

A RANDOMISED CROSS-OVER STUDY OF SILVER-COATED SILICONE FOLEY'S CATHETER AND 100% SILICONE FOLEY'S CATHETER IN PATIENTS REQUIRING LONG TERM INDWELLING CATHETERS

Hypothesis / aims of study

This randomised, cross-over study aims to compare the use of hydrogel silver-coated silicone catheter (SSC) and all-silicone catheter (ASC) in patients requiring long-term indwelling urinary catheter in terms of catheter-associated infection (CAUTI) rates, complications and patients satisfaction.

Study design, materials and methods

Patients who met the inclusion and exclusion criteria were randomized into the ASC and SSC groups. There was a mandatory cross-over to the other group after the 3rd month. However patients who experienced adverse events or unhappy with existing catheter but still keen to continue with the study were allowed to cross-over earlier.

Urine chemistry, urine full examination and microscopic elements (UFEME), urine culture and sensitivity will be taken at week 0, 1, 2 and 4. Any adverse events, CAUTI and patient satisfaction scores were recorded at each visit. A 24-hour urine chemistry was taken before the 3rd catheter change.

Results

12 patients, mean age of 68.4 years old were recruited and follow-up for a mean of 2.25 months. CAUTI rates and catheter blockage rates were significantly higher in the SSC group. Patient satisfaction scores were significantly lower in the SSC group. There was no difference in the time for colonization of catheters and bacteruria rates between the two groups. SSC seems to resist colonization by E coli but increases the risk of S aureus colonization. The study was terminated prematurely due to increased adverse events reported in the SSC group.

Concluding message

SSC was not superior to ASC. In fact SSC might be associated to increased CAUTI and complication rates.

References

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Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Khoo Teng Kew Goh Soon Noi
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes