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Reliability of Urinary Bladder Pressure Measurement in Critical Care

Melanie Horbal Shuster

RELIABILITY OF

URINARY BLADDER PRESSURE MEASUREMENT

IN CRITICAL CARE

A Dissertation

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By

Melanie Horbal Shuster

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ABSTRACT

RELIABILITY OF

URINARY BLADDER PRESSURE MEASUREMENT

IN CRITICAL CARE

By

Melanie Horbal Shuster, PhD, RN

Dissertation supervised by: L. Kathleen Sekula, PhD, APRN-BC, Associate Professor of Nursing

Background of the study: Intra abdominal pressure (IAP) theoretically may be a predictor of enteral nutrition tolerance (EN). Urinary bladder pressure (UBP) is the gold standard for estimating IAP. Current recommendations for UBP measurement (UBPM) calls for the instillation of normal sterile saline (NSS) into the bladder while the patient is supine with a zero degree (0°) head of bed elevation (HOBE). How different instill volumes (IVs) and body positions influence UBPM were unknown, and the intra- and inter-observer reliability had not been adequately investigated.

Specific aims: 1) Systematically evaluate the relative contribution of bladder IV and subject's position upon UBPM. 2) Determine inter- and intra- observer reliability of UBPM. 3) Identify other factors that may influence IAP and UBPM: age, gender, Body Mass Index (BMI), net fluid balance (NFB), positive airway pressure, use of paralytic agents, EN and length of stay (LOS). **Method:** Prospective randomized study of 120

critically-ill adults who had UBPMs taken in four different positions and before and after

three different IVs. All UBPMs except 20 were obtained by the principle investigator

(PI). To determine inter-and intra-observer reliability the PI and a nurse co-investigator

obtained 20 UBPMs each in 10 subjects.

Results: Two way ANOVA showed a significant volume ($p<0.053$), position ($p<0.007$)

and volume-position interaction ($p<0.004$). 200 ml IVs gave higher UBP estimates and

variability, 0 ml IV gave lower UBP estimates, high variability and occasional negative

values. The supine-0° HOBE yielded lower values. No statistically significant

difference in UBP was observed among the three positions that were with a 30° HOBE

when measured with a 25 ml IV. Intra-and inter-observer reliability was high. BMI,

NFB, LOS, and EN use were found to be predictors of UBP.

Significance to nursing: The findings of this study impacts critical care (CC) nurses'

bedside practice by contributing data to develop an evidenced based UBPM procedure. It

also allows for further investigation of the relationship between increased IAP and the

gastrointestinal tract in critical illness and will facilitate the exploration of the

relationship between increased IAP and EN tolerance.

DEDICATION

This work is dedicated to:

My parents: Anthony and Dorothy Horbal……………..………………..
                                                                    Who gave me LIFE.

My Husband: Michael Shuster…………………………………....................
                                          Who has provided me with such a wonderful LIFE.

My Daughter: Mareena Shuster……………………………….....................
                                                  Who taught me the meaning of LIFE.

My Brother: Anthony Horbal…………………………………....................
                                      Who has shown me how to get the most out of LIFE.

My Extended Families:………………………………………………….....................
                                                            Who helped me enjoy LIFE.

My Boss: Jorge A. Vazquez, MD…………………………………………..
                                                 Who developed my professional LIFE.

My Advisor: L. Kathleen Sekula, PhD, APRN-BC………………………………
                                          Who cared about me………………………………..
                                          when she needed to care about her own LIFE.

My Committee: Lynn C. Simko, PhD, RN, CCRN
                       Carol Clark, RN
                       John Kern, PhD
                       Timothy Wolfe, MD……………………………………………..
                                                  Who enriched my academic LIFE.

My subjects and their families:………………………………………………..
                                                            Who touched my LIFE.

ACKNOWLEDGEMENTS

Finally, the wonderful organization of Wolfe-Tory Medical, Inc. whose support and guidance allowed the research study to come to fruition.

The dedicated commitment of ALL individuals and organizations involved in this academic and rigorous process made it fulfilling and rewarding. I acknowledge all of you with much gratitude, respect, and humility.

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LIST OF ABBREVIATIONS

AACN	American Association of Critical Care Nurses
ACS	Abdominal Compartment Syndrome
ANOVA	Analysis of Variance
BMI	Body Mass Index
CC	Critical Care
CCN	Critical Care Nurse
CCU	Critical Care Unit
cm H_2O	centimeters of water
CO_2	Carbon Dioxide
CPP	Cardio-pulmonary Pressure
CPPM	Cardio-pulmonary pressure monitoring
EN	Enteral Nutrition
GI	Gastrointestinal
HCP	Health Care Professional
HOB	Head of Bed
HOBE	Head of Bed Elevation
IAH	Intra-abdominal Hypertension
IAP	Intra-abdominal pressure
IV	Instill Volume
IVC	Inferior Vena Cava
LOS	Length of Stay
mmHg	millimeters of Mercury

MOFS	Multiple Organ Failure Syndrome
NFB	Net Fluid Balance
NSS	Normal Saline Solution
PACO	Pulmonary Artery Consensus Conference Organization
PAP	Pulmonary Artery Pressure
PV	Portal Vein
S-0°	Supine- zero degrees
S-30°	Supine-thirty degrees
S 30-25	Supine 30º HOBE position with a 25 ml instill bladder volume
S 0-25	Supine 0º HOBE position with a 25 ml instill bladder volume
SIRS	Systemic Inflammatory Response Syndrome
SERL	Screening, Enrollment, Randomization Log
RA	Right Atrium
RL-30°	Right lateral-thirty degrees
LL-30°	Left lateral-thirty degrees
UBP	Urinary Bladder Pressure
UBPM	Urinary Bladder Pressure Monitoring
UTI	Urinary Tract Infection
WSACS	World Society of Abdominal Compartment Syndrome

Chapter 1

Introduction

Background of the Study

Critically ill patients, like all humans, require nutrition to survive. Often, critically ill patients cannot eat secondary to endotracheal intubation, dysphagia, or an altered level of consciousness. Invasive nutritional support therefore must be provided to these individuals either via the parenteral or enteral route. Recent evidence supports preferential use of the enteral over the parenteral route to minimize the complications and poor outcomes that have been observed with parenteral nutrition (Heyland, Dhaliwal, Drover, Gramlich, & Dodek, 2003). However, the provision of enteral nutrition (EN) to critically ill patients is not without challenges (Guenter & Silkroski, 2001). The greatest difficulties are related to the initiation, advancement, and maintenance of EN (Bernard et al., 2004), which is under the purview of the bedside critical care nurse (CCN) who executes the prescribed EN orders while continuously monitoring the patients' response (Pinilla, Samphire, Arnold, Liu, & Thiessen, 2001).

Enteral nutrition administration is often limited by critically ill patients' intolerance. Intolerance is defined by Bernard and colleagues (2004) as side effects, adverse reactions, and complications that occur during the administration of EN. Intolerances include physical signs and symptoms such as nausea, vomiting, or bloating; metabolic derangements including hyperglycemia and altered electrolytes; and functional

or motility problems (ileus) which, individually or collectively, impedes the attainment of nutritional goals. Enteral nutrition intolerance is partially related to altered and/or compromised intestinal function. Currently there is no objective tool or reliable method to assess intestinal function in critically ill patients. Such a tool or method could be used to predict which patient will or will not tolerate EN, and would be most useful for nurses. A potential objective predictor of EN tolerance is intra-abdominal pressure (IAP).

Intra-abdominal pressure is the steady state pressure within the abdominal cavity. Intra-abdominal pressure varies between individuals, with position and activity. In normal human subjects in the supine position, IAP is zero or slightly positive (Tzelepis, Nasiff, McCool, & Hammond, 1996). The IAP normally increases during inspiration (diaphragmatic contraction) and decreases during expiration (relaxation) (Drye, 1948; Tzelepis et al., 1996). In hospitalized patients in the supine position, IAP ranges from 0 to 12.5 mmHg with a mean of 6.5 ± 3.3 mmHg (Sanchez et al., 2001). Intra-abdominal pressure increases when the volume (blood, air, water, etc.) inside the abdominal cavity increases or when abdominal wall compliance is reduced or inhibited (binders). A measured IAP value > 12 mmHg is considered intra-abdominal hypertension (IAH) (Malbrain, De Laet, & Cheatham, 2007). This commonly occurs with abdominal trauma or surgery or with aggressive fluid resuscitation secondary to shock states.

Intra-abdominal pressure may be a good prognostic indicator of EN tolerance, because gastrointestinal (GI) physiology is very sensitive to increased IAP. Intestinal, gastric and hepatic blood flows are reduced when IAP is > 10 mmHg causing intestinal hypoxemia, ischemia, and edema (Bongard, Pianim, Dubecz, & Klein, 1995; Caldwell & Ricotta, 1987; Diebel, Dulchavsky, & Wilson, 1992; Ivatury et al., 1998). As IAP

increases, intestinal perfusion decreases creating a cycle of cellular hypoxia, inflammation and edema that continues unabated until perfusion is restored or intestinal cellular death occurs. Intestinal ischemia and edema disrupts many of the protective intestinal barrier functions and may allow migration of bacteria from the intestinal lumen to the lymphatic system (Alverdy, Laughlin, & Wu, 2003; Diebel, Dulchavsky, & Brown, 1997; Gargiulo, Simon, Leon, & Machiedo, 1998; Steinberg, 2003), a process known as translocation. Bacteria also incite the production of pro-inflammatory cytokines further perpetuating this destructive cycle (Oda, Ivatury, Blocher, Malhotra, & Sugerman, 2002; Rezende-Neto et al., 2002). In the critical care unit (CCU), IAH and bacterial translocation have been implicated as an etiology of bacteremia, systemic inflammatory response syndrome (SIRS), and the development of the multiple organ failure syndrome (MOFS) (Balogh, McKinley, Cox et al., 2003; Moore, 1999)

Increased IAP also affects organ systems other than the GI tract. The cardiovascular system is affected by a decreased venous return leading to a decreased cardiac output (Kashtan, Green, Parsons, & Holcroft, 1981; Ridings, Bloomfield, Blocher, & Sugerman, 1995). The pulmonary system is affected because increased IAP elevates the diaphragm, which in turn reduces thoracic volume and lung compliance and increases intra-pleural pressure (Cullen, Coyle, Teplick, & Long, 1989). The renal system is affected due to compression of the renal veins and collecting systems (Harman, Kron, McLachlan, Freedlender, & Nolan, 1982). Finally, IAH can result in increased intra-thoracic pressure, which in turn may cause obstruction of cerebral venous blood flow leading to increased intra-cranial pressure and brain injury (Bloomfield, Ridings, Blocher, Marmarou, & Sugerman, 1997; Ertel, Oberholzer, Platz, Stocker, & Trentz,

2000). The development of organ dysfunction in one or more systems in association with IAH is known as abdominal compartment syndrome (ACS). Therefore, it stands to reasons that EN intolerance will occur with ACS. The treatment of ACS is abdominal decompression and is accomplished most effectively with surgery and less effectively with nasogastric suction or drainage tubes (De Keulenaer et al., 2003) and muscle relaxants (De Waele, Benoit, Hoste, & Colardyn, 2003). Effective decompression will decrease IAP and in turn permit EN tolerance.

Presently there is no reliable or accurate way to determine IAP by physical examination, but it can be measured by direct or indirect techniques. Because the abdomen is considered to be a relatively non-compressible cavity and primarily fluid in character, IAP can be measured directly by percutaneously inserting a catheter into any part of the abdomen or indirectly by inserting catheters into any hollow structure within the abdomen such as the inferior vena cava, uterus, or portal vein. The most commonly used indirect measurement techniques to assess IAP in the CCU are gastric, rectal, and urinary bladder catheters. Among these, the urinary bladder pressure (UBP) is the most widely used and is considered to be, by experts in the field, the gold standard for estimating IAP (Malbrain et al., 2006).

Many clinicians survey critically ill patients for IAH by measuring UBP. When ACS develops there is a need for emergent intervention, i.e. laparotomy or drainage of intra-abdominal fluid collections. However, there is no consensus as to the absolute value of UBP which indicates a need for intervention. Furthermore, the measurement of UBP is not standardized and may lead to under or over estimations. Underestimation of UBP may delay abdominal decompression in some individuals, while over estimation of

UBP may promote surgical intervention in some individuals when it is not warranted. Therefore, accurate and reliable UBP measurements as estimated by the bedside CCN is of crucial importance from the nursing, medical, and surgical standpoints, and to assess the usefulness of UBP as a predictor of enteral nutrition tolerance.

Urinary bladder pressure measurement in critically ill patients is a nursing responsibility, however the technical accuracy and reliability of UBP measurements taken by the bedside CCN is currently unknown. This is not surprising since the same can be said of cardio-pulmonary pressure monitoring (CPPM). Compared with bedside CPPM, bedside UBP monitoring (UBPM) is considered to be in its infancy with regards to experience, interpretation, and interventions based on the data. Research has shown that when monitoring equipment is properly assembled and calibrated, valid cardio-pulmonary pressure (CPP) measurements can be obtained (Ahrens, 1997; Gardner, 1996; Woods & Mansfield, 1976)

Therefore, variability in CPP measurements is not attributed to equipment problems but to differences in nurses' knowledge and skills. The nursing skills required for CPP measurements are proper positioning of patients, selecting the appropriate reference point, preparing the monitoring equipment, leveling and zeroing the transducer, assurance of waveform transmission, interpretation of the waveforms (Ahrens, Penick, & Tucker, 1995; Quaal, 1993) and recording the data. Unfortunately, little is known about the technical accuracy and reliability of CPP values obtained by nurses. The little that is known indicates CCNs' knowledge of CPPM is fragmented and inadequate (Ahrens, 1997, 1999).

Cardio-pulmonary pressure monitoring was introduced into clinical practice in the 1970's as a way to monitor patients with acute cardiac disease (Swan et al., 1970). Since then, CPPM has grown and guides therapy of critically ill non-cardiac patients as well. Cardio-pulmonary pressure is a measurement and monitoring technique usually performed or supervised by bedside CCNs and the information obtained is used by critical care practitioners to guide patient therapy. Nurses have been monitoring CPP for over 30 years. Despite the wisdom and experience gained over this period, the nursing knowledge and practice of CPPM is regrettably poor. In particular, the technical accuracy and reliability of CPPM is not known. The main reason for this situation is the absence of nursing research that validates and guides the practice of CPPM. Therefore, the validity and reliability of CPPM by CCNs, and its value to critical care practitioners as a tool for directing patient care is questionable.

Although many physicians believe that the information provided by CPPM is useful in guiding therapy and improving patient outcomes (Trottier & Taylor, 1997) others do not. Connors et al. (1983) reported that CPPM was associated with high mortality rates and high utilization of resources. Based on this data, in an accompanying editorial, Dalen and Bone (1996) called for a moratorium on the use of CPPM until more data were available from clinical trials.

As with CPPM, UBPM will be performed at the bedside by CCNs and data obtained will be used by critical care practitioners to guide patient care and for the potential monitoring of EN tolerance. Inaccurate and or unreliable UBP measurements will lead to improper patient care. Therefore, it is important that the technical accuracy and reliability of the UBP measurement procedure and monitoring technique be

established before it becomes widely used. Failure to perform the proper nursing studies now will promote tradition based nursing practice and not evidenced based practice.

Three major variables that can impact UBP measurement are bladder instill volume, patient position, and the nursing procedure for measurement. Bladder instill volume is the volume of normal sterile saline (NSS) injected into the urinary bladder prior to obtaining a pressure reading. It is assumed that the bladder needs to be distended to accurately transmit IAP (Kron, Harman, & Nolan, 1984; Malbrain, 1999) but UBP has been measured using no instill volume or as much as 250 milliliters (ml). Currently, it is not known how a small or large instill volume affects UBP.

Current guidelines recommend that UBP be measured in the supine position only (Gallagher, 2005; Lameier & NeCamp, 1990). Because patients in CCU are rarely positioned flat and supine, this implies that patients will need to be re-positioned before UBP is measured several times per day. This will disrupt patient's sleep and increase nurse's workload. Furthermore, patients who are enterally fed will need to have the EN stopped for the UBP measurement decreasing the amount of EN provided to the patient. Therefore, it is important to determine if UBP needs to be measured in the supine position only, or if it can be as effectively measured when the patient is in a more comfortable or required position, i.e. 30 degree head of bed elevation (30º HOBE). Further studies are needed to determine the affect of patient's position upon UBP and to decide if patients truly need to be flat and supine to have IAP measured accurately.

In the CCU, UBP may be measured once, several times per day, or continuously. The current literature most commonly reports UBP as a maximal or mean UBP, which is the average of four measurements usually measured every six hours during a 24-hour

period. Few data regarding the intra-observer reliability of a single measurement or for

repeated UBP measurements exists. Preliminary studies indicate that the coefficient of

variation of UBP is 4% to 66% (Malbrain, 2004; Malbrain et al., 2004; Malbrain, 1999).

The apparent large variation in UBP may be due to true diurnal variation of IAP, to inter-

observer variability, to intra-observer variability, or to other technical issues of the UBP

measurement technique such as leveling, zeroing, patient position, etc. Although nursing

procedures for UBP have been established and recommended for clinical use, these

procedures have been written, recommended, and advocated without scientific evidence

(Balogh & Moore, 2005a).

     In summary, EN intolerance occurs in critically ill patients. Presently, there is no

reliable objective method to evaluate GI physiology and its relationship to EN intolerance

or the potential for developing EN intolerance. Intra-abdominal pressure may be a tool to

assess GI physiology and EN tolerance. Intra-abdominal pressure can easily be measured

at the bedside indirectly using UBP, and CCNs are charged with the responsibility of

UBP measurement. Because UBP data is used by clinicians to guide patient care, it is

important to assure that UBP measurements are accurate and reliable. Unfortunately, the

technical accuracy and reliability of UBP measurements taken by bedside CCNs are

unknown. In addition, there is not a consensus regarding the effect of bladder instill

volume and patient's position upon UBP measurement. Therefore, before UBP

measurement becomes widespread and used as an index to assess EN tolerance, it is

important that nursing research be conducted to determine the role of bladder instill

volume and patient position upon the reliability of UBP measurements taken by CCNs at

the bedside. This study will provide the necessary data required to develop an evidenced

based procedure and protocol for CCNs to measure UBP at the bedside of critically ill patients. Establishing evidence based practice of bedside UBPM is necessary to avoid the controversies and problems that have occurred with CPPM, and evade the errors in the interpretation of the data that have been witnessed with bedside hemodynamic monitoring.

Purpose of the Study

The purpose of this study is to critically evaluate the process of UBPM in a naturalistic critical care setting. The specific aims are to:

1. Systematically evaluate the relative contribution of bladder instill volume upon UBP measurement.

2. Systematically evaluate the relative contribution of subject's position upon UBP measurement.

3. Determine the inter-observer reliability of UBP measurement.

4. Determine the intra-observer reliability of UBP measurement.

5. Identify other factors that may influence IAP and UBP measurement: age, gender, Body Mass Index (BMI), fluid balance, respiratory or ventilatory status, and paralytic agents.

6. Develop evidence-based recommendations for UBP measurement by bedside CCNs.

Research Questions

1. Does the amount of bladder instill volume effect UBP measurement?

2. Does subject's body position effect UBP measurement?

3. What is the inter-observer reliability of UBP measurement?

4. What is the intra-observer reliability of UBP measurement?

5. What other factors influence UBP measurement?

6. What are the elements of an evidenced based protocol necessary for CCNs to reliably perform bedside UBP measurement?

Definition of Terms

Instill volume is the amount of NSS instilled into the urinary bladder prior to obtaining a bladder pressure measurement. This volume is assumed to be necessary to distend the bladder to assure that a bladder pressure can be transduced to a bedside monitor and measured and is reflecting the IAP.

Critical care unit (CCU) is a geographic location within the hospital where critically ill adult patients are admitted for aggressive and intensive medical and nursing care. The term critical care unit is used as the preferred term reflecting the concept of acuity. However, it also includes intensive care unit (ICU) as these are designations of specific units. Adults patients admitted to any of the six critical care units: trauma, surgical ICU, medical ICU, coronary care, and two neuro ICUs were screened for possible inclusion into the study.

Intra-abdominal pressure (IAP) is the steady state pressure within the abdominal cavity at any given time and in healthy individuals is zero when supine, but in critically ill patients can range from zero to 50 mmHg.

Position refers to one of four positions subjects assumed for bladder pressure measurement. Positions will vary by supine or back lying and lateral or side lying and by the degree of HOBE, zero or 30°.

- Supine-0° HOBE position: subject supine with 0° HOBE and a pillow under the head.

- Supine-30° HOBE position: subject supine with 30° HOBE and a pillow under the head.

- Right lateral-30° HOBE position: subject right side lying with a 30° HOBE and a pillow under the head and a second pillow placed between the legs. The right lateral position will also be maintained with a 45° wedged positioning pillow.

- Left lateral-30° HOBE position: subject left side lying with a 30°HOBE and a pillow under the head and a second pillow placed between the legs. The left lateral position will also be maintained with a 45° wedged positioning pillow.

Reliability has been defined by Dolter (1989) as consistency, stability, and repeatability of results. Acknowledging this definition and for the purpose of this study, reliability is further defined as the ability to reproduce and record the same or a very similar UBP measurements at two different times by one or more observers (within a 30 minute period) using the same procedure.

Urinary bladder pressure (UBP) is an indirect method of measuring IAP.

Validity for the purpose of the study refers to the ability of a UBP measurement to accurately measure IAP.

Assumptions

1. The abdominal cavity is a closed system that behaves according to Pascal's law.

2. Urinary bladder pressure is a valid method of measuring IAP.

3. Urinary bladder pressure measurement is an indirect measure of IAP.

4. Urinary bladder pressure measurement is an important clinical sign to be monitored in critically ill patients.

5. Measurement of UBP by hydrostatic methods is reliable.

6. Bedside monitoring equipment when properly calibrated and assembled accurately measures pressures.

7. Urinary bladder pressure measurement is an important nursing responsibility.

Limitations

1. Subjects were selected from multiple critical care units but only one clinical site was used.

2. A limited and selected number of bladder instill volumes were studied (0 ml, 25 ml, 50 ml, 200 ml).

3. A limited and selected variety of body positions were studied. Two positions were supine with zero and 30° HOBE, and two were side lying positions, right and left lateral, both with 30° HOBE.

4. This study did not include an independent measure of IAP to validate the indirect measurement of UBP in critically ill patients.

Strengths

1. The same observer completed multiple (480) UBP measurements.

2. A variety of subjects in varied clinical settings were measured by the same observer.

3. More subject positions and bladder instill volumes were studied by one observer than any other study to date.

4. Uniquely designed and highly powered human study of UBP measurement in a critical care setting.

Weaknesses

1. Only one clinical site for the study was used.

2. A limited population by age, gender, BMI, ethnicity, positive airway pressure, paralytic agents, and diagnosis was studied.

3. No changes in outcomes were measured.

4. Reliability was only determined between two nurses.

Significance of the Study

The intention of the study was to evaluate the important factors necessary to standardize the critical care nursing procedure for bedside UBP measurement. The findings of this study will have immediate impact upon CCN's bedside practice by contributing the data necessary to develop an evidenced based UBP measurement procedure that may be evaluated as a tool for enteral feeding tolerance.

The study also has broader implications for critical care nursing and medicine as it relates to the phenomenon of increased IAP and GI pathophysiology. In particular, it will allow for further investigation of the relationship between increased IAP and the physiological response of the GI tract in critical illness, as well as the investigation of the relationship between increased IAP and the function of other organ systems in critical illness. Specifically, the results of this study will facilitate the exploration of the relationship between increased IAP and EN tolerance.

Finally, the results of the study will have greater clinical implications. Once the technique of UBP measurement is standardized, UBP can be measured more frequently. More frequent measurement will be helpful in establishing circadian variances and differences that may be related to various critical care states. This will lead to prompt recognition and diagnosis of ACS and perhaps will lead to earlier treatment and interventions preventing patient compromise.

Chapter 2

Review of the Literature

Introduction

The purpose of this literature review is two fold. First, to discuss the basic pressure concepts upon which IAP and UBP measurements are based, and second to review studies of UBP validity and reliability measurements.

Intra-abdominal pressure can be measured like a variety of other bodily pressures, because pressures are generated within the human body secondary to fluid filled cavities being contained within semi rigid structures. Physical properties and flow dynamics influence these pressures. The literature review will evaluate the concepts of pressure measurement including: principles of hydrostatic pressure, intra-abdominal pressure physiology, clinical significance of increased IAP, factors affecting IAP measurement and interpretation, techniques of IAP measurement, and UBP measurement as an indicator of IAP.

Pressures that are generated in fluid filled cavities can be quantified or measured when compressed or cannulated, i.e. blood pressure measured with a cuff and manometer or an arterial line. Nurses frequently are responsible for measuring various patient pressures, using direct and indirect techniques, interpreting the measurements, and often initiating or altering therapy and treatments based on these observations by employing algorithms or by consulting with other practitioners. Urinary bladder pressure as an

indirect measure of IAP is one of the more recent cavity pressures to be measured at the

patient's bedside, and the literature review will examine animal and human studies of

validity and reliability of IAP and UBP measurements. The concepts of pressure

measurement and the relevant research studies together form the foundation upon which

the research questions and study design addressing nursing and UBP measurement rests.

The unifying theoretical model upon which the study is based is depicted in Figure 1.

The study investigated the left side of the model which is the role of nursing in the

accuracy and reliability of UBP measurement. However, it is important to acknowledge

the right side of the model, which represents the physiological and clinical relevance of

the study. At the center of the model is tolerance to EN which was the research

hypothesis that prompted the current study. It is hoped that the research findings

generated from this study will later be used to investigate if UBPM is a reliable predictor

of EN tolerance.
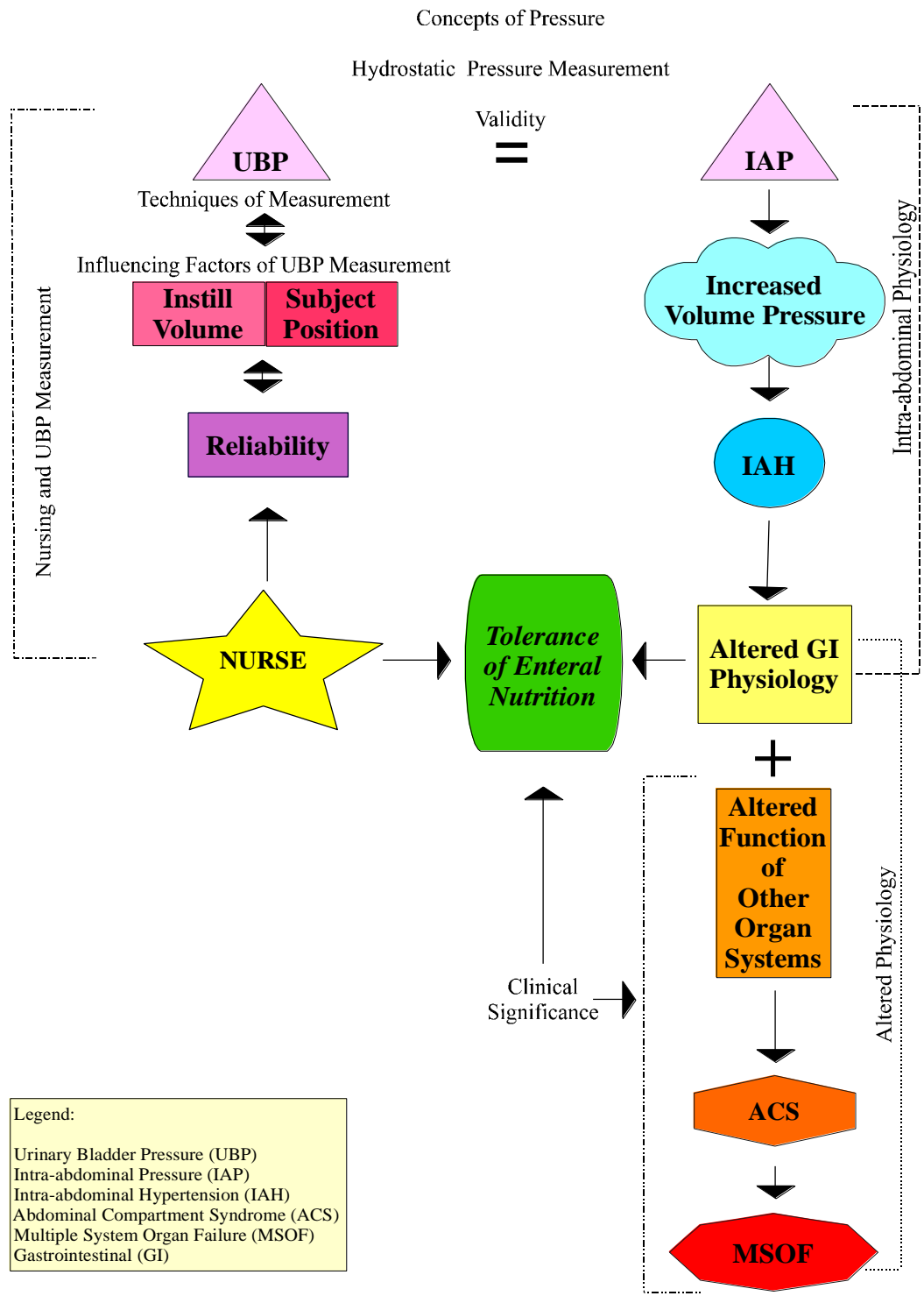
Figure 1. Theoretical model for reliability of bedside urinary bladder pressure measurement and enteral nutrition in critical care.

Although a nursing theory is not directly tested in the current study, the critical thinking theory of Benner (1982; 1996) as applied to nursing by Martin (1995) represents a theoretical framework for the rationale and nursing importance of the study. Critical thinking is the cerebral process employed by nurses in clinical decision making. According to this theory, nurses' critical thinking ascends from a low to a high level over time as a nurse becomes more knowledgeable and experienced (Figure 2). Benner (1987; 1992) describes five levels of nursing competence based on knowledge and years of experience: novice, new beginner, competent, proficient, and expert.

The novice is a student or new graduate and is transitioning from student to professional nurse. This is often facilitated in the orientation phase of an initial professional nursing position. Knowledge and experience are gained through mentoring and preceptoring relationships. Novice nurses use objective data to make clinical decisions with the assistance of others. The advanced beginner is a nurse with less than two years of experience whose practice is guided by policies and procedures and is focused on tasks, but uses a theoretical knowledge base. Nurses transitioning to the competent level integrate theoretical knowledge and experience and have mastered technical skills and have practiced nursing for two to three years. After three to five years of experience proficiency is attained. At this level nurses have in-depth knowledge and have a more global approach to patients and families and are able to respond to unplanned events. Finally, as an expert nurse with greater than five years of experience, care is delivered with confidence to patients and families both independently and collaboratively and is based upon a deep and wide knowledge foundation (Benner, 1982; Benner et al., 1992; Haag-Heitman & Kramer, 1998).
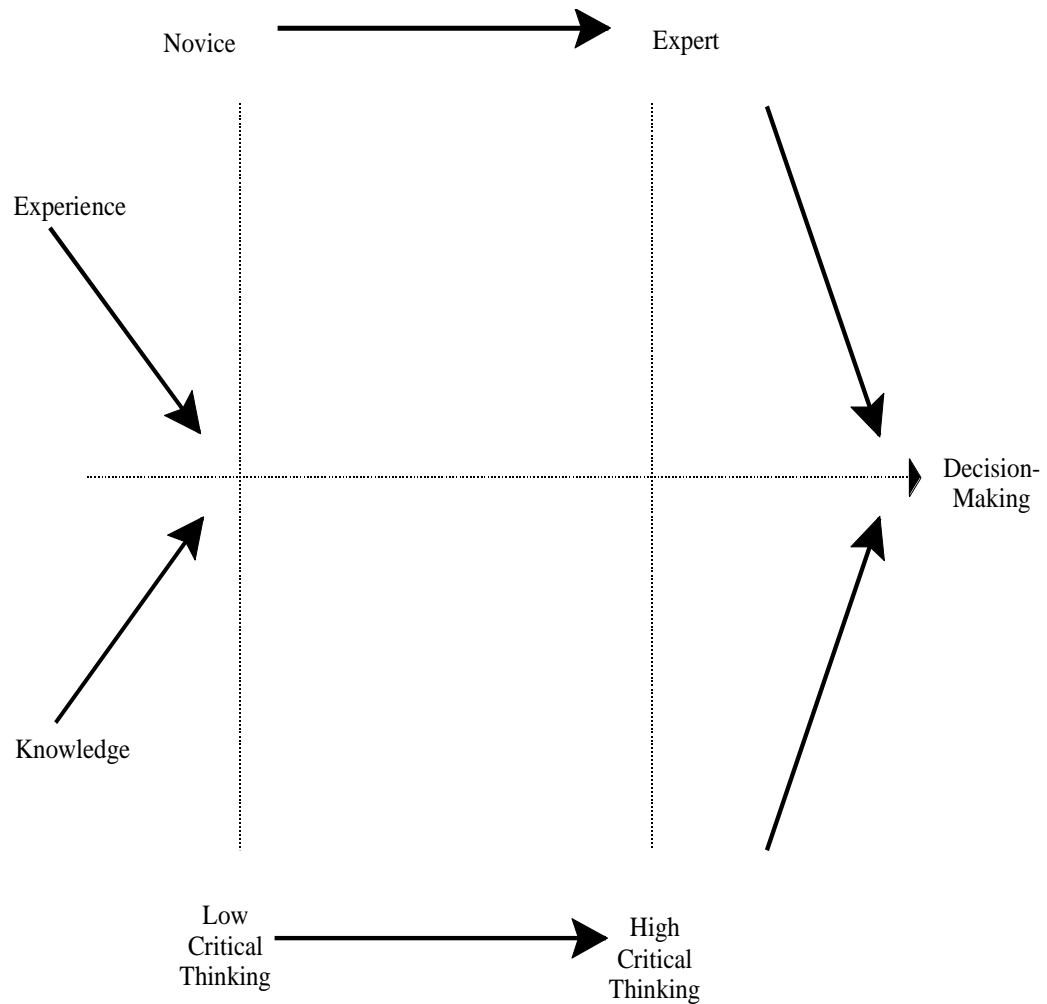
Figure 2. Critical thinking theory as applied to nursing.

Note. Adapted from *The Theory of Critical Thinking of Nursing,* by C. Martin, (2002). .

Applying the critical thinking theory of Benner (1982) to the decisions regarding

the administration of EN in critically ill patients is two fold. First, it could be

hypothesized that when comparing novice nurses to expert nurses, the expert nurse would

be better able to use subjective and objective data of GI tract function and would make

more appropriate decisions regarding initiation, advancement, and maintenance of EN, as

well as suspending and terminating EN. Second, it could be hypothesized that expert

nurses would also be more adept at recognizing subjective and objective signs of normal

GI tract function or dysfunction more readily and accurately when compared to novice nurses, therefore expert nurses would be better able to decide when to initiate, advance, maintain, suspend or terminate EN.

Furthermore, it is hoped that Benner's theory of critical thinking in nursing as applied to UBP would be able to demonstrate that novice nurses lack tolerance for patients who experience alterations in GI tract functions with EN and prematurely terminate feeding as compared to expert nurses. Continuing with this thought process and when considering the elements upon which EN administration decisions are made by bedside nurses, it would be expected that as nurses gain knowledge and experience with EN better decisions would be made in regards to successful administration of EN. Therefore, because an objective tool of assessing GI tract function or EN does not currently exist, it would be expected that patients cared for by expert nurses would achieve higher success in EN administration because such a nurse will rely more on experience (Figure 3). In contrast, patients cared for by novice nurses would be at a disadvantage due to lack of experience. Finally, the lack of an objective tool for GI tract function and assessment decreases the level of clinical decisions made by all levels of nurses and an objective reliable tool would be most helpful for all levels of practicing nurses.
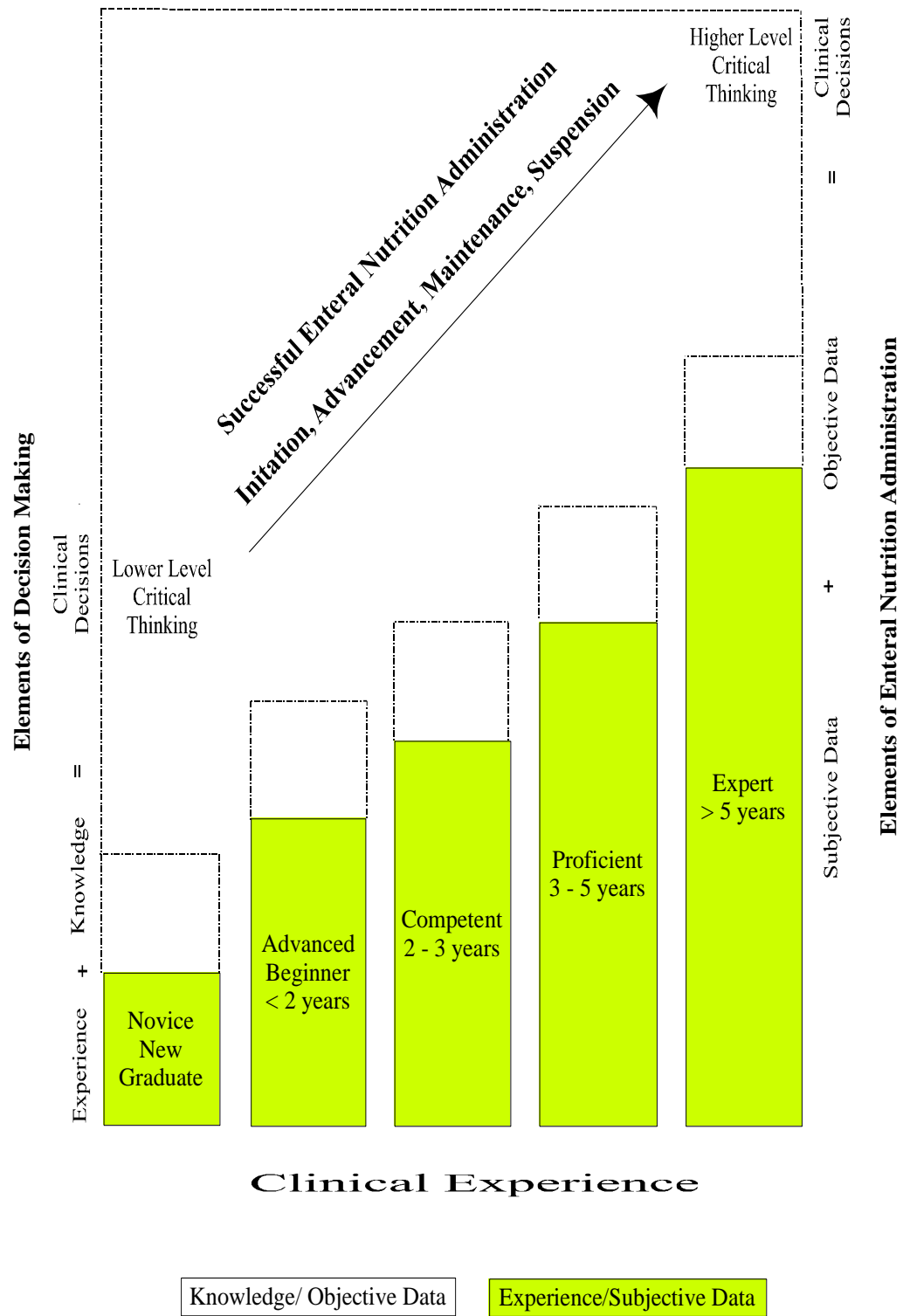
Figure 3. Theory of critical thinking of nursing as applied to enteral nutrition.

