



Evaluation of a Safe Infusion Device in reducing occupational exposure of nurses to antineoplastic drugs: a comparative prospective study



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Introduction

Despite the decreasing of environmental contamination throughout the anticancer drug circuit, **the administration of chemotherapies remains at risk of occupational exposure for nurses**. Many medical devices such as **Safe Infusion Devices (SIDs)** aim at securing administration, but **none have been scientifically evaluated to verify the actual improvement**.

Materials and Methods

Design: Monocentric **comparative before/after study** in a oncology day hospital (27 000 prep/y).

Primary objective: to evaluate the efficacy of SIDs in reducing drug exposure compared to usual perfusion practices (neutral solvent-purged infusers).

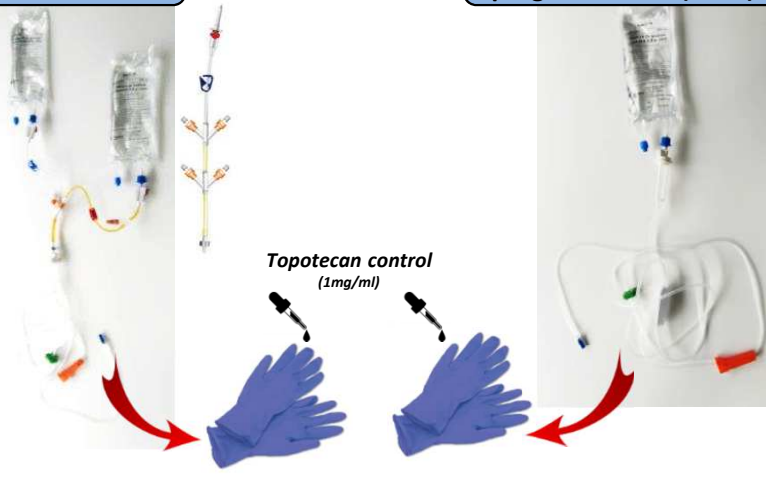
Primary endpoint: **rate of contaminated gloves** (n=120).

Drugs screened by HPLC SM/SM method: docetaxel, cyclophosphamide (CPM), etoposide, ifosfamide, irinotecan (IRN), methotrexate, paclitaxel, pemetrexed (PMX), topotecan (TPTC; internal control), vinblastine.

Eligible treatments: protocols containing CPM or PMX (highest therapeutic concentrations) and at least one step of infusion bag disconnection (FEC, TC, pemetrexed Pt...).

SIDs (n=60)

Neutral solvent-purged infusers (n=60)



Results

The usual practice led to a rate of 58.3% of contaminated samples while Safe Infusion Devices to a rate of 15%: **SIDs reduced the risk of gloves contamination by 84% in multivariate analysis (Odds ratio=0.16; 95% confidence interval=0.05-0.47; p<0.001)**. Topotecan was identified within 100% of the samples. Only one case of cross-contamination has occurred.

		Usual practice phase	SIDs phase
Contaminated samples		35/60 (58.3%)	9/60 (15%)
	TPTC (control)	60/60 (100%)	60/60 (100%)
Qualitative results	CPM	33/60 (55%)	7/60 (11.7%)
	IRN	0/60 (0%)	2/60 (3.3%)
	PMX	2/60 (3.3%)	0/60 (0%)
Quantitative results (ng/ml)	TPTC	Mean (sd) 16.2 (9.3)	12.3 (6.3)
	CPM	Mean (sd) 61.5 (91.5)	26.4 (39.3)
	IRN	Mean (sd) 0	32.5 (38.9)
	PMX	Mean (sd) 23,002 (32,524)	0

Discussion

Despite the current practice of using neutral solvent-purged infusers, **occupational exposure remains high for nurses and SIDs significantly reduced this risk of exposure**. However, glove contamination is only a surrogate endpoint.

Our results confirmed that the disconnection of empty bags resulted in occupational exposure. Except a contamination due to the leakage of a bag, **no cross-contamination was detected**. This validated the environmental quality of our cytotoxic drug circuit.

Safe Infusion Devices were highly effective but did not completely eliminate exposure.