

A Questionnaire Survey on Operability of Syringe Pumps for Prefilled Syringes

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Some types of syringe pumps currently available for use of prefilled syringes (PFS) require setting for syringe size which varies from manufacturer to manufacturer. We conducted a questionnaire survey for 10 nurses at the emergency critical care center of this hospital on the operating procedures of two different types of syringe pump (i.e., from turning on the power to PFS setting, PFS mounting, flow rate setting, and start of drug infusion), in terms of (1) manipulation time, (2) accuracy of task performance, and (3) operability. The syringe pumps used were: type A, TE-331S0N (Terumo Corporation), and type B, CSP-100S (Daiken Medical Co., Ltd.). The PFS product used was Inovon Injection 0.3% Syringe (dopamine hydrochloride injection; Kyowa Hakko Kirin Co., Ltd.). Type A required no mode setting for exclusive use of PFS, while mode setting for exclusive use of PFS is mandatory for type B. The task process from turning on the power to drug infusion start comprised 5 and 13 steps for type A and B, respectively. Manipulation time was significantly shorter with type A, compared to type B. As for accuracy of task performance, 90% of nurses performed manipulations accurately with type A; whereas with type B, 90% of nurses were close to failing or actually failed to follow the procedures appropriately, and only 10% followed accurately. Thus, type A proved superior in 4 of the 5 points of issue except "easy to set flow rate". In conclusion, the results indicate the importance of standardizing the syringe size and other specifications through the cooperation of pharmaceutical companies and medical device manufacturers to cope with the future spread of PFS.

Key words: prefilled syringe (PFS), syringe pump, operation time, safety management

INTRODUCTION

Prefilled syringe (hereinafter PFS) is a preparation, in which drug solution is aseptically filled in the syringe in advance, eliminating the preparation from the ampule or vial, and has rapidly spread in our country.

Recently, in the field of anesthesia and intensive care, dopamine hydrochloride, dobutamine hydrochloride, and propofol have been prefilled into a syringe, and prefilled syringes are frequently used with a syringe pump. And, when the syringe pump is used, the setting of the size might become necessary according to the manufacturer of the syringe used for PFS. For the syringe pump which requires exclusive mode setting, it is likely that operation time and operation are wasted in clinical sites. We have investigated how the differences of syringe pumps in using PFS affect on operation time, operationality, and medical safety.

MATERIALS AND METHODS

Inovon Injection 0.3% PFS (Kyowa Hakko Kirin Co., Ltd.) that uses the syringe made by the Terumo company is prepared. Two types of syringe pump were used. The models used were Type A, TE-331S0N, and Type B, CSP-100S. Type A can infuse drug solution with the same operation as that of the conventional disposable syringe, in using PFS syringe, and does not require special mode setting. However, Type B requires PFS exclusive mode setting. (Fig. 1). Ten nurses

(8 females and 2 males) who had more than one year experience in an emergency critical care center operated these two syringe pumps.

1) Comparison of operation time required to start the administration of PFS preparation using the syringe pump

The time requiring for a series of operation including turning on the power of the syringe pump, PFS setting, mounting of PFS, flow rate setting (3mL/h) and start of drug administration was measured.

Prior to the experiment, each of 2 types of syringe was operated 5 times for experience. The process of the tasks from power-on of the syringes to administration of the drug solution is shown in Table 1. Type A requires 5 steps from power-on to the start of administration of the drug solution, including (1) turning on the power switch, (2) PFS setting, (3) flow rate setting (3mL/h), (4) infusion tube priming (fast-forward) button, and (5) starting the switch of administration of the drug. Type B requires as many as 13 steps, including (1) turning on the power switch, (2) F key + change over key, (3) changeover switch 1, (4) changeover switch 2, (5) changeover switch 3, (6) flow rate setting decimal switch 1, (7) flow rate setting decimal switch 2, (8) starting switch, (9) stop switch, (10) setting of the syringe, (11) flow rate setting (3mL/h), (12) infusion tube priming (fast-forward), and (13) starting switch.



Fig. 1 Features of Two Different Pumps. Type A: TE-331S0N (Terumo Corporation): PFS syringe can be used without changing operational mode. Type B: CSP-100S (Daiken Medical Co., Ltd.): Operational mode must be changed before using PSF syringe.
Type A (left): TE-331S0N, Type B (right): CSP-100S,

Type A	Type B
1. Power button	1. Power button
2. Set syringe	2. Fn + Alt key
3. Set pumping rate	3. Shifting switch (1)
4. Priming button	4. Shifting switch (2)
5. Start button	5. Shifting switch (3)
	6. Pumping rate setting button (decimal number)
	7. Pumping rate setting button (decimal number)
	8. Start button
	9. Pause button
	10. Set syringe
	11. Set pumping rate
	12. Priming button
	13. Start button

Table 1 The process of the tasks from power-on of the syringes to administration of the drug solution. Type A requires 5 steps from power-on to the start of administration of the drug solution, and Type B requires as many as 13 steps.