Using the results from this study, further nursing research could be conducted to explore the relationships between nurse's skills of assessment of GI tract function and critical decision making skills in reference to initiating, advancing, maintaining, suspending, or terminating EN. If UBP is proved to be a reliable objective tool and an indicator of EN tolerance, then UBPM can be used by nurses at all levels of Benner's classification to help with the clinical decisions regarding administration of EN. It is predicted that such a tool will be useful for nurses at all levels, but it would be of greater importance to the novice and less-than-expert nurse since it would empower them with knowledge and a skill that can be readily acquired and is not dependent upon years of experience (Figure 4).
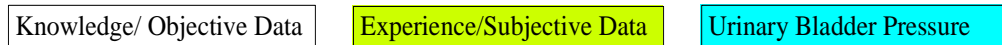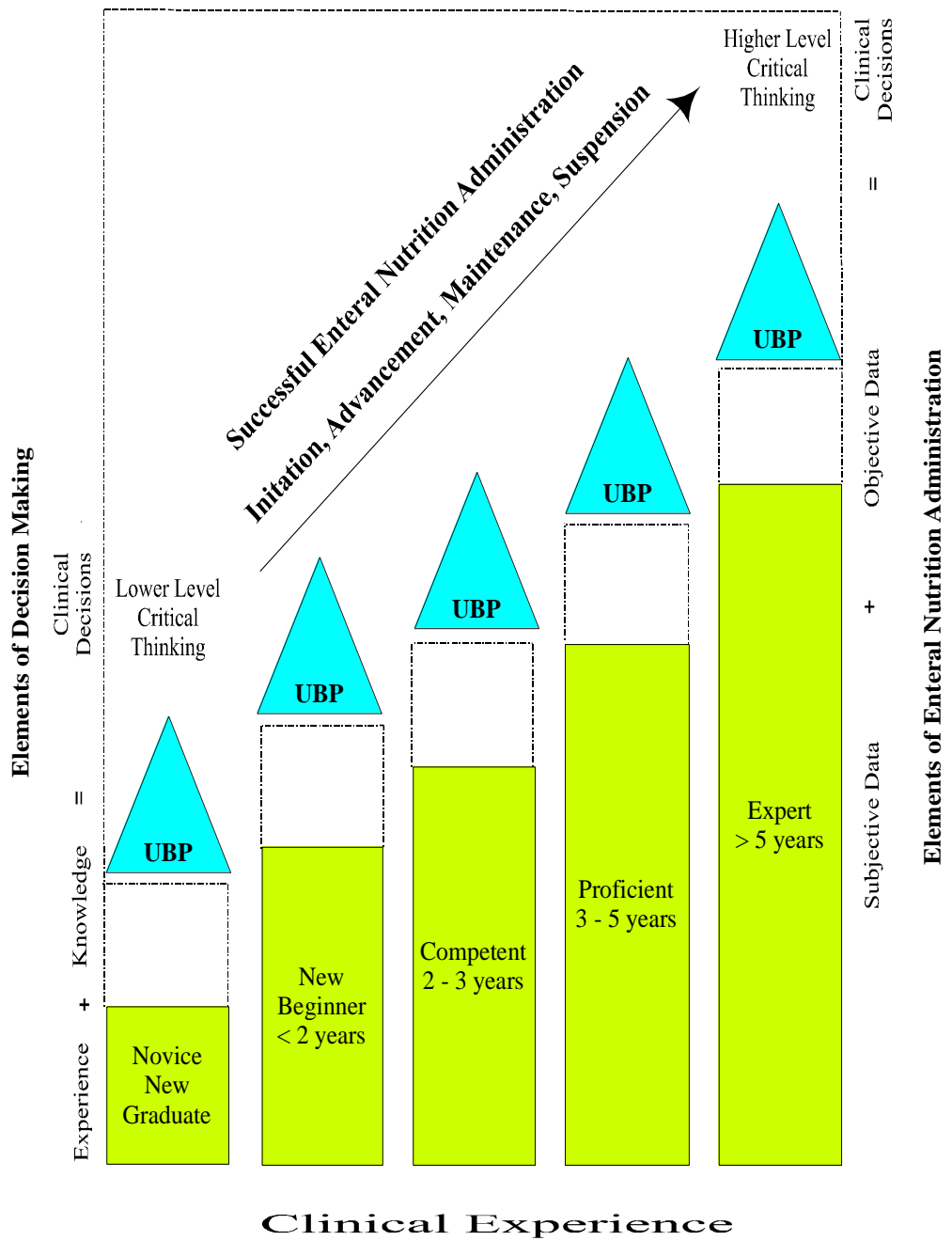
Figure 4. Hypothesized effect of urinary bladder pressure upon theory of critical thinking of nursing as related to enteral nutrition administration.

Hydrostatic Pressure Measurement

Urinary bladder pressure measurements like hemodynamic pressure measurements are based on hydrostatic pressure principles. To obtain pressure measurements, typically a fluid-filled catheter is placed into the chamber of interest (i.e. right or left atrium, or urinary bladder). The hydrostatic fluid pressure within the chamber is transmitted thru an opening in the catheter to a pressure transducer-amplifier-monitor system located at the patient's bedside. The transducer converts the pressure signals into an electrical signal that is amplified and recorded by the monitor (Ahrens, 1999).

To accomplish accurate bedside monitoring several concepts must be understood and incorporated into nursing procedures. First, physiologic pressures including CPP and IAP are measured against atmospheric pressure. Thus, the contribution of atmospheric pressure must be subtracted from the measured pressure. This is accomplished by opening the transducer to air. This procedure is known as zeroing and in effect makes the hydrostatic pressure at the opening of the catheter used for measuring equal to zero. In other words, the position of the catheter's measuring port in relation to the transducer will determine the relative hydrostatic fluid pressure within the chamber. To accurately measure the pressure in the cavity, hollow organ, or blood vessels it is important that the catheter used for measuring be at the same level as the transducer, and this procedure is referred to as positioning or leveling. Failure to level the transducer to the catheter's measuring orifice will result in erroneous measurements, either greater than or less than the true value. Erroneously lower pressure results when the transducer is higher than the

catheter opening, and erroneously higher pressure results when the transducer is lower than the catheter opening.

The second essential concept with regards to leveling is patient position. For optimal results, pressure measurements need to be taken when patients are in a standardized position. Very often, it is not possible to know exactly where the measuring orifice of the catheter is internally and an external landmark is used. For UBP measurement the transducer is most commonly leveled at the symphysis pubis. This is convenient because the symphysis pubis is an easily identifiable anatomic landmark and a reference point for the lower aspect of the bladder. Recently others have suggested using the mid-axillary line at the iliac crest as the zero reference point (Malbrain et al., 2007).

The accepted convention for CPPM is to level and zero the transducer at the phlebostatic axis (Winsor & Burch, 1945), which is an external marker for the right atrium (RA). When patients are in a flat supine (0° HOBE) position the phlebostatic axis is the point marked by the intersection of two planes: one vertical and one horizontal. The vertical plane is at the fourth intercostal space and the horizontal plane is the midpoint between the bed inferiorly and the sternum superiorly (Winsor & Burch, 1945). However, other markers have been proposed. Cuortois and colleagues (1995) recently suggested that for intra-cardiac measurements the transducer should be leveled at the uppermost blood level in the chamber for which the pressure is to be measured. This site can be measured for each patient by echocardiography or can be estimated if a large database is obtained.

It is important to emphasize that the reference point for leveling the transducer is specific to the position of the chamber of interest. It is not appropriate to use the

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phlebostatic axis for hemodynamic measurements when patients are supine with the head of bed (HOB) elevated (HOBE) or when the patient is in a lateral position, because the position of the right atrium may change. The phlebostatic axis was designed to be used for patients in the 0° HOBE position. Other reference points must be used when patients are in other positions besides a 0° HOBE position. Reference points that have been used for these purposes have been described by others. Paolella and colleagues (1988) used computerized tomography (CT) to determine the position of the RA. Kee and colleagues (1993) as well have used echocardiography to determine external anatomic references of the RA.

Intra-Abdominal Pressure Physiology

Intra-abdominal pressure is defined as the steady state pressure within the abdominal cavity, and has two major physiological roles. One is as a regulator of normal respiration and the other is the stability of the spinal column (Overholt, 1931; Salkin, 1934). The anatomic boundaries of the abdominal cavity are the movable diaphragm and the shifting costal arch superiorly, the rigid pelvis and the lumbar skeleton inferiorly and posteriorly, respectively, and the muscles that surround the abdominal cavity. The important muscles that provide shape and support to the abdominal cavity are the rectus abdominis, anteriorly; the external and internal oblique abdominal muscles and the transverses abdominis, laterally; and the muscles of the pelvic floor, inferiorly (Hall-Craggs, 1995; Snell, 1995). Because the abdominal cavity contains rigid components (i.e., spine and hip) it usually maintains its shape in various positions. Increases in IAP with changes in position and weight lifting are greatly due to gravitational effects of the organs and to contractions of the abdominal cavity muscles (De Troyer, 1983)

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The abdominal cavity contains solid organs (liver, pancreas, spleen) and hollow organs such as the gastrointestinal (GI) tract (stomach, small bowel and colon), uterus (in women), blood vessels (e.g. portal vein, inferior vena cava) and the urinary bladder. Normally, nothing else is contained within this space except for a small amount of peritoneal fluid that moistens and lubricates the surfaces. Because of these attributes the abdominal cavity is often considered to be a closed system containing a relatively non-compressible material and therefore should follow Pascal's law (Bradley & Bradley, 1947). Pascal's law states that an increase in pressure exerted at any point of a confined fluid will result in an equal increase in pressure at every other point within the container (Daugherty & Franzini, 1977). If this principle holds true for the abdomen, catheters placed at different points in the abdomen should register similar pressures reflective of IAP and should be sensitive to changes in patient's position.

Experimental support for these assumptions comes from the studies of Mead et al. (1990) and confirmed by Tzelepis and colleagues (1996) in healthy human subjects. These investigators measured IAP at different levels within the abdomen by placing catheters at various sites in the GI tract. Their results showed that changes in IAP induced by changes in position or breathing were of the same magnitude if measured in the upper or the lower part of the abdomen. The pressures in the lower part of the abdomen were five to 10 percent lower than the pressure in the upper part of the abdomen due to partial compression caused by air in the lower colon.

The physiological factors that normally determine IAP are the up and down movement of the diaphragm, tension or relaxation of the abdominal and pelvic muscles, the weight of the organs, and the degree of shearing decompression between the organs

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(Loring, Yoshino, Kimball, & Barnas, 1994). In healthy individuals lying supine, IAP is

zero or slightly negative (sub-atmospheric) or positive and normally increases with

inspiration and decreases during expiration (Tzelepis et al., 1996). Activities of daily

living increase IAP. Sitting or standing increases IAP by 5-10 mmHg (Twardowski et

al., 1986). Walking and running increases IAP to 22-38 mmHg and jumping produces an

increase to approximately 89 mmHg (Grillner, Nilsson, & Thorstensson, 1978;

Twardowski et al., 1986). Intra-abdominal pressure also increases with abdominal

compression, cough, the valsalva maneuver, and by lifting heavy objects (Twardowski et

al., 1986). Obesity (Sanchez et al., 2001; Sugerman, Windsor, Bessos, & Wolfe, 1997)

and pregnancy result in higher IAP (Soderberg, 1971).

Clinical significance

Intra-abdominal pressure ranges from zero to 12.5 mmHg with a mean of 6.5 $\pm$

3.3 mmHg (Sanchez et al., 2001) in hospitalized patients in the supine position. Intra-

abdominal pressure increases when the volume (blood, air, water, etc) inside the

abdominal cavity increases. Intra-abdominal pressure > 12 mmHg is considered intra-

abdominal hypertension (IAH) (Malbrain et al., 2004) and is a well-recognized

complication of certain types of surgeries (e.g. after reduction of large diaphragmatic

hernias or closure of the abdomen under excessive tension) and trauma when intra-

abdominal bleeding from splenic, hepatic and mesenteric injuries are common (Eddy,

Key, & Morris, 1994; Malbrain et al., 2004; Morken & West, 2001). Intra-abdominal

hypertension may also occur with medical illnesses such as hypovolemic shock and

massive fluid resuscitation, peritoneal dialysis, ileus, ascites, and acute pancreatitis.

Organ dysfunction in one or more systems in association with IAH is known as abdominal compartment syndrome (ACS). Abdominal compartment syndrome clinically presents as oliguria, decreased cardiac output, and rising peak airways pressures (Moore, Hargest, Martin, & Delicata, 2004). The exact incidence of ACS is unknown since, 1) IAP is not measured routinely in CCU (Mayberry et al., 1999; Ravishankar & Hunter, 2005) , 2) the methods of measuring IAP are not standardized, and 3) the heterogeneity of patients. The reported incidence of ACS ranges from 0.1% to 33% of postoperative and trauma patients (Eddy, Nunn, & Morris, 1997; Hong et al., 2002; Meldrum et al., 1997; Sugrue et al., 1995). Currently, there is no agreement on the absolute value of IAP that leads to ACS. Some patients may exhibits signs of organ dysfunctions with IAP of 10-12 mmHg while others will not develop clinical signs of organ failure until IAP rises to 15-18 mmHg. However, IAP > 20 mmHg should be considered clinically significant in every patient.

The treatment of ACS is abdominal decompression. Decompression can be accomplished by laparotomy or by draining intra-abdominal collections utilizing invasive radiologic guided procedures and techniques. Less commonly used methods of decompression are placement of nasogastric tubes for suction (De Keulenaer et al., 2003) and muscle relaxants (De Waele et al., 2003). Currently a consensus among researchers and clinicians on the best time to intervene in ACS is lacking. Ivatury and Sugerman (2000) have suggested intervention when IAP is > 25 mmHg as this may permit an opportunity to reverse some of the damage caused by IAH. In contrast, others have suggested waiting until clear signs of organ dysfunction are observed, such as increased airway pressure (Eddy et al., 1997) or oliguria (Meldrum et al., 1997) before intervening.

In trauma patients with ACS, early abdominal decompression is associated with improvement in organ functions. Unfortunately, only a small percentage of those who undergo decompression survive, and sadly even though 80% of patients who initially were treated with decompression responded, most did not survive. Survival rate after surgical decompression ranges from 17 to 75% (Sugrue et al., 2001). It appears that after an initial and often dramatic response to decompression, many patients eventually developed MOFS and died. These results suggest that once formed, ACS triggers a systemic inflammatory response that progresses to MOFS regardless of interventions (Oda et al., 2002).

Compared to trauma patients, less is known about the incidence, significance, and treatment of ACS in other types of surgical and medical patients. However, it is likely that general surgical and medical patients also suffer from potentially lethal pathophysiological decompensation associated with ACS as witnessed in trauma patients. Therefore, all critically ill patients could benefit from accurate and reliable monitoring of IAP provided the data obtained is accurate, reliable, and reproducible, and trends of IAP can be established.

The clinical data summarized underscores the need for routine monitoring of IAP in critically ill patients, both surgical and medical. Monitoring IAP is necessary to recognize IAH and to prevent and treat ACS in hope of reducing MOFS and death. Therefore, it is necessary to develop research based standardized protocols for use in the clinical setting to recognize early IAH and predict ACS. Several authors have called for greater awareness of IAP, and for more training in the measurement of IAP, and for the

early recognition and treatment of ACS in CCU (Balogh & Moore, 2005b; Malbrain, 2002; Malbrain, 2004; Malbrain et al., 2004; Sugrue, 2002)

Techniques of Intra-Abdominal Pressure Measurement

Physical examination cannot be used as a reliable or accurate method to determine IAP nor can it be used to predict the development of IAH and ACS. Kirpatrick and associates (2000) assessed the utility of a clinical abdominal examination in detecting IAP and IAH in patients admitted to a university affiliated trauma center. The specificity and sensitivity of a clinical abdominal examination in detecting clinically significant IAP (> 10 mmHg) was 40% and 94% respectively and of detecting very high IAP (> 15 mmHg) was 56% and 87%, respectively (Kirkpatrick et al., 2000). In a similar study, Sugrue et al. (2002) found that the specificity and sensitivity of a clinical examination in detecting IAH, defined as IAP > 18 mmHg, was 60.9% and 80.5% respectively. The positive predicted value was 45.2%, and the negative predicted value was 88.6%. These authors concluded that clinical examination is not an accurate method to assess IAP, nor is it an accurate tool to predict IAH, and further stated that IAP needs to be measured in the clinical setting. Other investigators have reached the same conclusion (Platell, Hall, Clarke, & Lawrence-Brown, 1990).

Direct or indirect measurement techniques can be used to measure IAP. The abdomen is considered to be a relatively non-compressible cavity and primarily fluid in character, therefore, IAP can be measured directly by percutaneously inserting a catheter into any part of the abdomen or indirectly by inserting catheters into any cavity within the abdomen such as the inferior vena cava (IVC), uterus, portal vein (PV), etc. Accurate IAP measurements have been taken using IVC, uterine, gastric, rectal and bladder

catheters (Gudmundsson, Viste, Gislason, & Svanes, 2002; Malbrain, 2004). However, obtaining access to the IVC, PV, or uterus is rather invasive and requires expertise not readily available in CCU. Similarly, placing an intra-peritoneal catheter for the sole purpose of measuring IAP is impractical and has the potential to add unnecessary risk to critically ill patients. Therefore, indirect measurement techniques are most commonly used to assess IAP in the CCU. Of the available techniques, UBP is used most widely. Furthermore, UBP is considered by experts in the field to be the gold standard for estimating IAP (Malbrain, 2004).

The UBP technique was first described by Kron et al. (1984) and their technique involves using a patient's existing urinary drainage catheter. For each measurement the catheter is disconnected from the collecting system and then 50 to 100 ml of a NSS is instilled into the bladder. The catheter is then clamped at a position distal to the sampling port and a 16-gauge needle, which is attached to primed pressure tubing and a transducer, is inserted into the sampling port. The transducer is leveled and zeroed at the symphysis pubis. The bladder pressure is then taken at end-expiration from the monitor or from a paper recording. The needle is then withdrawn and reinserted for each bladder pressure measurement that follows (Kron et al., 1984).

The technique of Kron et al. (1984) has been utilized extensively in clinical practice. The main problems with this technique are the repeated violation of the sterile system for each intermittent measurement, increased risk of urinary tract infections (UTI), time consuming, increased risk to nurses for needle stick injuries, and exposure to blood and body fluids. An additional clinical concern is with the advent of needleless systems and avoidance of needles, a needleless connection to measure UBP may not be

as accurate as a 16 gauge needle. However, there is no data examining the use of a needleless system in UBPM.

Kron and colleagues' (1984) original technique has been modified by Iberti et al. (1989), Cheatham and Safcsak (1998), and Malbrain et al. (2004). The main contribution of Iberti and colleagues (1989) was to convert Kron and colleagues' method from an open to a closed system by directly attaching a liter of NSS to the urinary catheter to make the instill volume easier to administer. Otherwise all the disadvantages of the original Kron and colleagues' technique also apply to Iberti's methods. For instance, Iberti's method still required insertion of a needle into the sampling port of the urinary drainage system with the risk to patients for infection and the risk to nurses for needle stick injuries and exposure to bodily fluids (Iberti et al., 1989).

Cheatman and Safcsak (1998) modified the method of Iberti et al. (1989) by attaching the urinary catheter to two three-way stopcocks connected in series. The first stopcock is attached to a liter of NSS, and the second stopcock is attached to a 60 ml syringe that facilitated the instillation of saline into the bladder. A plastic catheter then is inserted into the urinary drainage sampling port and left in place. This closed system allowed repeated UBP measurements over time without exposing the patient to infection from intermittent violation of the sterile system. However, eventually the connector port leaked causing problems, and again increasing the risk of urinary tract infection.

Malbrain (2004) modified Cheatman and Safcsak's (1998) technique by attaching a third stopcock in a series and eliminating the need to insert a needle into the sampling port, because the third stopcock was attached to the transducer. The system is primed with NSS and then the series of stopcocks are opened to air and the transducer is zeroed

and leveled at the symphysis pubis. This relatively closed system allowed repeated

measurements over days. In addition, it had the advantages of shortening UBP

measurement times and reducing the risks to patients and nurses as described above.

Commercially available systems for obtaining IAP measurement using UBP are

the latest innovation. The AbViser™ (Wolfe-Tory Medical, Inc. Salt Lake City, UT) is

one of two systems available and the FoleyManometer LV™ (Holtech Medical.

Charlottenlund, Denmark) is the other. The AbViser™ is a two-way valve that is

sterilely placed directly between the urinary catheter and the collection system. When the

AbViser™ is in the open position saline can be instilled into the bladder or the bladder

can be drained, and when the valve is in the closed position UBP can be measured. The

AbViser™ offers the same advantages as the Malbrain (2004) technique with three three-

way stopcocks in tandem, but in addition facilitates repeated measurements with ease,

decreased time, and decreased risk of infection.

Urinary bladder pressure measurement techniques as described by Kron et al.

(1984) and modified by others are based on hydrostatic pressure principles. Therefore,

all UBP measurements are prone to problems inherent in such a system. In particular,

accuracy will depend on the nurse's abilities to precisely perform the procedural

techniques for assembling, priming, zeroing, and leveling the transducer and maintaining

the monitoring equipment as well as positioning the patient appropriately. Because UBPs

are frequently measured in patients who are also undergoing hemodynamic

measurements, it is important that the dedicated transducer used for UBP measurement is

leveled at the symphysis pubis and not leveled with the other transducers used for CPP

measurements, where those transducers are zeroed and leveled at the phlebostatic axis.

In addition, it is important to re-level the transducer with changes in patient's position. Malposition of the transducer following a change in the patient's position may over- or under-estimate the UBP and IAP. It is also important to recognize and correct for over- and under-damping of the UBP waveform. Dampening can be caused by the presence of air-bubbles in the pressure tubing or by a tube that is too long or too compliant (De Waele, Billiet, Hoste, & Colardyn, 2004). However, a square wave test can be performed to insure integrity and accuracy of the monitoring system and assess for dampening (Kleinman, Powell, Kumar, & Gardner, 1992; Quaal, 1993).

Nursing and Urinary Bladder Pressure Measurement

Measurement of UBP in critically ill patients is a nursing responsibility. Data obtained by nurses is used by nurses and other clinicians to guide therapy. For this measurement to become a ubiquitous guide for clinicians as a determinate of therapy, it is essential that it is reliable. This is very important because, underestimation of UBP may delay abdominal decompression, while overestimation of UBP may promote surgical intervention when it is not warranted. Therefore, accurate and reliable UBP measurements obtained by nurses are of critical importance from the nursing, medical, and surgical standpoints. However, the technical accuracy and reliability of UBP measured by nurses is unknown. A review of the literature showed only one research study that assessed the technical accuracy, inter-observer, and intra-observer reliability of UBP measurement (Kimball, Mone, Wolfe, Baraghoshi, & Alder, 2007). This is not surprising because the same is true of CPPM which has been used for > 30 years.

Bedside UBPM is considered to be in its infancy with regards to experience, interpretation, and interventions based upon observed data when compared with bedside

CPPM. However, CPPM and UBPM share many similarities, and a review of the CPPM literature is relevant for this study to understand how a new bedside procedure was introduced, evaluated, accepted, and deemed essential by nurses and physicians and adopted as a standard of care by the critical care community. This knowledge is necessary to avoid the difficulties and errors that have been noted with hemodynamic pressure monitoring preceding UBP measurement.

There are many similarities between CPPM and UBPM. First, CPPM and UBPM will provide information to clinicians that are otherwise unobtainable by history and physical examination alone (Connors et al., 1983; Eisenberg, Jaffe, & Schuster, 1984; Kirkpatrick et al., 2000; Sugrue et al., 2002). Second, both are based on hydrostatic pressure principles and use similar equipment (transducers, amplifiers, and monitors). Moreover, proper measurement of CPP and UBP demand that the nurse level and zero the transducer properly for accurate measurement. Third, both require the insertion of a fluid-filled catheter for measurement (arterial, pulmonary artery, urinary bladder) to transmit the pressure waveform with fidelity. Fourth, CPPM and UBPM are performed at the bedside by CCNs and the data obtained is readily used by intensive care practitioners to monitor patient's response to treatment and to guide interventions. Therefore, as with other diagnostic modalities, the clinical utility of CPPM and UBPM depends greatly on the proper collection and interpretation of the data.

Research has shown that when monitoring equipment is properly assembled and calibrated, valid CPP measurements can be obtained (Ahrens, 1999; Gardner, 1996; Woods & Osguthorpe, 1993). Therefore, variability in CPP measurements is not due to equipment problems but to differences in nurses' knowledge and skills. The nursing

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skills required for CPP measurements are proper positioning of patients, selecting the appropriate reference point, preparing the monitoring equipment, leveling and zeroing the transducer, assurance of waveform transmission, interpretation of the waveforms (Ahrens, 1999; Quaal, 1993) and recording the data. Unfortunately, little is known about the technical accuracy and reliability of CPP values obtained by nurses. The little that is known indicates CCNs' knowledge of CPPM is fragmented and inadequate (Ahrens, 1997, 1999). Research has shown that nurses do not understand the process of zeroing and leveling and may perform these procedures in situations when it is not necessary (Ahrens et al., 1995). Research has also shown that nurses do not have a clear understanding of the square wave test (AACN, 1993; Quaal, 1995; Woods & Osguthorpe, 1993), an important measure, because over- and under-damping will result in under- and over-estimation of pressures, respectively. Additionally, research has shown that nurses have difficulty interpreting waveforms and determining the correct value as displayed on the bedside monitor particularly when there is respiratory artifact (Al-Kharrat, Zarich, Amoateng-Adjepong, & Manthous, 1999).

Review of the CPPM literature is also helpful to predict the usefulness of UBPM in patient care. In the 1970s CPPM was introduced into clinical practice as a way to monitor patients with acute cardiac disease (Swan et al., 1970). Since then, CPPM has grown and now guides therapy of critically ill non-cardiac patients. Many physicians believe that the information provided by CPPM is useful in guiding therapy and improving patients' outcomes (Trottier & Taylor, 1997). However, despite its wide acceptance and use by the nursing and medical communities, there is no consensus as to whether CPPM improves patient outcomes.

In 1996, Connors et al. (1996) reported that CPPM was associated with high

mortality and high utilization of resources. Based on this data, in an accompanying

editorial, Dalen and Bone (1996) called for a moratorium on the use of CPPM until more

data were available from clinical trials. As a response, several medical and nursing

societies formed the Pulmonary Artery Consensus Conference Organization (PACO) to

review the available data regarding the use of CPPM (Taylor, Calvin, & Matuschak,

1997). This review process confirmed that there was no evidence that CPPM improves

outcomes (Rackow, 1997). In addition, it became evident that CPPM lacked

standardization and data used by clinicians to make decisions was often flawed. The

review also revealed that physicians' and nurses' knowledge of CPPM and interpretation

of the data was poor. Based on this information, PACO made two major

recommendations regarding CPPM: First, PACO did not support a moratorium and

recommended to continue with CPPM, and second called for better training of physicians

and nurses in the technical aspects of CPPM and the interpretation of data gathered

(Taylor, 1997; Taylor et al., 1997; Trottier & Taylor, 1997).

One possible way to explain the lack of evidence that CPPM improved outcome is

that nurses' techniques are variable and sometimes leads to erroneous results and by

consequence erroneous clinical recommendations. Currently, no consensus regarding

many important aspects of CPPM exists.   One area of controversy is the selection of the

correct anatomic landmark for placement, leveling, and zeroing of the transducer to

insure accurate CPP values. For CPPM, the most widely used reference point for

leveling the transducer is the fourth inter-costal space at the midpoint of the anterior-

posterior diameter. This location is known as the phlebostatic axis and is intended to be

an external reference point for the RA (Winsor & Burch, 1945). However, recent imaging studies using computed tomography (Paolella et al., 1988) and echocardiography (Courtois et al., 1995; Kee et al., 1993) have cast doubts about the validity of this landmark for CPPM. Incorrect leveling of the transducer in reference to the RA will cause either over- or under-estimation of RA pressure.

Another area of practice that lacks consensus regarding procedures for CPPM is the influence and importance of patient positioning upon pressures. Most commonly, CPPM is performed with patients supine. However, in CCUs most patients rest with the HOB elevated to some degree and in the right or left lateral position, as well as supine. The nursing standard is to reposition patients unable to reposition themselves every two hours to prevent integument compromise (Baas, 2003; Perry & Potter, 1998; Reilly, 2001; Rodgers, 2001; Vollman & Aulbach, 1998). Therefore, nurses find patients in a variety of positions just before CPP measurement. Having to change a patient's position to obtain CPP will disturb patients sleep, rest, and comfort, which is against the primary goals of nursing. Patients who are able to reposition themselves would be forced to assume a position for measuring and then remain in a non-mobile steady state so a pressure measurement could be taken. Lastly, changing patient positions excessively increases nurses' workload and increases the risk of dislodging medical devices often used in critically ill patients. Obviously obtaining an accurate measurement in any position at anytime would be desirable for both nurses and patients.

At least a dozen nursing studies have investigated the effect of patient positioning and CPP measurements (Cason & Lambert, 1990; Chulay & Miller, 1984; Cline & Gurka, 1991; Clochesy, Hinshaw, & Otto, 1984; Dobbin, Wallace, Ahlberg, & Chulay,

1992; Groom, Frisch, & Elliott, 1990; Keating, Bolyard, Eichler, & Reed, 1986; Kennedy, Bryant, & Crawford, 1984; Laulive, 1982; Wilson, Bermingham-Mitchell, Wells, & Zachary, 1996; Woods, Grose, & Laurent-Bopp, 1982; Woods & Mansfield, 1976) . In most of these studies, various CPP measurements obtained in the supine-flat (0° HOB elevation) position were compared with measurements taken when patients were in the supine position with various degrees of HOB elevation (HOBE), the right lateral, and left lateral positions. Unfortunately, most nursing studies that investigated the importance of position in CPP measurement were underpowered, and suffered from major design flaws that make the results difficult to accept and use in clinical practice. The major design flaws identified in these studies were: 1) failure to validate the reference point, 2) failure to re-level the transducer with position changes; 3) failure to provide information about inter-observer and intra-observer reliability; and 4) failure to document the validity and reliability of the equilibrium period after each position change. The preponderance of the evidence suggests that pulmonary artery pressures (PAP) and other values do not greatly differ when subjects are supine–flat or supine with HOBE of 20-45°, but that lateral positioning does produce variables results. However, because of these serious research methodological problems, it is difficult to affirm with any degree of certainty whether one particular position is preferred over another for accuracy and reliability of CPPM. Currently, critical care nursing textbooks recommend CPPM be measured with patients in the spine position with the HOB elevated zero to 60° (Daily & Schroeder, 1981; Whalen & Kelleher, 1998) . Usually lateral positioning is not recommended (Cason & Lambert, 1993).

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The lack of definitive nursing research in regards to CPPM (i.e. well designed and fully powered studies) has created a great deal of confusion among nurses regarding proper patient positioning for CPPM. Grap, Pettrey, and Thornby (1997) assessed CPPM practices of 1000 members of the American Association of Critical Nurses (AACN) using a mailed questionnaire that both assessed knowledge with a quiz and questions regarding actual practice. The investigators found that nurses' knowledge regarding pulmonary artery pressure (PAP) measurement was reflected in practice. Respondents' knowledge of flat (supine-0° HOBE) positioning to measure PAP was 26.5% and 24.1% of the respondents reported always keeping the bed flat when measuring PAP. Tested knowledge found that 57.3% or nurses knew that the HOB should be < 45° and 55.9% of nurses reported elevating the HOB 30° or less in practice. Finally, 84.3% of nurses tested knew that the patient should be supine for measurement and 80.7% reported that patients are supine for measurements. Only 13.3% of nurses reported placing patients in lateral and other positions for PAP measurements. Although the results of this study demonstrates nurses knowledge guides nursing practice, it also suggest that there is great variability among nurses regarding the practice of CPPM which may greatly affect the pressure measurements obtained by nurses and may directly affect patient therapy.

In summary, CPP is a measurement and monitoring technique usually performed or supervised by bedside CCNs and the information obtained is used by critical care practitioners to guide patient therapy. Nurses have been monitoring CPP for over 30 years. Despite the wisdom and experience gained over this period, the nursing knowledge and practice of CPPM is regrettably poor. In particular, the technical accuracy and reliability of CPPM is not known. The main reason for this situation is the

absence of nursing research that validates and guides the practice of CPPM. Therefore, the validity and reliability of CPPM by CCNs and its value to critical care practitioners as a tool for directing patient care is questionable. Additional well-designed and fully powered nursing studies are needed to validate CPPM practice. Unfortunately, because CPPM is so widely accepted and frequently used at the bedside as a critical care nursing technique, it is highly unlikely that a study to establish reliability will ever be performed.

Urinary bladder pressure monitoring, as an indirect measure of IAP, is the new frontier of CCU monitoring. As with CPPM, UBPM will be performed at the bedside by CCNs and data obtained will be used by critical care practitioners to guide patient care. Inaccurate and or unreliable UBP estimations will lead to improper patient care. Therefore, it is important that technical accuracy and reliability of the UBP measurement technique and monitoring be established before it becomes widely used. Failure to perform the proper nursing studies now will only lead to the repeated errors that have been committed with CPPM.

Validity of Urinary Bladder Pressure Measurement

The UBP technique has been validated in both animal and human studies by comparing direct IAP measurements with UBP measurements.

Animal studies.

Iberti and colleagues (1987) measured IAP in dogs directly by placing an intra-abdominal catheter surgically into the peritoneal space, and indirectly by placing a urinary bladder catheter. These investigators found that IAP ranged from 10 ± 5 mmHg

to 70 ± 10 mmHg for the bladder catheter and those pressures accurately reflected IAP measured with the peritoneal catheter (Iberti et al., 1987). In an investigation of validity of indirect methods of IAP measurement in rabbits, IAP was gradually increased by inflation of an air-filled balloon (Lacey et al., 1987). These investigators found that only indirect IAP measured with the urinary bladder and inferior vena cava catheters had good statistical correlation with direct IAP measurement (Lacey et al., 1987). Intra-abdominal pressure measured using catheters placed in the stomach, rectum, superior vena cava, femoral and brachial artery were all poorly correlated with direct IAP measurements (Lacey et al., 1987). Ridings et al. (1995) measured IAP by a direct method and by UBP in a swine model. Intra-abdominal pressure was measured at baseline and after IAP was increased from 10 to 35 mmHg. The IAP measured directly was highly correlated with UBP (0.98, p<0.001). Gudmundsson et al. (2002) placed intra-peritoneal and bladder catheters in pigs and either progressively increased or decreased IAP in a stepwise fashion from 10 to 40 mmHg by instilling or withdrawing Ringer's solution into or from the abdomen. These investigators demonstrated that the IAP measured indirectly by the bladder pressure catheter paralleled increases or decreases in relation to IAP as measured directly via the intra-peritoneal catheter.

Human studies.

Iberti and colleagues (1989) compared IAP measured directly via surgically placed intra-peritoneal catheters and IAP measured indirectly with a urinary bladder catheter in sixteen postoperative patients. Measurement of IAP was done in three positions: supine, supine with gentle manual compression, and supine with the HOBE at

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a 45° angle. The researchers found that the IAP measured by the bladder and the peritoneal catheters resulted in nearly identical values regardless of the position. The correlation between the two methods of IAP measurement was 0.91 (p< 0.001) independent of patients' position.

Further validation of the urinary bladder catheter method as an accurate reflection of IAP in humans has been performed during laparoscopy. Researchers compared indirect IAP measured with a urinary bladder catheter with direct IAP measured with the CO_2 insufflator used for laparoscopic surgery in 40 patients before elective laparoscopic cholecystectomy (Yol, Kartal, Tavli, & Tatkan, 1998). The IAP's were measured before and after the IAP was raised to five, 10 and 15 mmHg by CO_2 insufflation. The results of the study are shown in Table 1.

Table 1.

Comparison of Direct and Indirect Measurements of Intra-Abdominal Pressure.

(Yol et al., 1998)

Insufflator Pressure Direct Measurement		Urinary Bladder Pressure Indirect Measurement (mean $\pm$ SD)
mmHg	cm H_2O	cm H_2O
0	0	2.5 ± 1.4
5	6.8	7.3 ± 1.5
10	13.6	12.9 ± 1.6
15	20.4	19.7 ± 1.5

There was very good correlation between IAP measured directly with the insufflator and indirectly by the urinary bladder catheter ($r = 0.973$, $p < 0.0001$). Further validation of the bladder technique was offered by Fusco et al. (2001). Like Yol et al. (1998), Fusco et al. (2001) compared insufflator pressures with bladder pressures in 37 patients prior to undergoing various laparoscopic surgeries. Each patient had UBP measured when IAP was set from zero to 25 mmHg by CO_2 insufflation and bladder instill volumes ranged from zero to 200 ml. Evaluating all bladder volumes together, bladder pressure correlated well with the insufflator pressure ($R^2 = .68$).

Other investigators have validated the bladder technique in humans by comparing direct to other indirect methods of IAP measurement. Collee and colleagues (1993) and

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Sugrue et al. (1994) also found good correlations between IAP measured with gastric and bladder catheters.

The validity of UBP measurement also has been recently investigated in neonates in CCUs. Davis, and colleagues (2005) measured IAP in 20 neonates (median age 10 days) who required peritoneal dialysis due to renal failure that developed after cardiac surgery. Intra-abdominal pressure was measured directly through the peritoneal dialysis catheter that was placed for dialysis and indirectly by urinary and gastric catheters. Urinary bladder pressure was measured after the bladder had drained and after instilling one, three, or five ml/kg of sterile normal saline solution (NSS) into the bladder. An instill volume of one ml/kg demonstrated close agreement between IAP measured by UBP and IAP measured directly by the peritoneal catheter. The UBP tended to give values that were between 0.07 and 1.23 mmHg higher than the IAP measured by the peritoneal catheter with limits of agreement between 3.08 mmHg higher and 1.79 mmHg lower than the peritoneal catheter. In summary, both animal and human studies have validated UBP as an accurate reflection of IAP.

Reliability of urinary bladder pressure measurement

Although UBP offers a valid estimate of IAP, the reliability of bedside UBP measurements taken by CCNs is unknown. Most studies reporting IAPs only show a one time value (usually the maximum) obtained over several hours of monitoring (O'Mara, Slater, Goldfarb, & Caushaj, 2005) and do not report whether these values were obtained by one or more observers. The first report of bladder pressure variability is one study designed to assess the prevalence of IAH in critically ill patients (Malbrain et al., 2004). This was a one-day study where bladder pressures were measured in patients admitted to

13 CCUs in seven European countries. The bladder pressure was measured four times

(12:00, 18:00, 24:00 and 6:00 hours) in 24 hours using the Cheatman and Safcsak (1998)

modification of the Kron technique (1984). The study included 97 surgical and medical

patients. All measurements were taken by the same standardized protocol with subjects

in the supine position with 50 ml of sterile NSS instilled into the bladder before the

measurements were taken. It is presumed that nurses took most if not all of the

measurements, but no information was provided to evaluate nurses' knowledge, level of

training and expertise using the UBP technique. The average UBP detected in this study

was 9.7 ± 4.7 mmHg. The average difference between the maximal and minimal four

daily UBPs was 5 ± 3.7 mmHg. When the measurements taken every six hours in each

patient were considered, the average coefficient of variation was 0.25 ± 0.13 or $25\% \pm$

13%. However, when the data from individual centers were compared the coefficient of

variation ranged from 4% to 66% among the centers (Malbrain et al., 2004). Since it is

not known if there is a diurnal variation in IAP, it is not possible to determine from this

data whether this variability reflects normal daily fluctuations, patient related changes, or

differences in measurements techniques between the same or different observers.

An extensive review of the literature revealed only one laboratory and one clinical

study that assessed reliability of UBPM (Wolfe & Kimball, 2005a). Wolfe and Kimball

(2005b) built a laboratory model of the abdomen by using a 210 liter container with a

urinary catheter exiting from its base. The proximal end of the urinary catheter tip was

sealed with a 100 ml bag to simulate the urinary bladder and it was placed at the base of

the container, and the other end was connected to an AbViser™ kit which in turn was

connected to a transducer and a monitor. The transducer was leveled at the level at the

simulated urinary bladder at the bottom of the container. A column of fluid was placed

within the container to simulate IAP of 5, 10, 15, 20, 25, 30, and 40 mmHg. Eleven (11)

observers then took five measurements each for each of the seven simulated IAPs. The

differences between the measured and the actual values were small the standard deviation

of the means were 0 to 0.49. The differences between the measured and actual values

were ± 1 mmHg. This study only assessed variability of the monitoring system but did

not address more important questions as variability introduced by subjects or by nurses'

techniques.

Kimball and associates (2007) estimated inter-reliability and intra-reliability of

UBP in subjects admitted to a CCU and at risk for IAH. One nurse measured UBP twice

and a second nurse measured it a third time in 18 subjects. The differences between the

two measurements taken by the first nurse were used to estimate intra-observer reliability

and the difference in the measurement between the first and second nurse was used to

estimate inter-observer reliability.

Overall, 89 nurses performed 212 sets of UBPM in 18 subjects. Urinary bladder

pressure was measured between 1-39 times per subjects. All subjects were measured in

the supine position and with 50 ml bladder instill volume. The UBP values ranged from

4-25 mmHg with average of 12.23 ± 4.68 mmHg. The Pearson correlation for the intra-

and inter-observer paired comparisons was 0.93 and 0.95, respectively. For the intra-

observer reliability the mean difference between the measurements was 0.570 mmHg (CI

0.306-0.834; limits of agreement -2.98 and 4.078 mmHg). For the inter-observer

reliability the mean difference between the measurements was 0 mmHg (CI -0.254 to

0.245; limit of agreement -3.069 to 3.069 mmHg). Kimball and associates (2007) found

that fluctuations of 4 mmHg (32% Coefficient of Variation) were very common between and within nurses and 10.5% of subjects had paired measurement fluctuations of > 2 mmHg. This variability may be of clinical significance since it may affect the definition of IAH and may also affect clinical decisions. The study of Kimball and associates (2007) was the first study to demonstrate low variability and therefore high reliability of UBP measurements in the CCU setting.

It stands to reason that specific knowledge and skills would be required to perform UBP, but the knowledge and skills of nurses related to UBP measurement has not been systematically studied. This is not surprising since the same can be said about the assessment of knowledge and skills of nurses regarding hemodynamic measurements even though this technique has been widely accepted and used for over 30 years (Rackow, 1997). For instance, little is known about inter- and intra-observer reliability of hemodynamic measurements taken by nurses (Ahrens, 1999; Rackow, 1997). Whatever is known suggests that nurses' knowledge and skills of hemodynamic measurements are poor (Ahrens, 1997; Al-Kharrat et al., 1999; Iberti et al., 1994).

Iberti et al. (1994) used a questionnaire to assess the level of understanding regarding the use of pulmonary artery catheters and hemodynamic measurements. Critical care nurses registered to attend a hemodynamic monitoring workshop sponsored by the AACN were surveyed (N=236) using questions in seven categories related to hemodynamic monitoring: complications, waveforms, patient management, insertion techniques, positioning, physiology, and calculations. The mean test score was 16.5 $\pm$ 5.7 or 48.5 %. Nurses correctly answered 63% of questions related to complications, 52.2 % of questions regarding waveforms, 50.5% of questions about patient management,

and 49.9% of questions dealing with insertion technique, 47.2 % of questions specific to positioning, 40.9% of questions addressing physiology, and 38.6% of questions concerning calculations. In a separate analysis of the data, it was found that test scores were significantly associated with years of experience in critical care, job title, being a certified critical care registered nurse, being responsible for repositioning and manipulating catheters, area of expertise, frequency of use of catheters, and self-assessed adequacy of knowledge. The same questionnaire was administered by Burns and Shively (1996) to another 168 critical care nurses with similar results. The mean test score for the 37 item questionnaire was 56.8%. Although not a consolation, it should be pointed out that nurses are not alone in this area. Other researchers reported low scores related to knowledge regarding hemodynamic measurements among critical care physicians as well (Iberti et al., 1990; Trottier & Taylor, 1997).

