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Hydrophilic Catheters

An Evidence-Based Analysis

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Abbreviations

CIC	Clean intermittent catheterization
E. Coli	Escherichia coli
NHS	National Health Service
PVC	Polyvinyl chloride
RCT	Randomized controlled trial
UTI	Urinary tract infection
VAS	Visual analogue scale

Glossary

Bacteriuria	The presence of bacteria in the urine with or without associated symptoms of infection.
Catheter-associated urinary tract infection (CAUTI)	The occurrence of local or distant clinical symptoms or signs attributable to bacteria present either within the urinary tract, or in the bloodstream (with the urinary tract as the source)
Clean procedure/technique	Hands are decontaminated before and after the procedure
Hydrophilic catheter	An intermittent catheter that, with the addition of water, allows virtually friction-free insertion and removal of the catheter without the use of a lubricating gel
Indwelling catheter	A catheter that is inserted into the bladder via the urethra and remains in place for a period of time
Intermittent catheter	A catheter that is inserted into the bladder only when urine needs to be drained
Self-catheterization	Urinary catheterization undertaken by the patient
Sterile procedure/technique	Free from any living micro-organisms (i.e., procedure uses gloves, single-use catheter)

Executive Summary

Objective

To review the evidence on the effectiveness of hydrophilic catheters for patients requiring intermittent catheterization.

Clinical Need

There are various reasons why a person would require catheterization, including surgery, urinary retention due to enlargement of the prostate, spinal cord injuries, or other physical disabilities. Urethral catheters are the most prevalent cause of nosocomial urinary tract infections, that is, those that start or occur in a hospital.

A urinary tract infection (UTI) occurs when bacteria adheres to the opening of the urethra. Most infections arise from *Escherichia coli,* from the colon. The bacteria spread into the bladder, resulting in the development of an infection.

The prevalence of UTIs varies with age and sex. There is a tenfold increase in incidence for females compared with males in childhood and throughout adult life until around 55 years, when the incidence of UTIs in men and women is equal, mostly as a consequence of prostatic problems in men. Investigators have reported that urethritis (inflammation of the urethra) is found in 2% to 19% of patients practising intermittent catheterization.

The Technology

Hydrophilic catheters have a polymer coating that binds o the surface of the catheter. When the polymer coating is submersed in water, it absorbs and binds the water to the catheter. The catheter surface becomes smooth and very slippery. This slippery surface remains intact upon insertion into the urethra and maintains lubrication through the length of the urethra. The hydrophilic coating is designed to reduce the friction, as the catheter is inserted with the intention of reducing the risk of urethral damage.

It has been suggested that because the hydrophilic catheters do not require manual lubrication they are more sterile and thus less likely to cause infection. Most hydrophilic catheters are prepackaged in sterile water, or there is a pouch of sterile water that is broken and released into the catheter package when the catheter is ready to use.

Review Strategy

The Medical Advisory Secretariat searched for reports of systematic reviews of randomized controlled trials (RCTs), meta-analyses of RCTs, and RCTs. The following databases were searched: Cochrane Library International Agency for Health Technology Assessment (fourth quarter 2005), Cochrane Database of Systematic Reviews (fourth quarter 2005), Cochrane Central Register of Controlled Trials (fourth quarter 2005), MEDLINE (1966 to the third week of November 2005), MEDLINE In-Process and Other Non-indexed Citations (1966 to November 2005), and EMBASE (1980 to week 49 in 2005). Search terms were urinary catheterization, hydrophilic, intermittent, and bladder catheter.

The Medical Advisory Secretariat also conducted Internet searches of Medscape (www.medscape.com) for recent reports on trials that were unpublished but presented at international conferences. In addition,

the Web site Current Controlled Trials (www.controlled-trials.com) was searched for ongoing trials on urinary catheterization.

Summary of Findings

Five RCTs were identified that compared hydrophilic catheters to standard catheters. There was substantial variation across the studies in terms of the reason for catheterization, inclusion criteria, and type of catheter used. Two studies used reusable catheters in the control arm, while the other 3 RCTs used single-use catheters in the control arm. All 5 RCTs focused mainly on males requiring intermittent catheterization. Age varied considerably across studies. One study consisted of young males (mean age 12 years), while another included older males (mean age 71 years).

