ACCURACY OF WATER DELIVERY IN ENTERAL NUTRITION PUMPS

A THESIS

SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE

DEGREE OF MASTERS OF SCIENCE IN NUTRITION

IN THE GRADUATE SCHOOL OF THE

TEXAS WOMAN'S UNIVERSITY

DEPARTMENT OF NUTRITION AND FOOD SCIENCES

COLLEGE OF HEALTH SCIENCES

BY

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DENTON, TEXAS

AUGUST 2018

ACKNOWLEDGMENTS

I would like to humbly acknowledge the committee who contributed time and effort in assisting me with the completion of my thesis. To Renee Walker, who not only introduced me to this topic, but also has been an incredible mentor and partner from day one. Your confidence in me through this process has helped impart self-assurance and independence, which has made me a better dietitian and professional. I would like to thank Dr. Anne Utech for being a much needed sounding board for the hurdles and roadblocks encountered, and for so graciously making many of our unforeseen deadlines your top priority without batting an eye. Renee Walker and Dr. Utech instilled in me the faith I needed to tackle the "insurmountable" thesis. To Dr. Carolyn Moore for all the insight and feedback throughout the editing and submission process. Your sharp point of view helped to produce a "bullet proof" project and made you an invaluable asset on the committee. Last but not least, to committee chair, Dr. Mindy Maziarz. You took on yet another project on top of several of your own, but ensured I had all the tools needed to succeed without skipping a beat. Through all the hours of editing and review, setbacks and accomplishments, it has been quite the pleasure to work under this committee's leadership. Thank you for providing me the opportunity to study and learn under a group of such strong minded, established women.

ABSTRACT

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Background: Adequate delivery of both enteral formula and water in patients receiving enteral nutrition (EN) is critical in illness recovery and maintaining hydration status. Pump malfunction has recently been identified as a factor that impedes enteral formula delivery, however rarely is inadequate enteral water delivery investigated. The purpose of this study was to explore the accuracy of delivering 1 L of water by EN pumps using different flush volumes and hang heights. *Methods:* Three EN pumps were used *in vitro* to flush 1 L of water at 50 mL per hour for 20 hours and 500 mL every 4 hours for 8 hours, at 0" and 18" hang heights. Fifteen test runs were conducted at each volume and hang height per pump. Actual delivered enteral water, remaining volume in feedbags, and volume reported by the pump were recorded. *Results:* Hang height of 18" delivered a mean 3.91% (95% CI, 3.25 to 4.57) more water than bags hung at 0" ($p < 0.0005$). When delivering water in 500 mL increments, 1.57% (95% CI, 0.92 to 2.23) more water was delivered than when delivered in 50 mL increments ($p < 0.005$). *Conclusion:* Appropriate hang height recommendations improve enteral water delivery in patients receiving EN. The most accurate setting was 500 mL at 18", resulting in adequate delivery in 97.8% of the test runs, while 50 mL at 0" delivered adequately 17.8% of the time. More research is needed to understand the implications of inadequate water delivery caused by EN pump inaccuracy.

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CHAPTER I

INTRODUCTION

When oral intake is inadequate in the presence of a functioning gut, timely and consistent administration of nutrition is recommended. Circumstances in which nutrition intake by mouth is either insufficient or contraindicated, enteral nutrition (EN) is required.[1,2] Enteral nutrition not only enables the administration of the patient's daily estimated nutrient needs, but also helps maintain hydration status via prescribed water flushes. Delivering EN to the gut can increase blood flow to the gastrointestinal tract, reduce infection and complications,[3] and decrease rates of mortality.[4] Two components of EN when delivered via pump include EN formula and water. The EN formula provides energy, macro- and micronutrients, as well as other dietary components to the patient, while water flushes contribute to fluid needs. Commonly, patients requiring EN are in the intensive care unit (ICU) due to trauma and are experiencing metabolic stress,[1] which may increase fluid loss and create a fluid deficit if not replaced. In these cases, maintaining hydration status via enteral routes is imperative and aids in medication absorption,[5,6] wound healing,[7] and an overall improvement in health outcomes.[8]

Several peer-reviewed studies have shown EN pumps are not accurate in delivering nutrient needs. Enteral pumps have been shown to underfeed and overfeed daily estimated energy needs by < 90% and > 110%,[9-11] respectively. The accuracy of EN pumps varies between ±7% to ±10%, or ±0.5 mL/hr, whichever is greater. [12-14] Multiple factors contribute to inaccurate nutrient delivery including EN interruptions for surgical procedures, increased gastric residual volume, intestinal dysfunction,[15-16] pump malfunction,[10,17-18] and the height of

the enteral bag.[19] Hang height recommendations by EN pump manufacturers are not commonly adhered to in clinical practice, likely due to lack of awareness. The influence of hang height on EN formula delivery has been investigated by clinicians at the Michael E. DeBakey Veterans Affairs Medical Center to identify accuracies, or lack thereof, of delivery.[19]

Many EN pumps have the ability to be programmed to deliver enteral water flushes. Therefore, in addition to inadequate delivery of energy and nutrients, pump inaccuracy can also contribute to a difference in total water administration to the patient. Dehydration has been recognized as a major health concern among hospitalized patients[20] resulting in readmission after discharge, particularly in the elderly.[21] Water loss and poor fluid intake can result in pressure injuries, prolonged recovery, increased length of stay, and may lead to death.[20] Hospital-acquired dehydration can also become an economic burden for patients after discharge. Pash[20] and colleagues found that total cost, length of stay, and increased rates of mortality were higher in those who suffered from hospital- acquired dehydration.

Although improving quality of life and patient care are top priority for practitioners, balancing health care costs are of equal importance and a rising concern. Health care costs associated with dehydration were estimated to be $446 million in a review conducted by Warren et al. in 1991.[22] Almost a decade later, Jones et al. [23] estimated health care costs related to the treatment of dehydration had tripled ($1.36 billion). Estimated healthcare costs incurred by a primary diagnosis of dehydration increased by 13.9% from 1996 to 2004 (per hospitalization; from $6,539 to $7,442).[23,24] The total economic burden was estimated to be $1.14 billion but is believed to be inaccurate as this estimate does not account for treatment costs of patients with dehydration as a secondary diagnosis, which would result in higher costs.

