Journal of Clinical Monitoring and Computing
https://doi.org/10.1007/s10877-020-00588-7

ORIGINAL RESEARCH

Simulation study on flow rate accuracy of infusion pumps in vibration conditions during emergency patient transport

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Received: 23 February 2020 / Accepted: 7 September 2020

Abstract

Infusion pumps are frequently used when transferring critically ill patients via patient transport cart, ambulance, or helicopter. However, the performance of various infusion pumps under these circumstances has not been explored. The aim of this study was to evaluate the flow rate accuracy of infusion pumps under various clinical vibration conditions. Experiments were conducted with four different types of pumps, including two conventional syringe pumps (Injectomat MC Agilia, Fresenius Kabi and TE-331, Terumo), one conventional peristaltic pump (Volumed μVP7000; Arcomed), and one new cylinder pump (H-100, Meinntech). The flow rate was measured using an infusion pump analyzer on a stable table (0 m/s^2) for 1 h with 1 ml/h and 5 ml/h. Experiments were repeated in mild vibration (2 m/s^2) (representing vibration of patients in a moving stretcher or ambulance), and in moderate vibration (6 m/s^2) (representing vibration in helicopter transport). Any accidental bolus occurrence in extreme vibration situations (20 m/s^2) was also analyzed. Simulated vibrations were reproduced by a custom-made vibration table. In the resting state without vibration and in mild vibration conditions, all pumps maintained good performance. However, in moderate vibration, flow rates in syringe pumps increased beyond their known error ranges, while flow rates in peristaltic pumps remained stable. In extreme vibration, accidental fluid bolus occurred in syringe pumps but not in peristaltic pumps. The newly developed cylinder pump maintained stable performance and was unaffected by external vibration environments.

Keywords Flow rate accuracy · Vibration · Emergency transport · Infusion pump · Cylinder pump

1 Introduction

Infusion pumps are not only used for in-hospital patients in beds but also during intra-, inter-, and out-of-hospital emergency transport of patients in critical conditions [1, 2]. Emergency transport involves limited medical resources in a confined space with vibrations and unexpected movements that may adversely affect the quality of resuscitation and patient management [3, 4]. Dosing errors of vasoactive drugs with narrow safety margins may lead to fatal hemodynamic responses in vulnerable patients [5], and stable performance of infusion pumps is essential to deliver correct flow rate and ensure patient safety.

As technical advancements continue to develop, conventional infusion pumps with demonstrated good performance are widely used in daily clinical practice [6]. However, flow rate accuracy can be affected by several factors [7, 8]. The performance of infusion pumps under various vibration conditions that may occur during emergency patient transport has not previously been evaluated. A cylinder pump that provides precise fluid injection by rotating two pistons inside a donut-shaped dedicated cylinder cartridge has recently been developed [9]. Theoretically, the cylinder pump will be less affected by surrounding environments [10]. In this experimental study, we compare the performance of infusion pumps under simulated vibrations that may occur during

This study was presented in part at the 14th World Congress of Intensive Care, Oct 14–18, 2019, Melbourne.

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s10877-020-00588-7) contains supplementary material, which is available to authorized users.

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Published online: 06 November 2020

emergency patient transport using stretcher, ambulances, or medical helicopters.

2 Methods

2.1 Study design

This is an experimental in vitro study observing the performance of four different infusion pumps under simulated vibration conditions mimicking patient transport situations. Ethics approval was not required for this study.

Possible vibration situations during in- and out-of-hospital patient transport, such as a moving stretcher, ambulance, or helicopter flight, were reproduced using a custom-made vibration table (DMVT-400, Dongmyung vibro, Korea). With reference to the previous literature, vibration during patient transport in a moving stretcher or ambulance was defined as mild vibration with an acceleration force of 2 m/s^2, and vibration during helicopter transport including both takeoff and landing was defined as moderate vibration with an acceleration force of 6 m/s^2 [11–13]. Infusion flow rates delivered by four different infusion pumps were analyzed in various vibration settings of resting state (0 m/s^2), mild vibration (2 m/s^2), moderate vibration (6 m/s^2), and extreme shock conditions (20 m/s^2).

2.2 Materials

Four different infusion pumps were used, including two conventional syringe pumps (Injectomat MC Agilia, Fresenius Kabi, France [14] and TE-331, Terumo, Tokyo, Japan [15]), one conventional peristaltic pump (Volumed μVP7000; Arcomed, Switzerland [16]), and one new-generation cylinder pump (Anyfusion H-100, Meinntech, Korea [9]). The operating principle of the new-generation cylinder pump has been described previously [17]. The cylinder pump has two parts: the main body and the disposable part (a donut-shaped cylinder cartridge). The cylinder pump has two parts: the main body and the disposable part (a donut-shaped cylinder cartridge). This new cylinder pump is considered to have two distinctive characteristics on flow accuracy and stability, by using the dedicated cylinder cartridge; (1) the new operating principle using high-precision motor control and (2) complete fixation of the cartridge to the pump body using an auto-lock system. The key mechanism of this pump is continuous cross-cycling of two pistons inside a dedicated donut-shaped cylinder cartridge, with independent motor control for each piston (Fig. 1, image of cylinder cartridge). This mechanism transforms the linear motion of one piston inside a conventional syringe into rotary motion of two pistons inside a round cylinder. In the donut-shaped cylinder, each piston is programmed to rotate in a distinct manner from the other piston, thereby allowing precise control of fluid infusion. The piston located between the fluid inlet and outlet has a stationary shaft (S or S′), while the other piston has a rotational shaft (R or R′) (Fig. 1). With precise control by an independent motor according to the set infusion rate, the rotational piston (R or R′) rotates counterclockwise, such that an accurate amount of fluid is simultaneously aspirated from the inlet and discharged to the outlet (Fig. 1).

In addition, when the dedicated cartridge is inserted at the pump body, the cylinder cartridge and the pump body are completely fixed by an automatic-locking system (Fig. 1). Once the dedicated cartridge is locked into the body of the cylinder pump, the fluid infusion is determined only by the movement of two pistons, which are adjusted by two independent precise motors. Because of the above distinct characteristics of the cylinder cartridge, the new cylinder pump is hypothesized to maintain a constant infusion rate, even under external vibration conditions.

A multi-channel infusion pump analyzer (IDA 4 Plus, Fluke Biomedical, Cleveland, OH, USA) was used to measure the actual flow rate delivered by the infusion pump. As stated by the manufacturer, the flow rate is calculated by measuring volume over time. The accuracy (maximal error range) is 1% reading ± 1 least significant digit (LSD) for flows of 16–200 ml/h after delivery of 20 ml, otherwise, it is 2% of reading ± 1 LSD after delivery of 10 ml under laboratory conditions [18]. In our institution, the infusion pump analyzer is managed by the Department of Biomedical Engineering and is periodically calibrated. In addition, as suggested by the manufacturer, one of the authors (YYK) checked the accuracy of flow measurement performance using a precision syringe pump, which had been verified using other calibrated equipment before the experiments [19].

2.3 Outcome parameters

Average flow rate delivered by each infusion pump with infusion settings of 1 ml/h and 5 ml/h was measured over 1 h.

2.4 Experimental set-up

The experimental set-up is shown in Fig. 2. The infusion system, composed of a 50 ml syringe (Shinchang Medical Co, Korea) filled with normal saline installed in the infusion pump, was connected to the infusion analyzer (IDA 4 Plus) through an intravenous tubing line and three-way stopcock. The infusion pump was positioned on the vibrating table.

Each experiment was performed for 1 h to analyze the flow actually delivered to the infusion pump analyzer with fluid infusion rate settings of 1 ml/h or 5 ml/h. Experiments were repeated under different simulated vibrations, including resting

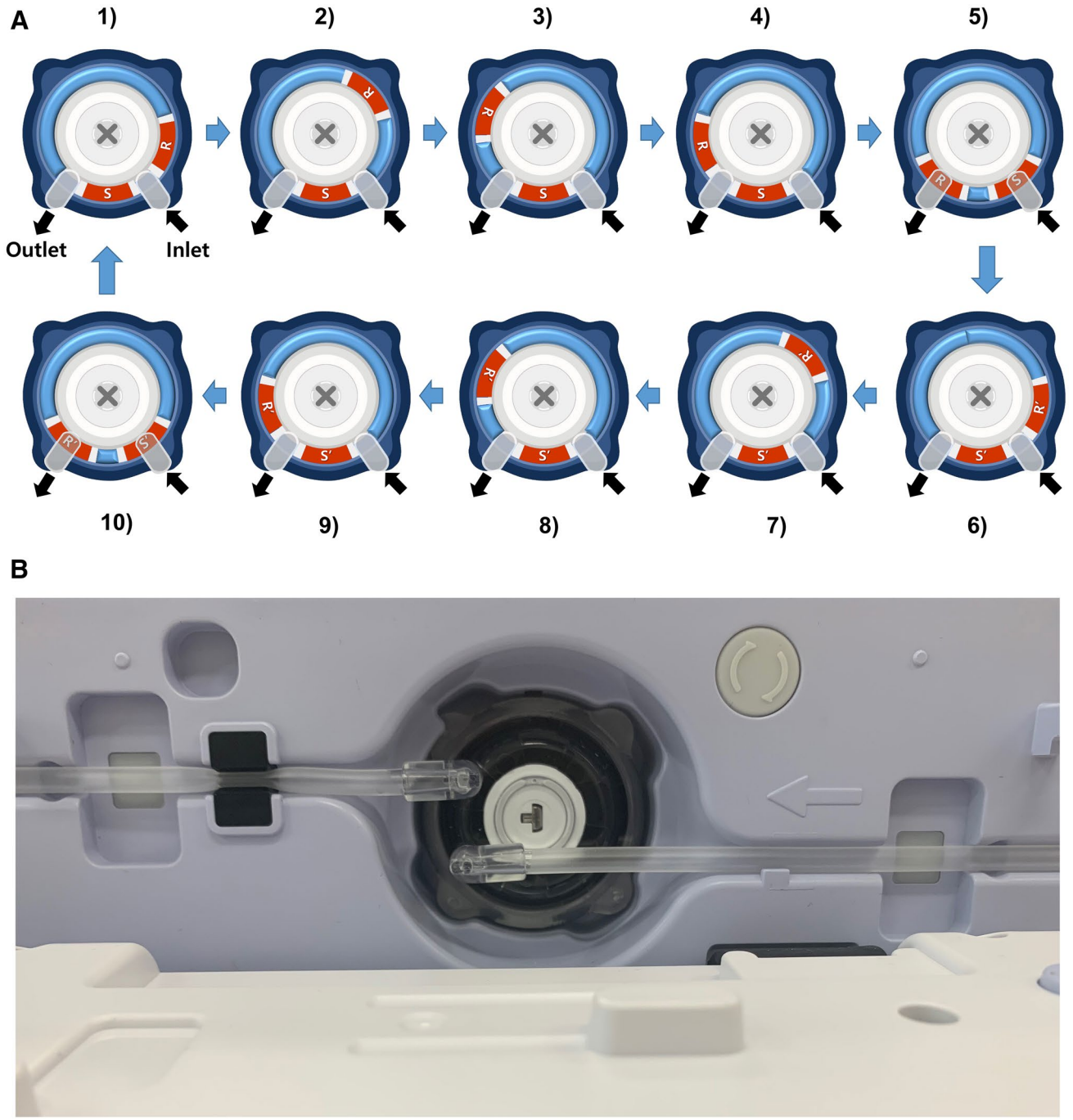

Fig. 1 **a** Core technology of new-generation cylinder pump. "Cross-cycling" of two pistons inside a donut-shaped dedicated cylinder cartridge allows precise control of fluid infusion and prevents any free flow or accidental bolus. The piston located between the fluid inlet and outlet is a stationary shaft (S or S′), while the other piston is a rotational shaft (R or R′). As in 4, when the rotational shaft (R) rotates one cycle, the rotational shaft (R) and the stationary shaft (S) move together as in 5. As in 6, the rotational shaft is changed to stationary shift (R → S′), and stationary shaft becomes rotational shaft (S → R′), changing the role. **b** Photo of a dedicated cylinder cartridge fixed to the pump body using an automatic-locking system

state (0 m/s^2), mild vibration (2 m/s^2) (reflecting vibrations in moving stretcher or ambulance), and moderate vibration (6 m/s^2) (reflecting vibration during medical helicopter flight). Experiments were also performed under extreme vibration situations (20 m/s^2) to observe if accidental bolus infusion would occur due to unexpected external shocks or irregular ground conditions, such as movement during an ambulance ride or abrupt air turbulence during a helicopter flight. To

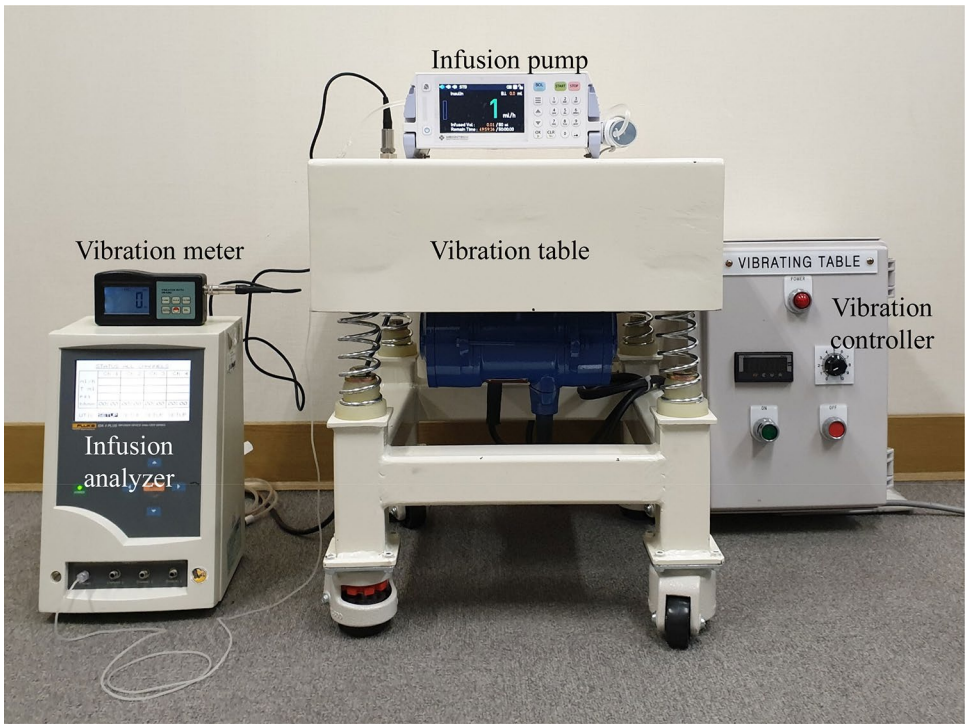

Fig. 2 Experimental set-up

verify adequate acceleration of vibration, the vibration level was measured using a vibration meter (VM-6360, Hong Kong, China) (Fig. 2). All experiments were repeated five times, except for the extreme vibrations test, which was conducted only once.

2.5 Statistical analysis

Data were tabulated and analyzed using SPSS 25.0 (SPSS, Inc., Chicago, IL) and GraphPad Prism 8 (GraphPad Software, Inc., La Jolla, CA). Changes of flow rate were considered significant if the error ranges increased beyond the known (manufacturer-provided) error ranges. In general, infusion error range is reported as less than 3% for syringe pumps [20, 21] and 5% for peristaltic pumps [22, 23]. To compare the flow rate accuracy between different infusion pumps under each simulated vibration condition, flow rates for one hour were analyzed with Kruskal–Wallis tests with post hoc pairwise Mann–Whitney analyses. The type I error rate for pairwise comparisons between infusion pumps was adjusted by Bonferroni's correction using $p = 0.05$ as the global level of significance with post-hoc p values set at $p < 0.008$ ($= 0.05/6$).

3 Results

A total of 128 1-h experimental procedures were analyzed to provide 128 h of data. In the resting state and under mild vibrating conditions, all pumps showed good performance within the known error range at both flow rates of 1 ml/h and 5 ml/h (Table 1). However, with both syringe pumps, flow rates increased over the known error range with moderate and higher vibrating conditions (5% of error range in Fresenius Kabi Agilia and 8% in Terumo TE-331 syringe pump). In addition, inadvertent fluid boluses were injected with extreme vibration (20 m/s^2). In a peristaltic pump (Arcomed Volumed µVP7000), flow rates remained mostly stable within the known error range, but overall under-infusion was found than obtaining the target volume (Fig. 3). This tendency was more pronounced at a lower flow rate (1 ml/h) under moderate vibration (Table 1, Fig. 3). In the new generation cylinder pump, stable flow rate was recorded with less than 2% of the manufacturer-provided error range under all simulated vibrations. No accidental bolus injection was observed with extreme vibrating conditions for both infusion and cylinder pumps (Fig. 4).