2) Comparison of correctness of task

We have investigated whether each operation is conducted correctly, and compared correctness of the task after completion of the test by classifying subjects into 3 groups: a group who (1) operated correctly, (2) came near to make mistakes, or (3) made mistakes.

3) Questionnaire survey on operability of the syringe pump

A questionnaire survey was conducted on 5 items that were evaluated 1 (poor)–5 (good) ranks by subjects who conducted the tasks of 2 types of syringe pump (Table 2). For statistics, Student test, and Mann-Whitney U test were used and $P < 0.05$ was defined as significant difference.

RESULTS

1) Comparison of operation time required to start of administration of PFS preparation

Mean operation time (second) of the syringe pump is shown in Fig. 2. Shown in black is Type A and in gray Type B. The mean operation time of Type A was 23.8 ± 3.7 seconds and that of Type B was 45.7 ± 6.7

seconds, showing that operation time of Type A was significantly shorter than that of Type B.

2) Comparison of correctness of the task

In Type A, those who answered that they (1) were able to operate correctly, (2) came near to make mistakes, and (3) actually made mistake were 90%, 10%, and 0%, respectively.

On the other hand, in Type B, they were 10%, 50%, and 40%, respectively. In Type B, a total of (2) and (3) accounted for 90% (Fig. 3).

3) Questionnaire Survey on operability of the syringe pumps.

The radar chart of the questionnaire survey is shown in Fig. 4, which was evaluated 5 ranks by subjects who conducted 2 types of task.

According to the questionnaire survey, Type A was superior to Type B for “easiness of change to PFS setting”, “easiness of PFS setting to the syringe pump”, “visibility of the switch”, and “visibility of panel display”. However, there is not significant difference in “easiness of the flow rate setting”.

Table 2 Questionnaire survey on the operability of syringe pump.

Question	Type A	Type B
Q1. Is it easy to shift operational mode for each type of syringe ?	1 2 3 4 5	1 2 3 4 5
Q2. Is it easy to set syringe to the pump ?	1 2 3 4 5	1 2 3 4 5
Q3. Is it easy to set pumping rate ?	1 2 3 4 5	1 2 3 4 5
Q4. Are the buttons highly visible ?	1 2 3 4 5	1 2 3 4 5
Q5. Is LCD* window highly visible ?	1 2 3 4 5	1 2 3 4 5

* Liquid Crystal Display

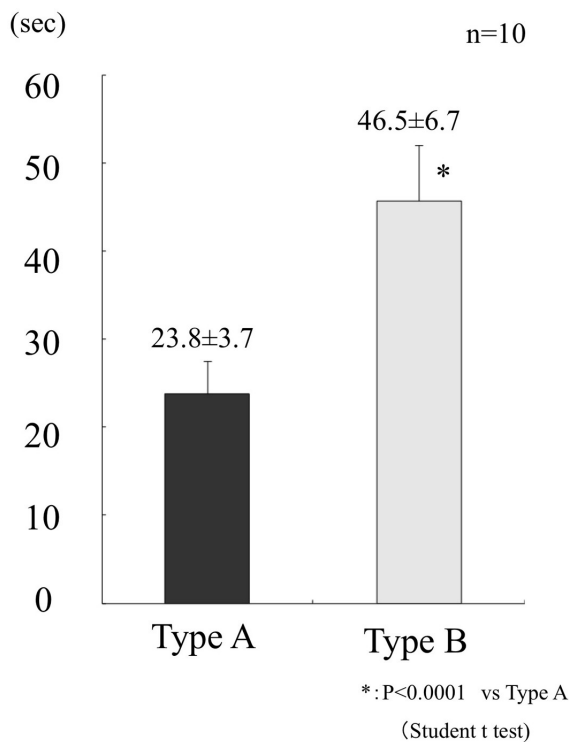


Fig. 2 Comparison of operation time required to start PFS preparation.

DISCUSSION

In Europe and America, many injection drugs are prefilled into a syringe, while not many drugs are prefilled in our country [1]. However, in the anesthesia and critical care medicine settings we are engaging, propofol, dopamine hydrochloride, dobutamine hydrochloride, epinephrine, heparin, heparinized physiologic saline, and local anesthetic drugs including xylocaine, mepivacaine, bupivacaine, and ropivacaine have been prefilled into a syringe one after another, recently.

It is known that PFS preparation has advantages over typical amples: preparation time of prefilled syringes for drugs which need dilution such as dopamine hydrochloride and dobutamine hydrochloride

is shortened to about 1/3 compared with ample drug preparation, and concentration is constant and there is no concentration variable with pharmacists engaging its preparation [2].