Xaio[24] also found that women and the elderly were treated less aggressively than their younger (and male) counterparts that could have influenced actual costs if symptoms of dehydration were easier to identify and held to the same regard as nutrition and/or malnutrition.[8] Furthermore, the Agency for Healthcare Research and Quality (AHRQ) identifies dehydration as one of the most common preventable diagnoses and approximates an annual health care cost upwards of $1.6 billion.[25]

Purpose

The purpose of this study was to explore the impact of flush volume and hang height on the accuracy of delivering 1 L of water by EN pumps. The overarching goal is to improve the adequacy of enteral water delivery in patients receiving EN support by implementing standard training for EN pump setup and operation in hospitals and other health-care settings nationwide.

Research Question

This project will investigate the accuracy of delivering 1 L of water at different flush volumes and bag hang heights and the effects on final water volume delivery from EN systems.

Hypotheses

Overall Null (H_0): Delivery of 1 L initial water volume administered at different flush volumes and different bag hang heights will yield 1 L final water volume.

- H0: No difference within - and between – groups in final water volume delivered at different bag hang heights.

- $H0_a$: Final water delivered at 50 mL every hour for 20 hours at 0” and 18” hang heights will not differ.
- $H0_b$: Final water delivered at 500 mL every 4 hours over 8 hours at 0”and 18” hang heights will not differ.

CHAPTER II

REVIEW OF LITERATURE

Introduction

Enteral nutrition (EN) is often used as a method to deliver nutrients to patients who have a functioning gastrointestinal tract when oral intake is unsafe, inadequate, or inappropriate.[26] Enteral nutrition not only enables the administration of the patient's daily estimated nutrient needs, but also helps maintain hydration status via prescribed water flushes. Current guidelines suggest the administration of adequate and timely nutrition support can reduce health complications for the patient and improve clinical outcomes.[1,2]

Feeding routes for EN consist of placing a feeding tube directly into the stomach (gastric feeds) or into the small bowel (post-pyloric). EN may be delivered by pump, gravity drip, or intermittent bolus feedings administer by a syringe. Three different enteral feeding accesses include nasoenteric tubes inserted via the nose and are used most often during short-term EN support (4-6 weeks),[27-28] or surgical placement of a percutaneous endoscopic gastrostomy (PEG) (or jejunostomy, PEJ) through a stoma in the abdominal wall.[26]

Percutaneous endoscopic tubes are utilized when esophageal access is blocked or long-term nutrition support is anticipated.[29] In cases of gastrointestinal intolerance or surgeries involving the hepatobiliary system, an extension can be fed though the PEG tube for delivery into the jejunum (small bowel) and is referred to as a percutaneous endoscopic jejunostomy.[30] Access to the small bowel (duodenum, jejunum, or ileum) can also be

achieved by using nasoduodenal or nasojejunal tubes and is found to be beneficial when patients experience gastroparesis or are at greater risk of aspiration.[31-32]

Indications for Enteral Delivery

According to the National Institute of Health Care Excellence,[33] EN should be considered only if nutrition requirements cannot be met with an oral diet. Conditions in which EN may be indicated include critical illness requiring admission to an ICU, acute pancreatitis and organ failure, recovering from major surgeries, sepsis, and major traumas (burns/traumatic brain injuries).[1] Additionally, EN is indicated for those with swallowing difficulties, head and neck cancers, malabsorption syndromes such as Celiac or Crohn's disease, gallbladder or pancreatic diseases, short bowel syndrome, poor appetite, or patients too weak to eat or drink adequate amounts to satisfy estimated nutritional needs.[34]

Implementation of Enteral Nutrition and Hydration

An EN regimen contains two main components: formula (calories, protein, and fat) and fluid delivery. Appropriate and timely nutrient and water delivery can lessen disease severity; reduce the amount of lean body mass lost by providing adequate calories during times of increased needs, and counterbalance fluid losses incurred from diarrhea, emesis, fever, diuretic therapy, blood loss,[5] burns, or nasogastric drainage.[35]

Implementation of EN in clinical practice requires the calculation of calorie, protein, and fluid needs using a weight-based predictive equation.[35] Once a Registered Dietitian Nutritionist (RDN) has calculated estimated needs, the clinician will choose a suitable enteral formula that will provide adequate nutrition and fluid as well as a schedule for delivery; recommendations for enteral hydration are made after considering fluid content and total

volume of formula in addition to intravenous fluids. Providing additional hydration through either periodic water boluses or water flushes using an EN pump[36] supports fluid requirements, maintains enteral feeding tube patency, and prevents clogging of the enteral device from medication administration. Considering the indications for EN and the many complications associated with the reasons for its use, it is no surprise that dehydration is the most common fluid and electrolyte imbalance found in tube-fed populations.[36]

Dehydration: Physiology and Complications

Although some claim there is no absolute definition,[37] dehydration is frequently defined as a medical condition where fluid losses are greater than fluids consumed[38] and is often accompanied by electrolyte abnormalities.[39] A negative fluid balance can occur due to sensible and insensible losses, a decrease in fluid intake, or a combination of the two.[40] Three forms of dehydration (hypertonic, hypotonic, and isotonic) have been identified and should be carefully considered when developing a treatment plan to correct the imbalance.[40-41]

