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A new drug handling device for preventing hazardous drug exposure

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Abstract

A comparison of two drug-handling systems was performed to test the ability of the novel Tevadaptor® system to prevent hazardous drug exposure, as compared to a conventional syringe needle system. The contamination of a hospital laboratory work environment by hazardous drugs was tested using technetium ($^{99m}TcO_4^-$) as a tracer, according to a previously published protocol by Nygren and colleagues [1]. Eleven operators ran simulated IV solution preparations, each using both systems consecutively. Various surfaces prone to contamination were monitored, including hood bench, vial cap or Vial Adaptor (for syringe operation or Tevadaptor® respectively), syringe or Syringe Adaptor, bag injection port or Bag Spike Adaptor, and gloves. Wipe samples were taken from each of the above surfaces by each operator. Contamination on the wipes was counted using a gamma counter. Technetium counts were converted into spill volumes. The results showed an unambiguous, statistically significant advantage of the Tevadaptor® system over the conventional syringe and needle. On some of the monitored surfaces this advantage was dramatic: a high level of contamination was found on vials that were handled using the traditional syringe needle method, whereas vials handled using the Tevadaptor® system were free of contamination. A user satisfaction survey that was simultaneously run, showed a unanimous preference for Tevadaptor® over the conventional method. The main reasons cited were the sense of safety, automatic venting, convenience and ease of use.

Introduction

The hazards associated with the handling of cytotoxic drugs are well documented. Routine exposure to drug vapours and aerosol, generated during reconstitution of such drugs, has undesirable mutagenic, fertility and malignant effects [2-4]. Tevadaptor®, a specialised hazardous drug-handling system recently introduced by Teva Medical, was developed to minimise the exposure of healthcare workers to such hazards.

Tevadaptor® was previously tested by independent laboratories for drug sterility maintenance [5, 6], and for effectiveness in preventing the release of toxic drug species, including vapour [7]. These tests showed excellent protection against both the ingress of environmental contaminants and the spread of all drug species into the environment. We report here on a series of environmental contamination tests that were conducted to compare Tevadaptor® to the conventional syringe and needle set.

Environmental contamination testing has routinely been performed by surface wiping followed by extraction and chromatographic analysis of drug traces. This method has serious disadvantages, as the need to extract the drug from the wipe affects recovery and hence sensitivity of the test. More importantly, background contamination may skew results, necessitating lengthy studies involving a large number of samples in order to detect statistically significant differences between different drug-handling systems. The method recently introduced by Nygren and colleagues [1], using the relatively short-lived isotope $^{99m}TcO_4^-$ as the contamination tracer, requires no extraction and thus virtually eliminates the issue of background noise.

In the current study, we have expanded on Nygren and colleagues' previous investigation of the drug-handling systems Phaseal® by Carmel Pharma [8] and Tevadaptor® by Teva Medical Ltd [9] by monitoring numerous surfaces, in an attempt to identify those most prone to contamination. The areas tested were the hood work surface, gloves, syringes, vials and infusion bags. The primary objective of this study was to assess the volume of contamination spills using the Tevadaptor® system versus the syringe needle set. The secondary objective was to compare operator satisfaction between the two drug-handling systems.

Materials and methods

Tevadaptor® components

The Tevadaptor® system consists of three main components: the Vial Adaptor, Syringe Adaptor and Spike Port Adaptor. The Vial Adaptor is a vial attachment device, providing automatic venting and contamination-spread prevention. The Syringe Adaptor prevents needle exposure and contamination spread, and the Spike Port Adaptor is an IV bag connector for the Syringe Adaptor, that further prevents the spread of contamination.

Drug reconstitution procedure

A pertechnetate ($^{99m}TcO_4^-$) stock solution was prepared in regular saline (0.9% w/v). Total activity was approximately 100 mCi/25 mL (4 mCi/mL). Vials (20 mL capacity) were each filled with 0.5 mL of stock solution and diluted to 10 mL with regular saline. The average measured total activity was 2.2 mCi per vial.

