preventing aspiration and pneumonia; further, it adds to the evidence that a distal small-bowel feeding site is associated with less aspiration than is the gastric feeding site. It is regrettable that the GRV component of the protocol could not be implemented and evaluated.

Strengths of the Study

The highly sensitive and specific pepsin assay allowed an accurate comparison of the two groups on aspiration and the large sample size provided adequate power to compare the usual care and ARRP groups on the major outcome variables (aspiration and pneumonia). The presence of skilled registered nurse research assistants for 16 hours a day, 7 days a week throughout both phases of the study allowed for uniformity in data collection procedures.

Limitations

A limitation of the study was the 28-month time lapse between the end of the usual care phase of the study and the beginning of the ARRP phase. It is conceivable that changes that occurred in the clinical site during that period could have accounted for some of the differences in outcomes.

Conclusions

Findings from this study suggest that a combination of a head-of-bed position elevated to at least 30 degrees and use of a small-bowel feeding site (especially beyond the first portion of the duodenum) can reduce the incidence of aspiration and aspiration-related pneumonia dramatically in critically ill, mechanically ventilated patients. It is highly probable that the presence of a skilled critical care nurse with special training in the placement of small-bowel feeding tubes played a significant role in encouraging ICU personnel at the study site to adopt the aspiration-reducing interventions and bring about the desired outcomes shown in this study.

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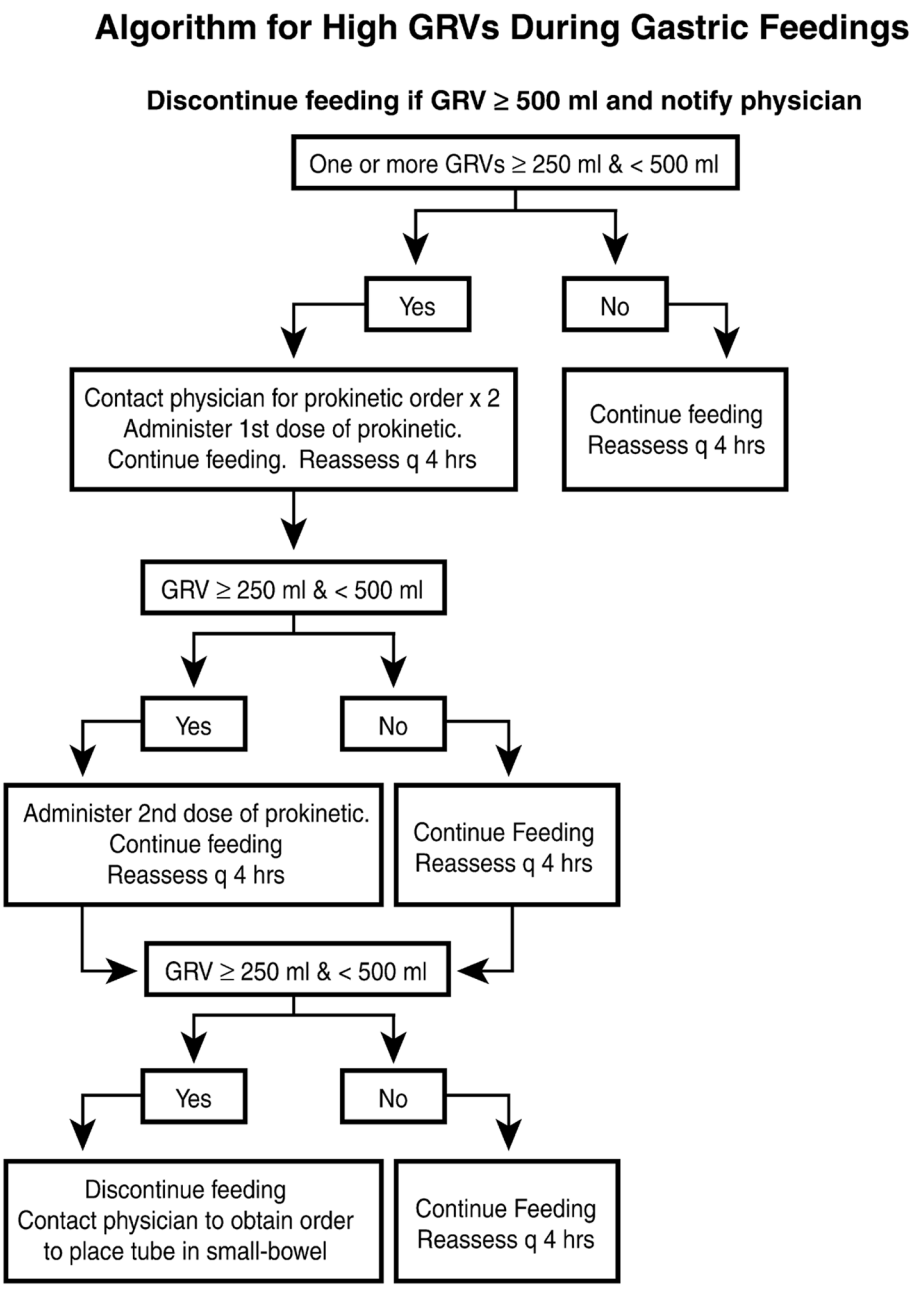

