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Accuracy of an Automatic Infusion Controller (AutoClamp) for Intravenous Fluid Administration

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Abstract: *Background*: This study was purposed to compare *in vitro* the volumetric accuracy of a newly introduced automatic infusion controller, AutoClamp with that of other commonly used infusion devices. *Methods*: Four different volumetric infusion devices were used to examine the accuracy: Terufusion TE-112; Volumed μVP7000; AutoClamp; and Infucon. Accuracy was determined for each flow rate (20, 40, 100, and 200 ml/h) by using infusate volumes collected after 3 h of initiating the fluid administration. Accuracy was calculated as the percentage difference between set volume and actual volume delivered. The influences of fluid viscosity and flow resistance on infusion device accuracy were also evaluated. *Results*: There were no cases of a greater-than-10% difference between set volume and actual delivered volume. The accuracy of the Infucon was significantly less than that of the other devices. Infusion devices proved to be consistent and unaffected by fluid viscosity or flow resistance except for the Infucon. *Conclusion*: The accuracy of the AutoClamp was comparable to that of other commonly used infusion pumps (Terufusion TE-112 and Volumed μVP7000) regardless of infusate viscosity and flow resistance.

Keywords: Accuracy, AutoClamp, colloid, crystalloid, fluid, infusion.

INTRODUCTION

A variety of infusion devices have been introduced for intravenous fluid administration. Although gravity-fed drop-counting controllers have been used widely for fluid infusion, their accuracy is not optimal. Several infusion devices are now available from different manufacturers and are marketed purporting to improve the accuracy of intravenous fluid administration [1, 2]. Accurate flow is crucial for proper fluid and medication delivery and for patient safety and should be maintained when infusion devices are exposed to a variety of clinical conditions [2, 3]. Pediatric patients or fluid-restricted patients may require a higher degree of infusion device accuracy than other patients [4]. Several infusion devices are now available from different manufacturers. Among them, the AutoClamp, newly introduced in the South Korean market, automatically measures the flow rate by detecting drops passing through infrared sensing devices. The AutoClamp infusion pump is the smallest one available in the market and is lightweight, and streamlined.

The purpose of the present study was to evaluate the volumetric accuracy of the AutoClamp *in vitro* at various flow rates compared to that of other commonly available infusion devices. We also assessed the influences of fluid viscosity using crystalloid, colloid, and dextrose 20% in water and flow resistance using intravenous catheters of different thickness and non-return valve on infusion device accuracy.

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METHODS

Four devices for fluid infusion were evaluated for flow rate accuracy: Terufusion TE-112 (Terumo Corporation, Tokyo), Volumed μVP7000 (Arcomed AG, Regensdorf, Switzerland), AutoClamp (ACE Medical, Seoul), and Infucon infusion (Sungwon Medical, Seoul) (Fig. **1**).

None of the infusion devices had been used previously. The infusion devices were tested using three kinds of solutions: 1000 ml bag of 0.9% saline as crystalloid, 500 ml bag of 6% hydroxyethyl starch as colloid, and 1000 ml bag of dextrose 20% in water (D20W) as a highly concentrated glucose solution.

To ensure accuracy and obtain reliable results, a gravimetric method of measuring fluid volumes was selected rather than depending on the visual reading of a fluid meniscus. A 100-ml volumetric flask was calibrated using distilled water for infusion [5, 6]. Weights were determined using an electronic balance (AP210, Ohaus, Omaha, NE, USA), and all calibrations were carried out at a constant operating-room temperature of 20-22°C). Identical intravenous tubing was used in all cases except for when the AutoClamp was used, which required manufacturer-specified tubing. An 18-gauge, 27-mm catheter was attached to the distal end of the tubing to deliver the infusate to a tared beaker. The infusate was weighed to an accuracy of 3 decimal places. To minimize evaporation, the opening of the measuring beaker was covered with a plastic wrap, with the catheter inserted centrally. A seal was created by melting paraffin wax around the catheter insertion sites. Infusion devices were placed 80 cm above the catheter insertion sites and were set to deliver 20 ml/h, 40 ml/h, 100 ml/h, and 200 ml/h for 3 h: 100 ml, 300 ml, 500 ml, and 800 ml beakers were used according to infusion velocity, respectively. Each delivery rate trial was repeated