The drug reconstitution procedure consisted of the following steps:

1. Connecting the Vial Adaptor to the $^{99m}TcO_4^-$ vial.
2. Connecting the Syringe Adaptor to a 10 ml Luer-lock syringe.
3. Connecting the Bag Spike Adaptor to the spike port of a 100 mL saline IV bag.
4. Connecting the Syringe Adaptor to the Vial Adaptor and drawing 5 mL of radioactive solution into the syringe.
5. Disconnecting the Syringe Adaptor from the Vial Adaptor and connecting it to the Bag Spike Adaptor.
6. Injecting the syringe contents into the bag and disconnecting the Syringe Adaptor from the Bag Spike Adaptor.

Table 1: Hood work surface

Operator No.	Tevadaptor®		Syringe needle	
	Average spill			
	(cpm)	(nL/cm²)	(cpm)	(nL/cm²)
1	43	<1	1.5×10^6	5
2	35	<1	41	<1
3	34	<1	39	<1
4	36	<1	30	<1
5	21	<1	25	<1
6	22	<1	22	<1
7	516	<1	6240	<1
8	70	<1	110	<1
9	26	<1	40045	<1
10	23	<1	31087	<1
11	42	<1	3.02×10^6	10
p value = 0.019 (n = 50; 54).				

Table 2: Gloves

Operator No.	Tevadaptor®		Syringe needle	
	Average spill			
	(cpm)	(nL/cm²)	(cpm)	(nL/cm²)
1	213	<1	523	<1
2	41	<1	527	<1
3	230	<1	120	<1
4	22	<1	18	<1
5	29	<1	189	<1
6	38	<1	35	<1
7	833	<1	563	<1
8	25	<1	55	<1
9	30	<1	7.45×10^6	18
10	3763	<1	1930	<1
11	1334	<1	657	<1
p value = 0.132 (n = 11).				

Each of the eleven operators performed this procedure five times on five different Tevadaptor® sets. Monitored surfaces were then wiped (see below for details) and the procedure was repeated with five sets of syringe and needle, using new vials filled with the same radioactive solution.

Environmental contamination testing

Testing for environmental contamination was performed by wiping the following surfaces with double-tipped cotton swabs, dipped in 0.3 N NaOH:

1. Work area, consisting of a 60 cm × 50 cm absorbent pad, with the non-adsorbing surface up, divided into five squares. Each of the squares (600 cm²) was wiped separately. The pad was changed for each product and each operator.
2. Vial Adaptor (or vial neck for syringe needle) (approximately 5 cm²).
3. Syringe Adaptor cylinder (or syringe body for syringe needle) (approximately 5 cm²).
4. Bag Spike Adaptor (or bag port for syringe needle) (approximately 5 cm²).
5. Gloves (approximately 840 cm² per pair).

Each test area was wiped with a separate pair of cotton-tipped sticks. The sticks were then inserted into the counter test tubes and counted.

Counting Procedure

Contamination was expressed as nL/cm². The baseline background count in the laboratory was 25–30 cpm. All monitored surfaces were efficiently wiped using cotton-tipped swabs. Counting was direct without extraction of the cotton.

Counting was performed within one hour of the drug reconstitution experiment. Since $^{99m}TcO_4^-$ has a half-life of six hours, a 1-hour delay represents a maximum 10% decay in radioactivity. Such a difference would have only a negligible effect on the results of the current study, thus a correction for decay was not made. Counts were performed using a gamma counter (Cobra II, Packard Instruments Company).

The primary outcome measure of this study was volume of spill. Counts were converted to volume of contaminant using the following calculation. The total activity of the solution in the vials was 2.2 mCi. The volume of the test solution was 10 mL. Thus, each 100 cpm represents 0.2 nL of solution. Statistical analysis was performed on the cpm results (non parametric median test), using SAS 9.1. P values were calculated from all runs and operators for each of the surfaces monitored.

Results

The results obtained by all operators and for all surfaces monitored are provided in Tables 1–6. For each operator and surface, the average spills of five runs are shown. Table 1 summarises the results for the hood work surface; Table 2 for gloves; Table 3 for syringe or Syringe Adaptor; Table 4 for vial or Vial Adaptor; Table 5 for infusion bag or Bag Port Adaptor, and Table 6 for operator satisfaction.