The RCTs reported conflicting results regarding the effectiveness of the hydrophilic catheters compared with standard catheters in terms of rates of UTIs. All 5 RCTs had serious limitations. Two of the studies were small, and likely underpowered to detect significant differences between groups. One RCT reported 12-month follow-up data for all 123 patients even though more than one-half of the patients had dropped out of the study by 12 months. Another RCT had unequal groups at baseline: the patients in the hydrophilic group had twice the mean number of UTIs at baseline compared with the standard catheter group. The fifth RCT used catheters to treat patients with bladder cancer; therefore, the results of their study are not generalizable to the population requiring intermittent catheterization.

Two studies did not find significant differences between the hydrophilic and standard catheter groups for patient satisfaction. Another RCT reported conflicting results; however, the overall opinion of the catheters was not significantly different between the treatment groups. A fourth RCT found that the hydrophilic catheters were substantially more comfortable than standard catheters. The fifth RCT did not report results for quality of life or patient satisfaction. Similar to the results for effectiveness, it is not possible to clearly establish if there is a significant difference in patient satisfaction between the patients using hydrophilic catheters and those using standard catheters.

Conclusions

Patients requiring intermittent catheterization use, on average, 4 to 5 intermittent catheters per day. Patients admitted to hospitals using intermittent catheters typically do not reuse catheters, owing to the potential increased risk of infection in hospital. Patients self-catheterizing at home are more likely to reuse catheters. Standard catheters cost about $1.00 to $1.50/catheter. Hydrophilic catheters cost about $2.00 to $5.00/catheter, depending on the type and whether they have antibiotics inside. All hydrophilic catheters are single-use.

At this time there is insufficient evidence to indicate whether hydrophilic catheters are associated with a lower rate of UTIs and improved patient satisfaction among people requiring intermittent catheterization.

Objective

To review the evidence on the effectiveness of hydrophilic catheters for patients requiring intermittent catheterization.

Background

Clinical Need: Target Population and Condition

There are various reasons why a person would require catheterization, including surgery, urinary retention due to enlargement of the prostate, spinal cord injuries or other physical disabilities. Urethral catheters are the most prevalent cause of nosocomial urinary tract infections (UTIs). (1)

There are 2 broad types of catheterization: intermittent and indwelling.

Intermittent catheterization (sometimes called "in and out" catheterization) involves short-term catheterization. The catheter is inserted to drain the bladder, and then the catheter is removed. A person may self-catheterize up to 4 to 5 times per day. Candidates for intermittent catheterization should have a residual volume of greater than 100 mL, good manual dexterity and eyesight, and a willingness to perform the catheterization (or a care provider who is willing to provide it). (2)

Catheters that are inserted into the bladder and remain in the bladder are called indwelling catheters. Indwelling catheters are used for a variety of reasons, and an estimated 15% to 25% of all hospital patients use indwelling catheters to monitor urine output or to provide urine drainage. (3)

Outside of hospital, catheters are used in a variety of settings including complex continuing care facilities, long-term care homes, and in the community. Between 19% and 90% of patients in complex continuing care facilities use catheterization (either indwelling or intermittent) (Canadian Institute for Health Information, 2004 119 /id}). It is difficult to estimate the number of patients in acute care settings or in the community that use catheters. Even though an estimated 90% of residents in long-term care homes are incontinent, only about 2.5% of the residents in Ontario's long-term care homes use some form of catheterization. (Personal communication, Ministry of Health and Long-Term Care, March 2006) Some long-term care homes will not accept residents who require catheterization.

Intermittent Versus Indwelling Catheterization

Indwelling catheters are much more cumbersome than are intermittent catheters because they require a drainage bag. Intermittent catheterization allows patients more independence and improved quality of life compared with indwelling catheterization, because patients are not continually wearing or carrying a drainage bag. (4) The duration of catheterization is the most important risk factor for the development of catheter-associated UTIs. (1) The risk of UTI with a single catheterization is 1% to 2%. (1) A study published by Warren et al. (5) in 1982 estimated that the risk of a patient having bacteria in their urine (bacteriuria) by 30 days after catheterization is almost 100%.

The randomized controlled trial (RCT) by van den Brand et al. (6) compared the rate of bacteriuria (the presence of bacteria in the urine) in patients using intermittent versus indwelling catheters (N = 99). They found that the men that used the intermittent catheters had significantly lower levels of bacteriuria than did men using indwelling catheters. There was a similar trend among the women in the study; however,

this difference was not significant. It is unclear if the study was sufficiently powered to detect a significant difference in the levels of bacteruria after 5 days of catheterization.

