

We have evaluated the durability of a noble metal coated CVC (the Bactiguard Infectious Protection, BIP CVC) and compared with an uncoated CVC for clinical tolerability (Adverse Events, AEs) and performance, in order to create a baseline for a large future study” Björling et al (2017).

Abstract:

The use of Central Venous Catheters (CVCs) commonly results in complications. Coatings with silver or metal alloys can reduce the risk associated with the use of CVC. We have evaluated the durability of a noble metal coated CVC (the Bactiguard Infectious Protection, BIP CVC) and compared with an uncoated CVC for clinical tolerability (Adverse Events, AEs) and performance, in order to create a baseline for a large future study. Patients undergoing major surgery, randomised at a 2:1 ratio to BIP CVC (n = 22) or standard CVC (n = 12), were catheterized 9 - 12 days, respectively. Adverse events, microbial colonization and metal release were measured.

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FINDINGS: There were no AEs in the BIP CVC-group, but 5 AEs occurred in 4 patients (1 patient had 2 AEs) in the standard CVC-group, $p = 0.011$ (whereof 3 were catheter related). The BIP CVC showed an initial release of coating metals in blood (gold, silver and palladium), which rapidly decreased and were far below Permitted Paily Exposure (PDE) for chonical use. The levels of silver concentration were far below those needed to develop microbial resistance. The performance was equal, and there was no difference concerning microbial colonization, for the two CVCs.

CONCLUSION: In this pilot study the BIP CVC had significantly lower AEs and showed a comparable performance to the standard CVC. The coating was durable throughout the study length (up to 16 days) and toxicological evaluation showed good safety margins. Larger studies are needed.

Reference:

Björling, G., Johansson, D., Bergström, L., Strekalovsky, A., Sanchez, J., Frostell, C. and Kalman, S. (2017) Evaluation of central venous catheters coated with a noble metal alloy-A randomized clinical pilot study of coating durability, performance and tolerability. Journal of Biomedical Materials Research. November 6th. .

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