Clinical Critical Care

E-ISSN 2774-0048

VOLUME 31 NUMBER 1

JANUARY-DECEMBER 2023

Clinical Critical Care
eISSN 2774-0048

Clinical Critical Care
Volume 31, Article ID e0009, 6 pages
https://doi.org/10.54205/ccc.v31.261440

RESEARCH PROTOCOL

The accuracy of the new non-invasive intra-abdominal pressure measurement by physical examination and ultrasound to diagnose intra-abdominal hypertension: The research protocol

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OPEN ACCESS
Citation:
Achavanuntakul C, Sirilaksanamanon P, Bootjeamjai P. The accuracy of the new non-invasive intra-abdominal pressure measurement by physical examination and ultrasound to diagnose intra-abdominal hypertension: The research protocol. Clin Crit Care 2023; 31: e0009.

Received: February 20, 2023
Revised: April 17, 2023
Accepted: May 9, 2023

Data Availability Statement:
The data and code were available upon reasonable request (Chompoonut Achavanuntakul, email address: nut_jiew@hotmail.com)

Funding:
Ratchadapiseksompotch Fund, Graduate Affairs, Faculty of Medicine, Chulalongkorn University.

Competing interests:
No potential conflict of interest relevant to this article was reported.

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ABSTRACT:

Background: Twenty-five percent of critically ill patients in the intensive care unit have intra-abdominal hypertension, which causes high morbidity and mortality. The gold standard non-invasive method for measuring intra-abdominal pressure to diagnose intra-abdominal hypertension is intravesical pressure measurement. Unfortunately, the standard method has several limitations. The aim of this study is to invent a new, non-invasive method to diagnose intra-abdominal hypertension.

Methods: This is a cross-sectional study to determine the accuracy of the new non-invasive intra-abdominal pressure measurement by physical examination and ultrasound to diagnose intra-abdominal hypertension compared to the intravesical pressure measurement.

Hypothesis: We hypothesize that physical examination and ultrasound can be used to diagnose intra-abdominal hypertension and the ratio of maximal anteroposterior to transverse abdominal diameter minus fat thickness and intra-abdominal pressure has a correlation.

Ethics and dissemination: The study received ethical approval from the Institutional Review Board of Faculty of Medicine, Chulalongkorn University. We plan to disseminate the results in peer-reviewed journals related to critical care medicine or surgery and at national or international conferences.

Trial registration: TCTR20220831002

Keywords: Intra-abdominal hypertension, Ultrasonography, Intravesical pressure, Ratio of anteroposterior to transverse abdominal diameter, Intra-abdominal pressure

INTRODUCTION

It is well known that critically ill patients in the intensive care unit (ICU) twenty-five percent have intra-abdominal hypertension (IAH) [1] defined as intra-abdominal pressure (IAP) equal to or greater than 12 millimeters of mercury, continuously. Normal IAP is approximately 5-7 mmHg in critically ill patients [2]. Abdominal compartment syndrome (ACS) is defined as a sustained IAP > 20 mmHg (with or without an APP less than 60 mmHg) that is associated with new organ dysfunction or failure [2]. The World Society of the Abdominal Compartment Syndrome (WSACS) [2] divides IAH into 4 grades, as shown in Table 1. As a consequence of IAH, the blood supply to the intra-abdominal organ decreases. In the same way as in the equation, abdominal perfusion pressure = mean arterial pressure – intra-abdominal pressure [3]. When intra-abdominal pressure increases, abdominal perfusion pressure decreases. This phenomenon affects every intra-abdominal organ with insufficiency of blood supply, ischemia, injury and then organ failure. Finally, it can cause the death of patients. Some patients have a delayed diagnosis of IAH that leads to abdominal compartment syndrome (ACS), IAP equal to or greater than 20 millimeters of mercury and end organ failure. The ACS is related to high mortality (60–75 percent) [4, 5]. Nowadays, ACS is found in critically ill patients in 3-5 percent of cases [1].

Table 1. Intra-abdominal hypertension grading

Grade	Intra-abdominal pressure (mmHg)
I	12-15
II	16-20
III	21-25
IV	>25

IAH is divided into 3 categories. First, primary IAH, defined as IAH caused by intra-abdominal organ disease or injury, for example, intra-abdominal bleeding, ruptured abdominal aortic aneurysm, ruptured hepatoma and pancreatitis. Second, secondary IAH, defined as IAH that is caused by disease or injury of an organ outside the abdomen, for instance, a severe burn or severe sepsis with massive resuscitation. Third, recurrent IAH, defined as a condition in which IAH redevelops following previous surgical or medical treatment of primary or secondary IAH or ACS [4-6].