Clean Versus Sterile Intermittent Catheters

There is some debate regarding the reusability of catheters. It has been proposed that reusable intermittent catheters are associated with higher infection rates. A systematic review published in 1999 by Shekelle et al. (7) identified 3 controlled trials (2 randomized, 1 not randomized) that compared sterile (single-use) versus clean (reuse) catheters. They reported inconsistent results across the studies. The 2 RCTs reported no statistical difference in the rate of UTIs between patients using sterile and patients using clean catheters; however, Shekelle et al. suspected that 1 of the trials was not sufficiently powered to detect a significant difference between t groups. The controlled trial found a significant difference in the rate of bacteriuria in favour of patients using the sterile catheter versus the clean catheter; however, this trial was not randomized.

Since the systematic review by Shekelle et al., 1 RCT was identified that compared sterile versus clean intermittent catheters. In 2001, Schlager et al. (8) reported the results of a randomized crossover study comparing sterile (single-use) catheters to clean (reused) catheters in 10 children with neurogenic bladders. They found that after patients had used each of the catheters for 4 months, that there was no difference in the rate of bacteriuria between those who had used the sterile versus the clean catheters.

In 2004, Bogaert et al. (9) investigated methods for cleaning catheters. They compared microwave heat versus alcohol. They found that using the microwave to disinfect the catheter resulted in minor damage in the physical quality of the catheter, as did submerging the catheter in a 70% alcohol solution for more than 45 minutes. They evaluated the antimicrobial effect on 3 types of bacteria: *Escherichia Coli (E. Coli), Pseudomonas aeruginosa*, and *Staphylococcus aureus*. Microwaving eliminated *E. Coli*, but not the other 2 strains. The 70% alcohol solution had a complete antimicrobial effect on all 3 types of bacteria after 5 minutes.

Based on the evidence available, it is unclear if there is an increased risk of UTI in patients who reuse catheters versus those who use sterile, single-use catheters.

Types of Intermittent Catheters

Hydrophilic Catheters

Hydrophilic catheters have a polymer coating that binds to the surface of the catheter. When the polymer coating is submersed in water, it absorbs and binds the water to the catheter. The catheter surface becomes smooth and slippery. This slippery surface remains intact upon insertion into the urethra and maintains lubrication through the length of the urethra. The hydrophilic coating is designed to reduce the friction as the catheter is inserted with the intention of reducing the risk of urethral damage.

It is suggested that because hydrophilic catheters do not require manual lubrication they are more sterile and thus less likely to cause infection. Most hydrophilic catheters are prepackaged in sterile water, or there is a pouch of sterile water that is broken and released into the catheter package when the catheter is ready to use.

Catheters With Introducer Tips

The purpose of the introducer tip is to prevent pushing bacteria into the bladder which can cause bladder infections. Each time a catheter is inserted there is a risk of infection, urethral trauma, and/or bleeding.

Increased rates of bacteria in the perineum and urethra are observed more often in patients using catheters than in patients not using catheters. (10-12) The purpose of the introducer tip on the catheter is to bypass the bacteria at the base of the urethra, so that the catheter does not push the bacteria into the bladder.

Antibiotic-Impregnated Catheters

As the name suggests, these catheters contain antibiotics to decrease infections. Antibiotic-impregnated catheters are not widely used owing to the risk of developing resistance to the antibiotics.

Standard Catheters

This group of catheters includes all noncoated catheters. They are usually made of polyvinyl chloride (PVC), silicone, latex, or Teflon. Intermittent standard catheters can be washed and reused for up to 1 week. Reusing catheters is not practised in health care facilities because of the risk of infection. Patients who live at home are likely to reuse catheters.

Existing Treatments Other Than Technology Being Reviewed

The alternative to intermittent catheterization is either to use indwelling catheters or, for patients with urinary incontinence, to use diapers or pads. As noted, indwelling catheters are associated with a lower quality of life than are intermittent catheters because of the lack of independence associated with indwelling catheterization. (4) Alternatives to hydrophilic catheters as listed in the previous section are catheters with introducer tips, antibiotic-impregnated catheters, or standard catheters.