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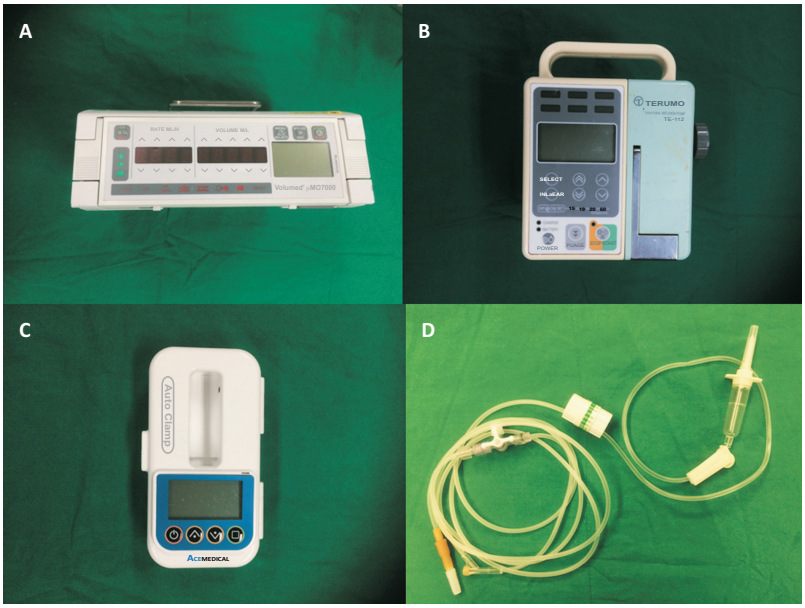

Fig. (1). Infusion device configurations as investigated. (**A**) Terufusion TE-112, (**B**) Volumed μVP7000, (**C**) AutoClamp, and (**D**) Infucon infusion.

three times, so each pump was tested for 36 hours. To evaluate the effect of flow resistance, we additionally tested the devices by using a 24-gauge, 19-mm catheter and non-return valve: experiments were performed as described, and the crystalloid infusate was used. An outcome assessor who was blinded to the infusion device being tested weighed the collected infusates in the tared beakers by using an electronic balance. Infusate volume was calculated by dividing the weight of the collected solution by the specific gravity of the individual study solution. Two well-trained investigators (IJY and OHL) rigorously oversaw the infusion device settings and ensured adherence to the study protocol for the duration of the experiments. All procedures and measurements were performed in an operating room at Chung-Ang University Hospital.

STATISTICAL ANALYSIS

The influence of the various tested parameters, including solution viscosity (crystalloid solution versus colloid solution versus D20W), gauge difference (18 gauge versus 24 gauge), and flow rate (20 ml/h, 40 ml/h, 100 ml/h, and 200 ml/h), on the accuracy and reliability of infusate delivery was statistically examined for each infusion device. For accuracy of infusate delivery, data are expressed as delivered flow rate/set flow rate (%). To assess the reliability of the delivery flow rate, the limits of agreement were calculated as defined by Bland and Altman [7]. For overall comparisons between infusion devices, data were first evaluated for normality by using the Shapiro-Wilk test and for sphericity by using Mauchly's sphericity test. Because all data passed the normality and sphericity tests, overall comparisons were made using two-way repeated measures of analysis of variance with a posthoc Tukey test. A P value less than 0.05 was considered statistically significant. Statistical analyses were performed using SPSS 18.0 (IBM Corp., Armonk, NY, USA).

