IN VITRO COMPARISON OF GASTRIC ASPIRATE METHODS AND FEEDING

TUBE PROPERTIES ON THE QUANTITY AND RELIABILITY OF OBTAINED

ASPIRATE VOLUME

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ABSTRACT

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ASPIRATE VOLUME

Gastric residual volume (GRV) is a clinical assessment to evaluate gastric

emptying and enteral feeding tolerance. Factors such as the tube size, tube material, tube

port configuration, placement of the tube in the gastric fluid, the amount of fluid and

person completing the assessment may influence the accuracy of residual volume

assessment. Little attention has been paid to assessing the accuracy of GRV measurement

when the actual volume being aspirated is known, and no studies have compared the

accuracy in obtaining RV using the three different techniques reported in the literature

that are used to obtain aspirate in practice (syringe, suction, and gravity drainage).

This in vitro study evaluated three different methods for aspirating feeding

formula through two different tube sizes (10 Fr [small] and 18 Fr [large]), tube

materials (polyvinyl chloride and polyurethane), using four levels of nursing experience

(student, novice, experienced and expert) blinded to the five fixed fluid volumes of

feeding formula in a simulated stomach, to determine if the RV can be accurately

obtained. The study design consisted of a 3x2x2x4x5 completely randomized factorial

ANOVA (with a total of 240 cells) and 479 RV assessments were made by the four

nurse participants.

All three methods (syringe, suction and gravity) used to aspirate RV did not perform substantially well in aspirating fluid, and on average, the methods were able to aspirate about 50% of the volume available. The syringe and suction techniques were comparable and produced higher proportions of RVs, although the interrater reliability of RV assessment was better with the syringe method. The gravity technique generally performed poorly. Overall, the polyvinyl chloride material and smaller tubes were associated with higher RV assessments.

RV assessment is a variable assessment and the three methods did not perform well in this in vitro study. These findings should be further explored and confirmed using larger samples. This knowledge will be important in establishing the best technique for assessing RV to maximize EN delivery in practice and will contribute to future research to test strategies to optimize EN intake in critically ill patients.

Marsha L. Ellett, PhD, RN, Chair

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LIST OF ABBREVIATIONS

CCK   cholecystokinin
cP   centiPoise
EN   enteral nutrition
Fr   French size
GI   gastrointestinal
GRV   gastric residual volume
ICC   intraclass correlations
ICU   intensive care unit
IRB   Institutional Review Board
LR   likelihood ratios
MMC   migrating motor complex
NG   nasogastric tube
PVC   polyvinyl chloride
RV   residual volume
US   ultrasound

CHAPTER ONE

INTRODUCTION

Enteral nutrition (EN) delivery in critical illness is a common intervention as early initiation within the first 72 hours of critical illness reduces complications compared with parenteral nutrition or no nutritional support. Impaired gastrointestinal (GI) motility and delayed gastric emptying (gastroparesis) are common in critical illness, and the greater the severity of illness the more likely a patient is to experience delayed gastric emptying (McClave, Marsano, & Lukan, 2002b). Impaired gastric emptying increases gastric retention of EN and GI secretions as the frequency of contractions is decreased often leading to EN intolerance (Dive, Moulart, Jonard, Jamart, & Mahieu, 1994). Patients in the intensive care unit (ICU) are periodically evaluated for EN intolerance by aspirating stomach contents, including fed feeding formula, from the feeding tube. Any amount of fluid that remains in the stomach from the feeding, along with stomach secretions, is known as gastric residual volume (GRV). Although assessing GRV volume results in brief cessations of tube feedings, elevated GRV volume results in cessation of tube feedings for variable lengths of time, in which case the patient does not receive their prescribed caloric intake. The reliability of GRV volume assessment may be influenced by a number of factors such as tube size, tube material, the nurse performing the assessment, the volume available to aspirate, the method used to aspirate GRV, and placement of the tube in the gastric fluid pool.

McClave and co-investigators (1992) state that the measurement of GRV volume provides somewhat of a quantitative representation of gastric motility and gastric

emptying although these investigators believe the assessment is neither valid or reliable as a measure of gastric emptying nor as a measure to predict pulmonary aspiration.

While EN in critically ill is associated with positive patient outcomes, aspiration of large volumes of GRV is a feared complication. Nursing textbooks recommend that GRV between 200 mL and 500 mL should raise awareness and concern for aspiration, based on "The North American Summit on Aspiration in the Critically Ill Patient: Consensus Statement" (McClave et al., 2002a). Other guidelines indicate similar GRV threshold volumes, but feedings should not be held for GRVs less than 500 mL as patients who have EN held because of GRV do not receive their prescribed nutrition (McClave et al., 2009). There is no agreement, however, as to what volume of GRV represents delayed gastric emptying. Healthcare researchers and clinicians recognize the importance of providing EN within the first 24–48 hours after admission to the ICU (Doig, Heighes, Simpson, Sweetman, & Davies, 2009); however, research evidence is inconsistent in how to best assess GRV and how to interpret GRV in the provision of EN.

Investigators have studied a variety of threshold volumes to establish criteria for withholding EN when GRV is high, ranging from 50 mL up to 500 mL. One survey identified "high" GRVs ranged from 50 mL up to 400 mL (Marshall & West, 2006). Other investigators have suggested eliminating GRV measurement and attempted to establish that patients do not experience more adverse complications such as vomiting or ventilator associated pneumonia (Poulard et al., 2010) when GRV measurement is not used. These studies have been conducted in multiple sites across the world using a variety of protocols from clinical practice and a variety of different types of feeding tubes, with varying port configuration and varying methods for aspirating contents. Some sites use a

50 mL–60 mL syringe to aspirate GRV for measuring intolerance, while others use suction or gravity drainage. The lack of evidence with regard to the validity and reliability of GRV assessment may be influenced by several factors such as syringe size, tube caliber, tube material, and position of the tube in the gastric fluid pool when measurements are made. The controversy in establishing an efficacious GRV threshold for tolerance may partially be explained by these factors as well as variation in the measurement technique used to assess GRV (Metheny, Stewart, Neuetzel, Oliver, & Clouse, 2005).

Statement of the Problem

If GRV measurement will be retained as a measure of EN intolerance, then tube size, port configuration, and the material of which the tube is constructed needs to be further studied to determine how these factors might affect the accuracy of GRV measurements as well as the method used to obtain the aspirate. While these considerations have been studied, little attention has been paid to assessing the accuracy of GRV measurement when the actual volume being aspirated is known, and no studies have compared the accuracy in obtaining GRV using the three different techniques reported in the literature that are used to obtain aspirate in practice. Tube diameter and port configuration have been shown in vivo to be important variables in the measurement of GRV (Metheny et al., 2005). In addition, while aspirating stomach contents with a 50 mL–60 mL syringe is the most commonly reported and recommended practice for assessing GRV, a few other studies report using intermittent wall suction and gravity drainage as alternate methods for assessing GRV. The research conducted to date has been in vivo where the precise GRVs are unknown, and the method for aspirating and

assessing the GRVs are varied. Thus, it is important to explore the effect of feeding tube properties and methods for accurately measuring the assessment of residual volumes (RVs) in vitro to establish the scientific basis for measuring GRV before attempting to identify a specific GRV threshold for application in clinical practice.

Purpose of the Study

The purpose of this study was to evaluate how three methods for aspirating feeding formula (syringe, suction, and gravity), in conjunction with a variety of nasogastric (NG) tubes, in vitro, affect the proportion of aspirate that can be assessed to determine if GRV assessments can be accurately obtained.

Research Questions

This study addressed the following research questions:

1. Which technique for pulling on the syringe plunger (fast, intermittent, and slow) yields the largest quantity of RV in the assessment of aspirate?

2. Can the slow and intermittent syringe pull techniques be used interchangeably?

3. How do methods for aspirating GRV (syringe, suction and gravity), tube size (10 Fr and 18 Fr), tube material (polyvinyl chloride [PVC] and polyurethane), experience of the nurse (student, novice, experienced, and expert) and total volume available (50 mL, 150 mL, 300 mL, 500 mL, and 600 mL) influence the amount of aspirated feeding formula in an in vitro experimental trial?

4. What is the effect of tube size, tube material, and level of nurse experience on the proportion of assessed RV?

5. What is the effect of the four feeding tubes evaluated in this study and the level of nurse experience on the proportion of aspirated RV?

6. Is one method for aspirating RV (syringe, suction, or gravity) better than another in assessing the proportion of aspirated RV?

7. Is one tube better than another tube within each of the three methods (syringe, suction, and gravity) in assessing the proportion of aspirated RV?

8. What is the effect of volume on the proportion of aspirated RV?

9. How well does RV assessment identify measurements that would be considered intolerant to EN in practice?

10. Is there evidence of interrater reliability in RV assessment across the level of nurse experience when the nurses are treated as raters?

Definition of Terms

There are a number of terms that are important to clarify. These conceptual definitions and operational definitions are added for clarity and will be used throughout this study.

GRV—Volume of fluid removed from the stomach of patients receiving tube feedings. Measured in practice as an indicator of how well the stomach in emptying. GRV is measured in mL.

In vitro—In vitro is the experimental environment outside the living body. For the purpose of this study in vitro refers to experiments conducted in a laboratory to simulate the human stomach.

In vivo—In vivo is the environment inside the human body. For the purpose of this study, in vivo refers to invasive studies conducted on human subjects.

RV—The volume of fluid removed from the in vitro simulated stomach using either a syringe attached to the NG tube, suction connected to the end of the NG tube or drainage by gravity by connecting a drainage tube to the NG tube, measured in mLs.

Nurse rater—This is the nurse participant in this study representing one of the levels of practice experience.

Nursing student—A nursing student is a beginning nursing student who has completed a basic skills course with competency in NG tube management.

Novice nurse—A novice nurse is a nurse with less than three years of practice experience as a registered nurse in an intensive care setting.

Experienced nurse—An experienced nurse is defined as a nurse with more than three years of practice experience in an intensive care setting.

Expert nurse—An expert nurse is defined as a nurse with expertise in EN delivery either as a nutrition support nurse and/or a nurse who has published in the nutrition/EN literature.

CHAPTER TWO

REVIEW OF THE LITERATURE

The review of literature for this study focuses on three areas: (a) normal GI anatomy and physiology; (b) gastric motility, gastric emptying, and GRV assessment in patients with critical illness; and (c) the variables and techniques that affect the ability to accurately measure GRV. These variables include feeding tube properties (tube size, material, and port configuration), the position of the tube in the fluid pool as well as the variation in techniques reported in the literature to evaluate GRV. This last section will include a review of the literature that surrounds the value of GRV in assessing a patient's tolerance to EN.

Normal GI Anatomy and Physiology of the Stomach

An understanding of the normal GI anatomy and physiology is important because EN is provided via the GI tract and any dysfunction of the GI tract may delay gastric emptying and therefore increase GRV. The GI tract serves to supply the body with nutrients and fluid through digestion and absorption, remove waste through excretion, and provide host defense through intestinal bacteria and an intricate lymphoid system (Barrett, 2006). The anatomical structure of the GI tract that supports these functions consists of a long hollow muscular structure that runs from the mouth to the anus. The main portions of the GI tract include the esophagus, stomach, duodenum, jejunum, ileum, and colon. Accessory organs are connected to the GI tract to aid in the storage and secretion of enzymes necessary for digestion and absorption of nutrients. GI function relies on exogenous food and fluid to provide the body with nutrients; to facilitate nutrient intake, the GI tract requires functional secretory and motility abilities along the

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length of the tract. The anatomy and physiology relevant to understanding EN delivery is discussed in the following section.

GI Anatomy Relevant to Food Intake

Food normally enters the GI tract through the oral cavity of the mouth where chewing with the teeth helps to mechanically reduce the size of the food and saliva coats the surface of the food to help with swallowing. The food bolus is then moved from the oral cavity to the esophagus before entering the stomach. The esophagus is separated from the stomach by the esophageal sphincter that is controlled by neurogenic and hormonal factors as well as the diaphragm (Barrett, 2006). The pressure in the lower portion of the esophagus is higher than the pressure of the stomach to prevent reflux of stomach contents back into the esophagus. Once the food crosses the lower esophageal sphincter, it empties into the stomach. In EN, the NG tube is inserted via the nare into the stomach where it delivers EN.

Anatomy of the Stomach

The stomach is a J-shaped pouch located in the left side of the upper portion of the abdominal cavity that serves mainly as a reservoir for a meal and controls the rate of delivery of the meal to the lower intestines for absorption. The stomach consists of four sections (cardia, fundus, body [corpus], and pylorus) based on cellular differentiation, secretory function, and motility.

The proximal/orad region is differentiated in function, from the distal/caudad by its ability of accommodation (Weisbrodt, 2001). The proximal stomach is able to accommodate food and act as a reservoir through receptive relaxation, a vagally mediated reflex that functions to control the transfer of food from the proximal to the distal portion

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of the stomach (Vanden Berghe, Janssen, Kindt, Vos, & Tack, 2009). Control mechanisms for gastric accommodation are not fully understood; however, based on several animal and human studies, the mechanoreceptors in the gastric wall are thought to allow for gastric accommodation via vagovagal reflex pathways. Based on Currò, Ipavec, and Preziosi's review of the literature (2008), the neurotransmitters thought to be responsible for relaxation appear to be nitric oxide and vasoactive intestinal polypeptide. The distal portion of the stomach is involved in the mixing of the intragastric juices and the food bolus to create chyme. Both the proximal and distal areas of the stomach are responsible for gastric motility.

Physiology of the Stomach

      Myoelectrical activity and gastric innervation. The GI tract is regulated by external control through the autonomic nervous system as well as through an intrinsic system known as the enteric nervous system. The enteric nervous system consists of two plexuses: the submucosal and the myenteric. Neurons from these plexuses innervate the GI tract from the esophagus to the anus (Tortora & Derrickson, 2008). The neurons consist of motor neurons, interneurons and sensory neurons (Tortora & Derrickson, 2008). The muscularis mucosa is innervated by a plexus of nerve cell bodies known as the submucosal plexus. Sensory neurons are located in the mucosal epithelium and function as chemoreceptors and stretch receptors in response to luminal contents, such as gastric secretions and EN delivery (Tortora & Derrickson, 2008).

      The wall of the GI tract consists of four layers. The deepest layer that lines the lumen of the GI tract is the mucosa, followed by the submucosa, muscularis mucosa, and the outer most layer, the serosa. The muscularis portion contains the smooth muscle

layers, the longitudinal and circular layers that modulate gut motility. The longitudinal

and circular muscle layers are supplied by the motor neurons of the myenteric plexus that

work to control the motility of the muscularis. These layers act to reduce the diameter of

the GI tract during contraction of the smooth muscle through interneurons to provide the

motility patterns necessary for gut motility.

Gastric motility. GI motility is controlled by neural and humoral influences

(Chapman, Nguyen, & Fraser, 2007). The three primary motor functions of the GI tract

are to mix and propel food particles to allow for absorption of nutrition, clean the GI tract

of residual food and bacteria and enable mass movement (Ukleja, 2010). The motor

activity of the GI tract is differentiated by the fasting and fed states and is influenced by

an electrical rhythm known as the migrating motor complex (MMC). The MMC serves to

sweep the GI tract of food residue and bacteria in the interdigestive period, which is why

it is known as the "housekeeper" (Appleyard, 2010; Johnson, 2001). The MMC is

initiated with gastric emptying either in the stomach or duodenum, migrates along the GI

tract from the small intestines to the distal ileum and takes approximately 1.5–2 hours to

span the small bowel (Miedema et al., 2002; Miedema, Schwab, Burgess, Simmons, &

Metzler, 2001). The MMC can be divided into three phases: phase I, motor quiescence;

phase II, intermittent activity; and phase III, maximal motor activity propagated by slow

wave frequencies (Bornstein, Furness, Kunzee, & Bertrand, 2002). In healthy individuals,

the MMC is abolished and replaced by random motor activity when feeding is delivered

into the stomach or small bowel (Miedema et al., 2001).

There are three types of contractions that function to mix and propel food boluses

in the gut; these include rhythmic phasic contractions, ultra propulsive contractions and

tone (Schuster, Crowell, & Kock, 2002). When these propulsions are slowed, motility

does not propel food and fluid forward into the GI tract and can lead to gastric retention.

The smooth muscle activity of the stomach is affected by an underlying rhythm of slow

waves that occurs as regular oscillations in the membrane potential, originating from

specialized groups of cells known as the interstitial cells of Cajal (Chapman et al., 2007).

The interstitial cells of Cajal provides a pathway for electrical transmission of slow

waves and serves as the pacemaker for the GI tract as slow waves determine the

frequency of smooth muscle contractions (Fruhwald, Holzer, & Metzler, 2007). The

smooth muscle cells have a coupled arrangement, leading to simultaneous and

synchronous circular muscle slow waves. Neural and humoral inputs dictate whether the

fluctuations in resting membrane potential lead to initiation of mechanical contraction

(Chapman et al., 2007). Electrical coupling results from gap junctions that have a low

resistance to cell to cell excitation (Schuster et al., 2002; Weisbrodt, 2001). Propulsion of

contractions and the regulation of ingested mixing depends upon the frequency,

amplitude, duration, and direction of propagating contractions (Schuster et al., 2002).

Slow waves result in higher frequency cell propagation in the proximal cell to the most

distal cell. Thus the slow waves move circumferentially giving an appearance of a ring

like contraction moving superiorly to distally in the stomach (Schuster et al., 2002).

When food enters the stomach, the proximal stomach experiences slow sustained

contractions, that last 1–6 minutes (Appleyard, 2010). The stomach distends in response

to food intake, and then the proximal stomach forces the contents to the distal stomach.

The contractions in the distal stomach are more powerful forcing the contents against the

pylorus. The pylorus only allows a small amount of fluid to enter the duodenum at a time,

so the majority of the contents are sent backwards into the stomach; this serves to mix the chyme with digestive enzymes. The pyloric sphincter is under the influence of neurohormonal regulation to allow a maximum delivery rate of 2–3 kcal/min that regulates the transfer of chyme to the duodenum (Brener, Hendrix, & McHugh, 1983). The transfer of food from the stomach to the duodenum (gastric emptying) is a complex process influenced by a series of negative feedback loops to be discussed later.

Normal gastric volume. The adult GI tract may produce approximately five to six liters of gastric secretions daily that are reabsorbed in the lower GI tract with about 50 mL excreted in the feces (Edwards & Metheny, 2000). It has been estimated that in the normally fed adult, a volume of 188 mL per hour is present in the stomach, when the estimated daily salivary output of 1,500 mL is combined with 3,000 mL of gastric secretions (Lin & Van Citters, 1997). Normal GI motility allows peristaltic activity to move secretions and semi-digested food particles in a caudal direction into the duodenum at a rate that allows for intestinal absorption. The amount of fluid present in the stomach depends on the amount being instilled into the stomach, the volume of gastric and salivary secretions and the emptying of the stomach into the duodenum. The empty human stomach may have a volume as small as 50 mL and at full capacity, the stomach can accommodate up to 1.5 liter of food (Appleyard, 2010). Despite the ability to accommodate large volumes of food/fluid, the stomach experiences little change in intragastric pressure. The stomach undergoes receptive relaxation, a vagally mediated process that allows the volume to increase in the stomach without raising intraluminal pressure.

Normal gastric emptying results in coordination of contractions between the stomach, pylorus and proximal small intestine (Johnson, 2001). The movement of chyme out of the stomach (gastric emptying) occurs gradually over time. The rate of gastric emptying differs between liquids and solids, with liquids emptying faster than solids (Appleyard, 2010). When gastric motility is optimal, gastric emptying occurs in a linear fashion. The stomach is the smallest during fasting conditions and even under fasting conditions, the healthy individual may have residual fluid present in the stomach. McClave et al. (1992) reported that in healthy volunteers, 90% of the time RV were less than 10 mL when obtained with a 60-mL leur lock syringe in fasting conditions. In comparison, they also found in their critical care patients ($n = 10$), medical patients ($n = 8$), and healthy volunteers ($n = 20$), fasting RVs ranged from 10 mL to 100 mL (McClave et al., 1992); however, this volume may increase more when dysmotility is present which presumably can be aspirated to assess for how much volume is present in the stomach.

Normal gastric emptying. Multiple factors influence the GI emptying rate. Gastric emptying is impacted by intestinal absorption and a variety of negative feedback loops from the GI tract to the stomach. One of these negative feedback loops occurs when cholecystokinin (CCK) is secreted by I cells in the duodenum and proximal jejenum. In this response, CCK helps absorption in the small intestine and also facilitates pancreatic secretions that catalyze digestion of fat, protein and carbohydrate (Asai, 2007); however, this also reduces gastric emptying into the duodenum. Other hormones having an inhibitory effect on gastric emptying include amylin, glucagon and glucagon like peptide-1 that are released when food enters the proximal intestine (Ukleja, 2010).

Gastric motility and gastric emptying in critical illness. In the critically ill

patient, GI dysfunction spans all parts of the GI tract to include the esophagus, proximal

and distal stomach and the intestines that may impair EN delivery (Chapman et al.,

2007). Motility disturbances can lead to delayed gastric emptying and prolonged small

intestinal emptying, impeding EN delivery and affecting anywhere from 45%–80% of

critically ill patients (Heyland, Tougas, King, & Cook, 1996; Montejo, 1999; Ritz et al.,

2001, Tarling et al., 1997). Patients at risk for delayed gastric motility include patients

with diabetes, recent trauma, burns or surgery, sepsis, electrolyte abnormalities, and those

receiving medications such as narcotic analgesics (Chapman et al., 2007; Edwards &

Metheny, 2000); this represents a majority of those cared for in an ICU. Other motility

disturbances seen in the critically ill may be related to shock, inflammatory cytokines,

electrolyte abnormalities, hyperglycemia, medications, and disease (Ukleja, 2010).

Röhm, Boldt, and Piper (2009) described the pathophysiological disturbances and

clinical systems associated with motility disturbances spanning the entire GI tract.

Reduction in the frequency and amplitude of contractions in the esophagus are associated

with regurgitation, and low or absent pressure in the lower esophageal sphincter is

associated with reflux of gastric contents. In the stomach increased pyloric activity and

antral hypomotility are associated with higher GRVs and gastroparesis (Röhm et al.,

2009). Motility disturbances have been described in the critically ill patient that appears

to effect antral contractions and loss of phase III gastric activity possibly influenced by

sedation (Dive, Foret, Jamart, Bulpa, & Installé, 2000). The fundus of the stomach may

also be affected (Fraser & Bryant, 2010). The loss of interstitial cells of Cajal may be

etiologically responsible for some human GI motility disorders, and interstitial cells of

Cajal may also be diminished in response to inflammation (Sanders, 2006). In post-aortic surgery patients, the origin of migrating motor complex patterns in the duodenum results in prolonged small bowel transit leading to longer times for defecation (Miedema et al., 2002). Inhibitory hormone secretions might be responsible for motility disturbances. Nguyen and colleagues (2007a) demonstrated that plasma CCK levels increase in critical illness and the CCK levels were higher in critically ill patients with feeding intolerance ($n = 14$) compared with those feeding tolerant ($n = 9$ critically ill; $n = 28$ healthy subjects, $p < .01$), although the cause or mechanism is not fully understood. Asai (2007) hypothesizes that the increasing concentration of CCK might act to limit food intake. The exact mechanisms underlying delayed gastric motility in critically ill patients are not known, and the ability to measure and evaluate gastric motility and emptying in these patients is difficult.

GRV Assessment in Critical Illness

Clinicians assess GRV at regular intervals to help monitor feeding tolerance in an attempt to prevent aspiration of stomach contents. The assumption guiding the use of GRV is that a high GRV represents delayed gastric emptying; however, this relationship is weak (Zaloga, 2005). There are multiple factors that may effect this relationship including feeding tube properties (tube size, material, and port configuration), and the position of the tube in the fluid pool. The most common approach to remove aspirate is to use a syringe, but a few studies have reported using suction and draining the stomach contents by gravity. These factors will be discussed along with other methods available to assess gastric emptying.