Urinary Tract Infections

The prevalence of UTIs varies with age and sex. There is a tenfold increase in the incidence for females compared with males in childhood and throughout adult life until around 55 years, when the incidence of UTIs in men and women is equal, mostly as a consequence of prostatic problems in men. (13) Vaidyanathan et al. (14) have reported that urethritis occurs in 2% to 19% of patients using intermittent catheterization.

Catheter-associated urinary tract infections (CAUTI) are caused by a variety of organisms, including *E. coli, Klebsiella, Proteus*, enterococcus, *Pseudomonas, Enterobacter, Serratia*, and *Candida*. Many of these organisms are a natural part of a patient's bowel flora, but they can also be acquired by cross-contamination from other patients or hospital personnel, or by exposure to nonsterile equipment. (15) Organisms that inhabit the distal urethra can be introduced directly into the bladder when the catheter is inserted. (from (16) in review by Center of Disease Control (15)).

Types of Urinary Tract Infections

The following are types of UTIs: (13)

- Urethritis: This is an infection of the urethra.
- Cystitis: This is an infection of the bladder. (This is the most common form of UTI.)
- Ureteritis: This is an infection of the ureter.
- Pyelonephritis: This is an infection of the kidney.

Urinary tract infections are diagnosed through assessing the number of bacteria and white blood cells in a urine sample. Most UTIs are effectively treated with antibiotics such as trimethoprim-sulfamethoxazole, amoxicillin, or fluoroquinolones.

Infections complicated by bladder outlet obstructions (e.g., kidney stones) and other risk factors (e.g., spinal cord injury) may require surgery to correct the cause of the UTI. Kidney infections may require extended antibiotic treatment.

Regulatory Status of Hydrophilic Catheters

Hydrophilic catheters are licensed for use by Health Canada. There are about 20 types of hydrophilic catheters licensed in Canada.

Literature Review on Effectiveness

Research Questions

- Are hydrophilic intermittent catheters associated with significantly lower rates of UTIs compared with standard intermittent catheters?
- Is quality of life better for patients using hydrophilic catheters compared with patients using standard catheters?

Methods

Outcomes of Interest

- Rate of UTIs
- Quality of life

Inclusion Criteria

- Full reports of systematic reviews of RCTs, meta-analyses of RCTs, and RCTs
- > 20 patients included in the study
- Studies that included patients who required catheterization for any reason
- English-language studies
- Studies that reported te baseline characteristics of patients in treatment groups
- Studies that reported at least one of the aforementioned outcomes of interest.

Exclusion Criteria

- RCTs comparing 2 or more types of hydrophilic catheters
- Non-human studies
- Studies reported in a language other than English
- Nonrandomized studies, prospective case series, case reports, retrospective studies, editorials, letters

Databases and Search Strategy

- Search date: December 6, 2005
- Databases: Cochrane Library International Agency for Health Technology Assessment (fourth quarter 2005), Cochrane Database of Systematic Reviews (fourth quarter 2005), Cochrane Central Register of Controlled Trials (fourth quarter 2005), MEDLINE (1966 to third week of November 2005), MEDLINE In-Process and Other Non-indexed Citations (1966 to November 2005), and EMBASE

(1980 to week 49 of 2005)
- Search terms: urinary catheterization, hydrophilic, intermittent, bladder catheter.

The Medical Advisory Secretariat also conducted Internet searches of Medscape (www.medscape.com) for recent reports on trials that were unpublished but were presented at international conferences. In addition, the Web site Current Controlled Trials (www.controlled-trials.com) was searched for ongoing trials on urinary catheterization.

The detailed literature search strategy is listed in Appendix 1.

Results of Literature Review

Summary of Existing Health Technology Assessments

No health technology assessments were identified that specifically investigated hydrophilic intermittent catheters. The Cochrane Incontinence Group (17-20) has published several reviews on the use of catheters; however, they primarily reviewed indwelling catheters, not intermittent catheters.

The National Health Service (NHS) (21) in the United Kingdom published a best practice statement in June 2004 on urinary catheterization and catheter care. The report focused mostly on the use of indwelling catheters; however, there was also a section on the use of intermittent catheters. The statement did not include an extensive review of the literature, but it contained conclusions from the review. They reported that intermittent catheterization is preferred over indwelling catheterization because of the decreased risk of infection and increased independence associated with self-catheterization. (4)

In 2001, Hedlund et al. (22) published a review comparing hydrophilic intermittent catheters to standard catheters. The review did not include a literature search strategy or a list of sources checked for citations. It did include a summary of retrospective and prospective studies. The authors concluded that they could not make a reliable conclusion on the efficacy of hydrophilic catheters. They indicated that a long-term RCT detailing the rate of UTIs, complications, and patient satisfaction was required, and that the study should include information on the cost-effectiveness of hydrophilic catheters. In late 2005, De Ridder et al. (23) reported the results of a long-term RCT as a response to the Hedlund et al. review. The De Ridder et al. RCT is described in detail later in this review.