With timely diagnosis, it is a rapid and effective treatment; thus, it can reduce the mortality rate by 16-37 percent [5]. Therefore, this is why early diagnosis and treatment are important for better outcomes [5]. This study explores, for the first time, the new method for diagnosing IAH with the non-invasive bedside tool of physical examination and ultrasound to find the ratio of maximal anteroposterior to transverse abdominal diameter.

The intra-abdominal pressure can be measured by many methods, such as direct measurement, (for instance, a direct catheter in the intraabdomen or measuring while performing laparoscopic surgery), indirect measurement, (like measuring via intragastric, intrarectal, and intravesical pressure), The gold standard for non-invasive intra-abdominal pressure measurement is intravesical pressure [5]. On the other hand, intravesical pressure has several limitations, an example is that it is unreliable or cannot be evaluated in a patient with a history of cystectomy, adhesive disease, neurogenic bladder, or external compression such as pelvic packing and preperitoneal packing [4, 6]. Furthermore, intravesical pressure has disadvantages to illustrate, cumbersomeness, risk of infection if improper sterile technique is used, and a static value.

KEY MESSAGES:

- This study compares the new non-invasive intra-abdominal pressure measurement by physical examination and ultrasound to diagnose intra-abdominal hypertension with the gold standard diagnosis test.
- The new method uses the ratio of maximal anteroposterior to transverse abdominal diameter, which is measured by physical examination, minus fat thickness, which is measured by ultrasound.
- We hypothesize that the new method can be used to diagnose intra-abdominal hypertension, especially in patients with contraindications or unreliable intravesical pressure.

In their widely acclaimed work, they discuss a new method for evaluating the IAP that is less invasive, convenient and can be continuously monitored. For instance, strain gauge, respiratory inductance plethysmography (RIP), tensiometry, ultrasound tonometry, ultrasound assessment of the abdominal wall in combination with external pressure, ultrasound doppler tonometry, laser ultrasound, bioelectrical impedance, microwave reflection, digital image correlation and wireless motility capsule [1]. Each method has its own advantages, disadvantages and compatibility with the specific ICU environment. No one size fits all and no method can replace intravesical pressure.

Several studies have found that features from computerized tomography (CT scan) and ultrasound [4, 7-9] are correlated with IAH or ACS, for instance, elevated diaphragm, rounded configuration of the abdominal wall (anteroposterior-to-lateral girth ratio > 0.8), increase in ascites, hemoperitoneum, flattened inferior vena cava, flattened renal veins, mosaic liver perfusion, increased bowel enhancement, increased gastric wall enhancement, gastric distention, reduced diastolic flow in portal, hepatic, or renal veins on sonography, mosaic liver perfusion, deformation of solid abdominal viscera, thoracic disease at the lung base and bilateral inguinal herniation.

The first report from Perry J. Pickhardt et al. [9] found that the round belly sign, likewise, the ratio of maximal anteroposterior to transverse abdominal diameter greater than 0.8 at the level of the left renal vein across the aorta minus fat thickness, is associated with the IAP greater than 35 millimeters of mercury. The sensitivity

is 100 percent and the specificity is 94 percent. The studies by Rivka Zissin [10] and S. Bouveresse et al. [7] have shed more light on this relationship. They reported that the round belly sign has sensitivity of 0.24 (95% CI 0.1-0.46), specificity of 1 (95% CI 0.81-1.00), positive predictive value of 1 (95% CI 1.00-100), negative predictive value of 0.56 (95% CI 0.39-0.72) and an AUC of 0.767 (95% CI 0.623-0.910) to diagnose IAH. It has not yet been established whether the round belly sign or the ratio of maximal anteroposterior to transverse abdominal diameter can be evaluated by physical examination and ultrasound to diagnose the IAH. The presented data show that point-of-care ultrasonography (POCUS) deserves a wider application in the diagnosis and monitoring of critically ill patients with suspected IAH. For this reason, the authors decided to use this ratio and evaluate it by physical examination and ultrasound in place of a CT scan as the non-invasive bedside tool to diagnose the IAH.

OBJECTIVES

Primary objective

The primary objective is to validate the accuracy of the new non-invasive intra-abdominal pressure measurement by physical examination and ultrasound to diagnose intra-abdominal hypertension.