RESULTS

All tested infusion devices except for the Infucon were found to deliver fluids with a high degree of accuracy under all conditions; the detailed results are presented in Table **1**. There were no cases of a greater-than-10% difference between the set volume and the actual delivered volume. For the crystalloid solution delivered using the 18-gauge catheter, the Infucon delivered an average of 8.98% more infusate than the set volume, while the Terufusion TE-112, Volumed μVP7000, and AutoClamp delivered an average of 2.41%, 1.13%, and 0.37% less infusate than the set volume, respectively (Fig. **2**). Similar results were shown for the crystalloid solution delivered using the 24-gauge catheter and non-return valve: the Infucon delivered an average of 8.44% more infusate than did the set volume, and the Terufusion TE-112, Volumed μVP7000, and AutoClamp delivered an average of 2.53%, 1.25%, and 0.49%, respectively, less infusate than did the set volume (Fig. **3**); the Infucon delivered an average of 8.45% more infusate than did the set volume, and the Terufusion TE-112, Volumed μVP7000, and AutoClamp delivered an average of 2.36%, 2.78%, and 1.55%, respectively, less infusate than did the set volume (Table **1**). For the colloid solution, the Infucon delivered an average of 39.5% less infusate than did the set volume, and the Terufusion TE-112, Volumed μVP7000, and AutoClamp delivered an average of 0.66%, 0.59%, and 2.07%, respectively, more infusate than did the set volume (Fig. **4**). For the D20W, the Infucon, Terufusion TE-112 and Volumed μVP7000 delivered an average of 18.51%, 1.49% and 1.62% less infusate than the set volume, while the AutoClamp delivered an average of 1.16% more infusate than did the set volume (Table **1**). Overall accuracy was not significantly different in a comparison of the Terufusion TE-112, Volumed μVP7000, and AutoClamp. However, the accuracy of the Infucon was significantly less than that of the other devices.

Table 1. Pump flow rate as a percentage of the rate at which the pump was set.

Infusate	Flow rate (ml/hr)	Terfusion	Volumed	AutoClamp	Infucon
Crystalloid /c 18G catheter	20	98.33 ± 3.96	98.89 ± 3.36	100.00 ± 3.10	110.28 ± 2.55*†‡
	40	98.19 ± 3.64	99.58 ± 2.06	99.86 ± 2.95	107.08 ± 3.75*†‡
	100	96.72 ± 3.40	98.06 ± 4.15	99.33 ± 3.28	108.33 ± 2.54*†‡
	200	97.11 ± 3.34	98.97 ± 3.04	99.33 ± 2.97	110.22 ± 4.00*†‡
Crystalloid /c 24 G catheter	20	98.06 ± 4.81	98.61 ± 4.60	99.72 ± 3.47	109.17 ± 4.35*†‡
	40	98.06 ± 3.96	99.44 ± 2.26	99.72 ± 2.93	106.53 ± 3.59*†‡
	100	96.67 ± 3.38	95.83 ± 4.14	99.28 ± 3.24	108.11 ± 2.60*†‡
	200	97.08 ± 3.37	98.94 ± 3.08	99.31 ± 2.91	109.96 ± 4.33*†‡
Crystalloid /c non-return valve	20	97.97 ± 4.81	97.21 ± 3.60	98.34 ± 4.41	109.17 ± 4.35*†‡
	40	97.34 ± 2.99	97.44 ± 4.22	98.79 ± 3.94	106.53 ± 3.59*†‡
	100	97.67 ± 4.12	96.89 ± 3.99	98.28 ± 4.24	108.11 ± 2.60*†‡
	200	97.58 ± 3.29	97.34 ± 4.01	98.38 ± 3.92	109.96 ± 4.33*†‡
Colloid	20	100.83 ± 3.30	100.83 ± 3.86	102.50 ± 2.97	62.22 ± 2.87*†‡
	40	101.39 ± 4.04	101.25 ± 3.98	103.19 ± 3.74	60.14 ± 3.39*†‡
	100	99.94 ± 3.35	100.11 ± 3.53	101.17 ± 2.63	61.39 ± 1.54*†‡
	200	100.50 ± 2.68	100.17 ± 3.44	101.42 ± 2.02	58.14 ± 0.61*†‡
D20W	20	98.84 ± 3.28	98.93 ± 2.83	101.20 ± 1.99	82.22 ± 4.82*†‡
	40	98.38 ± 3.97	98.15 ± 2.99	101.20 ± 2.79	80.19 ± 4.32*†‡
	100	98.44 ± 3.13	98.23 ± 4.53	101.12 ± 3.69	81.39 ± 2.58*†‡
	200	98.24 ± 2.79	98.23 ± 2.34	101.12 ± 3.99	82.15 ± 4.61*†‡

