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RESEARCH ARTICLE

Agreement between Intravesicular Pressure Measurements obtained by Two Different Methods using a Simple, Low-cost, Locally Assembled Manometer System

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ABSTRACT

Objective: To compare the agreement between intravesicular pressure measurements obtained by two different methods, using a locally assembled manometer system.

Materials and methods: At the Academic Unit, Teaching Hospital, Mahamodara, Galle, among those undergoing laparoscopy, 21 women from January 1 to 31, 2016, and 20 women from February 2 to 28, 2016, had their intravesicular pressure measured using the locally assembled manometer system, with the women in the supine position, using different references for zero intravesical pressure levels and different volumes of normal saline instilled into the bladder, at 0, 5, 10, 15, 20, and 25 mm Hg of intraabdominal pressure (IAP), which was established with a laparoscopic carbon dioxide insufflator.

Results: The correlation between results of the two methods was excellent (r = 0.98, p < 0001). A mean difference of 2.6 mm Hg (p < 0.001) was seen between the two methods at an IAP of 25 mm Hg. The limits of agreement between the two methods ranged from –3.0 mm Hg [95% confidence interval (CI) –4.3 to –1.7] at 10 mm Hg to 6.1 mm Hg (95% CI 4.4 to 7.7) at 25 mm Hg. The difference between the results of the new method and the old method as a percentage of the new method was maximum (–27%) at 0 mm Hg of IAP and ranged from approximately 3 to 5% between 5 and 20 mm Hg of IAP.

Conclusion: There was good agreement between the intravesicular pressure measurements obtained by the two methods, especially between 5 and 20 mm Hg of IAP.

Keywords: Agreement, Intravesicular pressure measurements, Intravesicular volumes, Mid-axillary line, Symphysis pubis, Zero reference levels.

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INTRODUCTION

Intraabdominal pressure is defined as pressure concealed within the abdominal cavity in healthy adults that ranges from 0 to 5 mm Hg. Intraabdominal hypertension (IAH) is defined as sustained or pathological elevation of IAP more than 12 mm Hg, and abdominal compartment syndrome (ACS) as a sustained IAP of 20 mm Hg or more that is associated with new organ dysfunction/failure.[1] Among critically ill adults, IAH and ACS syndrome are common and are associated with acute and chronic renal failure, multiorgan dysfunction syndrome, and substantial morbidity and mortality.[2,3] Intra-abdominal hypertension has been shown to be associated with pregnancy-induced hypertension (PIH) and it has been suggested that IAH could have a role in the pathogenesis of PIH.[4,5]

Although there is controversy about the ideal method for measuring IAP, the measurement of intravesical pressure is commonly used, and it is associated with considerable variability not only in the technique of measurement but also among different researchers and institutions.[6,7] A simple, low-cost, locally assembled manometer system, comprising materials readily available in any low-resource setting, was designed and validated for the measurement of intravesicular pressure, to estimate IAP, by the authors (Jayasundara et al, awaiting publication). It is a simple method and similar to a central venous pressure manometer, and it can be easily set up. Two different methods have been described for the measurement of the intravesicular pressure using manometers, viz., considering the upper border of the symphysis pubis as the zero intravesical pressure level and the instillation of 50 mL normal saline into the bladder (old method)[6,7] and considering the mid-axillary line as the zero intravesical pressure level and the instillation of 25 mL normal saline into the bladder (new method).[8] The rationale for the changes of the standards in the new method are on account of the

mid-axillary line being considered more appropriate to reflect the middle of the bladder rather than the upper border of the symphysis pubis, which would be at a higher level than the bladder when a patient is in the supine position, and thus lead to a better estimation of the intravesicular pressure, and the fact that a larger volume of saline in the bladder could lead to overestimation of the intravesicular pressure.[8] The objective of this study was to evaluate these hypotheses by comparing the use of the new method with the old method when measuring the intravesicular pressure with the locally assembled manometer system.

MATERIALS AND METHODS

Anticipating the detection of a correlation coefficient (r) of 0.8 with a significance level of 1% and power of 90%, the minimum sample size was calculated to be 15 subjects.[9] In Phase 1 of the study, informed written consent was obtained from all eligible subjects who underwent diagnostic laparoscopy for subfertility or laparoscopic sterilization from January 1 to 31, 2016, until it was possible to obtain all six required IAP and intravesicular pressure measurements from the subjects (n = 21). Criteria for exclusion included previous urinary bladder injury/surgery, neurogenic bladder/bladder outflow obstruction, difficult catheterization, IAP >0 mm Hg at the time of Veress needle insertion and prior to carbon dioxide insufflation, and the use of the open technique of insertion of Veress needle.

