Evaluation of Devices for the Reconstitution of Cytotoxic Drugs

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Study Objective

The objective of this study was to determine which system for drug preparation would best protect health-care professionals in general and pharmacists in particular from exposure to hazardous substances (e.g. cytotoxic pharmaceuticals), while reducing the risk associated with needle stick injuries.

Materials & Methods

Using a vial of prepared Fluorescein to simulate a cytotoxic drug, IV preparations were made using either the Tevadaptor system or a control system (commonly-used spike connector and syringe, needle and syringe). All systems were evaluated as to the extent of drug leakage observed, with the intention of minimizing health-care professionals' risk of exposure to hazardous pharmaceuticals.

Conclusions

The Tevadaptor™ drug reconstitution system was found to be both safe and user-friendly. Its use is intuitive, being very similar to the conventional use of syringe and needle for drug transfer.

Introduction

Cytotoxic drugs are known to affect not only malignant tumors but also healthy tissue. Long-term exposure to cytotoxic drug spills and vapor may have mutagenic as well as carcinogenic effects. This is why organizations such as NIOSH, ASHP and ISOPP have issued guidelines on how health care professionals are to handle such drugs. In addition to using protective gowns and gloves and working in ventilated hoods, it is strongly recommended to use devices dedicated to the safe handling of such drugs.

We present the results of a study comparing the performance of Tevadaptor™, a recently introduced cytotoxic drug reconstitution device, to that of a syringe with a needle or dispensing pin in simulated admixture applications.

Materials and Methods

A comparison was made between three devices used for solution transfer: Tevadaptor™: and a needle-syringe set consisting of a 10ml luer lock syringe, an 18G, 1.5" needle, and a Codan vented spike. Drug transfer from vials into separate 250ml Saline (0.9%) infusion bags was simulated using a 0.1% fluorescein aqueous solution. All simulated drug transfer procedures were carried out in a safety hood equipped with UV lamp. The hood floor was covered with absorbent paper for easy detection of fluorescent spills. All elastomer septa, fluid openings and work area were monitored using a UV light. Control dots of the fluorescent solution of approximately 5 microliters were deposited on the absorbent paper to test the detection sensitivity.

The fluorescein containing vial was accessed using a syringe with its respective vial puncturing device (needle, spike or Tevadaptor™ Vial Adaptor and Syringe Adaptor), and 1-2ml of solution were drawn into the syringe. The syringe or syringe assembly was disconnected from the vial. This was repeated 5 times for each system (syringe and needle, bare syringe, or syringe with Syringe Adaptor respectively).

Each respective bag-accessing device (needle through injection port or Tevadaptor™ Syringe Adaptor and bag Connecting Set) was connected to a bag, and the fluorescent solution injected. The syringe assembly was then disconnected from the bag. These steps were repeated three times for each system tested.

Upon each disconnection all exposed surfaces were observed for fluorescent drops. Work area and devices were photographed under UV illumination.

Results

The use of Tevadaptor™ resulted in completely clean work surfaces, and no fluorescent material leaked onto the septa or any other surface outside the system (Figs. 3 & 4). With the control systems, on the other hand, leakage is clearly observed: in the syringe and needle system, both the bag injection port and the syringe needle are badly contaminated (Fig. 2). In the spike, both syringe tip and spike luer are highly contaminated after disconnection (Fig. 1).

Conclusion

Tevadaptor™ is a safe and user friendly system for the handling of hazardous drugs compared to the use of a standard needle and syringe or vial spike and syringe method.

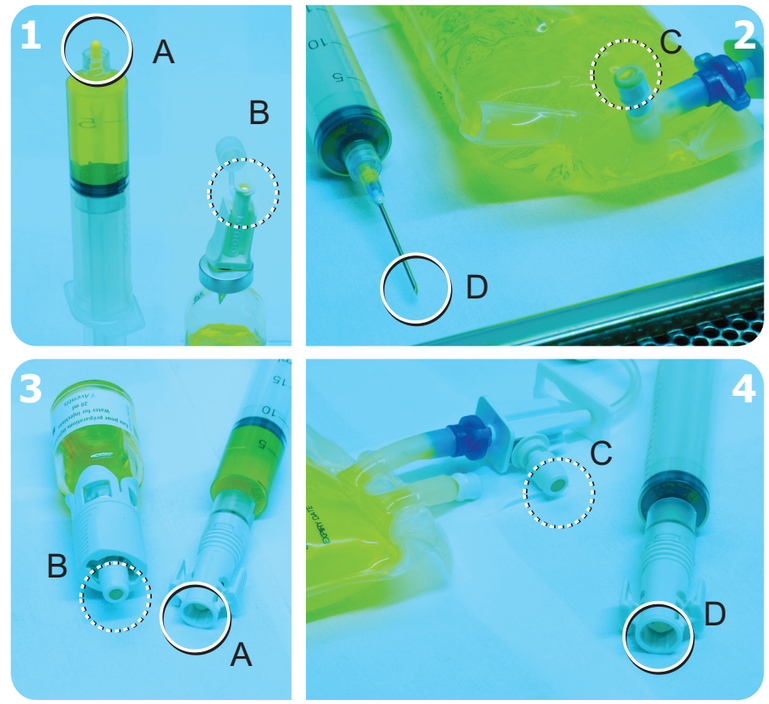

Fig. 1 & 2: Bag injection port and syringe needle: note fluorescein contamination on both the syringe tip and spike luer (fig. 1). Also note the contaminated syringe needle and bag injection port. **Fig. 3 & 4:** No leakage was observed on any system part with use of the Tevadaptor system.

Circles:

A: (fig 1 & 3) Correspond to the compared drug preparation systems. Note the residual fluorescein contamination present at the tip of the syringe on fig 1. There is no residual contamination on syringe with use of the Tevadaptor™ system.

B: (fig 1 & 3) Note that the spike, but not the Tevadaptor™ system, is contaminated with fluorescein after the syringes are filled.

C: (fig 2 & 4) After the drug is injected into the bag using the control system, contamination of the injection port is evident. Use of the Tevadaptor™ system prevents port contamination.

D: (fig 2 & 4) The Tevadaptor™ system and the control syringe after fluorescein injection.

References:

1.Burgaz S, et al. ***Hum Toxicol 1988;***7 557-60. 2. Skov T, et al. ***Br J Ind Med 1992;***49:855-61. 3. Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings. ***NIOSH Alert, Dept Health & Human Services, CDC, 2004***. 4. ASHP Guidelines on Handling Hazardous Drugs. ***Am J Health Syst Pharm 2006;*** 63:1172-93. 5. Safe Handling of Cytotoxics, ***ISOPP Standards of Practice, 2006***.