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Aberrant halt of syringe pump motion: an improved system to prevent false setting of the syringe

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Abstract A syringe pump is used to inject precise doses of drugs having a strong action; for example, vasoactive drugs. Unexpected and undetected halt of a syringe pump can lead to potentially life-threatening complications. We experienced a sudden halt in the movement of a syringe pump (Terufusion syringe pump; Terumo, Tokyo, Japan) in two patients while administering norepinephrine in the intensive care unit (ICU). Fortunately, the patients had only transient hypotension, which was immediately detected and promptly treated, without any untoward sequelae. As a result of the occurrence of such cases, we conducted a detailed investigation of the causes of this sudden halt in the syringe pump. We could not reproduce the aberration of the syringe pump and thus could not specify the cause in the first patient. In the second patient, however, a false setting on the syringe was suspected to be the cause of the problem. In order to prove this, we tried to reproduce the situation where a syringe pump, due to a false syringe setting, abruptly terminated while giving a "syringe loss" warning, after a period of precise functioning. Once we had determined how a false setting of the syringe could occur without the syringe pump giving off an alarm from the onset, we collaborated with the Terumo Company to revise their current instruction manual to incorporate this as a warning. We also helped in the development of a new model, including a new safety feature that would prevent a false setting of the syringe from occurring at all. This new model was released in December 2003.

Key words Syringe pump · Aberrant movement halt · False setting of syringe

Introduction

A syringe pump is an invaluable device that is used to inject such drugs as vasoactive drugs, which need to be administered in small, continuous, and precise doses. Any error associated with the use of a syringe pump can often lead to life-threatening consequences. We experienced a sudden halt in the movement of a syringe pump (Terufusion syringe pump; Terumo, Tokyo, Japan) in two patients during the administration of norepinephrine in the intensive care unit (ICU). A false setting of the syringe was thought to have been responsible for the aberrant movement halt. In collaboration with the manufacturer, we developed a safety system to prevent such a false syringe setting from occurring.

Case 1

A patient in the ICU was receiving norepinephrine, administered through a syringe pump, at a rate of $3.5\,ml{\cdot}h^{-1}$ ($0.3\,\mu g{\cdot}kg^{-1}{\cdot}min^{-1}$), as a circulatory agonist after coronary bypass surgery. The syringe pump suddenly terminated, with a warning. A nurse who was observing the patient arranged an intravenous infusion of a hypertensive agent, and reported the incident to a doctor. Rapid infusion of fluids was done, and a freshly prepared norepinephrine infusion was recommenced. The patient suffered transient hypotension, but the event did not affect his clinical course. The situation at the time of the alarm was not clear, because the nurse discarded the syringe. However, the nurse did remember that the warning was a "syringe loss" warning, with a flashing of the syringe size lamp. Our Medical Electronics (ME) center, when requested to check the syringe pump for any abnormalities, was unsuccessful in finding the cause of such a termination. Hence, we forwarded the syringe pump to the manufacturer (Terumo), for more detailed inspection, however, this also did not provide any further information as to the cause of the incident.

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Case 2

A post-coronary bypass graft surgery patient in the ICU was receiving norepinephrine, administered with a syringe pump at a rate of 4.2 ml·h^{-1} (0.4 μg·kg^{-1}·min^{-1}). This syringe pump was the same type as that used in case 1, but was not the same one. The syringe pump terminated with a sudden warning. A nurse and a doctor, who were observing the patient, confirmed the warning to be a syringe loss warning. The doctor removed the syringe from the pump and reset it, while simultaneously administering a hypertensive agent. The blood pressure of the patient deteriorated to a systolic blood pressure of 60 torr; however, the patient subsequently recovered without any untoward sequelae. The doctor noticed that the syringe seemed to be slightly elevated from its normal position before he reset it. Once again, after an inconclusive check by our ME Center engineer, we sent this syringe pump to the manufacturer for an advanced inspection.

The manufacturer made a close inspection of the following functions of the syringe pump: syringe size detection function, alarms, continuous operation test, vibration test, impact test, movement reliability test under low and high environmental temperatures, voltage variation test, and electromagnetic compatibility test. Furthermore, the pump was dismantled, and the electric circuit board was checked, but no aberrations were found.

We therefore supposed that the aberrant halt of the syringe pump movement was caused by a false syringe setting, because (1) there was no detectable abnormality in the syringe pump, (2) the halt in the movement of the pump was accompanied by a syringe loss warning, and (3) the doctor observed that he felt the syringe rise when re-inserted. Taking these facts into account, we tried various kinds of false syringe settings and examined whether the situation could be reproduced. As a result, we found that the syringe false setting described here could reproduce the aberrant movement halt (Figs 1 and 2). When the plunger (called "pestle") of the syringe was set on the slider hook (Fig. 1), the slider hook lifted the plunger of the syringe. This resulted in the syringe being gradually raised from the pump (Fig. 2), and this led to the pump sensing it as a syringe loss, and issuing the appropriate warning, followed by an aberrant movement halt. We therefore concluded that the false setting of the syringe was the cause of the problem.