The most frequently reported assessment to evaluate gastric emptying and tolerance of EN in the critically ill patient is the measurement of gastric aspirate, also known as GRV. The gastric aspirate contains a mixture of saliva, gastric secretions and residual feeding formula and possibly duodenal reflux. The assessment technique can generally be easily performed at the bedside. The American Society for Parenteral and Enteral Nutrition's (A.S.P.E.N.) "Enteral Nutrition Practice Recommendations" indicate that GRV should be assessed every four hours in critically ill adult patients (McClave et al., 2009). The timing of the assessment varies and may occur every four to eight hours depending on patient tolerance and assessment findings (Edwards & Metheny, 2000; Guenter, Ericson, & Jones, 1997). GRVs tend to be higher in the first 72 hours after EN initiation so investigators suggest that it might be appropriate to stop checking GRVs, if the GRVs are low in the first 48–72 hours of successful feedings (Johnson, 2009).

The most common method to aspirate stomach contents is to stop the infusion of EN and assess gastric aspirate with a syringe. When checking GRV, 20 mL of air is first injected into the tube via the syringe to clear the tube of any secretions and to move the ports away from the mucosal folds (Metheny, Reed, Worseck, & Clark, 1993). Metheny and colleagues reported that the 30 mL syringe was important in the air injection process as manufacturers of the small bore tubes suggested this syringe size to prevent rupture of the tubes from the amount of force applied. Using this technique, in 93.8% of attempts, researchers were able to withdraw aspirate from tubes in volumes sufficient to check the pH of the aspirates. A 50 mL–60 mL syringe is indicated to prevent tube collapse in aspirating residuals (Kirby, DeLegge, & Fleming, 1995), but some references support using a 30 mL syringe to aspirate stomach contents (Pullen, 2004; Zaloga, 2005).

Variables and Factors that Affect the Ability to Accurately Measure GRV

Tube Sizes

Part of the variability in the measurement of GRV might be explained by differences in the type of tubes and the port configuration of the tubes. Most often tubes sized 12 Fr and smaller are considered small bore, while larger than a size 12 Fr is a large bore tube (Lord, 1997; Metheny et al., 2005). While these sizes refer to the outer diameter of the tube, the internal diameters of the small bore tubes are much smaller ranging from 3 F to 8.5 F (Lord, 1997). The diameter of the tube may affect the quantity of aspirate (Metheny, 2006); small-diameter (bore) tubes may underestimate GRV (Metheny et al., 2005).

While feeding tube sizes range in various Fr sizes, representing variation in lumen size, there is intra-tube variation that may influence the flow rate and thus the rate of speed with which the fluid can be aspirated within and across feeding tube sizes. Fluid dynamics or the study of fluids in motion may inform what occurs during the aspiration of fluids through a feeding tube and explain the effect of pulling on the syringe to aspirate fluids. Tube lumen sizes, variation and duration of the pulling on the syringe plunger might affect whether the clinician is successful in aspirating contents. Longer tubes and larger internal diameters may require more force in order to successfully aspirate contents from the proximal end of the tube. However, it is unknown how much force needs to be applied to the plunger over what period of time to aspirate a known volume of fluid.

Tube Materials

Nursing textbooks at least over the last 30 years have advocated GRV measurement. Investigators began reporting difficulty in obtaining aspirates in the 1980s

after commercially available feeding tubes were made in smaller bore sizes to prevent skin complications from the tubes. Prior to that time, the larger tubes were associated with problems like tissue irritation and esophageal sphincter incompetence (Rassias, Ball, & Corwin, 1998), so more pliable tubes were introduced to the market. These new smaller bore tubes were made of silicone rubber and polyurethane but had reports of difficulty in aspirating from the tube because the tube material was so pliable. The larger tubes were made of plastic, like PVC and did not tend to collapse. Small bore tubes are better for providing EN as they minimize discomfort to the patient and do not compromise the lower esophageal sphincter to the extent of larger bore tubes (Metheny, 2006).

There is concern that small-bore tubes are associated with clogging and collapsibility during the aspiration of GRVs (Crocker, Krey, & Steffee, 1981; McClave & Snider, 2002; Metheny, Spies, Eisenburg, Messer, & Hanson, 1988); these complications would interrupt tube feedings. O'Meara et al. (2008) found that GRVs from both small bore tubes and orogastric decompression tubes led to feeding interruptions for a mean of 495 minutes CI [354.67, 636.30] or 8 hours and 15 minutes across the 10-day study period, although the biggest reason for feeding interruptions in this study was related to the small bore tubes being either clogged or absent. In a descriptive pilot study, nurses self-reported that they were successful 45% of the time in trying to aspirate at least 5 mL of fluid from small-bore (8 Fr) tubes made of silicone and polyurethane while they were able to aspirate fluid 79% of the time from large bore tubes made of PVC (Metheny et al., 1988).

Measured GRVs may be greater in larger feeding tubes due to the material of the tube being stronger, but it also may be related to the diameter of the tube. Metheny and colleagues (2005) addressed these concerns in their study comparing the gastric contents obtained from small and large diameter tubes concurrently positioned in the stomachs of 62 critically ill patients and found that mean volume of aspirate was two times higher from larger tubes (14 Fr–18 Fr) compared to smaller diameter tubes (10 Fr). In this study, GRVs were aspirated from the smaller bore tube then returned to the stomach and aspirated from the larger bore tubes. The 10 Fr tube used in this study was constructed from polyurethane with 3 oval ports concentrically located 4 cm above the distal end of the tube. The large diameter PVC tubes used in this study both had five ports on one side and six on the other side, and the ports spanned 7 cm from the distal end of the tube. Metheny and investigators (2005) reported that the GRVs were about 1.5 times greater ($p < .001$) in 14 Fr and 18 Fr sump tubes as compared with smaller 10 Fr tubes. The larger bore tubes yielded significantly higher volumes of aspirate; thus, there is the potential that smaller-diameter tubes underestimate the actual volume of gastric contents. This was the first published study that explored differences in tube properties on the amount of GRV obtained; however, this study was conducted in vivo, and there was no way to know the true volume of gastric contents in the stomach at the time of aspiration. Thus, it is unknown what true effect the tube size and tube properties played in the aspiration of gastric contents.

Tube Port Configuration

Feeding tube measurement of GRV may be difficult because the tube ports may be above the gastric fluid pool or it may be that little fluid actually is present in the

stomach. When GRV is assessed with a syringe, the syringe connected to the proximal end of the feeding tube removes air from the tube, creating a partial vacuum within it. This negative air pressure allows the fluid to be aspirated up through the tube. In order for the fluid in the gastric pool to be pulled into the feeding tube, the air in the feeding tube must be removed first and then the fluid will be drawn upwards. As the syringe removes air from the tube, the pressure above the gastric pool within the tube is reduced. The greater air pressure outside the tube pushes the gastric pool contents up the tube. However, the ability to aspirate fluids is based on all of the following factors:

- location of the ports in the gastric pool,

- placement of the ports on the tube in relation to the gastric pool, and

- coiling/noncoiling of the tube with regard to factors 1 and 2.

These factors that influence the ability to aspirate fluid from the feeding tube were demonstrated in a preliminary laboratory study (Bartlett Ellis, 2011) conducted by the co-investigator to apply the principles of physics. In this experiment, a 10 Fr salem sump tube, with 11 circumferentially placed ports, was submerged in a quart of water; each port was aligned across from another on either side of the radiopaque line from the distal end and the most proximal port was positioned directly on the radiopaque line. In the first part of this experiment, all of the ports were submerged completely in the water. A 60 mL syringe was connected to the proximal end of the tube and the plunger was pulled in order to aspirate fluids. Once the air was removed from the tube, the water flowed freely into the syringe. Following this experiment, the tube was pulled back in the container of water to expose one port to the air, while keeping the remaining ports submerged in water. The syringe plunger was pulled again; however, only air could be aspirated from

the tube even though 10 of the 11 ports were submerged in the water. In the last experiment, the tube was submerged in the water; however, the natural coiling of the tube was allowed in which the middle and proximal ports ($n = 7$) were under water and the most distal ports stuck up out of the fluid pool. In this design, when the syringe plunger was pulled, fluid was aspirated into the syringe chamber.

These experiments demonstrate that increasing the number of ports on the tube does not increase the probability of aspirating fluids; however, increasing the number of ports may increase the likelihood of the ports coming in contact with the fluid pool (Metheny et al., 2005), although the ability to utilize the port to aspirate fluid relies on the relationship between the port and the air in the proximal portion of the tube. The increased probability only occurs when the more proximal ports on the tube are in direct contact with the fluid pool. Smaller bore tubes are more likely to migrate from their position within the stomach or occlude (de Aguilar-Nascimento & Kudsk, 2007), limiting the ability to aspirate contents consistently from the same location in the stomach. Additionally, weighting of the tube, in which the distal end of the tube is pulled in a downward direction, may not be effective in improving the likelihood of aspirating contents as all of the proximal ports from the fluid pool up the tube must be submerged in order to aspirate the fluid pool in which the tube lies (Bartlett Ellis, 2011; McClave & Snider, 2002; Metheny, Reed, Worseck, & Clark, 1993).

Nursing Practice

The assessment of GRV may be influenced by the consistency and reliability across the nurses performing the assessment. To date, there are no known studies that have assessed interrater reliability in performing GRV assessment across nurses and level

of experience. However, studies have reported a lack of standardization in the protocols and decisions made while aspirating GRV. Metheny et al. (1988) collected data from nurses to investigate the reliability of GRV assessment using a syringe method by asking the nurses their perception of adequacy in obtaining GRV using large and small bore tubes. Practice experience was not considered in this investigation, nor was interrater reliability in the assessment of GRV. In this descriptive study, nurses reported that they were able to adequately assess GRV 90% of the time using the larger bore tubes compared with on adequate assessments 48% of the time using an 8 Fr sized tube.

Two more recent investigations have explored variability in nursing practice, but the focus of these studies was on how often nurses checked GRV, frequency of physicians orders to assess GRV and documentation and decisions related to holding GRV for high volumes (Ahmad, Le, Kaitha, Morton, & Ali, 2012; Bollineni & Minocha, 2011). Again, these studies did not address practice experience. Given that there is a wide variety of nurse practice experience ranging from the student nurse to the expert nurse, these factors should be considered as well as to how they might affect the assessment of GRV. Specifically, nursing experience and interrater reliability with regard to the variability in GRV assessments related to nursing experience is unknown.

Fluid Properties

The physical properties of the fluid present in the stomach may influence how much GRV can be aspirated. The thicker the fluid, also known as viscosity, the more difficult it becomes to aspirate through a tube. In physics, the viscosity of the fluid and the radius of the tube through which it flows influence the laminar flow of fluid. The influence of the radius of the tube on fluid flow is described in Poiseuille's law.

Poiseulle's law states that the laminar flow rate of an incompressible fluid along a pipe is proportional to the pipe's radius to the fourth power (Cutnell & Johnson, 2009; Tipler & Mosca, 2008). The force necessary to aspirate fluids from the distal end of the tube, known as pressure 2 (p2), up to the connected syringe, known as pressure 1 (p1), is equal to the difference in pressures at the ends of the tube (p1- p2) that can be found by using Poiseuille's law. Applying Poiseuille's Law, we find that the amount of fluid volume flow will quadruple when the tube radius is doubled, such as might occur at about the 50 cm mark on the tube.

Poiseuille's law indicates that a fluid with viscosity η, flowing through a pipe, or in this case a tube, with radius R and length L will have a flow rate Q given by: $Q = \frac{\pi R^4 (P_2 - P_1)}{8\eta L}$

Poiseuille's law is valid if the fluid flow remains laminar. To understand the physical properties of laminar flow, the fluid in the feeding tube can be thought of as thin horizontal layers, each with uniformly changing velocities that move together, known as laminar flow. Laminar flow is smooth and the fluid forms layers that remain together as it flows. If the layers of fluid break up, the fluid becomes turbulent. Turbulence can occur when fluid flows at high speeds. Laminar flow can be determined experimentally using Reynold's number (Re), which is defined as the ratio of the inertia force on an element of fluid to the viscous force. Flows with large Reynolds numbers, especially with high velocity and/or low viscosity, tend to be turbulent; whereas, fluids with high viscosity and/or low velocities have low Re numbers and tend to be laminar. If Re is less than 2000, the fluid is flowing in laminar flow and the fluid flow will be predictable,

indicating that the pressure of the fluid can be determined using Poiseuille's law

(Cutnell & Johnson, 2009; Tipler & Mosca, 2008).

Fluid viscosity. Feeding formula viscosity at room temperature varies by product. Thin liquids range from 1–50 centiPoise (cP; a standard unit of measure for viscosity; Abbott Nutrition, 2009) to nectar-like consistency 51–350 cP. Viscosity decreases with higher temperatures and increases when pH decreases (Hofsteter & Allen, 1992). Viscosity is important because it changes the velocity with which fluid moves, such as the fluid that is aspirated from a feeding tube. Studies have investigated viscosity and flow rate through gravity drainage. In a study comparing three polyurethane tubes with different calibers (8, 10, and 12 Fr) and one nasojejuneal tube, Casas-Augustench and Salas-Salvado (2009) demonstrated that higher viscosity formulas took longer to infuse by gravity drainage in vitro and the larger the tube caliber the faster the flow. In these studies, viscosity was measured using a viscometer; however, formula manufacturers do not report a quantitative measure of viscosity. Manufacturers report a qualitative description of the formula consistency.

Volume flow rate. In physics, the volume flow rate is inversely proportional to viscosity of the fluid and higher viscosity fluids do not flow as readily as lower viscosity fluids (Cutnell & Johnson, 2009). The viscous fluid flow has a slower velocity at the surface of the inner tube wall where the speed of the fluid is zero, and it increases to a maximum along the center axis of the tube (Cutnell & Johnson, 2009). The more viscous the fluid, the larger the force is needed to move the fluid. The amount of force required to move the fluid with constant velocity depends on the following factors:

- Larger areas A, require larger forces, where the force is proportional to the contact area (F ∞ A).

- Greater speeds require larger forces; the force is proportional to the speed (F ∞ v).

- The larger the distance y, the smaller the force required to achieve a given speed.

- The force is inversely proportional to the perpendicular distance between the top fluid layer and bottom fluid layer (F ∞ Av / y).

- The larger the viscosity of the fluid, the larger the force that needs to be applied.

Thus the force needed to move a layer of viscous fluid with constant velocity can be described as the magnitude of the tangential force F required to move a fluid layer at a constant speed v, when the layer has an area A and is located at a perpendicular distance y from an immobile surface, given in the equation: $F = \dfrac{nAv}{y}$

Methods Used for Aspirating GRVs

There are three methods identified in the literature that are used in practice to assess GRV: (a) syringe method, (b) suction method, and (c,) gravity drainage method. Each of the methods is described separately along with the relevant literature.

Syringe Method Technique

The use of a syringe to aspirate GRV is a blind method, meaning that the actual volume of GRV present is unknown. In order to draw up residual into the tube, negative pressure is applied by pulling back on the plunger of the syringe. A hard quick pull is unlikely to yield any residual and often when this is done in practice, the nurse

determines no residual is present. A hard quick pull may cause the tube to collapse. The ability to withdraw fluid from the tube may be time intensive. The technique used to aspirate GRV using a syringe influences the amount of aspirate obtainable. In response to Metheny and colleagues (2008), one practicing nurse noted that a slow and gentle aspiration with reinstallation each time vacuum lock was felt was more effective in obtaining aspirate compared with a quick hard pull on the syringe plunger (Stambovsky, 2009). Metheny responded that a steady slow method was used for aspirating residuals in her studies.

Suction Method Technique

While the syringe method is the most common method for assessing GRV, there a few reports that described using suction. Zaloga (2005), reported that he informally studied the accuracy of assessing GRV using the syringe method for aspirating contents compared with continuous suction in small bore feeding tubes (10 Fr) versus the standard feeding tube (16 Fr) using a 30 mL syringe and a small sample of eight patients per feeding tube size group. These aspirates were measured then re-instilled and suctioned at a continuous rate for five minutes was applied while the patient was rolled from side to side. Zaloga did not report the amount of suction (mm Hg) nor the procedure for using suction. The results of this study demonstrated that neither tube (10 Fr 108 ± 35 mL versus 16 Fr 137 ± 20 mL) was very accurate in measurement when compared with the continuous suction for five minutes (10 Fr 165 ± 27 mL versus 16 Fr 156 ± 28 mL). This difference suggests that suction might remove more aspirate than the syringe technique. Zaloga concluded that the aspirations were underestimated with the syringe technique when using a 30 mL syringe. Additionally, this same author also indicated that he had

experience with nurses in Washington who used continuous suction to assess GRVs

rather than the syringe technique. In this practice setting, nurses attached a suction

canister to the feeding tube and aspirated contents slowly over 15 minutes (McClave &

Snider, 2002). There were no details reported about suction pressure settings used in this

procedure.

Gravity Drainage Method Technique

The most recent randomized controlled trial comparing the effects of an increased

GRV limit on the adequacy of EN intake and frequency of complications reported using

two different methods for assessing GRVs, the traditional syringe method and gravity

drainage. This multicenter study was conducted in 28 ICUs in Spain (Montejo et al.,

2010). In this study, critically ill ventilated adult patients were randomized to either a 200

mL ($n = 165$) threshold or a 500 mL ($n = 157$) threshold to determine feeding intolerance.

GRV was measured in varying intervals, starting with every six hours the first day, then

every eight hours the second day, and then daily after the second day if the patient was

tolerating feedings. Two different methods for GRV measurement were used, based on

the routine practice of the investigating centers. The first method used a gravity drainage

system for 10 minutes and the second method used a 50 mL syringe to aspirate GRV

directly from the tube. No attempt was made to control for patient position at the time of

the GRV; however, patients were managed in the semi-recumbent position ranging from

35–40 degrees. There was no significant difference in the methods used to obtain GRV in

the two threshold groups (200 mL and 500 mL), and the effect of the two methods used

on the amount of GRV obtained was not reported. Tube diameters reported in this study

included less than 8 Fr, 8 Fr, 10 Fr, 12 Fr, and greater than 12 Fr, although there was no

significant difference in the tube caliber between the two study groups. Patients in the

200 mL threshold group had higher frequencies of GI complications due to high GRVs;

whereas the first week, the mean GRV was higher in the 500 mL threshold group. There

was no difference in patient outcomes between the two groups (ICU mortality $p =.28$,

hospital mortality $p = .53$), and there was no significant difference in vomiting,

regurgitation, aspiration or ventilator-associated pneumonia. While there were no

significant differences reported in the GRVs obtained from the two different methods,

these two methods are worthy of exploring more to determine if the method for aspirating

GRV affects the accuracy of the GRV assessment.

The results from these few studies suggest that suctioning the stomach may

produce greater volumes of tube aspirates compared with the syringe technique.

However, these results have not been validated nor have similar findings been reported

elsewhere. Additionally, the effect of gravity drainage on the volume of aspirates

obtained is unknown as well. The frequent monitoring of tolerance is critical to prevent

complications, so it is important to study methods that might facilitate better assessment

of GRV and ultimately patient tolerance of EN.

<p align="center">**Methods for Assessing Gastric Emptying**</p>

Alternative methods to evaluate gastric emptying are available. Each of these

methods will be described and the feasibility of applying these techniques to the

monitoring of EN in the ICU will be discussed.

Scintigraphy

The gold standard for assessment of gastric emptying is scintigraphy that records

gastric emptying by a gamma-scintillation camera following ingestion of an isotope

labeled test meal (Moreira & McQuiggan, 2009). The results of this study are generally reported as the time required to empty half of the isotope (T½). Gastric emptying scintigraphy provides a more accurate picture of gastric emptying when done on an empty stomach and is often performed in the morning following fasting (Maurer, Parkman, Knight, & Fisher, 2002). There are significant limitations with scintigraphy that prevent its frequent use. First, this is a very costly procedure that uses sophisticated equipment and specially trained personnel; therefore, it has limited use in frequent assessment of gastric emptying such as the assessments required in critically ill patients. Additionally, because there is significant delayed gastric emptying in the critically ill, the half emptying times may be time intensive and not feasible to report. Nguyen et al. (2008) used scintigraphy to assess gastric emptying in critically ill patients and were unable to report emptying time because 9 of the 28 patients did not reach T½ during the four-hour study period. In addition, this procedure exposes the patient to ionizing radiation, so it should not be performed repeatedly and requires the patient be transported out of the ICU. This test is more useful for diagnostic purposes on a limited basis and should be reserved for functional bowel problems. Therefore, it probably is the least likely method to have clinical usefulness in assessing for EN tube feeding tolerance at the bedside.

Paracetamol Absorption Test

Paracetamol has been used to assess gastric emptying because paracetamol is absorbed in the duodenum. Paracetamol can be detected in blood plasma; therefore, it can be used as an indirect marker of gastric emptying. This test requires a dose of 1–2 g of paracetamol be diluted in water and administered through the feeding tube. The tube is

then clamped and blood draws are performed at regular intervals. The results are plotted as the area under the paracetamol concentration curve. This test is limited in the ICU because it has the potential for hepatoxicity so it should not be used in patients with hepatic dysfunction or in malnutrished patients (Moreira & McQuiggan, 2009) and because it requires the tube to be clamped and feedings withheld, it reduces the patient's EN intake. The paracetamol absorption test has been studied in the critically ill. Landzinski, Kiser, Fish, Wishmeyer, and MacLaren (2008) studied two groups of critically ill patients to compare their gastric empting rates using paracetamol emptying curves. This heterogeneous population of medical, surgical and neurological patients were selected based on whether they were tolerant (feeding rate supplying 75% of calories, and 24 hour cumulative GRV less than 120 mL) compared with those who were labeled intolerant, defined as a single GRV greater than 150 mL within a 24-hour period. All patients in this study had a 10 Fr tube. These patients had already been receiving EN for up to three days when they were enrolled in the study. The intolerant group had significantly higher cumulative GRVs in the 24 hours prior to starting the paracetamol (620.6 ± 233.6 mL) compared with the tolerant group (55.6 ± 55.9 mL). This study found that those in the intolerant group, noted by elevated GRVs, despite being within their target caloric intake range, also had significantly slower gastric emptying rates. With the use of prokinetic therapy, the emptying rates aligned more with the tolerant group.

Tarling and colleagues (1997) also used the paracetamol absorption test in medical and surgical patients ($n = 27$) to assess gastric emptying. These investigators used a gastric tonometer to assess the gastric mucosal pH (pHi), a marker of splanchnic blood flow and perfusion of the gastric mucosa. This study did not find a correlation

between GRV and gastric emptying times nor a correlation between pHi and the APACHE II score for the 24 hours prior to the study. The authors suggest that the study sample was relatively uncomplicated with regard to the severity of illness, such that they were unlikely to have experienced gut hypoperfusion. The APACHE score on admission was used to calculate a rate of death score. The rate of death was associated with faster gastric emptying times, but the APACHE score calculated in the 24 hours prior to the study was not related to gastric emptying rate. The authors suggested that this difference may have been a result of various medication therapies, received in the 24 hours prior rather than related to physiological factors. If this is the case, medication therapies warrant further investigation and may be a possible explanation for the varying GRVs found in the study.

Stable Isotope Breath Test

The stable isotope breath test is a relatively new test that uses stable isotopes and does not expose the patient to irradiation. ^{13}C-octanoic acid is a medium chain fatty acid that can be rapidly absorbed in the duodenum and is metabolized by the liver. This process was originally reported by Ghoos et al. in 1993 (Galmiche, Delbende, Perri, & Andriulli, 1998). The process of oxidation releases CO_2 that can be measured in the breath using isotope ratio mass spectrometry. A gastric emptying coefficient is calculated for the gastric emptying rate based on the appearance and disappearance of the isotope, and gastric half emptying time is determined using the area under the $^{13}CO_2$ curve. Ritz and co-investigators (2001) defined delayed gastric emptying as T50 of more than 140 minutes and/or gastric emptying coefficient of less than 3.2.