Secondary objective

The secondary objective is to validate the relationship between the ratio of maximal anteroposterior to transverse abdominal diameter minus fat thickness by physical examination, ultrasound, and intra-abdominal pressure.

MATERIALS AND METHODS

Study design

This is a cross-sectional diagnostic study.

Study setting

This study is carried out in the surgical intensive care unit of King Chulalongkorn Memorial Hospital.

Eligibility criteria

Inclusion criteria

1. Age 18 years or older
2. Admitted to the surgical intensive care unit (ICU) at King Chulalongkorn Memorial Hospital
3. Retain the Foley catheter.

Exclusion criteria

1. Pregnancy
2. History of cystectomy
3. Contraindication or unreliable intravesical pressure measurement such as bladder rupture, end-stage renal disease (ESRD), adhesive disease, neurogenic bladder, and external compression, for example, pelvic packing or preperitoneal packing and urinary tract infection.
4. Not cooperative or informed consent.
5. Unable to measure subcutaneous fat thickness by ultrasound ,such as skin infection, dermatitis.
6. Open abdomen with temporary abdominal closure, which is defined as the skin and fascia not being closed after laparotomy.
7. Missing medical data

Recruitment and consent

The investigator will directly contact the physicians who are in the surgical ICU to seek out the patient meets the inclusion and exclusion criteria. The patient or substitute decision-maker (vulnerable subjects) will inform all data about the study and will request informed consent.

Intervention

After the patient or substitute decision-maker gives their consent, the physical examination, ultrasound and intravesical pressure measurement will be carried out as a protocol. Demographics and clinical variables will be recorded in a case record form.

Research procedures

- **Intravesical pressure measurement** (Figure 1)

1. The patient will be placed in the absolute supine position.
2. The urine in the Foley catheter will be completely released.
3. The catheter will be clamped at the distal part beyond the sample port with a non-crushing clamp.
4. Sterile normal saline containing 25 milliliters will be injected into the Foley catheter via an extension tube connected to the sample port using a sterile technique.
5. The extension tube will be raised vertically, the reference point is the mid-axillary line across the iliac crest.
6. The fluid level in the extension tube will be measured at the end of expiration in the complete supine position after ensuring that abdominal muscle contractions are absent in units of centimeters of water column and then converted to millimeters of mercury by multiplying by 0.735.

Figure 1. Intravesical pressure measurement.

• **Ratio of the maximal anteroposterior to transverse abdominal diameter minus the fat thickness by physical examination and ultrasound**

1. Measure the longest distance from the right to the left side and from anterior to posterior of the body at the level of the lumbar spine 2 (the surface anatomy of the renal vessel) [11].

2. Measure fat thickness (from patient skin to fascia) at 4 points (midline anterior, midline posterior, right and left midaxillary lines) by a linear ultrasound probe at 7.5 MHz at the 2nd level of the lumbar spine.

3. By dividing the transverse diameter (longest distance from right to left) by the thickness of the fat on the right and left, the result is the transverse abdominal diameter.

4. By dividing the anteroposterior diameter by midline anterior and posterior fat thickness, the result is the anteroposterior abdominal diameter.

5. Divide the anteroposterior abdominal diameter by the transverse abdominal diameter, the result is the ratio of maximal anteroposterior to transverse abdominal diameter.

A level ruler with a water column will be used to measure the distance.

An ultrasound with a linear probe will be used to measure the thickness of the fat.

The researcher will ask the patient about pain and discomfort during the intervention and give analgesia if the patient feels pain or discomfort.

Outcome measurement

Primary outcome

To know the accuracy of the new non-invasive intra-abdominal pressure measurement by physical examination and ultrasound to diagnose intra-abdominal hypertension.

Secondary outcome

To know the relationship between the ratio of maximal anteroposterior to transverse abdominal diameter minus fat thickness and intra-abdominal pressure.

Study flow diagram

(Figure 2)

DATA MANAGEMENT AND DATA MONITORING

Sample size estimation

As a result of S. Bouveresse et al. [7] research, the ratio of maximal anteroposterior to transverse abdominal diameter greater than 0.8, or round belly sign, had an AUC of 0.767 (95% CI 0.623-0.910). We used this knowledge to calculate the sample size from the area under the ROC curve with the MedCalc program. The ratio of 1:3 between the patient with abdominal hypertension and the patient without abdominal hypertension was used according to the incidence of abdominal hypertension in the patient in the ICU of 25%. We stipulate type I error 0.05 and type II error 0.1, which give power 90% and a 2-sided significance level of 5% (Figure 3). Therefore, the subjects consisted of 64 patients (16 with abdominal hypertension and 48 without abdominal hypertension).

