Office of Evidence Based Practice – Specific Care Question: Efficacy of silver coated urinary catheter and infection prevention

Specific Care Question :

In the child who requires a urinary catheter (Foley) what is the efficacy, cost effectiveness and antimicrobial resistance of silver coated catheters versus catheters without silver coating?

Question Originator:

Angela Myers, MD

Plain Language Summary from the Office of Evidence Based Practice:

We make a weak recommendation not to use silver coated silicone urinary catheters based on low quality evidence. Alternative approaches are likely to be better for some patients under some circumstances. Further research (if performed) is likely to have an important influence on our confidence in the estimate of effect and may change the estimate. Data for this analysis was obtained from 3 single studies and one meta analysis.

The studies included in the meta analysis were split into two groups: pre 1995 and post 1995. This split occurs because the reported estimates of effect are markedly different within the two timeframes. The Number Needed to Treat (NNT) from studies published before 1995 is 4, meaning an infection will be prevented in every fourth patient in whom a silver coated urinary catheter is used. Juxtapose this to the NNT from studies published after 1995, where the NNT is 98, or an infection will be prevented in every 98th patient in whom a silver coated urinary catheter is used.

More recently, two large cohort studies (Karchmer, Giannetta, Muto, Strain, & Farr, 2000; Rupp et al., 2004) showed decreased number of infections per patient days and per catheter days. Both cohorts are before and after studies, where hospital wards were stocked with the silver alloy urinary catheters and rates were compared with historical rates. The major weakness of this design is that other factors other than the urinary catheter may have influenced the decrease, such as aggressive hand washing campaigns, changes in the procedures to place the catheters, etc

Finally, the one randomized control trial (RCT) (Pickard et al., 2012).showed that the odds of getting an urinary tract infection while the urinary catheter is in place, as well as infection one to six weeks after the catheter is removed, are the same. However, within one week after catheter removal, the odds of getting an infection were significantly lower in the silver coated urinary catheter group.

Only one of the studies included pediatric subjects (Rupp, et al., 2004). Pediatric units represented 20% of the hospital units included in the sample. Data from the units were not analyzed separately.

All urinary catheters used in the included studies were latex catheters. A major producer of urinary catheters (C.R.Bard) does make silver coated silicone catheters that can be used in a pediatric population.

No harm data was published. The Manufacturer and User Facility Device Experience (MAUDE) Database http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm was searched for reported problems of silver coated urinary catheters. Reported problems included: (a) unable to remove the catheter, (b) the catheter stops draining, and (c) hematuria.

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Search Strategy and Results:
Search completed on February 28, 2013
("Urinary Catheterization"[Mesh] OR "Urinary Catheters"[Mesh] OR "Foley"[TIAB]) AND ("Silver"[Mesh] OR "silver"[TIAB]) AND English[lang]
109 results
("Urinary Tract Infections/prevention and control"[Mesh] OR "Urinary Catheterization"[Mesh] OR "Urinary Catheters"[Mesh] OR "Foley"[TIAB]) AND ("Silver"[Mesh] OR "silver"[TIAB]) AND English[lang]
114 results
From this list, Dr. Myers selected five articles to be included in the review. Four studies (three randomized control trials and one meta-analysis were included in this review.

Studies included in this review:

Drekonja, D. M., Kuskowski, M. A., Wilt, T. J., & Johnson, J. R. (2008). Antimicrobial urinary catheters: a systematic review. *Expert Rev Med Devices, 5*(4), 495-506. doi: 10.1586/17434440.5.4.495

Karchmer, T. B., Giannetta, E. T., Muto, C. A., Strain, B. A., & Farr, B. M. (2000). A randomized crossover study of silver-coated urinary catheters in hospitalized patients. *Arch Intern Med, 160*(21), 3294-3298. doi: ioi00038 [pii]

Pickard, R., Lam, T., MacLennan, G., Starr, K., Kilonzo, M., McPherson, G., . . . N'Dow, J. (2012). Antimicrobial catheters for reduction of symptomatic urinary tract infection in adults requiring short-term catheterisation in hospital: a multicentre randomised controlled trial. *Lancet, 380*(9857), 1927-1935. doi: 10.1016/S0140-6736(12)61380-4

Rupp, M. E., Fitzgerald, T., Marion, N., Helget, V., Puumala, S., Anderson, J. R., & Fey, P. D. (2004). Effect of silver-coated urinary catheters: efficacy, cost-effectiveness, and antimicrobial resistance. *Am J Infect Control, 32*(8), 445-450. doi: S0196655304004742

Studies <u>not</u> included in this review with rationale for exclusion:

Johnson, J. R., Kuskowski, M. A., & Wilt, T. J. (2006). Systematic review: antimicrobial urinary catheters to prevent catheter-

associated urinary tract infection in hospitalized patients. *Ann Intern Med, 144*(2), 116-126. doi: 144/2/116 [pii] *Included the same studies as (Drekonja, Kuskowski, Wilt, & Johnson, 2008).*

Method Used for Appraisal and Synthesis:
The Cochrane Collaborative computer program, Review Manager (RevMan 5.1.7), was used to synthesize three of the included studies. The meta-analysis was synthesized by GRADE Profiler (GRADEPro).

