

## Evaluation of a Novel Fluid Monitoring Device for Hysteroscopic Surgery

Hatern Tintara, M.D.<sup>1\*</sup>, Kanadit Chetpattananondh, M.Eng.<sup>2</sup>, Hordia Binyara, B.N.S.<sup>3</sup>

<sup>1</sup>Department of Obstetrics and Gynecology, Faculty of Medicine, <sup>2</sup>Department of Electrical Engineering, Faculty of Engineering, <sup>3</sup>Songklanagarind Hospital, Faculty of Medicine, Prince of Songkla University, Hat Yai, Songkhla 90110, Thailand.

\*E-mail: hatern.t@psu.ac.th

Songkla Med J 2018;36(1):29-34

### Abstract:

**Objective:** To evaluate the performance of a simplified fluid monitoring device for monitoring fluid deficit and uterine perforation during hysteroscopic surgery.

**Material and Method:** A novel fluid deficit monitoring device was developed using a weighing system operated by a microcontroller. The deficit volume in milliliters (mL) is continuously monitored with an updated display every 30 seconds. The deficit LED is preset to begin flashing with an alarm sound if a fluid deficit reaches 750 mL, 1,000 mL, and 2,500 mL. A new algorithm for detection of small uterine perforations was also developed. The device can be loaded with a maximum of four bottles of 1 liter distention media and has two 2 liters collecting canisters. After having passed laboratory testing, the prototype was clinically used in hysteroscopic surgeries.

**Results:** The laboratory testing showed a precision of  $\pm 7$  mL at 500 mL, with an accuracy of  $\pm 8.9\%$  for deficit volume measurement with 100% alarm at the preset levels. The perforation alarm could detect a small uterine perforation with 80.0% accuracy in an average ( $\pm$ standard deviation; S.D.) latency time of  $3.2 \pm 0.2$  minutes with an average ( $\pm$ S.D.) fluid leakage of  $472 \pm 35$  mL. The device performed well in a preliminary series of 42 hysteroscopic surgery cases from October 2014 to February 2016. Deficit-volume detection by the device correlated well with clinical evaluations by operating room personnel ( $r=0.840$ ,  $p$ -value $<0.001$ ).

**Conclusion:** The newly developed fluid monitoring device can provide acceptable precision and accuracy for monitoring fluid deficits and detection of small uterine perforations during hysteroscopic surgery.

**Keywords:** fluid balance, fluid management, fluid monitoring, hysteroscopic surgery, uterine perforation

---

The research was support by grant from the Faculty of Medicine, Prince of Songkla University.