Other studies have shown that many nurses lack the basic skills related to zeroing and leveling of transducers and very often perform these procedures when not needed (Ahrens et al., 1995) and do not understand and know how to perform a square wave test (Quaal, 1995). A more recent study also indicated that CCNs have difficulty interpreting waveforms and calculating data obtained from pulmonary artery catheters (Al-Kharrat et al., 1999). A significant finding of Al-Kharrat's study (1999) was that upon re-interpretation of the data by critical care physicians, 30% of the pulmonary artery occlusion pressure values obtained by CCNs could have led to different therapeutic decisions (either failure to treat or inappropriate treatment). These observations question the inter-observer reliability of pressure measurements.

In summary, there is limited data addressing the intra- observer and inter-reliability of CCNs' ability to obtain UBPs (Kimball et al., 2007). Existing data indicates that the knowledge and the technical accuracy of CPPM, using skills similar to those required to obtain UBP, performed by CCNs are poor. Because, nurses use the same skills when measuring UBP as when measuring CPP, examining the existing data investigating nurses' knowledge of invasive monitoring is pertinent. Considering what is known about UBP measurement in combination with what is known regarding the reliability for other CPP, large variability, poor reliability, and questionable reproducibility of UBP measurement is to be expected. This creates a clinical problem since UBP, like CPPM, is one of the tools often used by critical care practitioners and surgeons to direct therapy. Over and/or underestimation of UBP may in some instances produce over utilization of resources while in other instances patients may be deprived of needed therapy that may reduce the risks of MOFS and death. In either situation patients may be at risk of receiving unwarranted treatment.

However, before definitive studies to determine reliability of UBP measurements can be performed, it is important that the measurement technique be standardized. Current protocols recommended for UBP measurement are not based on solid scientific research evidence. Two variables that may affect UBP measurement are bladder instill volume and patient position, both require further investigation.

Instill volume.

Sterile NSS is commonly instilled into the bladder before UBP measurement. The literature regarding the need for and the optimal amount of a sterile solution for instillation into the bladder prior to bladder pressure measurement is inconclusive. It is believed that instilling sterile NSS or water into the bladder improves pressure transmission and wave recognition. However, this could result in over-estimation of UBP and IAP if the instilled volume independently causes distention of the bladder. Researchers have claimed that with instill volumes of less that 100 ml the bladder acts as passive reservoir (Kron et al., 1984). However, a study to validate this statement was not provided. Animal and human bladder pressure studies have used instill volumes ranging from zero to 250 ml (Iberti et al., 1989; Obeid et al., 1995). Iberti et al. (1989) in their initial studies of dogs showed that accurate IAP measurements can be obtained with instill volumes ranging from zero to 100 ml. Iberti et al. (1989) also showed accurate IAP could be obtained with a 250 ml instill volume. Although some studies show that bladder pressure can be measured with a wide range of instill volumes, none can be used to support the use of one volume over another.

Gudmundsson et al. (2002) demonstrated that accurate IAP measurements can be obtained by measuring UBP with an instill volume of 0 ml in pigs. Using the same pig model these investigators later investigated the bladder instill volume required to increase bladder pressure by 2 mmHg. Intra-abdominal pressure was gradually increased by instilling Ringer's Lactate into the pig's abdomen until the desired pressure was achieved. To achieve an increase in bladder pressure by 2 mmHg when IAP was set at

< 8 mmHg an average of 131 ± 113 ml (range 30 to 300 ml) of NSS was required to be

instilled into the urinary bladder. However, when the IAP was set at 20 mmHg a much

lower average of 39 ± 23 ml (range 10 to 80 ml) was needed to be instilled into the

urinary bladder to increase bladder pressure by 2 mmHg. Data is shown in Table 2.

Moreover, for every paired data set, smaller volumes were needed when IAP pressure

was set at 20 mmHg as compared to when pressure was set at < 8 mmHg. This data

suggests that even instill volumes < 50 ml can influence IAP.   However, caution should

be exercised when extrapolating this data to humans, because of the anatomical

differences between humans and pigs. Specifically the urinary bladder in pigs is located

intra-peritoneally but in humans is located in the pelvis, and not within the peritoneal

space.

Table 2.

Effect of Bladder Instill Volumes on Intra-Abdominal Pressures.

Gudmundsson et al. (2002).

Animal #	IAP < 8 mmHg ml of NSS instilled to increase UBP 2 mmHg	IAP = 20 mmHg ml of NSS instilled to increase UBP 2 mmHg
1	150	15
2	300	80
3	300	60
4	30	10
5	40	30
6	80	50
7	120	40
8	30	40
Mean ± SD	131 ± 113	39 ± 23

Fusco et al. (2001) assessed the effects of bladder instill volumes on the accuracy of IAP measured using the bladder technique in humans with instill volumes that ranged from zero to 200 ml. In this study, IAP was increased by direct CO_2 insufflation prior to elective laparoscopic surgery. A good correlation between UBP and IAP measured with the insufflation needle was found. In addition, correlations between direct insufflation

and indirect UBP measured with instill volumes ranging from zero to 200 ml did not differ significantly from each other. When data from all volumes and pressures were considered the UBP was 3.8 ± 0.29 mmHg higher than direct insufflation pressure readings. A urinary bladder instill volume of 0 ml demonstrated the lowest bias differing from the insufflation pressure by -0.79 ± 0.73 mmHg and an instill volume of 200 ml demonstrated the higher bias differing from the insufflation pressure by -5.2 ± 0.60 mmHg. However, when only the data set obtained when the insufflation pressure was set at 25 mmHg (i.e. high IAP), instill volumes of 50 ml demonstrated a lower bias compared to 0 ml instill volume (1.5 vs. 2.0 mmHg).

Davis et al. (2005) investigated the effect of bladder instill volumes on the accuracy of IAP measurement in 20 children (median age 10 days) admitted to a surgical CCU. Urinary bladder pressure was measured after the bladder was drained and after instilling one, three, or five ml/kg of sterile saline into the bladder. The results were compared to IAP measured directly via a peritoneal catheter. Intra-abdominal pressure was most accurately estimated by UBP when one ml/kg of sterile saline was instilled into the bladder. Increasing the instill volume from one to three, or five led to a greater overestimation of IAP compared to the direct measurement. Decreasing the instill volume from one to 0 ml/kg led to more variability and wider limits of agreement. If these results can be applied to typical critically ill adults who weigh 50 to 100 kg, it could be predicted that instill volumes of 50 to 100 ml would lead to accurate UBP measurements.

De Waele et al. (2006) measured UBP in 20 subjects at risk of IAH admitted to a surgical CCU. Urinary bladder pressure was measured 10 times within a short period.

The first measurement was taken one minute after instilling 10 ml of sterile saline into the bladder. Subsequently, UBP measurements were taken after each 10 ml increment increase up to 100 ml. Measurements were taken after a one minute equilibration period elapsed following each instillation. An "oscillation test" was done after each instillation to evaluate whether the system was sensitive enough to detect the measurement. This test requires gently tapping the abdomen just above the symphysis pubis and observing the response in the monitoring system. The minimal instill volume required to detect a positive oscillation test was 10 ml. An instill volume of 10 ml gave the lower estimation of UBP and instill volumes of 50 and 100 ml were 17 and 33% higher than the UBP measured with an instill volume of 10 ml. These results suggest that small instill volumes (< 50 ml) may be desirable when measuring UBP.   However, it is interesting to note that 50 ml has been accepted as a usual or traditional volume for UBP measurement, and the current volume recommended by the World Society of Abdominal Compartment Syndrome (WSACS) is 25 ml or less. Unfortunately, the study if De Waele et al. (2006) had serious design flaws and involved a limited number of subjects; therefore using this work to make deductions is questionable. For example, the authors used a custom designed IAP monitoring set based on the technique of Cheatham et al. (1998) but did not clearly specify patient's positions or the technique for leveling and zeroing the transducer. All of these factors may greatly affect the results. In addition, 0 ml was not tested and the consecutive and cumulative effect of saline instillation upon the UBP steady sate is unknown.

Malbrain and Deeren (2006) investigated the effect of different volumes in UBP in 12 subjects admitted to a CCU. All subjects were sedated, ventilated and supine at the

time of the UBP measurement. The pressure transducers were zeroed at the symphysis pubis. Urinary bladder pressure was measured before any volume (0 ml) was instilled, then 25 ml NSS was added to the bladder consecutively up to a net bladder volume of 300 ml. Following each additional 25 ml bladder instill volume a UBPM was taken up to the total and final volume of 300 ml. One subject had a UBP of 0 mmHg with 0 ml bladder instill volume. Urinary bladder pressure was lowest with a 0 ml bladder instill volume and gradually increased with each 25 ml instill volume increment. The mean values of UBP for the 0 ml, 25 ml, 50 ml and 200 ml cumulative bladder instill volume were 6.2 ± 6 mmHg, 6.9 ± 7.5 mmHg, 8 ± 8 mmHg and 14.4 ± 13 mmHg, respectively.

Chiumello and associates (2007) also investigated the effect of instill volume on UBP measurements in 13 subjects admitted to a CCU. Initial UBP measurement was taken with a 50 ml NSS instill volume and then subsequently after each 25 ml addition of NSS to a maximum of 200 ml. All subjects were in the supine-0º HOBE position and the transducer was zeroed at the symphysis pubis for all measurements. After each saline addition, UBP was measured at five to 10 seconds and again after five minutes. The bladder catheter was closed during the five minute waiting period and drainage was inhibited. There was no difference in UBP when 50 ml and 100 ml of NSS were instilled into the bladder but there was a significant difference in UBP measurement between the 50 ml and the 150 ml and 200 ml of NSS instill volumes. In addition, with the 150 ml and 200 ml NSS instillation, the five minute UBP measurements were lower than the UBP measurements recorded at the five to 10 seconds interval after the instillation. This indicates that the bladder takes longer to reach a stable condition when large volumes are instilled into the bladder.

In summary, both animal and human data have shown that reliable estimates of IAP can be obtained with 0 ml instill volumes and higher UBPs are obtained with higher instill volumes (Chiumello et al., 2007; Davis et al., 2005; De Waele et al., 2006; Fusco et al., 2001; Gudmundsson et al., 2002; Malbrain & Deeren, 2006). Two of these studies were performed in settings other than CCU and one was done in neonates. Three of these studies reflect the complex clinical situation of a modern CCU, where most patients are receiving mechanical ventilation, intravenous fluids, and enteral nutrition, all which can impact upon IAP (Chiumello et al., 2007; Davis et al., 2005; Malbrain & Deeren, 2006). Therefore, it is likely that most critically ill patients in the CCU have an undetermined amount of urine contained within the bladder at any given time and instilling an additional fixed volume into the urinary bladder may falsely elevate bladder pressure, suggesting increased IAP erroneously. If Gudmundsson's (2002) data from pigs can be applied to humans, it would be difficult to predict which patient would or would not be affected by different instill volumes.

Finally, the studies of De Waele et al. (2006), Chiumello et al. (2007), and Malbrain and Deeren (2006) use a repeated measures design where instill volumes were successively increased using a fixed amount until a final target volume was reached. This design is flawed because the bladder was not emptied between measurements and is biased against higher instill volumes. In addition, the time that elapsed between consecutive measurements in these studies was usually one minute. A recent study by Kimball et al. (2007) suggests that a time interval less than eight minutes is associated with high variability. Therefore, the experimental design used by Chiumello et al.

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(2007), De Waele et al. (2006), and Malbrain and Deeren (2006) does not assess the effect of instill volume on UBP but rather measures urinary bladder compliance.

Positioning.

In healthy human volunteers, changing from the supine to other positions results in increases in IAP. Moving from a supine to a sitting and/or standing position increases IAP (Twardowski et al., 1986). Moving from the supine to the left lateral position increases IAP by 68% and moving from the supine to the right lateral position decreases IAP by 30% (Hebbard, Reid, Sun, Horowitz, & Dent, 1995). The changes in IAP secondary to position have been attributed to the gravitational effects of the organs and to contraction of abdominal muscles (Grillner et al., 1978; Hemborg, Moritz, & Lowing, 1985). De Troyer (1983) measured abdominal muscle activity as subjects moved serially from the 45º head down position, to supine, to 45º head up, to standing positions. He demonstrated that in the supine position the abdominal muscles were silent, but that abdominal muscle contraction occurs when subjects are gradually moved from the head down to the standing position.

Compared with healthy individuals, much less is known about the effect of position changes upon IAP measurements in hospitalized patients. Currently, UBP in hospitalized patients is nearly exclusively performed in the supine and flat (0° HOBE) position. However, there are no physiological or clinical reasons to suggest that this is the best position to measure bladder pressure. Indeed, there is no evidence that suggests that this position is superior to other positions regarding accuracy, variability, reliability, or reproducibility of the value.

The main advantages of using the 0° HOBE position for UBP measurement are: 1) standardization, 2) simple identification of an anatomic leveling point, and 3) nurses familiarity with position for performing hemodynamic measurements. However, it should be pointed out that the 0° HOBE position is not commonly used in the CCU. Presently, due to increased risk for aspiration pneumonia, patients in CCUs are rarely maintained in a 0° HOBE position for extended periods. Exceptions are situations where the preferred position with the HOB elevated is contraindicated for medical reasons, i.e. hemodynamic or neurological or spinal instability, difficulty with oxygenation, or an open chest or abdomen.

Therefore, changing a patient's position from some degree of HOBE to 0° HOBE for the sole purpose of UBP measurement disturbs patient's rest and sleep; increases the risk of equipment dislodgment, and increases nurse's work load. In addition, it is a common practice in the CCU to discontinue enteral nutrition (EN) when the patient is placed in the 0° HOBE position in an attempt to reduce the risk of aspiration pneumonia. Unfortunately this practice reduces the time patients receive EN contributing to weight loss and malnutrition in critically ill patients.

The current standard of care regarding the recommended position for CCU patients to prevent complications related to EN is supine with a 30º HOBE (Heyland et al., 2003). In addition, to prevent decubitus ulcer formation and improve patients comfort, CCNs are taught to rotate patient's position from back lying to side lying every two hours. Common rotation or positioning schedules are supine with a 30º HOBE, then rotate to the right or left lateral side lying position with a 30º HOBE, and then again to the supine position with a 30º HOBE, followed by left or right side lying position with a

30º HOBE, and so forth on a two hour schedule over a 24 hour period. Since it would be convenient to measure UBP without repositioning and causing patients discomfort, it is of interest to know if these commonly used positions affect UBP.

In the standing position, the urinary bladder is located in the inferior-dependent segment of the abdominal cavity within the pelvis and in the supine position the bladder is less dependent. Regardless of the position, the urinary bladder is always in contact with the abdominal cavity and capable of detecting and transmitting IAP. Increased IAP in critically ill patients is not due to the weight of the abdominal organs compressing the urinary bladder but rather due to an increase in abdominal volume (fluids or air) or to reduction in abdominal wall compliance.

Few research studies have directly assessed the effect of body position on UBP measurement in hospitalized patients. Iberti et al. (1989) measured UBP in 16 postoperative subjects in three positions: supine, supine with compression, and supine with 45° HOBE. All subjects had both an intra-peritoneal and a urinary drainage catheter that allowed the simultaneous measurement of IAP both directly and indirectly by UBP technique, respectively. An average of 250 ml of sterile NSS was instilled into the bladder before pressure measurements were taken and the transducer was leveled at the symphysis pubis.

The results showed a good correlation between the IAP measured directly via the intra-peritoneal catheters and those measured indirectly by urinary bladder catheters in all three positions. Unfortunately, Iberti et al. (1989) did not report individual bladder pressure values with each position, and the difference between the supine and supine with a 45° HOBE cannot be determined. In addition, bladder pressure was measured with a

large instill volume and the research report offered no assurance that the transducers were re-leveled with position changes.

The effect of abdominal compression on IAP was briefly assessed by Iberti et al. (1989). Data from an individual subject demonstrated acute UBP increases with abdominal compression, but the magnitude of the increase cannot be determined. Increases in IAP with compression are to be expected based on the assumption that the abdominal cavity is relatively non-compressible and follows Pascal's law. Coughing has also been observed to increase IAP (Drye, 1948) which further provides evidence supporting Pascal's law. Increases in IAP have also been found by investigators who have measured bladder pressures in patients in the prone position (Hering et al., 2002; Hering et al., 2001; Pelosi et al., 1998). Prone positioning is used in critically ill patients with acute lung injury when oxygenation (PaO_2) remains unacceptably low despite ventilation with high positive end-expiratory pressure (PEEP) and high-inspired fraction of oxygen (FiO_2). Although prone positioning improves oxygenation, these studies have shown that prone positioning restricts abdominal movement leading to increased IAP (Hering et al., 2002; Hering et al., 2001).

Obeid et al. (1995) measured changes in IAP in the supine, Trendelenburg and reverse-Trendelenburg positions in patients undergoing laparoscopic cholecystectomy. When IAP was increased from 10 to 16 mmHg by insufflating CO_2, UBP measured in the supine position accurately reflected the 6 mmHg increase (5.7 ± 9.8mmHg) in IAP. However, in the Trendelenburg and reverse-Trendelenburg (anti-Trendelenburg) positions UBP reflected smaller changes in IAP (2.1 ± 7.5 and 3.4 ± 6.2 mmHg), respectively.

Malbrain (2003) measured UBP in 10 critically ill subjects in four positions: supine, Trendelenburg, anti-Trendelenburg, and upright. This study was only reported as an abstract and minimal details about the experimental design are available. All 10 subjects were receiving mechanical ventilation. The results of the study showed that the upright and anti-Trendelenburg positions tended to give higher UBP values and the Trendelenburg position gave lower UBP values as compared to the supine position as displayed in Table 3. The strength of this data is that it was obtained with subjects typically seen in a CCU. However, this report suffers serious flaws making the usefulness of this information questionable. One problem is that the sample size was small. Although Malbrain et al. (2003) reported 79 paired observations, he only studied 10 subjects, therefore each subject was measured an average of 7.9 ± 4 times. Additionally, no information is provided explaining the rationale for subject positions, and it is unclear if the positioning was dictated by a research protocol or a clinical situation.

Table 3

Effect of Subject Position on Urinary Bladder Pressure

From Malbrain et al. (2003)

Position	IAP (mmHg)
Supine	8.8 ± 3.9
Trendelenburg	4.3 ± 3.8
Anti-Trendelenburg	13.3 ± 4.8
Upright	17.1 ± 6.1
Total	10.9 ± 6.8
P (ANOVA)	<0.0001

Without specific information, it is impossible to know if the differences in measured UBP as presented were related to position or to other clinical variables. Second, the choice of positions studied by Malbrain et al. (2003) warrants an explanation. Except for the upright position, which is used occasionally in patients with pulmonary edema, the others positions are rarely used in the CCU. The Trendelenburg position (head down at 45° and legs and feet over the edge of the table) is more commonly used during abdominal operations to push the abdominal organs toward the chest (Martin, 1995; Ostrow, 1997). Because of the gravitational forces produced by organ shift and the changes in abdominal muscle tone produced by the volume changes, decreases in IAP and by extension UBP, will be expected when changing from a supine to a Trendelenburg position. Finally, Malbrain et al. (2003) does not state his reference point for zeroing and

leveling the transducers nor does he mention if the transducer was re-leveled with changes in position.

Vasquez et al. (2007) measured UBP in 45 subjects admitted to an CCU due to trauma. In each subject, UBP was measured in five different supine positions that varied in the degree of HOBE. The positions investigated were supine-0º HOBE, supine-15º HOBE, supine-30º HOBE, supine-45º HOBE and supine-30º HOBE plus 15º of reverse Trendelenburg tilt. Each subject served as their own control and was assigned to three counterbalanced sequences of the five positions (of a possible 120 such sequences). Each subject was measured in each of the five positions three times to calculate a mean UBP for the position. After a minimum interval of one minute following repositioning, UBP measurements were obtained using a 50 ml bladder instill volume. The position of the pressure transducer was not reported and it was not changed with position changes. All measurements were taken within four hours to reduce the potential confounding factors introduced by changes in the subject's clinical status with time. A statistically significance effect of HOBE upon UBP was found. Post hoc analysis using the least significant difference test showed that all possible paired comparisons were significant from each other.

McBeth et al. (2007) measured UBP in the supine position with five different HOBE positions in 37 subjects admitted to a CCU who were at risk of developing IAH. All subjects were intubated and ventilated. Continuous UBP monitoring was performed using the Balogh technique (Balogh, Jones, D'Amours, Parr, & Sugrue, 2004). Continuous UBP monitoring differs from the intermittent UBP measurement technique of

Kron et al. (1984) that has been used in previous research studies and the study by Vasquez et al. (2007) discussed above.

Continuous UBP monitoring requires placement of a 3-way urinary bladder catheter. The third port which is traditionally used for continuous bladder irrigation is connected to an in-line pressure transducer and the monitoring system. The bladder was irrigated continuously with NSS at 4 ml/hr. The pressure transducer was positioned at the mid-axillary line at the iliac crest when the subjects were in the supine-0º position. Using this technique, UBP was measured in the supine-0º HOBE, supine-10º HOBE, supine-20º HOBE, supine-30º HOBE and supine-45º HOBE. The order of the position was not specified but the pressure transducer was not repositioned after each position change. The investigators also took intermittent measurements of UBP, using a 50 ml instill volume to validate the continuous and intermittent technique of UBP measurements but the data of the intermittent UBPM was not reported. The mean of the supine-0º HOBE estimated from a graph was 13.5 mmHg. Elevating the HOB to 10º, 20º, 30º, and 45º mmHg increased the UBP by 1.2 mmHg, 2.9 mmHg, 5.0 mmHg and 7.4 mmHg, respectively.

In summary, research studies have investigated the effects of select body positions on UBP measurements. Current research supports the fact that prone positioning increases UBP by compression of the abdominal wall (Hering et al., 2002). A preliminary study suggests that UBP decreases during Trendelenburg, and increases during anti-Trendelenburg and upright positions, but these positions are not relevant to CCU patients and flaws in the experimental design cast doubts regarding the validity of the findings. Except for the studies in the prone position, all studies suffered from small

sample size and did not address or identify the position of the transducer in relation to changes in patient positions nor were it stated if the transducer was re-leveled with position change. Prior to the initiation of this study no published studies assessed the effects of commonly used patient positions in critical care: supine with 30° HOBE and right or left lateral position with 30° HOBE. Recent studies have shown higher UBPs when subjects were measured in positions other than the supine-0º HOBE (McBeth et al., 2007; Vasquez et al., 2007). Up to now no study has assessed the effect of the right lateral and left lateral positions on UBP measurements.

Conclusion

The abdominal compartment is a closed system and its contents are considered to be mostly liquid and non-compressible. The pressure within the abdominal cavity depends on the gravitational weight of the organs, shearing forces and deformity, and on the actions of the muscles of the diaphragm, abdominal wall, and pelvic floor. Normally, IAP increases with natural movements and when individuals move from supine to the upright positions. Intra-abdominal pressure is physiologically important due to its role in the regulation of normal respiration and in the maintenance of the lumbar spine stability.

Intra-abdominal pressure can be estimated accurately by UBP. Several protocols exist for the measurement of UBP but none is evidence-based. There are questions regarding the effect of instill volume and subject's position that are required for UBP measurement. In addition, there is an urgent need to assess the inter- and intra-observer reliability of the UBP technique before it can be endorsed as a reliable monitoring technique and becomes widely used in critical care.

For these reasons, a nursing protocol for measuring UBP, as a reliable method for indirect IAP measurement, must be established. Furthermore, the protocol must be based on scientific evidence. Because there is a paucity of nursing literature regarding the reliability of UBP measurement, research efforts need to be directed towards establishing inter-observer and intra-observer reliability. Furthermore, prior to the development of a nursing protocol, research must be undertaken to establish the influence of position on UBP, as well as the instillation volumes influence on UBP. It is imperative that the nursing protocol and procedure be based on nursing research and scientific evidence prior to its widespread use in the clinical setting. Only after an evidenced based nursing procedure is established can UBP be tested as an objective measure of EN tolerance.

Chapter 3

Methodology

Design

This was a randomized prospective observational study. The study design is depicted in Figure 5. Subjects were recruited from the adult critical care patient population of a large metropolitan hospital as identified by a health care professional (HCP), primarily nurses or physicians, who had an established direct professional relationship with the patient. The HCP involved with the patient and providing direct care introduced the study to the patient, next of kin, or surrogate decision maker and notified the principal investigator (PI). The PI explained the study in detail and answered any questions asked by the subject or surrogate decision maker before any review if the medical record was undertaken. After the purpose and methods of the study were explained to the patient, next of kin, or surrogate decision maker, consent to participate was requested. Physician co-investigators obtained the informed consent (Appendix D). After informed consent was obtained consenting subject's medical records were screened according to the Screening, Enrollment, and Randomization Log (SERL) (Appendix A) for eligibility. If study criteria were met the subjects were enrolled and a study identification number and was assigned to a randomization group. The randomization scheme was prepared by the statistician and delivered to the PI in sealed envelopes. The envelopes were only opened after the subject signed the informed consent. The study

identification number was used throughout the study and was the only identifier for the

duration of the study. Demographic and clinical data were obtained from the medical

record and entered on to a Data Collection Form (Appendix B) which was used to enter

the study data into a computerized database.

Preliminary consent

Recruitment

Explain study

Obtain informed consent

Obtain demographic data

UBP measurement

Legend:

V = Instill volume

P = Body position

0° S = 0° HOBE, supine
30° S = 30° HOBE, supine
30° RL = 30° HOBE, right lateral
30° LL = 30° HOBE, left lateral

First Set of Measurements

V: 0 ml
25 ml
P: 30°S

120 subjects
120 sets 240 measurements
Made by Nurse A

Randomization

Second Set of Measurements

V: 0 ml 200 ml P: 0° S	V: 0 ml 200 ml P: 30° S	V: 0 ml 200 ml P: 30°RL	V: 0 ml 200 ml P: 30°LL
V: 0 ml 50 ml P: 0° S	V: 0 ml 50 ml P: 30° S	V: 0 ml 50 ml P: 30°RL	V: 0 ml 50 ml P: 30°LL
V:0 ml 25 ml P: 0° S		V: 0 ml 25 ml P: 30°RL	V: 0 ml 25 ml P: 30°LL

10 subjects per block
110 sets 220 measurements
Made by Nurse A

V: 0 ml
25 ml
P: 30° S

Intra-observer reliability
10 sets 20 measurements
Made by Nurse A

Third Set of Measurements

V: 0 ml
25 ml
P: 30° S

Inter-observer reliability
10 sets 20 measurements
Made by Nurse B

Figure 5. Study design.

All subjects had two sets of urinary bladder pressure (UBP) measurements taken. Each set had two UBP measurements taken for a total of four measurements per subject. The first set of UBP measurements was taken with subjects supine-30º HOBE with 0 ml instill volume followed quickly by another UBP measurement with a 25 ml instill volume. Subjects were then randomly assigned to one of twelve groups (Table 4). The second set of UBP measurements were taken in the randomized position using a 0 ml instill volume quickly followed by another UBP measurement with the instill volume as determined by randomization. The instill volume and position combinations were selected from one of three instill volumes and one of four positions. All UBP measurements (480) were taken by the PI.

Table 4

Study Groups for Bladder Instill Volume and Subject Position

	Head of Bed Elevation (HOBE)	0°	30°	30°	30°
Position	Trunk	Supine (S)	Supine (S)	Right Lateral (RL)	Left Lateral (LL)
	Leg	Flat	Flat	Right Lateral	Left Lateral
Bladder Instill Volume — 200 ml		S-0° 200 Group 9	S-30° 200 Group 10	RL-30° 200 Group 11	LL-30° 200 Group 12
50 ml		S-0° 50 Group 5	S-30° 50 Group 6	RL-30° 50 Group 7	LL-30° 50 Group 8
25 ml		S-0° 25 Group 1	S-30° 25 Group 2	RL-30° 25 Group 3	LL-30° 25 Group 4

The 10 subjects randomized to the supine-30° HOBE with a 25 ml instill volume had a third set of UBP measurements taken within 30 minutes of the first measurement. The third and final set of UBP measurements for this group was taken by the nurse co-investigator. Comparison between the second and the third set of UBP measurements (the second set done by the PI and the third set done by the nurse co-investigator) allowed assessment of inter-observer reliability of UBP measurements.

Each set of UBP measurements were taken within two to five minutes and measurements were obtained within 30 minutes or less. Each subject had the UBP measurements obtained on the same day and UBP measurements were not be repeated

again in the same subject regardless of how long they stay in the critical care unit (CCU).

Once all measurements were obtained, the PI or nurse co-investigator positioned the

subject in the most appropriate or comfortable position based on their medical condition

and wishes.

Urinary bladder pressure was measured in all subjects following the protocol

described in Table 5.

Table 5.

Protocol for Bedside Urinary Bladder Pressure Measurement

Step	Nurse	Action
1.	PI	Assure bedside monitor with electrocardiographic, respiratory, and pressure monitoring capabilities is available and functional
2.	PI	Gather materials and equipment
		• Sterile Gloves
		• AbViser™ kit
		• 500 ml NSS
		• Transducer
		• Laser level
		• Positioning wedged pillow
		• Hemostat
		• Clean gloves
		• Isopropyl alcohol wipes
3.	PI	Note subjects: Heart rate, respiratory rate and rhythm, blood pressure and mean arterial pressure, before positioning
4.	PI	Position the subject supine with a 30° HOBE
5.	PI	Open AbViser™ kit
6.	PI	Spike the NSS bag and prime tubing and transducer
7.	PI	Connect the transducer to the amplifier-monitor and select the lowest pressure scale
8.	PI	After cleansing the connection site and using sterile technique, connect the AbViser™ valve to the subject's urinary catheter
9.	PI	Place the catheter between the subject's legs and place the collection bag toward the foot of the bed and suspend the collection bag either to the right or to the left side preventing any increase in elevation of the collecting system or compression of the catheter or collecting system.
10.	PI	Level the transducer with the symphysis pubis

Table 5 (Continued)		
Step	Nurse	Action
11.	PI	Zero the transducer by opening the stopcock to air and selecting the zero option on the monitor
12.	PI	Assess the responsiveness of the monitoring system • Perform a manual square wave test • Close the stopcock to the subject • Inject saline against the transducer • Observe a square wave on the monitor.
13.	PI	Assess the conductivity of the fluid filled column • Squeeze the urinary drainage catheter proximal to the connection of the AbViser™ • Observe a pressure inflection on the bedside monitor
14.	PI	Determine if steady state is present • Compare vital signs (VS) prior to positioning with VS after positioning • Confirm difference is less than 10 percent
15.	PI	With no urine in the collection tubing clamp the urinary collection tubing with a hemostat distal to but as close as possible to the AbViser™ for the first UBP measurement
16.	PI	Empty the urimeter and record on the output record
17.	PI	Record the first UBP measurement of the first set from the monitor at the end of expiration: zero instill volume with 30º HOBE.
18.	PI	Unclamp the urinary drainage catheter distal to the AbViser™ valve by releasing the hemostat and allow the bladder to drain for 30 to 60 seconds noting the amount of urine that drains into the urimeter and record on the output record
19.	PI	Determine if steady state is present • Compare vital signs (VS) prior to positioning with VS after positioning • Confirm difference is less than 10 percent
20.	PI	Inject 25 ml of NSS into the bladder with the syringe
21.	PI	Record the second UBP measurement of the first set from the monitor at the end of expiration: 25 ml instill volume with 30° HOBE
22.	PI	The AbViser™ valve will automatically open to permit drainage noting the amount of urine and NSS that drains into the urimeter is $\geq$ 25 ml
23.	PI	Document the instill volume on the intake record and the drainage on the output record
24.	PI	Note subjects: Heart rate, respiratory rate and rhythm, blood pressure and mean arterial pressure, before positioning

Table 5 (Continued)		
Step	Nurse	Action
25.	PI	Position the subject according to randomization group and assure the catheter is between the subject's legs and place the collection bag toward the foot of the bed and suspend the collection bag either to the right or to the left side preventing any increase in elevation of the collecting system or compression of the catheter or collecting system.
26.	PI	Re-level the transducer with the symphysis pubis
27.	PI	Re-zero the transducer
28.	PI	Note subjects: Heart rate, respiratory rate and rhythm, blood pressure and mean arterial pressure after positioning
29.	PI	Determine if steady state is present
		• Compare vital signs (VS) prior to positioning with VS after positioning
		• Observed difference is less than 10 percent
30.	PI	With no urine in the collection tubing clamp the urinary collection tubing with a hemostat distal to but as close as possible to the AbViser™ for the first UBP measurement
31.	PI	Record the first UBP measurement of the second set from the monitor at the end of expiration: zero instill volume in the randomized position
32.	PI	Unclamp the urinary drainage catheter distal to the AbViser™ valve by releasing the hemostat and allow the bladder to drain for 30 to 60 seconds noting the amount of urine that drains into the urimeter
33.	PI	Document the instill volume on the intake record and the drainage on the output record
34.	PI	Determine if steady state is present
		• Compare vital signs (VS) prior to positioning with VS after positioning
		• Confirm difference is less than 10 percent
35.	PI	Inject the randomized instill volume (25, 50, 200 ml) of NSS into the bladder with the syringe
36.	PI	Record the first UBP measurement of the second set from the monitor at the end of expiration: randomized instill volume with randomized position
37.	PI	The AbViser™ valve will automatically open to permit drainage noting the amount of urine and NSS that drains into the urimeter is ≥ the randomized instill volume
38.	PI	Document the instill volume on the intake record and the drainage on the output record

Table 5 (Continued)		
Step	Nurse	Action
39.	Nurse co-investigator	For subjects randomized to the 30° HOBE in the supine position, the nurse co-investigator will make a third set of UBP measurements
40.	Nurse co-investigator	After verifying the subject's position the nurse co-investigator will place the catheter between the subject's legs and place the collection bag toward the foot of the bed and suspend the collection bag either to the right or to the left side preventing any increase in elevation of the collecting system or compression of the catheter or collecting system and will empty the urimeter
41.	Nurse co-investigator	Re-level the transducer with the symphysis pubis
42.	Nurse co-investigator	Re-zero the transducer
43.	Nurse co-investigator	Assess the responsiveness of the monitoring system
		• Perform a manual square wave test
		• Close the stopcock to the subject
		• Inject saline against the transducer
		• Observe a square wave on the monitor.
44.	Nurse co-investigator	Assess the conductivity of the fluid filled column
		• Squeeze the urinary drainage catheter proximal to the connection of the AbViser™
		• Observe a pressure inflection on the bedside monitor
45.	Nurse co-investigator	Determine if steady state is present
		• Compare vital signs (VS) prior to positioning with VS after positioning
		• Observed difference is less than 10 percent
46.	Nurse co-investigator	Clamp the urinary drainage catheter distal to the AbViser™
47.	Nurse co-investigator	Record the first UBP measurement of the third set of UBP measurements from the monitor at end expiration: zero instill volume with 30° HOBE
48.	Nurse co-investigator	Unclamp the urinary drainage catheter distal to the AbViser™ valve and allow the bladder to drain for 30 to 60 seconds noting the amount of urine that drains into the urimeter
49.	Nurse co-investigator	Inject 25 ml of NSS into the bladder with the syringe
50.	Nurse co-investigator	Record the second UBP measurement of the third set of UBP measurements from the monitor at end expiration: 25 ml instill volume with 30° HOBE

Table 5 (Continued)		
Step	Nurse	Action
51.	Nurse co-investigator	Document the 25 ml instill volume on the intake record
52.	Nurse co-investigator	The AbViser™ valve will automatically open to permit drainage noting the amount of urine and NSS in the urimeter is ≥ 25 ml and record in the output record
53.	PI or nurse co-investigator	Disconnect the NS administration set with pressure tubing and the transducer and from the AbViser™ valve
54.	PI or nurse co-investigator	Cap the end of the AbViser™ valve administration tubing and tape to the collection tubing which is to remain in place until the urinary catheter is removed
55.	PI or nurse co-investigator	Reposition the subject into a comfortable position as determined by the subject's or nurse's preference

Setting

Six adult critical care units, 80 beds, of a large, metropolitan tertiary-care and teaching hospital, total 778 beds, located in southwestern Pennsylvania.

Sample

Subjects were selected regardless of gender, race, ethnicity, diagnosis, or hospital treatment. Subjects were included in the study if: a) age > 18 years, b) signed informed consent was obtained from the subject, his/hers surrogate or power of attorney for health care, c) there was a clinical need for a urinary drainage catheter as determined by the primary care or attending physician or the critical care team, d) admitted to an CCU, and e) not pregnant.

Subjects were excluded if: a) informed consent was not obtained, b) not in a critical care unit, c) did not have a urinary drainage catheter in place, d) unable to assume

body positions as required for study, e) neurogenic bladder, f) bladder tumor, g) bladder perforation, and h) hematuria.

There were no clinical, physiological, or ethical reasons to exclude pregnant women or patients < 18 years of age but they were excluded since they are not admitted to the adult CCUs of the clinical site. Others subjects with bladder abnormalities were excluded because the bladder pressure measurement would either not be physically possible or the pressure measurements obtained would be unreliable.

Procedure for Urinary Bladder Pressure Measurement

The procedure for UBP measurement is depicted in Table 5. Bladder pressure was measured using the method of Kron et al. (1984) as modified by Cheatham et al. (1998) and Malbrain et al. (2004) except the AbViser™ was used instead of stopcocks. The AbViser™ is a medical device approved by the Food and Drug Administration (FDA) for intermittent UBP measurement. The AbViser™ is a two way valve that was sterilely attached to the subject's existent urinary bladder drainage catheter and in the open position the free flow of urine is permitted and when saline is injected across the value occlusion occurs and the saline that was injected into the bladder remains there until a UBP measurement can be taken. The AbViser™ kit contains the AbViser™ valve; a 20 ml syringe with sterile sleeve and a double check valve; tubing and spike for the sterile saline bag connection; infusion and pressure tubing; transducer and extra pole mounting tubing; zeroing stopcock and dead end caps; tape to secure the urinary catheter to the AbViser™ valve; S hook to hang the syringe at the bedside; sterile drape; and instructions for use. The AbViser™ kit was used for its approved and intended use.

To answer research questions number one and two: the effect of subject position and instill volumes on UBP, all subjects had two sets of UBP measurements taken within 30 minutes. A set of measurements consisted of two UBP measurements. One UBP measurement in the supine 30º HOBE position with a 0 ml instill volume and another with a 25 ml instill volume. The second set of UBP measurements were obtained in one of the 12 combinations of body position and instill volume described in Table 4. All UBP measurements were taken by the PI. The preparation of the equipment and the positioning of the patient took approximately 15-30 minutes, and the actual UBP measurements were taken within approximately two to five minutes of each other and both sets were taken within 30 minutes.

To answer research questions three and four the 10 subjects randomized to the supine-30º HOBE position with a 25 ml instill volume group had a third set of UBP measurements taken within 30 minutes of the first set of UBP measurements. The third and final set of UBP measurements were obtained by the nurse co-investigator. This group of subjects was used to assess inter-observer reliability.

Urinary bladder pressure measurements were obtained using the protocol for bedside UBP measurement as outlined in Table 5. The only difference between the first two UBP measurement sets were that the AbViser™ valve was not re-placed and the assembly of the AbViser™ (Table 5 steps five to eight) was not be repeated. This was done to maintain a closed system and to reduce the risk of infections in these subjects. Prior to departure from the bedside and after the third set of UBP measurements taken by the nurse coo-investigator, the pressure transducer was misaligned from the symphysis pubis. The nurse co-investigator prior to obtaining the final UBP measurement, 1)

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performed a manual square wave test to assure that the dynamic properties of the system were maintained, 2) confirmed the conduction of pressure from the catheter to the monitor, and 3) confirmed and/or re-positioned the subject into the appropriate position. The transducer was than leveled and zeroed again.

The urinary drainage catheter was clamped with a hemostat distal to the AbViser™. A measurement with zero volume was taken, and then using the pre-attached syringe instillation of 25 ml of NSS into the bladder was completed. The UBP was measured from the monitor at end expiration. Once the UBP was obtained, the AbViser™ valve automatically opened to permit drainage of the bladder and remained in place until the urinary drainage catheter was removed. The subject was returned to the most appropriate position based on his/her clinical condition and plan of care dictated by the bedside nurse. Finally, documentation of the bladder instill volume used in the UBP measurement was recorded on the intake and output record.

The medical record was reviewed to extract selective demographic and clinical information to determine what other subject or clinical factors may have influenced UBP. Subject data included age, gender, and height and weight for BMI determination. Relevant clinical data included, intake and output records to determine net fluid balance, and ventilatory and respiratory status for presence of positive airway pressure, and use of paralytic agents as these variables have been reported by others to influence IAP. This data was used to answer research question number five.

Justification of Body Positions

The selection of subject's positions was based on research necessity, clinical relevance, and interest. The supine-0° HOBE position was chosen because it is the

position most commonly recommended by experts for measurement of UBP (Gallagher, 2005; Lameier & NeCamp, 1990; Malbrain, 2004) . However, patients in CCUs are rarely positioned supine-0° HOBE unless there is a clinical indication, such as artificially closed abdomen or chest, ventilatory difficulties, or clinical instability. The supine-0° HOBE position is believed to predispose patients to aspiration pneumonias.