G, gauge; /c, with; D20W, 20% dextrose in water. Values are presented as mean ± standard deviation. *P < 0.05 compared with Terufusion. †P < 0.05 compared with Volumed. ‡P < 0.05 compared with AutoClamp.

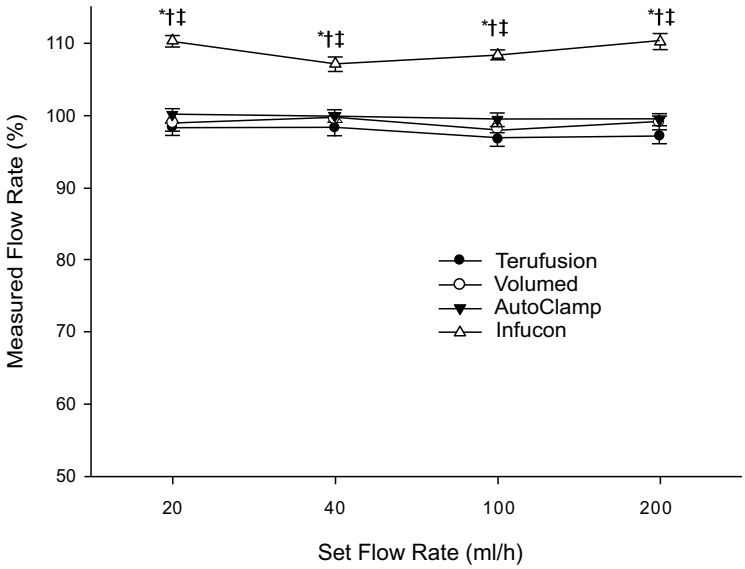

Fig. (2). Pump flow rate as a percentage of the rate at which the pump was set. The infusate was a crystalloid solution, and an 18-gauge catheter was used. Data are presented as mean ± standard error. * P < 0.05 compared with Terufusion. † P < 0.05 compared with Volumed. ‡ P < 0.05 compared with AutoClamp.

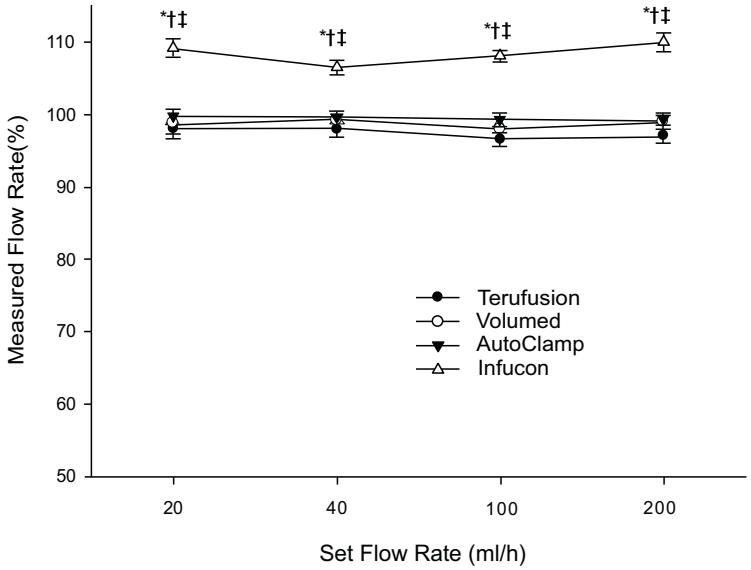

Fig. (3). Pump flow rate as a percentage of the rate at which the pump was set. The infusate was a crystalloid solution, and a 24-gauge catheter was used. Data are presented as mean ± standard error. * P < 0.05 compared with Terufusion. † P < 0.05 compared with Volumed. ‡ P < 0.05 compared with AutoClamp.

