

4th World Congress and Expo on

Applied Microbiology

September 19-21, 2016 Las Vegas, USA

Tolerability and performance of BIP central venous catheters with noble metal alloy coating: A randomized clinical evaluation study

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Central venous catheters (CVCs) are used for drug delivery, intravenous nutrition, monitoring and blood sampling. The complication risk is significant and coatings with silver or metal alloys may reduce or alter microbial colonization on the catheters. We aimed to evaluate and compare a CVC coated with gold, silver and palladium (BIP CVC), with an uncoated CVC for tolerability and performance. Degree of microbial catheter colonization, visual thrombus and coating metal leakage were also described. This was a single-centre, randomized, single-blind, controlled, first in man, post European certification and CE marking study. Patients N=34 undergoing elective major surgery were randomized at a 2:1 ratio to BIP CVC (n=22) or to uncoated standard CVC (n=12). We recorded adverse events (AE), CVC-related problems, visual signs of thrombus formation on the CVC, inspected the CVC insertion site, measured leakage of coating metals into blood, and sampled for microbial colonization of the CVC and blood. There were no AEs in the BIP CVC group. In the standard CVC group, 33% had AEs p=0.011. Occlusion during use was reported for 41% of patients in the BIP CVC group and 58% of patients in the standard CVC group. Metal concentrations in blood for the BIP CVC were below the toxicological safety limits for chronic exposure. BIP CVC has a good tolerability and comparable performance as the standard uncoated CVC when used in patients undergoing elective major surgery. However, due to our small group sizes larger studies are needed.

Biography

Gunilla Bjorling has completed her PhD in 2007 at Karolinska Institutet, Stockholm, Sweden and has since then performing clinical research at the same university, as well as at the Swedish Red Cross University College in the field of "Medicine, material science, patient safety and medical technical products". She has been invited speaker to several conferences in the field and has published over 15 scientific articles. She is currently a Program Director at the Swedish Red Cross University College.

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