The other positions selected represent positions most commonly assumed by patients in CCU. Nursing textbooks recommend that patients be repositioned every two hours to prevent decubitus ulcer formation caused by pressure points (Baas, 2003; Rodgers, 2001). Most commonly, nurses rotate patients following a turning schedule from supine to lateral positions, back to supine and then to the opposite lateral position (Baas, 2003). This rotation is repeated several times a day. Because most patients in CCUs are receiving enteral nutrition, it is recommended that the HOB be maintained at a minimum of 30º at all times to reduce the risk of tube feeding formula refluxing and causing aspiration pneumonia (Heyland et al., 2003). Therefore, the supine position with 30º HOBE was chosen, because it is one of the most common positions assumed by patients in today's CCU, and it is of interest to know if this modest degree of HOBE affects UBP measurement. The right and left lateral positions were chosen because they represent two of the most common alternative positions assumed by patients. Both right and left lateral positions were chosen because at least theoretically they could have a different effect on UBP. For instance, it can be argued that the pressure on the bladder exerted by the liver and stomach will be higher in the left lateral position. However, this will be against Pascal's law and the basic assumptions upon which the UBP technique is based. When patients are positioned in the right or left lateral position nurses commonly

support their back with pillows (Baas, 2003), to simulate this position, a 45º wedged positioning pillow to support the patient's back will be used to standardize the side lying position.

Other positions that have been previously studied regarding the effect on UBP were not chosen because they are not relevant in CCU setting. The Trendelenburg and anti-Trendelenburg are positions of interest during surgery (Obeid et al., 1995). However, these positions are used in CCU only when patients are unstable and therefore not of major clinical relevance for study (Ostrow, 1997). Head of bed elevations of 45º-90º positions are used in stable CCU patients who are at low risk for IAH, and UBP is rarely needed in these populations. The prone position only can be done in patients with normal IAP, because prone positioning is known to increase IAP.

Description of Body Positions

The body positions were standardized as follows:

Supine-0° HOBE position   *(Groups 1-5-9)*

Subjects were positioned on their back with head, back, legs and arms resting in one plane. The head of the bed was at zero degrees elevation. Legs were positioned together and arms rested comfortably on the bed at the subject's sides. The back of the head was supported with one pillow.

Supine-30º HOBE position   *(Groups 2-6-10)*

Subjects were positioned on their backs with arms at their sides and their head and back were elevated at 30º as determined by the bed angle protractor. The legs were

positioned flat in another plane at zero degrees. The head of the subject was supported with one pillow.

Right lateral-30º HOBE position   *(Groups 3-7-11)*

Subjects were positioned on their right side. The head of the bed was elevated at 30º as determined by the bed protractor. The left leg was positioned on top of the right leg and a pillow was placed between the legs. The back of the subject was resting against a 45º wedged positioning pillow. A pillow was placed under the right side of the face.

Left Lateral-30° HOBE position   *(Groups 4-8-12)*

Subjects were positioned on their left side. The head of the bed was elevated at 30º as determined by the bed protractor. The right leg was positioned on top of the left leg and a pillow was placed between the legs. The back of the subject was resting against a 45º wedged positioning pillow. A pillow was placed under the left side of the face.

Justification of Bladder Instill Volume

Selected bladder instill volumes were chosen from a critical review of previous studies of UBP measurement. Based on the current research questions relevant to the UBP measurement technique and the recommendations of the World Society of Abdominal Compartment Syndrome (WSACS) (Malbrain et al., 2007) several volumes were chosen. In the original description of the technique to measure UBP Kron et al. (1984) recommended instillation of 50 to 100 ml of saline to distend the bladder before measurement. Therefore, 50 ml was chosen to represent this range. Two hundred milliliters as an instill volume was chosen because this volume has the potential to be large enough to distend the bladder and increase bladder pressure independently of IAP.

The WSACS currently recommends a maximum instillation volume of 25 ml (Malbrain et al., 2007). Finally, no instill volume (0 ml) was chosen because animal and human studies have shown that a zero instill volume produces the lower measurement bias and the lowest risk of raising UBP independently of IAP (Fusco et al., 2001). In addition, a 0 ml instill volume would be the most convenient for nurses. Also it is of clinical interest to know if 0 ml would produce reliable results in the clinical setting.

Procedure for Data Collection

Only select and necessary data was extracted from the subject's medical record which included date of birth; usual and critical care unit (CCU) admission weight; height; gender; race; reason for hospital admission and reason for critical care unit admission; other medical and surgical diagnoses; intake and output records to determine the net fluid balance; amount of EN administered; respiratory and ventilatory status with the level of positive airway pressure used; blood pressure, heart rate, and respiratory rate to determine steady state; and use and dose of paralyzing agents. All data was recorded on the Data Collection Form (Appendix B). Data was entered into a computerized data base; all raw data was checked for errors before and after entering the data.

Procedure for Protection of Human Subjects

The study was reviewed and approved by The Human Protection Committee of Allegheny General Hospital – Allegheny Singer Research Institute and Duquesne University. Health care professionals who had knowledge of the study, primarily critical care physicians and nurses, and had a direct clinical relationship with potential subjects,

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obtained initial verbal consent that permitted the PI to introduce the study to potential

subjects. Upon an affirmative verbal consent the health care professional notified the PI,

who explained the study in detail and answered any questions asked by the subject or

surrogate decision maker before any review of the medical record is undertaken.

Subjects or surrogates were only approached with dignity by the PI and only if deemed to

be an acceptable and appropriate time by the bedside nurse and physician. The utmost

care and respect was given to subjects and surrogates who were experiencing a life

threatening and traumatic event. Following the initial explanatory process by the PI, one

of the physician co-investigators obtained a signed written informed consent from the

subject and /or appropriate surrogate decision maker. Consenting subjects' medical

records were then screened according to the Screening, Enrollment, and Randomization

Log (Appendix A) for study eligibility. If study criteria are met subjects were enrolled

and a study identification number was assigned and randomization to a study group was

done.

A copy of the informed consent was reviewed with the subjects or surrogate

decisions makers. They were informed that the risk of participating in the study was

minimal. There was a very small risk of developing urinary tract infection (UTI) because

it is necessary to open the urinary catheter drainage system for a brief moment to attach

the AbViser™. To minimize this risk, the PI attached the AbViser™ using sterile

technique under strict sterile conditions. Subjects would have been treated with

appropriate antibiotics had a UTI occurred. Subjects were informed that there may be a

temporary physical discomfort with repositioning. Every precaution was taken to avoid

discomfort and subjects were medicated for pain by the bedside nurse if necessary or

were immediately repositioned to a more comfortable position. The positions used for the study are commonly used positions by nurses when performing routine care for critically ill individuals. However, if the discomfort was too great the subject had the freedom to choose not to continue in the study. Subjects were informed of the very-low risk of equipment dislodgment with changes in position. Every precaution to prevent equipment dislodgement was taken.

Subjects were fully informed that their medical records will be reviewed to extract only pertinent information for the study and a separate record was created for the keeping of this data. A paper copy of the extracted data was recorded on the Screening, Enrollment and Randomization Log and Data Collection Form (Appendix A and B) and an electronic version as part of a database was created to record the data and facilitate statistical analysis.

There was a small risk of breech of confidentiality with these records. To minimize the risk of breech in confidentiality, measures were taken to collect only the least amount of information required for the study. The information was stored in a safe and secure manner. The PI was the sole possessor of this information. Collected data was only shared with limited personnel and only if necessary and no subject identifiers were shared. The paper copy of the Screening, Enrollment and Randomization Log that contains the study identification number, relevant study data, and subject identifiers will be destroyed at the PIs earliest convenience (see below). The electronic versions will be destroyed as soon as possible after academic requirements have been fulfilled and research findings have been disseminated via presentations or publications or two years following completion of the study.

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To further minimize the risk of breech of confidentiality several precautions were taken. First a limited amount of information that contains subject's unique identifiers was obtained. The data set was limited to the subject's initials, date of birth (to calculate age) and medical record number. No other unique subject identifiers such as address, phone number, social security number, insurance information, etc. were collected. Second, the limited data set was only collected on the Screening, Enrollment and Randomization Log which was kept in a locked file at all times in the PIs office and was accessible only to the PI. In the privacy of the PIs office the information was entered into the secure electronic database. The paper copy of the Screening, Enrollment and Randomization Log was destroyed. The electronic copy will be maintained until the data has been verified as correct, academic requirements have been fulfilled and publication and presentations disseminating the research findings are complete or two years after the study has been published. The paper copy of the Data Collection Form (Appendix B) will be shredded once data analysis is complete. Once a study number is assigned to the electronic data, only that study number will identify subjects. Third, access to the data sets without subject's identifiers was restricted to personnel only involved in the study (such as the PI, co-investigators, and statistician), regulatory personnel (AGH and Duquesne University IRB) and the dissertation committee. Fourth, subjects were notified that the data collected could be subpoenaed by a court order. Fifth, all data entered into a secure electronic database was protected by encryption and a password known only to the PI. The secure electronic data containing subject identifiers will be deleted two years after the study is published and presented.

No matter how high the UBP measurement was, no intervention was planned as part of the study. However, the results of the UBP measurements were available to the health care professionals caring for the subject and a printed progress note (Appendix C) was placed in the progress note section of the subject's medical record. Health care professionals responsible for the care of the subject decided if any intervention was needed. However, a disclaimer was displayed with the values of the UBP obtained during the study to explain that the values were obtained under non-standardized conditions and that the results should be considered together with other clinical data in making a decision to intervene.

The risk of participation in the study was minimal. Participation in this study did not impose risks to the subjects other than those associated with his/her illness and routine CCU care. The study did not include the use of investigational drugs or devices. All the methods and procedures used in the study were within the standards of care for critically ill patients. Urinary bladder pressure measurement is painless and quick (two-five minutes per set of UBP measurements). There was no financial risk to patient. There was no discomfort for patients while moving from one position to another. In addition, no equipment was dislodged during body position changes during the study. Position changes necessary for the study were customary positions performed daily by CCNs. To minimize the risk of equipment dislodgement, subjects were repositioned gently and special precautions were taken to ensure that no equipment is dislodged or malfunctions occurred during and after the maneuver.

The major risks to the subjects were development of UTI and breech of confidentiality. To minimize the risk of UTI, only subjects who required urinary

drainage catheters, as part of their routine care were selected, and the AbViser™ valve was connected under sterile conditions. Because the AbViser™ is a closed valve once it is in place there is no added risk for UTI and or septicemia associated with its use. To reduce the risk of UTI even further once the AbViser™ valve was placed, it was left in place and was not removed until the urinary catheter was discontinued.

Although the information obtained may be of benefit to other patients in similar conditions in the future, there was no immediate direct benefit to the subjects who participated in this study. However, participants may have benefited indirectly because they were monitored more intensively.

Sample Size Calculation

Sample size was calculated using PASS (Number Cruncher Statistical Software (NCSS) and PASS, 2004, Kaysville, UT). First a power analysis for a multiple linear regression analysis was performed for sample sizes ranging from five to 10 subjects per each of the 12 groups for position and volume. For this analysis it was assumed that the controlled variables of instill volume and position explain 50% of the variability and six other independent variables account for an additional 10 % of UBP variability. Level of significance (alpha) was set at 0.05 or 0.01. The result of the analysis is shown below.

Table 6

Power Calculation for the Study

N per group	N Total	$\alpha = 0.05$	$\alpha = 0.01$
5	60	70 %	
6	72	80%	
7	84	88%	57%
8	96	93%	79%
9	108	96%	86%
10	120	97%	91%

Assuming R^2 for controlled variables is 0.5 and R^2 for 6 independent variables is 0.01.

A sample size of 96 (8 per group) will have a 93-79 % power for an alpha of 0.01-0.05, respectfully. Based on these considerations a sample size of 120 (10 subjects per group) was chosen to allow for drop outs and/or incomplete data collection.

In addition, PASS was used to calculate the sample size needed for the inter- and intra-observer reliability phase of the study. A sample size of 10 subjects achieves a 97% power to detect a difference of 0.8 between the null hypothesis correlation of 0.9 and the alternative hypothesis correlation of 0.01 using a two-sided hypothesis test with a significance level of 0.05. The total sample size for the study was 120 subjects for the multiple linear regression analysis and 20 subjects were measured an additional time for the inter- and intra-observer reliability study.

Procedure for Data Analysis

Data were analyzed using SPSS statistical software (Graduate pack 14.0, 2005, SPSS, Inc. Chicago, IL) and figures were created using GraphPad Prism 4 (GraphPad Software Inc. 2005, San Diego, CA). Demographic data was analyzed with frequencies, means, standard deviations, and ranges and is presented in graphic and tabular form in Chapter 4. Mean, standard deviation ranges, and other descriptive statistics of UBP were also calculated.

Statistical analysis included both parametric and non-parametric techniques as the data were not always normally distributed. These procedures included the Pearson correlation, Kruskal-Wallis with post analysis Dunns, Wilcoxon Signed-Rank test, and one and two way ANOVA with Neuman-Kuels post hoc analysis. The main statistical method performed was multiple linear regression analysis. Urinary bladder pressure was the dependent variable and bladder instill volumes and subject positions were considered the controlled independent variables. Additional independent variables that were examined in a stepwise analysis includes age, BMI (kg/m^2), net fluid balance (ml/day), positive airway pressure (cm H_2O), and dose of paralyzing agents (mcg/Kg/min) as these are known to influence IAP. The limits of agreement as described by Bland Altman method was used to analyze the inter-and intra-observer reliability data (Bland & Altman, 1986)

Chapter 4

Results

Population Description

Two hundred and eighty (280) patients identified by their nurse or physician as potential subjects were screened by the principal investigator (PI) to determine eligibility to participate in the study. One hundred and sixty patients (57%) were excluded from the study. Sixty-two (22%) of the total pool of potential subjects declined to participate after a detailed explanation of the study was given. Fifty-nine subjects (21%) did not meet inclusion criteria, such as ¸18 years of age, anuria, hematuria, or neurogenic bladder and were ineligible to participate. Eighteen patients (6%) were unable to participate for other reasons, such as the urinary bladder catheter had been removed or orders for transfer from the critical care unit (CCU) were written and adequate time to compete the study could not be guaranteed. Seventeen patients (6%) were unable to give informed consent because of sedation and their surrogate decision maker was not available to give consent. Finally, three patients' families (1%) declined participation, and one patient (0.4%) was not enrolled for an unknown reason.

The remaining 120 subjects (43%) agreed to participate in the study and were enrolled after a detailed explanation of the study was provided by the PI and a signed written informed consent was obtained. Table 7 shows the age, gender, ethnicity; body

mass index (BMI) and length of stay (LOS) of subjects categorized by instill volume and

position as determined by the randomization group.

Table 7

Select Characteristics of the Study Population: Randomization Group, Randomized

Instill Volume, Randomized Position, Age, Gender, Ethnicity, Body Mass Index (BMI),

and Length of Stay (LOS).

Random-ization Group	Instill volume	Randomized Position	Age (years) Mean ± SD Range	Gender (% male)	Ethnicity (% Caucasian)	BMI (kg/m^2) Mean ± SD Range	LOS (days) Mean ± SD Range
1	25 ml	Supine-0° HOBE	73.8 ± 5.4 66-79	60%	100%	27.6 ± 3.2 22.8-37.2	4.0 ± 2.8 1-9
2	25 ml	Supine-30° HOBE	75.8 ± 6.8 63-86	60%	100%	28.2 ± 6.4 20-37	3.3 ± 2.3 1-8
3	25 ml	RL-30° HOBE	64.7 ± 19 29-82	50%	100%	26.3 ± 3.5 21-32	4.2 ± 2.1 1-21
4	25 ml	LL-30° HOBE	66.3 ± 13 46-84	50%	80%	30.4 ± 9.2 18-51	4.2 ± 2.1 1-8
5	50 ml	Supine-0° HOBE	51.8 ± 16 23-70	70%	100%	29.2 ± 8 15.8-38	4.0 ± 3.8 1-12
6	50 ml	Supine-30° HOBE	55.0 ± 19 22-77	60%	100%	26.6 ± 7 22-51	5.8 ± 6.4 1-29
7	50 ml	RL-30° HOBE	64.2 ± 12 49-83	60%	100%	35.6 ± 9 22-51	5.1 ± 6.6 1-23
8	50 ml	LL-30° HOBE	59.1 ± 22 20-87	70%	100%	30.0 ± 10 20-54	7.7 ± 13 1-44
9	200 ml	Supine-0° HOBE	53.5 ± 24 18-78	60%	100%	25.7 ± 16 16-43	4.3 ± 3.1 1-12
10	200 ml	Supine-30° HOBE	72.7 ± 12 54-93	30%	100%	32.1 ± 7 22-40	3.2 ± 3.2 1-12
11	200 ml	RL-30° HOBE	58.2 ± 19 20-91	50%	80%	23.8 ± 3.2 20-30	2.5 ± 1.6 1-6
12	200 ml	LL-30° HOBE	66.5 ± 12 46-79	60%	80%	33.1 ± 6.0 23-40	7.7 ± 15 1-50
All Groups			63.5 ± 17.1 18-93	55%	97%	29.0 ± 7.3 15.8-54	4.7 ± 6.8 1-50

The subjects' ranged in age from 18 to 93 years with an average of 63.5 ± 17.1

years. Sixty-six (55%) of the subjects were male. One-hundred eleven (97 %) of study

subjects were Caucasian. The BMI ranged from 15.8 to 54 kg/m^2 with an average of 29.0

± 7.3 kg/m^2. The LOS in the CCU prior to UBP measurement ranged from one to 50

days with an average of 4.7 ± 6.8 days. Eight subjects (6.7 %) were mechanically

ventilated and five others (4.2 %) had some form of positive airway pressure for a total of

13 subjects (10.8%) collectively with positive airway pressure. Twenty-five subjects

(20.8 %) were in negative fluid balance, ranging from -7661 to -73 ml, and 95 subjects

(79.2 %) were in positive fluid balance, ranging from 1 to 35,497 ml. None of the

subjects were receiving paralytic agents.

Using a one way ANOVA no statistical significant difference was observed

among the 12 groups for length of stay (LOS), but significant differences were observed

for age (F = 2.5, R^2 0.2, p = 0.0069) and BMI (F = 2.5, R^2 0.2, p = 0.0074). For age,

group 2 (supine-30° HOBE position with a 25 ml instill volume) differed from group 5

(supine-0° HOBE position with a 50 ml instill volume) (p = 0.048) and for BMI group 7

(RL-30° HOBE position with a 50 ml instill volume) differed from group 11 (RL-30°

HOBE position with a 200 ml instill volume) (p = 0.014). Subjects randomized to the

supine-30° HOBE position with 25 ml instill volume (group 2) were on average $75.8 \pm$

6.8 years old and differed in age from the subjects randomized to the supine-0° HOBE

position with 50 ml instill volume (group 1) (51.8 ± 15.5 years). Subjects randomized to

the RL-30° HOBE position with a 50 ml instill volume (group 7) had a mean BMI of

35.5 ± 9.3 kg/m^2 and differed from subjects randomized to the LL-30° HOBE position

with 200 ml instill volume (group 11) who had a mean BMI of $23.8 \pm 3.2\ 3$ kg/m^2. All other paired comparisons were not significant.

Eight subjects (6.7 %) were receiving enteral feedings at the time of UBP measurement, and 67 (55.8%) had some form of abdominal pathology, i.e., abdominal trauma, surgery, ascites, or pancreatitis. Seventeen subjects (14.2 %) had a UBP ≥ 12 mmHg for all four measurements, thus meeting the criteria for the diagnosis of IAH. Three subjects (2.5 %) had ACS, which is a sustained IAP ≥ 20 mmHg with or without an abdominal perfusion pressure (APP) <60 mmHg that is associated with new organ dysfunction or failure. Only three subjects (2.5 %) had an APP < 60 mmHg in all four measurements.

Subjects were recruited from six adult critical care units. Forty-eight (40 %) subjects were recruited from the trauma unit, 25 (20.8 %) were from the two neurosurgical intensive care units (NICU), 18 (15%) were from the medical intensive care unit (MICU), 15 (12.5%) were from the coronary care unit (CCU) and 14 (11.7%) were from the surgical intensive care unit (SICU).

Initial Urinary Bladder Pressure Measurement

All 120 subjects had one pair of UBP measurements recorded in the initial study position of supine-30º HOBE. The first UBP measurement was obtained after the subject was properly positioned and the monitoring equipment correctly assembled, calibrated, and leveled but before any instill volume (0 ml) was injected into the bladder. The second measurement was obtained after 25 ml of NSS was instilled into the bladder. The supine-30º HOBE position represents the most common position subjects assumed at the

time of enrollment and in general is the most common position assumed by patients in CCUs. Therefore, UBP measured in the supine-30º HOBE position represents a neutral and undisturbed value since subjects were untouched and the bladder was not altered by changes in positions or saline instillation. The individual UBP measurements obtained for each subject with 0 and 25 ml instill volumes for all patients are shown in Figure 6. All 240 UBP measurements were taken by the PI. The average time elapsed between the first and second UBP measurements with 0 ml and 25 ml instill volumes, respectively, was 2.88 ± 2 minutes, ranging from one to 15 minutes.
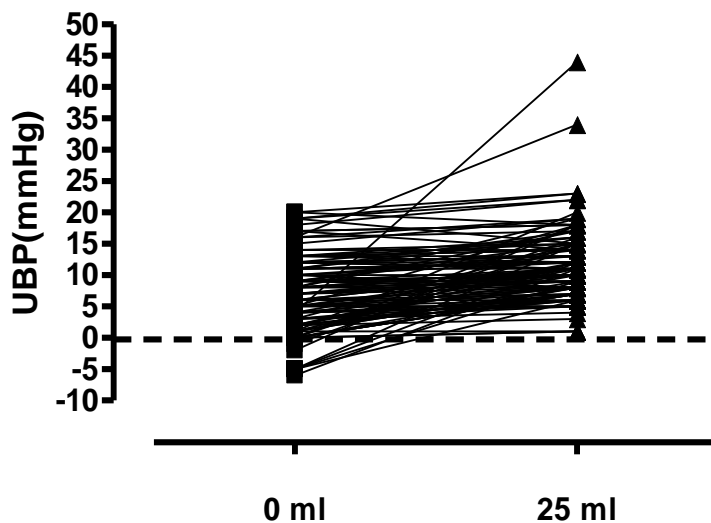
Figure 6. Individual UBP measurements of all subjects (n=120) measured in the supine-30° HOBE position with 0 ml and 25 ml instill volumes by the PI.

Urinary bladder pressures in the supine-30º HOBE position with 0 ml instill volume ranged from -6 to 20 mmHg. Seven subjects (5.8 %) had UBP < 0 mmHg and 29 subjects (24.2 %) had UBP ≥ 12 mmHg. The negative UBP values when UBP was measured with 0 ml instill volume persisted despite flushing of the monitoring system

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and after re-leveling and re-calibrating the monitoring equipment. According to the study procedure for UBP measurement the urinary catheter and the drainage collection tubing remained on the bed in the same plane as the subjects lower extremities.

Urinary bladder pressures in the supine-30° HOBE with a 25 ml instill volume yielded values that ranged from 1 to 44 mmHg. None of the subjects had UBPs < 0 mmHg and 53 (44.2 %) had values $\geq$ 12 mmHg. Of the UBPs measured with 25 ml instill volume 112 (93.3 %) were greater than or equal to the UBP measured with a 0 ml instill volume. The eight UBP values that were lower in the second measurement as compared to the first differed by 1 mmHg in five subjects, 2 mmHg in two subjects, and 4 mmHg in one subject. As a result there was a statistically significance increase from the UBP measured with 0 ml to that measured with 25 ml instill volumes (7.0 ± 5.9 vs. 11.6 ± 5.9, respectively, $p < 0.0001$) by the Wilcoxon Signed-Rank test (Figure 7).
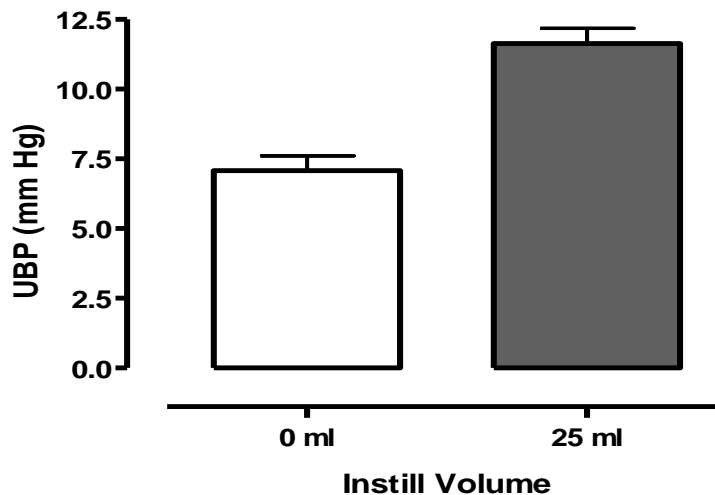
Figure 7. Mean $\pm$ SD of urinary bladder pressure measured with 0 ml and 25 ml instill volumes for all subjects (n = 120 for each group).

Linear regression analysis was employed to develop an equation to predict UBP measured in the supine-30° HOBE with 25 ml instill volume (S30-25) based on UBP measured in the supine-30° HOBE with 0 ml volume (S30-0). Two subjects who had unusually high UBPs when measured with the 25 ml instill volume (34 mmHg and 44 mmHg) were omitted from the analysis (Figure 6). Omission of this data does not radically alter the coefficient estimates but increased the explained variability of the equation from 20 to 30%. The predictive equation that results after fitting the remaining 118 pairs is:

$$UBP(S30\text{-}25) = 0.4499*UBP(S30\text{-}0) + 8.168.$$

Multiple linear regression analysis was employed to explore the relationship of UBP (S30-25) with pertinent other variables. For this analysis the UBP (S30-25) was considered to be the dependent variable and BMI (kg/m^2), age (y), gender (male or female), LOS (days), net fluid balance (ml), positive airway pressure (yes or no), abdominal pathology (yes or no) and enteral nutrition (yes or no), were considered to be the independent variables. For the reasons described above, the two outliers were also omitted from the analysis. This was necessary to satisfy model assumptions. Fitting the data from the remaining 118 subjects reveals that only BMI, enteral nutrition (EN), and net fluid balance (NFB) are significant predictors of UBP (S30-25). The estimated regression equation that best explains the relationship is:

$$UBP(S30\text{-}25) = 0.3460*BMI - 6.5061*EN + 0.000197*NFB + 1.3060.$$

This model roughly explains 31% of the variability of UBP (S30-25). Similar analysis was carried out using UBP(S30-0) as the dependent variable and the results were similar except that NFB was no longer a significant predictor of UBP.

Linear regression was used to identify relationships between UBP and the other independent variables of age, gender, BMI, ethnicity, NFB, and mechanical ventilation.

Age

Figure 8 is the regression lines for subjects' UBP values measured in the supine-30° HOBE position with a 25 ml instill volume as a function of age. There was no significant correlation between UBP and age ($r = -0.026$). Linear regression analysis showed that the slope of the best fit curve was not significant from zero ($F = 0.08502$, $DFn = 1.00$, $DFd = 117$, $p = 0.77$)
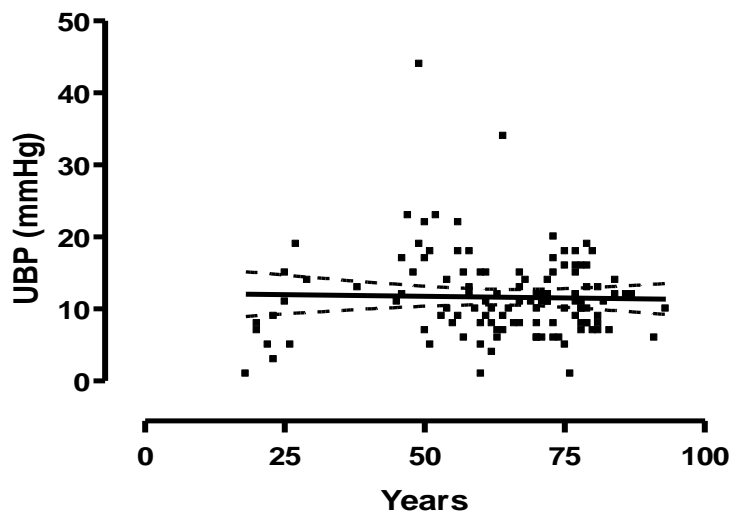
Figure 8. Urinary bladder pressure measurements in all subjects measured in the supine-30° HOBE position with a 25 ml instill volume by age.

Body Mass Index

Figure 9 is a plot of the in the subjects' individual UBP values measured in the supine-30° HOBE position with a 25 ml instill volume as a function of subject BMI.

There was a highly significant correlation between UBP and BMI (r = 0.47, p<0.0001). Urinary bladder pressure was found to be higher in subjects with higher BMIs. Linear regression analysis showed that the slope of the curve was significant from zero (F=33.82, DFn=1.0, DFd=118, p, 0.001).
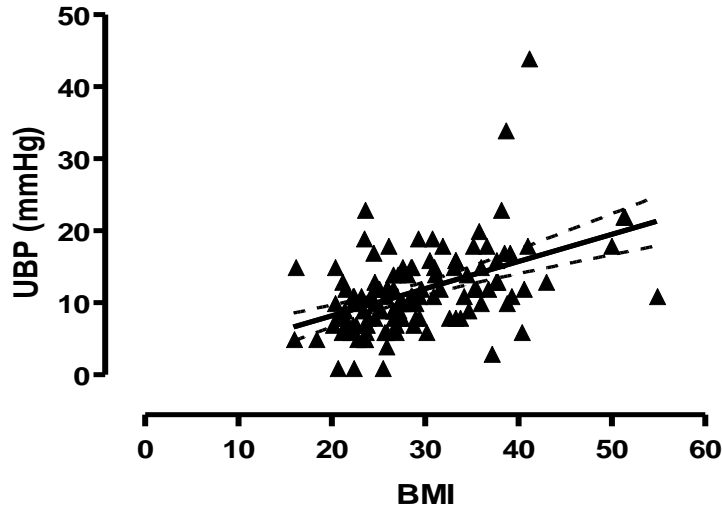
Figure 9. Urinary bladder pressure measurements in subjects positioned in the supine-30° HOBE position with a 25 ml instill volume by BMI.

Gender

To determine if subjects' gender influenced UBP, the mean ± SD of UBP's of males and females in the supine-30° HOBE position with a instill volume of 25 ml were compared using unpaired-t test. Males had slightly higher UBP than females (12.17 ± 6.89 vs. 11.0 ± 4.3) but did not reach statistical significance (t = 1.078, df = 118) (Figure 10).
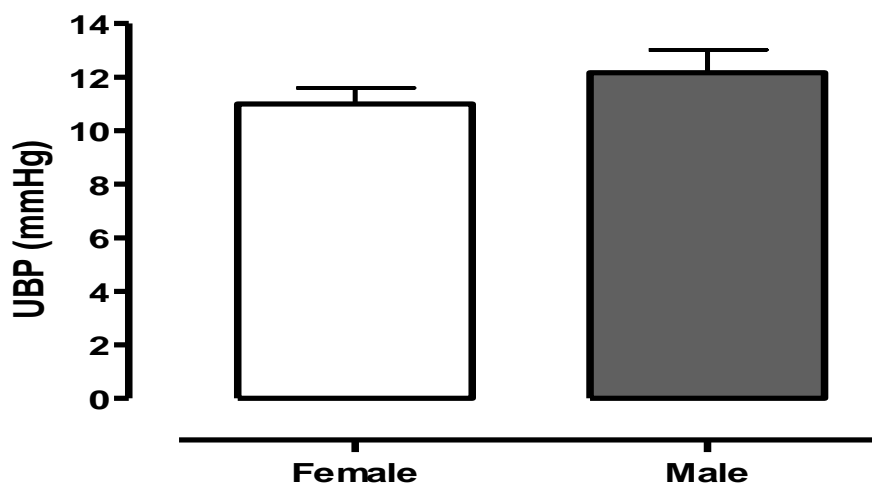
Figure 10. Urinary bladder pressure measurements in subjects in the supine-30° HOBE

position with a 25 ml instill volume by gender.

Ethnicity

Of the subjects recruited into the study three were African American, one was

Latino and 116 were Caucasian. To determine if UBP vary by ethnicity, the UBPs of

Caucasians was compared with non-Caucasian by unpaired t test (Figure 11).
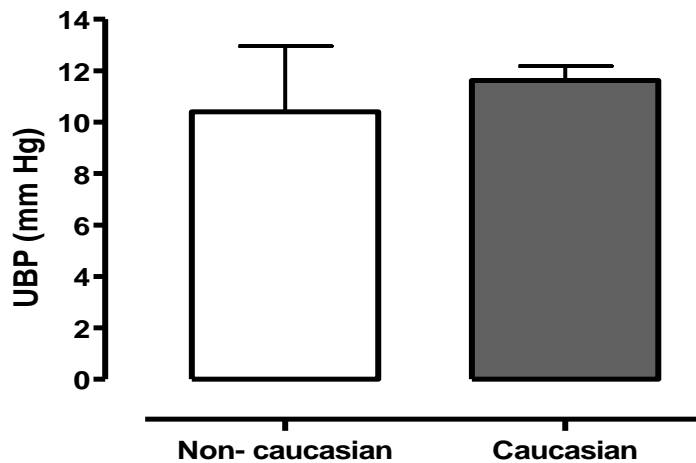
Figure 11. Urinary bladder pressure measurements in the supine-30° HOBE position with a 25 ml instill volume by ethnicity.

There were no significant differences in UBP measurements between Caucasian and non-Caucasian (11.6 ± 5.9 vs. 12.2 ± 4, $t = 0.2088$, $df = 118$).

Fluid Balance

Figure 12 is a plot of the in subject's individual UBP values when measured in the supine-30° HOBE position with an instill volume of 25 ml as a function of subjects' net fluid balance at the time of the study. There was a highly significant correlation between UBP and fluid balance ($r = 0.2244$, $p<0.0001$). Urinary bladder pressure was higher in subjects with greater fluid balance. A linear regression analysis showed that the slope of the curve was significant from zero ($F = 6.20$, $DFn = 1.0$, $DFd = 118$, p, 0.0141).
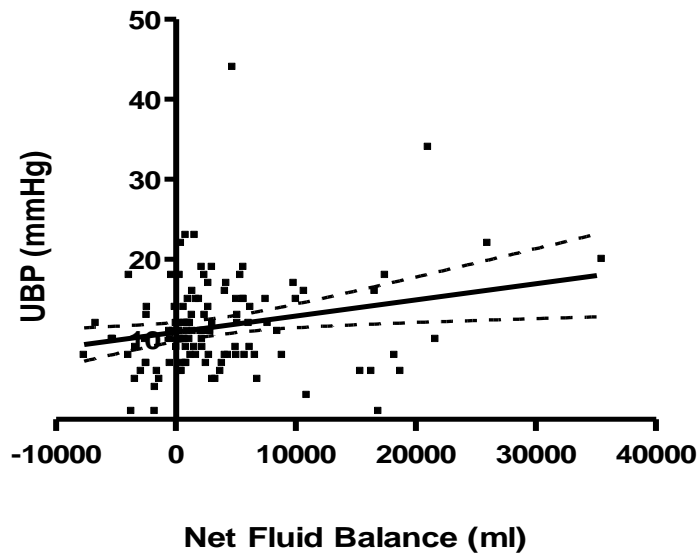
Figure 12. Urinary bladder pressure measurements in subjects measured in the supine-30°

HOBE position with a 25 ml instill volume by net fluid balance.

Effect of Ventilation

To determine if positive airway pressure influenced UBP, the mean ± SD of UBP

measurement taken in subjects requiring mechanical ventilation were compared to the

UBP measurements taken in subjects not receiving mechanical ventilation using

unpaired-t test. Subjects receiving mechanical ventilation had slightly higher UBP

measurements than those subjects not receiving mechanical ventilation (13.0 ± 10.6 vs.

11.5 ± 5.4) but did not reach statistical significance (t = 0.6722, df = 118, p = 0.5028)

(Figure 13).

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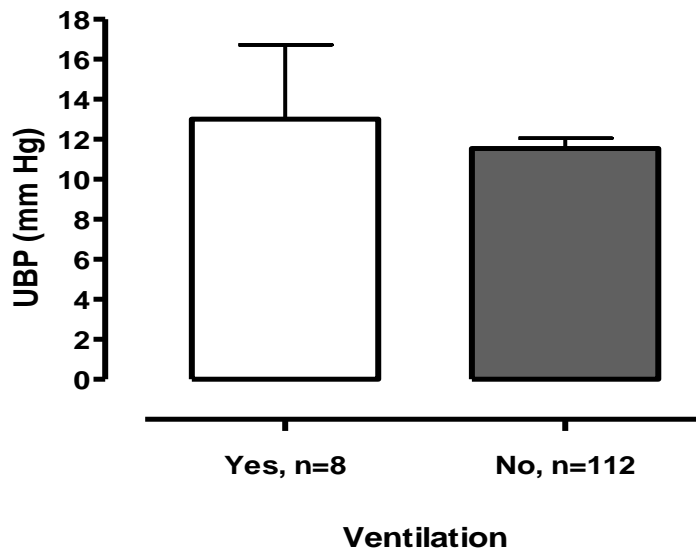
Figure 13. Urinary bladder pressure measurements in subjects in the supine-30° HOBE position with a 25 ml instill volume by use of mechanical ventilation.

