Case report

Ms Pui was a 32 year-old lady who was admitted to the Palliative Care Unit of Caritas Medical Centre in April 2008 for pain management. She suffered from left sided renal tumor with metastasis to the left sided supraclavicular lymph node in June 2006. Biopsy of lymph node revealed metastatic adenocarcinoma. She declined chemotherapy suggested by oncologist. She subsequently developed bilateral leg weakness in February 2008 due to extensive left paraspinal tumor invasion from the twelfth thoracic spine to the third lumbar spine. After radiotherapy, Ms Pui was transferred to palliative care unit for pain control.

Ms Pui’s pain originated from abdominal tumor, spinal metastasis and sacral score. Tramadol and gabapentin were ineffective in pain relief. Morphine was not considered due to renal impairment. The switch to methadone provided short term control of back pain. Ms Pui’s physical condition declined gradually and she could not take drugs orally. Therefore she was commenced on fentanyl infusion at a daily dose of 200mcg administered subcutaneously through a syringe driver. Fentanyl was stepped up to 400mcg next day to achieve a better pain relief. Upon scheduled nursing observation, it was discovered that the syringe barrel was emptied at four hours after the commencement of fentanyl infusion. Re-checking of the Graseby MS16A syringe driver confirmed an incorrect infusion rate setting at 48mm per hour instead of at 2mm per hour, i.e. the presumed daily dose of 400mcg of fentanyl was administrated within one hour. Ms Pui’s vital signs were closely monitored and she remained stable. She preferred to continue the fentanyl infusion through the syringe driver for pain control. She died peacefully after 19 days. The medication incident was reported to Hospital Authority via the Advanced Incidents Reporting System.

Discussion

Syringe drivers are commonly used in the palliative care setting to treat pain and other distressing symptoms. In United Kingdom (UK), it was first described in 1979 by Dr. Patrick Russell who reported the use of the Graseby syringe driver to deliver continuous subcutaneous infusion in hospice context. This technology offers an effective method of drug administration that is particularly suited to and has been firmly established in palliative care. Since their introduction in the UK, syringe drivers have played a role in enhancing ambulatory and home based care outside of hospital environment, thereby increasing the options of place of care for palliative patients. The most widely used models of syringe driver in the UK are Graseby MS26 and MS16A (Fig. 1). The length of fluid in syringe barrel determined the rate of infusion. The MS16A is calibrated in millimeter (mm) per hour and the MS26 is designed in mm per 24 hour.

Figure 1. The Graseby MS16A syringe driver
The Graseby syringe drivers have the advantages in terms of simplicity in use, being lightweight, ambulatory and low cost to run (one 9 voltage PP3 battery lasts for up to 50 infusions). However, there has been a number of operator related problems associated with syringe drivers. In the UK, monitoring of standards for electronic syringe drivers comes under the auspices of the Medical Devices Agency, which issues alerts and hazard warnings relating to these problems since 1994. In particular, there is continuing reporting of incidents in which confusion between MS16A and MS26 syringe drivers has led to incorrect infusion rates being set. The two models are visually similar and users have mistakenly set rates on an MS16A (calibrated in mm/hour) thinking it was an MS26 calibrated in mm per 24 hour. This has resulted in serious over-infusion and fatality. The manufacturer Graseby Medical have introduced enhanced labeling for the front panel of new syringe drivers. Old style devices should also be fitted with the appropriate new label. The term “Graseby syringe driver” is commonly used for both models and is not recommended as it fails to differentiate between the two. Furthermore, to minimize mixing up of the two drivers, it is advised to avoid keeping two similar devices in the same ward or palliative care unit.

Inadequate user training has also been identified as one of the factors that contribute towards adverse incidents related to the use of syringe driver. A survey done in a syringe driver study day discovered that none of the 180 staff knew how to test the syringe drivers before use. It is essential that users should be provided with adequate training and updating knowledge, particularly those who only come in contact with the syringe driver infrequently. Apart from face-to-face training session, online learning is an alternative and innovative strategy to meet this education and training need. In the UK, an online learning programme on the use of Graseby syringe drivers in palliative care organized by “Nurse Learning” had been established in 2003. Report of three years experience showed that this flexible form of learning environment is acceptable to learners and can lead to improvements in both knowledge and understanding of the palliative care issues. However, the course is not intended to replace the face-to-face training where this is available.

Despite the availability of education programmes on the use of syringe drivers, there are intrinsic problems of Graseby MS16A and MS26. (Table 1) The two devices failed to comply with the appropriate standard such as International Electrotechnical Commission IEC 60601-2-24 which is particular requirement for safety of infusion pumps. They also failed to fulfill any safety features that the Medicines and Healthcare products Regulatory Agency of the UK considered to be important for infusion devices. Regulators in several countries, including Australia and the UK have previously issued safety alert in relation to these devices. Unfortunately, some of the adverse events could not be fully analyzed as the syringe driver does not have a memory of events and alarms that may have proven useful in the full investigation. From October 2007, these devices are no longer compliant with the best practice standards for contemporary devices as set by the Therapeutic Goods Administration of Australia and have been voluntarily withdrawn from the market.

**Table 1: Intrinsic problems of Grasby MS16A and MS26 syringe drivers**

- The visually similar MS16A and MS26 models have a 24-fold difference in infusion rate. Confusing the two has resulted in multiple serious adverse events
- The device does not use standard measuring units requiring a calculation to set the flow rate, thus introducing the risk of error.
- The pump lacks a stop button.
- The rate can be changed while the pump is in operation.
- There is no protection against misleading of the syringe, air entrainment, tampering or siphoning.
- The occlusion response characteristics of this pump are very poor.
- The pump does not retain a record of operation.
- A “prime” button provides maximum infusion rate when depressed. There is no limitation on the number of times this may be activated nor a record of activation. Serious adverse outcomes have resulted from inappropriate use.
While they can no longer be purchased, the manufacturer Smiths Medical has a formal agreement to continue to provide maintenance and service support for a further five years. Discontinuation of supply occurred at the same time in New Zealand.

Palliative care Australia had launched the search of alternative devices and another newer syringe driver Niki T34 or McKinley T34 became adopted widely in Australia. (Fig 2) A number of hospices in the UK are currently piloting the T34 which was launched in the UK in May 2005. The T34 is similar in size to the Graseby MS26 and MS16A. It is designed to deliver the contents of a 2 to 50ml syringe over a specific duration or at a given rate in millilitre per hour (ml/hr). It is equally suitable for both adult and paediatric use. Some of the advantages are summarized in Table 2. More importantly, T34 complies with the safety consideration mentioned in the Hospital Authority Operation Guidelines on Safe Use of Infusion Pump Guidance which became effective from February 2009. T34 had recently been available in our palliative care unit to replace all the Graseby MS16A syringe driver. Further clinical experience and evaluation are required to confirm its effectiveness and safety in palliative care setting.

![Figure 2. The Niki/McKinley T34 syringe pump](image)

Table 2: Some of advantages of McKinley T34 syringe driver

- Its size makes it suitable for ambulant patients
- Its ability to detect syringe size automatically and calculate the rate of delivery using the volume of the fluid in the syringe.
- It can be programmed to infusion in ml/hr rather than mm/24 hour, reducing the potential for user error, and also serious under-/overdose of drugs.
- Its design ensures it addresses all the safety features as that the MHRA recommends and IEC 60601-24 proposes as essential.
- Infusion rate cannot be altered once the device is infusing
- No bolus facility.

References


The safe use of syringe driver in palliative care

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