Data collection

The case record form is used to collect the data (baseline characteristics and outcomes) (Tables 2 and 3). All data will be recorded by the investigators.

Data management

All data will be recorded and reached only by investigators to ensure data security and respect for autonomy.

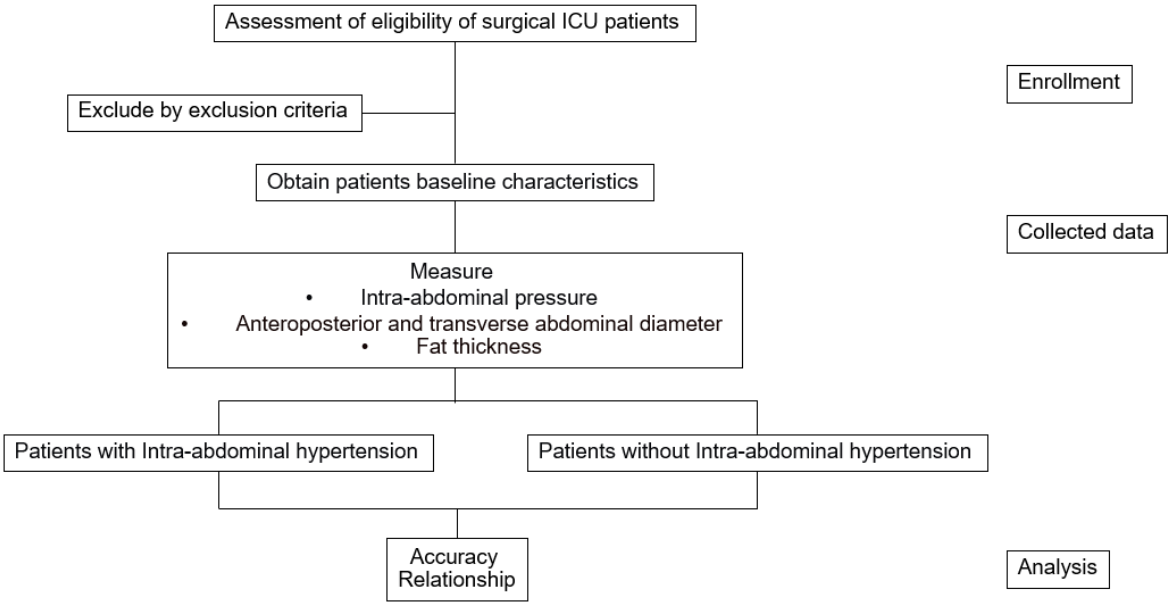

Figure 2. Study flow diagram.

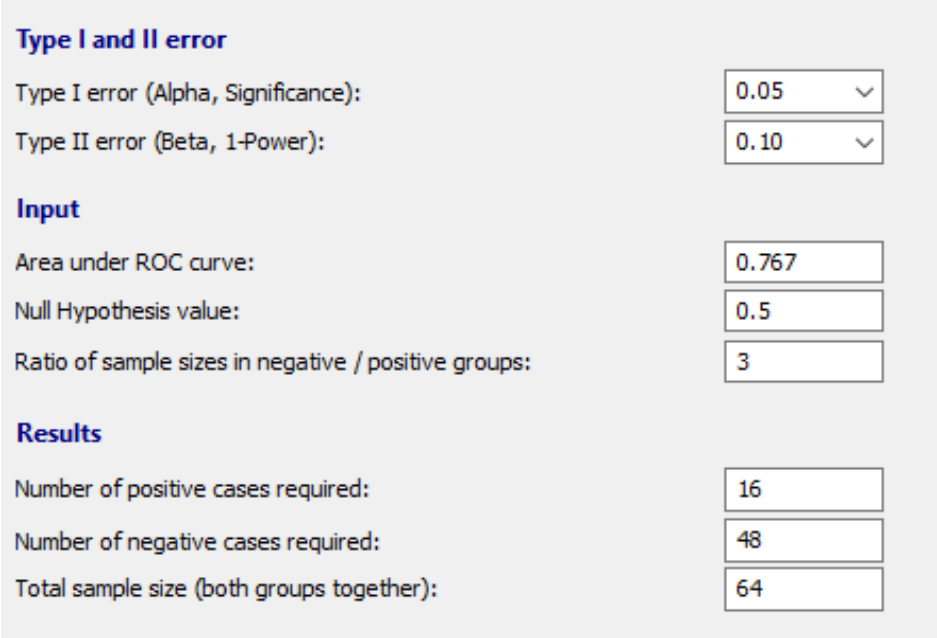

Figure 3. Sample size calculation.