A simple, low-cost, locally assembled intravesicular pressure measurement system was set up using two three-way stopcocks (A and B), two intravenous (IV) infusion tubes, a pressure monitoring line, one 50 mL syringe, one 500 mL normal saline pack, and a central venous pressure measuring scale. Using the normal saline in the pack, the system was primed to prevent air bubbles collecting within the system (Figs 1 and 2).



Fig. 1: The locally assembled, simple, low-cost, intravesicular pressure measurement manometer system

Subjects were placed in the supine position, intubated, underwent general anesthesia, and were ventilated with a tidal volume of 12 mL/kg. Medications used in the general anesthesia were fentanyl, morphine, midazolam, propofol, atracurium, and isoflurane/halothane. Prior to each set of measurements, the Richmond Agitation-Sedation Scale (RASS)[10] was assessed and confirmed to be at least –4. A Foley catheter was inserted to the bladder and after collecting urine samples for analysis including microscopy and culture, the bladder was emptied. The proximal end of the Foley catheter was connected to the intravesicular pressure measurement system described

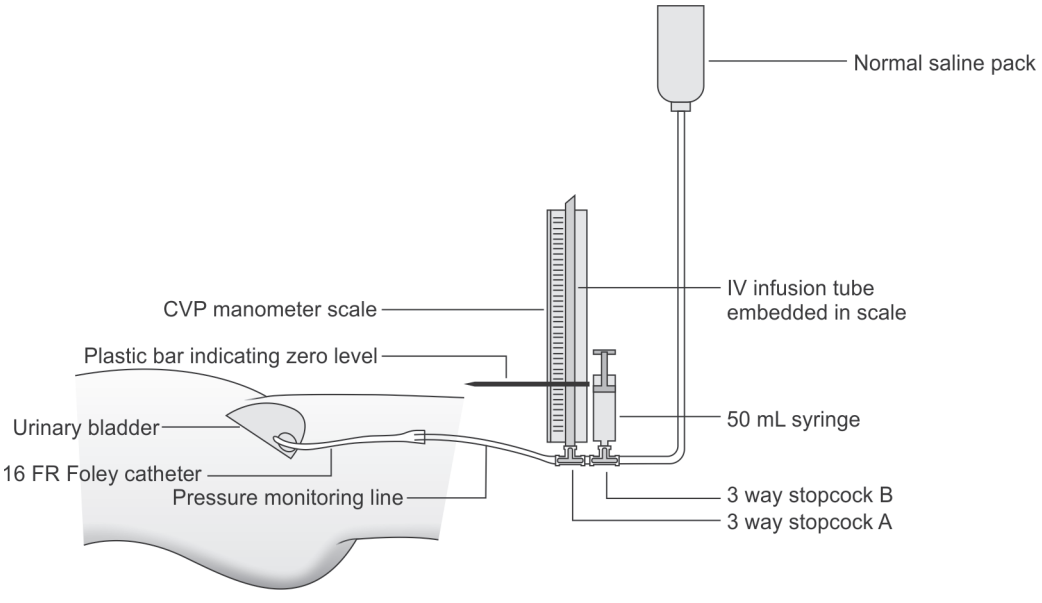


Fig. 2: Schematic diagram of the locally assembled, simple, low-cost intravesicular pressure measurement manometer system

earlier. After closing connection between stopcocks A and B, 50 mL of normal saline was withdrawn into the 50 mL syringe from the normal saline pack. Thereafter the stopcock B connection to the normal saline pack was closed. Then the connection between stopcocks A and B was opened, stopcock A connection to the manometer was closed, and the 50 mL normal saline pushed into the system so that 50 mL of normal saline was instilled into the bladder. The plastic bar indicating the zero level in the central venous pressure measuring scale was adjusted to be at the superior border of the symphysis pubis.[6,7]