The ^{13}C-octanoic acid breath test has been evaluated in clinical studies in critically ill patients. Published studies have examined gastric emptying in critically ill patients and have used the ^{13}C-octanoic acid breath test as a measure of gastric emptying and motility. Ritz and co-investigators (2001) used this technique to evaluate the prevalence of delayed gastric emptying in 20 mechanically ventilated ICU patients compared with 22 healthy volunteers. In their study, feedings were placed on hold four hours prior to the test meal that consisted of 100 mL of liquid formula (Ensure®) labeled with the isotope. The researchers did not find that the test interfered with patient care except for the times the feedings were placed on hold to perform the test. Using the gastric emptying coefficient, critical care patients in this study were found to have slower gastric emptying 3.58 (3.18–3.79) compared with the healthy volunteers 2.93 (2.17–3.39; $p < .008$). Gastric half emptying time 155 minutes (130–220 minutes) versus 133 minutes (120–145 minutes).

Chapman et al. (2005) used the ^{13}C-octanoic acid breath test to evaluate the relationship between gastric emptying and gastric motility and to describe antro-pyloro-duodenal motility during fasting and in response to nutrient infusion to both the stomach and duodenum in critically ill patients. In their study, 15 mechanically ventilated ICU patients and 10 healthy volunteers were evaluated with the breath test using the same techniques for infusion used by Ritz and investigators (2001). Based on observations made during this study, critically ill patient have less antral MMC activity, and nutrient intake did not inhibit fasting motility. These results demonstrate that critically ill patients do experience delayed gastric emptying. Another study evaluated the ^{13}C-octanoic acid breath test against the scintigraphy in 25 mechanically ventilated patients as well as 14 healthy subjects. There was good correlation between the breath

test and scintigraphy in both the critically ill patients and the healthy volunteers at 120 minutes (r = 0.57 healthy; r = 0.56 patients; $p \leq .002$)

Chapman et al. (2011) compared the breath test with scintigraphy in 25 mechanically ventilated patients and 14 healthy volunteers and found a correlation between the two tests. However, as with many of the techniques used in acute care, the metabolic state of the patient in critical care may influence the values of the breath test. The exhaled CO_2 used in this measure depends on the blood bicarbonate system so it may not adequately assess gastric emptying (Moreira & McQuiggan, 2009). This test has been compared with scintigraphy and may have clinical usefulness and reliability for assessing gastric emptying. This method is also non-invasive, safe to perform and has promise in measuring gastric emptying for both liquids and solids.

Nguyen and co-investigators (2007b) used the ^{13}C-octanoic acid breath test technique for the measurement of gastric emptying in critically ill patients. Feedings were placed on hold for four hours in this study, and then 100 mL of ^{13}C-octanoate (100 mg/mL) added to 100 mL of Ensure® was instilled into the feeding tube, similar to the technique used by Ritz and investigators (2001). Prior to the test, all stomach contents were aspirated and then discarded. Results showed that 60% of the patients had delayed gastric emptying; however, because the authors aspirated prior enteral feedings, they altered the pH balance of the stomach. Additionally, the Ensure® altered the feeding content that the patient had been receiving. Although this study demonstrated delayed gastric emptying in the critically ill, mechanically ventilated patient, the methods employed were not consistent with standards of practice.

Refractometry

Refractometry is a method for measuring gastric contents with a handheld device that measures the bending of light in degrees as it passes between two substances with different densities (Chang, McClave, Hsieh, & Chao, 2007), such that the density of a solution increases proportionally to the refractive index (light bending). The refractometry method is able to determine concentrations of feeding formula and differentiate it from gastric and salivary secretions from an equation and value known as the Brix value. This technique, like GRV assessment, requires stomach contents to be aspirated. The Brix value is a calculation of the total soluble in a solute, in this case formula and gastric and salivary secretions that correspond to molar fractions associated with the mixture components (Chang, McClave, Lee, & Chao, 2004). This means that the Brix value and the refractometer can differentiate concentrations of fluid from one another to determine how much formula is present in a solution compared with gastric contents. The theory behind this procedure is that the higher the concentration of the formula, the more likely there may delayed gastric emptying. Chang and investigators (2007) evaluated refractometry and Brix value calculations both in vitro and in vivo to evaluate concentrations of formula during EN using a hand-held refractometer. Chang and colleagues' method was able to identify how much GRV was present in the stomach using simple calculations and does not require large volumes of GRV to complete the assessment; only one mL of stomach content is required to perform the test and calculate the Brix value to obtain concentrations and predict the actual volume. This approach to assessing gastric emptying has not been validated with scintigraphy.

Ultrasound

Ultrasound (US) is a non-invasive technique that has been used to assess gastric emptying by taking cross sectional scans of the stomach and calculating the gastric volume. The US is usually completed after a fast to obtain a baseline scan. A test meal is then administered and several sequential scans every 5–10 minutes are completed to derive calculations for the half emptying time of the gastric volume.

Bateman and Whittingham (1982) first US used with 10 enrolled volunteer participants and performed several cross sectional scans. Scans were obtained at regular intervals (5, 10, 15, 20, 30, and 40 minutes) following administration of 500 mL of orange cordial at 37 degrees Celsius following an overnight fast. The half emptying times followed a log-linear relationship. Holt, Cervantes, Wallace, and Wilkinson (1986) first compared US with the gold-standard scintigraphy when they simultaneously performed both the scintigraphy and US in 14 subjects every 15 minutes over one hour. These investigators found a significant correlation for the T½ emptying time between the US and SCT (r = .84, $p < .05$).

In a prospective observational study, Perlas, Chan, Lupu, Mitsakakis, and Hanbidge (2009) studied the feasibility of using portable US for assessing gastric content and volume by describing the appearance of the US images over all portions of the stomach before and after ingesting standardized volumes of fluid and solids. In this study the antral cross sectional images were the best measure of gastric volume, and the images

approximated a linear relationship when up to 300 mL was present in the antrum and the images were taken in the right lateral decubitus position.

Irvine, Tougas, Lappalainen, and Bathurst (1993) demonstrated good interobserver agreement with the use of US in their study of 20 healthy volunteers undergoing US imaging following ingestion of a liquid meal. Scans were performed at 10-minute intervals for up to one hour. In this study, two observers simultaneously evaluated nine subjects. The US evaluations in this study demonstrated strong correlations between the two sets of measurements (r = .83) with good intraobserver concordance between two observers (ICC = .625), indicating US may be reproducible in measuring gastric emptying; however, intrasubject measurement variability was poor in the nine subjects evaluated (r = 0.585), reflecting day-to-day variation. This variation across days suggests US is a better indicator of a patient's current gastric empting state versus being able to predict future emptying properties.

The US is non-invasive and readily accessible in clinical practice, however studies addressing the validity of US in assessing gastric empting in the critically ill have not been conducted. Furthermore, the multiple scans may not be easily performed in the critical care setting without significant caloric intake loss while feedings would be placed on hold.

SmartPill

The SmartPill® is a motility capsule with wireless transmitting capability that is used to assess gastric emptying. The SmartPill® was introduced in the United States in 2006 and is made of a polyurethane body (Rauch, Krueger, Turan, Roewer, & Sessler, 2009). The gastric emptying capsule is an easy procedure that can be performed in the

office setting to calculate transit time of the entire GI system (SmartPill, 2009). The

SmartPill® is capable of monitoring pH, pressures and temperature as it moves through

the GI tract. The SmartPill® has been evaluated and correlated with scintigraphy

measurement. Kuo et al. (2008) used simultaneous measurements with the SmartPill® and

scintigraphy in 77 healthy individuals and 48 adults with gastroparesis to compare the

two measures. The four-hour measure between the capsule emptying time and the

scintigraphy emptying time was significantly correlated r = .73, CI [.61, .82], and the

capsule was able to discriminate well between those who were healthy and those with

gastroparesis. The investigators created two groups, those who had gastroparesis defined

by the gastric emptying four hours after administration of the test meal and those with

normal emptying. Any amount of meal remaining greater than 10% of the volume was

considered as delayed emptying. Sensitivity and specificity analyses were performed to

compare how well the SmartPill® and the scintigraphy performed in gastroparesis.

Sensitivity refers to the proportion of cases identified by the test as gastroparetic when

they truly had gastroparesis. Specificity refers to the tests ability to identify someone with

normal emptying times, given they really are classified as normal. The SmartPill® had a

sensitivity of .65 and specificity of .87, which was comparable to the scintigraphy results

(sensitivity .44 and specificity .93). While the capsule demonstrates promise as an

alternative method for evaluating gastric emptying, the capsule also must be swallowed,

which presents a problem for the critically ill patient population. One case report has

been published by Rauch et al. (2009), who developed a method to deploy the capsule, in

eight critically ill patients who were sedated and receiving mechanical ventilation and

suspected of gastroparesis. These investigators were able to safely deploy the capsule

using endoscopic equipment; however, no data were reported to indicate if the device was able to capture necessary data to perform gastric emptying studies in the critically ill patient.

Summary of the Literature

Despite the ability of scintigraphy, breath tests and paracetamol absorption tests to detect delayed gastric emptying problems in critically ill patients, they are impractical in routine clinical practice. These tests all require feedings to be put on hold and test meals inconsistent with the feeding formula properties to be administered. These measures are practical to identify those with delayed gastric emptying; however, it is known that critically ill patients are at risk for delayed gastric emptying because of the nature of their illness. Bedside assessment methods need to be able to be performed frequently and easily with little disruption to the continuous feeding of EN. For this reason, the current method of GRV is the best method available; however, there is opportunity to evaluate the method of obtaining the GRV and selecting the most accurate measurement technique.

Studies suggest that clinicians are able to obtain greater RVs from larger feeding tubes compared with smaller feeding tubes. Furthermore, smaller bore feeding tubes are thought to be more collapsible during aspiration leading to smaller residual amounts. The position of the tube in the gastric pool may also influence the amount of aspirate that is obtained. All studies that have suggested these properties have been performed in vivo where it is not possible to visualize the impact of tube size and aspiration techniques on various tube properties and lumen sizes. The techniques used to aspirate residual vary in practice and there is some evidence to suggest that suction may be better in small and

large bore tubes in assessing GRV (Zaloga, 2005), although this has not been evaluated when the actual volume of contents is known. Because there is a potential for variation in the technique used to aspirate with a syringe, this will be explored in this research study. Specifically interrater agreement has not been evaluated. While there is one published study (McClave et al., 1992) that has analyzed the reliability of GRV assessment with a syringe as compared to physical examination findings and radiological interpretation, there is no published literature that has assessed the reliability of the various methods of aspirating stomach contents or studies which have assessed inter-rater reliability for each method of assessment.

In addition to tube properties in the aspiration of gastric contents, there are three techniques that have been reported in the literature for assessing gastric aspirates, these include syringe aspiration, drainage to gravity and drainage to suction although none of these methods have been compared to determine the reliability in the amount of GRV obtained. This study will serve to identify if GRV assessment can be accurately performed in vitro and compare the three techniques identified in the literature (syringe, suction, gravity) to determine which method, if any, can be used to assess GRV.

CHAPTER THREE

MATERIALS AND METHODS

This study was conducted in two phases. In Phase I, three different techniques for pulling on the syringe plunger were evaluated in vitro using a force measurement test system to measure force variation across the techniques and the total proportion of feeding formula that could be aspirated with 100 mL available fluid. In Phase II, the syringe technique from Phase I that performed best in aspirating contents was assessed along with the continuous suction and gravity drainage approaches to assess each of the research questions. Phase I methods and results will be discussed first, followed by the methods and findings from Phase II.

Phase I Materials and Methods

The aim of Phase I was to evaluate three different techniques for pulling on the syringe (fast, intermittent, and slow) in the assessment of RV to determine which technique yielded the largest quantity of fluid volume to assess RV. The syringe pull technique that produced the largest quantities on average in Phase I was then used in Phase II of this study. The three different syringe pull techniques were evaluated across four types of feeding tubes with the distal ports of the feeding tubes submerged or partially submerged in two different types of fluid to determine which technique yields the greatest amount of RV for assessment of RV.

Sample and Setting

Phase I of the study was conducted in a metrology laboratory on the campus of a regional academic center. The laboratory is a controlled environment maintained at an average temperature (19.99° Celsius) and 31% humidity during Phase I. For this

component of the study, 117 RV measurements were made. Seventy-two of the

measurements were made with all of the oval ports of the distal end of the tube

completely submerged and 36 of the measurements made with the most distal port

exposed to air, while all the other more proximal ports were submerged. Additionally,

nine measurements were made with only the most proximal oval port exposed to air for

illustration purposes; these data were not included in the analysis.

In the in vitro Phase I of this study, a 60 mL straight tipped syringe (Monoject)

was attached to a feeding tube and clamped into a vertical position within a force

measurement test system (Starrett; Figure 1). The force measurement test system allows a

machine to use push/pull forces on a syringe while simultaneously recording the force

required to move the plunger through the syringe barrel over the duration of the

pull/push.
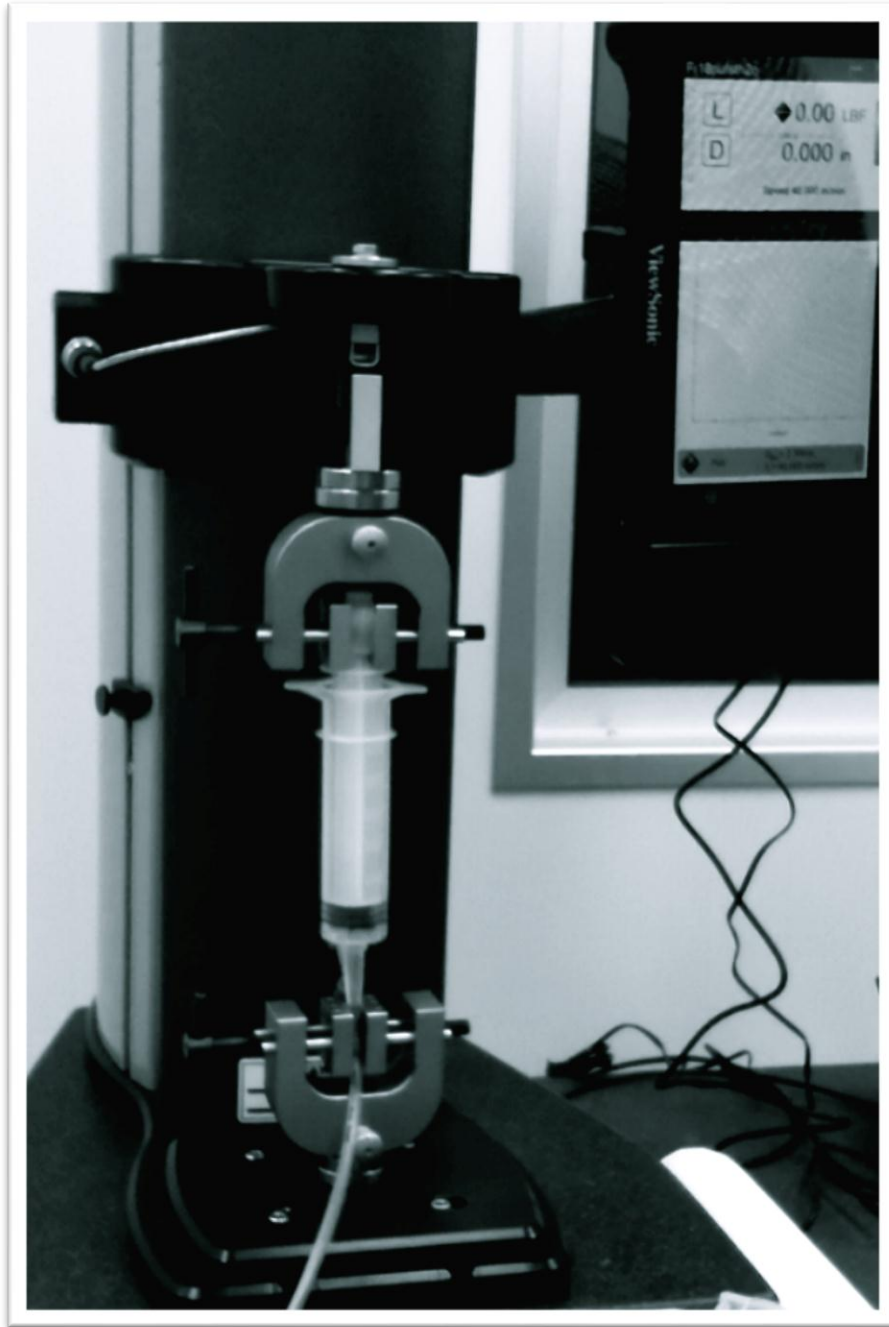
Figure 1. Photograph demonstrating 60 mL straight tipped syringe attached to a feeding tube. The photograph demonstrates a 60 mL straight tipped syringe attached to a feeding tube then clamped into a vertical position within a force measurement test system force measurement system with syringe.

The force measurement system allowed the syringe plunger to be pulled by the

machine, while controlling the velocity of the plunger during the assessment of RVs. In

this experiment, the distal end of the feeding tube was placed in a canister filled with

100 mL of fluid. Two different fluids were used in this study: (a) 100 mL of Ensure[®] High Protein Shake and (b) 100 mL of tap water. The force measurement system pulled on the syringe plunger until the investigator observed air in the feeding tube and no additional fluid could be drawn up into the tube. In all attempts, this required the force measurement system to pull on the syringe plunger two complete pulls, as the syringe only holds a maximum of 60 mL at a time. In this study, the force of the pull was recorded along with the RV that could be drawn up in the syringe at the three speeds of pull on the plunger.

Techniques for Pulling on Syringe Plunger

The force measurement system was used to set and control three different techniques for pulling on the syringe plunger of a 60 mL syringe. The syringe plunger was pulled upwards by the force measurement system until the plunger reached 3.3 inches on the barrel. This same distance was set as the stopping point for all measurements performed in Phase I. The force measurement system recorded the continuous force required to move the syringe plunger upwards during the aspiration of fluid in each assessment.

The first technique consisted of a fast pull on the syringe plunger. The force measurement system was set to pull the syringe plunger at a constant speed of 40 inches per minute. The second technique evaluated was a slow steady pull on the plunger, with the force measurement system set to pull the plunger at a constant speed of 10 inches per minute. The third technique consisted of an intermittent pull on the syringe plunger, with a slow pull, 10 inches per minute and then a pause occurring every 1.1 inches up on the syringe barrel. In all three techniques, the force measurement system pulled on the

syringe plunger until the plunger was pulled 3.3 inches up on the barrel and then all measurements ceased.

Once the syringe plunger reached 3.3 inches, the distal end of the feeding tube was placed in a measurement beaker and the force syringe system was used to push the fluid from the syringe into the measurement beaker. The distal end of the feeding tube was placed back into the canister containing the fluid and subsequent pulls were made on the syringe plunger until only air was pulled into the syringe, indicative that all the fluid had been aspirated. Measurements were repeated three times for each of the syringe pull techniques to determine if the technique was reproducible.

RV Assessment

RV was calculated by taking the difference between the actual volume available (100 mL) and the amount of fluid drawn up in each of the syringe pulls, with each full assessment requiring two pulls on the syringe plunger. The first volume drawn up in the syringe was subtracted from 100 mL. The remaining amount was then used as the total volume available in the second assessment. The volume assessed on the second pull was then added to the first volume and divided by the total amount available at the start, less the amount assess on the first assessment. The calculation of RV for Phase I follows:

$$\text{Phase I RV} = \frac{\text{RV first syringe pull} + \text{RV second syringe pull}}{100\text{mL} - \text{first assessment}}$$

Feeding Tubes Used in Study

Four NG feeding tubes with two different calibers (10 Fr and 18 Fr) were used in both phases of this study. Two polyurethane NG tubes (10 Fr and 18 Fr Maxter) and two PVC tubes (10 Fr and 18 Fr Rusch) were each used. All tubes were the same length (120 cm), with four oval ports located on the distal tip of the tube (see Figure 1). These tubes

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were chosen purposefully to control for the number of distal ports and length of the feeding tube, however the placement of the ports on the distal end of the tubes are different as depicted in Table 1. The PVC tubes have oval ports located in a concentric fashion while the polyurethane tubes have oval ports each aligned on one side of the tube.

Table 1

Characteristics of Feeding Tubes Tested

Fr Size	Tube Type	Length (cm)	Distribution of holes[a]
10	Polyurethane (Maxter)	120	Linear
18	Polyurethane (Maxter)	120	Linear
10	PVC (Rusch)	120	Concentric
18	PVC (Rusch)	120	Concentric

[a]Each tube had four holes.

Fluid and Viscosity Measurement

Viscosity was measured for each type of fluid used in this study (Ensure®, water, and quarter-strength Ensure®). The Ensure® and tap water used in this study were both kept at room temperature in the laboratory for at least 18 hours prior to measurements. Water was also included as a test fluid to provide confidence in the testing procedure. Viscosity was determined using a falling ball viscometer. The manufacturer's estimate of viscosity for the Ensure® high protein drink was between 0 cP and 50 cP (Abbott Nutrition, 2009). Based on that information and the range data for each size of tube given previously, the Gilmont size 2 tube was chosen to perform the viscosity measurements. A quarter-inch diameter stainless steel ball was used for the analysis. Approximate K values for each size of available viscosimeter tube as well as the approximate range of viscosity for each tube are shown in Table 2.

Table 2

Viscosimeter Tube Sizes Based on Viscosity

Gilmont Size No	Approx K	Stainless Steel[a]
1	0.3	1 to 10
2	3.3	10 to 100
3	35	100 to 1000

[a]Range in cP.

To compute the density of the Ensure® high protein drink, a beaker, and scale were employed. Table 3 presents data presents data for both water and Ensure®, using water as a calibration/check standard for the measurement.

Table 3

Fluid Characteristics

Liquid	Volume (mL)	Mass (gms)	Density (gms/mL)
Water	100	99.2	0.99
Ensure	100	103.85	1.04

To compute the absolute viscosity, the size 2 tube was filled with each type of fluid in separate measurements. The tube was marked with an upper line and a lower line. A stainless ball was dropped into the fluid and the time it took for the ball to cross between the first and second mark was measured with a stop watch. The ball drop time was measured three times and the average of the three measurements was used to calculate the absolute viscosity (measured in cP) for each type of fluid using the following equation:

Absolute Viscosity $\mu = K(\rho_t - \rho)t$

Where: μ = absolute viscosity in cP

K = viscosimeter constant

ρ_t = density of ball (8.02 grams/ml for stainless steel)

ρ = density of liquid (grams/ml)

t = time of descent (minutes)

The results of the viscosity assessments are shown in Table 4. Viscosity is measured

using absolute viscosity and measured in centipoise units.

Table 4

Viscosity Measurements of Fluid

Liquid	Time (secs)	Time (mins)	Absolute Viscosity (cP)
Water	2.9	0.048	1.11
Ensure[®]	31.0	0.517	11.91
Diluted Ensure[®]	4.2	0.070	1.61

The full strength Ensure[®] had the highest viscosity measurement. The

quarter-strength Ensure[®] used in Phase II had viscosity similar to that of water alone,

although it was slightly more viscous than the water.

Data Analysis Phase I

All analyses were performed using SPSS, version 20.0. Categorical level

variables were described using counts and frequencies (%) and continuous level variables

were expressed with measures of central tendency (mean, median) and variability

(standard deviation, range). A one-way ANOVA was used to compare the RV across the

three syringe pull techniques. Exploratory descriptive statistics were run including means,

medians, standard deviations, and interquartile ranges with plots for the amount of fluid

aspirated by tube type, location of the distal ports in the fluid, type of fluid and the force technique. Assumptions for the appropriateness of using parametric statistical methods were examined using the Kolmogorov-Smirnov test. RV is expressed as a proportion. Alpha was set to 0.05 in all analyses.

A Bland-Altman analysis using the 95% limits of agreement method was used to compare agreement between any non-significant differences in syringe pull technique in Phase I and Phase II of the study. The Bland-Altman analysis is useful in comparing two different measurement methods to determine if the methods can be used interchangeably and is more appropriate for this purpose than correlation coefficients (Bland & Altman, 1990). A mean bias of +/- 1.96 SD was used as the range of agreement and 17% mL was set a priori as the clinically acceptable difference for determining bias between the RV assessment methods. This value is derived from 500 mL as the recommended cut off value for symptomatic intolerance divided by 3000 mL the typical gastric secretions secreted by the typical stomach daily (McClave & Snider, 2002). At this criterion, if the precision exceeds this value, then the proposed superior method would be an unacceptable alternative to the baseline one.