Urinary Bladder Pressure Measurements after Randomization

A second pair of UBP measurements was obtained after subjects were repositioned either supine-0º HOBE, supine-30º HOBE, RL-30º HOBE or LL-30º HOBE as per the randomization assignment. The first measurement was obtained before any volume was instilled into the bladder (0 ml) and the second measurement was obtained after instillation of 25 ml, 50 ml or 200 ml, as per the randomization assignment. One subject randomized to group 9 (supine-0º HOBE position with a 200 ml instill volume) was unable to assume the supine-0º HOBE position due to respiratory and ventilatory issues. Figures 8, 9 and 10 show the individual values of the remaining 119 pairs of UBP measurements obtained in their respective randomized position and volume. All 119 pairs or 238 measurements were taken by the PI.
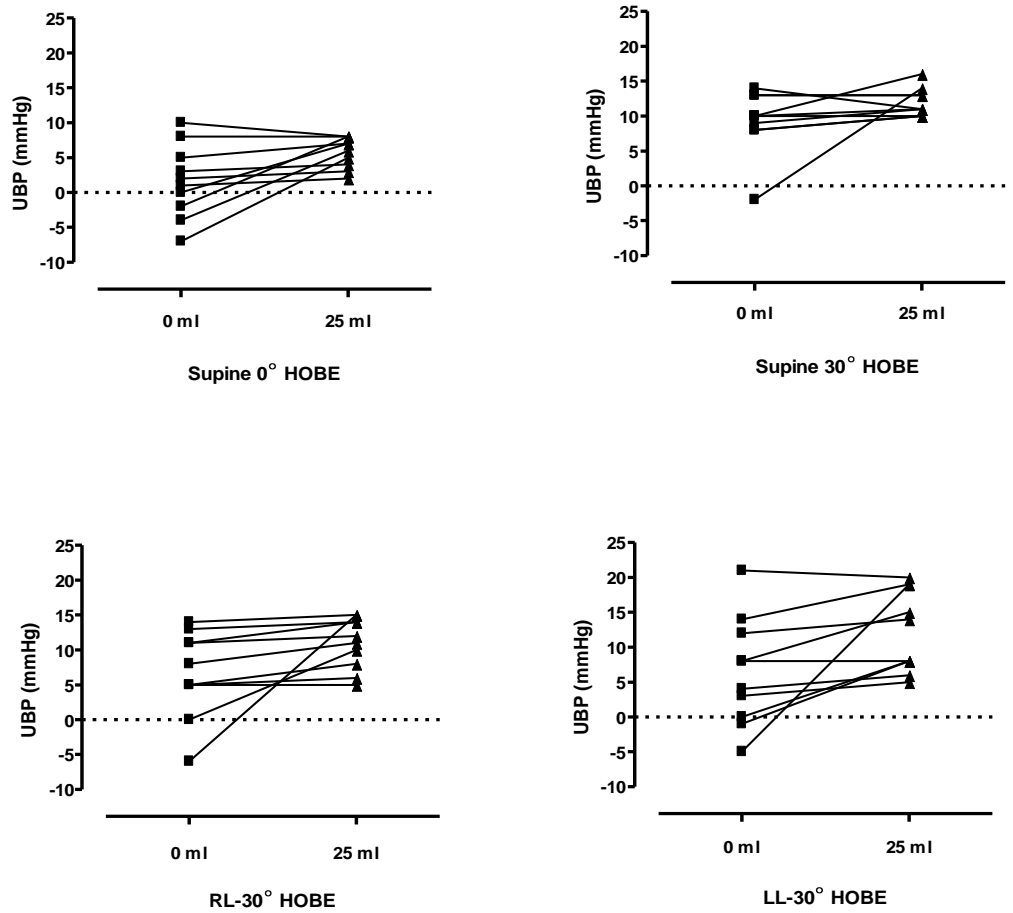
Figure 14. Summary of the second pair of urinary bladder pressure measurements in the four randomized positions with 0 ml and 25 ml instill volumes. n = 10 per each group.
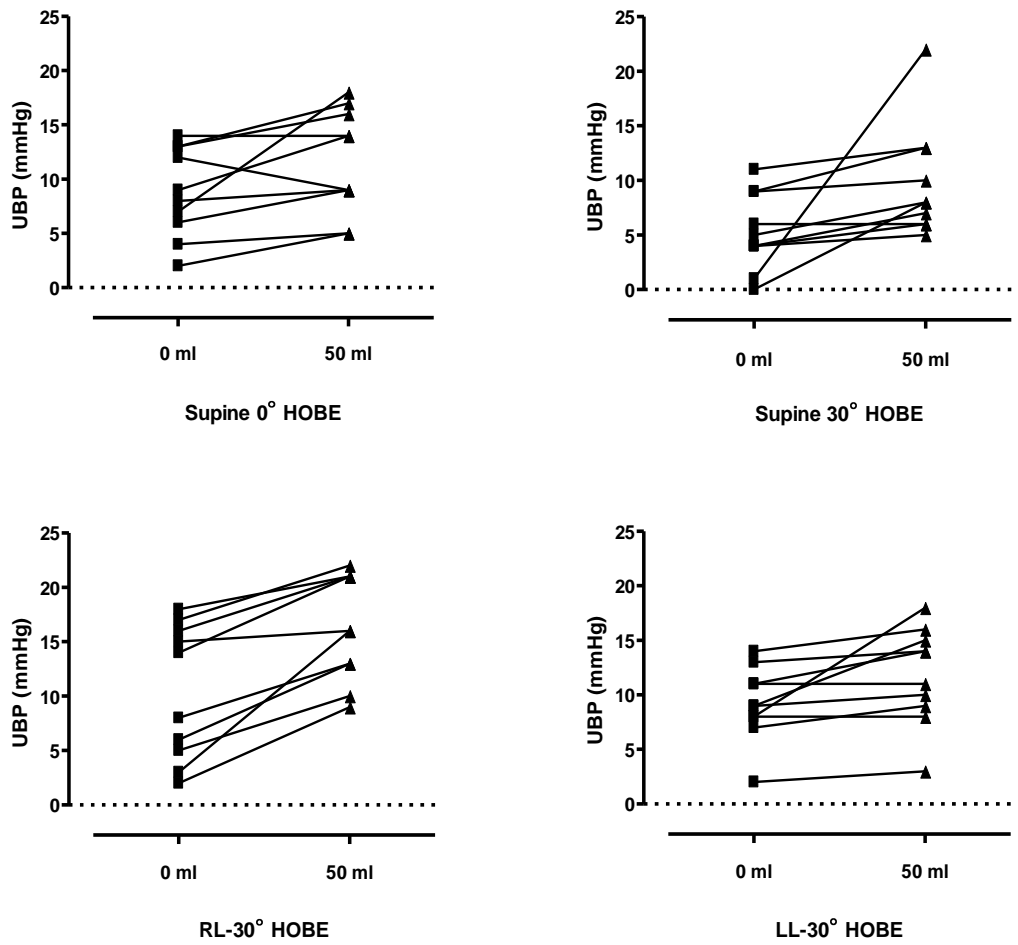
Figure 15. Summary of the second pair of urinary bladder pressure measurements in all four of the randomized positions with 0 ml and 50 ml instill volumes. n = 10 per group.
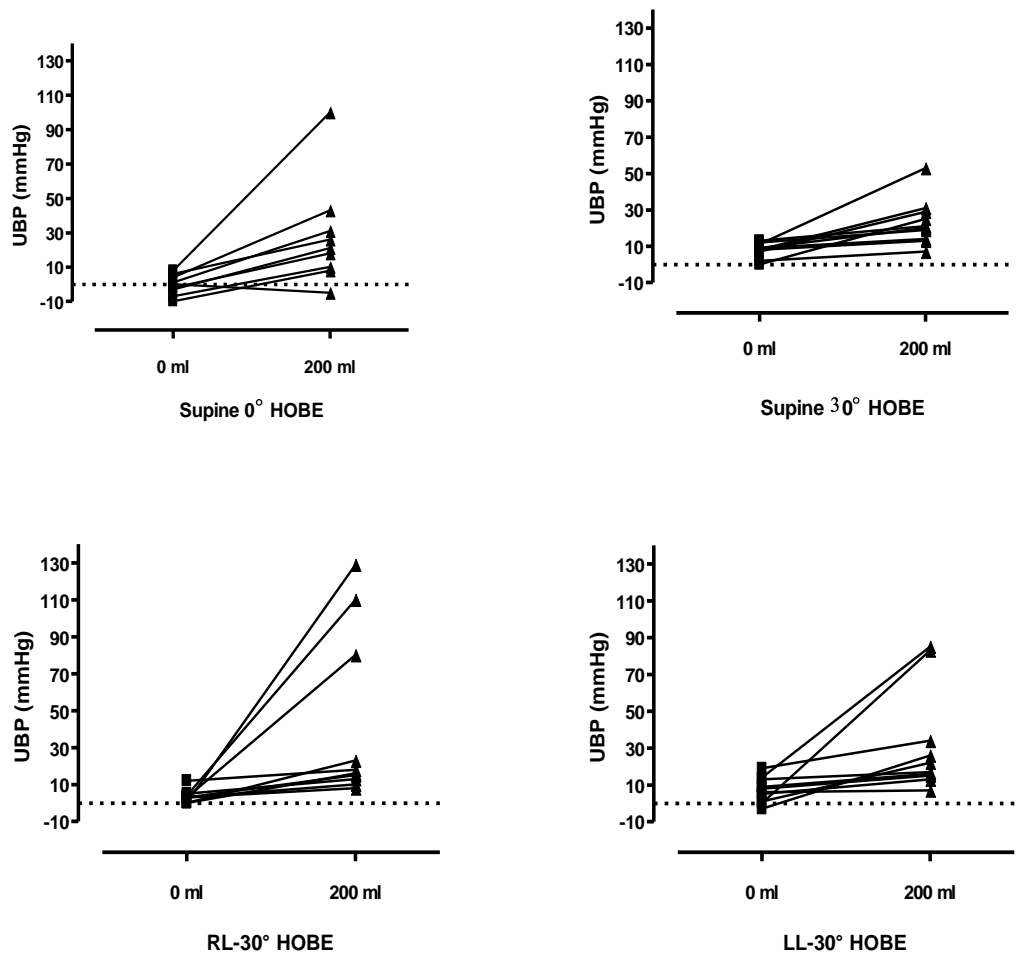
Figure 16. Summary of the second pair of urinary bladder pressure measurements in all four of the randomized positions with 0 ml and 200 ml instill volumes. n = 9 for the supine-0 ° HOBE group and n = 10 for the other groups.

Thirteen of 119 subjects (10.9 %) had UBP values < 0 mmHg when measured in the randomized position with 0 ml instill volumes. Again, the negative values persisted even when the urinary catheter and drainage collection tubing were at the level of the subject's lower extremities and after the monitoring system was flushed, and the equipment was recalibrated and re-leveled. Five minutes on average elapsed between the

subject's position change and the UBP measurement. Of these subjects, seven were

randomized to the supine position, three to the LL-30º HOBE, two to the supine-30º

HOBE position, and one to the RL-30º HOBE position. When randomized volume was

considered in these thirteen subjects with negative UBPs, eight were randomized to a 25

ml instill volume and five were randomized to the 200 ml instill volume groups. None of

the subjects randomized to any of the four positions with a 50 ml instill volume had

negative UBPs when measured with 0 ml instill volume. Likewise, no negative UBPs

were detected when the UBPs were measured using any of the three randomized

volumes. For all groups, the UBP value was higher in the randomized position and the

randomized volume when compared to the randomized position and 0 ml instill volume.

The greatest changes were observed between the pairs of UBP values obtained in the

groups randomized to the 200 ml instill volume (Figure 16).

Overall, 20 of the 240 UBP measurements taken with a 0 ml instill volume

yielded a negative UBP (8.3%). Nine were measured in the supine-30° HOBE position

(6.0 %), seven in the supine-0° HOBE position (23.3 %), three in the LL-30° HOBE

position (10 %) and one in the RL-30° HOBE position (3.3 %). These 20 negative UBP

measurements were taken in 15 subjects. Almost half of the subjects (7) had a UBP < 0

mmHg in the initial study position and five of these subjects continued to have a negative

UBP value when placed in the randomized position with 0 ml instill volume. The other

eight subjects had initial UBP measurements that ranged between 0 and 11 mmHg (mean

$\pm$ SD = 4.9 $\pm$ 5 mmHg) and half were $\leq$ 4 mmHg, but when positioned in the randomized

positions the UBP measurements became negative. Values ranged between -1 and -7

mmHg (mean $\pm$ SD = -3.8 $\pm$ 2 mmHg). Four of these subjects were randomized to the

supine-0° HOBE position, two to the LL-30° HOBE position, and one each to the supine-30° HOBE and the RL-30° HOBE positions.

Effect of Instill Volume on Urinary Bladder Pressure Measurement

To asses the effects of instill volume on UBP measurements, each of the pairs of UBP measurements obtained after randomization was first tested for significance using the Wilcoxon Signed-Rank test. In each position the UBP was higher when measured with the randomized instill volume as compared to the 0 ml instill volume. All paired comparisons were statistically significant except the supine-30° HOBE group. Statistical significance ranged from 0.02 to 0.002 (Table 8).

Table 8

Results of Wilcoxon Signed-Rank Test

Comparison	Body Position			
	Supine-0° HOBE	Supine-30° HOBE	RL-30° HOBE	LL-30° HOBE
0 ml vs 25 ml	p = 0.0273	p = 0.1505.	p = 0.0039	p = 0.0078
0 ml vs 50 ml	p = 0.0039	p = 0.0273	p = 0.0020	p = 0.0078
0 ml vs 200 ml	p = 0.0078	p = 0.0020	p = 0.0020	p = 0.0020

Next, UBP measurements were stratified based on randomized instill volume. Since subjects were not randomized to a 0 ml instill volume, the aggregate of the UBP values obtained with a 0 ml instill volume for the respective positions was used for this comparison. Figure 17 shows the UBPs at 0 ml and the randomized instill volume for each position and for all positions grouped together.

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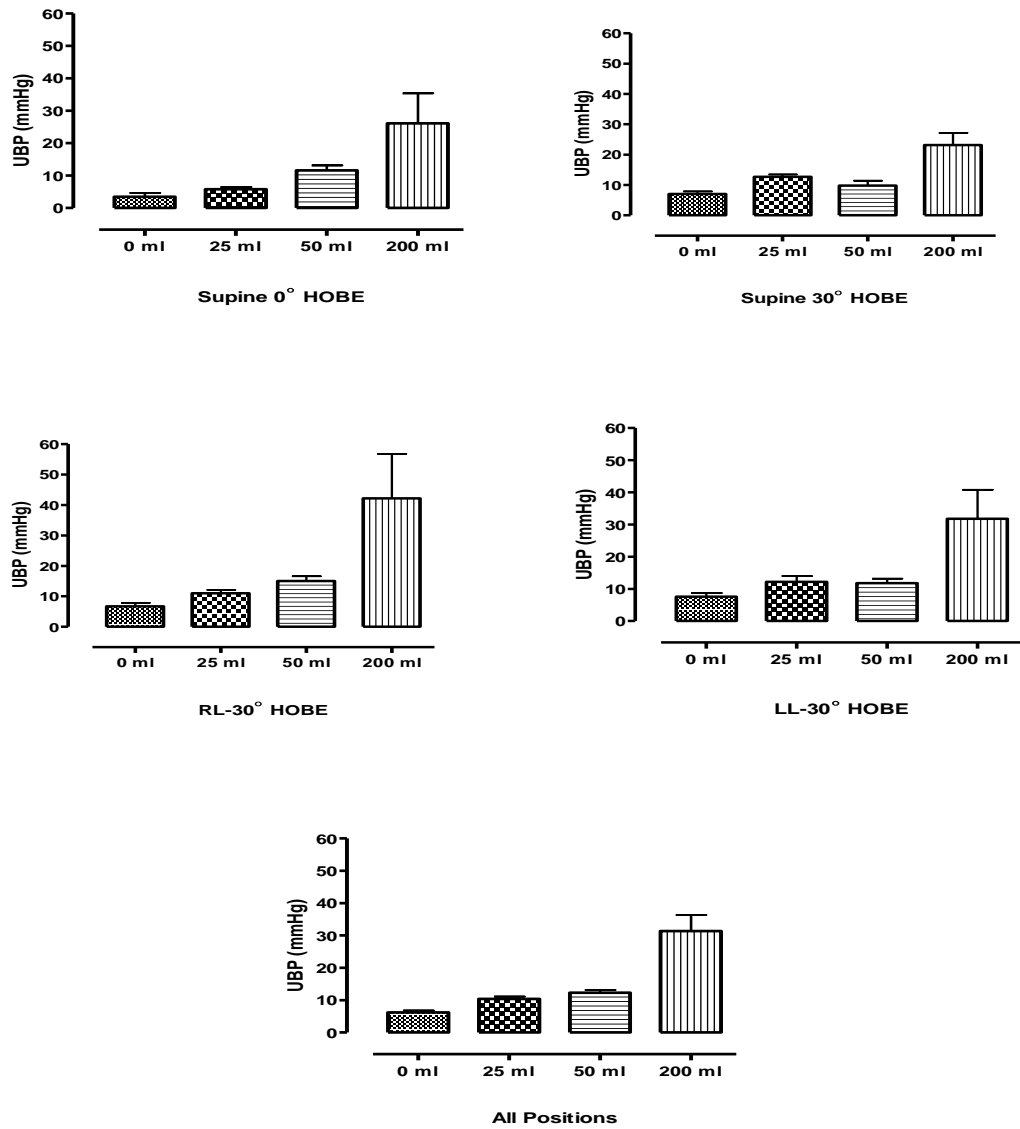
Figure 17. Urinary bladder pressure as a function of instill volume for each position and all positions grouped together. For each position n = 30 for 0 ml volume except for supine n = 29, n = 10 for the randomized volume groups (25 ml, 50 ml), and n = 9 for the 200 ml

For all positions, UBP measured with 0 ml (Figure 11) and 200 ml instill volumes yielded the lowest and highest values, respectively. For the supine-0° HOBE position and

the RL-30º HOBE position, UBP progressively increased as instill volume increased. However, for the supine-30º HOBE position UBP was higher when measured with an instill volume of 25 ml as opposed to the 50 ml instill volume, while for the for the LL-30º HOBE position the UBP value measured with a 50 ml and 25 ml instill volume were similar (Figure 18).
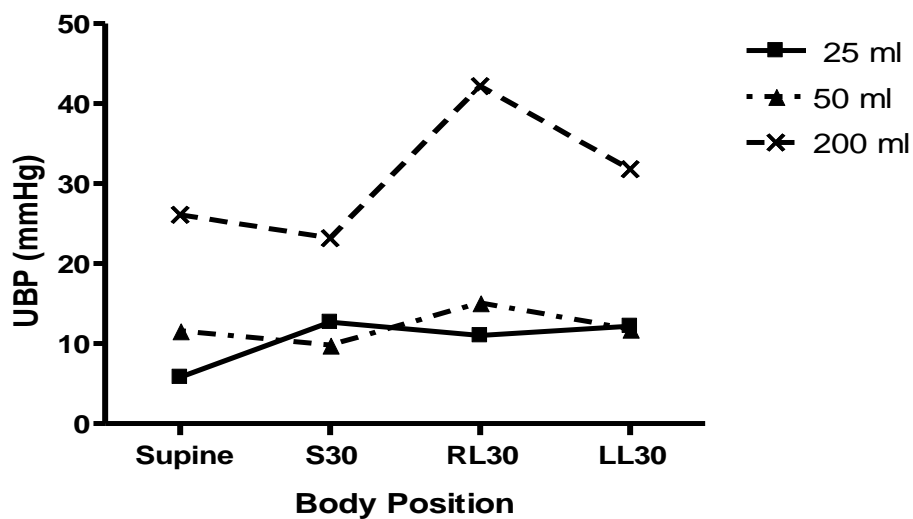
Figure 18. Observed mean urinary bladder pressures for each of the 12 randomized positions-volume combinations. Note the interaction of position and volume for the 25 ml and the 50 ml volume groups.

Lastly, a Kruskal-Wallis test of UBP measurements by instill volume was carried out. There were statistically significant effects of volume on UBP in every position, as well as when all positions are considered together (Table 9).

Table 9

Kruskal-Wallis Test of Urinary Bladder Pressures for Effect of Instill

Volume

			Position		
Volume	Supine-0º HOBE	Supine- 30 º HOBE	RL- 30º HOBE	LL- 30º HOBE	All
25 ml	5.8 ± 2.2	12.7 ± 2.7	11.0 ± 3.7	12.2 ± 5.8	10.4 ± 4.6
50 ml	11.6 ± 4.8	9.8 ± 5.1	15.1 ± 4.9	11.8 ± 4.7	12.4 ± 5.2
200 ml	26.19 ± 29.7	23.2 ± 12.8	42.2 ± 45.5	31.8 ± 28.5	31.8 ± 31.2
Kruskal-Wallis	p = 0.0022	p = 0.0025	p = 0.0275	p = 0.0358	p < 0.0001

Post hoc analysis using the Dunns comparison test showed that there were no statistically significant differences in UBPs measured with a 25 ml or 50 ml instill volume regardless of the position. (Table 10).

Table 10

Dunns Post Hoc Comparison for the Effect of Volume on Urinary Bladder Pressure by

Position

	Randomized Position				
Comparison	Supine-0° HOBE	Supine-30° HOBE	RL-30° HOBE	LL-30° HOBE	All
25 vs 50 ml	p>0.05	p>0.05	p>0.05	p>0.05	p>0.05

Effect of Position on Urinary Bladder Pressure Measurement

To assess the effect of position upon UBP the data was stratified by body

position. Figure 19 shows the UBP measurements for each instill volume and each

randomized position and the aggregate.
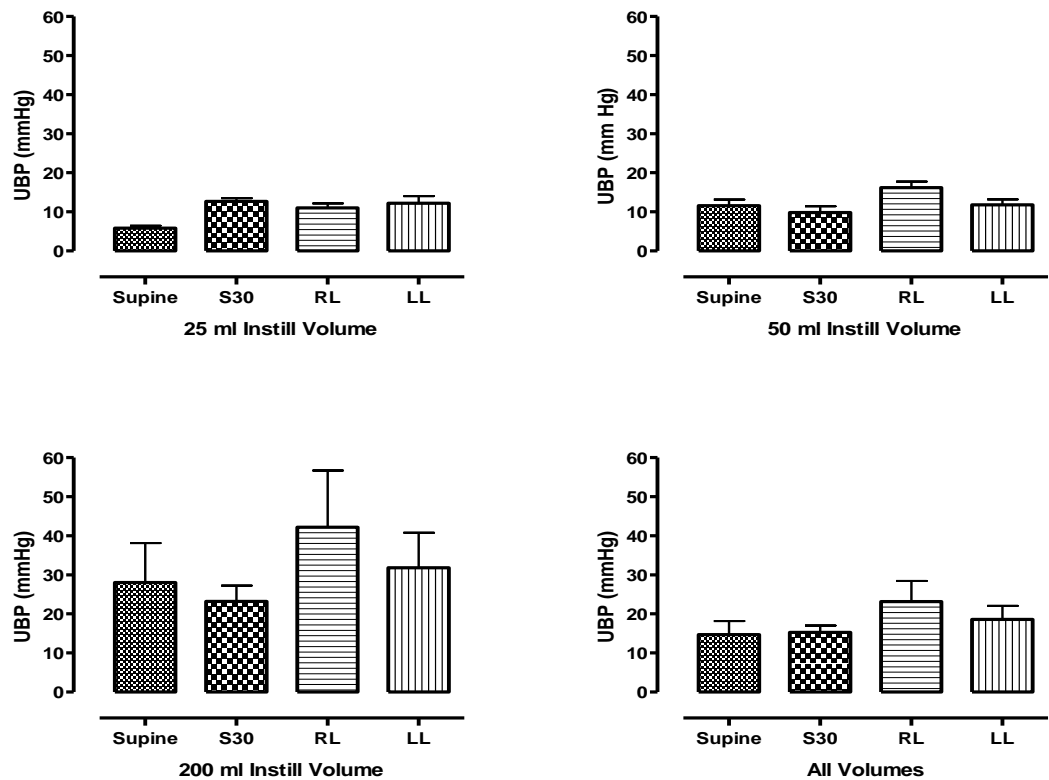
Figure 19. Urinary bladder pressure as a function of position for each volume and for all volumes grouped together, n = 10 for each of the randomized volume groups except the group in the supine position with a 200 ml instill volume, n = 9.

Note. For the all volumes graph n = 29 for supine-0º HOBE position and n = 30 for the supine-30º HOBE, RL-30º HOBE, and the LL-30º HOBE positions.

One way ANOVA demonstrated a significant effect of position on UBP (Table 11) in the 25 ml and 50 ml instill volume groups but not with the 200 ml group and not when all instill volumes are considered together in aggregate. The large variability within the 200 ml instill volume group was too great to appreciate any significance related to position effect at this volume, therefore no statistically significant difference in

any position or when all positions are considered together is found when an instill volume of 200 ml is used for UBP measurement.

Table 11

Analysis of Variance of Urinary Bladder Pressure for Effect of Position

Position	Volume			
	25 ml	50 ml	200 ml	All
Supine-0° HOBE	5.8 ± 2.2	11.6 ± 4.8	28.0 ± 30.4	14.7 ± 19.0
Supine-30° HOBE	12.7 ± 2.7	9.8 ± 5.1	23.2 ± 12.8	15.23 ± 9.7
RL-30° HOBE	11.0 ± 3.7	16.2 ± 4.9	42.20 ± 45.9	23.3 ± 29.32
LL-30 ° HOBE	12.2 ± 5.84	11.8 ± 4.7	31.8 ± 28.5	18.6 ± 18.9
ANOVA	$F = 6.711$	$F = 3.18$	$F = 0.64$	$F = 1.072$
	$R^2 = 0.3587$	$R^2 = 0.2095$	$R^2 = 0.05$	$R^2 = 0.027$
	$p = 0.0010$	$p = 0.0355$	$p = 0.5912$	$p = 0.3638$

The post hoc Neuman-Keuls multiple comparison test is shown in Table 12. In the groups randomized to 25 ml instill volume the UBPs measured in the supine position were significantly lower than when measured in the supine-30º HOBE, RL-30º HOBE and LL-30º HOBE positions. In the groups randomized to the 50 ml instill volume the only significant difference was between the supine-30º HOBE and the RL-30º HOBE positions.

Table 12

Neuman-Keuls Post Hoc Comparison for the Effect of Position on Urinary Bladder

Pressure by Instill Volume

Comparison	Randomized Volume			All Volumes
	25 ml	50 ml	200 ml	
Supine-0° HOBE vs Supine-30° HOBE	**p<0.01**	p>0.05	p>0.05	p>0.05
Supine-0° HOBE vs RL-30° HOBE	**p<0.01**	p>0.05	p>0.05	p>0.05
Supine-0° HOBE vs LL-30° HOBE	**p<0.01**	p>0.05	p>0.05	p>0.05
Supine-30° HOBE vs RL-30° HOBE	p>0.05	**p<0.05**	p>0.05	p>0.05
Supine-30° HOBE vs LL-30° HOBE	p>0.05	p>0.05	p>0.05	p>0.05
RL-30° HOBE vs LL-30° HOBE	p>0.05	p>0.05	p>0.05	p>0.05

To further assess if body position was a significant contributor to UBP a multiple

linear regression analysis was performed. For this analysis the dependent variable was

UBP measured in subjects when positioned in the randomized position with 0 ml instill

volume, thus examining the position effect without the influence of instill volume. The

independent variables were BMI, age (years), gender (male or female), EN (yes or no),

NFB (ml), positive airway pressure (PAP) (yes or no), LOS (days), and abdominal

pathology (yes or no), in addition to position. This model meets criteria for linearity,

normality, independence and homoskedasticity. The only significant predictors of UBP

in this model were BMI and position. The estimated regression equation is:

$$UBP(S30\text{-}0) = 0.2052*BMI + 3.34588*S30 + 3.1557*RL + 3.460*LL - 2.2786.$$

In this equation the supine-0° HOBE position is represented by the intercept

(-2.2786) and S30, RL, LL are indicator variables for the positions of supine-30° HOBE, RL-30° HOBE, and LL-30° HOBE, respectively. For each position the numeric variable is 1 if the measurement was taken in that position and otherwise is 0. Thus, the supine-0° HOBE position results in a lower UBP than the other three positions. For the average subject's BMI in this study (29 Kg/m^2) the supine-0° HOBE position results in a UBP 3.67 mmHg lower than any other position. No significant distinctions can be made among the other three positions. These results are in agreement with the ANOVA using instill volumes of 25 ml (Tables 12 and 13) where the mean UBP in the supine-30° HOBE position is significantly lower than in the other three positions. Furthermore, there were no other significant paired comparisons among the other three positions.

A two-way ANOVA was carried out to further investigate the effects of position, volume, and position-volume interaction. Urinary bladder pressure measurements with a 200 ml instill volume exhibited massive variability relative to the UBP measurements obtained with 25 ml or 50 ml instill volumes. Inclusion of this data did not meet model criteria and were not included. The eight other groups (80 subjects) were found to have similar variability using a Brown-Forsythe test and therefore were included in the analysis. The results are shown in Table 13.

Table 13

Two-way ANOVA for Effect of Position, Volume, and Position-Volume Interaction

Effect	Df	Mean square	F	P
		Main effects		
Position	3	83.412	4.369	0.007
Volume	1	74.113	3.882	0.053
		Interaction		
Position-volume	3	90.71	4.752	0.004

A statistically significant position effect was found. Post hoc comparison shows that the only significant difference was between the supine-0° HOBE and the RL-30° HOBE (p = 0.04). The volume effect was significant at the 5% level (p = 0.0526). The interaction between volume and position was also highly significant (p = 0.004).

To assess if position and volume are significant predictors of UBP in the presence of other explanatory variables further statistical analysis of the data was performed. Multiple linear regression was used to examine the effect of volume and position as a predictor of UBP for eight of the 12 randomized groups selected above. In this model the dependent variable is UBP measured in any of the four positions with 25 ml or 50 ml instill volumes and the independent variables were BMI (kg/m^2), age (years), gender (male or female), EN (yes or no), NFB (ml), PAP (yes or no), LOS (days), and abdominal pathology (yes or no), in addition to position. The results indicate that position is significant in predicting mean UBP (p = 0.0041), but no significant difference was found in the mean UBP between 25 ml and 50 ml instill volumes overall (p = 0.0731). Interestingly, within each position, the effect of increasing instill volumes from 25 ml to

50 ml on UBP was significantly different (p = 0.0162). The LOS and BMI were

significant in predicting the UBP in the randomized position and volume as well (p =

0.0292 and <0.0001 respectively). The model for predicting mean UBP in any of the

randomized positions at volumes 25 ml and 50 ml is:

$$UBP = 0.27*(BMI) + (Position/Volume\ effect) - 0.15*(LOS) + 4.74.$$

For the above equation the position-volume effect values are obtained from Table

14.

Table 14

Position/Volume Effect Values

	Supine-0° HOBE	Supine-30° HOBE	RL-30° HOBE	LL-30° HOBE
25ml	-0.593	0.76	-0.24	-0.17
50ml	-0.53	-1.33	2.51	0

To further assess the effect of body position on UBP the differences in UBP

measured by the PI in the supine-30° HOBE position with a 25 ml instill volume and the

UBP measured in each of the three other randomized positions were calculated. For this

analysis the instill volume was kept constant at 25 ml (Figure 20).
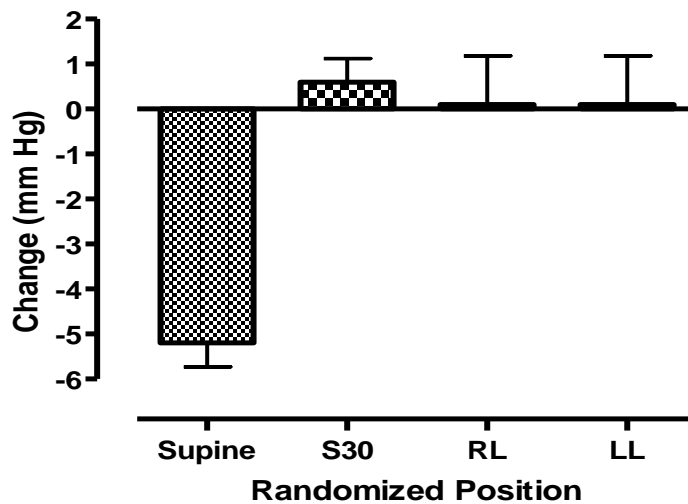
Figure 20. Differences in urinary bladder pressure when subjects were moved from the supine-30° HOBE to the respective randomized position.

Note. Instill volume was 25 ml for all paired UBP differences (n = 10 for each group). Supine = supine-0º HOBE, S30 = supine-30º HOBE, RL = Right Lateral-30º HOBE, LL = Left Lateral-30º HOBE.

When subjects changed from the supine-30º HOBE position to the supine-0º HOBE position the UBP decreased by 5.2 ± 1.7 mmHg. However only small changes occurred when the subjects remained in the supine-30º HOBE position (0.6 ± 1.6 mmHg), or when repositioned in the RL-30 º HOBE position (0.1 ± 3.4 mmHg) or the LL-30º HOBE position (0.0 ± 3.3 mmHg). One way ANOVA showed significant differences between the four groups (F = 10.43, R^2 = 0.46, p<0.0001). Post hoc analysis using the Newman-Keuls multiple comparison test showed that the supine-0º HOBE

position was significantly different from the other three positions. Furthermore, no significant differences were found among these other three positions.

<center>*Current Recommendations for Urinary Bladder Pressure Measurement*</center>

To further explore how body position and instill volume affects UBP measurement, subjects randomized to the two groups that follow the current recommendations for UBP measurement according to the American Association of Critical Care Nurses (AACN) and the World Society of Abdominal Compartment Syndrome (WSACS) were compared to the initial standardized position of the study (supine-30° HOBE position with a 25 ml instill volume). Following the recommendations of the AACN a change in both position (from supine-30º HOBE to supine-0º HOBE) and an instill volume (from 25 ml to 50 ml) is required and using the WSACS recommendations only a change in position (from the supine-30º HOBE to the supine-0º HOBE) is required.
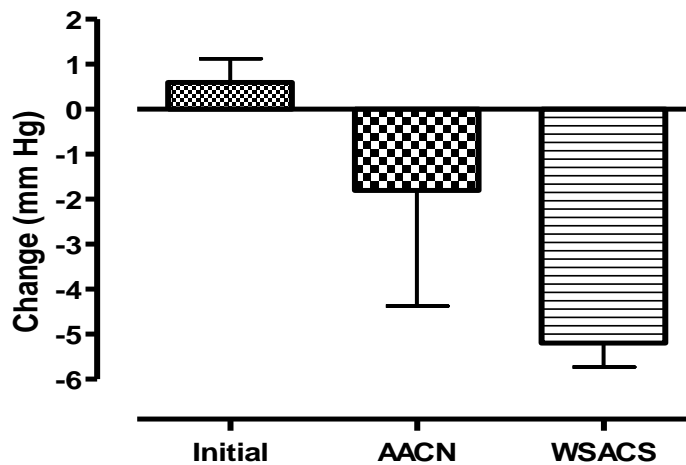
Figure 21. Changes in UBP in subjects when moved from the supine-30° HOBE with a 25 ml instill volume to the randomized body position.

Note. Instill volumes recommended by AACN (supine-0° HOBE with an instill volume of 50 ml) and WSACS (supine-0° HOBE with a 25 ml instill volume), n = 10 for both groups.

When comparing the UBP measured using the WSACS recommendations for UBP measurement against the initial study position the UBP decreased significantly when subjects moved from a supine-30º HOBE position to a supine 0º HOBE position. Urinary bladder pressure fell by -5.2 ± 1.7 mmHg. However, when the initial study position was compared to the AACN recommendations the UBP only decreased by -1.8 ± 8.1 mmHg and when the patient remained in the initial study position the UBP increased by 0.6 ± 1.6 mmHg. A one way ANOVA showed there was a significant difference between these groups (F = 3.6, R^2 = 0.21, p = 0.04). The post hoc analysis using the Newman-Keuls multiple comparison test found only a statistically significant difference between the net difference in UBP measured in the initial study position and that of the

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WSACS position recommendation for UBP measurement ($p < 0.05$). There was no statistically significant difference between the net difference in UBP from the initial study position and that of the AACN position recommendation for UBP measurement ($p > 0.05$).

Inter-Observer Reliability

In clinical practice, UBP may be measured by one or more nurses and it is important to establish if the results are reliable when two different nurses obtain the results. To establish the inter-observer reliability of UBP measurements, another experienced CCU nurse who agreed to be a co-investigator obtained a third pair of UBP measurements in subjects who were randomized to the supine-30º HOBE position with an instill volume of 25 ml. A pair of UBP measurements consisted of one measurement taken after the equipment was assembled, the transducer was calibrated and leveled at the symphysis pubis with 0 ml instill volume and the other measurement was obtained after instilling 25 ml NSS into the bladder. The results were compared with the second pair of measurements obtained by the PI in the same group. Figure 22 shows the individual values for these measurements with an instill volume of 0 ml.
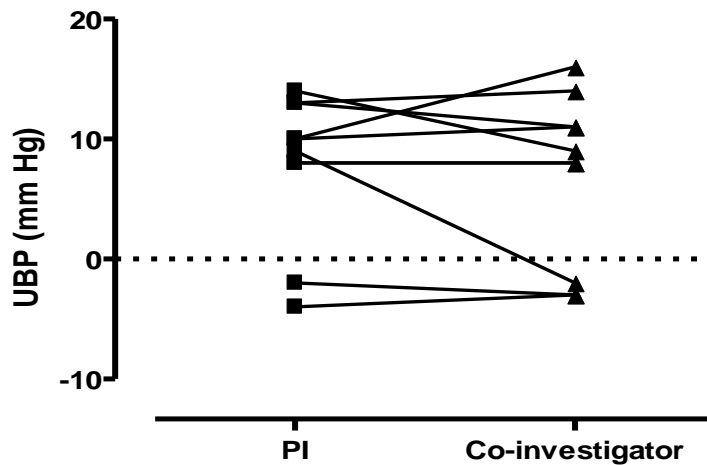
Figure 22. Urinary bladder pressure measurements obtained in subjects in the supine-30º HOBE position with a 0 ml instill volume by the principal investigator and a nurse co-investigator (n = 10).

When the UBP measurements taken with 0 ml instill volumes are considered, the nurse co-investigator obtained UBP values that were the same as the PI in two subjects, lower in four, and higher in four. Except for one subject, UBP measurements taken by the PI and the nurse co-investigator were comparable. The subject with the lower UBP values obtained by the PI also had the lowest UBP values of their group when measured by the nurse co-investigator. The PI and nurse co-investigator obtained UBP values that ranged from -4 to 14 mmHg and -3 to 16 mmHg, respectively. The mean ± SD of the measurements taken by the PI and co-investigator were 7.9 ± 6.1 mmHg and 6.9 ± 7.1 mmHg, respectively. The mean difference between the two measurements was 1.0 mmHg. When comparing the mean UBP measurements using a paired t-test, significance was not demonstrated (95 % CI -2.2 to 4.2, t = 0.7, df = 9, p = 0.5). The Pearson

correlation between the paired measurements taken by the PI and the nurse co-investigator was very high ($r = 0.7791$, $p<0.0039$).

The agreement between the two UBP measurements obtained by the PI and co-investigator was performed by the method of Bland and Altman (1986). This is another method to assess agreement between two different observers and is a graphical and analytical method for comparisons was used to assess inter-observer reliability. The Bland-Altman plot graphs the difference between the two measurements as a function of the average of the two measurements for each subject, which is considered to be the best estimate of the true value. Bias is the difference between one measurement and the other. If one measurement is sometimes higher and, sometimes the second measurement is higher, then the average of the difference should be close to zero. If the bias is not close to zero, this indicates that the two measurements are not similar. The Bland-Altman plot for the measurements taken by the PI and the nurse co-investigator with 0 ml instill volume is shown in Figure 23. The bias of the measurement was 1.0 and the limits of agreement were between -7.76 and 9.76.
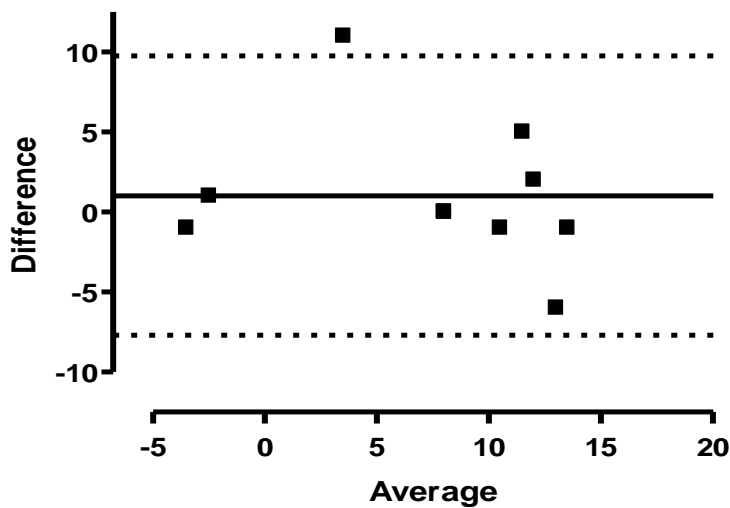
Figure 23. Bland Altman plot of the UBP measurements taken by the principal investigator and the nurse co-investigator in subjects in the supine-30º HOBE position with a 0 ml instill volume. The solid lines represent the bias and the dotted lines the limits of agreement.

The individual values of the measurements taken by the PI and the nurse co-investigator when 25 ml instill volumes were used to measure UBP is shown in Figure 24. All values taken by the nurse co-investigator were higher than 0 mmHg and in five subjects the UBP was higher than the PIs measurement, lower in four subjects and the same in one subject. The mean ± SD of the UBP measurements taken by the PI and the nurse co-investigator were 12.7 ± 2.7 mmHg and 13.4 ± 4.1 mmHg, respectively with ranges of 10 to 18 mmHg and 8 to 20 mmHg, respectively. No significant differences were found comparing the mean UBP measurements using a paired t-test. The mean difference between the two measurements was -0.700 (95 % CI -2.454 to 1.054, t = 0.9,

df = 9, p = 0.4). The Pearson correlation of the two samples was high (r = 0.8, p = 0.0018).
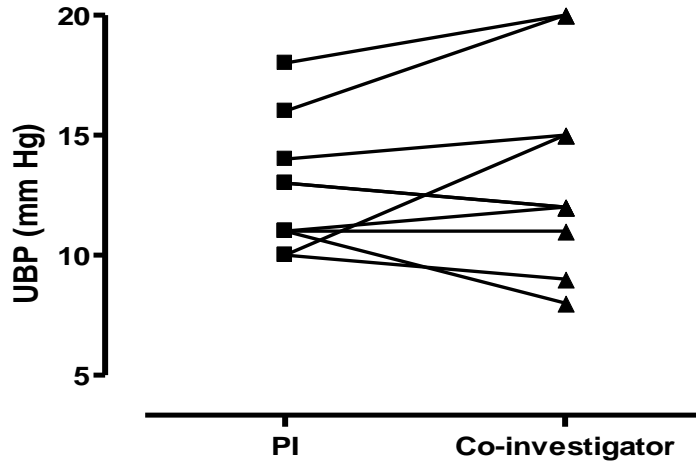
Figure 24. Urinary bladder pressure measurements obtained in subjects in the supine-30º HOBE position with a 25 ml instill volume by the principal investigator and the nurse-co investigator (n = 10).

The Bland- Altman plot of the measurements taken by the PI and the nurse co-investigator with 25 ml instill volumes is shown in Figure 25. The bias of the measurement was -0.7 and the limits of agreement were between -5.5 to 4.0.
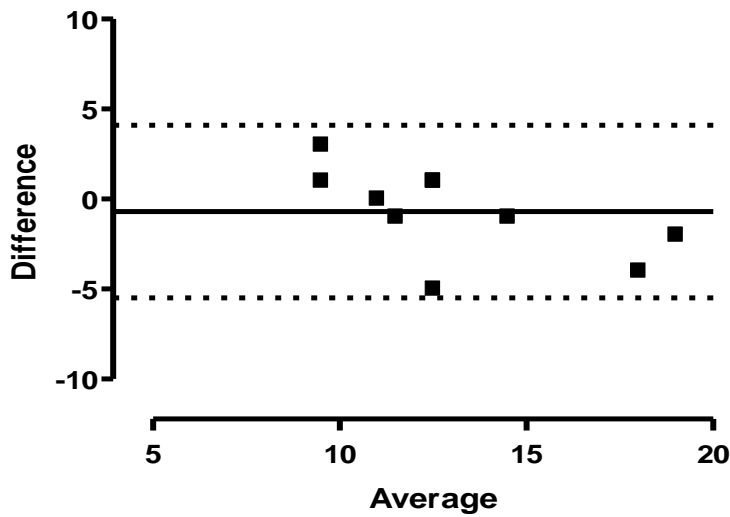
Figure 25. Bland Altman plot of the urinary bladder pressure measurements taken by the principal investigator and the nurse co-investigator in subjects in the supine-30º HOBE position with a 25 ml instill volume. The solid line represents the bias and the dotted lines the limits of agreement   (n = 10).