Figure 1.
Algorithm outlining actions for high gastric residual volumes observed during gastric feedings.

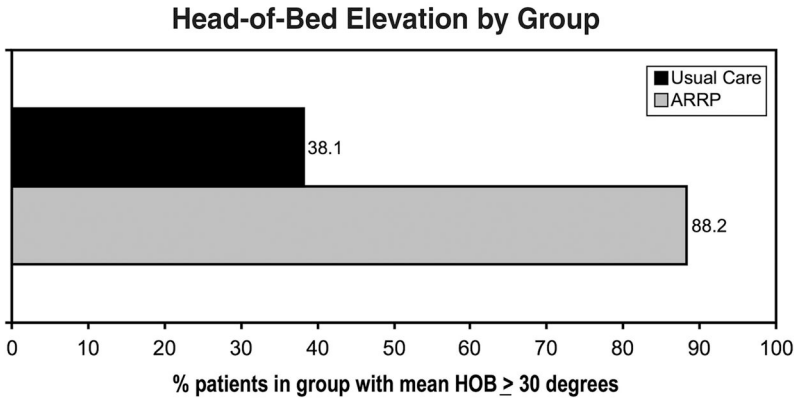

Figure 2.
Comparison of percentages of mean head-of-bed elevations equal to or greater than 30 degrees in the usual care and ARRP groups.