It is evident that the largest spills were observed using the conventional work method. The maximum spill (by cpm) using this method (operator No. 11, vial) was 1,170 nL/cm². In contrast, the maximum spill using Tevadaptor® (operator No. 10, gloves) was less than 1 nL/cm². None of the Tevadaptor® results from any of the surfaces tested exceeded 1 nL/cm². The cpm differences between the systems on all monitored surfaces, except for gloves, were statistically significant.

Based on the results of the operator satisfaction survey (see Table 6), it is clear that the operators unanimously preferred Tevadaptor® over the syringe needle set for its convenience and safety.

Table 3: Syringe

Operator No.	Tevadaptor®		Syringe needle	
	Average spill			
	(cpm)	(nL/cm²)	(cpm)	(nL/cm²)
1	30	<1	131	<1
2	34	<1	39	<1
3	32	<1	33	<1
4	22	<1	44	<1
5	19	<1	24	<1
6	30	<1	22	<1
7	28	<1	4943	2
8	33	<1	25	<1
9	35	<1	42	<1
10	33	<1	46	<1
11	25	<1	1636	<1
p value = 0.014 (n = 55).				

Table 4: Vial

Operator No.	Tevadaptor®		Syringe needle	
	Average spill			
	(cpm)	(nL/cm²)	(cpm)	(nL/cm²)
1	32	<1	980309	392
2	23	<1	1349	<1
3	28	<1	3767	1.5
4	25	<1	1160	<1
5	26	<1	43	<1
6	25	<1	35	<1
7	24	<1	146486	58
8	28	<1	39	<1
9	34	<1	742230	297
10	73	<1	55145	22
11	27	<1	2.94×10^6	1170

p value = 0.0001 (n = 55).

Table 6: Customer satisfaction

Operator No.	Tevadaptor®		Syringe needle	
	User friend-liness	Safety advan-tage	User friend-liness	Safety advant-age
1	+	+	-	-
2	+	+	-	-
3	+	+	-	-
4	+	+	-	-
5	+	+	-	-
6	+	+	-	-
7	+	+	-	-
8	+	+	-	-
9	+	+	-	-
10	+	+	-	-
11	+	+	-	-

Discussion

Environmental radioactive contamination was monitored on both the work surface and the laboratory devices, to compare the extent of contamination between two drug-handling systems: the conventional syringe needle system and the novel Tevadaptor® system. The test results were unambiguous: for all surfaces monitored, with the exception of gloves, a clear, statistically significant advantage of Tevadaptor® was observed. The number of glove samples was small, as they were not changed after each preparation, but rather after completion of each series. Therefore, even though a Tevadaptor® advantage also seems apparent for the gloves based on cpm, the difference is not statistically significant. On some of the surfaces, especially drug vials, the difference was dramatic. Whereas the majority of vials in the conventional preparations were highly contaminated, none of the Tevadaptor®-associated vials showed any significant contamination.

Table 5: Bag port

Operator No.	Tevadaptor®		Syringe needle	
	Average spill			
	(cpm)	(nL/cm²)	(cpm)	(nL/cm²)
1	24	<1	45	<1
2	28	<1	37	<1
3	25	<1	33	<1
4	22	<1	743	<1
5	27	<1	51	<1
6	22	<1	27	<1
7	594	<1	38	<1
8	38	<1	23	<1
9	29	<1	31	<1
10	30	<1	35	<1
11	26	<1	120	<1

p value = 0.019 (n = 55).

These results can be explained based on the fact that it is extremely difficult to remove a conventional syringe from a non-vented vial with zero pressure difference. This causes drug solution drops to be deposited on and around the vial cap. The Tevadaptor® system is devised in such a way that the pressure equalisation is automatic and continuous. Moreover, the Syringe Adaptor needle is never exposed during use, thereby preventing contamination.

The operator satisfaction survey, taken by the operators running this test, revealed a unanimous preference for Tevadaptor®. The reasons cited were convenience and safety, attributed specifically to the automatic venting, ease of use and absence of spills. We consider user-friendliness to be an extremely important safety feature, essential for the avoidance of mistakes and accidents.

Conclusion

In the current study, Tevadaptor® was found to offer unambiguous advantages over the conventional syringe and needle method, both in protection against inadvertent spills, and in user satisfaction.

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