Physiology of Dehydration

Approximately 60-75% of the human body is comprised of water,[42-43] with the majority of water residing in intracellular spaces and the remainder confined to the extracellular (intravascular and interstitial) spaces.[5] Symptoms of dehydration can begin to manifest with fluid losses as little as 2-3%.[44] Fluid equilibrium is achieved by regulating serum sodium levels as well as effective osmolality (both occurring outside of the cell) which in turn exerts osmotic force across the cell membrane and produces equal tonicity between compartments.[37] When solute concentrations are altered or there is a drop in blood volume, corresponding receptors will initiate a salt craving, which signals a thirst response and

encourages the body to ingest fluids.[5] A blood urea nitrogen (BUN) to creatinine ratio greater than 20, changes in serum sodium (hyponatremia <135 mEq/L and hypernatremia >145 mEq/L), and a serum osmolality greater than 295 milliosmoles[41] are common biomarkers used to identify fluid derangements.[5]

Hypertonic dehydration is an underlying cause of hypernatremia[5] and occurs when water loss is greater than sodium loss in the extracellular fluid compartments.[39] The loss of fluid in the extracellular spaces increases the ratio of sodium to water. In an effort to establish balance, a shift occurs drawing water from intracellular to extracellular spaces and results in increased intracellular sodium levels.[5] Hypertonic dehydration may result from excessive sweating, a decrease in fluid intake brought on by thirst impairment seen in the elderly,[39] or when patients are unable to obtain water on their own.

Hypotonic dehydration takes place when the loss of sodium is greater than water and the fluid outside of the cell becomes depleted.[5] According to El-Sharkawy, [39] losses incurred during osmotic diuretic therapy and the weeping of burn wounds can bring on this form of dehydration.

Isotonic dehydration occurs when water loss is equivalent to sodium loss, therefore patients with this type of dehydration will not present with low serum sodium levels. Isotonic dehydration can result from diarrhea, emesis, or ascites where sodium and water losses are equal.[39]

Complications

Dehydration is documented as one of the most common fluid imbalances in the elderly and a major health concern among hospitalized patients.[20,34] When this preventable

and reversible condition is left untreated,[5] dehydration can lead to more serious complications such as constipation, urinary tract infections, kidney stones, pneumonia, pressure injuries and delayed wound healing, inflammation of the gastrointestinal tract, uncontrolled diabetes, a decline or an accelerated decline of kidney function, organ failure,[24] and alteration of medication absorption due to fluid loss within the cell.[5-6] Dehydration and many of the complications can be problematic because they could lead to readmission after discharge (particularly in the elderly),[21] prolonged recovery, increased length of stay,[1] and increased mortality rates post discharge.[20]

Importance of Adequate Nutrition

Nutrition Support

According to The American Society for Parenteral and Enteral Nutrition and Society of Critical Care guidelines,[1] it was first thought that nutrition support simply prevented muscle loss in the critically ill by providing the necessary calories and protein needed through times of decreased intake due to chronic illness and metabolic stress.

After years of research, early and adequate delivery of nutrition utilizing EN support has also been found to improve immune response, reduce oxidative injury, as well as support patients during the stress response where immune health is paramount.[1]

Hydration

Complications from dehydration can lead to prolonged recovery and increased rates of mortality.[22] In 1991, a review conducted by Warren[22] et al. analyzed data from over 10 million hospital admissions obtained from the Medicare Provider Analysis and Review (maintained by Health Care Financing Administration, unpublished data) to understand the

burden and consequences linked to dehydration. Patient data included those admitted for volume depletion or dehydration as the primary diagnosis or as an associated diagnosis; 1.4% had dehydration documented as a primary diagnosis (146,960 hospitalization) and 6.7% had dehydration as an associated diagnosis (731,695 patients). The results showed nearly 50% of patients with dehydration died within the first year; 17.4% percent within one month of admission and 30.6% expired within the remaining 11 months. Although this review was conducted nearly 3 decades ago, it was the first of its kind to demonstrate a cause and effect relationship between dehydration and negative health outcomes with an emphasis on increased economic burden.

Robles et al.[21] performed a retrospective chart review of patients older than 65 years who were re-hospitalized within 30 days of entering a long-term care facility. Serum sodium of more than 145 mg/dL and BUN and Creatinine ratios of greater than 20:1 were used to define low hydration. Other data collected included electrolyte changes, reasons for transfer, admission diagnosis, co-morbid conditions, and demographics. Of the 261 patients that were re-hospitalized over a 6-month period, approximately 70% met one or more criteria for low hydration from hospitalization to readmission. However, only 2-3% of patients were found to have dehydration listed as a diagnosis. The small sample size as well as only using patients from one hospital limited this study. Also, dehydration can be difficult to identify, therefore recognition is limited to the knowledge and experience of facility staff.

In 2014, Pash[20] et al. reported on the health care system economic burden due to post-admission dehydration (PAD). Data from 4.2 million inpatient discharges indicated PAD in 86,398 patients upon discharge; suspected dehydration at admission was excluded. The mean

total costs of the PAD group were approximately $11,500 higher than the non-PAD group, with a higher incidence of catheter-associated urinary tract infections and an increased length of stay of 4.7 days. Moreover, mortality rates were 0.8% higher. The findings of this study strengthen the assertion that dehydration places a significant economic strain on the health care community.

Accurate Delivery Enteral Nutrition

Factors Contributing to Inaccurate Delivery

Limited peer-reviewed studies are available exploring the inadequate delivery of nutrition by EN pumps. Even fewer studies exist that examine the accuracy of enteral water delivery. A factor contributing to the limited number of studies in this area could be that the EN pumps did not contain an automatic enteral water flush option until the late 1990s.[15] Three studies investigating the cause of inadequate enteral delivery found enteral pump malfunction to be a factor in the under and overfeeding of daily estimated energy needs by <90% and >110%,[9-11] respectively. The acceptable accuracy of EN pumps are variable and range between ±7% to ±10% of prescribed volume (increased variance will occur with formula density greater than 1.0 kcal/mL), or ±0.5 mL/hr of fluid, whichever is greater. [12-14]

Factors contributing to inaccurate nutrient delivery when EN is indicated include tube feed interruptions due to surgery, procedural holds, increased gastric residual volume, deviation from recommended bed elevation of 30 degrees (i.e. activities of daily living), and intestinal dysfunction.[10,15-18] Of utmost importance, an interruption in enteral formula delivery will also halt enteral water administration and therefore alter the of water delivered to the patient. Furthermore, pump malfunction can occur due to user error (stopping pumps

and not promptly restarting),[15-16] pump inaccuracy (calibration, pump error),[15,17-18] and distance from the enteral feedbag to the pump monitor inconsistent with the hang height recommended by the manufacturer.[19] A study conducted by Walker et al.[19] found both hang height and formula viscosity (1 kcal/mL vs 2 kcal/mL) to be a factor in the accuracy of enteral delivery.