Phase I Results

In Phase I, a total of 108 in vitro RV measurements were analyzed to compare the fast, intermittent, and slow syringe pull techniques to determine which syringe pull technique produces the greatest amount of RV. Additionally, four different feeding tubes and two different fluids were used to assess the viscosity effect on the amount of RV with the placement of the distal end of the feeding tube in varying depths of fluid.

Comparisons were made on the proportion of RVs assessed across the syringe pull techniques and tube type with the tube tip placement of the distal ports in varying depths of fluid. Three measurements were made for each tube type with the most proximal ports of the feeding tube placed in Ensure®. Three measurements were also made for each tube type with all the distal ports submerged in water as well. The distribution of mean RV assessed from each syringe pull technique is depicted in Table 5.

Table 5

Phase I Distribution of RV Measurements

Location of Ports in Fluid	*N*	Slow *M* (*SD*)	Intermittent *M* (*SD*)	Fast *M* (*SD*)
All Submerged	24	0.69 (0.28)	0.71 (0.24)	0.55 (0.26)
Proximal Submerged	12	0.64 (0.13)	0.66 (0.09)	0.58 (0.20)
Distal Submerged	3	0.00	0.00	0.00

The distribution of RVs for each type of fluid viscosity within each of the syringe pull techniques is shown in Table 6. The intermittent technique produced the greatest amount of RV 0.69 ± 0.20 mL (Range 0.14–0.98 mL) compared with the slow 0.66 ± 0.24 mL (Range 0.08–1.00 mL) and fast techniques 0.56 ± 0.24 mL (Range 0.09–0.91 mL).

Table 6

Distribution of RV (mL) by Syringe Pull Method and Fluid Viscosity

Tube		Slow		Intermittent		Fast	
		Water	Formula	Water	Formula	Water	Formula
10 Fr Poly[a] Tube	Submerged (*n* = 3)	0.93 (0.09)	0.47 (0.19)	0.95 (0.01)	0.63 (0.05)	0.61 (0.01)	0.46 (0.23)
	Proximal Submerged (*n* = 3)		0.69 (0.14)		0.74 (0.04)		0.71 (0.05)
18 Fr Poly[a] Tube	Submerged (*n* = 3)	0.98 (0.02)	0.18 (0.11)	9.0.1 (0.07)	0.28 (0.13)	0.90 (0.01)	0.25 (0.26)
	Proximal Submerged (*n* = 3)		0.57 (0.03)		0.63 (0.03)		0.50 (0.02)
10 Fr PVC Tube	Submerged (*n* = 3)	0.78 (0.05)	0.66 (0.07)	0.74 (0.07)	0.75 (0.12)	0.83 (0.02)	0.44 (0.24)
	Proximal Submerged (*n* = 3)		0.65 (0.26)		0.71 (0.02)		0.77 (0.18)
18 Fr PVC Tube	Submerged (*n* = 3)	0.90 (0.06)	0.50 (0.01)	0.97 (0.01)	0.47 (0.04)	0.70 (0.01)	0.26 (0.01)
	Proximal Submerged (*n* = 3)		0.64 (0.02)		0.54 (0.07)		0.35 (0.15)

Note. Values reported are *Means* (*SD*).
[a]Poly is an abbreviated form for polyurethane.

Research Question 1

Which technique for pulling on the syringe plunger (fast, intermittent, and slow)

yields the largest quantity of RV in the assessment of aspirate?

A one-way ANOVA was used to compare the three syringe pull techniques (fast,

intermittent, and slow) after confirming homogeneity of variances with Levene's test

($p = .326$). The ANOVA showed significant differences in the assessment of RV across

the three syringe pull techniques $F(2, 105) = 3.218$, $p = .044$ as shown in Figure 2.

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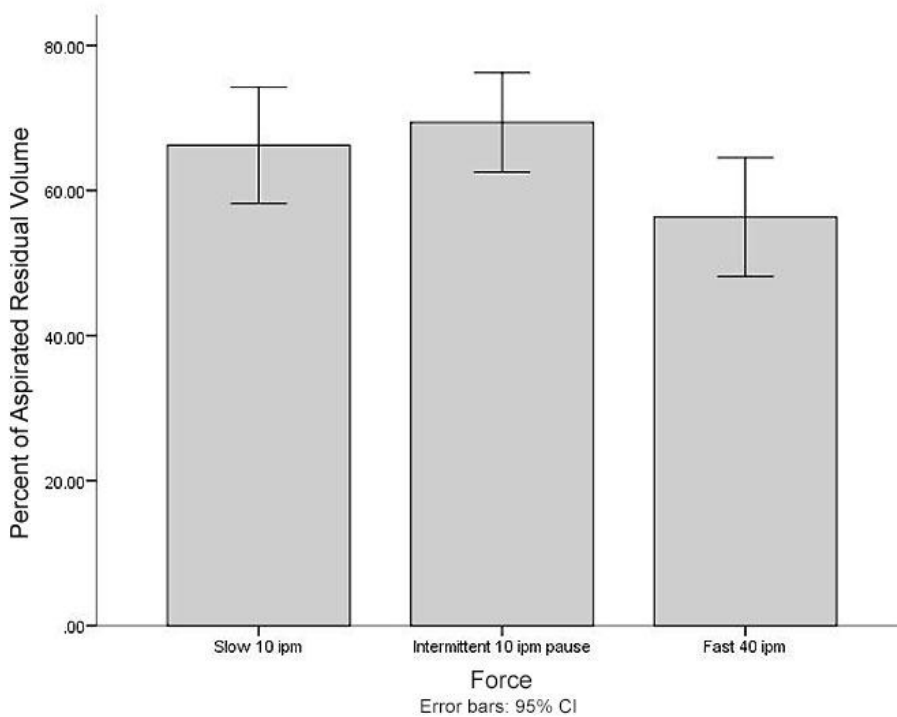
Figure 2. Comparison of syringe pull techniques on percent of aspirated RV showed
significant differences.

Post hoc tests using bonferroni comparisons revealed significant differences

between the intermittent syringe pull technique and the fast syringe pull technique

($\alpha = .02$); the intermittent and slow pull techniques were not significantly different from

each other ($p = 1.00$). While there was no difference in these techniques, the intermittent

technique had lower variability (Range 0.14–0.98 mL) in the assessed volumes compared

with the slow technique (Range 0.08–1.00 mL). The variability in the amount of assessed

RV across methods remained significant in the one-way ANOVA, $F(2, 33) = 6.8$,

$p = .003$) in the lower viscous fluid (water), however, there were no significant differences

F(2, 69) = 2.6, p =.08) between the three pull methods in the higher viscous fluid

(Ensure®).

Research Question 2

Can the slow and intermittent syringe pull techniques be used interchangeably?

To assess for consistency in RV and determine if the two syringe pull techniques

could be used interchangeably, scatterplots, correlation coefficient (r) and 95% CIs were

assessed to compare the agreement between the intermittent pull and slow syringe pull

techniques (*n* = 36 pairs). The scatterplot (Figure 3) shows some agreement in the

positive direction for both methods, the Pearson Product-moment correlation was

r = .827, *p* < .001. The Bland-Altman was used to further assess the bias in this

relationship to determine both the magnitude and direction of the bias.
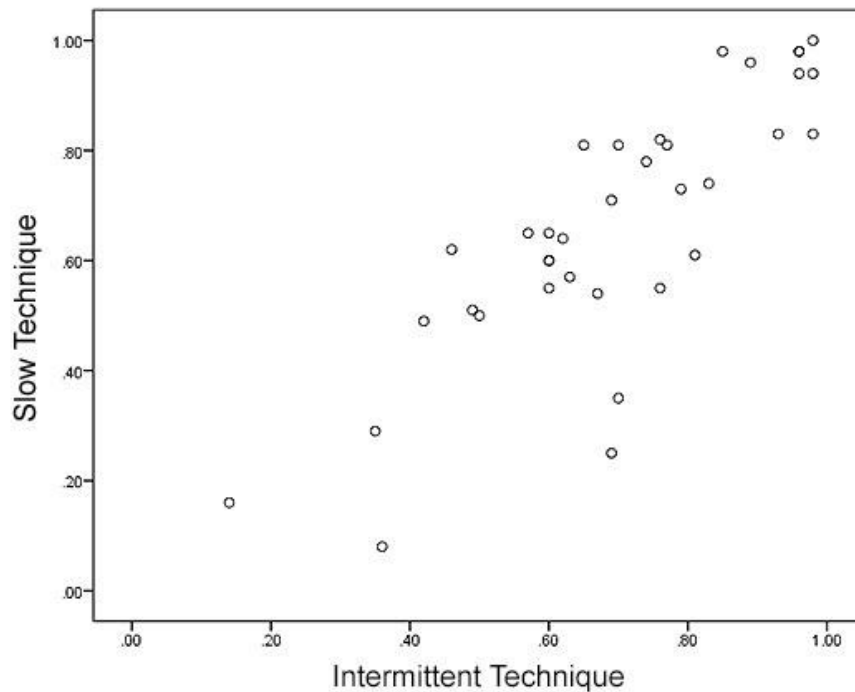
Figure 3. Scatterplot comparing intermittent to slow pull techniques. The scatterplot
comparing intermittent to slow pull techniques shows some agreement.

The Bland-Altman analysis indicates that the 95% limits of agreement between the intermittent pull and slow pull techniques ranged from -0.22 to 0.29 percent of the total fluid volume. The bias for each of the paired measurement points varied from -0.23 to 0.29, across all 36 pairs of measurements and the average mean difference was .0314. 95% of the differences in the bias in the sample are expected to be between the upper limit of 0.29 and the lower limit of -0.22 (see Figure 4). The confidence limit of .51% exceeds the a priori criterion of 0.17, indicating that the intermittent method produced a larger volume of RV, the repeatability of assessment is not consistent and thus the two methods cannot be considered equivalent and used interchangeably.
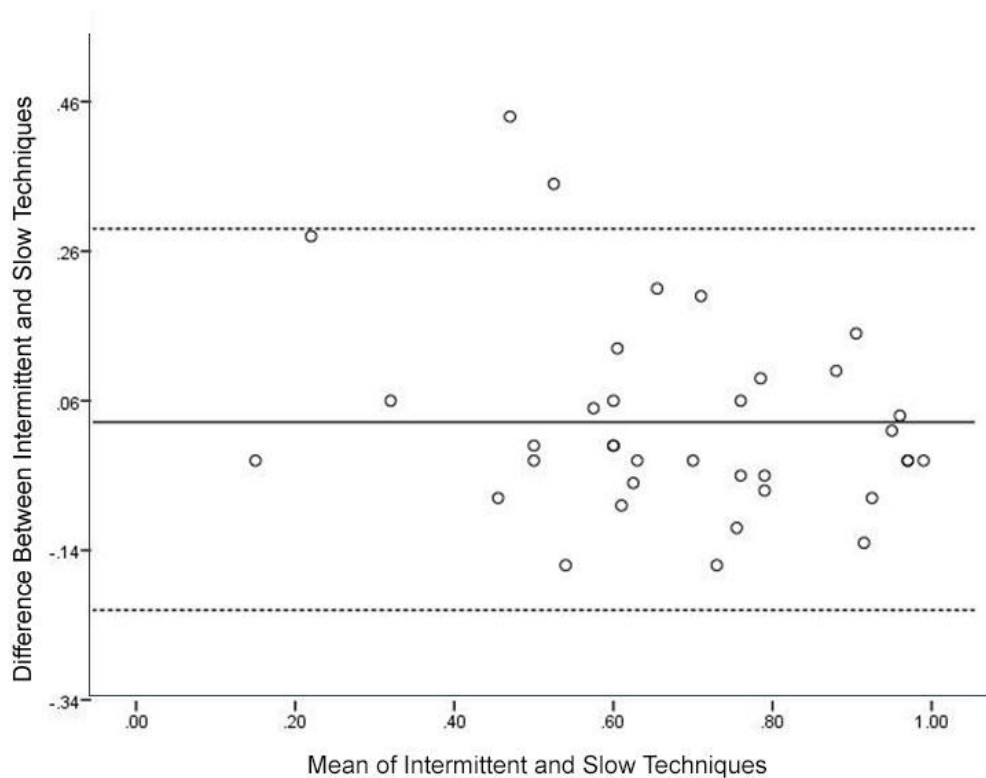
Figure 4. Bland Altman plot of differences comparing the intermittent to slow pull technique ranged from -0.22 to 0.29 percent of the total fluid volume.

The plot of difference against means, demonstrates that the difference between the two techniques becomes similar at higher levels. Thus it is unlikely, $p < .05$, that

measurement made using the slow and intermittent methods, on the same individuals, would differ by more than 50%. This difference becomes particularly meaningful with larger available volumes of total available volume. In the cases where a large volume aspirate is anticipated, the intermittent syringe pull technique should be used as it produces the larger amount of RV.

The two methods for pulling on the syringe plunger, slow and intermittent pull techniques did not provide similar measurements of RV. The difference between measurement agreements is such that there is a level of disagreement includes clinically meaningful discrepancies. As such, the intermittent syringe pull technique was selected for use in Phase II of this study.

Phase II Methods

Phase II of this study consisted of a completely crossed randomized factorial design to evaluate in vitro three different methods (syringe, suction, and gravity) for aspirating feeding formula by nurses ($n = 4$) through two types of feeding tubes (10 Fr and 18 Fr tubes) made of two types of material (PVC and polyurethane) with five available volumes (50 mL, 150 mL, 300 mL, 500 mL, and 600 mL) to determine the proportion of the actual amount of aspirate that could be obtained within each method used to assess GRV.

Study Design

Design of the study conforms to a completely balanced randomized complete block design with two replications within each block. The blocking factor in this study is the method (syringe suction and gravity) with factors to include: two tube sizes (10 F and 18 F), two tube materials (PVC and polyurethane), four levels of nurse experience

(student, novice, experienced, and expert) and five volumes of formula (50 mL, 150 mL, 300 mL, 500 mL, and 600 mL).

Setting

This study was conducted in the simulation laboratory at the university's school of nursing. The nursing laboratory is set up to simulate the acute care environment. In this study, the stomach was simulated using a clear feeding bag secured in a metal claw clamped to a chemistry ring stand. An additional clamp was placed at the top of the ring stand pole and the feeding tube was secured in the upper most clamp, while the end of the feeding tube was placed into the feeding bag simulated stomach containing feeding formula for each level of fluid assessed in this study (50 mL, 150 mL, 300 mL, 500 mL, and 600 mL). All of the ports at the end of the feeding tube were submerged in the fluid prior to setting up the ring stand for each measurement. All feeding tubes in the study were placed in the top clamp at the 55 cm mark. The feeding tube was secured to the ring stand in the upright position to simulate patient positioning with the head of the bed at 90 degrees, the recommended patient position to prevent ventilator associated pneumonia (Kattelmann et al., 2006).

The simulated stomach and ring stand were then placed inside a box to shield the content of the simulated stomach from the nurses during all assessments. The nurses were blinded to the amount of fluid in each assessment and had no knowledge of the volumes used in this study. The simulation room used in this study is equipped with a portable suction machine and canister (MODEL) that was used in the study for both the suction and gravity methods.

Protection of Human Subjects

This study was reviewed and approved (Appendix A) by the Indiana University Institutional Review Board (IRB) prior to implementation. This study met the criteria of exempt research as described in the Federal regulations at 45 CFR 46.101(b), paragraph(s) (2) as determined by the IRB. As such, there was no requirement for an informed consent; however, participants were provided with study information sheet (Appendix B) for exempt research approved by the IRB. Participation in this study was voluntary and participants had the right to choose not to participate in the study at any time.

Study Sample

Four nurses were recruited to participate in this study who met the study inclusion criteria. Participants were recruited from through the regional university's school of nursing.

Inclusion and Exclusion Criteria

Inclusion criteria. Participants were included in the study after agreeing to voluntarily participate in the study. Each participant was provided an IRB-approved description of the study (Appendix B). Participants were included in the study if they met the practice requirements required by the study design. The practice requirements consisted of the following:

1. A nursing student (a beginning nursing student) who had completed a basic skills course with competency in NG tube management.

2. A novice nurse with less than three years of practice experience as a registered nurse in an ICU setting.

3. An experienced nurse with more than three years of practice experience in an ICU setting.

4. An expert nurse with expertise in EN delivery either as a nutrition support nurse and/or a nurse who has published in the nutrition/EN literature.

The first person, meeting inclusion criteria for a specific experience level, who volunteered to participate in the study, was selected for each of the four experience levels.

Exclusion criteria. Participants were excluded from the study if their experience level represented an experience level that was already enrolled in the study.

Phase II Procedure

Once the nurse raters were enrolled in the study, each participant was oriented to the simulation laboratory and the methods used in this study to aspirate RV by the student co-investigator. The nurse raters were shown each of the three methods (syringe, suction, and gravity) for removing (aspirating) feeding formula through the feeding tubes, allowed to ask questions then try each method prior to data collection.

The syringe technique, continuous suction and gravity drainage methods were used by the nurse raters to collect and measure the amount of feeding formula that they were able to aspirate from each of the feeding tubes used in this study. The same four types of tubes used in Phase I were also used in Phase II.

- 10 Fr polyurethane tube
- 10 Fr PVC tube
- 18 Fr polyurethane tube
- 18 Fr PVC tube

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All of the tubes used in this study were the same length with the same number of ports over the end of the distal end of the feeding tube.

Random assignment of the nurse rater to each of the treatment conditions (method, tube size, and feeding formula volume) was performed using the Web-based Research Randomizer (http://www.randomizer.org/) program.

At the beginning of each assessment, the nurse rater assessed the position of the feeding tube at the top of the ring stand clamp and documented the marking from the feeding tube, indicating length of tube inserted, on the data collection form. The nurse was told prior to each assessment which method would be used for that assessment. The nurse was blinded to the simulated stomach and the amount of feeding formula available to aspirate for each assessment.

Prior to each assessment, the nurse drew up 30 mL of air into the syringe, connected the syringe to the proximal end of the feeding tube and instilled the 30 mL of air into the tube, just as s/he would do in practice. Participants then used assigned method (syringe, suction, and gravity) to draw up and remove feeding formula through the tube.

Once the feeding formula was aspirated through the feeding tube using the assigned method, the collected formula was placed in a graduated cylinder by the nurse rater, measured, and documented on the case report form.

The nurse raters completed this procedure for each of the different sizes and materials of tubes across each level of volume with two repetitions completed at independent times according to the randomization.

Each nurse made 120 measurements across the three methods. Participants were not permitted to spend more than eight consecutive hours in the laboratory on a given day to prevent fatigue.

Description of Methods for Assessing RV

Syringe technique method. The nurse raters drew up 30 mL of air into the syringe and connected the syringe to the proximal end of the feeding tube. After instilling the 30 mL of air into the tube, they then manually aspirated the contents by pulling on the syringe plunger using a slow intermittent syringe pull technique, pausing briefly at each 20 mL mark on the syringe barrel. Syringe contents were then emptied into a graduated cylinder and the nurse would repeat the process until he/she was unable to aspirate additional feeding formula. All contents removed from the syringe were measured by the nurse and recorded on the data collection form.

Suction technique method. After instilling the 30 mL of air into the feeding tube using the syringe, the nurse rater connected the feeding tube to the vacuum pump suction set at 20 mmHg continuous suction. Continuous suction ran for no more than five minutes or until air was seen in the tubing suggesting that all the simulated stomach contents had been removed. If there was a continuous flow of fluid coming through the tube at the five-minute mark, the suction was turned off and the fluid was allowed to flow until no additional formula flowed through the tubing. All contents collected in the suction canister were then emptied by the participant into the graduated cylinder, measured and recorded on the data collection form.

Gravity technique method. The gravity technique method also started by injecting 30 mL of air through the feeding tube. The suction tubing was then connected to

the proximal end of the feeding tube and the vacuum pump suction (20 mmHg) was used

to prime the tube. Once the nurse rater saw the feeding formula in the tubing and

presumed the fluid to be below the level of the simulated stomach, the nurse rater turned

off the suction and allowed the feeding formula to drain by gravity. The suction canister

and vacuum pump sat floor level to allow drainage. Drainage was allowed to flow freely

until no additional formula flowed through the tubing. The aspirated volume was then

emptied in a graduated cylinder, measured and documented on the data collection form

by the nurse rater.

Description of Feeding Formula

The formula used to fill the simulated stomachs consisted of quarter-strength

Ensure[®] formula (Abbott Nutrition, 2009). The viscosity of this formula was 1.61 cP. All

formula was kept at room temperature and mixed with tap water at a ratio of one part

formula to four parts water throughout the study. This formula concentration was mixed

as needed, prior to each assessment to prevent separation of the formula.

CHAPTER FOUR

DATA ANALYSIS

This chapter presents the data analysis for the research questions three through ten that were evaluated in Phase II of this study. Question 3 of this research study served as the overall research for which the study was designed. The design consisted of a total of 240 cells with all factors considered fixed.

Research Question 3

How do methods for aspirating GRV (syringe, suction, and gravity), tube size (10 Fr and 18 Fr), tube material (PVC and polyurethane), experience of the nurse (student, novice, experienced, and expert) and total volume available (50 mL, 150 mL, 300 mL, 500 mL, and 600 mL) influence the amount of aspirated feeding formula in an in vitro experimental trial?

In research Question 3, the proportion of aspirated RV serves as the dependent variable, with higher values representing a greater amount of assessed RV. The five independent variables factorially combined are: three levels of methods (syringe suction and gravity), two tube sizes (10 F and 18 F), two tube materials (PVC and polyurethane), four levels of nurse experience (student, novice, experienced, and expert) and five volumes of formula (50 mL, 150 mL, 300 mL, 500 mL, and 600 mL). Because the three methods used in practice to assess RV (syringe, suction, and gravity) would not be used in combination with each other, each of the three methods was evaluated separately (syringe, suction, and gravity). A 2x2x4x5 analysis of variance (ANOVA) provides a test of the effects of tube size, tube material experience of the nurse, and levels of volume available to aspirate.

Analyses were performed using GLM with 4-way interactions assessed, using Type II Sum of Squares to account for unequal *n*. Assumptions of normality, homogeneity of variance, and heteroscedasticity are questionable so interpretations are made with caution. ANOVA was used to examine the interaction effects starting with the highest level of interactions and proceeding as appropriate. Three-way interactions with tube sizes, tube material, level of nurse experience and five fixed volumes were assessed by method (syringe, suction, and gravity) for significance, alpha = .05.

Power Analysis

A priori power analysis, based on the proposed design for a 3x2x2x4x5 Balanced Completely Randomized Factorial ANOVA (with a total of 240 cells), indicated that adequate power of 90% could be obtained for all effects using two independent complete repetitions per cell for a total $n = 480$ (see Appendix C). With the proposed sample size of 480, the proposed simple effects analysis for the 5-way interaction was planned to detect effects sizes of $f = .27$ at $1-\beta = .85$ and $\alpha / 5 = .01$.

Due to an unequal number of RV assessments in the cells, the Type II sum of squares method was used. This method gives equal priority to main effects and the sample sizes reflect the importance of the cells (Tabachnick & Fidell, 2007). Equalizing cells sizes by random deletion of cases is not a favorable approach in this study given the relatively small sample size within each cell. Therefore the Type II sum of squares was determined to be the most suitable approach for dealing with the unequal cell sizes.

There were not any specific a priori questions developed for post hoc comparisons, but planned comparisons were to be performed for any significant interactions. Given the exploratory nature of this research and the potential to identify

areas for future research, post hoc analyses using Bonferroni , α / number of comparisons, were performed to identify any significant of differences among the factors.

