Accuracy test of intravenous infusion pump : Comparison between a novel cylinder pump and a traditio infusion pump

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This study examines the efficacy of cylinder-type drug infusion pump (®Anyfusion V-100) by comparing the actual administrated volume to a conventional peristaltic flow controlled device, and evaluate the stability test by identifying clinical symptoms and adverse reactions from the healthy volunteers during the infusion period.

Through two different infusion pumps, 400 ml of physiological saline (0.9% NaCl) and 10% glucose solution were injected for 90 minutes to volunteers from the age of 19 to 45.

This study concludes that the flow rate deviation (the ratio of volume to be administrated and administrated actual volume) of Anyfusion V-100 device and conventional device is statistically significant in both physiological saline solution (0.9% NaCl) and glucose infusion groups. The Anyfusion V-100 device showed lower flow rate deviation of 0.54 ± 1.2% and 3.22 ± 1.24%, compared to the conventional device's flow rate deviation of 14.5 ± 3.77% and 13.7 ± 3.06%, tested on the physiological saline solution (0.9% NaCl) and glucose infusion group.

The results of this clinical trial aimed at healthy volunteers showed that in the comparative test between the cylinder-type drug infusion pump (®Anyfusion V-100) and the existing P device(peristaltic) had no significant adverse reaction and the Anyfusion V-100 device showed a significantly lower flow rate deviation compared to existing P devices. Consequentially, Anyfusion V-100 device is considered a safer and more accurate drug infusion pump.

Introduction

"IV infusion pump" is a medical device that injects certain amount of drug or liquid into a patient safely and accurately. It is used in various medical areas such as ward, emergency room, operating room, patients with chronic disease; where continuous drug injection is necessary.

Depending on the injection method and purpose of usage, IV infusion pumps are mainly classified into Syringe Pumps (low capacity, high precision) and Infusion Pumps (large capacity, low precision). The traditional IV Infusion Pump is a device that uses medicine injection with a flow control by sequential peristaltic compression of tube that is connected to the IV bag, that has a flow rate deviation (the ratio of difference in the volume to be administrated and the actual administrated volume) between ± 5% ~ 20% every hour depending on the material and elasticity of the tube.[1]

Besides, IV Infusion Pump must be replaced or reset for the location change in the event of tube recoil problem; and Syringe Pump, used for the precise injection, is incompatible with different syringe sizes, also requiring frequent resetting and replacements for large volume injection.

Having such issues in drug injecting pumps for over 60 years, many attempts have been made to solve such problems by developing new software, using different pump for different purposes, etc. However due to the limitations of the underlying hardware technology, inconvenience of inaccuracy has been largely ignored and the problem remains despite the continuous effort for an alternative technology.[2] Since FDA has a separate management department and recommends continuous monitoring and problem solving to companies, Mainntech Co., Ltd. developed the first Cylinder-type drug infusion pump (®Anyfusion V-100) as an alternative technology

The Cylinder-type infusion pump (®Anyfusion V-100) is a pump that allows accurate drug and liquid injection at the set flow rate and speed to the patients by using a specially developed circular cylinder cartridge. With its huge drug compatibility, Anyfusion V-100 can utilize the conventional IV Infusion Pumps with the method of sequential peristaltic finger mechanism and in the Syringe Pumps that require a precise control.

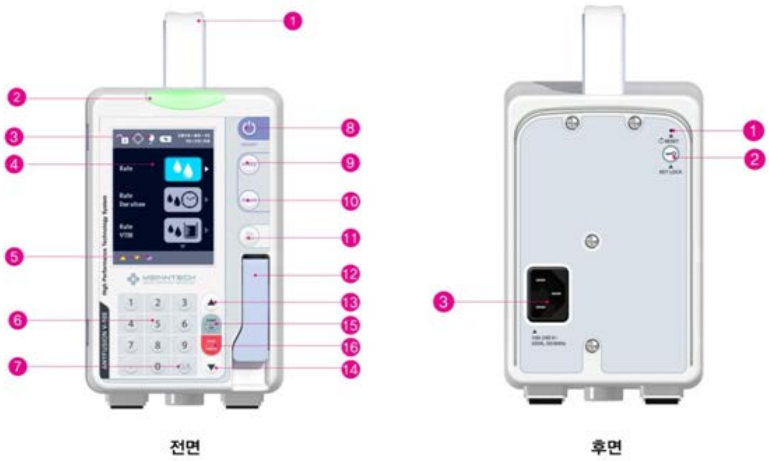

Figure 1. Anyfusion V-100

This device is a pump for the accurate drug and liquid injection at the set flow rate and speed to a patient using a specially developed circular cylinder cartridge.
The Cylinder-type drug infusion pump has a system that rotates two disks inside a donut-shaped cylinder (disposable cylinder cartridge) with two cylinders operated with individual motors, and can deliver liquid (medicine), gas, fluidic solid (food, blood), etc. injection without being influenced by the gravity or location with principle of suction and push mechanism.