Summary of Medical Advisory Secretariat Review

Four RCTs and 1 random crossover study were identified that compared hydrophilic to standard catheters. The studies were heterogeneous; there were differences in length of catheter usage, previous catheter usage, reason for catheterization, gender, age, length of follow-up, and the method of reporting results. For this reason, the studies could not be grouped for meta-analysis. The studies will be described individually below. A summary of them is shown in Tables 2 through 6.

Table 1: Quality of Evidence of Included Studies*

Study Design	Level of Evidence	Number of Eligible Studies
Large RCT, systematic reviews of RCTs	1	2
Large RCT unpublished but reported to an international scientific meeting	1(g)	0
Small RCT	2	3
Small RCT unpublished but reported to an international scientific meeting	2(g)	0

Non-RCT with contemporaneous controls	3a	0
Non-RCT with historical controls	3b	0
Non-RCT presented at international conference	3(g)	0
Surveillance (database or register)	4a	0
Case series (multisite)	4b	0
Case series (single site)	4c	0
Retrospective review, modeling	4d	0
Case series presented at international conference	4(g)	0

*RCT refers to randomized controlled trial; g, grey literature.

Table 2: Quality of RCTs Comparing Hydrophilic Versus Standard Intermittent Catheters*

Study, Year	Study	Randomiz-ation Method	Adequate Sample Size	Allocation Concealment/ Blinding	Reliability of Method to Measure Outcome	ITT Analysis	Lost to Follow-Up	Overall quality
De Ridder et al.,† 2005 (23)	RCT	Computer-generated list	No	No	Yes	No	57/123 patients completed the 12-month study	Low
Cindolo et al., 2004 (24)	RCT	NR Groups similar at baseline	Unclear	Yes (patient blind)	Yes—not generalizable to population	No	83/100 completed the study	Low to moderate
Vapnek et al., 2003 (25)	RCT	Sealed list Groups—may not be similar at baseline	Unclear	No	Yes	No	49/62 completed 12-month study	Low
Pachler et al., 1999 (26)	Cross-over study	NR	Unclear	No	Yes	No	32/43 completed the study	Low
Sutherland etal., 1996 (27)	RCT	NR Groups similar at baseline	Unclear	No	Yes	No	3 pts withdrew	Low

*ITT refers to intention-to-treat; NR, not reported; RCT, randomized controlled trial; UTI, urinary tract infection.
†This study was designed to have a minimum of 50 participants in each arm. At the study's onset, there were 123 patients enrolled; however, at 12 months, only 57 patients remained. Thus, for the final analysis, the study was underpowered.

De Ridder et al., 2005

In the RCT by De Ridder et al. (23) that compared hydrophilic to standard PVC catheters in patients with spinal cord injuries, the primary outcomes of interest were the occurrence of symptomatic UTIs and hematuria (blood in the urine). Also reported was ease of use of the catheters.

De Ridder et al. found that the rate of UTIs in the hydrophilic catheter arm was lower than that in the standard catheter arm (64% vs. 82%, $P = .02$). However, they also reported that the median number of UTIs per 1,000 catheter days was not significantly different between the 2 arms (5.4 for the hydrophilic catheter arm, 8.1 for the standard catheter arm). There were a similar number of catheterizations per day at the end of the study in the 2 groups (3.4 per day for the hydrophilic catheter arm, 3.6 for the standard catheter arm). De Ridder et al. also found no significant difference in the number of bleeding episodes

between the 2 treatment groups. In the hydrophilic catheter arm, 38 of 55 patients had a bleeding episode, compared with 32 of 59 patients in the standard catheter arm.

