

STUDY PROTOCOL

Validation of the standard optimal volume for measuring intra-abdominal pressure.

Background: Abdominal compartment syndrome (ACS) is a significant problem in the critically ill patient. In adults it has been reported to have an incidence of about 5% in a mixed intensive care population (medical and surgical patients)^{1,2} In children the incidence appears to be lower reported as 0.6% in a mixed pediatric ICU.³ However the mortality associated with ACS is very high varying from 28-68%.⁴ Objective measurement of intra-abdominal pressure (IAP) may help in the early recognition and intervention of intra-abdominal hypertension or ACS.

There are various techniques for measuring IAP. The gold standard is the direct method.⁵ This can be achieved by the use of a catheter or needle in the peritoneal space.⁶ The gold standard for measurement of IAP using the indirect method is the intravesical method.⁷ We recently demonstrated that the optimal volume for measuring IAP in children using the intravesical technique is 3ml.⁸ This study aims to validate our findings by comparing IAP obtained by the direct method with IAP obtained by the intravesical technique using 3 ml as the bladder instillation volume.

Objective:

1. To compare the IAP measured directly via a peritoneal catheter with intravesical methods using 3ml of saline.
2. To test whether using 3ml for indirect IAP measurements accurately measures IAP in patients with intra-abdominal hypertension or ACS.

Hypothesis: Using the standard optimal volume of 3ml for measuring IAP using the intra-vesical method results in accurate IAP.

Design: Prospective observational study.

Population: 30 Children < 18 years with peritoneal drains.

Exclusion criteria: Patients with contraindications for placement of a urethral catheter e.g. urethral trauma, patients with recent bladder surgery and premature babies less than 36 weeks gestation.

Method: Pediatric patients who have peritoneal drains placed for various indications will be consented and enrolled in the study. There are two categories of patients with peritoneal drains.

1. The patients with peritoneal drains in place for performing peritoneal dialysis
 - a. Outpatients who have ongoing (chronic) peritoneal dialysis
 - b. Inpatients admitted who have need for ongoing peritoneal dialysis
 - c. Inpatients with initiation of peritoneal dialysis
2. The patients with peritoneal drains for draining ascites fluid or for treatment of intra-abdominal hypertension or abdominal compartment syndrome

Recruitment Plan: The principal investigator and co-investigators will obtain consent at the bedside, if the patient is an inpatient or in the dialysis clinic if the patient is an outpatient. A wide indication for placement of peritoneal drains will enable enrollment of patients with and without evidence of intra-abdominal hypertension or ACS.

Intervention: A urethral catheter will be placed (mainly for outpatients, many inpatients will already have urethral catheters) if not already in place to allow for indirect IAP measurements to be obtained. A transducer will be connected to the end of the peritoneal drain via a three-way stopcock to allow for direct measurement of IAP via the peritoneal drain. (The measurement of IAP via peritoneal drains is not experimental and is done for clinical purposes by the methods we intend to use in this study). The Abviser[®] is a monitoring kit that is FDA approved and routinely used for indirect measurement of IAP in children and adults. It will be set up in the usual fashion and connected to a urethral catheter. The IAP will be measured using the direct method via the peritoneal drain. At the same time the IAP will be measured using the indirect method via the urethral catheter using an instillation volume of 3 ml. The IAP using both methods will be taken every 2 hours for 24 hours in the patient with the peritoneal drain not undergoing peritoneal dialysis. For patients with peritoneal drains placed for peritoneal dialysis, the measurements will be taken during the dwell phase and the drain phase of the dialysis cycle every 5 minutes for 2 cycles to enable us determine whether measurements remain accurate with elevated IAP (expected in the dwell phase).

Outcome measures:

- IAP using the direct method (via peritoneal drain)
- IAP using the indirect method (via a bladder catheter)

Statistical Analysis: Correlation coefficients will be determined between direct IAP and indirect IAP measurements. Bland Altman plots will be used for comparing the different methods of obtaining IAP.

Risks and Benefits: There is no risk above the risk associated with the presence of a urethral catheter in patients having IAP measured using the intravesical method.^{8,9} There is minimal risk involved in attaching a pressure transducer to the end of a peritoneal drain for IAP measurements by the direct technique. Taking a pressure measurement by this method only involves turning the direction of the three way stop cock after the transducer has been added therefore the risk is no greater than the standard risk associated with having a peritoneal drain in place. There is no direct benefit to the subjects participating in this study. However there is a \$25.00 gift certificate given upon completion of the research.

References:

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