Evaluation of the efficacy and safety of a novel dermatotomy device for central venous cannulation

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INTRODUCTION

The Guideblade® is a novel, wire-guided scalpel for central venous cannulation (CVC) using the Seldinger technique.

Figure: Guideblade® loaded with 0.035 guidewire to enable a precise dermatotomy incision adjacent to the wire.

Hypothesis: the Guideblade® is safe and effective for CVC.

MATERIALS AND METHOD

Subjects: 100 pts requiring CVC
Operators: Anesthesia residents ,fellows and attending
Catheters: Table 1.
Primary outcome:
- Success rate of CVC without additional equipment.

Secondary Outcomes:
- Dermatotomy attempts, wire kinking, operator injury or need for additional tools.
- Bleeding at the insertion site at 30 min and immediately after operation.

Guideblade® is supplied by Ambitus Medical Supplies LLC

STUDY RESULTS

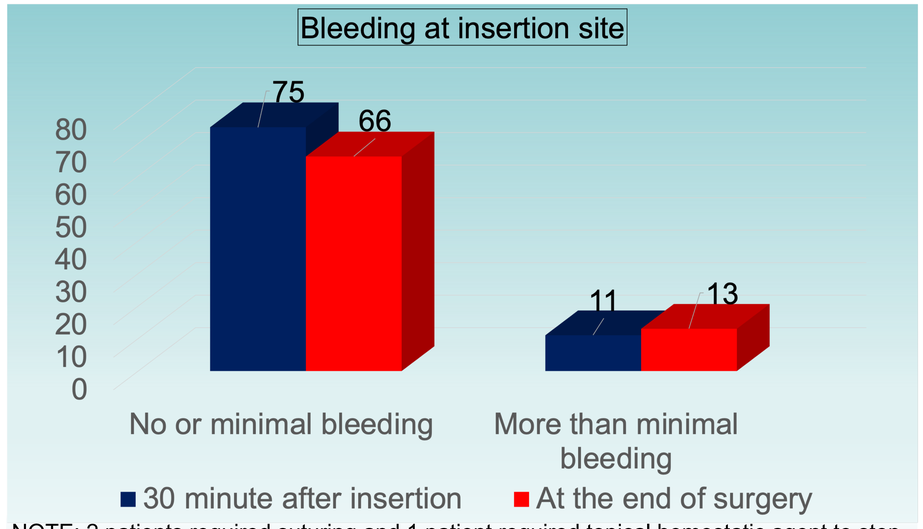
Table 1: Demographic Data

Demographic data	Values
Age (year) (mean±SD, range)	61.19 ±15.32, 19-80
Number of patients	100
Male	62 (62%)
Female	38 (38%)
Body weight (kg) (mean±SD, range)	84.92 ±21.48, 37.2-141
Height (cm) (mean±SD, range)	172.03± 9.89, 149-195
BMI (kg/m2) (mean±SD, range)	28.53 ±6.18, 16.53-45.86
Number of lines (total)	188
single CVC (patients)	12 (12%)
Double CVC (patients)	88 (88%)
Type of lines	
Triple lumen catheter (n)	93
9 Fr introducer (PSI®) (n)	67
Multi-lumen access catheter(MAC®) (n)	28

Table 2: Outcome measurement

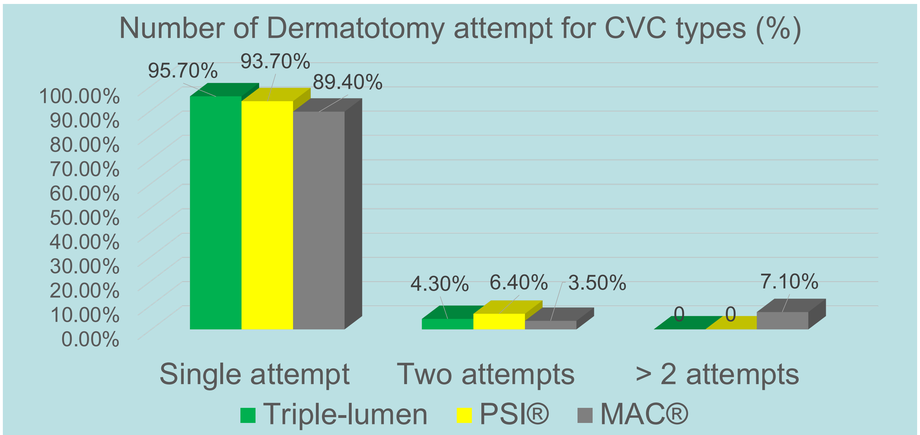
Outcome	Number (%)
Primary outcome: Successful lines insertion without additional instrument	188 (100%)
Wire damage	0 (0%)
Operator injury	0 (0%)

Figure 1 : Bleeding at the insertion sites



NOTE: 2 patients required suturing and 1 patient required topical hemostatic agent to stop bleeding. Both were classified as “bleeding coming out from dressing”

Figure 2 : Numbers of Dermatotomy Attempts



DISCUSSION

The Guideblade® was safe and effective for CVC with 100% success. The Glideblade® design was safe for operators and there was no or minimal bleeding at the CVC site in majority of patients. The Guideblade was particularly useful in patients with a thick neck, severely limited neck range of motion, prior scarring, or when the sterile field was partially obscured.

CONCLUSION

The Gideblade® was a safe and effective tool for creating a precise and consistent dermatotomy incision for CVC with a 100% success rate and a very high first attempt success rate with no user injuries.

REFERENCE

1. Alsaad AA, Bhide VY, Moss JL Jr, Silvers SM, Johnson MM, Maniaci MJ. Central Line Proficiency Test Outcomes after Simulation Training versus Traditional Training to Competence. Ann Am Thorac Soc. 2017 Apr;14(4):550-554.