Title: Closed Catheter Systems for Prevention of Urinary Tract Infections: A Review of the Clinical Effectiveness

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Context and Policy Issues:

Urinary tract infections (UTI) are the most common cause of nosocomial infections, causing 40% of all hospital acquired infections, 80% of which are catheter-associated urinary tract infections (CAUTI). Although the majority of CAUTI are asymptomatic, a relationship exists between symptomatic CAUTI and increased mortality in diabetic, immunocompromised, and debilitated patients. For both short and long term indwelling catheters, the frequency of infection is directly related to the duration of catheterization. Short term catheterization is associated with an infection risk of approximately 3% - 7%, and the risk of infection for patients with long term catheterization is 3% - 10%. For patients in long term care, chronic catheterization is associated with increased mortality. This relationship, however, is confounded by the fact that patients with long-term indwelling catheters are more likely to have comorbid conditions and reduced mobility.

Risk factors associated with developing symptomatic infection include trauma to genitourinary mucosa, obstruction of the urinary catheter or drainage system, and fecal incontinence. For long term catheterization, it is uncertain whether catheter care can help to prevent infection, as procedures such as flushing catheters with saline and perineal care with antiseptics or antimicrobials, have been shown to be ineffective. Prophylactic antimicrobials and newer catheters that incorporate antimicrobials have been developed, but the use of these agents raises concerns regarding antimicrobial resistance.

Maintaining a closed urinary drainage system may prevent the development of CAUTI. Closed urinary drainage systems are systems in which the drainage from bladder to the collection bag is closed. In a pre-connected closed system, the collection system and catheter are connected with a tamper evident seal, which prevents breaking of the closed system. However, CAUTI is still reported to occur with the use of a closed system. Because of the ongoing problems with

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CAUTI and claims that closed catheter systems may reduce infection risk, it is necessary to review the evidence for the short and long term use of closed urinary catheters to determine their clinical effectiveness for reducing UTI.

**RESEARCH QUESTION:**

What is the clinical effectiveness of closed urinary catheter systems for the reduction of urinary tract infections?

**METHODS:**

A limited literature search was conducted on key health technology assessment resources, including PubMed, OVID CINAHL, The Cochrane Library (Issue 4, 2008), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international health technology agencies, and a focused Internet search. Results include articles published between 2003 and November 2008, and are limited to English language publications only. No filters were applied to limit the retrieval by study type.

HTIS reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials (RCTs), observational studies, and evidence-based guidelines.

**SUMMARY OF FINDINGS:**

One RCT, three observational studies, and one evidence-based guideline were identified on the use of closed catheter systems for the prevention of CAUTI. No health technology assessments or systematic reviews were identified.

**Randomized controlled trials**

Leone *et al.* (2003) examined urinary drainage systems to compare the rate of UTI. A total of 311 patients who required a urinary catheter were randomized to receive either a two-chamber drainage system (TCDS; 149 patients) or a complex closed drainage system (CCDS; 162 patients). There were no differences between the study groups in terms of baseline characteristics. Urine samples were collected and tested for bacteriuria (bacteria in the urine) at weekly intervals during catheterization, and 24 hours after removal of the catheter. The incidence of bacteriuria was similar between the groups (12/149 versus 14/162 in the TDCS and CCDS groups, respectively). The TCDS group had a significantly longer stay in the intensive care unit compared to the CCDS group (29±17 days versus 19±8 days; p<0.05), and a significantly longer catheterization duration (21.5±11 days versus 15±6.3 days; p<0.05). Overall, the authors concluded that there was no difference in the rate of infection between the closed system (CCDS) and TCDS.

**Observational studies**

A recent prospective study examined CAUTIs in five Japanese hospitals to determine risk factors and catheter care practice. A total of 555 patients who were catheterized (using closed drainage systems or pre-connected closed systems) for three or more days were included in the study. The rate of CAUTI was 3.9/1000 device-days. Using a non-pre-connected closed system was identified as a risk factor for CAUTI. A multivariate analysis found the relative risk of CAUTI...
with use of a non-preconnected closed system was 2.35. The authors concluded that the incidence of CAUTI could be reduced by 50% with the use of a pre-connected closed system and daily cleansing of the perineal area.

Pre-connected closed urinary catheter systems were compared with traditional bag and catheter systems in a 2005 study.² It is unclear whether the traditional system in this study was a closed system. The baseline group used the traditional system (n=104) between October 2002 and March 2003. The pre-connected system was later introduced, and there were 104 patients in the intervention group that used the pre-connected system between September 2003 and March 2004. There were 37.8 cases of CAUTI per 1000 catheter days in the baseline group, and 22.4 cases of CAUTI per 1000 catheter days in the intervention group. The intervention group had a 41% lower rate of CAUTI than the baseline group. This study suggested that the pre-connected system protects against CAUTI. There are limitations to these results as the groups were not studied at the same time, so other factors may have contributed to the lower rate of CAUTI.

Closed urinary drainage system (CUDS) use was evaluated in a 2004 study.⁶ Databases of hospitalized patients in acute care in Spanish hospitals were searched and data was collected from a chart review to determine the usage of CUDS. There were 76,788 patients included. This study found a 23.5% increase in the portion of patients using CUDS (56.5% in 1990 versus 69.8% in 2000). The prevalence of UTI decreased from 9.2% to 5.6%, which correlated with the increase in CUDS use.

Evidence-based guidelines

European and Asian guidelines on the management and prevention of catheter-associated UTIs were published in 2008.⁷ The authors systematically searched the literature for randomized controlled trials on CAUTI. The guidelines focused on methods of catheterization, urine drainage, prevention of bacteriuria, and treatment of bacteriuria. The guidelines stated that the catheter system should remain closed (Grade of A; based on good quality clinical studies; including at least one RCT). No other mention of closed catheters was included in these guidelines.

Limitations

There was limited information on the use of closed urinary drainage systems identified. No health technology assessments or systematic reviews were found. There was only one RCT published in 2003 that was identified.⁵ The other studies that were identified were observational studies, which are subject to potential selection bias and are unable to control for confounding factors. None of these studies evaluated the clinical effectiveness of closed catheter systems based on duration of catheterization.

Both groups in one of the observational studies used a closed system (pre-connected and non-preconnected) so the clinical effectiveness of using a closed system cannot be determined.⁴ No control group was included in one observational study, and therefore, other factors may have contributed to the reduced CAUTI rate.⁶ Furthermore, the other observational study compared a pre-connected system to a traditional system, and it is unclear whether the traditional system was closed.
The RCT was conducted in France and the observational studies were from Japan, Spain, and the UK; therefore it is unclear whether these studies would be generalizable to a Canadian population. Furthermore, no North American guidelines were identified.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

The evidence for the clinical effectiveness of closed catheter systems is limited. Although the RCT suggested that bacteriuria incidence was similar between a closed system and a two-chamber drainage system, one observational study suggested that CAUTI was reduced with use of closed systems. This evidence must be interpreted with caution, however, as there were limitations to these studies. The use of a pre-connected urinary catheter system appears to reduce CAUTI, but it may be the “preconnected” feature of the system and not the “closed” feature that is relevant. The low quality of the available evidence must be considered when deciding whether to used closed urinary drainage systems over other types of urinary catheters for the prevention of UTI. Other interventions such as perineal and catheter care, should also be considered.

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