Evaluation of Assumptions

Prior to analysis, the study variables were examined for accuracy of data entry, missing values and fit between the variables distribution and the assumptions of multivariate analysis. Each variable in the study was examined separately. Two cases were found to have included a volume available of 600 mL rather than 500 mL, thus creating an unbalanced design. This was corrected in the data, which resulted in three repetitions within in two cells. There was only one repetition in the cell for the 500 mL volume for syringe method using a 10 Fr polyurethane tube, by the experienced nurse rater and one repetition for the novice nurse for the 500 mL volume for suction using an 18 Fr PVC tube.

Data were assessed for outliers and one significant outlier was noted. The Mahalanobis distance (X^2 distribution, $p < .001$, with 1 *df*) was used to assess for outliers. Descriptive statistics were run to assess for univariate outliers among the feeding tubes and the level of nurse experience on the dependent variable, proportion of aspirated RV. Negative skew is evident in these variables, with significant skew noted for the student nurse using the syringe method and a 10 Fr polyurethane tube (skew statistic = -2.12) and the expert nurse using the suction method and the18 Fr polyurethane tube (skew statistic = -2.02). The log transformation (plus one because many values were zero) was explored, along with the inverse and arcsine transformations; however, there was no improvement in the skew and the data were left untransformed. Leverage values were assessed and no significant outliers were noted. While none of the cases were considered

outliers based on Mahalanobis, one of the cases was further examined and determined to be an outlier. Specifically, it was believed that the assessment of 0 mL of RV when there was 600 mL available to aspirate was a true measurement error and that the suction was not properly connected. This one case was deleted leaving 479 cases for analysis.

Independence of nurse experience in the assessment of RVs was demonstrated by comparing the studentized residuals against the order of the repetitions performed by the nurse raters and as there was no relationship evident, independence of measures was assumed. Furthermore, paired *t* tests were performed on the assessed RVs for each level of nurse experience to determine if there were differences between the repetitions. There was no difference in the repetitions and therefore level of nurse experience was only modeled as a between subjects factor and not assessed for within level of nurse experience differences.

Homogeneity of Variance was assessed formally using Levene's test of equality of error variances. Because of the small sample size and not enough degrees of freedom, Levene's test was not able to be calculated for the 2x2x4x5 ANOVA used to evaluate Question 3. Homogeneity of variance was not confirmed therefore the results of the between subjects analysis are provided to identify factors that may be significant in explaining variability of the DV; however, because of the risk for Type I error, post hoc comparisons are interpreted with caution. The volume factor had non-constant variance and therefore after running the 2x2x4x5 between subjects ANOVA, the model was reduced to a 2x2x4 ANOVA, eliminating volume as a factor. This was addressed in research Question 4.

Research Question 4

What is the effect of tube size, tube material, and level of nurse experience on the proportion of assessed RV?

Research Question 4 was posed because the volume factor contained significant heterogeneity of variance; therefore, it was removed as a factor and a reduced model containing tube size, tube material, and level of nurse experience was performed in addition to the model discussed previously using a 2x2x4 ANOVA. The results of the 2x2x4 ANOVA assessing for variability in the proportion of aspirated RV by tube size, tube material, and level of nurse experience, are provided along with a separate one-way ANOVA with Brown-Forsyth corrections used to explore the effects of volume on the proportion of aspirated RV. Levene's was considered significant at $\alpha = .01$.

Research Question 5

What is the effect of the four feeding tubes evaluated in this study and the level of nurse experience on the proportion of aspirated RV?

Because in practice, the tube material is not separate from the tube size, it is important to explore the effects of these combined factors as well as to evaluate how they influence the proportion of aspirated RV separately. There were four feeding tubes evaluated in this study. A 4x4 ANOVA was performed to evaluate the effect of the four feeding tubes (10 Fr polyurethane tube, 10 Fr PVC tube, 18 Fr polyurethane tube, 18 Fr PVC tube) and the levels of nurse experience on the proportion of aspirated RV for each of the three methods (syringe, suction, and gravity) factorially combined. Analyses were

performed using GLM with 2-way interactions assessed, using Type II Sum of Squares to account for unequal *n*. Homogeneity of variance was assumed in this model, with Levene's test for homogeneity of variance, $p = .01$.

Research Question 6

Is one method for aspirating RV (syringe, suction, and gravity) better than another in assessing RV?

Research Question 6 was evaluated using a one-way ANOVA. The dependent variable was the proportion of RV and the methods used to assess RV were compared with each other (syringe, suction, and gravity). The Brown-Forsyth statistic was used interpret significant results where homogeneity of variance was not assumed. Significant results were followed up with post hoc tests using Games-Howell.

Research Question 7

Is one tube better than another tube within each of the three methods (syringe, suction, and gravity) in assessing the proportion of aspirated RV?

Research Question 7 was evaluated with a one-way ANOVA to evaluate the effect of the four feeding tubes used in this study on the variability in the proportion of aspirated RV within each of the methods used to aspirate RV (syringe, suction, and gravity). The Brown-Forsyth statistic was used interpret significant results where homogeneity of variance was not assumed. Significant results were followed up with post hoc tests using Games-Howell.

Research Question 8

What is the effect of volume of the proportion of aspirated RV?

Research Question 8 was evaluated with a one-way ANOVA to evaluate the effect of volume on the variability in the proportion of aspirated RV within each of the methods used to aspirate RV (syringe, suction, and gravity). The Brown-Forsyth statistic was used interpret significant results where homogeneity of variance was not assumed. Significant results were followed up with post hoc tests using Games-Howell.

Research Question 9

How well does RV assessment identify measurements that would be considered intolerant to EN in practice?

Sensitivity and specificity analyses were performed to determine the validity and accuracy of RV assessments to address Question 9 in this study. An overall sensitivity and specificity analysis was performed across all three methods and then the same analyses were performed for each of the three methods (syringe, suction, and gravity). Sensitivity refers to a tests ability to correctly identify those who have a disease and in this study sensitivity refers to the RV assessments ability to correctly identify RV assessments that in practice would be considered feeding tube intolerance (volumes greater than or equal to 500 mL). Specificity is the ability of a test to correctly identify individuals who do not have a disease and in this study; specificity is used to identify RV volumes less than 500 mL when the available volume was less than 500 mL.

Sensitivity and specificity are helpful in selecting appropriate diagnostic tests, but they cannot be used to estimate probability of a disease or condition in individual patients; likelihood ratios (LR) combine the sensitivity and specificity of a test and are

more clinically meaningful because they can be used to calculate the probability of disease for individual patients (Akobeng, 2007). LR for a positive test (LR+) is the probability of individuals with a disease having a positive test divided by the probability on an individual without the disease having a positive test. The LR for a negative test (LR-) is the probability that an individual with the disease having a negative test divided by the probability that an individual without the disease has a negative test. When a LR- is less than one, there is less chance that a negative test will occur in those with the disease. In this study, LR- values less than one suggest that there is a lesser likelihood of a person with intolerance having an RV assessment that would be of a lower value (less than 500 mLs). LRs were calculated using a weighted formula (Lowry, 2012) based on the prevalence of volumes consistent with intolerance in this study, calculated as follows:

Likelihood Ration Negative [weighted for prevalence] $= \dfrac{Probability\ of\ false\ negative\ result}{Probability\ of\ true\ negative\ result}$

$$= \dfrac{(Prevalence)(1 - Sensitivity)}{(1 - Prevalence)(specificity)}$$

Research Question 10

Is there evidence of interrater reliability in RV assessment across the level of nurse experience when the nurses are treated as raters?

To assess consistency in nurse assessments, intraclass correlations (ICCs) were calculated to evaluate interrater agreement and calculated as an index of rater consistency. Two different types of ICC were calculated following methods described by Shrout and Fleiss (1979) and Spence Laschinger (1992); formulas are provided later in this section. In the first calculation, raters were treated as if they were randomly sampled from the population and this ICC provides a reliability estimate of interrater agreement where the ICC can be considered as a measure of reliability of whether or not raters can

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be considered interchangeable, denoted by ICC (2, 4) where two represents the ICC for agreement and four represents the number of raters included in the calculation. The second ICC estimated in this study considers the raters as fixed and applies to the reliability of only the raters studied in the design. The ICC for interrater consistency is denoted as ICC (3, 4) where three represents the consistency model and four again represents the number of raters. Due to the limited sample size ($n = 4$) of raters, external validity is limited, and thus the generalizability to all other raters in each of the four experience categories.

The calculation of the ICC when raters are considered randomly sampled is estimated by:

$$ICC(2, k) = \frac{MS\,P - MS\,E}{MS\,P + (k{-}1)\,MS\,E + k\,(MSR - MSE)/n}$$

The calculation of the ICC when raters are considered fixed and is a measure of consistency is estimated by:

$$ICC(3, k) = \frac{MS\,P - MS\,E}{MS\,P + (k{-}1)\,MS\,E}$$

Where: k = number of raters

n = number of persons

$MS\,P$ = mean square persons

$MS\,E$ = total $MS - MS\,P$ - MSR obtained from the two-way ANOVA

MSR = mean square raters

$MS\,E$ = total $MS - MS\,P$ - MSR

The F values were obtained from the two-way ANOVA and used to construct confidence intervals using the methods described by Shrout and Fleiss (1979) and Steiger (2004). $\omega^2_{partial}$ provide an estimate of the ICC and can provide an estimate of the ICC for the *nurse experience*, if nurse experience were considered random rather than fixed (The

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fixed values in the design actually cover the entire range of nurse experience). ICCs were

considered acceptable if they were 0.75 or greater (Shrout & Fleiss, 1979).

CHAPTER FIVE

PHASE II RESULTS

This chapter presents the results of the data analysis and a summary of findings for each research question addressed in Phase II; research Questions 3 through 10. The overall main research question, main effects, and any significant interactions are discussed.

Sample Description

Four nurses participated in this study, representing the practice experience levels of student, novice, experienced, and expert nurse. The four nurses each completed a total of 120 RV measurements, with 40 measurements for each method (syringe, suction, and gravity). Within each method, each nurse assessed RVs with a PVC tube (20 measurements) and a polyurethane tube (20 measurements). The tube sizes consisted of 10 Fr (20 measurements) and 18 Fr (20 measurements) and each volume of fluid was assessed twice using the combination of all of these factors.

Description of RV

There were 479 RV assessments analyzed in this study comprising two repetitions of measurements across the levels of each factor evaluated in this study (method, tube size, tube material, and volumes) by the four nurse participants. The two repetition groups were partitioned based on the order in which the combination of the factors were evaluated and then compared with each other. An initial screening of the data found two cases where the planned available volume in the in vitro experiment were inappropriately used, such that in two cases where the volume should have been 500 mL, there was actually 600 mL available. As a result, there were unequal cell sizes. This discrepancy

resulted in one less observation for the suction method: syringe ($n = 160$), suction ($n = 159$), and gravity drainage ($n = 160$).

There were 120 RV measurements made by each nurse. The mean proportion assessed RV across all methods was 0.56 mL (*SD* 0.36 mL) with assessed RVs varying from 0 to over 1.00. In 10 cases, the RVs assessed by the nurses were higher than the amount that was available to aspirate (greater than 100% total volume available). This difference could be related to measurement error in reading the amount of fluid in the graduated cylinder or because the formula pooled in the lid and tubing of the suction canister and may have caused these discrepancies.

Descriptive statistics were used to compare the three methods used to aspirate RV and the proportion of assessed RV by level of nurse rater experience, tube type, tube material, and volumes available to aspirate. All three methods used to aspirate RV did not perform substantially well in aspirating residual simulated stomach contents, and on average, the methods were only able to aspirate about 50% of the volume available.

Across the three methods, 19% ($n = 92$) of the time, RV assessments produced 5% or less of the total volume present in the simulated stomach. Across the three methods used to aspirate RV in this study, 17% (82/479) of the assessments produced no volume (0 mL). These findings of 0 mLs were similar within each of the methods; syringe method, 18% (29/160); suction method, 11% (18/159); and gravity method, 22% (35/160). Across all three methods evaluated to assess RV, the gravity technique produced lower aspirated RVs (0.47 mL ± 0.37 mL) compared with the syringe (0.57 mL ± 0.36 mL) and suction techniques (0.63 mL ± 0.34 mL). The gravity method

had lower aspirated volumes across the tube sizes and tube materials as depicted in

Table 7.

Table 7

Proportion of RVs Measured in Milliliters by Method

Factor	Syringe	Suction	Gravity	F	P
Nurse Experience					
Student	0.64 (0.34)	0.66 (0.33)	0.49 (0.38)	2.97	.050
Novice	0.45 (0.36)	0.58 (0.32)	0.49 (0.35)	1.53	.200
Experienced	0.57 (0.38)	0.59 (0.35)	0.37 (0.36)	4.40	.010
Expert	0.60 (0.34)	0.69 (0.34)	0.53 (0.40)	1.80	.170
Tube Size					
10 Fr	0.64 (0.39)	0.65(0.34)	0.48(0.38)	5.16	.006
18 Fr	0.49 (0.32)	0.62(0.33)	0.46(0.37)	4.61	.010
Tube Material					
Polyurethane	0.49 (0.36)	0.56 (0.35)	0.39 (0.35)	5.01	.007
PVC	0.65 (0.35)	0.69 (0.33)	0.55 (0.38)	3.72	.026
Volume					
50 mL	0.25 (0.39)	0.38 (0.39)	0.26 (0.36)	1.09	.342
150 mL	0.52 (0.39)	0.61 (0.33)	0.36 (0.40)	3.58	.032
300 mL	0.62 (0.31)	0.71 (0.29)	0.59 (0.34)	1.27	.286
500 mL	0.72 (0.23)	0.77 (0.30)	0.64 (0.30)	1.82	.167
600 mL	0.73 (0.23)	0.67 (0.27)	0.49 (0.33)	6.50	.002[a]
Total	0.57 (0.36)	0.63 (0.34)	0.47 (0.37)	8.27	<. 001

[a]Brown-Forsythe adjustment.

There were 239 measurements made with the 10 Fr tube size and 240

measurements made with the 18 Fr tube size. The smaller 10 Fr Tubes produced higher

mean volumes (0.59 mL ± 0.37 mL) compared with the larger 18 Fr tubes

(0.52 mL ± 0.35 mL) across all three methods and within each method, the 10 Fr tube

continued to produce the larger quantities of RV. The polyurethane tubes

(0.48 mL ± 0.36 mL) produced smaller RV assessment quantities compared with the

PVC (0.63 mL ± 0.35 mL) tubes across the three methods and similarly within each technique.

In assessing the average amount of aspirated RV within each level of fluid, the smaller quantities of available volume (50 mL) had lower amounts of assessed RV. Table 8 shows the distribution of RVs for this study expressed as counts and frequencies across the volumes available to aspirate. Figure 5 shows the distribution of volume by method used to aspirate the RV. The quantity of the RVs increased as the amount of available volume increased across the three methods.

Table 8

Frequencies of Assessed RV

Percent Aspirated	50 mL $N = 96$	150 mL $N = 96$	300 mL $N = 96$	500 mL $N = 94$	600 mL $N = 97$
$= 0\%$	46 (48 %)	18 (19%)	9 (9 %)	3 (3 %)	6 (6 %)
$\leq 5\%$	47 (49 %)	24 (25 %)	9 (9 %)	4 (4 %)	8 (8 %)
$\leq 25\%$	59 (61 %)	32 (33%)	15 (16 %)	6 (6 %)	13 (13 %)
$\leq 50\%$	74 (77 %)	50 (52 %)	34 (35 %)	24 (26 %)	29 (3 %)
$\leq 75\%$	76 (79 %)	61 (64 %)	56 (58 %)	45 (48 %)	53 (55 %)
$\leq 90\%$	83 (86 %)	77 (80 %)	71 (74 %)	74 (79 %)	80 (82 %)
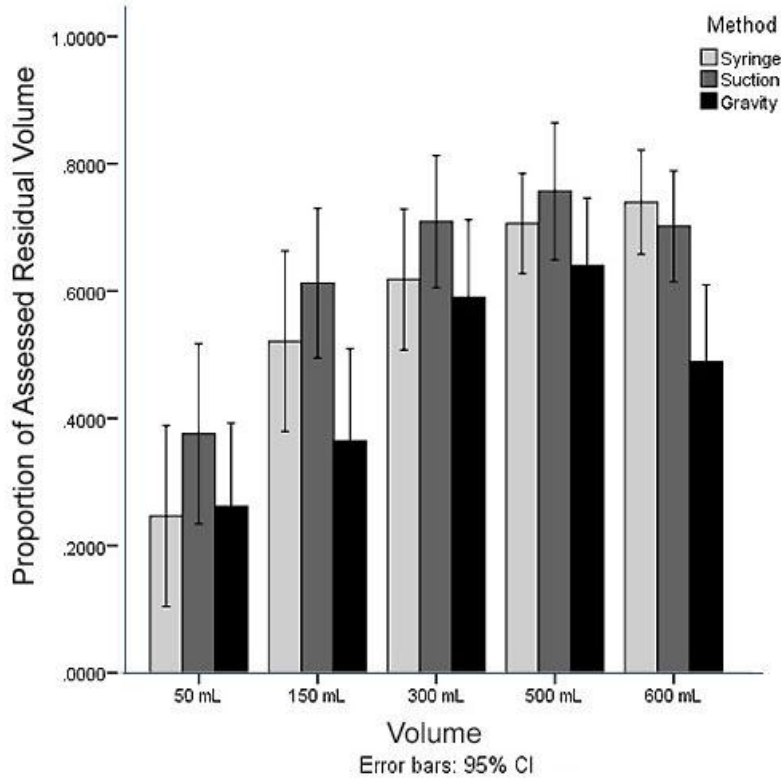
Figure 5. Proportion of assessed RV level of volume by method.

Results of Research Questions in Phase II

Research Question 3

How do methods for aspirating GRV (syringe, suction and gravity), tube size

(10 Fr and 18 Fr), tube material (PVC and polyurethane), experience of the nurse

(student, novice, experienced, and expert) and total volume available (50 mL, 150 mL,

300 mL, 500 mL, and 600 mL) influence the amount of aspirated feeding formula in an

in-vitro experimental trial?

To address research question three, a 2x2x4x5 between subjects analysis of

variance (ANOVA) was performed on the proportion of aspirated RV for each method

used to aspirate RV. The ANOVA model results are presented for each method used to

aspirate RV. Significant main effects and interactions are presented for each of the

methods used to aspirate RV separately. Variability explained by the model for each method of assessing RV is presented as well.

Syringe method 2x2x4x5 results. Within the syringe method, for the 2x2x4x5 ANOVA, proportion of aspirated RV significantly varied by tube size $F(1, 159) = 9.77$, $p = .002$, tube material $F(1, 159) = 11.88$, $p = .001$, level of nurse experience $F(3, 159) = 3.06$, $p = .033$ and volume $F(4, 159) = 14.78$, $p < .001$. The marginal means displayed in Table 9 with 95% confidence intervals show that the 10 Fr tube produced higher aspirated RVs and the 18 Fr tube had lower aspirated RVs, although this difference was not significant, $p = .54$. The PVC tube produced greater aspirated RVs than the polyurethane tubes which was found to be significantly different using pairwise comparisons, $F(1, 80) = 11.83$, $p = .001$, 95% CI [.07, .25]. The expert and the student nurse had similar RV assessments and produced higher proportions of RVs followed by the experienced nurse and lastly the novice nurse. Multiple comparisons demonstrated significant differences between the student and the novice nurse on assessed RVs, $F(3, 80) = 8.23$, $\underline{p} = .03$, 95% CI [0.01, 0.36]; all the other levels of nurses were not significantly different on the amount of assessed RV using the syringe technique.

Pairwise comparisons to explore the differences in the proportion of aspirated RV across volumes demonstrated that the 50 mL volume was significantly different from each of the other volumes evaluated in this study, $p < .001$. The difference between the proportion of assessed RV with the 50 mL and the 150 mL, 300 mL, 500 mL, and 600 mL volumes ranged from 27 % difference to as much as 48 % difference in the assessed RV.

The 150 mL also was significantly different from other volumes evaluated in this study, but the differences were seen with the higher 500 mL and 600 mL volumes. There was variation between the 150 mL volume and the 500 mL volume such that there were greater proportions of aspirated RV in the 500 mL volume, $F(1, 159) = 6.89$, $p = .01$. This was similar when comparing the 150 mL volume with the 600 mL volume, $F(1, 159) = 8.52$, $p = .005$. Using the estimated means for these volumes, both the 500 mL and 600 mL volumes had aspirated RVs approximately 20% higher than when there was only 150 mL available to aspirate.

Table 9

Estimated Means for Factors Evaluated in the ANOVA Model for Syringe Method

Factors	*Mean* (SE)	95 % CI
Tube Size		
10 Fr	0.64 (0.03)	[0.57, 0.70]
18 Fr	0.49 (0.03)	[0.43, 0.56]
Tube Material		
Poly	0.49 (0.03)	[0.42, 0.55]
PVC	0.65 (0.03)	[0.58, 0.71]
Nurse Experience		
Student	0.64 (0.05)	[0.55, 0.73]
Novice	0.46 (0.05)	[0.36, 0.55]
Experienced	0.57 (0.05)	[0.47, 0.66]
Expert	0.60 (0.05)	[0.51, 0.69]
Volume		
50 mL	0.25 (0.05)	[0.14, 0.35]
150 mL	0.52 (0.05)	[0.42, 0.62]
300 mL	0.62 (0.05)	[0.52, 0.72]
500 mL	0.72 (0.05)	[0.61, 0.82]
600 mL	0.73(0.05)	[0.63, 0.83]

There was a significant interaction present between tube size and level of nurse experience, $F(3, 159) = 2.78$, $p = .05$; however, tube size by level of nurse experience

interaction effect was the only significant two-way interaction. Again the relationship between the assessed RV and this interaction was weak ($\eta^2 = .003$). Estimated means and 95% confidence intervals for the interaction effects are shown in Table 10. All levels of nurse experience had greater assessed RVs using the 10 Fr tube; however, the experienced nurse produced almost equivalent RV assessments using both tubes. Pairwise comparisons found significant differences between the student and each of the other practice levels using the 10 Fr tube, $p < .001$: novice $F(3, 80) = 7.08$; experienced $F(3, 80) = 41.75$; expert $F(3, 80) = 5.91$. Figure 6 is helpful in demonstrating the differences between the tube size and the levels of nurse experience.
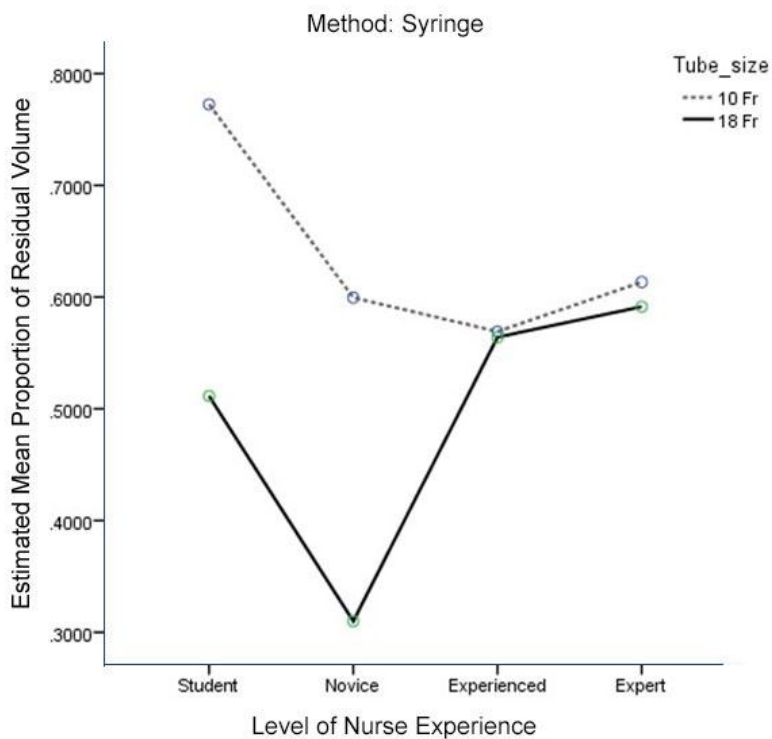
Figure 6. Interaction of nurse experience with tube size.