Concerns Related to Inaccurate Delivery

Appropriate water delivery in patients receiving EN is critical in maintaining fluid balance and recovery. Accurate delivery of both nutrition and water using an EN pump is important for disease recovery in the critically ill experiencing increased needs due to metabolic stress and for those that rely on others to deliver complete nutritional needs. Concerns related to inaccurate delivery include:

1. Overfeeding critically ill patients due to over estimation of energy needs and/or pump inaccuracy.
2. Underfeeding patients with increased calorie needs due to holds, procedures, human factor, intestinal dysfunction, and/or pump inaccuracy.
3. Pump inaccuracy due to errors noted at pump monitor, faulty set-up, or incorrect timing of stop and restart of EN.

Inaccuracies of Enteral Delivery

Summarized below is evidence evaluating accurate administration of enteral formula and water in critically ill patients. Although the overall purpose of this research project was to examine the accuracy of water delivery via an enteral pump, limited studies are published

in this area. Thus, the summary will also include data providing outcomes associated with enteral formula and water.

Overfeeding Patients Receiving EN

Excessive calorie intake has proven harmful to patient populations receiving EN and was associated with increased protein catabolism, hyperglycemia, an increased risk of infection,[45] and overall poor outcomes.[1] The difference between calories prescribed and calories delivered were analyzed in a study conducted at the Michael E. DeBakey VA Hospital by Walker and colleagues.[46] Twenty-six stable patients receiving EN at goal rate for were observed from 3-5 days. Ready-to-hang (1 L bottles of concentrated and unconcentrated formulas) were weighed before and after each 24-hr period to determine actual volume of formula delivered, then compared to the recommended delivery amount. Results confirmed over delivery of formula by 5-21% of prescribed calories, with EN pump inaccuracy suspected to be the main contributing factor. This study concluded that enteral feeding using volume-based goals (1800 mL/day) versus rate-based goals (60 mL/hr) was recommended for more accurate enteral delivery.

Strack van Schijndel et al.[10] also evaluated the differences between prescribed and delivered enteral formulas by evaluating caloric delivery in 32 hospitalized patients. One-hundred formula bags were weighed, the EN pump was turned on, and the bags were weighed again after at least 4 hours. Inappropriate calorie delivery was defined as < 90% and > 110% of prescribed calorie needs. Of the 100 measurements, approximately 10% delivered calories in excess of 110%. Additionally, 81 of the 100 measurements recorded were not caused by interruption in tube-feedings and could not be explained. Contributing factors

thought to be related to the interruptions were pump malfunction, formula characteristics, or the actual bag and tubing system used. Unexplained EN inaccuracy in 81% of the sample size is an interesting finding and further warrants continued research in this area.

Underfeeding Patients Receiving EN

In 2005, O'Leary et al.[9] investigated accuracy of EN delivery in mechanically ventilated patients (N = 60) while reviewing the risk of malnutrition of this ICU population, factors contributing to inadequate delivery, and reiterated the dangers of over and under feeding the critically ill. Formula, formula volume, reasons for interruptions, and duration of the EN hold were documented for three days. Instances of excessive gastric residual volumes, emesis, diarrhea, and replacement of feeding tubes were also documented. Results of this study found 68.3% of patients were underfed (received less than 90% of estimated energy needs); with 38% significantly underfed receiving less than 50% of estimated energy needs. The most common explanation for underfeeding was EN holds due to ICU tests and procedures (71.7%). Although the sample size was small, a strength of the study is the utilization of indirect calorimetry, the "gold standard" for metabolic measurement, to calculate nutrient needs in 25 out of 60 patients (41.6%).

Difference in calories prescribed versus calories delivered was also investigated using data collected from 51 patients in the ICU receiving nutrition enterally for more than two days.[16] A 1 kcal/mL enteral formula was delivered using a continuous EN pump over 24 hrs. Interruptions due to gastrointestinal intolerance, procedures (including mechanical ventilation), and EN pump malfunction were recorded. Energy requirements were calculated using the Harris Benedict Equation (HBE); accuracy of this formula was examined as a

contributing factor, possibly adding to the calorie deficits caused by EN interruptions. Sixty-three percent of the calories from the combined nutrition support regimen were provided enterally. According to the HBE, more than 50% of the patients received less than 70% of the estimated required needs.

Based on results from the study, unreliable prescription of energy needs calculated using the HBE were complicated by airway management (30.8%), gastrointestinal intolerance (27.7%), ICU tests and procedures (26.6%), and mechanical issues (14.9%). Incorporated in each subset, improper timing of stopping and restarting EN pumps and physician's disinterest in the nutritional support aspect in ICU patient care (low-level of importance comparatively) were also thought to influence calories delivered. Findings from this study show the prevalence of gastrointestinal intolerance (a known cause of EN holds and reductions in EN delivery) in ICU patients who are known to be at higher risk of infection and require adequate nutrition for optimum immune function. These results also provide evidence on the extent to which ICU patients are underfed and lend to the suggestion that when patients experience EN holds for formula, it is likely EN water flushes are being held as well.

Inaccurate Delivery Due to Pump Malfunction

Strack van Schijndel et al.[10] recognized the need for more research on EN pump accuracy due to the limited attention EN pumps receive as a contributing factor. A one-month observational study of 32 ICU patients receiving EN at goal was conducted to evaluate EN pump accuracy. Differences in the weight of bag from start to stop time and total bag hang time were recorded to obtain calories delivered. This study also recorded

interruption cause and frequency. Out of 100 bags, 55 showed delivery of less than 90% of calories prescribed. Enteral holds accounted for inaccuracy in 19% of the cases mentioned, and pump inaccuracy was thought to be responsible for the remaining 81%.