Intra-Observer Reliability

To assess the intra-observer reliability of UBP measurements the 10 subjects who were randomized to the supine-30º HOBE with a 25 ml instill volume remained in this position for a second pair of UBP measurements (one measurement with 0 ml and another with a 25 ml instill volume). The two pairs of UBP measurements were taken within 30 minutes of each other by the PI. Figure 26 shows each pair of the UBP measurements obtained with 0 ml instill volumes.
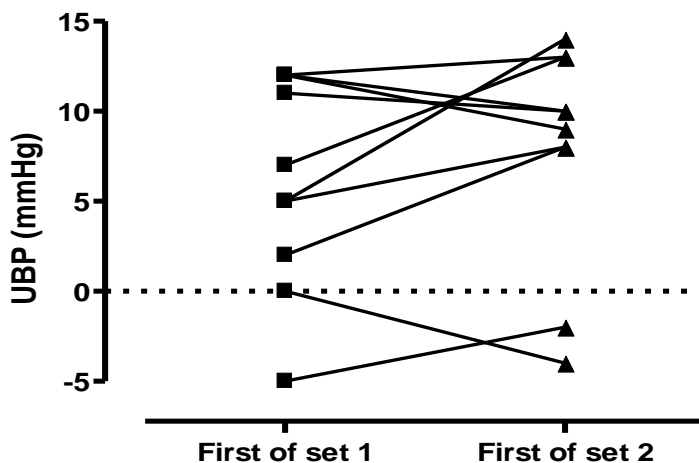
Figure 26. Urinary bladder pressure measurements taken by the principal investigator in subjects randomized to the supine-30º HOBE position with a 0 ml instill volume (n = 10).

The PI obtained the first UBP measurement of the first set. Urinary bladder pressure ranged from -5 to 12 mmHg with a mean ± SD of 6.1 ± 5.9 mmHg. Eight subjects had a positive UBP measurement taken, one subject had UBP of 0 mmHg, and another had a value of -5 mmHg. Comparing the first UBP measurement of the first set to the first UBP measurement of the second set six subjects had relatively higher values and four subjects had lower values. The subject with the negative value for the first UBP measurement of the first set remained negative for the first measurement of the second set taken with a 0 ml instill volume. The four subjects who had lower UBP values in the first measurement of the second set of measurements as compared to the first UBP measurement differed by 1, 2, 3, and 4 mmHg. The first UBP measurement of the second set of measurements taken by the PI with a 0 ml instill volume were quite similar with range from -4 to 14 mmHg with a mean ± SD of 7.9 ± 6.1 mmHg. The mean difference between the two measurements was -1.8 mmHg (95 % CI -4.9 to 1.3, R^2 = 0.2). There

were no statistically significant differences between the pairs of UBP measurements taken at the 0 ml volume in the supine-30° HOBE position (paired t test, t = 1.3, df = 9, p = 0.22). There was a very high correlation between the first UBP measurements of both sets taken by the PI (Pearson correlation r = 0.74, p = 0.0073).

The Bland-Altman plot for the two UBP measurements taken by the PI in subjects in the supine 30°- HOBE position with 0 ml instill volume is presented in Figure 27.
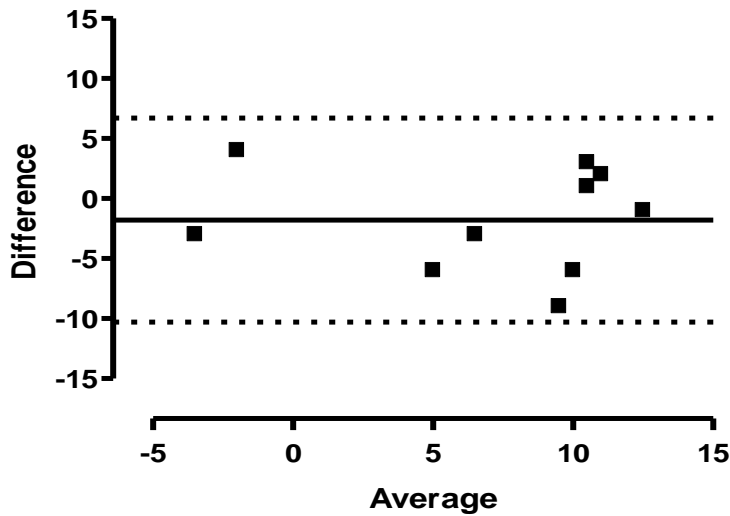
Figure 27. Bland Altman plot for the two UBP measurements taken by the principal investigator with subjects in the supine-30° HOBE position with a 0 ml instill volume. The solid line represents the bias and the dotted lines the limits of agreement (n = 10).

When the two measurements taken by the PI with 0 ml instill volumes were analyzed the bias was estimated to be -1.8. The limits of agreement or the expected difference between measurements of future samples was between -10.3 to 6.7 mmHg.

Figure 28 shows the pairs of urinary bladder pressure measurements obtained by the principal investigator in subjects in the supine-30° HOBE position with a 25 ml instill volume.
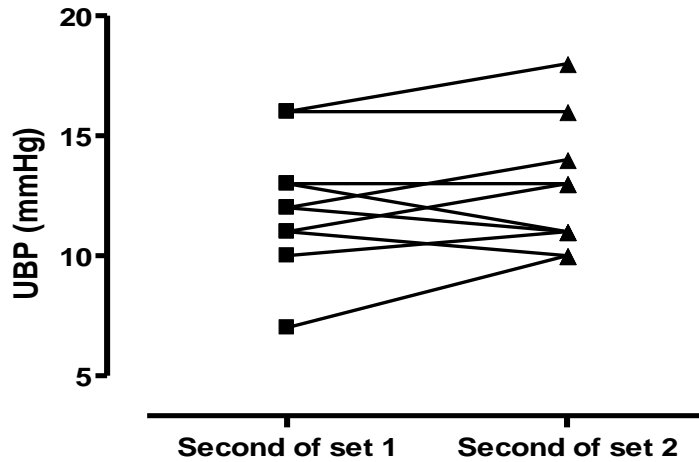
Figure 28. Urinary bladder pressure measurements taken by the principal investigator with subjects in the supine-30° HOBE position with a 25 ml instill volume (n = 10).

When the PI measured subjects in the supine-30° HOBE position with a 25 ml instill volume the second measurement of the first set ranged from 7 to 16 mmHg. The second measurement of the second set ranged from 10 to 18 mmHg. The second UBP measurements of the second set taken by the PI were higher than the second measurement of the first set on five occasions, lower on three and the same on two occasions. The averages of the second measurement of the first set and the second measurement of the second set were 12.1 ± 2.7 mmHg and 12.7 ± 2.7 mmHg, respectively. The average difference of the two samples was -0.6 mmHg. Using a paired t-test to compare the means no statistically significant differences were observed (95 % CI -1.78 to 0.6, R^2 0.1,

paired t-test, t = 1.2, df = 9, p = 0.3). The two samples were highly correlated (Pearson

correlation = 0.8, p = 0.002).

The Bland-Altman plot for the two UBP measurements obtained by the PI with

subjects in the supine-30° HOBE with a 25 ml instill volume is presented in Figure 29.

The bias of the measurements was close to 0 at -0.6 mmHg and the limits of agreement

were between -3.82 to 2.62, which were both lower than the set of UBP measurements

obtained with a 0 ml instill volume.
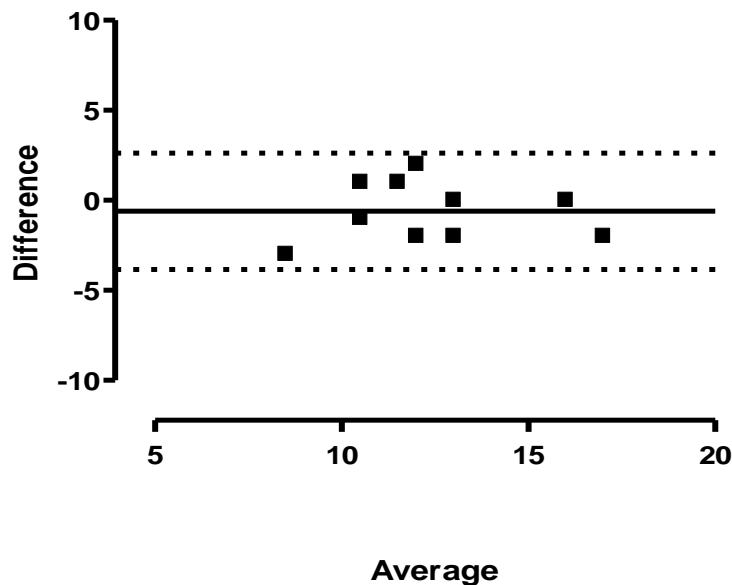
Figure 29. Bland Altman plot of the two measurements taken by the principal investigator

in subjects randomized to the supine-30º HOBE position with a 25 ml instill volume.

The solid line represents the bias and the dotted lines the limits of agreement (n = 10).

Abdominal Perfusion Pressure

Intra-abdominal hypertension (IAH) is associated with multiple organ failure

syndrome (MOFS). The main mechanism contributing to MOFS with IAH is the

reduction of blood flow to the abdominal organs as reflected by the abdominal perfusion

pressure (APP). Abdominal perfusion pressure has also been recognized as a better

indicator of fluid resuscitation when treating the critically ill. To investigate if APP is

affected by the body position or the bladder instill volume, the APP of all 120 patients

was calculated and stratified by the 4 body positions and by instill volumes. Figure 30

shows the APP for each of the four randomized positions. The APP in the supine-0º

HOBE, supine-30º HOBE, RL-30º HOBE and LL-30º HOBE positions was 72 ± 10

mmHg, 70 ± 17 mmHg, 69 ± 15 mmHg, and 67 ± 20 mmHg, respectively. Analysis of

variance showed no significant statistically differences in APP among the four body

positions studied (F = 0.6, R^2 = 0.02, p = 0.6).
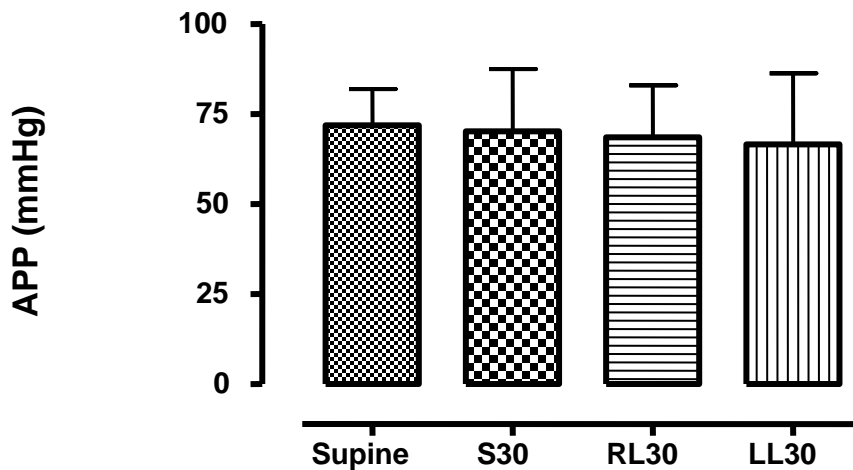
Figure 30. Abdominal perfusion pressure of all subjects stratified by randomized position.

S30 = supine-30º HOBE, RL = right lateral 30º HOBE, LL = left lateral 30º HOBE. (n =

30 in each group).

However, statistically significant differences were found among the groups in

regards to the APP when a one way ANOVA examined the effect of the bladder instill

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volume used to measure UBP (F = 10.18, R^2 = 0.12, dF = 3, p<0.001) (Figure 31). Post

hoc Neuman-Keuls multiple comparison test demonstrated that the 200 ml instill bladder

volume produced a significantly lower APP (56 ± 36 mmHg) as compared to 0 ml (75 ±

15 mmHg), 25 ml (71 ± 13 mmHg), and 50 ml (70 ± 14 mmHg) bladder instill volumes.

There were no statistically significance differences in APP between 0 ml and 25 ml.

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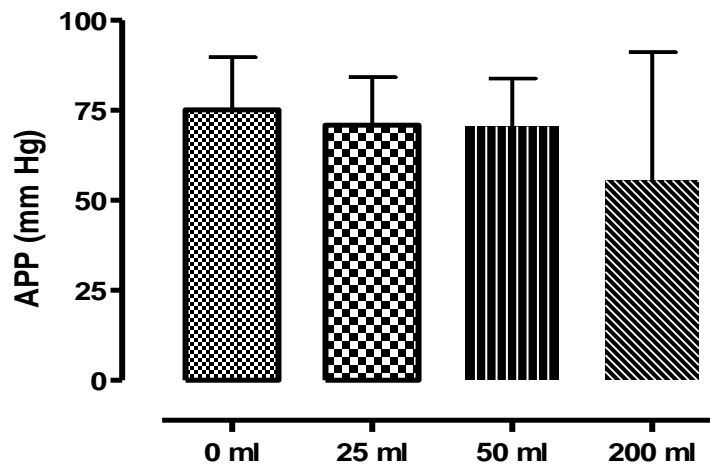
Figure 31. Abdominal perfusion pressures stratified by bladder instill volumes. n = 120

for 0 ml. n = 40 for 25 and 50 ml. n = 39 for the 200 ml instill volume.

Intra-Abdominal Hypertension

Elevated intra-abdominal pressures (IAP) are associated with abdominal organ

dysfunctions leading to the development of abdominal compartment syndrome (ACS).

The level of IAP that causes organ dysfunction and ACS varies among individuals and

depends not only on IAP but also on other clinical variables such as previous organ

dysfunction, abdominal perfusion pressure, and BMI, to name a few. Although there is

no consensus among researchers on the level of IAP that most accurately predicts organ

dysfunction or the need for clinical interventions, the WSACS has defined a UBP > 12

mmHg (when measured in the supine position) as IAH and is an indication for more frequent measurement of UBP. The prevalence of IAH (UBP>12 mmHg) was calculated for the supine-30º HOBE position at 0 ml and 25 ml instill volumes. The prevalence of IAH was 1.8 fold higher when a 25 ml instill volume was used as compared to a 0 ml instill volume (53 vs. 29).

In summary, the data collected during this prospective observational study was accomplished according to the design. Descriptive statistics of the study population and further analysis including correlation, Bland-Altman, ANOVA, linear regression and multiple linear regression were able to be completed and satisfactorily answered the research questions.

Chapter 5

Discussion

Introduction

Urinary bladder pressure (UBP) measurement accurately reflects intra-abdominal pressure (IAP) (Fusco et al., 2001) and is considered to be the gold standard for estimating IAP at the bedside (Malbrain, 2004). Currently, UBP is measured using one of several variations of the method initially described by Kron and colleagues (1984). This technique of UBP measurement utilizes hydrostatic pressure principles which are frequently used by critical care nurses (CCNs) for bedside hemodynamic monitoring. Therefore, most CCNs possess the basic knowledge and skills required for UBP measurement.

An elevated IAP that is > 12 mmHg is considered intra-abdominal hypertension (IAH) and can evolve into abdominal compartment syndrome (ACS) when one or more organ systems are negatively affected (Balogh, McKinley, Holcomb et al., 2003). The gastrointestinal (GI) system is one of the many organ systems that is compromised with IAH and that contributes to the development of multiple organ failure syndrome (MOFS) (Balogh, McKinley, Cox et al., 2003). Given the anatomic location of the intestines within the abdominal compartment, it is reasonable to speculate that increased IAH may directly or indirectly contribute to altered GI function.

Dysfunction of the GI system has implications for nursing because enteral feeding is the preferred route for nourishing critically ill patients, and if GI function is compromised enteral feeding can be challenging. Recognition of GI system dysfunction is difficult by physical examination alone but clinically important. Use of objective data to assess and evaluate GI dysfunction and/or enteral feeding tolerance by bedside nurses has been limited. Traditionally nurses have relied on data such as bowel sounds, residual volumes, and diarrhea, but all of these depend on subjective interpretation and are prone to errors. Having an objective tool available at the bedside to assess when patients are intolerant to enteral nutrition (EN) would theoretically improve patient care as predicted by Benner's theory of nursing (Benner, 1982).

Benner's theory, from novice to expert, (1982) utilizing critical thinking as applied to nursing by Martin (2002) explains the educational and experiential development of nurses as a process that occurs over several years. If an objective measure could provide clinically meaningful data to determine enteral feeding tolerance, the novice nurse's level of practice could be escalated to place the nurse's practice at a higher level of function in a shorter period of time. Having more data available at the bedside to guide patient care, it is theorized, would improve bedside nursing care at all levels from novice to expert which in turn would improve patient outcomes (Benner, 1982). A goal of nursing research would be to identify such tools and was the impetus for this nursing study.

During the initial stages of study design, the original hypothesis was to determine if UBP could become an objective predictor of enteral feeding tolerance. If UBP measurement could in some way be linked to enteral feeding tolerance, the nursing

process of enteral nutrition administration and monitoring for the critically ill would be greatly enhanced. Unfortunately, that hypothesis was unable to be tested because after an extensive review of the medical and nursing literature, it became apparent that UBP measurement at the bedside of critically ill patients had not been standardized.

Over the years, the process of bedside UBP measurement has evolved from a single measurement of IAP during surgical procedures to frequent intermittent measurements in the CCUs to diagnose and monitor for IAH and ACS. Initially, UBP in CCUs was measured exclusively by physicians and the procedure was copied from the procedures used in the surgical suite or laboratory (Iberti et al., 1987; Iberti et al., 1989; Kron et al., 1984). With time, the responsibility of UBP measurement in CCU was transitioned from the physician to the critical care nurse (CCN) but the procedure was not changed and did not take into account the nursing needs or the recent recommendations to improve patients care in the CCU. For example, the current recommendation is to only measure UBP when patients are positioned supine-0º HOBE. This position is not recommended in CCU due to the higher risk for aspiration pneumonia (Heyland et al., 2003). In addition, the supine-0º HOBE is inconvenient for patients and nurses; no nursing research has been carried out to determine if UBP can be measured in other positions. Likewise, UBP measurements require instillation of NSS into the bladder and physicians have used volumes ranging from 10 ml to 250 ml in the past. Nursing research had not been carried out to investigate the most appropriate volume for UBP measurement and instead nurses arbitrarily chosen instill volumes based on what physicians have found in the laboratory (Iberti et al., 1989; Kron et al., 1984).

Furthermore, no research had been carried out by nurses to assess the inter- and intra-observer reliability of UBP measurement to ascertain the utility of this technique in CCU.

Because of the lack of standardization regarding position and instill volume and the void of data regarding the reliability of UBP measurement by nurses, the initial hypothesis could not be tested. The experimental design to test the hypothesis requires subjects to be in the recommended supine-30º HOBE as well as multiple UBP measurements taken over time by the same or different nurses. Thus, the PI took a step back and critically reflected on the UBP measurement process as currently practiced by CCNs. After a thorough review of the literature it was apparent that the three elements with the greatest potential to influence UBP measurement are bladder instill volume, subject position, and inter- and intra-rater reliability.

The purpose then of this research was to critically evaluate the process of UBP measurement employed by professional nurses at the bedside of critically ill patients. The ultimate aim of the research was to develop an evidence based nursing protocol for bedside UBP measurement using hydrostatic pressure principles that can be used for clinical and research purposes.

General Observations

The study was designed to recruit a large number subjects who would have a wide range of bladder pressures, clinical conditions and demographics. Although the sample size and many important goals were achieved, other goals were not. For example, few mechanically ventilated subjects, no subjects requiring paralyzing agents, and few non-Caucasian subjects were recruited into the study. One reason for failing to enroll certain

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segments of the CCU population was the boundaries imposed by ethical and federal regulations, i.e. The Health Insurance Portability and Accountability Act (HIPAA), making clinical research in CCUs difficult (Ciroldi et al., 2007).

Specifically, recruitment of subjects for participation in a research study is challenging because current federal guidelines do not allow direct contact of potential subjects by the investigator for the screening. Therefore, subjects for this study had to be recruited by health professionals who had a previous relationship with the subject. The nurse or physician directly caring for the subject had to introduce the study to the potential subject first and if acceptable the PI could provide a full explanation of the study followed by a signed informed consent if agreement to participate was acceptable. In this study, nurses and or physicians blocked access to some of the most critically ill patients and on other occasions the surrogate felt that the risk of the study was too high and did not sign the informed consent. These limitations have not been present or acknowledged in many of the other studies investigating UBP because many of the PIs were physicians directly involved in the care of the subject and because UBP measurements were considered the standard of care and an informed consent was not required by the IRB of the institution (Malbrain & Deeren, 2006). This situation is not unique to this study since others have also found difficulty in obtaining informed consent for research studies in critically ill patients (Ciroldi et al., 2007).

The current study involved subjects who were critically ill but in a stable state. While most of the previous studies have investigated UBP in subjects who where critically ill, sedated and at risk for intra-abdominal hypertension (IAH) and abdominal compartment syndrome (ACS), this study investigated a range of subjects who were not

sedated and at a lower risk for IAH and ACS. Because this study is laying the ground

work for additional research examining the relationship of EN and UBP in a critically ill

population, it was important to study a variety of patients who would range in risk of IAH

and ACS from high to low. The UBP data gathered from this diverse population is

actually more relevant to the ultimate goal of establishing UBP as a predictor of enteral

feeding tolerance since UBP is intended not to be a diagnostic tool for IAH and ACS.

The values for UBP obtained in this research study reflect the UBP values

reported by other investigators. For instance, Sanchez et al. (2001) measured UBP in

hospitalized, non-critically ill patients in the supine position with a 50 ml instill volume

using a manometric technique and reported UBP values ranging from 0.2 to 16.2 mmHg

with a mean of 6.5 mmHg. Values were measured in cm H_20 and reported by the authors

in mmHg. Malbrain et al. (2004) using a technique similar to the one used in this study

measured UBP in critically ill patients in the supine position with a 50 ml bladder instill

volume and reported mean values of 9.8 ± 4.7 mmHg. Many if not all of these subjects

were sedated and receiving mechanical ventilation at the time of the study. Kimball and

colleagues (2007) reported mean values of three different UBP measurements taken by

89 nurses in 18 subjects that ranged between 12.2 ± 4.7 to 12.8 ± 4.9 mmHg. In

comparison, the UBP values obtained in this study in the supine-30º HOBE with 0 ml and

25 ml instill volumes were 7.1 ± 5.9 mmHg and 11.6 ± 5.9, respectively. When only the

values of the 10 subjects randomized to the supine-0º HOBE position with a 50 ml instill

volume are considered the UBP values ranged from 3 to 23 mmHg with a mean of $12.5 \pm$

6.3 mmHg, nearly identical to the findings of Kimball and colleagues (2007). The

slightly higher values found in this study as compared to Sanchez et al. (2001) and

Malbrain et al. (2004) may be due to differences in subject position, and/or technical differences of UBP measurement or subject factors, such as the effect of sedation which would decrease UBP. Since none of the subjects were sedated in this study it could be predicted that higher UBP may be observed.

A novel and unexpected finding of this study is the sub-atmospheric UBP values obtained by the PI under certain conditions. When all 478 UBP measurements taken in this study are considered, 20 were < 0 mmHg (4.2 %). Sub-atmospheric UBP values were only observed in subjects with a 0 ml bladder instill volume but occurred in all positions. Sub-atmospheric UBP values most frequently occurred in the supine-0° HOBE position (23.3 %) followed by the LL-30° HOBE position (10 %), the supine-30° HOBE (6.0 %), and the RL-30° HOBE (3.3 %). Five of the seven subjects who had negative UBP values in the initial position remained negative when positioned in the randomized position and these values became more negative in subjects who were randomized to the supine-0º HOBE position.

These negative values were not likely due to errors in the investigator's procedural execution or technical skills as these findings occurred late in the study after the investigator had become proficient in all aspects of UBP measurement. In addition, during the early stages of data collection when the first negative value was observed the engineers at Wolfe-Tory Medical, Inc., manufacturers of the AbViser™, were contacted. The only explanation that was offered that could conceivably clarify negative values was related to the position of the urinary catheter and drainage collection system in reference to the transducer and the urinary bladder and perhaps the presence of fluid in the drainage tubing. However, these recommendations were already addressed by the PI.

One possible explanation of these findings is that in some subjects IAP was truly sub-atmospheric. Intra-abdominal pressure may be highly variable among individuals secondary to subject characteristics (fluid administration or sedation) or the conditions of measurement (transducer location, zeroing and leveling procedures) and the knowledge and expertise of nurses. Because the abdominal cavity is considered to be a closed box that contains both partially rigid (ribs, spinal cord, and pelvis) and flexible boundaries (diaphragm and abdominal muscles) as well as compressible visceral organs, at any single moment IAP may vary as influenced by the character of respiration, abdominal wall muscle tone, position of the individual and relative position of the abdominal organs, and posture. All of these variables impact IAP and UBP measurement.

Wagoner (1926) measured intra-abdominal pressure using a water manometer in animals after introducing a needle or catheter into the abdominal cavity. He demonstrated that when precautions were taken to ensure a closed-air system the IAP in animals was between -2 to -55 mm H_2O (-0.15 to -4 mmHg). Negative IAP was also observed in recently deceased human subjects or cadavers. Forty-one of 50 cadavers with no evidence of abdominal disease, had negative IAPs ranging from -2 to -106 mm water (-0.15 to -6.6 mmHg). However, cadavers with abdominal disease such as tumors, obesity, ascites, and pneumonia with edematous intestines showed positive IAP ranging 4 to 150 mm water (0.3 to 11.5 mmHg). Further studies in animals by Overholt (1931) and Salkin (1934) showed sub-atmospheric IAP when the animals were horizontal and when the cannulae were positioned in the upper part of the abdomen. Twardowski et al. (1986) measured IAP in patients undergoing peritoneal dialysis with an intra-abdominal pressure transducer and showed zero or sub-atmospheric IAP when the subjects were

supine and relaxed but positive IAP when subjects were relaxed and in a sitting or upright position.

A second possible explanation for the sub-atmospheric pressures observed in this study is that the transducer was leveled at a position higher than the fluid line of the bladder volume. This is possible since it is difficult to determine the intrinsic bladder volume of a critically ill subject at any moment because they are receiving IV fluids, diuretics, vasoactive medications, and other treatments that may affect urinary output. It is possible that subjects who had a UBP ≥ 0 mmHg had urinary catheters that did not fully empty the bladder while in the subjects with UBP < 0 mmHg had urinary catheters that completely emptied the bladder.

In summary, the supine-0° HOBE position with a 0 ml instill volume produces sub-atmospheric UBP about 23.3 % of the time and the supine-30° HOBE position with a 0 ml instill volume produces sub-atmospheric UBP about 6 % of the time. As of this writing and to the knowledge of the PI, sub-atmospheric pressures have not been previously reported in clinical studies. However, Malbrain and Deeren (2006) have recently reported 0 mmHg in one subject.

Research Questions

Research Question 1: Does the Amount of Bladder Instill Volume Affect UBP Measurement?

The results of this research study showed that UBP is affected by the amount of NSS instilled into the bladder before measurement. The evidence supporting this assertion is three fold: First, the initial set of paired UBP measurements showed a

statistically significant higher UBP value in subjects who were placed in a supine-30º

HOBE position with a bladder instill volume of 25 ml as compared to a 0 ml instill

volume (Figure 7). Second, UBP was higher when measured in any of the randomized

volumes. In each position, the UBP was higher when measured with the randomized

volume as compared to zero volume. Third, the one way ANOVA showed a significant

effect of volume and a two way ANOVA also showed a significant effect of volume and

volume-position interaction on UBP.

The results of this research study are comparable with recent studies investigating

the effect of bladder instill volume on UBP measurement (Chiumello et al., 2007; De

Waele et al., 2006; Malbrain & Deeren, 2006). All of these studies use the same

experimental design where UBP is measured in the same subject multiple times using

serial additions of NSS into the bladder. This design does not take into account normal

physiology of the bladder. Urinary bladder pressure measurement is an indirect

measurement of IAP only if the bladder detrusor muscle pressure (DMP) is zero or near

zero (UBP = IAP + DMP) at the time of measurement (Von Garrelts, 1957) and only if

biomechanical factors that control bladder function such as compliance and

accommodation are not activated. Compliance (C) is defined as the change in volume

(V) relative to a corresponding change in intra-vesicular pressure (P) ($C = \Delta V / \Delta P$).

Subjects with poor bladder compliance produce higher changes in UBP for a given instill

volume. With time, the detrusor muscle and connective tissue re-arrange or accommodate

in a process that will result in a lower pressure for a given volume. The time needed for

full accommodation of the bladder after a given instill volume is not known but it is

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likely to be > one minute, which is the time between instillations used in the above studies.

Evidence for the effect of compliance and accommodation in the measurement of UBP comes from the study of Malbrain and Deeren (2006) and Chiumello and others (2007). Malbrain and Deeren (2006) showed marked differences in UBP measurements among subjects with different degrees of bladder compliance and (Chiumello et al., 2007) showed the effect of bladder accommodation by observing lower UBP measurements five minutes after saline instillation as compared to the UBP when measured five to ten seconds after saline instillation. Kimball et al. (2007) also recognized the concept of bladder accommodation when they observed higher UBP variability when successive UBP measurements were taken less than eight minutes apart.

In addition to the experimental design, the present study differs from the previously discussed studies in several ways. First, the sample size of the present study (n = 120) is significantly larger than the previously discussed studies thus increasing the power and validity. Second, the majority of subjects in the present study was not at risk for IAH and ACS, nor was they sedated and mechanically ventilated. (All of the subjects in the previous studies were at risk for IAH and ACS and were sedated and mechanically ventilated at the time of measurement.) Both sedation (De Waele et al., 2003) and LOS (Biancofiore et al., 2003; De Waele & De Laet, 2007) have been shown to affect UBP and may have altered the results. Third, in this study the effect of volume was tested in positions that have not been previously reported. Findings of this study demonstrate that there is a significant volume-position interaction. Higher UBP measurements were always obtained with any instill volume as compared to 0 ml instill volumes regardless of

position. In the positions of supine-0º HOBE and RL-30º HOBE UBP measurements increased sequentially when measured with the increasing study volumes, thus higher instill volumes produced higher UBP measurements. However in subjects positioned in the supine-30º HOBE or LL-30º HOBE higher UBP measurements were obtained with a 25 ml instill volume as compared to a 50 ml instill volume demonstrating a volume position interaction (Figure 18 and Table 9). In all groups the lowest UBP values were measured with 0 ml instill volumes and the highest were measured with the 200 ml instill volumes.

In summary, the results of this study and other studies (Chiumello et al., 2007; De Waele et al., 2006; Malbrain & Deeren, 2006) demonstrate that the amount of NSS instilled into the bladder at the time of UBP measurement affects the UBP results. A unique and original contribution of this study is the discovery of a significant volume-position interaction when measuring UBP. A bladder instill volume of 0 ml gives a lower UBP value but also increases the probability of obtaining a negative UBP value as well as greater variability for both inter- and intra-observer reliability (see research questions 3 and 4). A bladder instill volume of 200 ml was also associated with more variability and produced higher UBP values while the 25 ml and 50 ml instill volumes produced comparable results in all positions.

Research Question 2: Does the Subject's Body Position Affect UBP Measurement?

The second research question explored the effect of body position on UBP measurement. The findings of this study demonstrate that body position affects UBP. This conclusion is supported by the ANOVA and the multiple regression analyses.

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Urinary bladder pressure is lower when measured in the supine-0° HOBE position than when measured in any of the other three positions studied which were all with a 30º HOBE (Figure 18). However, the differences in UBP with changes in body position only reached statistical significance when 25 ml and 50 ml bladder instill volumes were used again indicating significant volume-position interaction (Table 11 and Figure 18).

This study has the largest data base of UBP measurements taken in critically ill subjects in the supine-30º HOBE position. The study of the supine-30º HOBE position is of clinical interest because it represents the most common position assumed by critically ill patients and is the recommended position of many critical care experts and reflected in consensus standards published by professional organizations to prevent and decrease the incidence of ventilator associated pneumonia and aspiration pneumonia frequently found in critically ill patients (Chinsky, 2002). It is also the preferred position for patients who cannot assume the supine-0º HOBE position. Furthermore, this position would be necessary for centers that employ the continuous UBP measurement technique of Balogh (Balogh et al., 2004).

The data obtained from the current study found that UBP measured in the supine-0º HOBE position was 3 - 5 mmHg lower than when compared to the supine-30º HOBE position. This was calculated in two ways: First by using the equation that predicts changes in UBP in the supine-0º HOBE position with zero volume. For this calculation, BMI was considered to be the average for the study (29 Kg/m^2) and supine-30º HOBE value was one (1) and the RL-30º HOBE and LL-30º HOBE positions were at zero (0). This calculation shows that UBP measured in the supine-0º HOBE position will result in a value that is 3.67 mmHg lower than when measured in any of the other positions.

Second, for the 10 subjects randomized to the supine-0º HOBE position with a 25 ml instill volume the difference in the UBP value from the supine-30º HOBE position with a 25 ml instill bladder volume was calculated (Figure 20). This calculation yielded a lower mean difference of 5 mmHg. Mc Beth et al. (2007) also found UBP to be 5 mmHg lower when measured in the supine-0º HOBE position as compared to the supine-30º HOBE position.

When the present study was designed the supine-30º HOBE position had not been previously investigated, but since then two studies have been published showing UBP measurement data in this position (McBeth et al., 2007; Vasquez et al., 2007). Both of these studies show that UBP when measured in the supine position with varying degrees of HOBE (10º, 15º or 30º) is higher than when measured in the supine-0º HOBE position. The major difference between the present study and the studies of Vasquez et al. (2007) and McBeth et al. (2007) is the position and leveling of the pressure transducer. In both of the previous studies the pressure transducers were not changed after each position change, while in the present study, the pressure transducer was re-leveled and re-calibrated after each position change. This is important because changes in body position may change the relationship of the transducer to the anatomic landmark that is calibrated at zero pressure.

Results of the present study add to the knowledge regarding UBP measurement because it uses two lateral positions that have not been investigated before. These lateral positions were chosen because after the supine-30º HOBE they represent the most common positions assumed by critically ill patients in CCU and are positions recommended to prevent the complications of immobility such as impaired skin integrity

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(Baas, 2003). These lateral positions are more common than the supine-0º HOBE and the supine-10 º, 20 º, or 45 º HOBE positions studied by Vasquez, and colleagues (2007) and McBeth et al. (2007). The results of the present study demonstrate no significant difference in UBP between the supine-30º HOBE position and the RL- and LL-30º HOBE positions (Table 12). This was unexpected because positioning subjects in the LL-30º HOBE position should result in a shift of weight of the abdominal viscera that could have increased the UBP secondary to the gravitational effect of the organs on the bladder resulting in higher UBP values (Hebbard et al., 1995).

The results of this study have direct clinical relevance. Specifically, they show that the absolute UBP value is higher when it is measured in the supine-30º HOBE as compared to the UBP measured in the supine-0º HOBE position. These slightly higher UBP values are to be expected in the supine-30º HOBE position because of the tension in abdominal wall musculature and the gravitational effects of the abdominal viscera contents on the bladder with HOBE (Grillner et al., 1978; Hebbard et al., 1995). Supporting these findings are the results of McBeth and colleagues (2007) who reported similar increases in UBP measurements with a 30º HOBE position. Therefore, it will be acceptable to measure UBP in the supine-30º HOBE position. This position can be used as an alternative position to the supine-0º HOBE position for all subjects who are able to assume this position, providing that the relatively higher values in this position are recognized. Accepting this alternative UBP measuring position, ongoing research will be required to obtain more data under different circumstances. Finally, it will also require revised definitions of IAH and ACS.

Research Question 3: What is the Inter-Observer Reliability of UBP Measurement?

The third research question assessed the inter-observer reliability of UBP measurements. The reliability of UBP measurements is a function of the process of UBP measurement that includes the accuracy of equipment, the technique of the nurse or observer, and other patient related clinical factors. Previous studies have shown that when properly calibrated the bedside monitoring equipment is sensitive and produces a reliable transduction of hydrostatic pressures (Ahrens, 1999; Ahrens et al., 1995). Some of the most pertinent clinical factors related to subjects that may affect UBP variability from one measurement to another are body weight, use of sedatives, breathing and ventilatory status with positive airway pressure, net fluid balance, and activity. Influencing factors that can contribute to UBP measurement variability related to the nurse's technique includes the accuracy of positioning the subject, proper assembly of the equipment, i.e. assuring that there are no air bubbles in the line, proper placement and leveling of the transducer, zeroing of the pressure transducer, proper identification of the wave form, and reading the monitor at end expiration.

Because subjects in CCUs are very ill and receiving multiple therapies, subject clinical factors are very difficult to standardize and it would be expected to contribute significantly to the variability of paired UBP measurements. Of the three areas cited as potential factors of variability, the nursing process of UBP measurement may be the most influential and is one of the foci to limit variability during UBP measurement. Therefore, it is possible to reduce variability of UBP measurement if the nurse's technique is standardized. In order to account for this potential variability, the present study was designed to simulate the necessary steps a CCN must take to obtain reliable UBP

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measurements. To that end, after the initial measurement, the transducer was misaligned by the PI and the nurse co-investigator was required to recheck the subject position and to re-level and to re-zero the pressure transducer and to perform a square wave test before the second set of UBP measurements were taken. When all factors are considered the results show that UBP can be measured with low variability, and therefore high inter-observer reliability. Furthermore, the bias and coefficient of agreement between the two measurements as calculated by the Bland-Altman analysis were both smaller when measured with a 25 ml instill volume as compared to a 0 ml bladder instill volume (Figure 23 and Figure 24). Davis and associates (2005) also showed more variability in UBP measurements when a 0 ml instill volume was used.

One experimental and one clinical study previously assessed inter-observer reliability of UBP measurement. Wolfe and Kimball (2005b) built a laboratory model of the abdomen by using a 210 liter container with a urinary catheter exiting from its base. The proximal end of the urinary catheter tip was sealed with a 100 ml bag and was placed at the base of the container simulating a urinary bladder and the distal end was connected to the AbViser™ Kit that in turn was connected to a transducer and a monitor. The transducer was leveled at the level of the simulated bladder at the bottom of the container. A column of fluid was placed within the container to simulate IAP of 5, 10, 15, 20, 25, 30 and 40 mmHg. Eleven (11) observers each took five measurements for each of the seven simulated IAPs. These investigators found very little inter-observer variability of the measurements and the standard deviations of the measurements were very small (0.1 to 0.5). This study assessed variability of the monitoring system but did not address the

more important questions such as variability introduced by subjects or by nurse's technique.

The inter-observer reliability of UBP found in the present study is in agreement with the study of Kimball et al. (2007) which is the only other study that has assessed inter-observer reliability of UBP measurement with a technique and clinical setting similar to the present study. For example, the mean UBP measurements from the two nurses in the study of Kimball et al. were 12.37 ± 4 mmHg and 12.37 ± 4.84 mmHg, when measured in the supine-0º HOBE with a 50 ml instill volume and in this study were 12.7 ± 6.6 mmHg and 13.4 ± 4.11 mmHg, when measured in the supine-30º HOBE and 25 ml instill volume. Both pairs of UBP measurements in both the study of Kimball and this study were not statistically significant by paired t-test. The paired samples in the study of Kimball et al. (2007) had a slightly higher Pearson correlation than in the present study (0.95 vs. 0.82, respectively) and a lower mean difference between them (0.0 vs. -0.7), respectively. Therefore, both studies showed low variability and high inter-observer reliability.

The slightly higher inter-observer correlation in the study of Kimball et al. (2007) as compared to the present study may be explained by three important differences in the experimental design. First, in the study of Kimball et al. (2007) UBP was measured with subjects positioned supine-0º HOBE with a 50 ml bladder instill volume, while in the present study subjects were positioned in the supine-30º HOBE with a bladder instill volume of 25 ml. This is important because of the volume-position interaction affects UBP as demonstrated in this study. Second, but equally important, is related to the position of the pressure transducer, which remained fixed at the symphysis pubis and was

not re-leveled or re-zeroed between UBP measurements in the study of Kimball and colleagues (2007) while in the present study the pressure transducer was re-leveled and re-zeroed, and the entire monitoring system was re-checked and a square wave test was performed between UBP measurements. Thus, the paired sample data obtained in the present study not only reflects the administration of NSS, and the variability of reading the monitor as in the study of Kimball and colleagues (2007) but also includes the variability added to the measurement due to differences in transducer positioning, leveling, and square wave testing between nurses.

Lastly, the study of Kimball et al. (2007) had a larger study population (18 vs. 10) as compared to the present study as well as a larger sample size (181 vs. 10 paired samples). However, in the study of Kimball et al. subjects contributed anywhere from 1 to 39 paired samples for analysis and some of the paired samples were excluded from the analysis because they exceeded the collection time. Omitting data from the analysis and having a few subjects contribute a large number of the sample data points will bias the data towards a lower variability and higher correlation. In contrast, the present study had 10 subjects who each contributed one data set and no data set was omitted from the analysis.

The high inter-observer reliability of UBP measurement found in this study has several major clinical relevancies. First, it demonstrates that it is possible for different observers to obtain highly reproducible UBP measurements with subjects in the supine-30º HOBE position if a standardized protocol is followed. This is important in clinical practice where patients are cared for by more than one nurse in a day and UBP measurements are taken more than once per day, and this would be the position assumed

by patients when receiving enteral nutrition. Second, it adds to the current literature that confirms and validates the previous results of Kimball et al. (2007) obtained on subjects in the supine-0º HOBE. Finally, it contributes new nursing knowledge for performing bedside UBP measurement that is evidenced based.

Research Question 4: What is the Intra-Observer Reliability of UBP Measurements?

Intra-observer reliability of UBP measurement was determined in the present study by comparing the two pairs of UBP measurements taken by the PI in the 10 subjects randomized to the supine-30º HOBE. The results demonstrated a very high Pearson correlation between the two pairs of measurements obtained with bladder instill volumes of 0 ml and 25 ml. In addition, there was no difference in mean values of the paired measurements by paired t-test. The bias and the limits of agreement between the measurements were calculated with the Bland-Altman analysis and both were lower when the measurements were taken with a bladder instill volume of 25 ml than as opposed to being measured with a bladder instill volume of 0 ml. This data indicates that a bladder instill volume of 25 ml reduces the variability of repeated measurements and therefore increases the intra-observer reliability of UBP measurements. The intra-observer reliability of UBP measurement from this study is in agreement with the study of Kimball et al. (2007) despite the differences in methodology and design as described above.