Received 23 February 2017 Accepted 12 June 2017

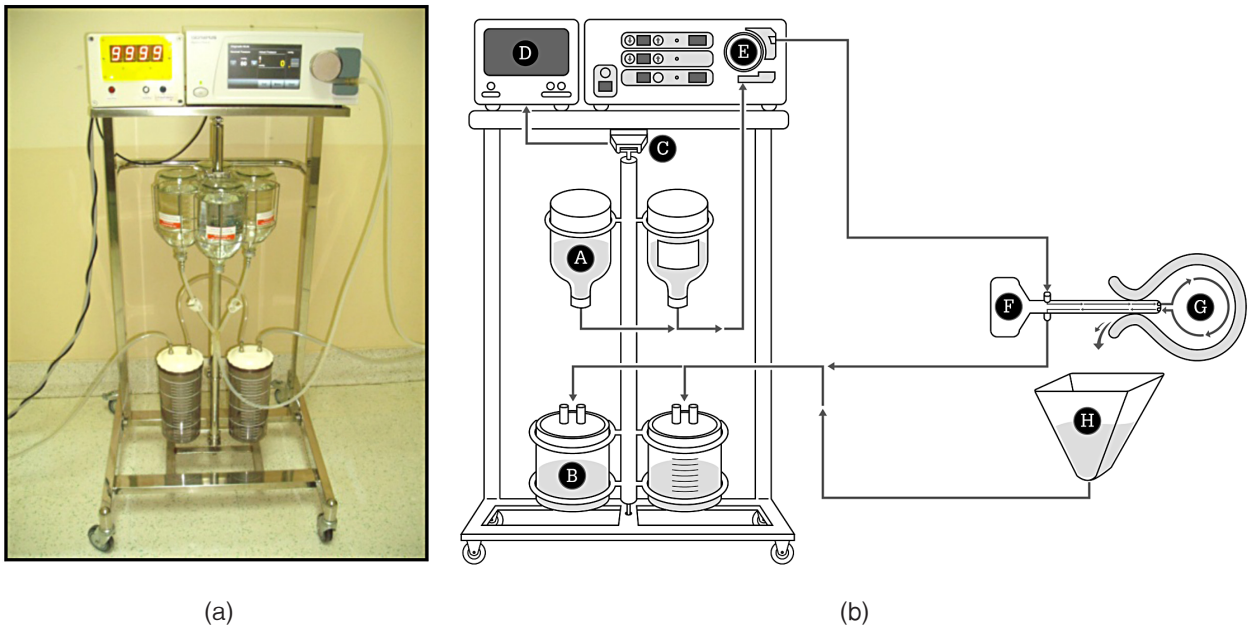
## Introduction

Monitoring the intake and output volumes of distension fluid is essential during hysteroscopic surgeries. Fluid loss into a patient or fluid deficits are the result of intravasation via a raw surface in the uterine cavity and/or fluid leaking into the peritoneal cavity via a uterine perforation.<sup>1</sup> A large amount of fluid loss into a patient can cause hyponatremia, hypoosmolarity and/or hypervolemia, any of which can be catastrophic for the patient.<sup>2,3</sup> Consequently, the use of automated fluid monitoring systems are recommended during hysteroscopic surgery to minimize the risk of complications and avoid human error.<sup>4,5</sup> Uterine perforations are one of the most detrimental complications during hysteroscopic surgery.<sup>1,2</sup> A large uterine perforation can be detected almost immediately by the surgeon due to a sudden loss of visual field and/or sudden noticeable bleeding in the uterine cavity. However, if a uterine perforation was small, a standard hysteroscopic pump would automatically increase the flow rate to maintain the preset intra-uterine pressure. As a result, a small perforation may not be recognized by the surgeon during the operation, resulting in the leakage of a large amount of distension fluid into the abdominal cavity before clinical detection.<sup>6</sup> To address this issue, we developed an automated microcontroller monitoring device for continuously monitoring fluid-deficit volume and detection of small uterine perforations. This study aims to evaluate the precision and accuracy of this device in monitoring fluid deficits and detection of small uterine perforations, initially in a laboratory setting and then in actual clinical practice of hysteroscopic surgeries.

## Material and Method

We developed an automated microcontroller monitoring device using the concept of a single load cell weighing system.<sup>7-9</sup> The device consists of a mobile cart with a weighing system and a monitoring unit (Figure 1a).

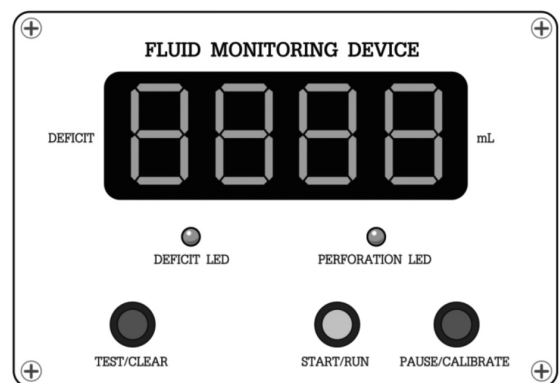
The weighing system consists of fluid bottle holders and collecting canister holders fixed together, and is held under a load cell (bending beam load-cell MT 1022, Mettler-Toledo, Greifensee, Switzerland) as a weight-measuring sensor. The weighing system was stabilized at the lower end with a minimal friction mechanic to prevent swaying in the system. The distension fluid bottle holders can load a maximum of four 1,000 millilitre (mL) distension fluid bottles and two 2,000 mL reusable collecting canisters (Technologie Medicale, Cedex, France). The monitoring unit receives weight signals from the load cell and is operated by a microcontroller (PIC<sup>®</sup> 16F887, Microchip Technology, Chandler, AZ). Because all distension fluids have a specific gravity of approximately 1.0 (the specific gravities of commonly used distension fluids 0.9% normal saline, 1.5% glycine, and 5.0% mannitol are 1.005, 1.006 and 1.019 respectively), one gram of fluid is approximately 1 mL. The microcontroller is programmed to perform two processes, first: monitor the volume of fluid loss to determine a deficit, and second: monitor the rate of fluid loss to determine the presence of uterine perforation. The unit alarm is activated when a preset deficit level is reached or continuous fluid loss is detected. The maximum deficit display is 9,999 mL with two alarm light emitting diodes (LEDs), one for deficit monitoring and the other for perforation monitoring. The alarm unit alerts the surgical team of a problem by a flashing LED light and a beeping sound. The monitoring unit is designed to be user friendly with one main power switch and 3 push-button switches for Test/Clear, Start/Run and Pause/Calibrate (Figure 2). The monitoring unit is already preset to alert the surgeon of a problem when the deficit reaches 750 mL with flashing LED light and beep sounds every 3 minutes. When the deficit reaches 1,000 mL the beep sound occurs every minute, and when the deficit reaches 2,500 mL the beep sound occurs every 3 seconds. The other function of the monitoring unit is to continuously monitor the rate of fluid



