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Flow Rate Measurement of Gravity Infusion Set and Functional Evaluation of Drop Counter: A Pilot Study

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ABSTRACT

Developing a novel drop counter by introducing the Internet of Things concept has been vigorously conducted in recent years. Understanding the newly introduced drop counter's flow rate control accuracy and flow rate count feature is essential for improving safety in infusion management. This study aimed to verify if the new drop counters could secure accurate flow rate and drip count by conducting actual flow rate measurements using gravimetry and functional evaluation. A drop counter was attached to each drip chamber of the infusion set, and an IV drip was conducted at the 100 ml/h flow rate. The weight of discharged physiological saline was measured to plot trumpet curves. Next, three different types of drop counters were evaluated to determine if they maintained drip count accuracy according to the changes in their position angles. The flow rate errors in all conditions indicated trumpet-like curves, exhibiting an overall error range within ±10% in all observation windows. Although every drop counter successfully detected and measured dripping, it was challenging in some counters to detect dripping when the drip chamber was tilted. In comparing adult and pediatric IV sets, the adult IV set was found to be less likely to detect dripping in the angled position. No significant differences in results were confirmed between high and low flow rates, suggesting that the drop count function would not be affected by the flow rate in the ranges of typical infusion practices. Doppler sensors have a wide range of measurements and high sensitivity; the dripping was detected successfully even when the drip chamber was tilted, probably due to the advantages of these sensors. In contrast, miscounts occurred in those equipped with infrared sensors, which could not detect light intensity changes in tilted positions. Understanding the tendencies in flow rate

errors in infusion can be valuable information for infusion management.

1. INTRODUCTION

The IV flow rate is conventionally controlled by adjusting the drip clamp in administering agents to patients in natural dripping. The method is widely known to have difficulties maintaining the initial flow rate for various reasons [1, 2]. These reasons are roughly classified into infusion-related and patient-related factors. The former includes changes in viscosity, temperature, density, surface tension, and volume of infusion solution [3, 4]. The latter includes bending or pressure at the puncture point, the IV route, the angle of the IV set chamber, and other relevant factors [5, 6].

It is physically impossible for the medical staff to monitor patients constantly during IV fluid administration. Thus, a drop counter introducing IoT technology has recently been developed for dripping status monitoring, flow rate log management, and sending alarms to external devices [7, 8]. Some of these drop counters are attached to the drip tube to measure natural dripping infusion in real-time and enable users to monitor the situation remotely with smartphones or PCs using Bluetooth connections [9, 10]. Patients and the medical staff will benefit greatly if these drop counters are able to regulate the infusion flow rate effectively.

IV sets using natural dripping, in which the dripping is performed by gravity, are required to conform to ISO8536-4, which specifies that 20 droplets of distilled water at a rate of 50 drops per minute must equal 1 ml. Since this standard allows a tolerance of ±0.1 ml, the accuracy of the IV set is considered to be within 10% [11]. Therefore, we decided to examine whether the drop counter developed by our collaborators can be used as well as existing drop counters.

IV set users in natural dripping infusion must grasp the flow rate accuracy of infusion and consider the degree of possible flow rate fluctuations due to each factor comprehensively. Understanding the degree of flow rate error should lead to safety improvement in infusion management. Various drop counters have been developed, although there are few reports comparing their functionality. This study aimed to verify if these new drop counters using IoT technology could secure accurate flow rates and drip counts by conducting actual flow rate measurements using gravimetry and evaluating the drop count function.

2. MATERIALS AND METHODS

Figure 1 shows the schematic diagram of the actual flow rate measurement using gravimetry. A drip bag (Normal Saline 1000 ml, Otsuka, Japan) was attached to the stand, and an IV set was attached to the drip bag. A total of six IV sets, three adult IV and three pediatric IV sets, were used in this study: Terufusion Infusion Set (TI-U250PTI-U250P, TK-U25, Terumo, Japan), Nipro Infusion Set (ISA-200A00Z, ISP-201E00, Nipro, Japan), and JSM Infusion Set (JY-ND323A, JY-ND363A, JMS, Japan). The elevation difference between the drip bag and the IV set was set at 1 m, and the drip counter A (Dr-Mark, Mark Electronics Co., Ltd., Japan) was attached to the drip chamber of the IV set. A has a function to send the drip count signals to the mobile device through a Bluetooth connection and convert the signal to the flow rate.