Using the η^2 as a measure of effect size, the interaction between tube size and level of nurse experience was very weak and accounted for only 3% of the variability in proportion of aspirated RV. Relatively weak effects were found for tube size ($\eta^2 = .04$),

tube material ($\eta^2 = .05$) and level of nurse experience ($\eta^2 = .04$). However, volume had a

large effect and accounted for 24% ($\eta^2 = .24$) of the variability in the proportion of

aspirated RV. Overall, the full 2x2x4x5 ANOVA accounted for 67% of the variance in

the proportion of assessed RV using the syringe method to perform RV assessments

(R^2 Squared = .671; Adjusted $R^2 = .346$).

Table 10

Estimated Means for Significant Interactions in Syringe Method

Tube size	Nurse Experience	*Mean*	Std. Error	95% Confidence Interval	
				Lower Bound	Upper Bound
10 Fr	Student	0.77	0.07	0.64	0.90
	Novice	0.60	0.07	0.47	0.73
	Experienced	0.57	0.07	0.44	0.70
	Expert	0.61	0.07	0.48	0.74
18 Fr	Student	0.51	0.07	0.38	0.64
	Novice	0.31	0.07	0.18	0.44
	Experienced	0.56	0.07	0.43	0.69
	Expert	0.59	0.07	0.46	0.72

Suction method 2x2x4x5 results. Within the suction method, evaluated by the

2x2x4x5 ANOVA, RV varied significantly with the tube material $F(1, 158) = 7.14$,

$p = .009$, $\eta^2 = .04$ and volume $F(4, 158) = 7.31$, $p < .001$, $\eta^2 = .16$. The estimated means

and confidence intervals for all effects are shown in Table 11. The main effects for nurse

experience and tube size were not significant nor were the higher order effects

significant. The PVC tube produced larger aspirated RVs compared with the

polyurethane tube. This difference between the PVC and polyurethane tubes was

statistically significant using post hoc comparison with Bonferroni adjustment

$F(1, 79) = 6.90$, $p = .01$. Pairwise comparisons were also performed to evaluate

significant differences within the volumes on the proportion of aspirated RV. When RV

was assessed using a total volume available of 50 mL volumes, the percentage of

assessed RV was significantly less than when there were 150 mL ($p = .004$),

300 mL ($p = .001$), 500 mL ($p < .001$), and 600 mL ($p = .001$) volumes available to

aspirate. The difference in the percent of aspirated RV when there was only 50 mL

available compared across the other volumes ranged from 23% to 32 % more aspirated

RV with the 150 mL and greater volumes using the estimated means for each volume.

Volume was a medium to large effect accounting for 16% of the variability in the

proportion of the aspirated RV, while tube material had a small effect. Overall, this

2x2x4x5 ANOVA model explained 56% of the variance in assessed RV ($R^2 = .56$;

Adjusted $R^2 = .119$).

Table 11

Estimated Means for Factors Evaluated in the ANOVA Model for Suction Method

Factors	*Mean* (SE)	95 % CI
Tube Size		
10 Fr	0.65 (.04)	[0.58, 0.72]
18 Fr	0.62 (.04)	[0.54, 0.69]
Tube Material		
Poly	0.56 (.04)	[0.49, 0.63]
PVC	0.70 (.04)	[0.62, 0.77]

Table continued

Nurse Experience		
Student	0.64 (0.05)	[0.54, 0.74]
Novice	0.58 (0.05)	[0.48, 0.68]
Experienced	0.59 (0.05)	[0.49, 0.69]
Expert	0.71 (0.05)	[0.61, 0.81]
Volume		
50 mL	0.38 (0.06)	[0.26, 0.49]
150 mL	0.61 (0.06)	[0.50, 0.72]
300 mL	0.71 (0.06)	[0.60, 0.82]
500 mL	0.75 (0.06)	[0.64, 0.87]
600 mL	0.70 (0.06)	[0.59, 0.82]

Gravity method 2x2x4x5 results. Using the gravity method to aspirate RVs, evaluated with the 2x2x4x5 ANOVA, the proportion of aspirated RV significantly varied by tube material $F(1, 159) = 10.603$, $p = .002$, $\eta^2 = .05$, and volume $F(1, 159) = 7.99$, $p < .001$, $\eta^2 = .14$. The estimated means and confidence intervals for all factors are summarized in Table 12. No statistically significant main effects for level of nurse experience and tube size were found.

The main effect for tube material was explored using pairwise comparisons. The PVC tubes produced greater proportions of assessed RV compared with the polyurethane tubes, $F(1, 80) = 10.603$, $p = .002$. Using the estimated means to make comparisons, the PVC tube produced 16% more RV than the polyurethane tube (.55 mL versus .39 mL).

For the significant main effect of volume on the proportion of aspirated RV, pairwise comparisons were used to assess for which volumes of fluid were significantly different from one another. The 50 mL volume was significantly different from the 300 mL, 500 mL, and 600 mL volumes. The 150 mL volume was significantly different from the 300 mL, 500 mL, and 500 mL volumes. Using the gravity technique, the proportion of aspirated RV from 600 mL volume was actually less than the proportions of

aspirated RV from both the 300 mL and 500 mL. This is evident in Table 12 comparing

the mean aspirated RVs for volume.

Table 12

Estimated Means for Factors Evaluated in the ANOVA Model for Gravity Method

Factors	*Mean* (SE)	95 % CI
Tube Size		
10 Fr	0.48 (0.04)	[0.41, 0.55]
18 Fr	0.46 (0.04)	[0.39, 0.53]
Tube Material		
Poly	0.39 (0.04)	[0.32, 0.46]
PVC	0.55 (0.04)	[0.48, 0.62]
Nurse Experience		
Student	0.49 (0.05)	[0.39, 0.58]
Novice	0.49 (0.05)	[0.39, 0.59]
Experienced	0.37 (0.05)	[0.27, 0.47]
Expert	0.53 (0.05)	[0.43, 0.63]
Volume		
50 mL	0.26 (0.06)	[0.15, 0.37]
150 mL	0.36 (0.06)	[0.25, 0.48]
300 mL	0.59 (0.06)	[0.48, 0.70]
500 mL	0.64 (0.06)	[0.53, 0.75]
600 mL	0.49 (0.06)	[0.38, 0.60]

There was a significant interaction between tube size, level of nurse experience

and volume, $F(12, 159) = 1.97$, $p = .04$, $\eta^2 = .11$. This was the only significant interaction

evident in the model and explained 11 % of the variability in the proportion of

aspirated RV.

Figure 7 demonstrates the differences in the proportion of RV for tube sizes and

level of nurse experience across the volumes for the gravity method.

Contrasts for tube size by level of nurse experience and volumes found significant

differences existed with the 10 Fr tubes in the 500 mL volumes for both the novice nurse,

where equal variances are not assumed, t (12.47) = 3.17, p = .008 and the expert nurse

t (9.42) = 3.16, p = .01. Additionally there were differences in the proportion of aspirated

RV noted with the student using the 18 Fr sized tube, equal variances not assumed,

t (9.65) = 5.39, p < .001. Overall, this model, using the gravity method to aspirate RV

accounted for 64% of the variance in proportion of aspirated RV (R^2 = .64,

Adjusted R^2 = .29).
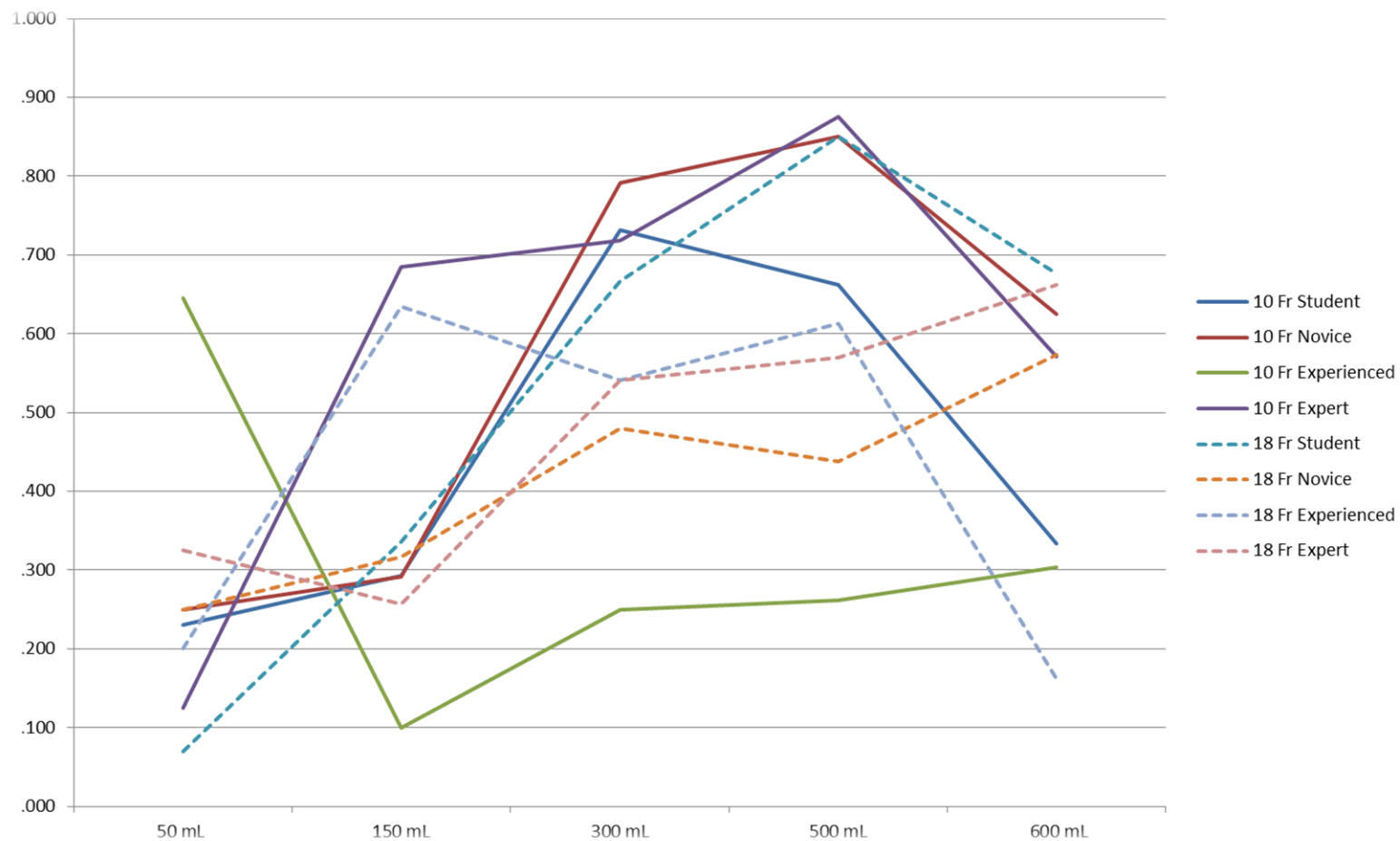
Figure 7. Estimated means for level of nurse experience, tube size, and volumes using gravity drainage method.

Summary of Research Question 3

  The three separate 2x2x4x5 ANOVAs for the syringe, suction, and gravity methods each had significant main effects for tube material and volume. Across all three methods, the PVC tube produced greater proportions of RV. The other similarity across the methods was that the smaller 50 mL volume of fluid had lower assessed proportions of RV. Across the syringe and suction methods, the proportion of assessed RV increased linearly with larger available volumes of fluid. This occurred also in the gravity method until the 600 mL volume when the assessed proportion's decreased. The syringe method was the only method that had a significant main effect for the level of nurse experience and the student nurse generally was better at aspirating RV. In the syringe method, the smaller sized 10 Fr tubes were associated with larger proportions of assessed RV.

Research Question 4

  What is the effect of tube size, tube material and level of nurse experience on the proportion of assessed RV?

  The ANOVA model results are presented for each method used to aspirate RV (syringe, suction, and gravity). Significant main effects and interactions are presented for each of the methods used to aspirate RV separately. Variability explained by the model for each method of assessing RV is presented as well.

  Syringe method 2x2x4 results. A 2x2x4 ANOVA showed a significant effect main effect for tube size, $F(1, 159) = 7.12$, $p = .008$ and main effect for tube material $F(1, 159) = 8.66$, $p = .004$ on the proportion of aspirated RV using the syringe method. However, both of these factors had relatively small effects on the variability in the proportion of aspirated RV (tube size, $\eta^2 = .04$; tube material, $\eta^2 = .05$). There was no

significant main effect for the level of the nurse experience, nor were there any significant interactions. The full model accounted for 18% of the variability in the proportion of aspirated RV ($R^2 = .18$, adjusted $R^2 = .10$). The estimated grand mean for the full model produced 0.57(*SE 0*.03) proportion of the aspirated RV, 95% CI [.51, .62]. Table 13 demonstrates the estimated means and confidence intervals for the significant main effects for the syringe technique along with the results of the suction and gravity ANOVA models. Pairwise comparisons for tube size found the 10 Fr tube was associated with higher RVs $F(1, 144) = 7.12$, $p = .008$. Comparing tube materials, the PVC tubes produced significantly different proportions of aspirated RV compared with the polyurethane tubes $F(1, 144) = 8.66$, $p = .004$.

Suction method 2x2x4 results. Evaluating the 2x2x4 ANOVA for effect on the proportion of aspirated RV for the suction method, only the main effect of tube material was significant $F(1, 158) = 6.40$, $p = .012$. The full model accounted for 11% of the variability in the proportion of aspirated RV ($R^2 = .11$, Adjusted $R^2 = .01$). The estimated grand mean for the full model produced .63 (*SE* .03) proportion of the aspirated RV, 95% CI [.58, .68]. Tube material had a relatively small effect on the proportion of aspirated RV ($\eta^2 = .04$). Pairwise comparisons demonstrated that the PVC tube performed significantly better compared with the polyurethane tube $F(1, 143) = 6.26$, $p = .01$.

Gravity method 2x2x4 results. Evaluating the 2x2x4 ANOVA for effects on the proportion of aspirated RV for the gravity method, only the main effect of tube material was significant $F(1, 159) = 7.90$, $p = .006$. Tube material had a small effect on the proportion of aspirated RV ($\eta^2 = .05$). The full model accounted for 14% of the

variability in the proportion of aspirated RV (R^2 = .14, Adjusted R^2 = .45). The estimated grand mean for the full model produced 0.47 mLs (*SE0* .03) proportion of the aspirated RV, 95% CI [.41, .53]. Pairwise comparisons found the PVC tube to produce the larger proportions of aspirated RV $F(1, 144)$ = 7.90, p = .006.

Table 13

Significant Main Effects and Estimated Mean Proportions of Aspirated RV

Syringe Method	*Mean* (SE)	95 % CI
Tube size		
10 Fr	0.64 (0.04)[a]	[0.56, 0.71]
18 Fr	0.49 (0.04)	[0.42, 0.57]
Tube Material		
Polyurethane	0.49 (0.04)	[0.41, 0.56]
PVC	0.65 (0.04)[a]	[0.57 - 0.72]
Suction Method		
Tube material		
Polyurethane	0.56 (0.04)	[0.49, 0.64]
PVC	0.70 (0. 04)	[0.62, 0.77]
Gravity Method		
Tube material		
Polyurethane	0.39 (0.04)	[0.31, 0.47]
PVC	0.55 (0. 04)[a]	[0.47, 0.63]

[a]Significant at p < .025

Summary of Research Question 4

    The three separate 2x2x4x5 ANOVA's for the syringe, suction, and gravity methods each had significant main effects for tube material. In each method, the PVC

tube was associated with higher assessed proportions of RV. In the syringe method, tube size also had a significant main effect. The 10 Fr sized tube was associated with higher assessed RVs.

Research Question 5

What is the effect of the four feeding tubes evaluated in this study and the level of the nurse experience on the proportion of aspirated RV?

The 4x4 ANOVA model results are presented for each method used to aspirate RV. All three methods used to assess RV (syringe, suction, and gravity) had only significant main effects for tubes. There were no significant interactions between the feeding tubes used to assess RV and the level of nurse experience. Each method is described separately using post hoc comparisons to identify which levels were significantly different. Variability explained by the model for each method of assessing RV is presented as well.

Syringe method 4x4 ANOVA model. In the syringe method, the four tubes had a significant main effect, $F(3, 159) = 5.45$, $p = .001$. The four tubes had a moderate effect on the proportion of aspirated volume, $\eta^2 = .09$. Post hoc comparisons found significant differences between the 10 Fr PVC tubes and the 18 Fr polyurethane tubes, $p = .001$, where the 10 Fr PVC was able to aspirate a greater proportion of RV. The other tubes in the study did not produce significantly different proportions of aspirated RV. The estimated mean proportion of aspirated RV for this 4x4 model was 0.57 mL (*SE* 0.03), 95% CI [0.51, 0.62]. Overall, this model explained 18% of the variability in the proportion of aspirated RV (Adjusted $R^2 = .10$).

Suction method 4x4 ANOVA model. In the suction method, the four tubes had a significant main effect, $F(3, 159) = 2.63$, $p = .05$. The four tubes had a small effect on the proportion of aspirated volume, $\eta^2 = .05$. Post hoc comparisons did not yield any significant differences between the tubes. The estimated mean proportion of aspirated RV for this 4x4 model was 0.63 mLs (SE 0.03), 95% CI [0.58, 0.68]. Overall, this model explained 11% of the variability in the proportion of aspirated RV (Adjusted $R^2 = .01$).

Gravity method 4x4 ANOVA model. In the gravity method, the four tubes had a significant main effect, $F(3, 159) = 2.73$, $p = .05$. The four tubes had a small effect on the proportion of aspirated volume, $\eta^2 = .05$ using the suction technique. Post hoc comparisons did not yield any significant differences between the tubes. The estimated mean proportion of aspirated RV for this 4x4 model was .47 mL (SE 0.03), CI [0.41, 0.53]. Overall, this model explained 13% of the variability in the proportion of aspirated RV (Adjusted $R^2 = .04$).

Summary of Research Question 5

The three separate 4x4 ANOVAs for the syringe, suction,n and gravity methods each had significant main effects for the tubes used to assess RV. In the syringe method, the 10 Fr PVC tube performed better than the 18 Fr, but there were not any differences among the other tubes evaluated in the study. Although the suction and gravity methods had a significant main effect for the tubes, one tube was not any better than another within those methods.

Research Question 6

Is one method for aspirating RV (syringe versus suction versus gravity) better than any other method?

A one-way ANOVA comparing the three methods on the proportion of aspirated RV was performed and significant differences were noted between the three methods, $F(4, 278) = 8.28$, $p < .001$. Post hoc tests using Bonferroni, demonstrated significant differences between the suction and gravity methods, $t = 0.40$, $p < .001$, CI [0.05, 0.27]; however, the syringe and suction methods were not significantly different from one another in their effect on aspirating RVs, $p = .23$. Pairwise comparisons were used to determine if either the syringe or suction methods were better methods, but there was no difference demonstrated, $t (476) = -1.63$, $p = .11$.

Research Question 7

Is one tube better than another tube within each of the three methods used to aspirate RV?

A one-way ANOVA was used to evaluate the effect of the four feeding tubes used in this study on the variability in the proportion of aspirated RV within each of the methods used to aspirate RV (syringe, suction, and gravity). Post hoc comparisons were used and any significant differences were further explored with pairwise contrasts. Only the syringe method had significant differences noted in the tubes on the proportion of aspirated RV with the Brown-Forsythe, $F(3, 147.97) = 5.31$, $p = .002$. Post hoc comparisons with Games-Howell found significant differences between the 10 Fr PVC

tube and the 18 Fr PVC tube, $p < .001$. Pairwise contrasts were used and the 10 Fr PVC

tube was slightly significantly better performing in the ability to aspirate larger

proportions of RV on average, t (78.00) = 2.45, p = .017.

Research Question 8

What is the effect of volume on the proportion of aspirated RV?

     Syringe method. A one-way ANOVA showed a significant effect of volume on

the proportion of aspirated RV, $F(4, 139.35)$ = 7.53, $p < .001$. Levene's test for

homogeneity of variance was significant therefore the Brown-Forsyth statistic was

utilized with post hoc tests using Games-Howell. Post hoc tests demonstrated a

significant difference between the 50 mL of volume with the 300 mL, 500 mL, and

600 mLs of volume (50 mL versus 300 mL, p = .003; 50 mL versus 500 mL, $p < . 001$;

50 mL versus 600 mL, $p < . 002$). Pairwise comparisons were used to evaluate

differences in volumes that are considered in practice to represent tolerance of EN

feeding (50 mL, 150 mL, and 300 mL) and with volumes in practice that would be

considered indicative of feeding intolerance (500 mL and 600 mL) to assess if there are

differences on the proportion of assessed RV. There were significant differences between

the low volumes and the high volumes on the proportion of assessed RV using the

syringe method t (149.21) = 5.59, $p < .000$, variances not assumed to be equal. Additional

contrasts assessed for differences between 300 mL versus 500 mL volumes and 600 mLs,

combined, and there was no significant differences found between these volumes,

t (47.94) = 1.72, p = .09.

     Suction. A one-way ANOVA showed a significant effect of volume on the

proportion of aspirated RV, $F(4, 139.35)$ = 7.53, $p <. 001$. Levene's test for homogeneity

of variance was significant therefore the Brown-Forsyth statistic was utilized with post hoc tests provided using Games-Howell. Significant differences were noted between the 50 mL of volume and the 300 mL, 500 mL, and 600 mL of volume (50 mL versus 300 mL, $p = .003$; 50 mL versus 500 mL, $p < .001$; 50 mL versus 600 mL, $p = .002$). Planned contrasts were used to compare for differences in volumes that are considered in practice to represent tolerance of EN feeding (50 mL, 150 mL, and 300 mL) with volumes in practice that would be considered indicative of feeding intolerance (500 mL and 600 mL) to assess if there are differences on the proportion of assessed RV. There were significant differences between the low volumes and the high volumes on the proportion of assessed RV using the suction method $t\ (140.25) = 3.37$, $p = .001$, variances not assumed to be equal. Additional contrasts assessed for differences between 300 mL versus 500 mL volumes and 600 mLs and there was no significant differences found between these volumes, $t\ (58.45) = 0.33$, $p = .743$.

Gravity. A one-way ANOVA showed a significant effect of volume on the proportion of aspirated RV, $F(4,\ 159) = 6.46$, $p < .001$, with equal variances assumed. Post hoc comparisons demonstrated a significant difference between the 50 mL of volume with the 300 mL and 500 mL (50 mL versus 300 mL, $p = .004$; 50 mL versus 500 mL, $p < .001$; 50 mL versus 600 mL, $p = .002$). Planned contrasts were used to compare for differences in volumes that are considered in practice to represent tolerance of EN feeding (50 mL, 150 mL, and 300 mL) with volumes in practice that would be considered indicative of feeding intolerance (500 mL and 600 mL) to assess if there are differences on the proportion of assess RV. There were significant differences between the low volumes and the high volumes on the proportion of assessed RV using the

suction method t (14.03) = 2.91, p = .004, variances not assumed to be equal. Additional

contrasts assessed for differences between 300 mL versus 500 mL volumes and 600 mLs,

and there was no significant differences found between these volumes, t (58.35) = - 0.33,

p = .72.

Summary of Research Question 8

Across all three methods used to aspirate RV, the smallest volume, 50 mL, had

significantly smaller proportions of assessed RV compared to the larger volumes of

500 mLs and 600 mLs. When the fixed volumes evaluated in this study were 300 mL or

less, the proportion of aspirated RVs was less than when the volumes were 500 mLs and

600 mLs, but there were not differences between the 300 mL volume and the larger

volumes. While larger amounts of volume are associated with larger assessments, there is

no difference in the proportions of assessed volumes when the volume available is

300 mL, 500 mL, and 600 mL. At these volume levels, an increase of 300 mL (the

difference from the 300 mL and the 600 mL) does not yield significantly higher

assessments, suggesting great variability in all three methods used to aspirate RV.