**Figure 1** (a) Prototype of the fluid monitoring device comprised of a mobile cart with monitoring unit and hysteroscopic pump. (b) The diagram shows the mechanism of action of the fluid monitoring device. The irrigation fluid bottle holder (A) is fixed to the suction canister holder (B) as one weighing unit and hung under a load cell (C) which is connected to the monitoring unit (D). The irrigation tube is connected via the hysteroscopic pump (E) to the hysteroscope (F) which is inserted into the uterine cavity (G). The suction tubes from the hysteroscope (F) and collecting sac (H) are connected to the suction canister (B).

loss in order to detect small uterine perforations during an operation. A ‘small uterine perforation’ is defined as a perforation with a fluid loss rate between 50–100 mL/30 seconds (sec) or 100–200 mL/minute (min). Given the definition of small uterine perforation, our monitoring unit uses a pump with maximum flow rate setting of 200/mL/min.

The prototype of the monitoring device was tested in a laboratory setting and subsequently approved by the Ethics Committee of the Faculty of Medicine, Prince of Songkla University for clinical evaluation study (REC 56–047–12–1–2).



**Figure 2** The monitoring unit display of the fluid monitoring device

**Laboratory setting**

The precision of measurement at 500 mL was tested with 500 gm standard weight. The accuracy of deficit monitoring was tested by running a hysteroscopic pump (Uteromat Fluid Control, Olympus, Hamburg, Germany) with a preset pressure of 80 mmHg and a maximum flow rate of 200 mL/min. The deficit volume of fluid at each alarm level was measured using a 1,000 mL measuring cylinder (B.S. 604, Volac, Great Britain). The preset alarm levels were 750 mL, 1,000 mL and 2,500 mL. Perforation detection was tested by connecting the outflow tube from the hysteroscopic pump to a flowmeter (Mini-Master® Flowmeter, MMA-38, Dwyer Instruments, Michigan City, IN). The hysteroscopic pump pressure was preset at 80 mmHg with a maximum flow rate of 200 mL/min. After the pump was turned on, the flowmeter was adjusted for a leakage flow rate of 150 mL/min, then volume loss was recorded using a 1,000 mL measuring cylinder. The time duration in which the device signaled a perforation alarm and the volume of fluid loss were recorded. All tests were performed 20 times.

**Clinical experience**

The prototype was used for operative hysteroscopies from October 2014 to February 2016 with a hysteroscopic pump (Hystero Flow II, Olympus, Hamburg, Germany) with a pressure setting of 80 mmHg and a maximum flow rate of 200 mL/min. The irrigation tube was connected to the inflow valve of the hysteroscope sheath, and the outflow valve of the hysteroscope sheath was connected to the suction tube from the collection canister. A plastic sac with a tube drain was placed under the patient’s buttocks to collect leakage fluid from the vagina, and the tube drain was connected to the same

suction tube. The suction canisters were connected to a wall-suction outlet (Figure 1b). The circulating nurse manually recorded the volume of distension fluid used and the volume of fluid in the collection canisters during the operation as in standard practice. At the end of the operation, the volume of fluid in the collection canisters was subtracted from the volume of distension media that was used. The resulting value was the deficit volume by manual calculation. The deficit volume detected by the monitoring device at the end of the operation was also recorded.