The clinical importance of these findings is that this is the first study to show that intra-observer reliability of UBP measurement in the supine 30º-HOBE is very high and similar to what others have measured in the supine-0º HOBE.

Research Question 5: What Other Factors Influence UBP Measurements?

The purpose of the fifth question was to assess the effect of select clinical variables on UBP. The variables selected for the analysis a priori were age, gender, Body Mass Index (BMI), net fluid balance (NFB), positive airway pressure (PAP) by evaluating respiratory or ventilatory status, and paralytic agents. Additionally, length of stay (LOS), the use of enteral nutrition (EN) via an enteral feeding tube, and the presence of abdominal pathology were added to the analysis post data collection. The question was explored by investigating the relationship of the above listed variables when the UBP was measured in the supine-30º HOBE position with an instill volume of 0 ml or 25 ml using multiple linear regression analysis. Very few subjects who were enrolled into the study were treated with mechanical ventilation or paralytic agents. Therefore, the influences of PAP and paralytic agents could not be adequately tested. The multiple regression analysis found that the most influential variables on UBP were BMI, EN, LOS, and NFB.

Of these variables, BMI appears to be the most important because it was a significant factor in all three predictive equations and accounted for a relatively large portion of the variability of UBP measurements. The effect of BMI on UBP is likely due to its direct relationship with intra-abdominal fat (Lambert, Marceau, & Forse, 2005). The intra-abdominal fat acts as another solid organ that may greatly affect intra-abdominal volume and may also exert a significant gravitational effect on UBP measurement. Other investigators have also found a direct link between BMI and UBP (Sanchez et al., 2001; Sugerman et al., 1998; Sugerman et al., 1997; Vasquez et al., 2007).

In a series of studies during the early 90's Dr. Harvey Sugerman and associates (1998; 1997) from the Medical College of Virginia were the first to show that UBP and BMI were positively related. In this series of experiments, these investigators found that morbidly obese individuals have elevated UBP which decreases with weight loss. In these studies, the first UBP measurements were taken while the subjects were anesthetized and sedated before open gastric bypass and the second UBP measurement was taken one year later after the subjects lost an average of 50 kg. Urinary bladder pressure was measured using a manometric technique and a100 ml bladder instill volume. The UBP measurement before surgery was approximately 18 cm H_2O (13.5 mmHg) and fell to approximately 10 cm H_2O (7.4 mmHg) after weight loss a year later. Sanchez et al. (2001) also showed higher UBP values in obese subjects. Using data collected in 97 subject who participated in a multicenter-epidemiological study of the prevalence of IAH in CCUs throughout Europe, Malbrain et al. (2004) also found that obese subjects (BMI > 30 kg/m^2) were associated with IAH (UBP > 12 mmHg). More recently, Vasquez and associates (2007) measured UBP in 45 subjects in the supine position with different degrees of HOBE and found that at all positions studied, obese subjects (BMI >30 kg/m^2) had significantly higher UBP measurements than subjects who were overweight (BMI 25-29.99 kg/m^2) and normal weight (BMI 18.5- 24.99 kg/m^2).

The current study also found a positive relationship between UBP and net fluid balance. This is consistent with a recent report of Daugherty and colleagues (2007) who found IAH and ACS in medical subjects who had a NFB > five liters. The present findings are also consistent with other studies that have also reported a positive relationship between UBP and the amount or rate of fluid resuscitation (Balogh,

McKinley, Holcomb et al., 2003). Aggressive crystalloid administration is common in

patients admitted to CCUs because frequently hypotension due to sepsis or bleeding

occurs prior to admission. These patients are aggressively resuscitated early and

vigorously with intravenous crystalloid fluid administration and blood products such as

packed RBC transfusions as well as vasoactive agents. This strategy has been found to

decrease mortality with improvements in other clinical outcomes (Rivers et al., 2001) but

it is also associated with fluid overload (O'Mara et al., 2005) and the development of

ACS (Balogh, McKinley, Cocanour et al., 2003).

The multiple linear regression analysis discovered UBP to be inversely related to

LOS and EN. These results were unexpected and were not part of the a priori analysis,

but were detected in the post hoc analysis of the data. The LOS in this study ranged from

one to 50 days with an average of 4.8 ± 6.9 days. There are two possible explanations for

these findings. First, patients who require admission to CCUs frequently receive

aggressive fluid resuscitation that can lead to ascites and intestinal edema putting them at

higher risk for increased IAP (Balogh, McKinley, Cox et al., 2003). Likewise, patients

undergoing abdominal surgery or who have experienced abdominal trauma are at risk of

developing ACS and also develop IAH during the first 24 hours after admission to CCUs

which progressively decreases over time (Biancofiore et al., 2003).   Therefore, longer

LOS may be a marker of less severity. Second, LOS may be a marker for longer duration

of urinary bladder catheterization. De Waele (2006) observed that prolonged urinary

bladder catheterization was associated with higher UBP. A possible explanation for this

observation is that continuous drainage decreases bladder compliance thus resulting in

higher UBP. Hypocompliance of the urinary bladder has been observed in other patients

requiring prolong catheterization such as patients with spinal cord injury (Hackler, Hall, & Zampieri, 1989).

The inverse relationship of UBP and EN found in this study is compatible with the original hypothesis of the PI that UBP may be used as a predictor of enteral feeding tolerance. It indicates that the use of EN in the critically ill is linked to lower UBP. From this finding it can be inferred that high UBP values will be linked to enteral feeding intolerance. However, the study was not designed to enterally feed all subjects and it was not powered for this factor. Therefore, it is not possible to reach any conclusion regarding EN and UBP.

It should be pointed out that the predicative equations that that resulted from this study explained no more than 30% of the variability of UBP. Other factors that may contribute to UBP variability remain to be identified. The results of this study demonstrate that age, sex and ethnicity did not contribute to the variability of UBP. The lack of a relationship with age and gender with UBP has been observed by other investigators as well (Frezza, Shebani, Robertson, & Wachtel, 2007; Sanchez et al., 2001; Sugerman et al., 1997). Clinical factors that have been previously identified as potential contributors to UBP, such as mechanical ventilation and sedation were part of the a priori analysis of this study. Unfortunately, they could not be evaluated because very few subjects were recruited with these conditions. Other clinical indices that are measures of severity of illness, such as the APACHE or SOFA score may also be useful to explain some of the variability. In addition, the position of the transducer and other nursing factors related to the performance of UBP measurement, such as years of experience, knowledge and expertise in hydrostatic pressure measurements may also contribute to

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variability. Lastly, other factors such as the length, material and compliance of the

urinary catheter may contribute to some variability of UBP measurement.

Research Question 6: What are the Elements of an Evidenced based Protocol Necessary

for CCNs to Reliably Perform Bedside UBP Measurement?

The sixth and final research question aimed to identify the elements of an

evidenced based protocol necessary for CCNs to reliably perform bedside UBP

measurement based on the results of the study. The observations and recommendations

made below are based on the experience of the PI obtained during the study who

performed 498 UBP measurements in 120 subjects who were in one of four different

body positions and one of three bladder instill volumes. This is the largest data set for

UBP measurement for a single individual reported thus far. Vasquez and colleagues

(2007) reported 675 measurements on 45 subjects but each subject was measured 3 times

in five different positions to obtain an average UBP measurement for each position.

Therefore, statistically the data set is 225 UBP measurements. In addition, it is not clear

from their report if the data was obtained by the same person or if it was obtained by a

nurse, a physician or a technician. There were two other reports by Malbrain and

colleagues with 97 subjects (2004) and 265 subjects (2005), respectively. Both of these

studies were multi center studies and UBP was measured by different observers and it

was not clear if a standardized procedure was used.

UBP is a relatively simple technique that is within the scope of practice of most

CCNs. However, like other technical skills, nurses will need to acquire procedural

knowledge and technical skills to obtain reliable results. Several aspects of the bedside

process of UBP measurement include: subject position, bladder instill volume, pressure

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transducer position, equipment, education and training, and patient related variables. Each one of these will be discussed.

Subject position

The results of the present and other studies found that subject's position is one of the factors that affect UBP measurement. The WSACS recommends that UBP be measured in the supine-0°HOBE position only but a rationale for the exclusive use of this position is not given. Of all the body positions pertinent to the care of the critically ill patients that have been studied to date, the supine-0° HOBE position gives the lowest estimate of UBP and it is in principle a body position that is easy to standardize. In addition, this is a position that is used in laboratory studies by physicians but is not a position that is commonly used in critically ill patients. The supine-0° HOBE position is not common in CCU and changing patients to the supine position only for the purpose of measuring UBP is time consuming, and places patients at high risk for developing aspiration pneumonia and equipment dislodgment. Furthermore, there are patients who cannot assume this position because of pulmonary compromise. Therefore, it is important that an alternative body position be available for these patients. In this study UBP was assessed in four of the most common positions used in critical care. Based on the results of this study, the position that is best suited for UBP measurement is the supine-30º HOBE. The arguments in favor of this position are:

  a. The supine-30° HOBE is the standardized position favored in CCUs to reduce aspiration and ventilator associated pneumonia.

  b. The supine-30° HOBE allows patients to have UBP measurements taken in the most frequently used CCU position and will result in less UBP

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variability due to patient factors that may be caused by changes in

position. As a matter of fact, once patients have UBP measurements taken

in the supine-0º HOBE position they are returned to the more common and

usual supine-30° HOBE position which will result in a relatively higher

UBP.

c. The supine-30º HOBE position has intra- and inter-observer reliability

comparable with the supine-0º HOBE (Figure 24).

d. The supine-30º HOBE will permit EN administration and there is no need

to hold EN during the UBP measurement. Therefore, a higher delivery of

nutrients will be possible and is a goal in critically ill patients.

e. The supine-30º HOBE position will promote greater patient comfort.

f. The supine-30º HOBE position will decrease CCN nurse work load and

increase efficiency.

However, it is important to recognize that the supine-30º HOBE position results in

UBP measurements that are on average three to five mmHg higher than UBP

measurement taken in the supine-0º HOBE. This difference is large enough to warrant a

change in the definition of IAH and ACS. This means that the definition of IAH and the

grades of IAH will need to be revised upward if the supine-30º HOBE position is

accepted as a standard for UBP measurement.

Bladder Instill Volume

The results of this study demonstrate that the amount of NSS instilled into the

bladder before UBP measurement affects the absolute value and also the reliability of

UBP measurements. In general, the higher the bladder instill volume the higher the UBP, but UBP values are not always linear when position is considered. It should be pointed out that UBP does not increase as volume increases in certain positions, because of the volume-position interaction (Figure 18). Accepting the volume-position interaction, it is possible to find that a higher bladder instill volume may produce a lower UBP value. On average, lower UBP values were obtained with 0 ml and 25 ml bladder instill volumes as compared to 50 ml and 200 ml bladder instill volumes but each instill volume yielded reasonable results in selected subjects. However, the use of 0 ml bladder instill volumes resulted in negative UBP values. In subjects positioned in the supine-0° HOBE position negative UBP values were found 17.5 % of the time, while in subjects positioned in the supine-30° HOBE position rarely had negative UBP measurements (1.3 %). In addition, the intra- and inter-observer reliability was lower in the supine-30° HOBE position with a 0 ml volume as compared to the 25 ml instill volume. The use of a 200 ml instill volume was associated with higher UBP values, lower abdominal perfusion pressure (APP) values, and overestimation of IAH in both positions. Based on these considerations an instill volume > 0 and ≤ 25 ml produces UBP measurements with the higher reliability. Some investigators (De Waele et al., 2006) have recommended the use of bladder instill volumes as low as 10 ml for UBP measurement as this was the smallest volume that produced a positive oscillation test which is the generation of a waveform on the bedside monitor by manual palpation of the lower abdomen over the urinary bladder. However, this recommendation is not based on important physiological, clinical, or statistical principles but rather on a mechanical action and should not be used a criterion for selecting the best instill volume to use for UBP measurement.

Pressure Transducer Position

UBP is measured via a fluid filled catheter and is based on hydrostatic pressure principles. When properly assembled this system is capable of transmitting accurate pressure waveforms, but for quantitative assessment of pressure the fluid in the chamber of interest must be referenced to the fluid filled system. To accomplish this, the open end of the measuring catheter in the fluid filled chamber must be referenced to an external anatomic landmark and the system opened to atmospheric pressure to establish a common zero pressure reference. In this technique the only factor that determines the magnitude of the pressure of the chamber is the relationship of the transducer to the anatomic landmark. The height of the external transducer to the uppermost fluid level in the chamber in which the pressure is being measured determines the pressure. Therefore, UBP may be under- or over-estimated depending on the position of the pressure transducer to the level of fluid within the bladder. The optimal placement of the pressure transducer to measure UBPs is still unknown and was not investigated in the present study.

Traditionally the pressure transducer has been placed at the level of the symphysis pubis as was done in the present study. Recently, the WSACS recommended the pressure transducer be positioned at the intersection of the mid-axillary line and the iliac crest because these are anatomic landmarks that are easily identifiable. However, the WSACS has failed to produce data on how the UBP measurement would differ from the previous recommendation to use the symphysis pubis. It could be predicted that the proposed leveling of the transducer at the cross-section of the mid-axillary line at the iliac crest will

change as the position of the patient changes. In the supine-0° HOBE position there may

not be an error but in the supine-30° HOBE position and or the lateral positions

differences may be observed.

The symphysis pubis is also an easily identifiable anatomic landmark and is the

closest reference point to the bladder. The only difficulty of leveling the pressure

transducer to the symphysis pubis found in this study was in the very obese patient with a

large pannus. Therefore, until further data is forthcoming, the external transducer is to be

leveled and zeroed at the symphysis pubis, because it is theoretically the external

landmark most reflective of the urinary bladder.

Standardized Equipment

The procedure for measuring UBP has undergone several modifications since the

original description in 1984 by Kron and colleagues (1984). The latest modification of

this technique is the use of commercially available kits for UBP measurement. One of

the kits available is the AbViser™. This kit has all the necessary components to connect

the urinary drainage catheter to the external monitoring system. By using this kit the

potential for variability is reduced. Using the home-made "Jerry-rigged" set up for

measurement of UBP allows for additional errors in measurement. The only

disadvantage of using the AbViser™ kit is the cost but considering the cost and time

expended in assembling a home-made system and the multiple errors in measurement that

are possible the cost differential is acceptable. Furthermore, the possibility of infection

with the home-made kit is greater (Iberti et al., 1989).

Education and Training

Measurement of UBP by hydrostatic principles is similar to the technique of hemodynamic pressure measurements commonly performed in CCUs around the world. Thus, most experienced CCNs will have a basic understanding of the principles and mechanics of hydrostatic UBP measurements. However, the reliability of hemodynamic measurements taken by nurses is low and similar findings are to be expected when nurses measure UBP as well if they are not properly trained. This study showed a high intra- and inter-observer reliability between experienced CCNs. To minimize variability, nurses should undergo education, training, and supervision until they are proficient in UBP measurements and before independently measuring UBP. Based on the experience of this PI, 10-20 supervised measurements are required before a CCN would be consider proficient in UBP measurements.

Clinical Variables

All subjects were measured in Hill-Rom® total care beds. Subjects in beds that did not have a solid mattress and a mechanism to elevate the HOB at 30° were not selected for the study. Therefore, it was easy to standardize the position. Any patient who required an air or an air-fluid bed was excluded from the study.

The majority of urinary catheters were latex or silicone urinary drainage catheters manufactured by Bard®. Several subjects had catheters that were thermometric. The material of the catheter is important as the compliance of the plastic plays a role in the conductivity of the pressure from the bladder to the monitoring equipment, and a stiffer

and smaller caliber catheter may produce different results. The effect of the catheter material was not investigated in this study.

Limitations of the Study

The major limitation of the study was in subject recruitment. Unfortunately the very critically ill subjects who where ventilated and sedated were not accessible to the PI secondary to restrictions of patient privacy and access. Also very few minorities were enrolled. However, evaluating UBP in a critical care setting with subjects not at risk for IAH provides data that has not been reported before.

Another limitation of the study was that only selected bladder instill volumes were studied and limited to three volumes 25 ml, 50 ml and 200 ml. It would have been desirable to have subjects randomized to a 0 ml volume group. In addition, using an instill volume of 100 ml as opposed to 200 ml may have produced more interpretable and meaningful data.   The 200 ml instill volume clearly produced UBPs that were in excess, and exhibited extreme variability.

Future Research

The findings of this study are important and have many clinical implications for the bedside measurement of UBP in the critical care setting and also raise many other interesting research questions worthy of investigation by nurses.

1.) Prospective research studies are recommended to:

a.   Investigate the optimal position for placement of the pressure transducer.

b.   Re-define IAH and ACS using the supine-30° HOBE.

c. Use UBP as a predictor of enteral nutrition tolerance in critically ill patients.

d. Evaluate UBP measurement in other types of beds

e. Evaluate UBP measurement using different urinary bladder catheters to evaluate the effect of the catheter in transmitting wave forms.

2.) A longitudinal study is recommended to assess the diurnal variation of UBP.

Summary and Conclusion

UBP measurement is the gold standard technique for estimation of IAP in patients admitted to CCUs. Urinary bladder pressure is measured at the bedside by CCNs based on hydrostatic pressure principles using a modification of the technique originally described by Kron and colleagues (1984). Experts recommend that UBP be measured in most patients admitted to CCU to monitor the resuscitation efforts and to monitor for ACS (Malbrain et al., 2007). Urinary bladder pressure measurement is a responsibility that has been transitioned to the CCN. Therefore, it was important that the nursing process for UBP measurement be subjected to rigorous clinical testing before it becomes wide spread and avoids the pitfalls that have been associated with hemodynamic pressure monitoring (Dalen & Bone, 1996). In addition, if UBP is to be investigated as an objective measure of enteral feeding tolerance, the procedure and process of the UBP measurement technique must be reliable to insure consistent interpretation and clinical decisions. Otherwise, clinical decisions will be fraught with error.

A review of the literature revealed a lack of consensus for the optimal body position patients should assume when measuring UBP as well as the amount of bladder instill volume needed for UBP measurement. The current research was undertaken to

answer five questions related to body position, amount of instill volume, intra- and inter-observer reliability, and other factors that may influence UBP measurement in the CCUs. A sixth question was to describe the elements of an evidence based protocol necessary for reliable measurement of UBP. Answers to these questions are necessary if the application of UBP measurement as a tool for enteral feeding tolerance is to be investigated.

The findings of this study demonstrate that the effect of volume and position in UBP measurement is complex and there are significant interactions of body position and bladder instill volume on UBP measurement. In addition, it demonstrated that when this research protocol is followed, UBP measurements have high intra- and inter-reliability and are influenced by BMI, NFB, LOS, and EN; but not age or gender. The conclusions of this study are strengthened by the experimental design, the large heterogeneous sample size and by having all measurements performed by the same nurse observer. Utilizing the technique of UBP measurement investigated in this study, all future research can be comparable because the measurement of UBP will be standardized. The greatest contribution of this study is the provision of a common denominator for all future UBP research.

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Appendix A Subject screening, enrollment, and randomization log

Screening, Enrollment, Randomization Log

Date: _____   Time: _____

Location: Trauma   NICU   SICU   CCU   MICU

Initials FML	Date of Birth	Randomization Group	Medical Record Number

Preliminary Consent Signed:	NO	YES
Age: >18	NO	YES
Presence of Urinary Bladder Catheter:	NO	YES

Bladder perforation	YES	NO
Bladder tumor	YES	NO
Hematuria	YES	NO
Neurogenic bladder	YES	NO
Anuria	YES	NO
Pregnant	YES	NO
Unable to assume body positions	YES	NO

Eligible for study:	NO	YES

Study Number: _____

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Appendix B Data Collection Form

Subject Demographics					
Study Date			**Hospital LOS in days**		
Study ID #			**ICU LOS in days**		
Age			**Hospital ICU**		
Gender			**Enteral nutrition**	**Type**	**Rate**
Race			**MAP @ UBP**		

Randomization				
Study group (1-12)				
Instill volume		**25 ml**	**50 ml**	**200 ml**
Body position	**Supine-0º**	**Supine-30º**	**RL-30º**	**LL-30º**

UBP Measurements				
Measurement Set 1	**Supine-30° HOBE**	**0 ml @**		**25 ml @**
			AM/PM	**AM/PM**
PI	**MAP**		**mmHg**	**mmHg**
Measurement Set 2	**Randomized P & V**	**0 ml @**		**25, 50, 200 ml @**
			AM/PM	**AM/PM**
PI	**MAP**		**mmHg**	**mmHg**
Measurement Set 3	**Supine-30° HOBE**	**0 ml @**		**25 ml @**
			AM/PM	**AM/PM**
Nurse Co-investigator	**MAP**		**mmHg**	**mmHg**

Other Variables					
Usual weight		**ICU weight**		**Height**	
Net LOS fluid balance			**mls**		
Respiratory/ Ventilatory Status	**None**	**AC**	**SIMV**	**PS**	
	PEEP	**BiPAP**	**CPAP**		
Paralytic agents	**Name and dose:**				

Medical/ Surgical Diagnoses			
1.	6.		Notes:
2.	7.		
3.	8.		
4.	9.		
5.	10.		
Remarks:			

Appendix C: Progress Notes

Progress Notes

Allegheny General Hospital
Pittsburgh, Pennsylvania

ALLEGHENY
GENERAL HOSPITAL
WEST PENN ALLEGHENY HEALTH SYSTEM

IMPRINT PATIENT'S PLATE HERE

This patient was a subject in RC-3996 a study evaluating the Reliability of Urinary Bladder Pressure Measurement in Critical Care. **The UBP values below are the values obtained during the study.**

Urinary Bladder Pressure Measurements (UBPM)

First Set of UBPM		Second Set of UBPM		Third Set of UBPM	
Subject Position	**Bladder Instill Volume**	**Subject Randomization Position**	**Randomized Bladder Instill Volume**	**Subject Position**	**Bladder Instill Volume**
Supine 30° HOBE	0 ml ___ mmHg	Supine Flat	0 ml ___ mmHg	Supine 30° HOBE	0 ml ___ mmHg
	25 ml ___ mmHg	Supine 30° HOBE	25 ml ___ mmHg		25 ml ___ mmHg
		RL 30° HOBE	50 ml ___ mmHg		
		LL 30° HOBE	200 ml ___ mmHg		

HOBE = Head of Bed Elevation, RL = Right Lateral, LL = Left Lateral

*UBPM are provided for information only. The interpretation of these values is unknown at this time. These values are **not** meant to be used in isolation for clinical decision making at this time.*

Date and Time: _____

_____
Melanie Shuster, RN
Principal Investigator

301-20   Rev. 2/05-front

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Appendix D Informed Consent

Allegheny Singer Research Institute-Allegheny General Hospital

First informed consent: November 27, 2006

Duquesne University

First informed consent   February 2, 2007

Allegheny Singer Research Institute-Allegheny General Hospital

Second approval following ASRI-AGH annual review   September 19, 2007

Duquesne University

Review following ASRI-AGH annual review   February 2, 2007 date moved
to lower left corner

ALLEGHENY
GENERAL HOSPITAL

Title of the Document:	Informed Consent Form

RC Number and Title:	3996 Reliability of Urinary Bladder Pressure Measurement in Critical Care

Principal Investigator:	Melanie Shuster, RN

Department:	Allegheny Center for Digestive Health, Allegheny Specialty Practice Network Department of Medicine, Allegheny General Hospital

Introduction: You are invited to participate in a research study because you are in an adult intensive care unit (ICU) at Allegheny General Hospital and require very careful monitoring of your body's functions. In the ICU it is very common to place a number of different wires on your skin and tubes in your veins, arteries, and urinary bladder to monitor your heart, blood pressure and kidney functions. These measurements are made so your doctors and nurses can treat you the best way possible.

Catheters placed in your bladder are used primarily to collect urine which monitors kidney function. The same catheter can also be used to measure the pressure within the urinary bladder, which is an indirect measure of the pressure inside the whole abdomen. Physicians like to monitor their patient's bladder pressures because high values are linked to kidney, lung, liver and intestine failures, which in turn may result in a prolonged and more difficult hospitalization. To measure bladder pressure, one end of a small plastic valve is attached to the urinary catheter outside the patient's body using sterile technique (very clean and aseptic technique) and the other end is connected to the hospital's monitoring equipment. In addition a small amount of sterile salt water is added to the bladder moments before the measurement is taken. This process is very safe, painless and takes 2- 5 minutes to complete.

Purpose: This is a study that involves research and has four purposes. The first purpose is to find out how much sterile salt water needs to be added to the bladder before a urinary bladder pressure measurement can be made. Testing will be done to find out if differences in bladder pressures occur when 0, 1, 2, or 6 ounces of sterile salt water are added to the bladder before measurement. The second purpose is to find out if the subject's position can change the bladder pressure measurement. Most commonly urinary bladder pressure is measured with subjects lying flat on their back, but it would be important to know if the pressure can be measured accurately when subjects have the head of their bed elevated or when they are lying on their right or left side. The third purpose is to find out if there is close agreement when the same or a different nurse takes two pressure measurements within a short period. The fourth and last purpose is to find out if some subject or treatment-related factors can affect bladder pressure measurements.

Procedure: A total of 120 subjects will be recruited for the study. You will be randomized to one of the 12 groups. Randomization is like drawing straws and each

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subject has an equal chance of being placed in any one of the 12 groups. Each group will have 10 subjects. One of the doctors that are taking care of you will ask you to participate in the study. These doctors can be your primary care doctor (that is the doctor who took care of you prior to your admission to the hospital or the surgeon who did your operation) or one of the doctors who are experts in critical care that has been asked by your primary care doctor or surgeon to help take care of you while you are critically ill. Many of these doctors are co-investigators for this study along with Dr. Jorge A. Vazquez, medical nutritionist.

If you agree to participate in this study, your primary care doctor, your surgeon or the critical care doctors, will continue to provide you with the best care they believe necessary. In addition, one of these doctors will order the urinary bladder pressure measurement be taken according to the group you are assigned by the randomization process. You will have your urinary bladder pressure measured in one of the 12 possible and different ways. Eleven of the 12 groups will have 2 sets of bladder pressures measurements taken by Melanie Shuster, RN and 1 of the 12 groups will have 3 sets of bladder pressure measurements taken. The first 2 measurement sets by Melanie Shuster, RN and the third set by Tammy Haines, RN. One set of bladder pressure measurement consists of two measurements: one measurement taken before any sterile liquid (salt water) is added to the bladder and the other one is taken after a fixed amount of sterile liquid (salt water) is added to the bladder. All bladder pressure measurements will be taken within a 30 minute period.

To measure the urinary bladder pressure a small valve will be attached using sterile technique to your bladder catheter, which is outside your body, and this valve will also be attached to the hospital monitoring system. You will then be positioned in bed lying on your back with the head of the bed elevated to 30 degrees. A bladder pressure measurement will be taken by Melanie Shuster, RN when you are comfortable with no added sterile salt water in your bladder and again after twenty-five milliliters (about one ounce) of sterile salt water is added to your bladder. After the first set of measurements, Melanie Shuster, RN will reposition you to be either lying on your back with the head of the bed flat with a pillow under your head, or lying on your right or left side with the head of the bed elevated to 30 degrees with a pillow under your head and one pillow between your knees. Your back will be supported with a foam wedge and your head will be supported with a pillow under the right or left side of your face if you are lying on your side. These are usual positions patients normally assume while sleeping at home or while in ICU's. See the following pictures of the positions subjects will be placed in for the measurement of urinary bladder pressure.

The remainder of the page is left intentionally blank.

Table 1. Study groups for bladder instill volume and subject position

Group	Position	Instill Volume	Nurse
1		25 ml	Melanie Shuster, RN
5	See Above	50 ml	Melanie Shuster, RN
9	See Above	200ml	Melanie Shuster, RN
2		25 ml	Melanie Shuster, RN Tammy Haines, RN
6	See Above	50 ml	Melanie Shuster, RN
10	See Above	200 ml	Melanie Shuster, RN
3		25 ml	Melanie Shuster, RN
7	See Above Right Side Lying	50 ml	Melanie Shuster, RN
11	See Above Right Side Lying	200 ml	Melanie Shuster, RN
4	Same as above Left Side Lying	25 ml	Melanie Shuster, RN
8	Same as above Left Side Lying	50 ml	Melanie Shuster, RN
12	Same as above Left Side Lying	200 ml	Melanie Shuster, RN

Once you are comfortable and settled in the next position, another set of bladder pressure measurements will be taken by Melanie Shuster, RN. The first measurement will be taken before any sterile salt water is added to the bladder and the other measurement will be taken after approximately 1, 2, or 6 ounces of sterile salt water is added to your bladder. You will receive only one of the 3 amounts of sterile salt water listed above and you will assume only one of the 4 positions shown above. You will only be in this position for just as long as necessary to complete the two sets of urinary bladder pressure measurements.

If you are one of the 10 subjects assigned to group 4, (see shaded area in Table 1) you will have 3 sets of bladder pressure measurements taken. You will be kept in bed lying on your back with the head of bed elevated to 30 degrees for all 3 sets of bladder pressure measurements. The third set of bladder pressure measurements will be taken by Tammy Haines, RN.

Each set of measurements takes two to five minutes and the whole study will be done in 30 minutes or less. All the measurements will be taken on the same day and will not be repeated again regardless of how long you stay in the ICU. After all measurements are completed, Melanie Shuster, RN or Tammy Haines, RN will reposition you to the most comfortable position for you.

Your hospital record will be reviewed and your date of birth, date of hospital admission, reason for hospital admission, and the type of treatment you received will be recorded on a separate piece of paper. All information taken from your record will be kept confidential and you will not be identified on this piece paper.

This is an observational study and no further diagnostic or therapeutic treatment is planned as part of the study regardless of the value of the urinary bladder pressure measurement. However, the values of the urinary bladder pressure will be made available to your primary care physician and the critical care team physicians. They will decide if additional testing or treatments are necessary which will be outside of the study protocol.

The remainder of this page left intentionally blank.

Risks: The risks for participating in this study are minimal. You will receive routine care as necessary for your medical or surgical condition and participating in this study will not delay or alter your treatments in any way. The placement of the urinary bladder catheter is considered a standard of care for nearly anyone in the ICU. Bladder pressure is measured in selective subjects admitted to ICU's at Allegheny General Hospital and is routinely measured in many other hospitals in the United States and Europe. The bladder pressure will be measured using a Federal Drug Agency (FDA) approved device called the AbViser™ that is placed very carefully on the outside end of the urinary bladder catheter while maintaining a sterile condition. Thus, there is a very small risk of developing a urinary tract or other infection because it is necessary to open the urinary catheter drainage system for a brief moment when attaching this device, but the attaching the device will be done under sterile conditions. Urinary bladder pressure measurement is painless and quick; each set of measurements takes two-five minutes to complete. There may be a temporary physical discomfort when you are positioned into one of the four positions for measurement and a small chance that medical equipment will get disconnected. However, most ICU patients are placed in these positions for routine nursing care at some time during a 24-hour period and every precaution will be taken to prevent these problems. There is no anticipated physical, metabolic, social, psychological, legal, or financial risk associated with participation in the study.

This is an observational study and no further diagnostic or therapeutic treatment is planned as part of the study regardless of the value of the UBP measurement. However, the values of the urinary bladder pressure will be made available to your primary care physician and the critical care team physicians. They will decide if additional testing or treatments are necessary which will be outside of the study protocol.

There is a very small but real risk of losing confidentiality. Your medical record will be reviewed to extract only the information needed to complete the study. A separate piece of paper will be created to keep the information that is gathered during the study. To minimize the risks of losing confidentiality the people reviewing your medical record will be limited to the principal investigator. The least amount of information needed for the completion of the study will be collected. A study specific identification number will be assigned to you at the beginning of the study and most personal or confidential data such as your social security number, home address, telephone number, insurance information that could identify you will **not** be collected.

Common risks (Incidence >10%)	Less Common Risks (Incidence >1%-<10%)	Rare Risks (Incidence < 1%)
Minor risks: • None *Severe risks:* • None	*Minor risks:* • ***None*** *Severe risks:* • None	*Minor risks:* ▪ Urinary tract infection

Benefits: There are no immediate direct benefits to you by participating in this study although the information obtained may be of benefit to other patients in similar conditions in the future. You may benefit immediately because you will be monitored more intensively than other patients

in the ICU. All information gathered by, the researcher will be available to the primary care physician and critical care team.

Alternative procedures: You may choose not to participate in this study.

Costs and Payments: The cost of routine medical care provided to you while in the ICU will be billed to your medical insurance. Participating in this study will not increase the cost of your ICU care. Neither you nor your insurance company will be billed for the costs of measuring the bladder pressure. The costs of the AbViser® device used to measure your bladder pressure will be paid for by funds provided through a grant or will be provided by the manufacturer. You will not receive payment for participation in this study.

Confidentiality: Information obtained about you as a result of participation in this study will be kept strictly confidential, however as with all medical records, they may be obtained with a court order. The research records that will be created for this study will be kept separately and are not part of your hospital medical record. Your identity, medical records, and data related to this study will be kept confidential, except as required by law and except for inspections by the Food and Drug Administration (FDA) and the Institutional Review Board of Allegheny General Hospital (the committee that oversees research). Results of the research may be published or presented to scientific groups, however, your identity will not be revealed.

Compensation: You have been informed and acknowledge that in the event of your voluntary participation in this research protocol results in the need for you to receive medical care, that no money or free medical care will be made available to you by Allegheny General Hospital or Allegheny-Singer Research Institute.

Research Study Authorization of Protected Health Information & HIPAA Authorization:

In 1996 the government passed a law known as The Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-191. This law, among other things will improve how your health care information is protected and kept confidential when it is shared with others. This includes your medical records and insurance information as well as other personal health information. It also assures that everyone who shares this information will have to follow this law. This consent form describes to you how information about you may be used or shared if you are in a research study. It is important that you read this carefully.

In order to participate in this research study, you must permit (allow) certain research records to be made about you in addition to the usual records the hospital and doctors create about your medical treatment. These research records will contain private medical and other information, which is protected by law. The researchers will only create the minimum amount of research records necessary to carry out the research.

Type(s) of research records that may be shared is (are):
- ☐ Tissue Samples:
- **X   Medical Records: Medical and surgical history, medication history**
- ☐ Lab Results:
- ☐ Other:

In addition to using these research records to carry out the research and, perhaps, to treat you, the researchers will share portions of these research records to third parties involved in the research study. The third parties, who receive research information, may further share the information

about you in accordance with their policies, practices and what the law requires. However, some third parties (such as the Sponsor) may not need to follow the HIPAA law. To the best of our knowledge, a complete and accurate description of who the third parties are and how they will use or share the information are as follows:

THIRD PARTY	PURPOSE
Allegheny General Hospital Allegheny-Singer Research Institute	May share this signed consent form and records that identify you to meet regulatory requirements or for purposes related to this research.

The release of information described above will be the minimum necessary to abide by the law complete the research, and, perhaps, publish the research.

Unlike your medical records, you will not have access to research records made about you. Although every effort will be made to keep research records about you private, complete confidentiality cannot be guaranteed. Such research records may be subject to subpoena or court order. The researcher has set up safeguards to keep private information about you confidential.

There is no expiration for this Authorization unless you revoke (cancel) it. You may revoke this Authorization by writing to the Principal Investigator. If you revoke your Authorization, you will also be removed from the study. Revoking your Authorization only affects the use and sharing of your information after the written request is received. Any information obtained prior to receiving the written request, may be used to maintain integrity of the study.

Principal Investigator Address: Melanie Shuster, RN
Allegheny Center for Digestive Health
1307 Federal Street, Suite 301
Pittsburgh, PA 15212

If you choose to not sign this Authorization, you will not be permitted to participate in this research study. In order to participate in this study, you must agree to share your information with the groups above. Upon completion of the study, or if you withdraw from the study at any time, the research records about you will be kept by the researcher (s) and all of the information provided above will continue to apply to your research records.

You give permission that your research records can be used and disclosed as described.

Voluntary Participation/Right to Withdraw: Participation is voluntary, and refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You are free to refuse to participate in this study. If you agree to participate, you are also free to withdraw from the study at any time. Your decision to refuse to participate or to withdraw from the study will not adversely affect your care at this hospital.

Inquires: If you should you have any questions regarding your rights as a research participant, you may contact the Institutional Review Board of Allegheny General Hospital at 412.359.3156. Any questions about the research have been answered or will be answered to your satisfaction by Melanie Shuster, RN, at (412) 359-8958. If you have any additional questions about the research you may contact the Investigators or the IRB Office (412) 359-3156. In the event of a research-related injury, you should -contact Melanie Shuster, RN at (412) 359-8958.

Recruitment: The investigator is committed to comply with the basic principles of the NIH guidelines on inclusion of women and minorities in research and will make every effort to enroll subjects into the study from all minority groups. You will receive a signed copy of this consent form.

Subject's Name   _____ Date _____
(Please Print)

Subject's Signature   _____ Date _____
Surrogate Decision
Maker's Signature   _____ Date _____
(If Applicable)

Witness' Signature   _____ Date _____

Investigator's Signature _____ Date _____

ALLEGHENY GENERAL HOSPITAL

WEST PENN ALLEGHENY HEALTH SYSTEM

Title of the Document: Informed Consent Form

RC Number and Title: 3996 Reliability of Urinary Bladder Pressure Measurement in Critical Care

Principal Investigator: Melanie Shuster, RN

Department: Allegheny Center for Digestive Health, Allegheny Specialty Practice Network Department of Medicine, Allegheny General Hospital

Introduction: You are invited to participate in a research study because you are in an adult intensive care unit (ICU) at Allegheny General Hospital and require very careful monitoring of your body's functions. In the ICU it is very common to place a number of different wires on your skin and tubes in your veins, arteries, and urinary bladder to monitor your heart, blood pressure and kidney functions. These measurements are made so your doctors and nurses can treat you the best way possible.

Catheters placed in your bladder are used primarily to collect urine which monitors kidney function. The same catheter can also be used to measure the pressure within the urinary bladder, which is an indirect measure of the pressure inside the whole abdomen. Physicians like to monitor their patient's bladder pressures because high values are linked to kidney, lung, liver and intestine failures, which in turn may result in a prolonged and more difficult hospitalization. To measure bladder pressure, one end of a small plastic valve is attached to the urinary catheter outside the patient's body using sterile technique (very clean and aseptic technique) and the other end is connected to the hospital's monitoring equipment. In addition a small amount of sterile salt water is added to the bladder moments before the measurement is taken. This process is very safe, painless and takes 2- 5 minutes to complete.

Purpose: This is a study that involves research and has four purposes. The first purpose is to find out how much sterile salt water needs to be added to the bladder before a urinary bladder pressure measurement can be made. Testing will be done to find out if differences in bladder pressures occur when 0, 1, 2, or 6 ounces of sterile salt water are added to the bladder before measurement. The second purpose is to find out if the subject's position can change the bladder pressure measurement. Most commonly urinary bladder pressure is measured with subjects lying flat on their back, but it would be important to know if the pressure can be measured accurately when subjects have the head of their bed elevated or when they are lying on their right or left side. The third purpose is to find out if there is close agreement when the same or a different nurse takes two pressure measurements within a short period. The fourth and last purpose is to find out if some subject or treatment-related factors can affect bladder pressure measurements.

Procedure: A total of 120 subjects will be recruited for the study. You will be randomized to one of the 12 groups. Randomization is like drawing straws and each

subject has an equal chance of being placed in any one of the 12 groups. Each group will have 10 subjects. One of the doctors that are taking care of you will ask you to participate in the study. These doctors can be your primary care doctor (that is the doctor who took care of you prior to your admission to the hospital or the surgeon who did your operation) or one of the doctors who are experts in critical care that has been asked by your primary care doctor or surgeon to help take care of you while you are critically ill. Many of these doctors are co-investigators for this study along with Dr. Jorge A. Vazquez, medical nutritionist.

If you agree to participate in this study, your primary care doctor, your surgeon or the critical care doctors, will continue to provide you with the best care they believe necessary. In addition, one of these doctors will order the urinary bladder pressure measurement be taken according to the group you are assigned by the randomization process. You will have your urinary bladder pressure measured in one of the 12 possible and different ways. Eleven of the 12 groups will have 2 sets of bladder pressures measurements taken by Melanie Shuster, RN and 1 of the 12 groups will have 3 sets of bladder pressure measurements taken. The first 2 measurement sets by Melanie Shuster, RN and the third set by Tammy Haines, RN. One set of bladder pressure measurement consists of two measurements: one measurement taken before any sterile liquid (salt water) is added to the bladder and the other one is taken after a fixed amount of sterile liquid (salt water) is added to the bladder. All bladder pressure measurements will be taken within a 30 minute period.

To measure the urinary bladder pressure a small valve will be attached using sterile technique to your bladder catheter, which is outside your body, and this valve will also be attached to the hospital monitoring system. You will then be positioned in bed lying on your back with the head of the bed elevated to 30 degrees. A bladder pressure measurement will be taken by Melanie Shuster, RN when you are comfortable with no added sterile salt water in your bladder and again after twenty-five milliliters (about one ounce) of sterile salt water is added to your bladder. After the first set of measurements, Melanie Shuster, RN will reposition you to be either lying on your back with the head of the bed flat with a pillow under your head, or lying on your right or left side with the head of the bed elevated to 30 degrees with a pillow under your head and one pillow between your knees. Your back will be supported with a foam wedge and your head will be supported with a pillow under the right or left side of your face if you are lying on your side. These are usual positions patients normally assume while sleeping at home or while in ICU's. See the following pictures of the positions subjects will be placed in for the measurement of urinary bladder pressure.