We discussed this issue with the manufacturer of the syringe pump, asking for an improvement in the warning against such a false syringe setting. The manufakturer tried to develop a new function to protect against the false setting of the syringe, but such a development was difficult and could not be achieved. We pointed out that, although the syringe had been malpositioned from the outset, the pump did not sense this immediately, and hence, initially started functioning in spite of this

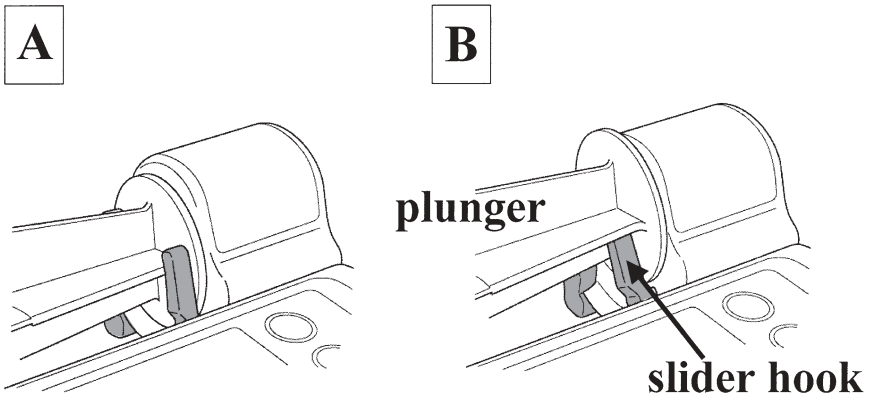

Fig. 1. Setting of the syringe. **A** Correct setting; **B** false setting (the plunger of the syringe was lifted by the slider hook)

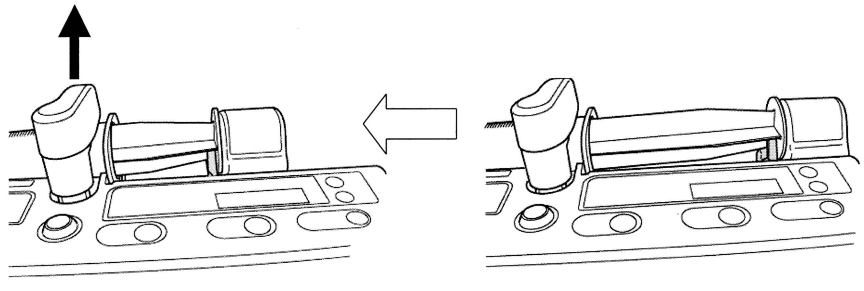

Fig. 2. Syringe loss warning. When the plunger is pushed, the syringe rises (*vertical arrow*), and a warning occurs

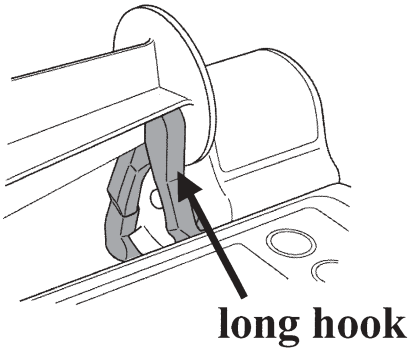

Fig. 3. Mechanism for preventing false setting of the syringe. We lengthened the slider hook. If the syringe is wrongly positioned, the pin for syringe detection comes off, and a warning occurs. Therefore, the syringe pump does not start

malpositioning. Therefore, we asked for the development of a system whereby a false setting itself could be impossible. As a result of much deliberation and discussion, we concluded that improvement of the slider hook was the simplest, easiest, and most effective way to overcome this problem. Keeping this in mind, the manufacturer set about to improve the slider hook. After some trials, they found that lengthening the slider hook resulted in an alarm sounding immediately the syringe was wrongly positioned (Fig. 3). This improvement made a false setting itself totally impossible, by virtue of the design of the hook.

Sudden halts in the movement of the syringe pump have been reported by other medical institutions to the manufacturer. In each case the reason for the halt in movement remained unknown. While there have been no incident reports filed for the new model, occasional incident reports are still filed for the old model with the previous wording of the manufacturer's warning.

There is no similar report of a sudden halt in movement for syringe pumps manufactured by other companies.

Discussion

Reports of medical accidents due to syringe pumps are rare, and are limited to specific situations, such as electric shock [1]. In the clinical setting, however, false syringe placements often occur in syringe pumps. One such example is a false setting of the syringe, such that the plunger is not correctly mounted on the slider.

The slider hook was a safety system developed so that the pump could not be started with an inappropriately fitted syringe. As we found, the safety system itself resulted in a different kind of false syringe setting. It is possible that trying to prevent one type of accident can lead to the probability of a new risk. For example, we discovered that the basal flow setting of oxygen in an anesthesia machine decreased the sensitivity of the conventional breathing system leak test in pre-anesthetic inspections [2]. Although the basal flow setting of oxygen in this machine is set to prevent hypoxia to in the patient, some users sometimes handle an apparatus in an unexpected way, leading to inappropriate results. Therefore, it is important to clarify whether new safety systems are associated with the possibility of other risks. Risk managers of institutions should check whether the apparatus and instruments are being used in the correct way, and they should also inform and educate users about the appropriate handling of equipment. In addition, if an unexpected incident occurs, detailed records about it should be collected and maintained. This will greatly aid in finding the cause of the problem and resolving it, ultimately resulting in the development of a new apparatus design.

It is difficult to satisfactorily answer the question, "How should we improve syringe pumps for safe control in future?". This is because conventional syringe pumps function sufficiently well for the precise administration of solution if they are handled correctly and according to the manufacturer's instructions. To produce the ideal, safe, syringe pump, a study of ergonomics is required to protect against human error in their operation. In addition, operators should receive training to operate syringe pumps correctly.

In conclusion, we experienced two cases of the aberrant halt of movement in a syringe pump caused by syringe malpositioning. We analyzed and discussed the problem with the manufacturer of the syringe pump, resulting in the development of a new safety system to prevent a false setting of the syringe. This case is a model for crisis control management for incidents involving medical apparatus and instruments.

Note (1)

A new model syringe pump was released in December 2003, and it has the new safety system described above. For the old model, we collaborated with the manufacturer to produce a new instruction manual directing attention to this potential hazard.

Note (2)

In the old model, the aberrant movement halt due to a false syringe setting in the syringe pump occurs only with 30-ml and 50-ml syringes, but not with 20-ml syringes.

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