4 Discussion

We evaluated the performance of infusion pumps in various vibration conditions possible during emergency patient transport. In mild vibration, all infusion pumps maintained good performance with accurate flow rate. However, in moderate vibration, flow rates in syringe pumps increased beyond their known error ranges, while flow rates in peristaltic pumps remained within the known error ranges. In extreme vibration conditions, accidental fluid bolus was

Table 1 Performance of various infusion pumps

	Syringe pump Kabi	Syringe pump Terumo	Peristaltic pump Arcomed	Cylinder pump Meinntech
Infusion rate at 1 ml/h				
Resting (0 m/s^2)	1.01 ± 0.03 (1%)	1.03 ± 0.01 (3%)	0.96 ± 0.02 (4%)	0.98 ± 0.01 (2%)
Mild (2 m/s^2)	1.01 ± 0.02 (1%)	1.01 ± 0.05 (1%)	0.96 ± 0.01 (4%)	0.99 ± 0.02 (1%)
Moderate (6 m/s^2)	1.01 ± 0.01 (1%)	1.03 ± 0.03 (3%)	0.93 ± 0.03 (7%[a])	0.99 ± 0.03 (1%)
Inadvertent bolus at extreme vibrations (20 m/s^2)	Yes	Yes	No	No
Infusion rate at 5 ml/h				
Resting (0 m/s^2)	5.10 ± 0.06 (2%)	5.04 ± 0.06 (0.8%)	4.78 ± 0.02 (4.4%)	4.96 ± 0.04 (0.8%)
Mild (2 m/s^2)	5.03 ± 0.01 (0.6%)	5.05 ± 0.04 (1%)	4.79 ± 0.09 (4.2%)	4.92 ± 0.06 (1.6%)
Moderate (6 m/s^2)	5.25 ± 0.43 (5%[a])	5.40 ± 0.68 (8%[a])	4.77 ± 0.07 (4.6%)	4.95 ± 0.11 (1%)
Inadvertent bolus at extreme vibrations (20 m/s^2)	Yes	Yes	No	No

Data are presented as mean ± SD of delivered flow rate (ml/h) with percent error (%)

[a]Beyond manufacturer-provided error range of 3% in syringe pump, 5% in peristaltic pump, and 2% in cylinder pump