Research Question 9

How well does RV assessment identify measurements that would be considered

intolerant to EN in practice?

For the purpose of this study, the threshold volume to define intolerance consisted

of volumes that were 500 mL or greater. Any volume less than 500 mL was considered

tolerant. The frequencies for RV assessments made that would be considered tolerant

versus intolerant and when the RV assessment was large enough to be consistent with

those volumes are shown in Table 14.

Table 14

Frequencies of RV Assessments Considered to Be Intolerant Versus Intolerant

RV Assessment	Amount Consistent with Intolerance	Amount Inconsistent with Intolerance
RV Assessment Positive	53	0
RV Assessment Negative	138	288

Sensitivity and specificity analyses were performed to determine the validity and accuracy of RV assessment. Overall the three methods had a sensitivity of 0.28, 95% CI [0.22, 0.35] and specificity of 1.00, 95% CI [0.98, 1.00]. The specificity is high in this study and would be in practice as the definition of intolerance is based on having high RVs greater than 500 mL. It is impossible to aspirate a RV greater than 500 mL when there is less than 500 mL available. Because this was a controlled experiment the positive predictive values are not reported because they do not provide useful interpretations. The three methods are compared in Table 15. The suction method was the most sensitive to identifying volumes consistent with EN intolerance, although the syringe method was fairly similar.

Overall, the probability of assessing a RV that would indicate intolerance was 11% or 53/479 times. Given the number of volumes that were greater than 500 mL ($n = 191$), the likelihood of obtaining a RV that would be assessed as tolerant (< 500 mL) was 72% ($n = 138$), when in reality the amount that was available to be aspirated was not actually aspirated, which is consistent with the low sensitivity findings.

Table 15

Prevalence of Feeding Tube Intolerance, Sensitivity, and Specificity for Each Method

Variable	Syringe	Suction	Gravity
Prevalence	0.40	0.40	0.40
Sensitivity	0.31	0.38	0.14
Specificity	1	1	1

In the syringe method, the mean proportion of assessed RVs was 0.46 mLs when made in volumes less than 500 mLs. This finding was similar in the suction method where the LR- value was 0.41. Put another way, individuals who have their RV assessed with the syringe method and suction methods that are tolerating their EN are about twice as likely to have low RVs than individuals who are intolerant. The weighted LR- for the gravity method was 0.57, indicating the probability of aspirating lower RVs when the volume is less than 500 L is 1¾ times those with higher volumes of RV suggestive of intolerance.

Summary of Research Question 9

The syringe, suction and gravity techniques have low overall sensitivity in identifying assessments that would be considered intolerant to EN evaluated in this study. While assessed volumes may not be helpful in identifying intolerance, the assessed volumes in this study were fair indicators of tolerance. The syringe and suction techniques were more sensitive measures to identifying intolerance and performed better than the gravity technique.

Research Question 10

Is there evidence of interrater reliability in RV assessment across the level of nurse experience when the nurses are treated as raters?

A two-way ANOVA was used to obtain the ICCs to assess for absolute agreement, ICC (2, 4), and consistency, ICC (3, 4), in assessed RVs made by the nurses in this study to determine reliability. First, ICCs were constructed across the three methods used in the study to assess RV, for absolute agreement ICC (2, 4) and consistency ICC (3, 4) in the actual assessed volumes between the four levels of nurse experience where the nurse was considered a rater. Then, ICCs using both the absolute agreement and consistency calculations were constructed for each of the three methods (syringe, suction and gravity) for assessing RV used in this study.

Summary of Research Question 10

Overall, there was low interrater agreement across the three methods, ICC = .67, CI [.59, .74]. This ICC indicates that assessing RV using any of the three methods, the nurses are not interchangeable, meaning that there are differences across nurse raters. In terms of interrater consistency across the methods, the consistency was not acceptable, ICC = .67, 95% CI [.60, .74]. This indicates the four raters used in this study were inconsistent in the amount of their RV assessments not taking into consideration the type of method used for assessing RV.

The results of the reliability statistics for each method (syringe, suction, and gravity) used to assess for RV are depicted in Table 16. The only method that had an acceptable ICC (2, 4) was the syringe method. Using the syringe method, level of nurse experience is interchangeable and there is agreement in the amount of assessed RV;

however this is still questionable because the lower limit of the confidence interval in less

than the acceptable criteria for agreement suggested by Shrout and Fleiss (1979) of at

least .75. In terms of evaluating reliability between the fixed factors of level of nurse

experience evaluated in this study, the syringe method used to aspirate RV also had an

acceptable level of reliability, $F(3, 155) = 3.19$, $p = .03$. The inconsistencies and poor

agreement in assessed RVs between the suction, $F(3, 151) = 1.81$, $p = .15$ and gravity,

$F(3, 159) = 4.33$, $p = .006$ indicates that the raters have different effects in using these

methods, although the suction method has ICC values that on the upper end of the

confidence limits, indicate acceptable agreement and consistency.

Table 16

Nurse Rater Consistency and Agreement of RV Assessments by Method

ICC	Syringe	Suction	Gravity
ICC (2, 4)[a]	.80 [.70, .88]	.73 [.61, .84]	.45 [.29, .62]
ICC (3, 4)[b]	.81 [.71, .88]	.74 [.62, .84]	.47 [.31, .63]

[a]The calculation of interrater agreement using four raters. [b]The calculation of interrater consistency using four raters.

Summary of Research Question 10

Interrater agreement and consistency were evaluated to determine if there was

evidence of interrater reliability in the assessment of RV using the syringe, suction and

gravity techniques. There was greater consistency and agreement between the four raters

using the syringe method. The suction method had levels of agreement and consistency

that were approaching an acceptable level but there was greater variation between the

raters using the suction method. The gravity method had unacceptable reliability,

although the proportion of aspirated RV was consistent among the raters.

Chapter Six will summarize the findings of this study. Based on the study findings and discussion, implications for practice are discussed. Study limitations and recommendations for future research are presented.

CHAPTER SIX

DISCUSSION AND CONCLUSIONS

This chapter discusses the study findings, implications for practice and limitations of the study. Additionally, recommendations for future research are presented.

Discussion of Study Findings

This study evaluated the variation across tube size, tube material, and level of nurse experience in five levels of volume using three different methods to aspirate RV. This study sought to evaluate the influence of several factors that have been identified in practice and research to influence the assessment of GRV. This study builds on the body of evidence about RV measurement and explored many of the factors that have been questioned as influencing the ability to obtain an accurate GRV. Because this study was performed in vitro, it was also possible to determine how often RV measurements were consistent with the amount of volume that was available to be aspirated in the simulated stomach. This study found that overall; the amount of RV that can be aspirated in vitro is only about 50% of the volume available. With smaller volumes in the simulated stomach, the smaller the RVs, and in many cases, no RV could be aspirated, even across the levels of volumes studied.

Methods

The gravity method produced significantly lower RVs compared with the syringe and suction techniques. Furthermore, although the amount of time that it took for the nurses to assess each method was not studied directly, the gravity measurements took longer to complete than the syringe and suction methods. This was particularly true for the smaller 10 Fr tubes, which may make the gravity technique a poor method for

practice because it would lead to extended times that feeding would be held. The amount of time that it takes to assess GRV in practice has been reported as 5.25 minutes on average which can translate into about $2.2 million dollars in just nursing time alone for only100 patients assessed every four hours in all fifty states over one year (Parrish & McClave, 2008). Not only is GRV assessment costly for nursing care, in terms of patient care, the time that feedings are put on hold to perform this assessment is approximately 30 minutes per day, which reduces the patient's prescribed caloric intake.

There was no difference between the syringe and suction methods evaluated in this study, and both underestimated the amount of content present in the simulated stomach by 40% to as much as 100%. These findings support those of a study that evaluated the syringe and suction techniques across a small 10 Fr tube and larger 16 Fr tube in critically ill patients (Zaloga, 2005).

Tube Sizes

The smaller sized 10 Fr tube produced larger RVs compared with the larger 18 Fr tube, but the tube material and viscosity of the fluid influence the amount of RV, as does the person performing the assessment. This study did assess the effect of viscosity in the first phase of this study and found that larger volumes could be aspirated with the lower viscous fluid. These results are contrary to Metheny et al.'s findings (2005) that found in small and large bore tubes concurrently placed, that the smaller tubes produced over twice the amount of GRV compared with larger tubes. In all cases studied by Metheny et al., the 10 Fr tube was the first tube used to perform GRVs followed by a flush of water before the next GRV assessment from the large tube. The flush over water likely had less viscosity than what was in the stomach and, therefore, changed the overall

viscosity of the stomach contents for the large bore assessment, potentially leading to the ability to aspirate larger volumes of fluid. In Phase I of this study, the assessments made with water as the fluid, which is less viscous, produced larger RVs compared with the more viscous feeding formula. Therefore, in Metheny et al.'s study, the larger aspirated RVs obtained with the larger tubes were likely the effect of viscosity changes in the fluid in the stomach. These changes in the fluid viscosity could have resulted from adding a flush of water to the already fed formula and gastric juices present in the stomach, thus diluting the fluid and altering the viscosity to a thinner fluid.

Level of Nurse Experience

In this study, level of nurse experience varied in the proportion of aspirated RV. The student nurse was associated with larger aspirated RVs. This is one factor that has not been explored in research. The variation in assessment across the level of nurse experience may be an important factor. It is likely that the student nurse was more cautious in performing assessments, not having had any practice experience to rely upon. However, because this study used only one nurse per level of experience, it is unknown if there would be variation within each of the levels of practice experience; specifically, whether the sample size within each level of nurse experience would yield similar results.

Placement of Tube in Fluid Pool

While viscosity may play a role in the ability to aspirate sufficient quantities of RV, the placement of the tube within the fluid is more likely to influence the ability to aspirate the stomach contents and even when the most distal end of the tube is submerged in the fluid, if the most proximal port(s) are not in fluid, it is impossible to obtain any aspirate. This is evident in the data from Phase I compared with the data from Phase II.

There were more assessments in Phase II with 0 mL of measured volume when the tube was not controlled for in terms of placement within the fluid pool. There were also more assessments of 0 mL in the low quantity volumes of 50 mL and 150 mL, but in Phase I, when small volumes were used, there were not any assessments of 0 mL except when the most proximal port was exposed to air above the level of the fluid. In Phase II, prior to each assessment, the nurses injected 30 mL of air into the tube before aspirating RV. This practice may have displaced the tube from the fluid pool leading to small RV assessments. Because the placement of the tube in the fluid cannot be controlled for in practice, these study results and the mounting in vivo evidence provide increasing evidence that assessing GRVs in practice is unreliable. Furthermore, using arbitrary cutoff thresholds for which to hold nutrition support using an unreliable assessment technique appears to be questionable practice for which more research is needed.

Implications for Nursing Practice

The practice of assessing GRV is based on the assumption that aspiration occurs from gastric contents entering the lungs; however, it is known that aspiration of oropharyngeal secretion occurs with equal frequency (Huxley, Viroslav, Gray, & Pierce, 1978). While the most recent clinical practice guidelines call for higher GRVs (up to 500 mL) to increase caloric intake, there is controversy in the healthcare literature as to the relationship between GRV assessment and intolerance, and in particular, the relationship between GRV and aspiration. The largest concern with aspiration is the development of pneumonia; however, GRVs do not correlate with incidence of pneumonia, aspiration or regurgitation events and have not been well correlated with measures of gastric emptying. GRV may be helpful in identifying increasing risk for intolerance that can be considered

in the evaluation for determining a patient's risk for aspiration. Lowering the GRV threshold has not been shown to be helpful in reducing the incidence of pneumonia (McClave et al., 2005).

If GRV is retained in practice, the syringe and suction methods are the two better methods based on the factors in this study. However, given the many interruptions in a busy critical care unit, the suction method could place the patient at risk for prolonged cessation of feedings, especially if the nurse gets pulled away from the bedside for extended time periods. Because continuous suction was used in this study, this is something, if used in practice should be closely monitored to prevent any adverse events such as prolonged suction time, electrolyte imbalances and stomach wall lining damage. Overall, the results of this study demonstrate there was high variance in the proportion of actual volume obtained across all combinations of methods, and the obtained volume in all combinations underestimated the actual volume by half in 3% to 77% of the time in this experiment. These results invalidate the use of GRV as a measure of actual volume in all of these methods. In addition the variability in the obtained volume makes improving the prediction of actual volume by regression on the amount obtained, untenable. The results of this study demonstrate that the assessment of RV is a variable procedure and becomes even more variable when considering the number of factors that can influence a valid and reliable assessment.

Limitations

Because the design and analysis contained only fixed effects, inferences can only be drawn for the factors and levels of the factors used in this study. Additionally, although there was sufficient power and significance for the 2x2x4x5 model for each

method, there is risk of Type I error because of possible heterogeneity of variance due to the small cell size. The reduced models and separate analysis with adjustments where homogeneity was not assumed helped to strengthen the statistical conclusion validity that was difficult to justify with the full model. However, the assessment of RV is a highly variable procedure and therefore, that may be the main factor to consider in explaining the amount of heterogeneity seen in the data. Furthermore, the significant number of assessments that were unable to produce an assessment of RV were unanticipated and led to some of the heterogeneity and skewness in the data. This problem was not one necessarily limited to the design of this controlled experiment, but a problem that is likely often encountered in clinical practice.

Within each cell of this design, there were only two assessments made which may have led to the variance observed. The level of nurse experience was limited to only one subject per level of nurse experience, so there is only within subject variability that could be examined and not within level of nurse experience variance. This is a limitation of this study and a factor that should be explored in future research by increasing the number of subjects within each of the level of nurse experience to determine if subjects in the various levels of nurse experience have the same variability across all the factors evaluated in this study.

Additionally, because of the difference in the tube port configuration in the polyurethane and PVC tubes, conclusions about the PVC material are limited. Specifically, it is unknown if the difference in the proportion of aspirated RV is due to

the tube material or because the PVC tube ports are concentrically placed around the distal tip of the tube rather than in a linear placement as with the polyurethane tube. This variation in the tube port configuration should be explored further.

Future Research

Future research should focus on incorporating alternative methods for assessing enteral tube feeding tolerance as well as consideration for the effects that were found to be significant in the assessment of RV. As discussed previously refractometry is a method that can be used to predict the amount of GRV that may be present in the stomach by calculation the Brix index that is derived for concentrations of feeding formula present in the stomach. Bedside refractometry, using the Brix index may have clinical utility and deserves to be further explored. A majority of the research to date has been produced by physicians, and nurses have not studied many of the proposed techniques. The refractometry and Brix index needs validation with the gold standard scintigraphy, but there is potential that this technique could be beneficial in identifying the quantity of GRV present in the stomach. If refractometry can be considered as an alternative to the scintigraphy in assessing gastric emptying, then this method could be used in future research studies to assess how much volume is present in the stomach. Once a reliable tool is identified, then further research studies can be designed to identify a threshold volume that could be specific and sensitive to volumes that place the patient at risk for other complications such as aspiration of feeding content. One limitation in the current assessment of GRV is that an accurate assessment may rely on the placement of the tube tip in a large gastric pool; the refractometry with Brix index may provide accurate assessments and does not rely on the tube being placed in the gastric pool, as the

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test only requires one mL of fluid. Refractometry with the Brix index, along with RV assessment, and consideration for the types of tubes used for assessment and strong physical assessment skills may have clinical utility developing in a nurse driven protocol for assessing intolerance and clinical decision-making based on the many factors.

Significance of Study

Aspiration is the most feared complication of EN because there is concern that stomach contents will be aspirated into the respiratory tree leading to distress or pneumonia. GRV is used to monitor patient tolerance of the EN, and decisions are made to interrupt feedings based on GRV measurements and concern for a patient's risk for aspiration. Marshall and West (2006) found that 65.4% of nurses identified increased GRV measurements as the reason for delaying enteral tube feedings, and Elpern, Stutz, Peterson, Gurka, and Skipper (2004) found that GI intolerance (high GRVs, nausea, and vomiting) accounts for 21% of feeding interruptions. However, withholding feeding due to elevated GRV has its own negative consequences. In a multicenter study in France, researchers found that when GRV is measured in practice, patients ($n = 203$) experience a 38% increase in the risk of having a lower intake of calories compared to their prescribed calories (Quenot et al., 2010). Mean daily intake of $\leq 50\%$ of recommended EN is associated with hospital mortality (Singh, Gupta, Aggarwal, Agarwal, & Jindal, 2009). In some instances, patients receive only approximately 50% of their prescribed calories (O'Meara et al., 2008).

While GRV measurement may interfere with EN delivery, it is an important assessment along with physical examination that helps clinicians determine feeding tolerance. While a single elevated GRV may not be a predictor of complications, it may

be a signal that the patient is experiencing increasing intolerance due to reduced gastric motility and stomach emptying. An accurate measure of GRV will help clinicians make the best decisions for enteral feeding. A threshold value at which a GRV places a patient at risk for aspiration or other complications is unknown. This may be related to a lack of evidence to support the best practice of how to obtain GRV accurately and reliably. Specifically, it is uncertain if GRV can be accurately measured and which of these three methods (syringe, suction, gravity) is the most accurate for assessing GRV. An in vitro study is needed to evaluate how much of the actual available volume of fluid can be aspirated and determine if there is a difference in the amount that can be aspirated based on the assessment method and feeding tube characteristics. This knowledge will be important in establishing the best technique for assessing GRV to maximize nutritional intake in practice and will contribute to future research to test strategies to optimize EN intake in critically ill patients.

Contribution to the Science of Nursing

Research is needed to explore the effect of methods used in aspirating GRVs and tube properties effects on the ability to accurately measure GRVs before a threshold volume for GRVs and feeding tolerance can be established for clinical practice. This in vitro study focused on many of the variables that have been attributed to variation in the assessment and reliability of GRV. This study demonstrated great variation in the assessment of RV in vitro, which validates many of the concerns about the validity of the procedure suggested in practice, and provides evidence that other methods to assess patient's tolerance of tube feedings should be explored in future research studies. The

results of this study will be used to guide future research and develop a program of study

in EN delivery and tolerance of enteral tube feedings for critically ill patients.

APPENDIX A

INSTITUTIONAL REVIEW BOARD APPROVAL AND EXEMPTION

INDIANA UNIVERSITY INSTITUTIONAL REVIEW BOARD (IRB)
DOCUMENTATION OF REVIEW AND APPROVAL (DRA)

Reviewing IRB (please choose one):   IRB STUDY NUMBER: _1202007979_
Biomedical: ☐ IRB-02 ☐ IRB-03 ☒ IRB-04 ☐ IRB-05
Behavioral: ☐ IRB-01 ☐ IUB IRB

Please type only in the gray boxes. To mark a box as checked, double-click the box, select "checked", and click "OK".

SECTION I: INVESTIGATOR INFORMATION

Principal Investigator (advisor in the case of student/fellow/resident research):
Name *(Last, First, Middle Initial)*: **Ellett, Marsha L.**
Department: _Family Health_   Phone: _274-0051_   E-Mail: _mlellett@iupui.edu_
Fax: _278-2154_   Address: _1111 Middle Drive, Rm. 437, Indianapolis, IN_

Co-Principal Investigator (for student/fellow/resident research):
Name: _Ellis, Rebecca J._   Phone: _812/552-6060_   E-Mail: _rjbartle@iupui.edu_

☒ Student: ☐ Fellow   ☐ Resident
   ☐ Undergraduate
   ☒ Graduate

Additional Study Contact:
Name: _Janis Beckstrand_   Phone: _317/274-4120_ E-Mail: _jbeckstr@iupui.edu_

   Project Title: In Vitro Comparison of Gastric Aspirate Methods and Feeding Tube Properties on the Quantity and Reliability of
Obtained Aspirate Volume

Anticipated Project Completion Date: _5/2012_

Sponsor/Funding Agency: _N/A_   PI on Grant: _N/A_
Sponsor Protocol #/Grant #: _N/A_   Period: from: _N/A_ to _____
Sponsor Type: ☐ Federal ☐ State   ☐ Industry ☐ Not-for-Profit ☒ Unfunded ☐ Internally Funded
Funding Status: ☐ Pending ☐ Funded ☒ N/A
Grant Title (if different from project title): _____

SECTION II: TYPE OF REVIEW

☒ Exempt Review
☐ Expedited Review
☐ Full Board Review (*Choose One*) → ☐ Behavioral: ☐ IRB-01   ☐ IU Bloomington IRB
                                            ☐ Biomedical: ☐ IRB-02 ☐ IRB-03   ☐ IRB-04   ☐ IRB-05

SECTION III: DOCUMENTS INCLUDED WITH RESEARCH SUBMISSION

☐ Assent, dated: _____
   Number of assent documents: _____
☐ Authorization, dated: _____
   Number of authorizations: _____
☐ Clinical Investigator's Brochure, dated: _____
☐ Expedited Research Checklist, dated: _____
☒ Exempt Research Checklist, dated: _2/3/2012_
☐ HIPAA & Recruitment Checklist, dated: _____
☐ Informed Consent, dated: _____
   Number of consent documents: _____
☒ Investigator List, dated: _2/3/2012_

☒ Protocol, dated: _2/3/2012_
☒ Recruitment materials (please list and date):
Recruitment Flyer
☐ Request form(s) for vulnerable population(s) (please
   list and date): _____
☐ Surveys, questionnaires (please list and date): _____
☐ Summary Safeguard Statement or HUD Form, dated:
   _____
☒ Study Information Sheet, dated _2/3/2012_
☐ Other (please list and date): _____

1   IRB Form v01/01/2012

INDIANA UNIVERSITY
OFFICE OF RESEARCH ADMINISTRATION

To: MARSHA LEE ELLETT
NURSING

From: IU Human Subjects Office
Office of Research Administration – Indiana University

Date: February 29, 2012

RE: **EXEMPTION GRANTED**

Protocol Title:	In Vitro Comparison of Gastric Aspirate Methods and Feeding Tube Properties on the Quantity and Reliability of Obtained Aspirate Volume
Protocol #:	1202007979
Funding Agency/Sponsor:	None
IRB:	IRB-04, IRB00000219

Your study named above was accepted on February 27, 2012 as meeting the criteria of exempt research as described in the Federal regulations at 45 CFR 46.101(b), paragraph(s) (2) . This approval does not replace any departmental or other approvals that may be required.

As the principal investigator (or faculty sponsor in the case of a student protocol) of this study, you assume the following responsibilities:

Amendments: Any proposed changes to the research study must be reported to the IRB prior to implementation. To request approval, please complete an Amendment form and submit it, along with any revised study documents, to irb@iu.edu. Only after approval has been granted by the IRB can these changes be implemented.

Completion: Although a continuing review is not required for an exempt study, you are required to notify the IRB when this project is completed. In some cases, you will receive a request for current project status from our office. If we are unsuccessful at in our attempts to confirm the status of the project, we will consider the project closed. It is your responsibility to inform us of any address changes to ensure our records are kept current.

Per federal regulations, there is no requirement for the use of an informed consent document or study information sheet for exempt research, although one may be used if it is felt to be appropriate for the research being conducted. As such, these documents are returned without an IRB-approval stamp. Please note that if your submission included an informed consent statement or a study information sheet, the IRB requires the investigational team to use these documents.

You should retain a copy of this letter and any associated approved study documents for your records. Please refer to the project title and number in future correspondence with our office. Additional information is available on our website at http://researchadmin.iu.edu/HumanSubjects/index.html.

If you have any questions, please contact our office at the below address.

Thank you.

APPENDIX B

STUDY INFORMATION SHEET

INDIANA UNIVERSITY STUDY INFORMATION SHEET FOR

In Vitro Comparison of Gastric Aspirate Methods and Feeding Tube Properties on the Quantity and Reliability of Obtained Aspirate Volume

You are invited to participate in a research study of three different methods for drawing up (aspirating) feeding formula through four different types of feeding tubes and different amounts of formula in a laboratory study to evaluate if gastric residual volume, or GRV, assessments can be accurately obtained. You were selected as a possible subject because your level of nursing experience represents that commonly found in nursing practice. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

The study is being conducted by Dr. Marsha Ellett, PhD, RN, CNE, Professor of Nursing at Indiana University School of Nursing and Rebecca Ellis, Student Co-Investigator and Candidate for a Doctor of Philosophy in Nursing Science degree at Indiana University School of Nursing at Indianapolis.