Table 2. Baseline characteristics.

Baseline characteristics
Age
Sex
Weight
Height
BMI
Diagnosis
Medical history
Operation
Admit type
Place before ICU
Ventilator
RASS score
Sedative medication

Abbreviations: BMI: body mass index; ICU: intensive care unit; RASS: Richmond Agitation-Sedation Scale

Table 3. Outcome variables.

Outcomes
IAP
Anteroposterior diameter
Transverse diameter
Fat thickness
Ratio of maximal anteroposterior to transverse abdominal diameter minus fat thickness

Abbreviations: IAP: intra-abdominal Pressure

OUTCOME ANALYSIS PLAN

Statistical analysis

Data analysis was performed with STATA V. 14 software. Categorical data will be analyzed and reported in numbers and percent. Continuous data will be analyzed and reported in the mean and standard deviation, or median and interquartile range. The comparison of two groups will use the Chi-square test, Fisher's exact test, two-sample t test, or Mann-Whitney U test to analyze. The accuracy of the test will be determined using receiver operating characteristic (ROC) and area under the curve (AUC) to identify the cutoff point, sensitivity, specificity, positive predictive value and negative predictive value. The relationship between the ratio and abdominal hypertension will be determined using the Pearson correlation coefficient.

The Spearman rank correlation coefficient is to be analyzed. Significance levels were established at a p-value <0.05.

DISCUSSION

The authors conducted this study to find a new method with an easy, non-invasive bedside character to diagnose IAH. And the method that is suitable for patients with contraindications or unreliable intravesical pressure. If the results are satisfactory and reliable, the new non-invasive intra-abdominal pressure measurement by physical examination and ultrasound will be considered a new standard method for diagnosing IAH, especially in critically ill patients whose contraindications to intravesical pressure measurement are met and who cannot move outside the ICU or cannot perform the CT scan.

The strengths of this study are that it is the first study of a non-invasive, inexpensive, bedside innovation to diagnose intra-abdominal hypertension. The protocol is explicit and reproducible. This method can be adapted for patients with limitations or unreliable intravenous pressure.

However, there are several limitations to this study. First, the method uses physical examination and ultrasound to diagnose, which means high operator dependence. Second, this procedure is inappropriate for a patient with an abundant catheter because it is difficult to flip the patient.

ETHICS

The study received ethical approval from the Institutional Review Board of Faculty of Medicine of Chulalongkorn University (COA No. 1379/2022) and has been registered with Thai Clinical Trials Registry (TCTR20220831002).

CONFIDENTIALITY

Informed consents are obtained in the surgical ICU. All participants will not be specifically identified. A code number represents the patient's information rather than the patient's name / hospital number / admission number. All data are recorded only in the case record form and on the investigator's personal computer. After the research, the data will be erased and destroyed.

DISSEMINATION POLICY

We plan to disseminate the results in peer-reviewed journal related to critical care medicine or surgery, and national or international conferences.

ACKNOWLEDGEMENT

The authors thank all the patients and their families who agreed to join this project. Furthermore, we also would like to thank all the staff of the surgical intensive care unit at King Chulalongkorn Memorial Hospital for the excellent patient care and collaboration through this study.

AUTHORS' CONTRIBUTIONS

(I) Conceptualization: Chompoonut Achavanuntakul; (II) Data curation: Chompoonut Achavanuntakul, Paweenuch Bootjeamjai; (III) Formal analysis: Chompoonut Achavanuntakul; (IV) Funding acquisition: Paweenuch Bootjeamjai; (V) Methodology: Chompoonut Achavanuntakul; (VI) Project administration: Chompoonut Achavanuntakul; (VII) Visualization: Chompoonut Achavanuntakul; (VIII) Writing – original draft: Chompoonut Achavanuntakul; (IX) Writing – review & editing: Chompoonut Achavanuntakul, Paweenuch Bootjeamjai, Pongpol Sirilaksanamanon.

SUPPLEMENTARY MATERIALS

None

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