STUDY SUMMARY

Performance Evaluation of the PhaSeal® Luer Lock Injector (N35) and Connector™ Luer Lock (C45 & C40) in a Lab Study

PURPOSE

The purpose of this lab study was to identify risk factors associated with using the PhaSeal Luer Lock Injector component, which is part of the PhaSeal System (BD Medical) of chemotherapy delivery. According to the manufacturer, this Luer Lock Injector is intended to "attach to a standard syringe or IV tubing for a dry, leak-proof connection during drug preparation and administration".[1] This study investigated the following performance factors of the Luer Lock injector component: drug loss in the Injector, coring of the Injector after multiple activations, and the possibility of accidental needlestick due to improper assembly and handling of the injector.

BACKGROUND

To protect the healthcare worker from exposure to hazardous drugs, organizations such as OSHA and NIOSH have established recommended guidelines to follow during these procedures. Adherence to these recommended work practices, and the use of engineering controls and Personal Protective Equipment (PPE), have been shown to substantially reduce worker exposure to hazardous drugs. However, compliance throughout the entire safe handling continuum-from preparation to transportation to administration to disposal-is an issue, implying that various guidelines are not followed aggressively enough.[2,3,4,5,6,7] As an additional form of protection, these organizations have recommended the use of specialized IV equipment called closed system transfer devices (CSTD) to reduce patient and clinician exposure to these hazardous drugs. When evaluating a closed system transfer device, clinicians and healthcare facilities should consider the work practices and procedures of each products operation to determine which system is right for them.

MATERIALS AND METHODS

To simulate chemotherapeutic use of the PhaSeal System, 20 Luer Lock Injectors (N35, Lot 9170278) and 20 Connector Luer Locks (15: C40 Lot 7250546*, 5:C45 Lot 10100030) were assembled as per PhaSeal instructional protocol. Two tests were performed on the PhaSeal System. The first test was to ascertain whether there was drug loss in the Injector and the second test to was to determine if there was coring with the Injector and Connectors after 3-10 activations. In addition, our lab found that when a step is missed in the recommended Luer Lock Injector procedure, the injector needle becomes exposed with the resulting risk of a needle stick injury.

RESULTS

Injector Drug Loss: 60 mL syringes were preloaded with 30 mL of fluid and 15 Luer Lock Injectors were attached to the syringes to determine the extent of drug loss that could be caused by inadvertently exerting force on the syringe plunger. Such an inadvertent application of force can occur during preparation and transportation, (e.g. if the syringe is mishandled by bumping the syringe plunger or if the syringe is dropped). Measurable fluid loss ranging from 0.726 mLs to 1.035 mL, occurred with each of the 15 Luer Lock injectors. In working with the Luer Lock Injector, the lab noticed that it was easy to miss steps in the complicated PhaSeal set of instructions and doing so could result in further drug loss during administration, with as much as 1.321 mL of fluid loss into the injector.

Injector Coring: The Luer Lock Injector stainless steel cannula was activated by initiating compressions toward the Injector/Connector piece. Coring of the Injector's seal was noticed at 3-5 activations on all of the 20 Injectors, with an average coring at 4 activations. (The PhaSeal injector FAQ page claims all membranes can be punctured up to 10 times).

Injector Stainless Steel Cannula Exposure: The Injector Luer Lock directions for use require eight steps for proper protected product compliance. However, on step six, if the injector safety sleeve is not pulled back to shield the needle properly, the needle can become exposed, creating the possibility of a needle stick injury for the clinician.

* No longer commercially available. Engineering analysis concludes that the replacement C35 would produce equivalent results.

CONCLUSION

Work practices and procedures regarding product operation are an important factor in hazardous drug containment and needle safety in general, but are even more imperative when using the PhaSeal Luer Lock Injector. These lab study results show the potential for drug loss, coring, and needle exposure, events which increase the risks to healthcare workers, while using the Phaseal system.

References

1. Phaseal System Components Marketing Sheet
2. Valanis B, Shortridge L. Self protective practices of nurses handling antineoplastic drugs. Oncol Nurs Forum. 1987; 14:23-7.
3. Valanis B, McNeil V, Driscoll K. Staff members' compliance with their facility's antineoplastic drug handling policy. Oncol Nurs Forum. 1991; 18:571-6.
4. Mayer DK. Hazards of chemotherapy: implementing safe handling practices. Cancer. 1992; 70(suppl):988-92.
5. Valanis B, Vollmer WM, Labuhn K et al. Antineoplastic drug handling protection after OSHA guidelines: comparison by profession, handling activity and worksite. J Occup Med. 1992; 34:149-55.
6. Mahon SM, Caperson DS, Yackzan S et al. Safe handling practices of cytotoxic drugs: the results of a chapter survey. Oncol Nurs Forum. 1994; 21:1157-65.
7. Neiweg RMB, de Boer M, Dubbleman RC et al. Safe handling of antineoplastic drugs. Cancer Nurs. 1994; 17:501-11.
8. Christensen CJ, Lemasters GK, Wakeman MA. Work practices and policies of hospital pharmacists preparing antineoplastic agents. J Occup Med. 1990; 32:508-12