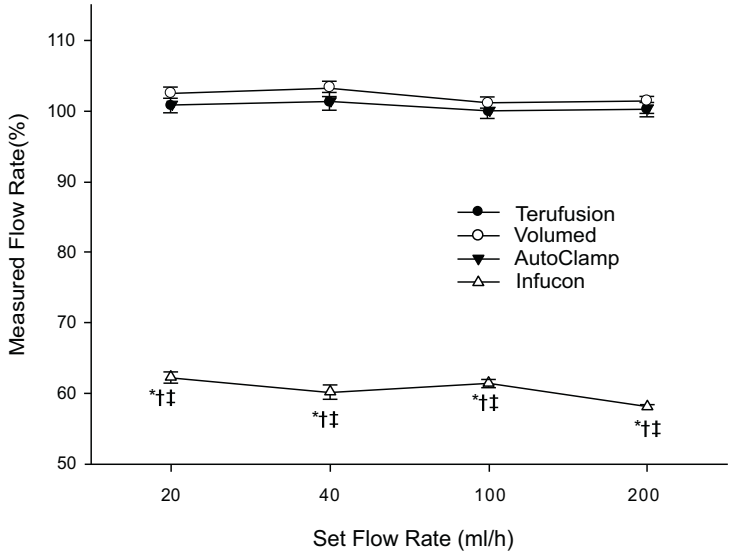

Fig. (4). Pump flow rate as a percentage of the rate at which the pump was set. The infusate was a colloid solution, and an 18-gauge catheter was used. Data are presented as mean ± standard error. * P < 0.05 compared with Terufusion. † P < 0.05 compared with Volumed. ‡ P < 0.05 compared with AutoClamp.

As defined by Bland and Altman [7], the limits of agreement for delivery of the crystalloid solution with an 18-gauge and a 24-gauge catheter were ±7.61, ±7.54, ±6.97, and ±5.98; ±6.77, ±6.95, ±6.23, and ±5.86 for the Infucon, Terufusion TE-112, Volumed μVP7000, and AutoClamp, respectively. For delivery of the colloid solution and D20W and for application of non-return valve, those limits were ±5.43, ±6.49, ±7.10, and ±5.75; ±5.97, ±6.23, ±6.12, and ±5.34; ±5.35, ±6.23, ±6.32, and ±7.32 for the Infucon, Terufusion TE-112, Volumed μVP7000, and AutoClamp, respectively.

DISCUSSION

This study shows the infusion rate accuracy of infusion devices used for intravenous fluid management. The Terufusion TE-112, Volumed μVP7000, and AutoClamp infusion pumps proved accurate throughout the range of infusion rates tested and regardless of infusate viscosity and flow resistance. However, the Infucon was significantly less accurate than were the other infusion pumps under all parameters tested.

Infusion pump devices are used extensively in clinical settings to increase the accuracy of fluid therapy and to decrease workload. They are used to administer replacement fluids, parenteral nutrition, and medication, which make consistent and accurate delivery crucial. Delivery may be influenced by intravenous tubing, filters, fluid viscosity, pump type, or pump mechanism [8, 9]. Expanded clinical applications—including administration of potent drugs by small fluid volumes at slow flow rates—necessitate greater infu-

sion pump accuracy [2]. The necessity for accurate infusion of fluids has encouraged manufacturers to develop electromechanically controlled infusion devices because of certain disadvantages with generally used gravity-fed intravenous infusion sets.