The weight of discharged physiological saline in the reservoir was measured using an electronic scale (EK2000i, A&D Company, Japan). The actual flow rate was obtained by dividing the volume of the discharged physiological saline by the measurement time. The flow rate error was confirmed by comparing the actual flow rate and the one measured by the drop counter attached to the drip chamber. The accuracy of flow rate error was evaluated by plotting trumpet curves. The measurement was made three times in each condition [12]. The measurement time was set as 180 minutes, and the infusion fluid was discharged at a 100 mL/h flow rate. The room temperature was 24.9˚C ± 1.1˚C, water temperature was 23.2˚C ± 1.0˚C, and the humidity was 78% ± 10%.

The evaluation of drop count function according to changes in position angles of drip chambers was performed on each drop counter, A, B (IDC-1501, ACTLAS, Japan), and C (DC-DT1P, Nipro, Japan) attached to drip chambers, respectively. Each counter was tilted vertically at 10 and 20 degrees to the sensor and determined if they could measure the flow rate correctly (Figure 2). The counter A has a function to save flow rate logs, and thus the presence/absence of miscounts was evaluated by reviewing the logs. Counters B and C do not have a log-saving function. Hence, the evaluation was performed by visual observation and video recording to determine if their drop count function was working correctly at each drip.

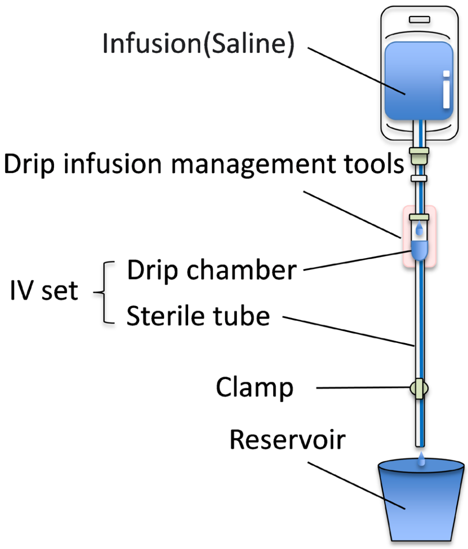

Figure 1. Overview of measurement of flow rate.

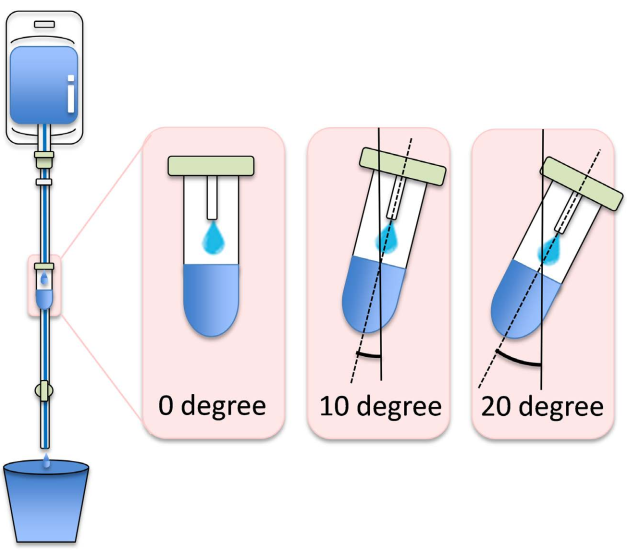

Figure 2. Overview of evaluation of drip counting function.

The angle conditions were set vertically to the sensor at 0, 10, and 20 degrees. The manufacturers of each drop counter published the angle threshold as 10 degrees for their products to perform drop count correctly. In this study, the angle conditions were set up to 20 degrees, twice the published threshold, and evaluated at high and low flow rates. The low flow rate was set at 20 ml/h for both pediatric and adult IV sets, while the high flow rate was set at 120 ml/h for pediatric IV sets and 250 ml/h for adult IV sets. The room temperature was 24.6˚C ± 0.8˚C, water temperature was 21.2˚C ± 1.3˚C, and the humidity was 48% ± 11%.

3. RESULTS

All flow rate errors of drop counter indicated trumpet-like curves. Figure 3 shows the flow rate errors in the drop counter A attached to the adult IV sets of three manufacturers. Likewise, Figure 4 shows the flow rate errors in the same counter A attached to the pediatric IV sets of three manufacturers. Max indicates the maximum flow rate error, while min indicates the minimum flow rate error, exhibiting flow rate errors in the T1 and T2 periods. All drop counters showed an overall error within ±10% in all observation windows. Every drop counter could successfully indicate the drop count confirmation upon detecting droplets either by flashing a light or showing a mark confirming drop detection.

