Evaluation of a New Safety Peripheral IV Catheter Designed to Reduce Mucocutaneous Blood Exposure

Background:
Current straight peripheral IV catheters (PIVC), including safety engineered devices do not completely protect the healthcare worker from possible exposure to bloodborne pathogens as blood may flow from the catheter hub after insertion.

Objectives:
BD evaluated performance and clinical acceptability of a new peripheral intravenous catheter (PIVC) designed to reduce blood exposure.

Methods:
A two phased, unblinded, randomized controlled trial was conducted at a clinical research center in New Jersey, USA. In Phase 1, clinicians were asked to evaluate two devices: a PIVC with blood control technology (BD Insyte™ Autoguard™ BC [Blood Control] Shielded IV Catheter), and a traditional non-blood control PIVC (BD Insyte™ Autoguard™ Shielded IV Catheter). In Phase 2, clinicians compared two insertions of the PIVC with blood control (PIVC BC); one with venous compression and one without. The PIVC BC was evaluated for superiority to the conventional PIVC with regard to blood exposure and for equivalence in general performance characteristics.

Results:
Seventy-eight clinicians (mean age: 41.4 years; 89.7% female) and 234 healthy volunteers (mean age: 40.2 years; 61.5% female) were enrolled. Blood leakage occurred significantly more in the traditional non-blood control PIVC group (39.1%) as compared to the PIVC BC group (2.0%) (difference: 37.1% [95% CI: 28.8%; 45.15%]). Blood leakage rates for the PIVC BC with or without use of venous compression were similar, 2.6% and 1.3% respectively (difference: 1.3% [95% CI: – 7.8%, 4.7%]). A total of 98.7% of clinicians rated the PIVC BC as clinically acceptable compared to 89.6% with the traditional non-blood control PIVC (difference: – 9.1; 95% CI: – 18; – 1.5%) and 98.7% agreed it replaced the need for venous compression during catheter insertion (95% CI: 92.8%; 100%).

Conclusion:
The PIVC with blood control demonstrated reduced blood leakage during insertion and was rated no different for clinical acceptability and insertion performance compared to the traditional non-blood control PIVC. Clinicians agreed that the new design replaced the need for venous compression to control blood flow during IV catheter insertion.