With the operating table horizontal, and the patient in the supine position, the Veress needle was inserted according to closed laparoscopic entry technique.[11] The double click, aspiration, and hanging drop procedures were performed to confirm correct intraperitoneal placement of the Veress needle.[12] The gas tubing was primed with CO_2 before connection of the Veress needle, all air from the line was purged, and the CO_2 flow rate was set at 1 L/minute. The IAP was obtained by a laparoscopic carbon dioxide insufflator (Electronic Endoflator Set, SCB 26430508-1, Karl Storz GmbH & Co., Tuttlingen, Germany), and these laparoscopic carbon dioxide insufflators have been validated for the measurement of IAP.[13] First, the IAP was adjusted by insufflation to 0 mm Hg and then increased stepwise to 5, 10, 15, 20, and 25 mm Hg. However, in some subjects, when the IAP overshot the required pressure level, some CO_2 had to be released from the peritoneal cavity and re-insufflated at a lower flow rate. At each IAP level, the intravesicular pressure was measured by considering 1 cm of saline in the manometer column to be equal to 1 cm of water. The readings in cm H_2O were converted into mm Hg by multiplying by 0.74. As the standard IAP achieved prior to safe insertion of primary trocar is 25 mm Hg,[11] the laparoscopic procedure was then continued. Urine samples were obtained prior to the procedure and 12 to 24-hour postoperatively, for microscopy and urine culture. Urinary tract infection (UTI) was defined as microbiological culture documentation of >100,000 colony-forming units per high power field of either a specific bacterium or fungus.[14]

From February 2 to 28, 2016, the study was repeated on 20 subjects (Phase 2). There were two differences in the Phase 2 of the study, viz., with the patient in the supine position, the zero intravesical pressure level was considered to be the mid-axillary line at the level of the superior border of the iliac crest (not the superior border of the symphysis pubis) and 25 mL normal saline (not 50 mL) was instilled into the bladder, prior to obtaining the intravesicular pressure measuments.[8] Lower flow rates of CO_2 were used for insufflation, to prevent the IAP exceeding the required pressure level. All the other procedures were the same.

The correlation between the two sets of measurements at each IAP using Pearson's correlation coefficient, the bias (the mean difference between the two sets of measurements at each IAP), the difference between the results of the new method and the old method as a percentage of the new method,[15] and the limits of agreement[16] were studied. Ethical approval was obtained from the Ethical Review Committee, Faculty of Medicine, University of Ruhuna, Galle, Sri Lanka (Ref. July 2, 2015:3.13).

RESULTS

In the women recruited for the study, there were no significant differences in the distribution of age or body mass indices between the two phases of the study, viz., old method and new method (Table 1). In the first phase of the study, 18 women had diagnostic laparoscopy for subfertility, but no significant pelvic pathology was detected, and three had laparoscopic sterilization. In 5 women the IAP was not increased up to 25 mm Hg, because pneumoperitoneum was considered to be clinically adequate before the IAP reached 25 mm Hg. In the second phase of the study (new method), 17 women had diagnostic laparoscopy for subfertility, but no significant pelvic pathology was detected, and 3 had laparoscopic sterilizations.

There was excellent correlation between the intravesicular pressures obtained by the two methods ($r = 0.98$, $p < 0001$). However, in comparison with the new method, the mean differences of the intravesicular pressure measurements obtained by the old method ranged from a nonsignificant 0.2 ($p = 0.080$) at an IAP of 0 mm Hg to a significant increase of 2.5 ($p < 0.001$) at an IAP of 25 mm Hg. The difference between the results of the new method and the old method as a percentage of the new method was maximum (–27%) at 0 mm Hg of IAP and ranged from approximately 3 to 5% between 5 and 20 mm Hg of IAP (Table 2).

The limits of agreement between the intravesicular pressure measurements obtained by the two methods ranged from –3.0 (95% CI –4.3 to –1.7) at 10 mm Hg to 6.1 (95% CI 4.4 to 7.7) at 25 mm Hg (Table 3 and Graph 1).