Tepaske et al.[18] conducted a study to investigate the reasons for inadequate protein delivery in ICU patients receiving nutrition via EN pumps. The experiment was conducted in a laboratory setting and is one of two studies evaluating delivery of enteral water utilizing demineralized or sterile water. Although the gastrointestinal tract is not a sterile environment and nasal/oral placement is not a sterile procedure,[48] many practitioners believe enteral water with impurities and bacteria removed is less harmful to EN patients than tap water,[49] especially for immunocompromised patients.[8] Thirteen different EN pumps delivered water and formulas of various viscosities for an uninterrupted 24-hr period. The 3 L bags were hung 1.5 meters from the floor and delivered into a 6 L container placed on the floor. Selection of a hang height distance was not explained by researchers and could not be verified for all 13 pumps as service manuals either did not annotate recommended hang heights or were not available for review. Six different formulas and water were used to perform 156 runs at 84 mL/hr; all 13 pumps were tested 12 times each. The eight pumps yielding the best reproducibility were used to carry out a one-way ANOVA analysis. Difference in delivery of demineralized water was found to be greater than ±100 mL/hr in 5 of the 13 pumps; one of which had a deficit greater than 200 mL (10%), and another with a deficit greater than 300 mL (15%); the intended delivered volume was approximately 2,000 mL. A weakness described in the study was using only one pump of each model that could limit reproducibility.

Other researchers have contested the assumption that the one pump of each model would be representative of all pumps of the same model. In a study by Spronk et al.,[17] 14 pumps of two different pump models were used, Kangaroo (St. Louis, MO) models 324 (n = 6), and 224 (n = 8). The pumps were preset to deliver 100 mL/hour for one-hour. Each pump was tested three separate times. Unlike similar studies, sterile water was included as well as standard enteral formula. The Kangaroo 224 was the least accurate, delivering deficits up to 24 mL (or 24%) of intended volume of sterile water. Results of this study supports the previous study conducted by Tepaske et al.[18] that found the error in delivery was caused by the EN pump and encourages frequent calibration of EN pumps used in the critically ill population.

Inaccuracies Due to Hang Height or Formula Viscosity

Another study conducted by Walker et al.[19] also evaluated EN delivery, with hang height (distance between the enteral feedbag and pump monitor) and formula viscosity investigated as possible variables that influenced the amount of EN delivered. Three different types of formulas of different viscosities were utilized, all of which provided variable calorie content (1.0, 1.5, and 2.0 kcal/mL). Three Covidien (Mansfield, MA) Kangaroo e-pumps were used to run each formula at four separate hang heights (0”, 6”, 12”, 18”) and infused at rates of 20, 40, and 80 mL/hr. The results of this study found greater inaccuracy with decreased hang height and increased formula viscosity (except for the 2.0 kcal/mL formula at 12” hang height). Strengths of this study included using multiple pumps of the same model to enhance reproducibility and running all three formulas at each hang height and infusion rate, across all pumps. This study also infused formula over a 24-hr period to replicate EN

delivery to patients. Limitations of the study included the simulation of EN delivery *in vitro* which excluded influences by patient position, route (i.e., PEG versus NG tube), and formula tolerance. The results highlight the importance of hang height as a key factor influencing the accuracy of EN delivery, including enteral water.

Dietscher et al.[11] also evaluated EN pumps in a controlled lab environment. The researchers used three different brands of EN pump; with a combined 15 (five pumps of each brand). Formulas of different viscosities (1.06, 1.49, and 2.18 kcal/mL, with powdered protein modular added to 2.18 kcal/mL) were infused at varying infusion rates of 10, 100, and 300 mL/hr. Formulas were run six times on each pump over a one-hour infusion period. Ultimately, less viscous formulas were found to have greater accuracy; this finding is similar to what Walker et al.[19] reported in the aforementioned study. The study's strengths consisted of a large sample size (90 total runs) and a variety of formulas infused. Limitations of this study included conducting the study *in vitro,* which may not reflect the variables observed during *in vivo* EN feedings. Patient position, placement of feeding tube, and height of the bag can influence *in vivo* EN delivery.

CHAPTER III

METHODOLOGY

Study Design

This project did not include the use of human subjects and was deemed exempt by the Baylor College of Medicine Institutional Review Board (see Appendix A). In the Clinical Nutrition Office located at the MEDVAMC in Houston, TX, three Covidien Kangaroo™ E-pump Enteral Feed and Flush Pumps with Pole Clamp (Mansfield, MA) were attached to vertical poles and used to deliver water at different volumes and bag hang heights (see Figure 1). Pumps were setup according to manufacturer specifications in the pump manual.[12] Maintenance and calibration of pumps were verified by the biomed department located at MEDVAMC prior to data collection. To test the hypotheses, each pump was programmed to deliver 1 L of tap water at two frequencies (50 mL once per hour for 20 hours and 500 mL every 4 hours for 8 hours) using Kangaroo™ E-pump flush bag set (see Figure 2) at two bag hang heights (0" and 18"). Each setting was run 15 times, for a final sample size of 180 (see Table 1).

Figure 1. Covidien Kangaroo™ E-pump Enteral Feed & Flush Pump with Pole Clamps.

Figure 2. Covidien 773662 Kangaroo™ E-pump Flush Bag Set, 1000 mL Capacity.