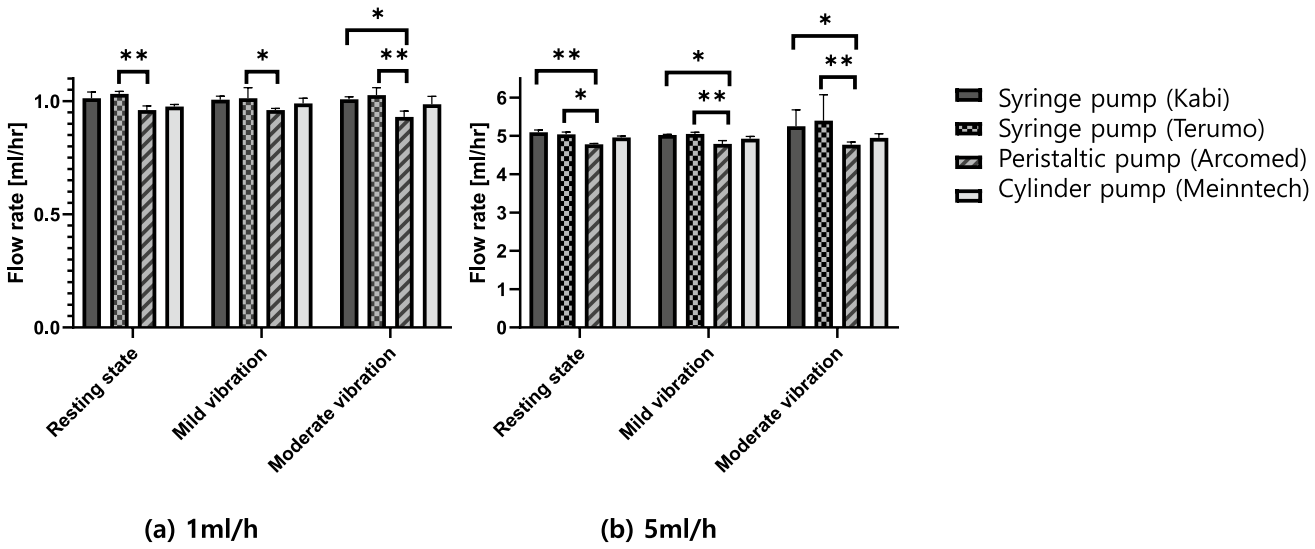

Fig. 3 Average flow rate for various infusion pumps with **a** 1 ml/h, **b** 5 ml/h. P values are statistically significant by Kruskal–Wallis test at both flow rates of 1 ml/h and 5 ml/h. Mann–Whitney test is conducted to calculate P values between groups; *P < 0.05 and **P < 0.01 after adjustment by Bonferroni correction

injected in the syringe pumps but not in the peristaltic pumps. The new cylinder pump maintained stable performance without being affected by the external vibrations.

4.1 Importance of pump performance during emergency patient transport

Inter-hospital patient transports are common, and many patients may be critically-ill requiring continuous drug infusion during transports [24–26]. Therefore, stable performance of infusion pumps, especially flow rate accuracy, is important for patient safety because even small dosage errors for vasoactive drugs may cause significant hemodynamic fluctuations in vulnerable patients [27–29]. Moreover, vibrations of varying intensities can occur continuously or abruptly during transports due to irregular road surfaces, sudden air flow turbulence during helicopter transport, and unexpected external shocks. However, the effects of these possible vibrations on pump performance are not clearly demonstrated.