As shown in Table 1, in the high flow rate condition, counter A could successfully perform drop count at all angle conditions, whereas counters B and C failed at 10 degrees for B and 20 degrees for C, respectively. The same result was obtained in the low flow rate condition, as shown in Table 2: Counter A could perform the correct drop count at all angle conditions, whereas counters B and C failed again at 10 degrees in B and 20 degrees in C. When comparing adult and pediatric IV sets, it was discovered that the adult IV sets had trouble detecting droplets in angled conditions.

4. DISCUSSION

The trumpet curve is a type of graph that indicates the time course from the infusion start to the accuracy stabilization in the infusion practices using low-viscosity fluid such as physiological saline, and it is one of the indicators of flow rate accuracy [13]. Various factors, including the characteristics of solutions or agents, various circumstantial changes in patients, and environmental factors, extensively influence the flow rate accuracy in actual clinical settings [14]. Therefore, the evaluation of drop counters in this study

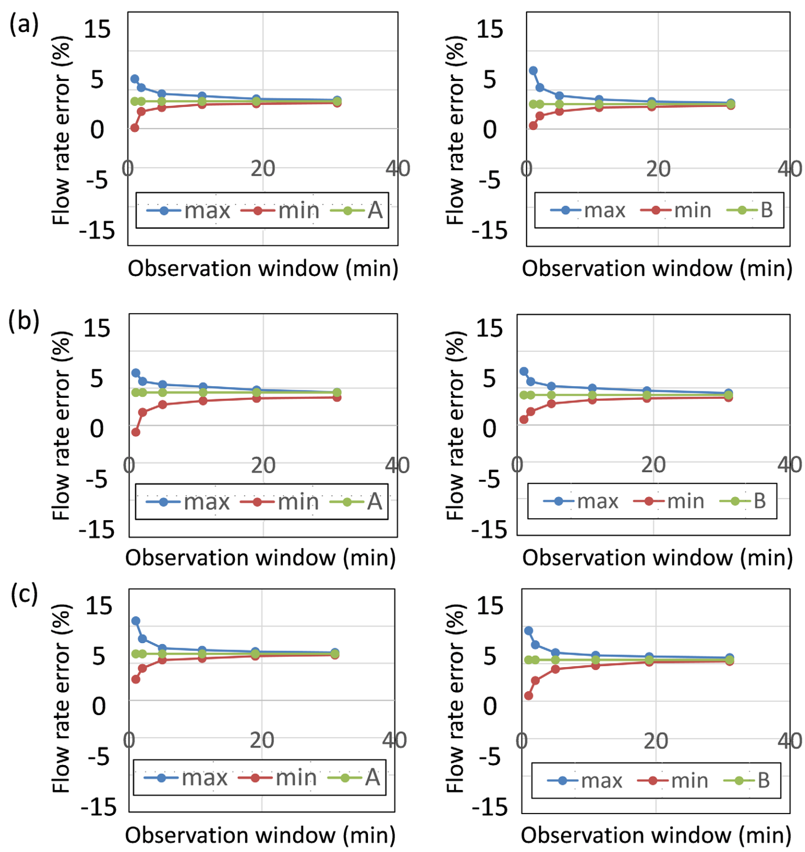

Figure 3. Trumpet curves of an adult infusion set. Left is T1. Right is T2. (a) Terumo; (b) Nipro; (c) JMS.