Electromechanical intravenous-fluid control devices can be classified on the basis of the accuracy, technology, and pressure gradients created between the device and the patient [10]. Positive-pressure devices deliver fluid through a rotary or linear peristaltic pumping mechanism. A rotary unit uses a roller that compresses the tubing into a semicircle, making contact with the tubing at the proximal end and breaking contact at the distal end. The linear peristaltic pump has a row of horizontally placed fingers that sequentially compress the intravenous tubing in a wavelike fashion [11, 12]. The accuracy of those devices is usually within 5-10% of the selected flow rate [13, 14]. The Terufusion TE-112 and Volumed μVP7000 used in the present study are microprocessor-controlled volumetric pumps that use a peristaltic system. Thus, it is not surprising that those two devices were accurate regardless of infusate viscosity or flow resistance. The AutoClamp is also a positive-pressure device under a peristaltic system, and the control method of flow rate is different from that of others. The control method of the AutoClamp measures the infusate flow rate by detecting drops passing through infrared sensing devices. The desired infusion flow rate for the AutoClamp is maintained by an adjustable controller in the lower compartment of the drip chamber. The controller calculates the movement of the stepping motor by measuring the difference between actual flow rate and set flow rate, and it controls the motor by locking and releasing the tubing of the chamber. Because there was no report regarding the accuracy of the AutoClamp, it was notable that the AutoClamp showed a level of accuracy similar to that of the Terufusion TE-112 and the Volumed μVP7000 in this study. Moreover, in the current study, comparable results among the three devices even when resistance to flow was applied using a non-return valve strongly support the high level of accuracy of the AutoClamp. Because there would be variable resistances against infusion flow in clinical settings, resistance is the crucial factor for evaluation of the accuracy of infusion devices [15]. Given similar levels of accuracy compared with other infusion pumps as well as the AutoClamp's smaller size and lighter weight than Terufusion TE-112 and Volumed μVP7000 the AutoClamp can be competitive and has beneficial properties.

There are infusion devices that use the force of gravity to deliver intravenous fluids [16, 17]. Such devices are limited by the small pressure gradient that exists between the fluid level in the solution container or drip chamber and the open lumen of the catheter. That small pressure gradient becomes a significant advantage for the patient because small elevations in occlusion pressure slow the flow rate [16]. That property especially has a benefit when caustic or irritating drugs are administered by infusion through peripheral veins. However, high flow rate errors of more than 20% are commonly seen with those devices, which is a considerable problem when critical drugs are infused [15, 18, 19]. Indeed, the Infucon device used in the present study was significantly less accurate than other devices studied, whereas the other tested devices were similarly accurate regardless of fluid viscosity and flow resistance. The Infucon has a precise intravenous flow regulator, which was designed as an ergonomic dial with ridges for easy adjustment. Although the Infucon can provide more-precise regulation of infusion flow than the drop-counting infusion method can, this device does not seem to be appropriate for delivery of colloid fluid or for medication delivery.

There are several limitations in this study. First, the number of infusion devices that were tested was small. Second, the kind of infusates that were administered was limited. Finally, the infusion devices were tested *in vitro*. There are numerous factors that cannot be controlled for when testing pumps *in vivo*, such as the diverse situations of individual patients for example, the patient's moving around, tissue resistance at the tip of the catheter, or accidental occlusion of intravenous tubing by kinking, air bubbles, or blood clots. Because infusion device accuracy was the primary focus of the present study, confounding factors were controlled for as much as possible. The study was conducted in an operating room, where temperature and humidity should remain constant. A fluid height of 80 cm above the catheter insertion site was chosen to simulate a clinical situation such as a patient lying in bed. An 18-gauge catheter was selected because that is the catheter used in our operating room. Further study by using more infusion devices and more infusates such as lipids, blood, or medication and by conducting studies *in vivo* will be necessary.

In conclusion, the accuracy of the AutoClamp was comparable to other commonly used infusion pumps (Terufusion TE-112 and Volumed μVP7000) regardless of infusate viscosity and flow resistance.

CONFLICT OF INTEREST

The authors confirm that this article content has no conflict of interest.

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