STUDY PURPOSE

The purpose of this study is to evaluate how three methods of aspirating feeding formula through four nasogastric tubes affect the amount of aspirated formula in a laboratory study, outside the body (in vitro), to determine if GRV measurements can be accurately obtained.

PROCEDURES FOR THE STUDY:

If you agree to be in the study, you will do the following things:

Participate in an orientation session with the student co-investigator in the Nursing Simulation Laboratory at Indiana University School of Nursing at Columbus (IUPUC). In the orientation session, you will be shown each of the three methods (syringe, suction and gravity) for removing (aspirating) feeding formula through the feeding tubes and allowed to ask questions and try each method.

These three methods: (a) the syringe technique, (b) continuous suction, and (c) gravity drainage methods will be used by you to collect and measure feeding formula that you will draw up through the feeding tubes that are being evaluated in this study. There will be a total of 4 different feeding tubes used in this study:
1. 10 Fr polyurethane tube
2. 10 Fr polyvinyl chloride tube
3. 18 Fr polyurethane tube
4. 18 Fr polyvinyl chloride tube

You will be able to schedule time to participate in this study at your convenience during regular business hours by contacting the student co-investigator. When you come during your scheduled times, the student co-investigator will have the feeding tubes set up and positioned in a bag of feeding formula and suspended from a special stand, known as a ring stand, that will securely hold the feeding tube in position.

The student co-investigator will know the amount of feeding formula volume in the bag, but this amount will not be shared with you. A curtain will be placed between yourself and the bag of feeding formula to prevent you from seeing how much volume is available to draw up in the tube. This is similar to the practice setting, because you are unable to see how much volume is in the stomach when you assess gastric residual volumes.

You will assess the position of the feeding tube at the top of the ring stand and document the marking from the feeding tube, indicating length of tube inserted, on the data collection form that will be given to you.

There will be 120 measurements made by you over the duration of this study. You will be using all three methods with each of the four feeding tubes to draw up and measure volumes of feeding formula. It is anticipated that across the duration of this study, you will spend approximately 30 hours in the laboratory performing measurements.

You will be able to take breaks as needed on the days you participate in data collection. You will not be allowed to spend more than 8 consecutive hours in the laboratory on a given day to prevent fatigue.

For each method that is used in this study, you will draw up 30 mL of air into the syringe and connect the syringe to the proximal end of the feeding tube. You will quickly instill the 30 mL of air into the tube, just as you would do in practice. You will then use one of the three methods (syringe, suction, or gravity) to draw up and remove feeding formula through the tube. The student co-investigator will instruct you on which method you will use for each of the measurements you perform. The method and tube may vary each time you perform the measurement.

The collected feeding formula will be measured by placing the collected formula in a graduated cylinder provided, and this amount will be documented on the data collection form for each measurement you make across all methods and tubes.

It is anticipated that each measurement will take approximately 15 minutes.

Video recording will be used during this study with the video camera directed at the feeding formula reservoir to assess feeding tube placement within the formula during the aspirations. You will not be video recorded. The recording device will be placed behind the blinding curtain that will be used to keep you from seeing the actual amount of feeding formula available to aspirate with the camera directed only at the reservoir that contains the feeding formula on the other side of the curtain.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published or in databases in which the results may be stored. The investigators will have access to the video recordings. The video recordings may be used in additional research projects or shared during future presentations and dissemination of the study findings.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP), who may need access to your research records.

PAYMENT

You will receive a $25 Target gift card at the conclusion of this study, in appreciation for taking part in this study.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study, contact the researcher Rebecca J. Ellis at 812/552-6060 or the faculty investigator Dr. Marsha Ellett at 317/274-0051 or via email mlellett@iupui.edu.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949.

VOLUNTARY NATURE OF STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Indiana University.

A PRIORI POWER ANALYSIS

Table C1

Expected Mean Squares for Fixed Effects Analysis of Variance

Effect	*df*	EMS	Denominator
Method A	2	160*varA + var within	MS Within
Material B	1	240*varB +var within	MS Within
AB	2	80*varAB +var within	MS Within
Size C	1	240*varB +var within	MS Within
AC	2	80*varAC + var within	MS Within
BC	1	120*varBC +var within	MS Within
ABC	2	40*varABC +var within	MS Within
Nurses D	3	120*varD +var within	MS Within
AD	6	40*varAD +var within	MS Within
BD	3	60*varBD +var within	MS Within
ABD	6	20*varD +var within	MS Within
CD	3	60*varCD +var within	MS Within
ACD	6	20*varACD +var within	MS Within
BCD	3	30*varBCD +var within	MS Within
ABCD	6	10*varABCD +var within	MS Within
Volumes E	4	96*varE +var within	MS Within
AE	8	32*varAB +var within	MS Within
BE	4	48*varBE +var within	MS Within
ABE	8	16*varABE +var within	MS Within
CE	4	48*varCE +var within	MS Within
ACE	8	16*varACE +var within	MS Within
BCE	4	24*varBCE +var within	MS Within
ABCE	8	8*varABCE +var within	MS Within
DE	12	24*varDE+var within	MS Within
ADE	24	8*varADE +var within	MS Within
BDE	12	12*varBDE +var within	MS Within
ABDE	24	4*varABDE +var within	MS Within
CDE	12	12*varCDE +var within	MS Within
ACDE	24	4*varABDE +var within	MS Within
BCDE	12	6*varBCDE +var within	MS Within
ABCDE	24	2*varABCDE +var within	MS Within
within	2*120=240	var within	

Note. In the outputted EMS table from the ωFace program, Lenth uses the shorthand notation, *var*, to designate the "treatment effects term" in the EMSs regardless of whether the treatment is specified as random or fixed (e.g., varAB) in the model inputted in πFace. As can be seen from the EMSs in the table, the expectations are for a fixed effect ANOVA.

The primary effects of interest and the ones that require the largest sample size to achieve a power of .90 are the ABCDE interaction and the ACDE and ABDE interactions with 24 *df*.
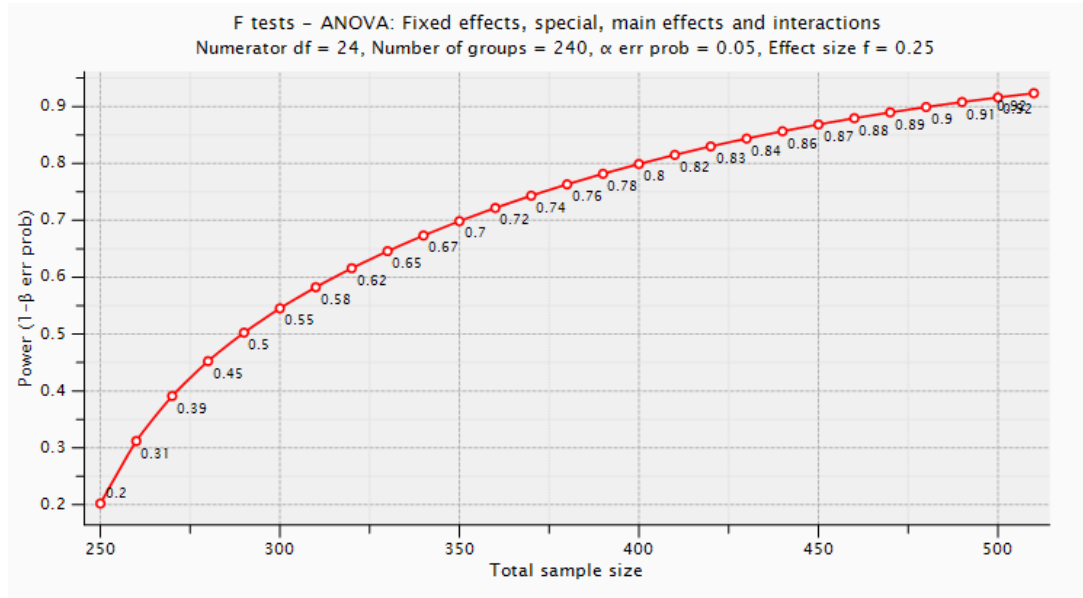

Figure C1. Highest order interactions with sample of 480 cases. For the highest order interactions (24 *df*), an a priori analysis for sample size in GPower, showed that a sample size of 480 cases (two independent reps per cell) would yield a power of .90 for an effect of size $f = .25$, at alpha $= .05$.
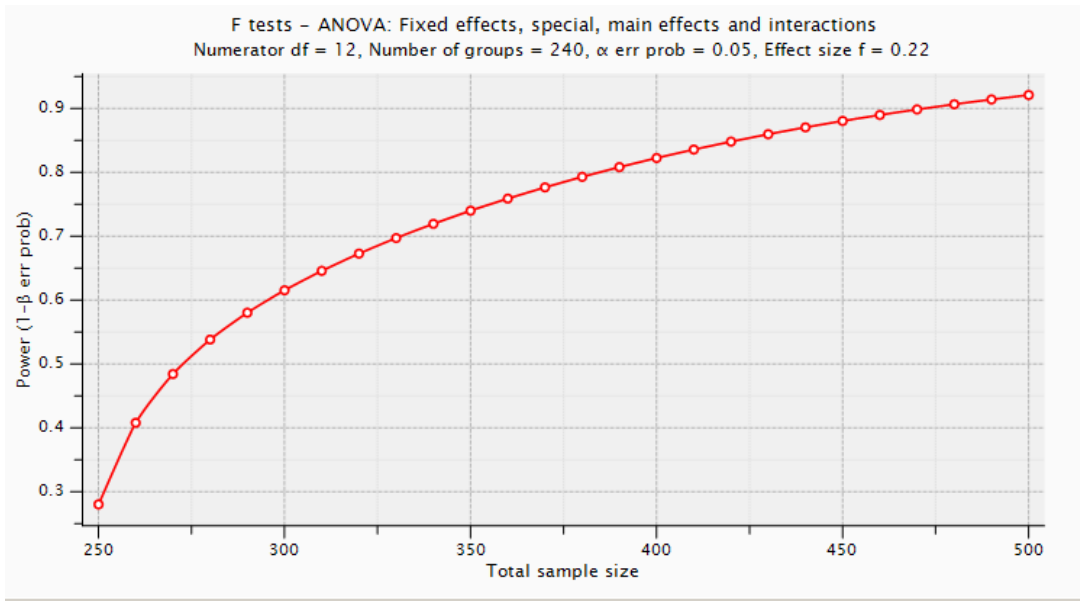
Figure C2. BCDE interaction and other interactions. The BCDE interaction and other interactions with *df*s = 12, showed that a sample size of 480 (two independent reps per cell) would yield a power of .90 for an effect of size *f* =.22, at alpha = .05.

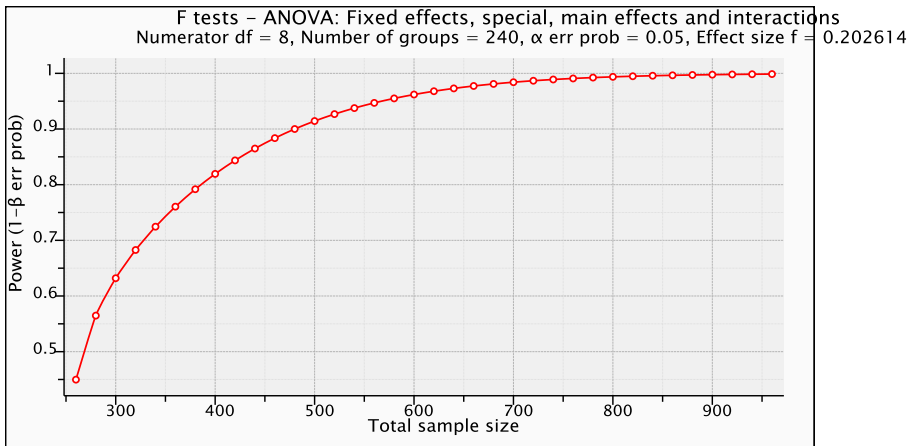*Figure C3*. The ABCD interaction with dfs = 8. The ABCD interaction and other interactions with *df*s = 8, showed that a sample size of 480 (two independent reps per cell) would yield a power of .90 for an effect of size *f* = .202, at alpha = .05.

The proposed sample size of 480 was also shown to be adequate using the Lenth's

$\pi Face$ program. The $\pi Face$ program for sample size is based on the estimates of the

"standard deviation" for each effect (e.g., SD(a*b). Figure C4 shows the size of the

SD(effect) that can be detected for each effect in the Anova Table (fixed effects) with the

proposed sample of 480 at a 90% power with alpha = .05. The SD(within) (σ_{error}) was

estimated in the power analysis as 20, based on a pilot study and also on previous
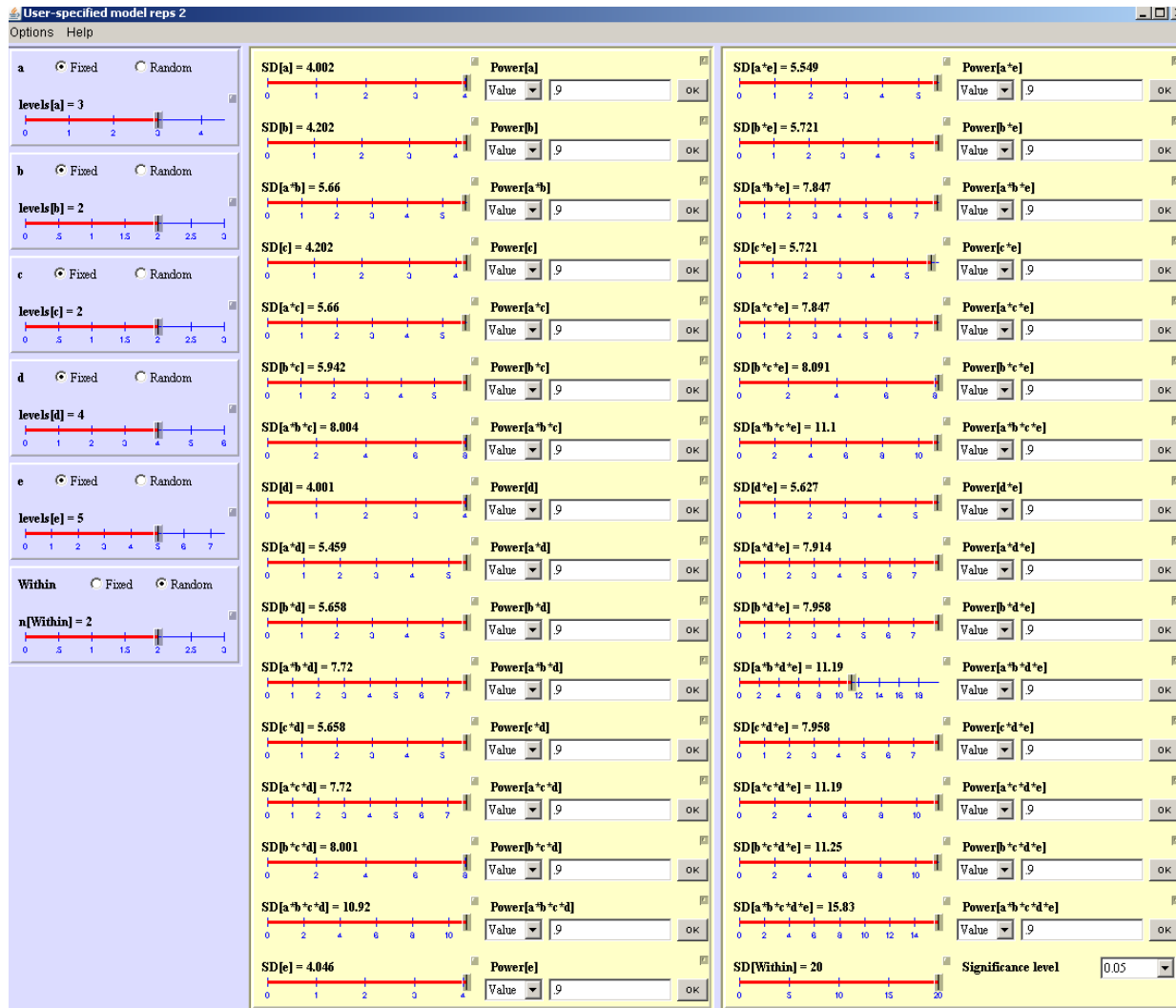
published data.

Figure C4. Size of the *SD*(effect) that can be detected for each effect in the Anova Table (fixed effects).

The relationship between the effect sizes in the Gpower program and the *SD*s in the Lenth program is as follows:

In GPower the effect size, is *f. For each effect, f* can be estimated as $f_{effect} = \sqrt{(df_{effect}/N)(F_{effect}-1)}$ *or as* $f_{effect} = \sqrt{(kr\sigma^2_{effect}/N\sigma^2_{error})}$, *where r is the number of replications and k is the product of the levels of the effects **not** in the effect being estimated* (as given by the multipliers for the *var(effect)* in the EMS table). (For example, one can see in the EMS Table (Figure C4) for the ABCE effect, k*r = 4*2=8, where r =2 replications and k = 4 is the number of levels in the D factor.)

The equivalence of the two methods of determining sample size and power.

The *SD*(effect)s in the π*Face* program are given because they estimate the actual values in the EMSs that one might expect to detect with the proposed sample size. One can check the equivalence of the two methods, using the equation, $f_{effect} = \sqrt{(kr\sigma^2_{effect}/N\sigma^2_{error})}$, to solve for the σ_{effect} outputted in the π*Face* Power Table when given the f_{effect} outputted from the GPower Program. Specifically, $\sigma_{effect} = \sqrt{(Nf^2_{effect}\sigma^2_e/rk)}$ where $r = 2$ replications and k = the product of the levels of the factors **not** in the effect (as given by the multipliers for the *var (effect)* in the EMS table). For example, for the 5-way interaction, *ABCDE*, f_{effect} is estimated as .25 by Gpower and this yields an estimate of $\sigma_{effect} = \sqrt{(480*.25^2*20^2/2)} = \sqrt{250} = 15.811$, *a value within round off error of the estimated of SD of 15.83 for the detectable 5-way interaction (SD(ABCDE) in* ωFace *for power =.90, alpha=.05 and N=480.*

One can equivalently specify the effect size as the familiar *eta-squared* η^2, $\eta^2 = f^2/(1+f^2)$, and conversely when solved for f, $f = \sqrt{(\eta^2/(1-\eta^2))}$. An unbiased

estimate of effect also related to f, is *partial omega squared*:

$$\omega^2_{partial}, \omega^2_{partial} = \frac{f^2}{1+f^2} = \frac{SS_{effect} - (df_{effect})MS_{error}}{SS_{effect} + MS_{error}}.$$

One can equivalently specify the effect size as the familiar *eta-squared* η^2, $\eta^2 = f^2 / (1 + f^2)$, and conversely when solved for f, $f = \sqrt{(\eta^2 / (1 - \eta^2))}$. An unbiased estimate of effect also related to f, is *partial omega squared*:

$$\omega^2_{partial}, \omega^2_{partial} = \frac{f^2}{1+f^2} = \frac{SS_{effect} - (df_{effect})MS_{error}}{SS_{effect} + MS_{error}}$$

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<div align="center">CURRICULUM VITAE</div>

NAME Rebecca J. Bartlett Ellis

EDUCATION

	Place	Degree	Date Awarded
GRADUATE	Indiana University School of Nursing Indianapolis, IN	PhD, Nursing Science Clinical Nursing Science concentrate	2013
	Indiana University School of Nursing Indianapolis, IN	MS, CNS, Adult Health	2008
UNDERGRADUATE	Indiana University School of Nursing Indianapolis, IN	BSN	2005
	Indiana Wesleyan Marion, IN	BS, Management	2003

CLINICAL APPOINTMENTS (inclusive dates):

Place	Title/Rank	Dates
Indiana University School of Nursing Columbus, IN	Clinical Assistant Professor	August 2008–Present

LICENSURE:
Registered Nurse, Indiana

PROFESSIONAL SOCIETIES
American Association of Critical Care Nurses
Simulation Innovation Resource Center, National League for Nursing
Team Based Learning Collaborative
The American Society of Enteral and Parenteral Nutrition, Professional Member

TEACHING ASSIGNMENTS

Date	Subject	Description	Type	Cr Hrs
2008–Present	NURS H365	Nursing Research: RN-BSN Program	Lecture	3.0
2008–Present	NURS H355	Data Analysis/Pract & Research: RN-BSN Program	Lecture	3.0
2011–Present	NURS H355	Data Analysis/Pract & Research: BSN Program	Lecture	3.0
2012–Present	NURS H365	Nursing Research: RN-BSN Program	Lecture	3.0

2012–Present	NURS K305	Innovations in Health and Healthcare: RN-BSN Program	Lecture	3.0
2009–2011	NURS S483	Clinical Nursing Practice Capstone: RN-BSN Program	Lecture	3.0
Spring 2011	NURS B249	Science and Technology of Nursing: Practicum	Clinical	2.0
Spring 2011	NURS B230	Developmental Issues and Health	Lecture	3.0

SERVICE

Academic Liaison, Southeast Indiana Simulation Consortium	2011–Present
Schneck Medical Center, Seymour, IN, Research Management Team, Research Consultant	2011–Present
Item writer, National Council of State Boards of Nursing	October 2009, July 2010

PROFESSIONAL ACTIVITIES

Research Coordinator, Respiratory & Critical Care Associates, Columbus, IN	2009–Present

PRESENTATIONS

Bartlett, R. J. (2008, September). *Navigating empirical research and linking the evidence to bedside practice*. Presentation at Columbus Regional Hospital Cardiovascular Symposium, Columbus, IN.

Bartlett, R., McEwen, K., & Young, J. (2006). *Service learning through a unique lens*. Paper presented at the Sigma Theta Tau International 17th International Nursing Research Congress Focusing on Evidence-Based Practice, Montreal, Quebec.

PUBLICATIONS

Teaching

Bartlett, R. (2011). *Collaborative partnership: Nursing student perspective* [Abstract]. 2006 Sigma Theta Tau International.

Bartlett, R. J., & Bateman, V. (2002). *Does my child have ADD/ADHD* [Educational brochure]. Columbus, IN: Columbus Regional Hospital Foundation.

Bartlett, R. J., & Bateman, V. (2002). *My child has ADD/ADHD* [Educational brochure]. Columbus, IN: Columbus Regional Hospital Foundation.

Bartlett, R. J. (2002). *Parental stress: Managing the emotions and the children too*. [Educational brochure]. Columbus, IN: Columbus Regional Hospital Foundation.

Research

Bartlett Ellis, R. (2011). *Feasibility of using the severity of gastrointestinal impairment instrument in clinical practice* [Abstract].

Bansal, S., Wilson, D. S., Bartlett, R. J. (2010). *Electro magnetic navigation bronchoscopy in patients with permanent cardiac pacemakers: A feasibility study* [Abstract]. Budapest, Hungary: World Congress Bronchology.

Wilson, D. S., & Bartlett, R. J. (2007). *Improved diagnostic yield of bronchoscopy in a community practice: Combination of electromagnetic navigation system and rapid on-site evaluation. Journal of Bronchology, 14*(4), 227–232.

<u>Service</u>
Jeffries, P. R., Battin, J., Franklin, M., Savage, R., Yowler, H., Sims, C., Hall, T., Eisert, S., Brown, S., Werskey, K., Bartlett Ellis, R. J., Everage, T., & Dorsey. (2012). Creating a professional development plan for a simulation consortium clinical simulation in nursing. *Clinical Simulation in Nursing*. doi:10.1016/j.ecns.2012.02.003.

AWARDS
Indiana University Trustee's Teaching Award   2012

GRANTS
Research Venture Award from IUPUI Research VC, "Restorative interventions to promote well-being and reduce medication errors in registered nurses" Co-Investigator.

Division of Nursing IUPUC research support, "Restorative interventions to promote well-being and reduce medication errors in registered nurses," Co-Investigator.