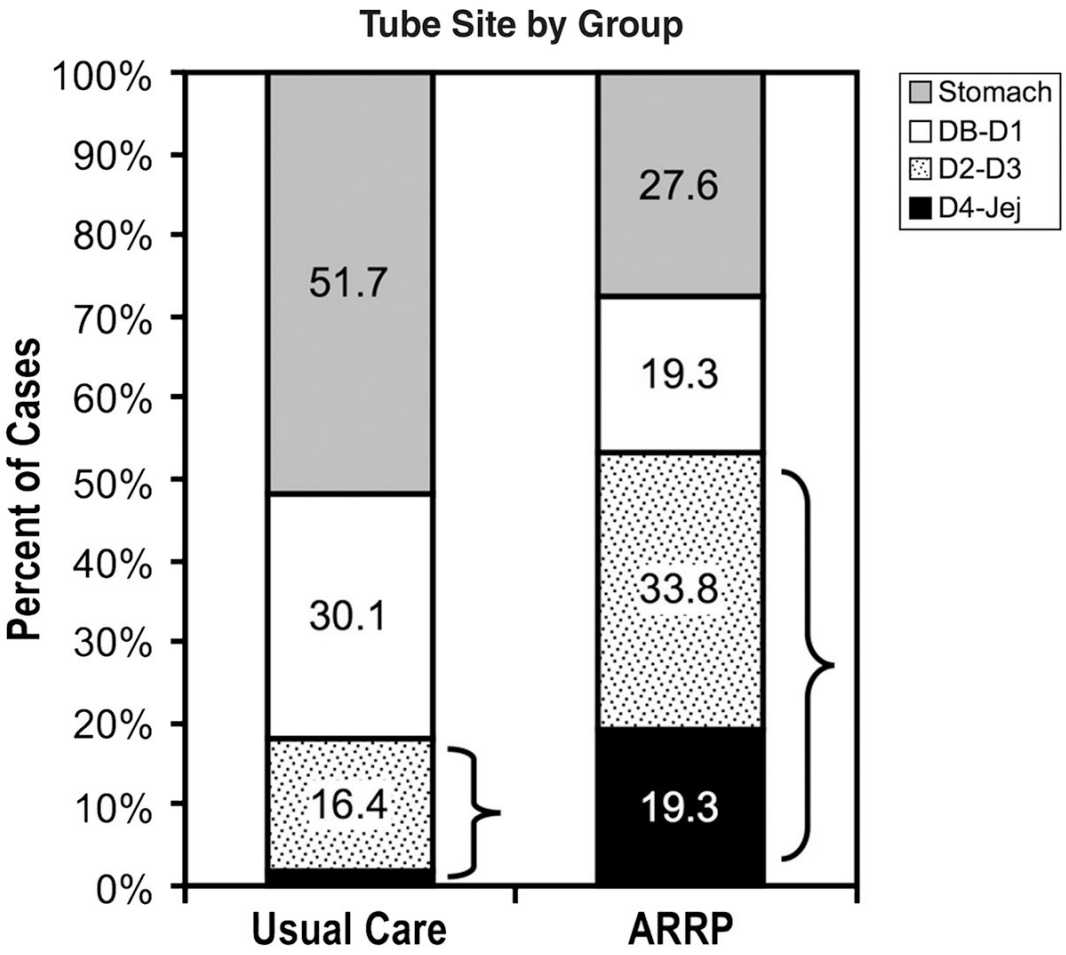

Figure 3.
Comparison of feeding tube sites in the usual care and ARRP groups.

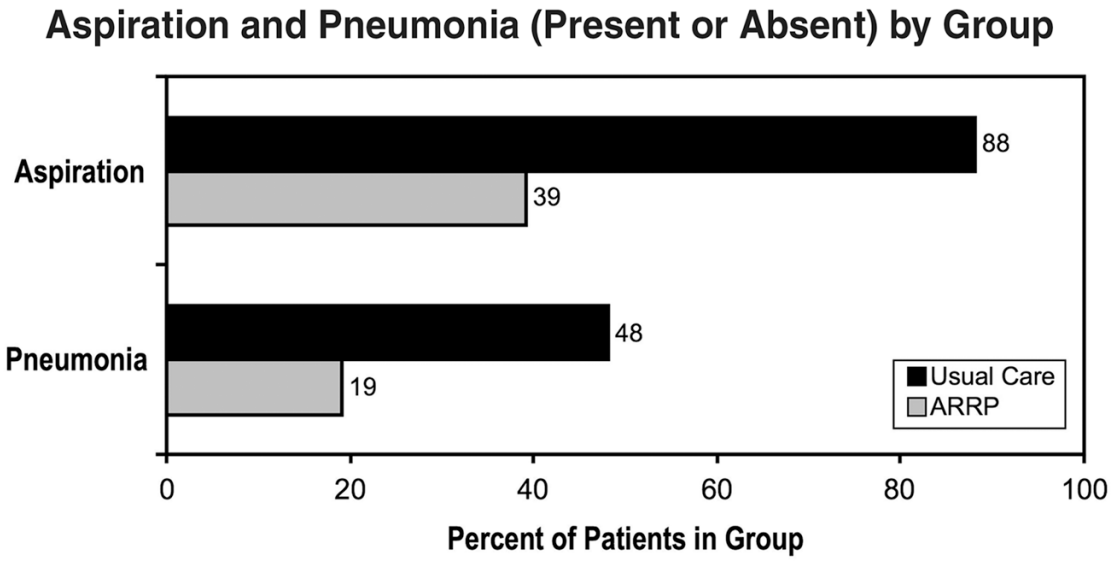

Figure 4.
Comparison of aspiration and pneumonia (present or absent) in the usual care and ARRP groups.

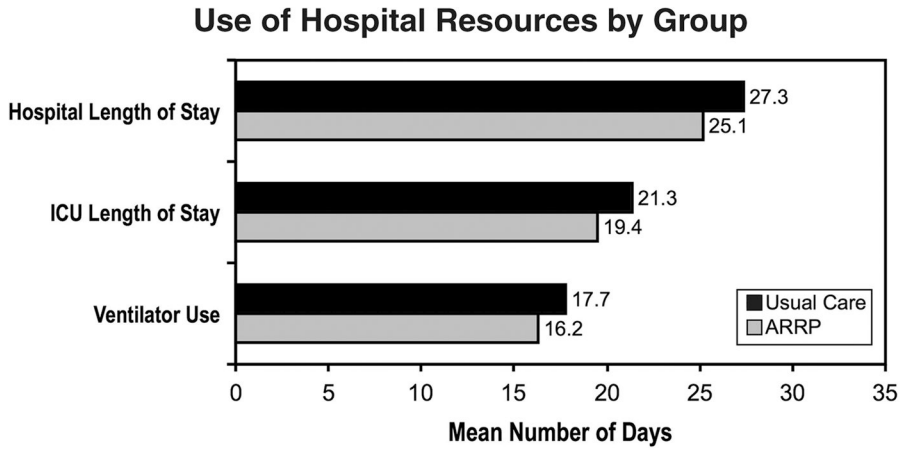

Figure 5.
Comparison of use of hospital resources by the usual care and ARRP groups.