Table 1. Methodology Table for Pump Set-Up

Pump	Hang Height	Volume and Frequency	Number of Runs Performed per Pump
1-3	0 inches	50 mL every hour for 20 hrs	15
1-3	18 inches	500 mL every 4 hrs for 8 hrs	15
1-3	0 inches	500 mL every 4 hrs for 8 hrs	15
1-3	18 inches	50 mL every hour for 20 hrs	15
Total runs for one pump:			60
Total runs for three pumps (final sample size):			180

Experiment Set-Up

The experiment was performed in triplicate to increase the reproducibility of the results and help identify erroneous data. Prior to data collection, the Ohaus CS Compact Scale calibration was performed using the scale's calibration feature to account for the weight of the collection container. Pumps were attached to a vertical metal pole numbered 1-3 and collection containers were labeled according to each pump number. Collection containers were placed on a filing cabinet at waist height to mimic the position of a patient's bed prior to beginning each run.

After taking in account the weight of the empty container, 1 L of water was weighed (1.0 kg) and transferred into the water flush bag of the E-pump flush bag set. Manufacturers of the EN pump provide a recommended hang height for optimal accuracy of enteral formula delivery in the instruction manual;[16-18] however, this is infrequently adhered to in daily clinical practice.[19] Therefore, EN bags were hung at two hang heights (0" and 18" above the EN pump

monitor) as shown in Figure 3. The 0” hang height is horizontally in line with the EN pump. The EN set contains two bags, one for enteral formula and one for water. Actual formula was not used to conserve resources and minimized waste. In lieu of enteral formula, water was used (250 mL of water was weighed and delivered at a rate of 10 mL/hr from the enteral feedbag) to mimic the viscosity of a 1.0 kcal/mL enteral formula. A flush volume was programmed into the EN pump and run for the prescribed amount of time; 50 mL water flush test runs were conducted once daily while 500 mL flushes were conducted 2-3 times per day.

Figure 3. Example of how hang height was measured.

Table 1 depicts the methodology for running the EN pumps. Two volumes (50 mL and 500 mL) were used at both hang heights (0” and 18”) with each pump for 60 runs per pump. Upon completion of the 1 L water flush, all fluid remaining in the enteral bag set (excluding water in lines) and collection container weight (grams) were recorded to assess actual water delivered (grams). The amount of “formula” delivered was measured by weighing the

remaining amount from the original 250 mL in the formula bag and subtracting from 250. The outcome measured was the difference in initial 1 L water flush volume weight (grams) and final delivered volume weight (grams), minus water delivered from the formula side of the feedbag set to obtain actual water delivered. The volume reported by the pump and start/stop time using time provided by a hardwired office phone (with hours, minutes, and seconds) were also recorded for analysis.

As uncovered in this study, the programmed water flushes were not provided until the end of the hour; thus creating a potential to miss a water flush which becomes more significant as the flush volume increases as this could lead to inaccuracies and later dehydration because the last flush may not deliver. During infusion of the 500 mL of water every 4 hours, the pump delivered the water flush at the end of each hour. This presented a problem with the 500 mL flush since it takes approximately 16 minutes to fully deliver 500 mL (flush rate is 32.7 mL/min);[12] therefore, to deliver the prescribed 1 L of fluid, the pumps were allowed to run for 8 hours and 16 minutes. If the pumps were stopped at exactly 8 hours, a substantial amount of water would not be delivered; in this case approximately 500 mL. Further, initial design for the 50 mL run was to administer 50 mL/hr for 20 hrs; however, the flushes deliver at the end of the hour therefore the last flush was not delivered because the pump was stopped at exactly 20 hours. Adjustments for these inconsistencies were made (initial volume was 950 mL for 50 mL and 1000 mL for 500 mL) in order to combine all data for comparison. The percent of prescribed water delivered was calculated and used as the measured outcome in the statistical analysis.

Supplies

- Three Covidien Kangaroo™ E-pump Enteral Feed & Flush Pump with Pole Clamps
- Ohaus CS Compact Scale – 5 KG capacity (with calibration capabilities)
- Four Plastic Collection Containers with >1000 mL Capacity
- Covidien 773662 Kangaroo™ E-pump Flush Bag Set, 1000 mL Capacity (includes lines and connections)

Statistical Analysis

To test the hypotheses, a total sample size of 180 was identified for adequate study power ($\alpha = 0.05$). To choose a sample size for adequate power, a priori power analysis using G*Power 3.1.9 was conducted to determine the minimum sample size at power of 0.8, alpha level of 0.05, and moderate effect of 0.25 for factorial ANOVA (3 pumps x 2 heights x 2 volumes). A minimal of 158 samples was determined as the sample size needed to achieve adequate power. A total of 180 samples were collected to allow 15% for invalid values and errors.

The percent of prescribed water delivered was examined using a two-way ANOVA to determine whether a statistical significance existed between what was prescribed and what was delivered, considering the different settings used in this experiment. A *p*-value of < 0.05 was considered statistically significant with a confidence level of 95%. Data analysis was performed using software SPSS, Version Statistics Standard 25.

CHAPTER IV

RESULTS

A one-way ANOVA was conducted to detect statistically significant differences in the actual volume delivered among the three pumps used in this experiment. The assumption of homogeneity of variances was tested using Levene's test and resulted in equal variances between all pumps ($p = 0.431$). A two-way ANOVA was then conducted using the percent of actual volume delivered as the dependent variable. This test was used to detect any interactions hang height and volume had on the actual volume delivered.

Interaction effect was tested to examine whether the two variables, hang height and volume, had an effect on one another. There was no statistically significant interaction found between hang height and volume, meaning the varying hang heights had the same effect on both volumes tested. The main effect of both variables was then analyzed resulting in a significant difference in the mean percent of prescribed water delivered for both hang height ($F(1,176) = 138.14$, $p < 0.0005$) and volume ($F(1,176) = 22.345$, $p < 0.0005$). Due to the results showing a difference in actual water delivered as the hang height and volume delivered varied, the overall null hypothesis was rejected.

Hang height of 18" delivered a mean percent of 3.91% (95% CI, 3.25 to 4.57) more than those bags hung at 0", a statistically significant difference ($p < 0.0005$). Notably, the manufacturer's manual defines "accurate delivery" as ±10% of prescribed volume.[12] When delivering water at 500 mL volume, 1.57% (95% CI, 0.92 to 2.23) more water was delivered than at 50 mL; also a statistically significant difference ($p < 0.005$).