**Results**

Laboratory tests (Table 1): The precision tests showed an error of ±7 mL at 500 mL. The accuracy tests for deficit were ±67 mL at 750 mL (8.9% error), ±73 mL at 1,000 mL (7.3% error), and ±115 mL at 2,500 mL (4.6% error). The average error for deficit in all three levels was 6.9%, so the accuracy of deficit detection was approximately 93%. The perforation alarm test was activated in 16 out of 20 tests (80.0% accuracy), and showed an average latency time of 3.2±0.2 minutes with an average (±standard deviation; S.D.) fluid leakage of 472±35 mL.

**Table 1** The results of laboratory test of fluid monitoring device

Deficit alarm	
Precision	±7 mL
Accuracy	93.0%
Perforation alarm	
Accuracy	80.0%
Latency	3.2±0.2 min
Volume leakage	472±35 mL

Clinical experience: In the clinical trials of 42 hysteroscopic surgery cases, including polypectomies, endometrial resections and myomectomies, the mean fluid deficits ( $\pm$ S.D.) were  $589\pm 616$  mL by manual calculation and  $502\pm 448$  mL by the monitoring device (Pearson's correlation coefficient=0.840, p-value<0.001). The device appropriately signaled warning signs in all cases when the designated level of volume deficits was reached. In one hysteroscopic myomectomy case the device made a perforation alarm, at which point the operation was immediately stopped. A pelvic ultrasound revealed a moderate amount of fluid in the cul-de-sac. The patient was admitted, her clinical condition stabilized after 24 hours of observation, and she was discharged.

## Discussion

We developed a simplified fluid monitoring device using a single load cell weighing system. With this system, fluid deficits during various hysteroscopic procedures could be continuously monitored and both light and sound alarms were triggered when preset levels are reached. Both laboratory and clinical trials have demonstrated the high precision and accuracy of the device. Furthermore, a new algorithm for detecting small uterine perforations was also developed as part of this system, with a reported 80.0% accuracy in laboratory tests. The preliminary clinical study showed a high correlation in fluid deficit measurements between our fluid monitoring device and the manual calculation of fluid deficits.

We used a weight-based fluid monitoring system in our device to overcome errors encountered in volume-based fluid monitoring systems as reported by Nikolopoulos et al.<sup>10</sup> and Nezhat et al.<sup>11</sup>

When compared to a commercially available fluid monitoring device (HysteroBalance II, Olympus, Hamburg, Germany) which has a precision of  $\pm 2$  mL and an

accuracy for deficits of  $\pm 6.0\%$ , our device had lower precision ( $\pm 7$  mL) and deficit accuracy ( $\pm 4.6$  to  $\pm 8.9\%$ ), but the variations were minimal and clinically acceptable during our preliminary experience. Our device used a single load cell weighing system because it was simple and cost-effective, but the system did have a major drawback involving the stability of the weighing unit. To improve the stability of the weighing unit, we hung the unit on a mobile cart instead of hanging it on the fluid stand. Nonetheless, our weighing unit still has some friction that could reduce its precision and accuracy of measurement.

For uterine perforation monitoring, one commercially available device signals an alarm when a fluid loss of more than 300 mL in 30 seconds is detected (Fluid Manager<sup>®</sup>, Richard Wolf, Vernon, IL). A high rate of fluid loss at that level is usually caused by a large uterine perforation and can be detected almost immediately by the surgeon due to a sudden loss of visual field and/or sudden noticeable bleeding in the uterine cavity. Most hysteroscopic pumps provide a maximum flow rate of 450–500 mL/min, a rate at which it is not possible to generate fluid loss more than 300 mL in 30 seconds and the perforation alarm cannot be triggered. But for a small uterine perforation that causes fluid loss at a rate of 100–200 mL/min there are no obvious clinical warning signs, and continuous monitoring is needed to detect such perforations in a timely manner. Early detection of this complication is crucial because prolonged failure to detect such a perforation can result in a large amount of fluid loss into the peritoneal cavity. When combined with intravasation of the fluid, failure to detect small uterine perforation can produce catastrophic complications.<sup>6</sup> Our device is able to detect small uterine perforations when used with a hysteroscopic pump set at a maximum flow rate of 200 mL/minute, at which rate it will initiate a perforation alarm after approximately 3 minutes resulting in an estimated

maximum of 600 mL fluid loss into the peritoneal cavity. This amount is about 60.0% of the maximum acceptable fluid deficit of 1,000 mL hypotonic solution suggested by AAGL.<sup>4</sup> Although during our preliminary experience there was only one perforation alarm that was probably caused by a uterine perforation, the laboratory testing of this device showed that the device could detect continuous fluid loss of 150 mL/min and signaled an alarm when fluid loss was  $472 \pm 35$  mL within  $3.2 \pm 0.2$  minutes. We used a lower limit of rate of fluid loss that is more than 100 mL/min because normally fluid can escape into the peritoneal cavity via patent fallopian tubes and is usually detected as a perforation.<sup>12</sup>

## Conclusion

**Our simplified fluid monitoring device can successfully monitor fluid deficits and detect small uterine perforations during hysteroscopic surgeries, thus minimizing human error during prolonged monitoring and increasing patient safety. Further clinical evaluations are necessary to confirm its full clinical applications.**

## References

- Munro MG, Christianson LA. Complications of hysteroscopic and uterine resectoscopic surgery. *COG* 2015; 58: 765 – 97.
- Propst AM, Liberman RF, Harlow BL, Ginsburg ES. Complications of hysteroscopic surgery: predicting patients at risk. *Obstet Gynecol* 2000; 96: 517 – 20.
- Hahn RG. Fluid absorption in endoscopic surgery. *Br J Anaesth* 2006; 96: 8 – 20.
- AAGL Advancing Minimally Invasive Gynecology Worldwide, Munro MG, Storz K, Abbott JA, Falcone T, Jacobs VR, et al. AAGL practice report: practice guidelines for the management of hysteroscopic distending media (replaces hysteroscopic fluid monitoring guidelines. *J Am Assoc Gynecol Laparosc* 2000; 7: 167 – 168.). *J Minim Invasive Gynecol* 2013; 20: 137 – 48.
- Deflieux X, Gauthier T, Menager N, Legendre G, Agostini A, Pierre F. Hysteroscopy: guidelines for clinical practice from the French College of Gynaecologists and Obstetricians. *Euro J Obstet Gynecol Repro Bio* 2014; 178: 114 – 22.
- Dubey PK, Prakash C, Bhardwaj G. Irrigation fluid extravasation during operative hysteroscopy. *J Clin Anesth* 2016; 28: 88 – 9.
- Ankum WM, Vonk J. The spring balance: a simple monitoring system for fluid overload during hysteroscopic surgery. *Lancet* 1994; 343: 836 – 7.
- Tomazevic T, Savnik L, Dintinjana M, Ribic-Pucelj M, Pompe-Tansek M, Vogler A, et al. Safe and effective fluid management by automated gravitation during hysteroscopy. *JSPS* 1998; 2: 51 – 5.
- Novak P, Hamou J, Wattiez A, inventors; Storz Endoscop GmbH, assignee. Device for the rinsing of body cavities. United States Patent No. 5,921,953. 1999 July 13.
- Nikolopoulos I, Phillips G. Reliability of fluid monitoring during operative hysteroscopy. *Gynecol Surg* 2016; 13: 23 – 6.
- Nezhat C, Fisher DT, Datta S. Investigation of often-reported ten percent hysteroscopy fluid overflow: Is this accurate? *J Minim Invasive Gynecol* 2007; 14: 489 – 93.
- Kumar A, Kumar A. New hysteroscopy pump to monitor real-time rate of fluid intravasation. *J Minim Invasive Gynecol* 2012; 19: 369 – 75.