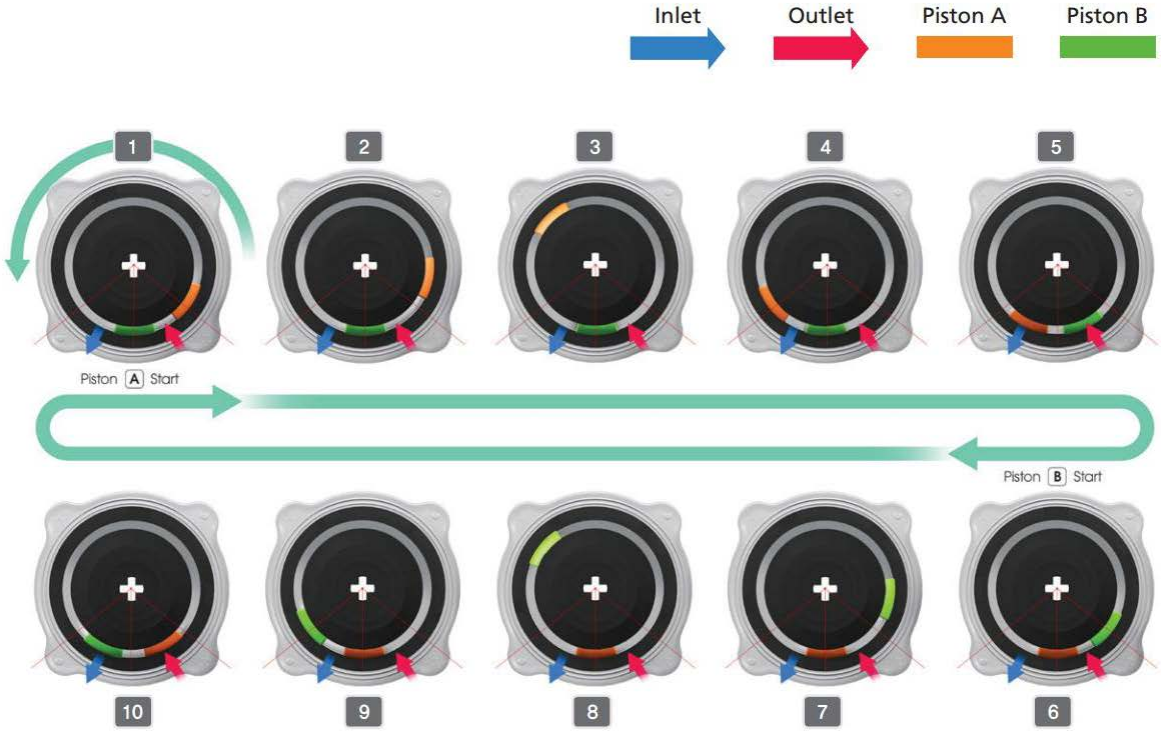

Figure 2. The mechanism of the Cylinder pump

The mechanisme of the Cylinder pump is suction and push mechanism, sequentially rotating each piston where two disks inside the donut-shaped cylinder cartridge are attached, each controlled by the electric motor. Pumping volume, discharged by single piston's circulation, is constant as the cylinder cartridge's capacity is standardized.

This study examines the efficacy of cylinder-type drug infusion pump (®Anyfusion V-100) by comparing the actual administrated volume to a conventional peristaltic flow controlled device P, and evaluate the stability test by identifying clinical symptoms and adverse reactions from the healthy volunteers during the infusion period.

Methods

Through two different infusion pumps, 400 ml of physiological saline (0.9% NaCl) and 10% glucose solution were injected for 90 minutes to volunteers from the age of 19 to 45 to measure the accuracy of pump depending on the viscocity.

To measure the ratio of the administered volume of fluid to the injected volume, the amount of fluid before and after the infusion of the two devices were compared.

The total weight including the fluid set was measured three times and 400ml of fluid was injected for 90 minutes. After injection through the intravenous line secured to the volunteer, the total weight was measured again three times.

The average of three measurements before and after the injection was calculated and the difference was defined as the actual injection amount. The ratio(%) of the difference between 400ml and the actual injected amount was calculated.