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Table 1. Study groups for bladder instill volume and subject position

Group	Position	Instill Volume	Nurse
1		25 ml	Melanie Shuster, RN
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2		2ml	Melanie Shuster, RN Tammy Haines, RN
6	See Above	50 ml	Melanie Shuster, RN
10	See Above	200 ml	Melanie Shuster, RN
3		25 ml	Melanie Shuster, RN
7	See Above Right Side Lying	50 ml	Melanie Shuster, RN
11	See Above Right Side Lying	200 ml	Melanie Shuster, RN
4	Same as above Left Side Lying	25 ml	Melanie Shuster, RN
8	Same as above Left Side Lying	50 ml	Melanie Shuster, RN
12	Same as above Left Side Lying	200 ml	Melanie Shuster, RN

Once you are comfortable and settled in the next position, another set of bladder pressure measurements will be taken by Melanie Shuster, RN. The first measurement will be taken before any sterile salt water is added to the bladder and the other measurement will be taken after approximately 1, 2, or 6 ounces of sterile salt water is added to your bladder. You will receive only one of the 3 amounts of sterile salt water listed above and you will assume only one of the 4 positions shown above. You will only be in this position for just as long as necessary to complete the two sets of urinary bladder pressure measurements.

If you are one of the 10 subjects assigned to group 4, (see shaded area in Table 1) you will have 3 sets of bladder pressure measurements taken. You will be kept in bed lying on your back with the head of bed elevated to 30 degrees for all 3 sets of bladder pressure measurements. The third set of bladder pressure measurements will be taken by Tammy Haines, RN.

Each set of measurements takes two to five minutes and the whole study will be done in 30 minutes or less. All the measurements will be taken on the same day and will not be repeated again regardless of how long you stay in the ICU. After all measurements are completed, Melanie Shuster, RN or Tammy Haines, RN will reposition you to the most comfortable position for you.

Your hospital record will be reviewed and your date of birth, date of hospital admission, reason for hospital admission, and the type of treatment you received will be recorded on a separate piece of paper. All information taken from your record will be kept confidential and you will not be identified on this piece paper.

This is an observational study and no further diagnostic or therapeutic treatment is planned as part of the study regardless of the value of the urinary bladder pressure measurement. However, the values of the urinary bladder pressure will be made available to your primary care physician and the critical care team physicians. They will decide if additional testing or treatments are necessary which will be outside of the study protocol.

The remainder of this page left intentionally blank.

Risks: The risks for participating in this study are minimal. You will receive routine care as necessary for your medical or surgical condition and participating in this study will not delay or alter your treatments in any way. The placement of the urinary bladder catheter is considered a standard of care for nearly anyone in the ICU. Bladder pressure is measured in selective subjects admitted to ICU's at Allegheny General Hospital and is routinely measured in many other hospitals in the United States and Europe. The bladder pressure will be measured using a Federal Drug Agency (FDA) approved device called the AbViser™ that is placed very carefully on the outside end of the urinary bladder catheter while maintaining a sterile condition. Thus, there is a very small risk of developing a urinary tract or other infection because it is necessary to open the urinary catheter drainage system for a brief moment when attaching this device, but the attaching the device will be done under sterile conditions. Urinary bladder pressure measurement is painless and quick; each set of measurements takes two-five minutes to complete. There may be a temporary physical discomfort when you are positioned into one of the four positions for measurement and a small chance that medical equipment will get disconnected. However, most ICU patients are placed in these positions for routine nursing care at some time during a 24-hour period and every precaution will be taken to prevent these problems. There is no anticipated physical, metabolic, social, psychological, legal, or financial risk associated with participation in the study.

This is an observational study and no further diagnostic or therapeutic treatment is planned as part of the study regardless of the value of the UBP measurement. However, the values of the urinary bladder pressure will be made available to your primary care physician and the critical care team physicians. They will decide if additional testing or treatments are necessary which will be outside of the study protocol.

There is a very small but real risk of losing confidentiality. Your medical record will be reviewed to extract only the information needed to complete the study. A separate piece of paper will be created to keep the information that is gathered during the study. To minimize the risks of losing confidentiality the people reviewing your medical record will be limited to the principal investigator. The least amount of information needed for the completion of the study will be collected. A study specific identification number will be assigned to you at the beginning of the study and most personal or confidential data such as your social security number, home address, telephone number, insurance information that could identify you will **not** be collected.

Common risks (Incidence $\geq$10%)	Less Common Risks (Incidence >1%-<10%)	Rare Risks (Incidence $\leq$ 1%)
Minor risks: • None *Severe risks:* • None	*Minor risks:* • ***None*** *Severe risks:* • None	*Minor risks:* ▪ Urinary tract infection

Benefits: There are no immediate direct benefits to you by participating in this study although the information obtained may be of benefit to other patients in similar conditions in the future. You may benefit immediately because you will be monitored more intensively than other patients

in the ICU. All information gathered by, the researcher will be available to the primary care physician and critical care team.

Alternative procedures: You may choose not to participate in this study.

Costs and Payments: The cost of routine medical care provided to you while in the ICU will be billed to your medical insurance. Participating in this study will not increase the cost of your ICU care. Neither you nor your insurance company will be billed for the costs of measuring the bladder pressure. The costs of the AbViser® device used to measure your bladder pressure will be paid for by funds provided through a grant or will be provided by the manufacturer. You will not receive payment for participation in this study.

Confidentiality: Information obtained about you as a result of participation in this study will be kept strictly confidential, however as with all medical records, they may be obtained with a court order. The research records that will be created for this study will be kept separately and are not part of your hospital medical record. Your identity, medical records, and data related to this study will be kept confidential, except as required by law and except for inspections by the Food and Drug Administration (FDA) and the Institutional Review Board of Allegheny General Hospital (the committee that oversees research). Results of the research may be published or presented to scientific groups, however, your identity will not be revealed.

Compensation: You have been informed and acknowledge that in the event of your voluntary participation in this research protocol results in the need for you to receive medical care, that no money or free medical care will be made available to you by Allegheny General Hospital or Allegheny-Singer Research Institute.

Research Study Authorization of Protected Health Information & HIPAA Authorization:

In 1996 the government passed a law known as The Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-191. This law, among other things will improve how your health care information is protected and kept confidential when it is shared with others. This includes your medical records and insurance information as well as other personal health information. It also assures that everyone who shares this information will have to follow this law. This consent form describes to you how information about you may be used or shared if you are in a research study. It is important that you read this carefully.

In order to participate in this research study, you must permit (allow) certain research records to be made about you in addition to the usual records the hospital and doctors create about your medical treatment. These research records will contain private medical and other information, which is protected by law. The researchers will only create the minimum amount of research records necessary to carry out the research.

Type(s) of research records that may be shared is (are):
- ☐ Tissue Samples:
- **X   Medical Records: Medical and surgical history, medication history**
- ☐ Lab Results:
- ☐ Other:

In addition to using these research records to carry out the research and, perhaps, to treat you, the researchers will share portions of these research records to third parties involved in the research study. The third parties, who receive research information, may further share the information

about you in accordance with their policies, practices and what the law requires. However, some third parties (such as the Sponsor) may not need to follow the HIPAA law. To the best of our knowledge, a complete and accurate description of who the third parties are and how they will use or share the information are as follows:

THIRD PARTY	PURPOSE
Allegheny General Hospital Allegheny-Singer Research Institute	May share this signed consent form and records that identify you to meet regulatory requirements or for purposes related to this research.

The release of information described above will be the minimum necessary to abide by the law complete the research, and, perhaps, publish the research.

Unlike your medical records, you will not have access to research records made about you. Although every effort will be made to keep research records about you private, complete confidentiality cannot be guaranteed. Such research records may be subject to subpoena or court order. The researcher has set up safeguards to keep private information about you confidential.

There is no expiration for this Authorization unless you revoke (cancel) it. You may revoke this Authorization by writing to the Principal Investigator. If you revoke your Authorization, you will also be removed from the study. Revoking your Authorization only affects the use and sharing of your information after the written request is received. Any information obtained prior to receiving the written request, may be used to maintain integrity of the study.

Principal Investigator Address: Melanie Shuster, RN
Allegheny Center for Digestive Health
1307 Federal Street, Suite 301
Pittsburgh, PA 15212

If you choose to not sign this Authorization, you will not be permitted to participate in this research study. In order to participate in this study, you must agree to share your information with the groups above. Upon completion of the study, or if you withdraw from the study at any time, the research records about you will be kept by the researcher (s) and all of the information provided above will continue to apply to your research records.

You give permission that your research records can be used and disclosed as described.

Voluntary Participation/Right to Withdraw: Participation is voluntary, and refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.   You are free to refuse to participate in this study. If you agree to participate, you are also free to withdraw from the study at any time. Your decision to refuse to   participate or to withdraw from the study will not adversely affect your care at this hospital.

Inquires: If you should you have any questions regarding your rights as a research participant, you may contact the Institutional Review Board of Allegheny General Hospital at 412.359.3156. Any questions about the research have been answered or will be answered to your satisfaction by Melanie Shuster, RN, at (412) 359-8958. If you have any additional questions about the research you may contact the Investigators or the IRB Office (412) 359-3156. In the event of a research-related injury, you should -contact Melanie Shuster, RN at (412) 359-8958.

Recruitment: The investigator is committed to comply with the basic principles of the NIH guidelines on inclusion of women and minorities in research and will make every effort to enroll subjects into the study from all minority groups. You will receive a signed copy of this consent form.

Subject's Name _____ Date _____
(Please Print)

Subject's Signature _____ _____ Date _____
Surrogate Decision
Maker's Signature _____ Date _____
(If Applicable)

Witness' Signature _____ Date _____

Investigator's Signature _____ Date _____

ALLEGHENY
GENERAL HOSPITAL

WEST PENN ALLEGHENY HEALTH SYSTEM

Title of the Document: Informed Consent Form

RC Number and Title: 3996   Reliability of Urinary Bladder Pressure
Measurement in Critical Care

Principal Investigator: Melanie Shuster, RN

Department: Allegheny Center for Digestive Health,
Allegheny Specialty Practice Network
Department of Medicine, Allegheny General Hospital

Introduction: You are invited to participate in a research study because you are in an adult intensive care unit (ICU) at Allegheny General Hospital and require very careful monitoring of your body's functions. In the ICU it is very common to place a number of different wires on your skin and tubes in your veins, arteries, and urinary bladder to monitor your heart, blood pressure and kidney functions. These measurements are made so your doctors and nurses can treat you the best way possible.

Catheters placed in your bladder are used primarily to collect urine which monitors kidney function. The same catheter can also be used to measure the pressure within the urinary bladder, which is an indirect measure of the pressure inside the whole abdomen. Physicians like to monitor their patient's bladder pressures because high values are linked to kidney, lung, liver and intestine failures, which in turn may result in a prolonged and more difficult hospitalization. To measure bladder pressure, one end of a small plastic valve is attached to the urinary catheter outside the patient's body using sterile technique (very clean and aseptic technique) and the other end is connected to the hospital's monitoring equipment. In addition a small amount of sterile salt water is added to the bladder moments before the measurement is taken. This process is very safe, painless and takes 2- 5 minutes to complete.

Purpose: This is a study that involves research and has four purposes. The first purpose is to find out how much sterile salt water needs to be added to the bladder before a urinary bladder pressure measurement can be made. Testing will be done to find out if differences in bladder pressure occurs when 0, 1, 2, or 6 ounces of sterile salt water are added to the bladder before measurement. The second purpose is to find out if the subject's position can change the bladder pressure measurement. Most commonly urinary bladder pressure is measured with subjects lying flat on their back, but it would be important to know if the pressure can be measured accurately when subjects have the head of the bed elevated or when they are lying on their right or left side. The third purpose is to find out if there is close agreement when the same or a different nurse takes two pressure measurements within a short period. The fourth and last purpose is to find out if some subject or treatment-related factors can affect bladder pressure measurements.

Procedure: A total of 120 subjects will be recruited for the study. You will be randomized to one of the 12 groups. Randomization is like drawing straws and each

subject has an equal chance of being placed in any one of the 12 groups. Each group will have 10 subjects. One of the doctors that are taking care of you will ask you to participate in the study. These doctors can be your primary care doctor (that is the doctor who took care of you prior to your admission to the hospital or the surgeon who did your operation) or one of the doctors who are experts in critical care that has been asked by your primary care doctor or surgeon to help take care of you while you are critically ill. Many of these doctors are co-investigators for this study along with Dr. Jorge A. Vazquez, medical nutritionist.

If you agree to participate in this study, your primary care doctor, your surgeon or the critical care doctors, will continue to provide you with the best care they believe necessary. In addition, one of these doctors will order the urinary bladder pressure measurement be taken according to the group you are assigned by the randomization process. You will have your urinary bladder pressure measured in one of the 12 possible and different ways. Eleven of the 12 groups will have 2 sets of bladder pressures measurements taken by Melanie Shuster, RN and 1 of the 12 groups will have 3 sets of bladder pressure measurements taken. The first 2 measurement sets by Melanie Shuster, RN and the third set by Tammy Haines, RN. One set of bladder pressure measurement consists of two measurements: one measurement taken before any sterile liquid (salt water) is added to the bladder and the other one is taken after a fixed amount of sterile liquid (salt water) is added to the bladder. All bladder pressure measurements will be taken within a 30 minute period.

To measure the urinary bladder pressure a small valve will be attached using sterile technique to your bladder catheter, which is outside your body, and this valve will also be attached to the hospital monitoring system. You will then be positioned in bed lying on your back with the head of the bed elevated to 30 degrees. A bladder pressure measurement will be taken by Melanie Shuster, RN when you are comfortable with no added sterile salt water in your bladder and again after twenty-five milliliters (about one ounce) of sterile salt water is added to your bladder. After the first set of measurements, Melanie Shuster, RN will reposition you to be either lying on your back with the head of the bed flat with a pillow under your head, or lying on your right or left side with the head of the bed elevated to 30 degrees with a pillow under your head and one pillow between your knees. Your back will be supported with a foam wedge and your head will be supported with a pillow under the right or left side of your face if you are lying on your side. These are usual positions patients normally assume while sleeping at home or while in ICU's. See the following pictures of the positions subjects will be placed in for the measurement of urinary bladder pressure.

The remainder of the page is left intentionally blank.

Table 1. Study groups for bladder instill volume and subject position

Group	Position	Instill Volume	Nurse
1		25 ml	Melanie Shuster, RN
5	See Above	50 ml	Melanie Shuster, RN
9	See Above	200ml	Melanie Shuster, RN
2		25 ml	Melanie Shuster, RN Tammy Haines, RN
6	See Above	50 ml	Melanie Shuster, RN
10	See Above	200 ml	Melanie Shuster, RN
3		25 ml	Melanie Shuster, RN
7	See Above Right Side Lying	50 ml	Melanie Shuster, RN
11	See Above Right Side Lying	200 ml	Melanie Shuster, RN
4	Same as above Left Side Lying	25 ml	Melanie Shuster, RN
8	Same as above Left Side Lying	50 ml	Melanie Shuster, RN
12	Same as above Left Side Lying	200 ml	Melanie Shuster, RN

Once you are comfortable and settled in the next position, another set of bladder pressure measurements will be taken by Melanie Shuster, RN. The first measurement will be taken before any sterile salt water is added to the bladder and the other measurement will be taken after approximately 1, 2, or 6 ounces of sterile salt water is added to your bladder. You will receive only one of the 3 amounts of sterile salt water listed above and you will assume only one of the 4 positions shown above. You will only be in this position for just as long as necessary to complete the two sets of urinary bladder pressure measurements.

If you are one of the 10 subjects assigned to group 4, (see shaded area in Table 1) you will have 3 sets of bladder pressure measurements taken. You will be kept in bed lying on your back with the head of bed elevated to 30 degrees for all 3 sets of bladder pressure measurements. The third set of bladder pressure measurements will be taken by Tammy Haines, RN.

Each set of measurements takes two to five minutes and the whole study will be done in 30 minutes or less. All the measurements will be taken on the same day and will not be repeated again regardless of how long you stay in the ICU. After all measurements are completed, Melanie Shuster, RN or Tammy Haines, RN will reposition you to the most comfortable position for you.

Your hospital record will be reviewed and your date of birth, date of hospital admission, reason for hospital admission, and the type of treatment you received will be recorded on a separate piece of paper. All information taken from your record will be kept confidential and you will not be identified on this piece paper.

This is an observational study and no further diagnostic or therapeutic treatment is planned as part of the study regardless of the value of the urinary bladder pressure measurement. However, the values of the urinary bladder pressure will be made available to your primary care physician and the critical care team physicians. They will decide if additional testing or treatments are necessary which will be outside of the study protocol.

The remainder of this page left intentionally blank.

Risks: The risks for participating in this study are minimal. You will receive routine care as necessary for your medical or surgical condition and participating in this study will not delay or alter your treatments in any way. The placement of the urinary bladder catheter is considered a standard of care for nearly anyone in the ICU. Bladder pressure is measured in selective subjects admitted to ICU's at Allegheny General Hospital and is routinely measured in many other hospitals in the United States and Europe. The bladder pressure will be measured using a Federal Drug Agency (FDA) approved device called the AbViser™ that is placed very carefully on the outside end of the urinary bladder catheter while maintaining a sterile condition. Thus, there is a very small risk of developing a urinary tract or other infection because it is necessary to open the urinary catheter drainage system for a brief moment when attaching this device, but the attaching the device will be done under sterile conditions. Urinary bladder pressure measurement is painless and quick; each set of measurements takes two-five minutes to complete. There may be a temporary physical discomfort when you are positioned into one of the four positions for measurement and a small chance that medical equipment will get disconnected. However, most ICU patients are placed in these positions for routine nursing care at some time during a 24-hour period and every precaution will be taken to prevent these problems. There is no anticipated physical, metabolic, social, psychological, legal, or financial risk associated with participation in the study.

This is an observational study and no further diagnostic or therapeutic treatment is planned as part of the study regardless of the value of the UBP measurement. However, the values of the urinary bladder pressure will be made available to your primary care physician and the critical care team physicians. They will decide if additional testing or treatments are necessary which will be outside of the study protocol.

There is a very small but real risk of losing confidentiality. Your medical record will be reviewed to extract only the information needed to complete the study. A separate piece of paper will be created to keep the information that is gathered during the study. To minimize the risks of losing confidentiality the people reviewing your medical record will be limited to the principal investigator. The least amount of information needed for the completion of the study will be collected. A study specific identification number will be assigned to you at the beginning of the study and most personal or confidential data such as your social security number, home address, telephone number, insurance information that could identify you will **not** be collected.

Benefits: There are no immediate direct benefits to you by participating in this study although the information obtained may be of benefit to other patients in similar conditions in the future. You may benefit immediately because you will be monitored more intensively than other patients in the ICU. All information gathered by, the researcher will be available to the primary care physician and critical care team.

Alternative procedures: You may choose not to participate in this study.

Costs and Payments: The cost of routine medical care provided to you while in the ICU will be billed to your medical insurance. Participating in this study will not increase the cost of your ICU care. Neither you nor your insurance company will be billed for the costs of measuring the bladder pressure. The costs of the AbViser® device used to measure your bladder pressure will be paid for by funds provided through a grant or will be provided by the manufacturer. You will not receive payment for participation in this study.

Confidentiality: Information obtained about you as a result of participation in this study will be kept strictly confidential, however as with all medical records, they may be obtained with a court order. The research records that will be created for this study will be kept separately and are not part of your hospital medical record. Your identity, medical records, and data related to this study will be kept confidential, except as required by law and except for inspections by the Food and Drug Administration (FDA) and the Institutional Review Board of Allegheny General Hospital (the committee that oversees research). Results of the research may be published or presented to scientific groups, however, your identity will not be revealed.

Compensation: You have been informed and acknowledge that in the event of your voluntary participation in this research protocol results in the need for you to receive medical care, that no money or free medical care will be made available to you by Allegheny General Hospital or Allegheny-Singer Research Institute.

Research Study Authorization of Protected Health Information & HIPAA Authorization:

In 1996 the government passed a law known as The Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-191. This law, among other things will improve how your health care information is protected and kept confidential when it is shared with others. This includes your medical records and insurance information as well as other personal health information. It also assures that everyone who shares this information will have to follow this law. This consent form describes to you how information about you may be used or shared if you are in a research study. It is important that you read this carefully.

In order to participate in this research study, you must permit (allow) certain research records to be made about you in addition to the usual records the hospital and doctors create about your medical treatment. These research records will contain private medical and other information, which is protected by law. The researchers will only create the minimum amount of research records necessary to carry out the research.

Type(s) of research records that may be shared is (are):
- ☐ Tissue Samples:
- **X Medical Records: Medical and surgical history, medication history**
- ☐ Lab Results:
- ☐ Other:

In addition to using these research records to carry out the research and, perhaps, to
treat you, the researchers will share portions of these research records to third parties involved in the research study. The third parties, who receive research information, may further share the information about you in accordance with their policies, practices and what the law requires. However, some third parties (such as the Sponsor) may not need to follow the HIPAA law. To the best of our knowledge, a complete and accurate description of who the third parties are and how they will use or share the information are as follows:

Third Party	Purpose
Allegheny General Hospital Allegheny-Singer Research Institute WPAHS Compliance Office	May share this signed consent form and records that identify you to meet regulatory requirements or for purposes related to this research.
Wolfe-Tory Medical, Inc.	Vendor of equipment used for the measurement of urinary bladder pressure and may need to verify the proper use of the device.

The release of information described above will be the minimum necessary to abide by the law complete the research, and, perhaps, publish the research.

Unlike your medical records, you will not have access to research records made about you. Although every effort will be made to keep research records about you private, complete confidentiality cannot be guaranteed. Such research records may be subject to subpoena or court order. The researcher has set up safeguards to keep private information about you confidential.

There is no expiration for this Authorization unless you revoke (cancel) it. You may revoke this Authorization by writing to the Principal Investigator. If you revoke your Authorization, you will also be removed from the study. Revoking your Authorization only affects the use and sharing of your information after the written request is received. Any information obtained prior to receiving the written request, may be used to maintain integrity of the study.

Principal Investigator Address: Melanie Shuster, RN
Allegheny Center for Digestive Health
1307 Federal Street, Suite 301
Pittsburgh, PA 15212

If you choose to not sign this Authorization, you will not be permitted to participate in this research study. In order to participate in this study, you must agree to share your information with the groups above. Upon completion of the study, or if you withdraw from the study at any time, the research records about you will be kept by the researcher (s) and all of the information provided above will continue to apply to your research records.

You give permission that your research records can be used and disclosed as described.

Voluntary Participation/Right to Withdraw: Participation is voluntary, and refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.   You are free to refuse to participate in this study. If you agree to participate, you are also free to withdraw from the study at any time. Your decision to refuse to participate or to withdraw from the study will not adversely affect your care at this hospital.

Inquires: If you should you have any questions regarding your rights as a research participant, you may contact the Institutional Review Board of Allegheny General Hospital at 412.359.3156. Any questions about the research have been answered or will be answered to your satisfaction by Melanie Shuster, RN, at (412) 359-8958. If you have any additional questions about the research you may contact the Investigators or the IRB Office (412) 359-3156. In the event of a research-related injury, you should contact Melanie Shuster, RN at (412) 359-8958.

Recruitment: The investigator is committed to comply with the basic principles of the NIH guidelines on inclusion of women and minorities in research and will make every effort to enroll subjects into the study from all minority groups. You will receive a signed copy of this consent form.

Subject's Name   _____ Date _____
(Please Print)

Subject's Signature   _____ Date _____
Surrogate Decision
Maker's Signature   _____ Date _____
(If Applicable)

Witness' Signature   _____ Date _____

Investigator's Signature _____ Date _____

**ALLEGHENY
GENERAL HOSPITAL**

WEST PENN ALLEGHENY HEALTH SYSTEM

320 EAST NORTH AVENUE, PITTSBURGH, PA 15212-4772

Title of the Document:	Informed Consent Form
RC Number and Title:	3996 Reliability of Urinary Bladder Pressure Measurement in Critical Care
Principal Investigator:	Melanie Shuster, RN
Department:	Allegheny Center for Digestive Health, Allegheny Specialty Practice Network Department of Medicine, Allegheny General Hospital

Introduction: You are invited to participate in a research study because you are in an adult intensive care unit (ICU) at Allegheny General Hospital and require very careful monitoring of your body's functions. In the ICU it is very common to place a number of different wires on your skin and tubes in your veins, arteries, and urinary bladder to monitor your heart, blood pressure and kidney functions. These measurements are made so your doctors and nurses can treat you the best way possible.

Catheters placed in your bladder are used primarily to collect urine which monitors kidney function. The same catheter can also be used to measure the pressure within the urinary bladder, which is an indirect measure of the pressure inside the whole abdomen. Physicians like to monitor their patient's bladder pressures because high values are linked to kidney, lung, liver and intestine failures, which in turn may result in a prolonged and more difficult hospitalization. To measure bladder pressure, one end of a small plastic valve is attached to the urinary catheter outside the patient's body using sterile technique (very clean and aseptic technique) and the other end is connected to the hospital's monitoring equipment. In addition a small amount of sterile salt water is added to the bladder moments before the measurement is taken. This process is very safe, painless and takes 2- 5 minutes to complete.

Purpose: This is a study that involves research and has four purposes. The first purpose is to find out how much sterile salt water needs to be added to the bladder before a urinary bladder pressure measurement can be made. Testing will be done to find out if differences in bladder pressure occurs when 0, 1, 2, or 6 ounces of sterile salt water are added to the bladder before measurement. The second purpose is to find out if the subject's position can change the bladder pressure measurement. Most commonly urinary bladder pressure is measured with subjects lying flat on their back, but it would be important to know if the pressure can be measured accurately when subjects have the head of the bed elevated or when they are lying on their right or left side. The third purpose is to find out if there is close agreement when the same or a different nurse takes two pressure measurements within a short period. The fourth and last purpose is to find out if some subject or treatment-related factors can affect bladder pressure measurements.

Procedure: A total of 120 subjects will be recruited for the study. You will be randomized to one of the 12 groups. Randomization is like drawing straws and each

Duquesne University
Institutional Review Board
Approval Date: 2/2/07
Expiration Date: 2/2/08

subject has an equal chance of being placed in any one of the 12 groups. Each group will have 10 subjects. One of the doctors that are taking care of you will ask you to participate in the study. These doctors can be your primary care doctor (that is the doctor who took care of you prior to your admission to the hospital or the surgeon who did your operation) or one of the doctors who are experts in critical care that has been asked by your primary care doctor or surgeon to help take care of you while you are critically ill. Many of these doctors are co-investigators for this study along with Dr. Jorge A. Vazquez, medical nutritionist.

If you agree to participate in this study, your primary care doctor, your surgeon or the critical care doctors, will continue to provide you with the best care they believe necessary. In addition, one of these doctors will order the urinary bladder pressure measurement be made according to the group you are assigned by the randomization process. You will have your urinary bladder pressure measured in one of the 12 possible and different ways. Eleven of the 12 groups will have 2 sets of bladder pressures measurements taken by Melanie Shuster, RN and 1 of the 12 groups will have 3 sets of bladder pressure measurements taken. The first 2 measurement sets by Melanie Shuster, RN and the third set by Tammy Haines, RN. One set of bladder pressure measurement consists of two measurements: one measurement taken before any sterile liquid (salt water) is added to the bladder and the other one is taken after a fixed amount of sterile liquid (salt water) is added to the bladder. All bladder pressure measurements will be taken within a 30 minute period.

To measure the urinary bladder pressure a small valve will be attached using sterile technique to your bladder catheter, which is outside your body, and this valve will also be attached to the hospital monitoring system. You will then be positioned in bed lying on your back with the head of the bed elevated to 30 degrees. A bladder pressure measurement will be taken by Melanie Shuster, RN when you are comfortable with no added sterile salt water in your bladder and again after twenty-five milliliters (about one ounce) of sterile salt water is added to your bladder. After the first set of measurements, Melanie Shuster, RN will reposition you to be either lying on your back with the head of the bed flat with a pillow under your head, or lying on your right or left side with the head of the bed elevated to 30 degrees with a pillow under your head and one pillow between your knees. Your back will be supported with a foam wedge and your head will be supported with a pillow under the right or left side of your face if you are lying on your side. These are usual positions patients normally assume while sleeping at home or while in ICU's. See the following pictures of the positions subjects will be placed in for the measurement of urinary bladder pressure.

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Table 1. Study groups for bladder instill volume and subject position

Group	Position	Instill Volume	Nurse
1		25 ml	Melanie Shuster, RN
5	See Above	50 ml	Melanie Shuster, RN
9	See Above	200ml	Melanie Shuster, RN
2		25 ml	Melanie Shuster, RN Tammy Haines, RN
6	See Above	50 ml	Melanie Shuster, RN
10	See Above	200 ml	Melanie Shuster, RN
3		25 ml	Melanie Shuster, RN
7	See Above Right Side Lying	50 ml	Melanie Shuster, RN
11	See Above Right Side Lying	200 ml	Melanie Shuster, RN
4	Same as above Left Side Lying	25 ml	Melanie Shuster, RN
8	Same as above Left Side Lying	50 ml	Melanie Shuster, RN
12	Same as above Left Side Lying	200 ml	Melanie Shuster, RN

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Once you are comfortable and settled in the next position, another set of bladder pressure measurements will be taken by Melanie Shuster, RN. The first measurement will be taken before any sterile salt water is added to the bladder and the other measurement will be made after approximately 1, 2, or 6 ounces of sterile salt water is added to your bladder. You will receive only one of the 3 amounts of sterile salt water listed above and you will assume only one of the 4 positions shown above. You will only be in this position for just as long as necessary to complete the two sets of urinary bladder pressure measurements.

If you are one of the 10 subjects assigned to group 4, (see shaded area in Table 1) you will have 3 sets of bladder pressure measurements taken. You will be kept in bed lying on your back with the head of bed elevated to 30 degrees for all 3 sets of bladder pressure measurements. The third set of bladder pressure measurements will be made by Tammy Haines, RN.

Each set of measurements takes two to five minutes and the whole study will be done in 30 minutes or less. All the measurements will be made on the same day and will not be repeated again regardless of how long you stay in the ICU. After all measurements are completed, Melanie Shuster, RN or Tammy Haines, RN will reposition you to the most comfortable position for you.

Your hospital record will be reviewed and your date of birth, date of hospital admission, reason for hospital admission, and the type of treatment you received will be recorded on a separate piece of paper. All information taken from your record will be kept confidential and you will not be identified on this piece paper.

This is an observational study and no further diagnostic or therapeutic treatment is planned as part of the study regardless of the value of the urinary bladder pressure measurement. However, the values of the urinary bladder pressure will be made available to your primary care physician and the critical care team physicians. They will decide if additional testing or treatments are necessary which will be outside of the study protocol.

The remainder of this page left intentionally blank.

Risks: The risks for participating in this study are minimal. You will receive routine care as necessary for your medical or surgical condition and participating in this study will not delay or alter your treatments in any way. The placement of the urinary bladder catheter is considered a standard of care for nearly anyone in the ICU. Bladder pressure is measured in selective subjects admitted to ICU's at Allegheny General Hospital and is routinely measured in many other hospitals in the United States and Europe. The bladder pressure will be measured using a Federal Drug Agency (FDA) approved device called the AbViser™ that is placed very carefully on the outside end of the urinary bladder catheter while maintaining a sterile condition. Thus, there is a very small risk of developing a urinary tract or other infection because it is necessary to open the urinary catheter drainage system for a brief moment when attaching this device, but the attaching the device will be done under sterile conditions. Urinary bladder pressure measurement is painless and quick; each set of measurements takes two-five minutes to complete. There may be a temporary physical discomfort when you are positioned into one of the four positions for measurement and a small chance that medical equipment will get disconnected. However, most ICU patients are placed in these positions for routine nursing care at some time during a 24-hour period and every precaution will be taken to prevent these problems. There is no anticipated physical, metabolic, social, psychological, legal, or financial risk associated with participation in the study. This is an observational study and no further diagnostic or therapeutic treatment is planned as part of the study regardless of the value of the UBP measurement. However, the values of the urinary bladder pressure will be made available to your primary care physician and the critical care team physicians. They will decide if additional testing or treatments are necessary which will be outside of the study protocol.

There is a very small but real risk of losing confidentiality. Your medical record will be reviewed to extract only the information needed to complete the study. A separate piece of paper will be created to keep the information that is gathered during the study. To minimize the risks of losing confidentiality the people reviewing your medical record will be limited to the principal investigator. The least amount of information needed for the completion of the study will be collected. A study specific identification number will be assigned to you at the beginning of the study and most personal or confidential data such as your social security number, home address, telephone number, insurance information that could identify you will **not** be collected.

Benefits: There are no immediate direct benefits to you by participating in this study although the information obtained may be of benefit to other patients in similar conditions in the future. You may benefit immediately because you will be monitored more intensively than other patients in the ICU. All information gathered by, the researcher will be available to the primary care physician and critical care team.

Alternative procedures: You may choose not to participate in this study.

Costs and Payments: The cost of routine medical care provided to you while in the ICU will be billed to your medical insurance. Participating in this study will not increase the cost of your ICU care. Neither you nor your insurance company will be billed for the costs of measuring the bladder pressure. The costs of the AbViser® device used to measure your bladder pressure will be paid for by funds provided through a grant or will be provided by the manufacturer. You will not receive payment for participation in this study.

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Confidentiality: Information obtained about you as a result of participation in this study will be kept strictly confidential, however as with all medical records, they may be obtained with a court order. The research records that will be created for this study will be kept separately and are not part of your hospital medical record. Your identity, medical records, and data related to this study will be kept confidential, except as required by law and except for inspections by the Food and Drug Administration (FDA) and the Institutional Review Board of Allegheny General Hospital (the committee that oversees research). Results of the research may be published or presented to scientific groups, however, your identity will not be revealed.

Compensation: You have been informed and acknowledge that in the event of your voluntary participation in this research protocol results in the need for you to receive medical care, that no money or free medical care will be made available to you by Allegheny General Hospital or Allegheny-Singer Research Institute.

Research Study Authorization of Protected Health Information & HIPAA Authorization:

In 1996 the government passed a law known as The Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-191. This law, among other things will improve how your health care information is protected and kept confidential when it is shared with others. This includes your medical records and insurance information as well as other personal health information. It also assures that everyone who shares this information will have to follow this law. This consent form describes to you how information about you may be used or shared if you are in a research study. It is important that you read this carefully.

In order to participate in this research study, you must permit (allow) certain research records to be made about you in addition to the usual records the hospital and doctors create about your medical treatment. These research records will contain private medical and other information, which is protected by law. The researchers will only create the minimum amount of research records necessary to carry out the research.

Type(s) of research records that may be shared is (are):
- ☐ Tissue Samples:
- X   Medical Records: Medical and surgical history, medication history
- ☐ Lab Results:
- ☐ Other:

In addition to using these research records to carry out the research and, perhaps, to treat you, the researchers will share portions of these research records to third parties involved in the research study. The third parties, who receive research information, may further share the information about you in accordance with their policies, practices and what the law requires. However, some third parties (such as the Sponsor) may not need to follow the HIPAA law. To the best of our knowledge, a complete and accurate description of who the third parties are and how they will use or share the information are as follows:

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Third Party	Purpose
Allegheny General Hospital Allegheny-Singer Research Institute WPAHS Compliance Office	May share this signed consent form and records that identify you to meet regulatory requirements or for purposes related to this research.
Wolfe-Tory Medical, Inc.	Vendor of equipment used for the measurement of urinary bladder pressure and may need to verify the proper use of the device.

The release of information described above will be the minimum necessary to abide by the law complete the research, and, perhaps, publish the research.

Unlike your medical records, you will not have access to research records made about you. Although every effort will be made to keep research records about you private, complete confidentiality cannot be guaranteed. Such research records may be subject to subpoena or court order. The researcher has set up safeguards to keep private information about you confidential.

There is no expiration for this Authorization unless you revoke (cancel) it. You may revoke this Authorization by writing to the Principal Investigator. If you revoke your Authorization, you will also be removed from the study. Revoking your Authorization only affects the use and sharing of your information after the written request is received. Any information obtained prior to receiving the written request, may be used to maintain integrity of the study.

Principal Investigator Address: Melanie Shuster, RN
Allegheny Center for Digestive Health
1307 Federal Street, Suite 301
Pittsburgh, PA 15212

If you choose to not sign this Authorization, you will not be permitted to participate in this research study. In order to participate in this study, you must agree to share your information with the groups above. Upon completion of the study, or if you withdraw from the study at any time, the research records about you will be kept by the researcher (s) and all of the information provided above will continue to apply to your research records.

You give permission that your research records can be used and disclosed as described.

Voluntary Participation/Right to Withdraw: Participation is voluntary, and refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You are free to refuse to participate in this study. If you agree to participate, you are also free to withdraw from the study at any time. Your decision to refuse to participate or to withdraw from the study will not adversely affect your care at this hospital.

Inquires: If you should you have any questions regarding your rights as a research participant, you may contact the Institutional Review Board of Allegheny General Hospital at 412.359.3156. Any questions about the research have been answered or will

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be answered to your satisfaction by Melanie Shuster, RN, at (412) 359-8958. If you have any additional questions about the research you may contact the Investigators or the IRB Office (412) 359-3156. In the event of a research-related injury, you should contact Melanie Shuster, RN at (412) 359-8958.

<u>Recruitment</u>: The investigator is committed to comply with the basic principles of the NIH guidelines on inclusion of women and minorities in research and will make every effort to enroll subjects into the study from all minority groups. You will receive a signed copy of this consent form.

Subject's Name   _____ Date _____
(Please Print)

Subject's Signature   _____ Date _____

Surrogate Decision
Maker's Signature   _____ Date _____
(If Applicable)

Witness' Signature   _____ Date _____

Investigator's Signature _____ Date _____

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Appendix E Institutional Review Board Approval Letters

Allegheny Singer Research Institute-Allegheny General Hospital November 27, 2006

Duquesne University   February 2, 2007

ALLEGHENY GENERAL HOSPITAL

INSTITUTIONAL REVIEW BOARD #01
FWA00009149
(EXPIRES MARCH 14, 2009)

November 27, 2006

Melanie Shuster RN, MSN
Allegheny Center for Digestive Health

RC-3996 Reliability of Urinary Bladder Pressure Measurement in Critical Care

Dear Ms. Shuster:

The Institutional Review Board (IRB) of Allegheny General Hospital has reviewed the information you submitted on November 17, 2006 in response to our letter dated September 27, 2006, regarding approval for the above-referenced protocol.

The IRB acknowledges receipt of the above-referenced protocol sponsored by Wolfe Tory Medical, (dated November 17, 2006), and the accompanying revised consent form (version dated November 17, 2006) for the above-referenced protocol. The IRB has fully reviewed the information and determined the protocol is **approved**. A stamped approved informed consent (stamp dated November 27, 2006) is attached for your use.

This protocol has been reviewed via the *"full review"* process and approved on its scientific, safety, ethical and socio-economic merits, and approved in accordance with Institutional, Federal and State regulations by the IRB. It is the responsibility of the investigator to obtain any other necessary approvals prior to implementation of the research (AGH and/or ASRI).

Please be aware of the record keeping responsibilities involved in your protocol. Your approved protocol will be subject to review within one year from the date of <u>initial review</u> by the IRB.

Sincerely,

Matthew R. Quigley, M.D.
Chairman
Institutional Review Board
MRQ/jss
cc: Department Chairperson
        Administrative Vice President

DUQUESNE UNIVERSITY

INSTITUTIONAL REVIEW BOARD

424 RANGOS BUILDING ◆ PITTSBURGH, PA 15282-0202

Dr. Paul Richer
Chair, Institutional Review Board
Human Protections Administrator
Phone (412) 396-6326 Fax (412) 396-5176
e-mail: richer@duq.edu

February 2, 2007

Ms. Melanie Shuster
231 Tech Road
Pittsburgh PA 15205

Re: "Reliability of urinary bladder pressure measurement in critical care" (Protocol #07/14)

Dear Ms. Shuster:

Thank you for submitting the research proposal to the IRB.

After review by IRB members, Dr. Linda Goodfellow and Dr. Joan Masters, along with the entire Board, the study is approved under the federal Common Rule, specifically 45-Federal Code of Regulations #46.101 and 46.111. In addition, HIPAA Compliance Officer, Dr. Joan Kiel, has approved the study.

Enclosed is the consent form already stamped with AGH approval. We have added our approval. You should use the form with both stamps as original for signed copies that you and subjects hold.

This approval will be renewed in one year as part of the IRB's continuing review. You will need to submit a progress report to the IRB at the address shown above. The report will involve supplying answers to a number of questions that will be sent to you. In addition, if you are still using the consent forms, you will need to obtain renewed approval.

If, prior to the annual review, you propose any changes in your procedure or consent process, you must inform the IRB Chair of those changes and wait for approval before implementing them. In addition, if any procedural complications or adverse effects on subjects are discovered before the annual review, they immediately must be reported to the IRB Chair before proceeding with the study.

In correspondence with out office about the study, please refer to the protocol number shown after the title above.

When the study is complete, provide the IRB with a summary, approximately one page. Often the completed study's Abstract suffices. You should keep a copy of your research records, other than those you have agreed to destroy for confidentiality, over a period of five years after the study's completion.

If you have any questions, feel free to contact me at any time.

Sincerely yours,

Paul Richer, Ph.D.

C: Dr. Kathleen Sekula
       Dr. Joan Kiel
       Dr. Linda Goodfellow
       Dr. Joan Masters
       IRB Records