Table 1: Characteristics of the women in the study (n = 41)

		Old method (n = 21)	*New method (n = 20)*	*p-value**
Age in years	Range	27–39	28–38	0.759
	Mean	32.57	32.3	
	SD	2.92	2.70	
BMI, kg/m^2	Range	21.4–26.5	21.4–25.6	0.918
	Mean	24.04	24.0	
	SD	1.25	1.07	

SD: Standard deviation; BMI: Body mass index; *by comparison of means with t-test

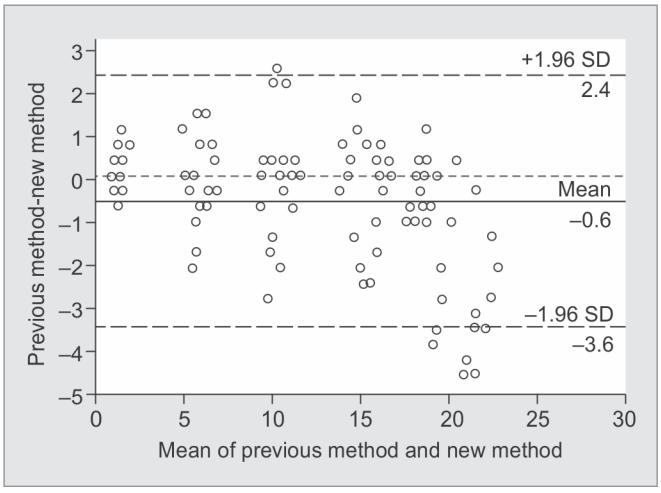
Table 2: Comparison of intravesicular pressure measurements obtained by the two methods

Intraabdominal pressure	Intravesicular pressure measurements—new method			Intravesicular pressure measurements—old method			Mean difference between results of new and old method	p-value*	Difference between new and old as a percentage of new
	n	Mean	SD	n	Mean	SD			
0	20	0.71	0.30	20	0.90	0.48	–0.19	0.159	–27%
5	20	5.64	0.72	21	5.48	0.77	0.16	0.491	2.8%
10	20	10.26	0.93	20	10.09	1.06	0.17	0.603	1.7%
15	20	15.52	1.15	21	15.16	1.06	0.36	0.312	2.3%
20	20	19.36	1.05	21	18.47	0.65	0.89	0.002	4.6%
25	20	23.17	1.13	16	20.59	1.16	2.58	<0.001	11.1%

SD: Standard deviation; *by comparison of means with t-test

Table 3: Limits of agreement between results of new method and the old method

Intraabdominal pressure	Mean intravesicular pressure		Limits of agreement between results of new method and old method			
	New method	Old method	Upper limit	95% confidence interval	Lower limit	95% confidence interval
0	0.71	0.90	0.90	0.42–1.38	–1.33	–1.80 to –0.85
5	5.64	5.48	2.02	1.23–2.80	–1.76	–2.55 to –0.98
10	10.25	10.09	2.91	1.71–4.11	–2.71	–3.92 to –1.51
15	15.51	15.16	2.77	1.75–3.79	–2.14	–3.16 to –1.12
20	19.35	18.47	3.58	2.47–4.69	–1.77	–2.88 to –0.66
25	23.17	20.59	6.09	4.39–7.72	–0.48	–2.11 to 1.14



Graph 1: Limits of agreement between the new method (n = 20) and the old method (n = 21)

Pre- and postprocedure urinary analysis and culture did not demonstrate any evidence of UTI in both phases of the study.

DISCUSSION

There was good agreement between the intravesicular pressure measurements obtained by the two methods, especially between 5 and 20 mm Hg of IAP. Although excellent correlations were seen between the intravesicular pressure measurements obtained by the two methods and the mean differences between the two sets of measurements were small, these are not considered to be valid methods for assessing agreement between two methods measuring the same continuous variable. Assessing the difference between the results of two method as a percentage of one method at each point of a continuous variable,[15] and calculating the limits of agreement by plotting the difference between the results of two measurements *vs* the mean of the two measurements at each point of a continuous variable[16] are considered as better methods of assessing the agreement between two methods of measurement. Therefore, the latter two methods too were used in the current study.

The main limitation of the current study is that the two methods of measurement of the intravesicular pressure were used in two different groups of subjects. For an ideal comparison between the methods, the same subjects should have been used. Nevertheless, since the age and body mass index (BMI) distribution of the subjects were not significantly different between the two groups, it could be assumed that the results of the current study are still valid. However, since it is important to have standardized methods to enable the comparison of results of studies carried out in different settings, the new method should be adopted when measuring the intravesicular pressure in order to estimate the IAP.

CONCLUSION

There was good agreement between the intravesicular pressure measurements obtained by the two methods, especially between 5 and 20 mm Hg of IAP.

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