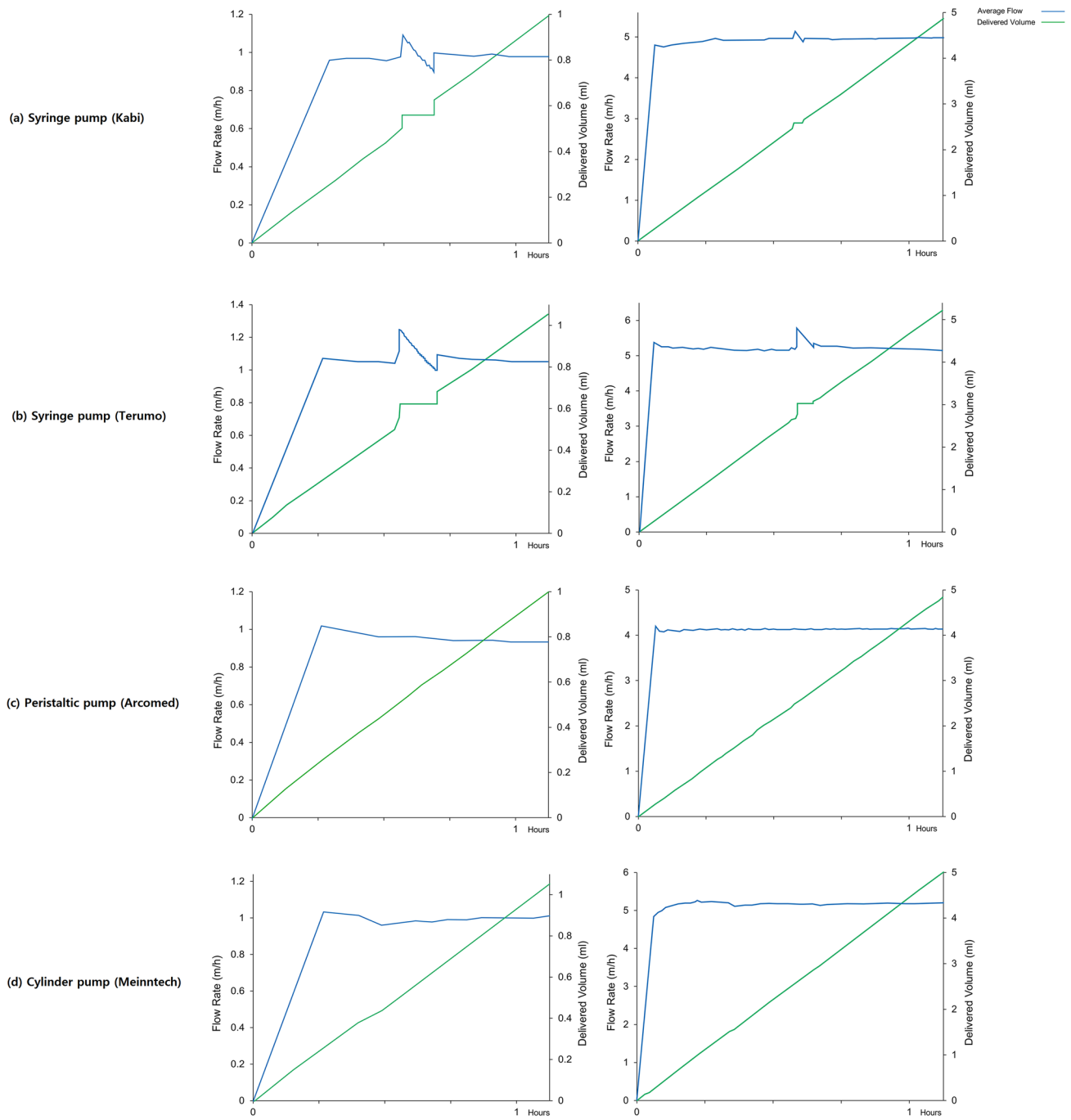

Fig. 4 Hydrograph of inadvertent bolus infusion with flow rate of 1 ml/h (left) and 5 ml/h (right), which is reproduced by an external shock (acceleration of 20 m/s^2 for 20 s) 30 min after the start of the experiment. Blue line indicates average flow rate and green line indicates delivered volume. **a** Syringe pump (Kabi), **b** Syringe pump (Terumo), **c** Peristaltic pump (Arcomed), **d** Cylinder pump (Meinntech)

4.2 Conventional infusion pumps and possible flow rate variability

With continuing technical advancements, various syringe and peristaltic pumps are indispensable in daily clinical practice. However, each infusion pump has distinct advantages and limitations. The entire infusion system consists of several components, including the fluid bag/syringe, fluid tubing line, attachments to the infusion pump, flow controller, and intravenous angio-catheter. Therefore, even if the electromechanical pump performs well as expected, injection errors may occur due to various external factors

[7, 30]. For example, the flow rate of a syringe pump may be affected by vertical displacement of the devices; lowering the pump position more than the patient temporarily reduces infusion volume [31], and raising the pump position above the patient may generate an inadvertent bolus injection [32]. Compliance with tubing lines and syringe size also affects flow rate accuracy [33–35]. Therefore, the vibration generated during patient transport is another important environmental factor that may influence flow accuracy. We hypothesized that the effects vary depending on the design and technology of different pump devices.

5 Our findings and interpretation

Syringe and peristaltic pumps are two representative infusion pumps for continuous micro-infusion. A peristaltic pump uses indirect operation in which a series of linear peristaltic actuators driven by a rotary stepper motor exert peristaltic movement on fluid in the infusion line, resulting in a relatively high margin of error. This is consistent with our results of around 5% under-infusion with peristaltic pumps. Syringe pumps use a sophisticated method to directly push the syringe, and rotary motion is converted to linear movement. As a result of its mechanics, this pump delivers fluid in small, precise volumes within 2–3% of the error range. The precision of syringe pumps was recreated in resting and mild vibration conditions of this experiment. Unlike with peristaltic pumps, however, unexpected bolus injections were observed with syringe pumps at 5 ml/h with moderate vibrations. This was also reproduced in additional experiments using extreme vibrations. This drawback may be partly explained by the incomplete fixation between the syringe and the pump body. Although the barrel flange of a syringe is fixed at the holder by a fixing disc, there would be still some space between the barrel flange and the holder, allowing the syringe movement, and the fixating disc can be accidentally detached.