Updated: April 26, 2013, May 6, 2013, May 16, 2013

Tables:

The included meta-analysis by Drekonja (2008) included nine RCTs. The studies were split into those done pre and post 1995, and reported separately. For pre 1995 studies (N=483) the OR = 0.24, 95% CI [0.15, 0.4] and the NNT was 4 (See Table 1). For post studies (N=12288) the OR= 0.79, 95% CI [0.66, 0.94] and the NNT was 98 (See Table 2.).

Table 1. Infection in catheters, pre 1995

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Silver treated urinary catheters made prior to 1995 be used	Non silver coated catheters	Relative (95% CI)	Absolute		
Infection catheters pre 1995												
4	randomized trials	serious[1,2]	no serious inconsistency	no serious indirectness	no serious imprecision	none	26/216 (12%)	94/267 (35.2%)	OR 0.24 (0.15 to 0.4)	237 fewer per 1000 (from 174 fewer to 277 fewer)	⊕⊕⊕O MODERATE	CRITICAL
								39.2%		258 fewer per 1000 (from 187 fewer to 304 fewer)		

[1] Attrition not reported
[2] Allocation concealment is not defined

Table 2. Infection in catheters, post 1995

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Made post-1995 Silver	Control	Relative (95% CI)	Absolute		
Infection catheters post 1995												
5	randomized trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	238/5986 (4%)	316/6302 (5%)	OR 0.79 (0.66 to 0.94)	10 fewer per 1000 (from 3 fewer to 16 fewer)	⊕⊕OO LOW	CRITICAL
								11.9%		23 fewer per 1000 (from 6 fewer to 37 fewer)		

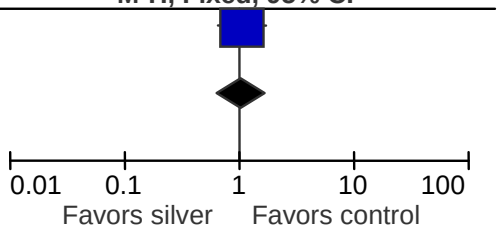
[1] 2 of the 5 studies used alternate week randomization
[2] Wide confidence intervals on 3 of the 5 included studies

Figures:

Pickard, et al. (2012) measured catheter associated urinary tract infection while the catheter was in place (N= 4241). An OR for acquiring a UTI equaled 1.05, 95% CI [0.65. 1.71] and an NNT > 150. It is important to note that the confidence interval for the OR crosses 1 and therefore we cannot definitively report that patients benefit with the use of a silver coated urinary catheter when UTI while the catheter is in place as an outcome (see Figure 1).

Figure 1. UTI while the catheter is in place.

	Silver		Control			Odds Ratio	Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI	M-H, Fixed, 95% CI
Pickard 2012	34	2097	33	2144	100.0%	1.05 [0.65, 1.71]	
Total (95% CI)		**2097**		**2144**	**100.0%**	**1.05 [0.65, 1.71]**	
Total events	34		33				
Heterogeneity: Not applicable							
Test for overall effect: Z = 0.21 (P = 0.83)							

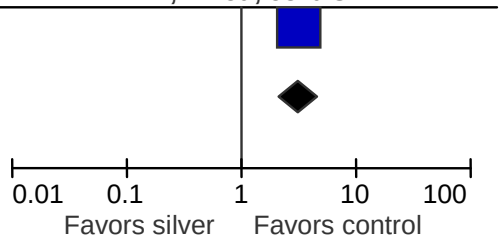


Pickard, et al. (2012) also measured UTI within one week of catheter removal (N=4241). An OR for acquiring a UTI equaled 3.17, 95% CI [2.13, 4.72], and a Number Needed to Harm (NNH) of 32. This means one in about every 32 patients will have a UTI within one week of catheter removal compared to the control group (see Figure 2).

Figure 2. UTI within one week of catheter removal.

	Silver		Control			Odds Ratio	Odds Ratio
Study or Subgroup	**Events**	**Total**	**Events**	**Total**	**Weight**	**M-H, Fixed, 95% CI**	**M-H, Fixed, 95% CI**
Pickard 2012	99	2097	33	2144	100.0%	3.17 [2.13, 4.72]	
Total (95% CI)		**2097**		**2144**	**100.0%**	**3.17 [2.13, 4.72]**	
Total events	99		33				

Heterogeneity: Not applicable
Test for overall effect: Z = 5.67 (P < 0.00001)

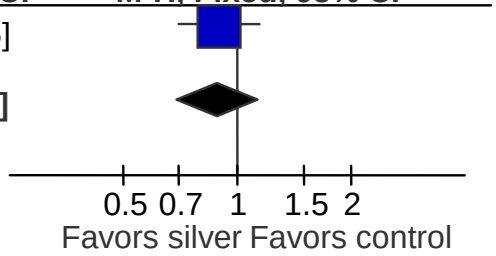


Finally Pickard, et al. (2012) measured the number of UTIs occurring between 1 and 6 weeks after catheter removal (N=4241).The analysis resulted in an OR equaling 0.90, 95% CI [0.70, 1.15], and a NNT of 152. It is important to note that the confidence interval for the OR crosses 1. Therefore we cannot report that patients benefit with the use of a silver coated urinary catheter when acquiring a UTI between 1 and 6 weeks post catheterization is an outcome (see Figure 3).