Figure 4. Percentage of Prescribed Water Delivered (+/- 1 SD).

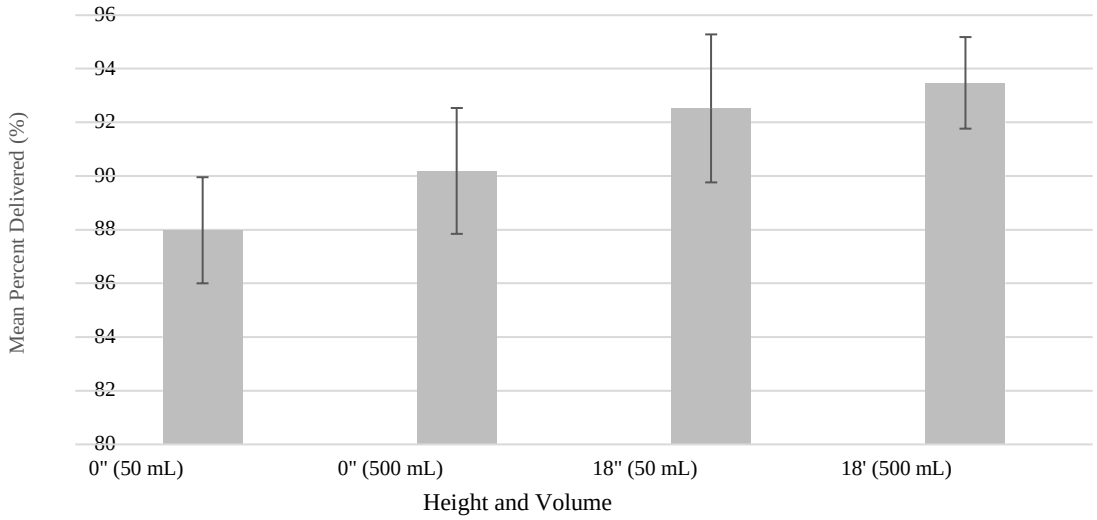

Figure 4 shows the percent of prescribed water delivered. The most accurate setting was 500 mL at 18”, resulting in adequate delivery (>/= 90% of prescribed volume) in 97.8% of the test runs. The second most accurate was 50 mL at 18” with adequate delivery found in 93.3% of the runs. The higher volume (500 mL) at 0” was more accurate than 50 mL at 0”, delivering adequately 57.8% of the time, while 50 mL at 0” delivered adequately 17.8% of the time.

Table 2. Comparison of Volume and Hang Height on Delivery of 1L[a] of Water

Pump	Volume (mL)	Height (in)	Mean of Final Water Delivered				Mean Difference between Volume Reported by the Pump & Actual Volume Delivered (mL)
			Actual Volume Delivered (mL)	Min. (mL)	Max. (mL)	Percent of Prescribed Water Delivered (mL)	
1	50	18	870	798	901	91.6	83
1	50	0	837.7	803	875	88.2	115
1	500	0	911.9	869	953	91.2	88
1	500	18	942.2	919	960	94.2	58
2	50	18	880.5	830	967	92.7	72
2	50	0	832.2	800	860	87.6	120
2	500	0	901.7	879	932	90.2	98
3	500	18	932.7	902	953	93.3	67
3	50	18	886.5	858	932	93.3	85
3	50	0	837.5	806	883	88.2	133
3	500	0	892.1	858	944	89.2	108
3	500	18	929.33	881	967	92.9	71

[a] 950 mL used for the 50 mL water flush and accounted for in measured outcome

CHAPTER V

DISCUSSION

The purpose of this study was to investigate the impact of flush volume and hang height on the accuracy of water delivered by EN pumps. The overarching goal is to improve the adequacy of enteral water delivery in patients receiving EN support by implementing standard training for EN pump setup and operation, nation-wide. This study found that bag hang height and delivery volume of enteral water influenced the accuracy of delivery.

Suboptimal fluid intake is associated with a higher incidence of falls, increased risk of urinary tract infections, infection, pneumonia, and overall poorer outcomes for hospitalized patients and the elderly.[41] Patients receiving daily fluid requirements via enteral water flushes could be more susceptible to under hydration and dehydration because they may be incapacitated and relying on others to administer fluids using an EN pump. Also, EN patients in the ICU may have increased fluid needs during times of metabolic stress.[47] Inadequate delivery of enteral water can create a deficit or continue to build on an existing fluid imbalance. Current research reports on inadequate delivery of enteral formula due to surgeries, procedures, and intolerances[9-10,16] with more recent studies bringing to light the influence pump malfunction may have on the inaccurate delivery of both formula and water.[11,15,17-19]

This study found that the bag hang height recommended by the manufacturer (18”) delivered a more accurate water volume compared to 0” hang height. Walker et al.[19] conducted an *in vitro* study to evaluate the influence of hang height, formula viscosity, and the rate of delivery on the accuracy of total EN delivered. Improved accuracy of enteral delivery was

found as hang height increased and formula viscosity decreased, with least deviation at the 18" hang height that was recommended by the EN pump manufacturer.

The inaccuracy of enteral water delivery shown in the results was due to pump malfunction. Several studies have found similar inaccuracies due to pump malfunction while delivering enteral formula, however only two available studies evaluated accuracy of enteral water. Tepaske et al.[18] and Spronk et al.[17] both analyzed commercial EN pumps in a simulated environment and found inaccurate delivery of water as well as enteral formula due to pump malfunction. The experiment by Tepaske et al.[18] found the difference in delivery of demineralized water to be greater than ±100 mL in 5 of the 13 pumps; one of which had a deficit greater than 200 mL (10% of the intended volume), and another resulted in a deficit greater than 300 mL (15% of the intended volume); the intended delivered volume was approximately 2,000 mL over a 24-hour period.

Similarly, Spronk et al.[17] used sterile water as well as standard enteral formula. Pumps were preset to deliver 100 mL/hour for one-hour. Each pump was tested three separate times. The Kangaroo 224 was the least accurate, delivering deficits up to 24 mL (or 24%) of intended volume of sterile water.

In another study, Strack[10] and colleagues found the instance of inaccurate delivery of formula to be 55% (55 of 100 EN feeding bags examined). With EN holds accounting for only 19% of these cases, researchers were led to believe that pump inaccuracy was responsible for the remaining 81%.

The statistical tests used to analyze data in this study were designed to determine whether volume and/or hang height had an influence on delivery. The actual percent of

prescribed water delivered for each volume and hang height was important to understand the "big-picture" since the statistical tests did not account for the variance allowed by the manufacturer (see Table 2). The pumps used in the study state that if the final delivered volume is within ±10% of prescribed volume,[12] is considered accurate. Adjustments were made during these calculations to find the percentage of what was actually delivered compared to what was intended to deliver.

Factors contributing to enteral delivery accuracies include interpersonal patient issues such as gastrointestinal intolerance and surgeries, but also interruption of the pump due to patient tests and procedures and daily nursing activities (i.e., bathing); [10,15,18] however, these contributing factors were of no concern during the study. Although the results showed a significant influence of hang height and volume on final volume delivered, it is possible to see even more inaccuracy when there are EN holds and interruptions being carried out due to patient care. In the present study, the confounding variables of holding EN for medication administration were eliminated; negative fluid deficits can compound further if the clinician does not resume EN promptly after medications are given. Clearly, the results presented are a "best case scenario" of fluid delivery using an EN pump. Complications can compound as patients rely on other individuals to provide fluids to improve hydration status. If a patient has a fluid deficit upon admission and several of the mentioned complications take place, these patients could continue to build on this deficit and rapidly begin to show signs and symptoms of dehydration.

One of the limitations identified in the study was that it was conducted *in vitro* and therefore did not accurately reflect EN formula and water delivery with a patient receiving EN

support. The results most likely are an over estimation of actual water delivered because unlike with an actual patient, the pumps in the study were not stopped to administer medications, conduct surgeries or procedures, or to allow for activities of daily living. Another limitation was the matter of flush timing. Although adjustments were made, the initiation of the water flush at the end of the hour could have been accounted for during the initial design of the experiment.

Strengths include consistency of testing procedures and data collection as the same person throughout the entire study did them. Other strengths identified included testing completed in triplicate, strengthening reproducibility, with all samples weighed in grams as well as measured in milliliters.

CHAPTER VI

CONCLUSION AND FUTURE RESEARCH OPPORTUNITIES

The objective of this study was to determine whether factors exist which effect enteral water delivery. Accuracy of enteral water is influenced significantly by hang height and volume. The most accurate setting for water delivery in this experiment was found to be 500 mL at 18", and accuracy decreased as the volume and hang height decreased. These factors together could compound inaccuracy with hang heights below 18" and when delivering water flushes in increments less than 500 mL. Although there are more studies evaluating enteral formula delivery than water delivery, based on the small number of studies available for consideration it is evident that many in clinical practice do not suspect enteral delivery to be inaccurate. Even further, pump malfunctions leading to inaccuracy is rarely examined. Likely, this is a product of false confidence clinicians may have in assuming EN pumps work as intended and/or assuring support staff has the proper knowledge to operate these pumps properly. The studies included in this review validate the importance of providing adequate nutrition and water and show the prevalence of inaccurate enteral formula and water delivery to patients requiring EN.

Dehydration should also be a topic of concern given the results provided in the present study. Preventative measures should be integrated into the care plan of not only patients receiving EN, but for elderly and hospitalized patients as well. The hope is to bring awareness of dehydration as a medical condition, increase understanding of the severe consequences and

related health care costs of this diagnosis, and reduce the instance of dehydration in patients relying on EN pumps for the delivery of daily fluid needs.

As EN support progresses, improvements will be made to devise new formulas and additives to allow further customization for more specific disease states, enhancement of pump performance by designing new and improved models, and delivery set-up will evolve to promote convenience and safety. Although change is necessary to improve patient care and efficiency, more research should be conducted to fully understand which factors influence the delivery of enteral formula and water and implement advances with these factors in mind.

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APPENDIX A

IRB Exception Letter

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MEMORANDUM

TO: GABRIEL HABIB, M.D.
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

FROM: ANNE UTECH
MEDICINE: GENERAL MED/VAMC

DATE: May 4, 2017

H-41272 - ACCURACY OF WATER DELIVERY IN ENTERAL NUTRITION PUMPS

On 4/27/2017 your office informed me of the intent to do the following:

In a simulated office setting (no human subjects), enteral nutrition pumps have been shown to deliver differing amounts of enteral formula, despite actual pump settings and recorded infusions (Walker, Probstfeld, Tucker, 2017, Nutrition in Clinical Practice). The same may be true for the free water these pumps deliver.
This study will be conducted without human subjects in an office using a simulated environment. Water will be infused through Covidien Kangaroo™ Epump Enteral Feed and Flush Pumps (Mansfield, MA) at pre-specified infusion rates and hang heights to determine accuracy of the free water flushes that the pump provides. No humans will be enrolled in this study protocol; water from the pumps is infused into beakers for weighing to determine actual free water delivery from the pump.

Given the assurances provided above, this memorandum serves as the BCM IRB and the BCM determination that this activity does not constitute human subjects research. The proposed activity does not constitute human subjects research as the data collected/used is not about living subjects as described in 45 CFR 46.102(f).. The activity does not fall under the regulations for IRB review of human subjects research found at 45 CFR 46 as the information to be collected is not about living individuals.

Please withdraw this protocol in BRAIN as it does no fall under the regulations for IRB review of human subjects research found at 45 CFR 46.

NOTE: A letter of the IRB determination is located in the Full Protocol/Grant/Brochure section of BRAIN for this protocol and may be downloaded to print a hardcopy for your files.