Table 1

Description of Usual Care and Aspiration Risk Reduction Protocol Groups

Variable	Usual Care (*n* = 329)	ARRP Group (*n* = 145)
Age (in years)	52.5 ± 18.1	48.8 ± 17.8*
Gender		
Female	42.9%	35.2%
Male	57.1%	64.8%
APACHE II	22.7 ± 6.4	19.5 ± 5.7**
Service		
Neuromedicine/Neurosurgery	30.4%	33.2%
Trauma/Surgery	39.8%	44.8%
General Medicine/Pulmonary Medicine	29.8%	22.1%
Level of consciousness (Mean Glasgow Coma Scale Score)	7.0 ± 2.8	6.9 ± 2.2
Level of sedation (Mean Vancouver Interaction & Calmness Score)	35.7 ± 4.1	36.5 ± 4.1*
Feeding site		
Stomach throughout study	47.7%	27.6%**
Small bowel throughout study	40.7%	69.7%
Switch from stomach to small bowel	4.0%	0.0%
Switch from small bowel to stomach	7.6%	2.8%
Type of device during gastric feedings		
10 Fr polyurethane tube	47.1%	75.0%**
14–18 Fr polyvinyl chloride tube	52.9%	25.0%
Type of device during small bowel feedings		
10 Fr polyurethane tube	100%	100%
One or more gastric residual volumes ≥ 250 ml in gastric-fed patients	15.9%	7.5%
Vomited at least once	5.8%	5.5%
Mean backrest elevation (degrees)	23.7 ± 12.4	37.8 ± 9.1**
Mean percent backrest elevation ≥ 30 degrees	37.7%	88.4%**
Died during hospitalization	19%	14%

Note. ARRP = Aspiration Risk Reduction Protocol Group; APACHE II = Acute Physiology and Chronic Health Evaluation II

* $p = < .05$;

** $p = < .001$

Table 2

Patient Measurements, Scoring, and Frequency

Measurements	Scoring	Frequency
Aspiration of Gastric Contents (Pepsin immunoassay performed on tracheal secretions)	1 = present, 0 = absent	Each time patient is suctioned
Pneumonia (Simplified Clinical Pulmonary Infection Score; CPIS)	Range 0–10	Every 24 hours
	≥ 6 positive for pneumonia	Days 1, 2, 3, 4
Use of Hospital Resources		
Hospital length of stay		Time of discharge or death
ICU length of stay	Days	
Ventilator use		
Head-of-bed angle	Degrees (0–90)	Every hour
Feeding site		
Stomach		Time of initial x-ray and every 4 hours thereafter
First portion of duodenum		
Second & third portion duodenum		
Fourth portion of duodenum		
Proximal jejunum		
Level of consciousness (Glasgow Coma Scale)	Range 3–15	Every 4 hours
Level of sedation (Vancouver Interaction and Calmness Score)	Range 10–60	Every 4 hours
Gastric Residual Volume	Number ≥ 250 ml	Every 4 hours
APACHE II Score	0–71	At time of admission to ICU

Note. APACHE II = Acute Physiology and Chronic Health Evaluation II

Table 3

Simplified Clinical Pulmonary Infection Score (CPIS)

Component	Value	Points
Temperature (Centigrade, degrees)	≥ 36.5 and ≤ 38.4	0
	≥ 38.5 and ≤ 38.9	1
	≥ 39.9 and ≤ 36.0	2
Blood leukocytes per mm^3	≥ 4,000 and ≤ 11,000	0
	< 4,000 or > 11,000	1
Tracheal secretions	Few	0
	Moderate	1
	Large	2
	Purulent	+1
Oxygenation (PaO_2/FiO_2 mm Hg)	> 240 or presence of ARDS	0
	≤ 240 and absence of ARDS	2
Chest radiograph	No infiltrate	0
	Patchy or diffuse infiltrate	1
	Localized infiltrate	2

Note. ARDS = Acute respiratory distress syndrome; CPIS = Clinical Pulmonary Infection Score