Figure 3. UTI infection between 1 and 6 weeks post catheterization

	Silver		Control			Odds Ratio	Odds Ratio
Study or Subgroup	**Events**	**Total**	**Events**	**Total**	**Weight**	**M-H, Fixed, 95% CI**	**M-H, Fixed, 95% CI**
Pickard 2012	127	2097	144	2144	100.0%	0.90 [0.70, 1.15]	
Total (95% CI)		**2097**		**2144**	**100.0%**	**0.90 [0.70, 1.15]**	
Total events	127		144				

Heterogeneity: Not applicable
Test for overall effect: Z = 0.88 (P = 0.38)



Characteristics of included studies:

Pickard 2012

Methods	RCT
Participants	7,102 adult patients undergoing urethral catheterization for an anticipated duration of up to 14 days
Interventions	Control group (N=2,120) received a standard polytetrafluoroethylene (PTFE)-coated latex catheter Experimental group (N=1,994) received a silver alloy latex catheter Experimental group (N=2,008) received a nitrofural impregnated catheter
Outcomes	Primary outcome: incidence of symptomatic catheter-associated UTI, defined as the presence of participant-reported symptoms of UTI and clinician prescription of antibiotic for a UTI at any time up to 6 weeks after randomization. Secondary outcomes: incidence of microbiologically confirmed symptomatic CAUTI, incidence of bacteriuria up to 3 days after catheter removal, changes in health-related quality of life during the 6 weeks of trial participation, and urethral discomfort related to catheterization.
Notes	Both the control and the silver alloy catheters are made with latex, which we wouldn't use at CMH.

Risk of bias table

Bias	Scholars' judgment	Support for judgment
Random sequence generation (selection bias)	Low risk	Computer generated randomization
Allocation concealment (selection bias)	Low risk	Users accessed the randomization through an automated telephone service or a secure web site.
Blinding of participants and personnel (performance bias)	Low risk	Blinding was not possible due to the distinctive appearance of each catheter, but risk is low.
Blinding of outcome assessment (detection bias)	Low risk	Participants were also outcome assessors in a way, since participants reported symptoms. Knowing which catheter they received may have affected detection of symptoms, but all reports of UTI symptoms were corroborated by an outside physician's prescription of an

		antibiotic.
Incomplete outcome data (attrition bias)	Low risk	Across the 3 groups, 6,394 (90%) of 7,102 enrolled were included in the main analysis. Out of those not included, some did not provide retrospective consent or withdrew their consent, some became ineligible due to not being catheterized. With such a large sample size, this is acceptable and all attrition is explained.
Selective reporting (reporting bias)	Low risk	All outcomes were reported.
Other bias	Unclear risk	

Critically Appraised Topic (CATs)

Author, date, country, and industry of funding	Patient Group	Level of Evidence (Oxford)	Research design	Significant results	Limitations
Karchmer, 2000 USA	Patients on adult hospital wards of 600 bed hospital, including intensive care units and step-down units. Excluded were pediatric wards, obstetrics,	See assessment of bias in the RevMan table	Wards were randomized. First six months Group 1 wards were stocked with silver-coated catheters Group 2 wards were stocked with uncoated catheters One Month washout-all wards stocked with uncoated catheters Second six months Group 1 wards were stocked with uncoated catheters Group 2 wards were stocked with silver-coated catheters	The relative risk of infection per 1000 patient days was 0.79, 95% CI [0.63-0.99]; P= 0.4) for study wards randomized to silver coated catheters compared to those randomized to uncoated catheters.	Important note to this study: pediatric wards were not included and these silver-coated catheters were latex which we do not use in our pediatric hospital due to the risk of allergic reaction or potential sensitivity to latex due to the risk factors of the pediatric population. This study article

	gynecology and psychiatry.				did not indicate if non-latex catheters with silver coating are even available.
Rupp 2004 USA	Ten patient care units at a tertiary medical center		Before and after comparison Before catheter- an uncoated latex catheter made by the same manufacturer After catheter silver alloy/hydrogel coated catheter was introduced November 2000 C. R. Bard, Inc Covington, GA	Following the introduction of silver alloy/hydrogel coated urinary catheters the overall rate of UTI per 1000 catheter days was lower in the group with the silver coated urinary catheters **<u>Catheter days</u>** **Silver coated group-** 2.62/1000 catheter days **Uncoated group-** 6.13/1000 catheter days P= 0.002 **<u>Patient days</u>** **Silver coated group-** 0.97/1000 patient days **Uncoated group-** 1.67/1000 patient days P= 0.002	Retrospective design. Other factors may have changed over the four year interval that had an impact on urinary tract infections in patients who were catheterized.