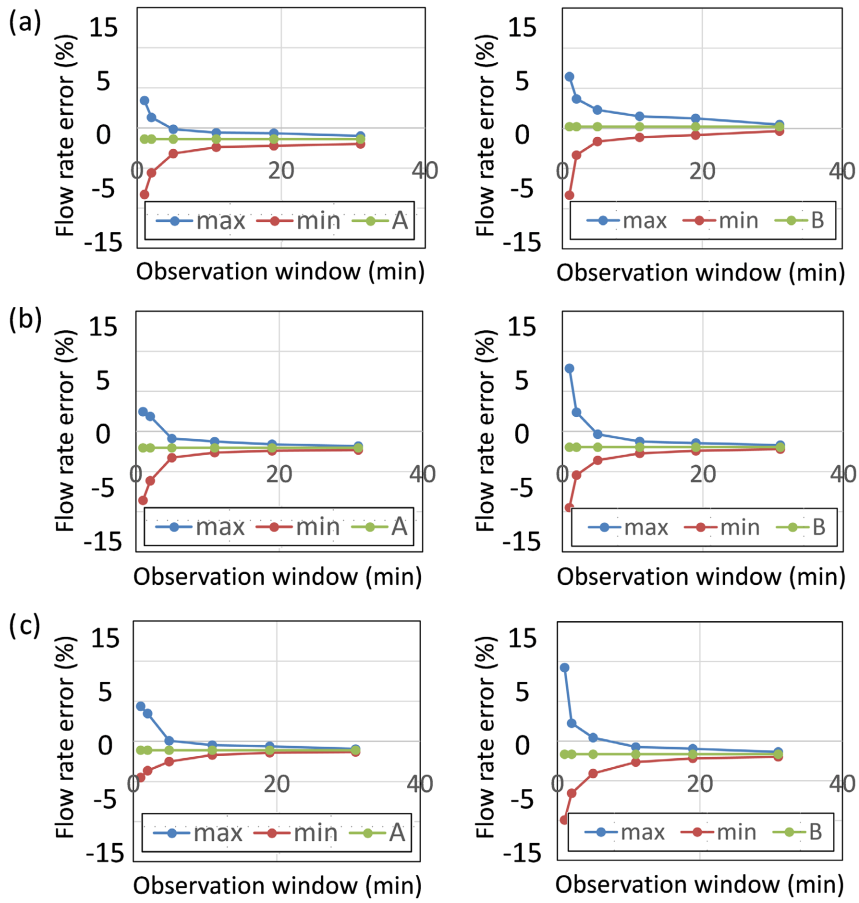

Figure 4. **Trumpet curves of a pediatric infusion set. Left is T1. Right is T2. (a) Terumo. (b) Nipro. (c) JMS.**

Table 1. **Evaluation of drip counting function at a high flow rate.**

	0 degree		10 degree		20 degree	
	Pediatric IV set	Adult IV set	Pediatric IV set	Adult IV set	Pediatric IV set	Adult IV set
A	Normally	Normally	Normally	Normally	Normally	Normally
B	Normally	Normally	Normally	Normally	Normally	Failure
C	Normally	Normally	Normally	Failure	Failure	Failure

Table 2. **Evaluation of drip counting function at a low flow rate.**

	0 degree		10 degree		20 degree	
	Pediatric IV set	Adult IV set	Pediatric IV set	Adult IV set	Pediatric IV set	Adult IV set
A	Normally	Normally	Normally	Normally	Normally	Normally
B	Normally	Normally	Normally	Normally	Normally	Failure
C	Normally	Normally	Normally	Failure	Failure	Failure

was conducted assuming that the drip chamber's position would be tilted due to the patient's body positions or IV routes. Understanding the tendencies in flow rate errors in drop counters, IV sets, and infusion solutions used in hospitals should be valuable information for infusion management [15].

The drop counter A performed accurate flow rate measurements in all angles and flow rate conditions in this study experiment. Counter A had a Doppler sensor, whereas counters B and C were fitted with an infrared sensor. A Doppler sensor is a sensor using microwaves. It has a wide measurement range and high sensitivity, which probably have contributed to the accurate droplet detection even in extensively angled conditions. In contrast, an infrared sensor performs drop count by detecting infrared light intensity fluctuations when moving objects obstruct the straight traveling infrared light. Counters B and C failed to perform drop count correctly, probably because the droplet would not travel in the sensor target range in largely angled conditions.

No significant differences were confirmed between high and low flow rate conditions, suggesting that the drop count function would not be affected by flow rates employed in conventional infusion practices. The reason why adult IV sets had difficulties in droplet detection at the angled condition was considered to be related to the shape of the droplet exit in the drip tube. Although the shape was slightly different in manufacturers, the pediatric IV sets had a slimmer and longer shape than the adult IV sets. The shape made the position of the droplet exit slightly lower than the adult counterpart. Thus, the positional relationship between droplet exit and sensor contributed to the successful drop count in the pediatric IV sets.

One possible cause of flow rate error was the fluctuations in liquid volumes per droplet. The flow rate error occurs in drop counters from changes in the volumes of each droplet. In the case of drop counter A, the liquid volume per droplet was input as 0.05 ml for the adult IV sets. If the dripping should be performed according to the product specification, the liquid volume of each droplet should be 0.05 ml in the adult IV sets. Actually, the volume of droplets would change due to various influences, including the IV set specifications and surface tension or viscosity of the solution. The difference between values input to the drop counters and those obtained through infusion practices probably led to the flow rate error. Users must thoroughly understand the characteristics of the drop counters and IV sets used in infusion management.

5. CONCLUSION

This study conducted the flow rate measurement and drop count function evaluation on infusion drop counters using IoT technology. In the drop counter A, the overall error range was observed to remain within ±10%, which demonstrated successful flow rate measurement, even in the conditions angled 20 degrees vertically to the sensor. Understanding the tendencies in infusion fluid-induced flow rate errors should be valuable information for infusion management. Users must fully understand the characteristics of drop counters and IV sets to conduct infusion management effectively.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest regarding the publication of this paper.

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