In the peristaltic pump, two actuators on either side of the infusion line act like a safety valve to prevent inadvertent bolus infusion even if a strong external shock is applied. With a syringe pump, accidental forward free flow can occur through the open end in the absence of a locking device that acts as a check valve to prevent unintended syringe movement from large external shocks.

A cylinder pump is a new concept infusion pump that combines the advantages of both infusion and syringe pumps. The cylinder pump operates on the principle of sucking and discharging fluid via two rotating pistons inside a dedicated cylinder cartridge. Due to the high-precision infusion control and complete auto-lock fixation between the dedicated cartridge and the pump body, flow rate accuracy and stability is maintained, and any free flow or accidental bolus is prevented.

6 Clinical implications of our study

In a stable environment, all pumps showed good performance, and the syringe pump was more beneficial for sophisticated flow control at lower error ranges compared to the peristaltic pump. However, in environments with moderate or higher vibrations expected, the peristaltic pump is better at preventing accidental bolus injection. When transferring small pediatric patients or critically ill patients with intravenous infusions of highly potent drugs, the use of syringe pumps requires careful attention, including fastening the pump to fixed racks to prevent sudden device movement or displacement. The new cylinder pump has combined advantages of both accurate injection of the syringe pump and free flow prevention of the peristaltic pump. Therefore, the cylinder pump should be considered in environments with moderate vibration expected.

7 Limitations

This study involves limitations. First, as a laboratory-level experimental study, it is difficult to predict the actual response in real patients. Clinical response may vary individually according to patient size and underlying cardiopulmonary function. Responses may be more pronounced in small pediatric patients or elderly patients with organ dysfunction. Second, simulated vibrations were used with reference to previous research [11–13], and the experiments were not performed in actual ambulances or helicopters. However, the vibration intensity during emergency transports is not fixed and varies from sitting in stable conditions (e.g., car 0.5 m/s^2, bus 0.6 m/s^2, helicopter 0.8 m/s^2) [36, 37] to strong vibrations with unreported intensities (strong vibration-generating conditions such as dropping the pump). Third, investigators were not blinded to the pump types during experiments. Although this experiment could not be blinded by its very nature, the sequences of infusion pump or vibration intensity were randomly selected to reduce selection bias [38]. In addition, all delivered flow rates were automatically recorded by the flow analyzer. Fourth, 50-cc syringes were used for the syringe pump. The performance results of syringe pumps using smaller syringes may differ. However, considering the clinical inconvenience of frequent syringe replacements, the use of 50-cc syringes could be considered reasonable. Finally, limited types of infusion pumps were used. Various commercially available infusion pumps would cause wide variations in performance and the results may

not be applicable to other models from the same or different manufacturers.

8 Conclusions

In this experimental study evaluating the performance of various infusion pumps in clinically possible vibrations, all infusion pumps maintained good performance with mild vibrations. However, the flow rate variability of syringe pumps increased beyond the known error ranges with moderate vibration and accidental bolus injection occurred with extreme vibrations, while the flow rate accuracy of peristaltic pumps was maintained. The new cylinder pump showed stable pump performance and was unaffected by external environmental vibration.

Acknowledgements For technical advice and discussion, the authors thank the Department of Biomedical Engineering at Samsung Medical Center.

Author contributions KYH, JHL, DKK and JJM conception and design of research; KYH and YYK performed experiments; KYH, YYK, SYY and JJM analyzed data; KYH, SYY, JHL, DKK and JJM interpreted results; KYH, SYY and JJM prepared figures; KYH and JJM drafted manuscript; KYH, SYY, JHL, DKK and JJM edited and revised the manuscript; KYH, YYK, SYY, JHL, DKK and JJM approved final version of manuscript.

Funding This work was supported by 'Supporting Project to evaluation New Domestic Medical Devices in Hospitals' funded by 'Ministry of Health and Welfare (MOHW)' and 'Korea Health Industry Development Institute (KHIDI)'.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This is an experimental observational study without involving any human/animal participant. Therefore, our Institutional Research Ethics Committee (Samsung Medical Center) has confirmed that no ethical approval is required.

Research involving human participants and/or animals This work did not to include research involving human participants and/or animals.

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