On the other hand, fat emulsion represented by propofol is considered to be prone to be contaminated by bacteria [3-7]. From 1989 to 1996, there were 39 cases on average annually where postoperative infection with propofol cannot be ruled out. We consider that prefilling drugs may furthermore reduce bacterial infection. Other advantages of PFS include prevention of needlestick accidents, drug mix-ups, wrong infusion, and easiness of waste separation [2, 8].

When we use PFS, many of PFS could be frequently used with a syringe pump.

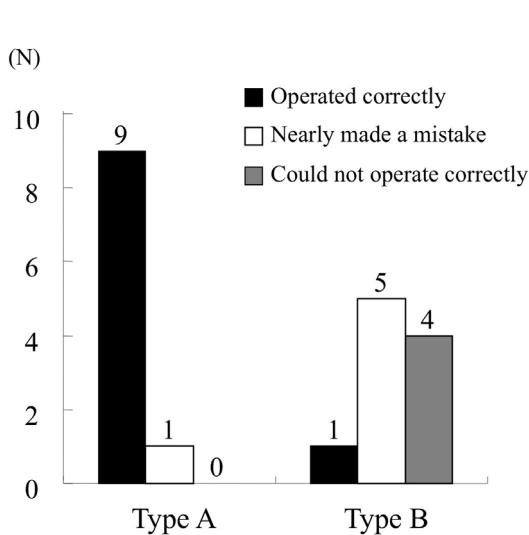


Fig.3 Comparison of precision of the task.

- 1: Operational mode shifting for each syringe type
- 2: Syringe setting to pump
- 3: Pumping rate setting
- 4: Visibility of buttons
- 5: Visibility of LCD window

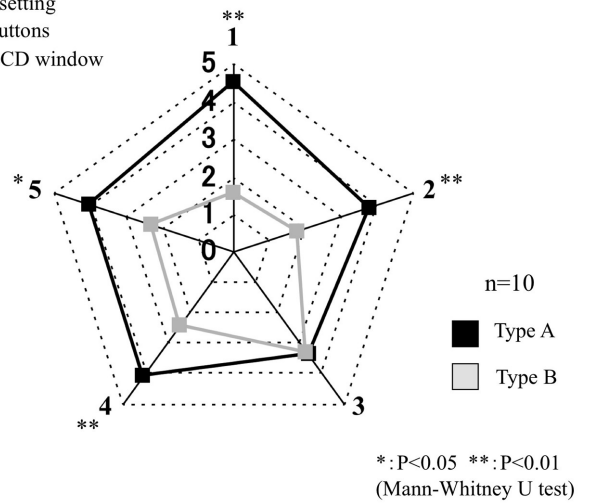


Fig.4 Questionnaire survey on the operability of syringe pump.
 1. Clearly inferior 2. Slightly inferior 3. Neither inferior nor superior 4. Slightly superior 5. Clearly superior

The infusion pumps are not good in the precision of flow rate compared with the syringe pump. There is a report on free flow accidents. Our hospital made policy to shift to the syringe pump, with phasing out infusion pumps, from medical safety perspective.

On the other hand, there is a model that should set the size of the syringe used beforehand in the syringe pump. For this case, we experienced that syringe pumps did not work in many cases, and once the power was off, it was necessary to set the pump. All together, the use of PFS was suspended, or disposable syringe was used instead of PFS with taking time to changing them, and those events lead to confusion in clinical setting, without utilizing the advantages of PFS.

The results of this study revealed that the syringe pump which needs exclusive mode setting, not only requires a considerable operation time for setting, but also has problems in medical safety. For example, even nurses who use it daily and are accustomed to its operation make mistakes or cannot operate correctly in many cases. At present, the size of the disposable syringe is not unified among the domestic makers. The de facto standard of the disposable syringe in Japan is Terumo Corporation, and if the PFS preparation is manufactured at the syringe size of Terumo Corporation, the trouble is considered to be less. However, if syringe pumps made by makers other than Terumo Corporation are used, it is necessary to check many items because the normal disposable syringe and the syringe used for PFS preparation are not completely the same. There is no international standard for the size of the disposable syringe, and if makers of PFS preparation are to market a number of PFS's without sufficient awareness of the syringe size or the syringe pump, the advantage of PFS cannot be utilized sufficiently. However, it is not possible to manage it accurately if it is not a syringe pump like Type B for

PFS that doesn't adopt the syringe from which it was made by the Terumo Corporation. It seems that preparing, and operating a simple manual to understand a complex tasks while seeing when the pump made by the Daiken Medical Co., Ltd. is used are necessary.

In order to develop PFS in the future, pharmaceutical industry and medical device manufacturing industry should work together and make efforts to improve operability and enhance safety, with sharing information. It is concluded that based on the results of this study, a lot of advantages are in PFS. However, cooperation and the standardization between manufacturers are important for the spread.

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