Results

The mean age of the volunteers was 24 years old, and the male to female ratio was 50%. No abnormal vital signs in terms of blood pressure, body temperature, pulse, and respiration rate of the volunteers enrolled in this study were observed. None of the vol unteers had any previous medical records regarding serious diseases/surgeries, and blood test results showed no abnormalities.

During the study, one patient (4.17%) had a minor skin rash on the injection site but was not clinically problematic, and the test continued. There was no discontinuation of the study due to severe adverse reactions.

In both the Anyfusion V-100 and P devices, no significant medical device operating errors occurred during study.

From total of 24 subjects, 3 of the cases injected with normal saline (0.9% NaCl) and 3 of the subjects injected with 10% glucose solution in the Anyfusion V-100 device were excluded from the analysis due to absence and measurement error. We also excluded the measurement values of the P device for this case.

In the matched 21 normall saline (0.9% NaCl) injection group, the average actual injection volume of Anyfusion V-100 device was 402.17 ml, which was 2.17 ml more. The ratio (%) between the volume to be administered and the volume actually administered was 100.54%, and the flow rate deviation was 0.54 ± 1.2%.

In the matched 21 physiological saline (0.9% NaCl) injection group, the average actual injection amount of P device was 341.73 ml, which means that 58.27 ml was injected less. The ratio of the volume to be administered and the volume actually administered was 85.43%, and the resulting flow rate deviation was 14.5 ± 3.77%.

In the matched twenty-one 10% glucose solution injection group, the average actual injection amount of Anyfusion V-100 device was 412.90 ml, which means that an average of 12.90 ml was further injected. The percentage of the volume to be administered and the volume actually administered was 103.23%, and the resulting flow rate deviation was 3.22 ± 1.24%.

In the 21 matched 10% glucose solution injection group, the average actual injection volume of P device was 344.84 ml, which was less than the mean injection volume of 55.16 ml. The ratio of the volume to be administered to the actual volume was 86.21% The flow rate deviation was 13.7 ± 3.06%.

Statistical analysis of the results of each group showed statistically significant difference in p-value 0.002 in normal saline (0.9% NaCl) injected group in Anyfusion V-100 device. The other groups did not have a normal distribution.

On the assumption that it follows the normal distribution , we conducted a t-test with a parametric test . The difference was statistically significant in both normal saline-infused and glucose-infused groups (P-value = 0.000).

In the nonparametric test using the Wilcoxon sign rank test, there was a significant differ ence (p-
value = 0.000) between the Anyfusion V00 device and the P device in both normal saline infused and glucose infused groups.

Discussion and Conclusions

Conventional IV infusion pump uses a method of injecting medicine by sequential peristaltic flow control of the tube and has a problem of the flow rate deviation(the ratio of volume to be administrated and administrated actual volume) between ± 5% ~ 20% every hour depending on the material and elasticity of the tube. Cylinder-type drug infusion pump (®Anyfusion V-100), developed in order to overcome such problem, is expected to be able to accurately inject drug and liquid at the set flow rate and speed using a specially developed circular cylinder cartridge.

In this study, we intended to examine the efficacy by comparing the actual administrated volume between a cylinder-type drug infusion pump (®Anyfusion V-100) and a conventional device(P), which is a peristaltic flow control system, and evaluate the stability test to identify subjective and objective symptoms and adverse reactions of the healthy volunteers during the infusion period.

As a result of the study, flow rate deviation(the ratio of volume to be administrated and administrated actual volume) of Anyfusion V-100 device and P device showed a statistically significant difference in both physiological saline solution (0.9% NaCl) and glucose infusion groups.

The flow rate deviation was 0.54 ± 1.2% and 3.22 ± 1.24% in the physiological saline solution (0.9% NaCl) and glucose infusion group in the Anyfusion V-100 device, whereas the flow rate deviation of the P device was 14.5 ± 3.77% and 13.7 ± 3.06%, which was much lower level.

We confirmed once again that the average flow rate deviation of the flow control type devices using the peristaltic method is about ± 5% ~ 20%, and the flow rate deviation of the new cylinder-type drug injection pump, Anyfusion V-100, is less than 5%, which accuracy is considerably higher than conventional devices.

The adverse reaction that occurred in this study was 1 case of mild skin rashes during infusion, which was not related to medical devices. There was no additional serious adverse reaction, and thus this device is considered to be safe.

In conclusion, the results of this clinical comparative trial between the cylinder-type drug infusion pump (®Anyfusion V-100) and the existing P device(peristaltic) aimed at healthy volunteers showed no significant extraordinary reaction, and the Anyfusion V-100 device showed a significantly lower flow rate deviation compared to existing P devices. Consequentially, Anyfusion V-100 device is considered as a safer and more accurate drug infusion pump.