There were some serious limitations in De Ridder et al.'s study. One hundred and twenty-three patients were randomized to receive intermittent catheterization with either hydrophilic catheters or standard catheters. They reported that they needed 50 patients in each arm for 90% power to detect a difference between the groups using a two-group t test with a .05 one-sided significance level. However, at the end of the study (12 months), only 57 patients remained in the study (25 in hydrophilic catheter group, 33 in standard catheter group). As noted, De. Ridder and colleagues reported a significant difference in the rate of UTIs between the groups; however, even though only 57 completed 12 months of follow-up, the rate of UTIs was reported for the entire group of patients (N = 123). Moreover, the median length of follow-up was not reported; therefore, it is not possible to tell if the data on the patients who did not have an UTI are accurate, given that De Ridder et al. do not note how long these patients were followed-up.

Of the 65 patients who dropped out, 28 had protocol violations, 18 withdrew their consent, 7 suffered from adverse effects, 10 were lost to follow-up, 1 died, and there was no information for 1 patient. De Ridder et al. reported that some patients dropped out of the study because they had restored urinary function (thus they no longer needed catheters), but the number of these patients and the arms to which they had been randomized were not reported. They reported that there was no significant difference in macroscopic bleeding episodes, and no difference in the occurrence of hematuria, leukocyturia (the discharge of leukocytes into the urine), and bacteriuria between the 2 groups. There were also no significant differences in patient satisfaction at 6 or 12 months. The only significant difference reported was the rate of UTI; however, as noted, the rate reported is unreliable due to the lack of appropriate follow-up data on more than one-half of the patients. Failure to detect differences between these 2 arms could have been attributed to at type II error.

Cindolo et al., 2004

The RCT by Cindolo et al. (24) included 100 patients undergoing therapy for bladder cancer. The purpose of the RCT was to evaluate the bacteriological safety and overall comfort of hydrophilic catheters compared with standard catheters. The catheters were being used for the treatment of bladder cancer, rather than for urine drainage like the other studies; therefore, the results of this study are not generalizable to the general population.

Rather than reporting the rate of infection among the patients, Cindolo et al. reported the rate of infection according to the number of catheterizations per group. In total, there were 952 catheterizations (482 in the hydrophilic catheter group and 470 in the standard catheter group). The rate of infection was significantly higher in the standard catheter group compared with the hydrophilic catheter group (7.4% vs. 3.5%, $P < .01$).

Cindolo et al. reported that 7 patients in the standard catheter group and 3 patients in the hydrophilic catheter group suffered from 2 or more UTIs during the 24-month study. When the Medical Advisory Secretariat calculated odds ratios for these results, there was no significant difference between groups in terms of the rate of 2 or more UTIs. This is true when calculated for all patients (50 per group; odds ratio [OR] 0.39; 95% confidence interval [CI], 0.095–1.61) or for the patients that remained in the study after 24 months (39 in standard catheter arm, 44 in hydrophilic catheter arm; OR, 0.33; 95% CI, 0.080–1.40). Once again, failure to detect significant differences could have been attributed to a type II error.

Cindolo et al. reported the mean visual analogue scale (VAS) score for discomfort for the 2 treatment groups. They used a 5-point VAS scale to measure discomfort, 0 being no discomfort and 5 being severe discomfort. The patients using the hydrophilic catheters reported significantly lower VAS scores for

discomfort compared with the patients using the standard catheters (1.3 vs. 2.1, $P < .001$).

Vapnek et al, 2003

Vapnek et al. (25) did an RCT that compared hydrophilic to standard catheters in patients with neurogenic bladder. The primary outcome of interest was the rate of UTIs during the 12-month study period.

Sixty-two patients were randomized to receive intermittent catheterization with either hydrophilic catheters or standard catheters. Patients randomized to the hydrophilic catheter group used single-use catheters. Patients that used standard catheters group used reusable catheters (4–5 times before discarding). Vapnek et al. reported that the groups were comparable at baseline; however, they also noted that the mean number of UTIs per month in the hydrophilic catheter group was 0.45 (SD, 0.62), compared with 0.20 (SD, 0.26) in the standard catheter group. They reported that this difference was not significant. Vapnek et al. used Fisher's permutation test to determine the statistical relevance between groups in terms of the number of UTIs. This test is designed to compare dichotomous variables, not continuous variables like means. So, this difference at baseline cannot be clearly defined as significant or not. It is relevant because the primary outcome of this study was the number of UTIs (i.e., the differences in this between groups), and if the groups are not comparable at baseline then the study's results are unreliable.

Vapnek et al. reported that there was no significant difference in the rate of UTIs at the end of the study between the groups ($P > .3$). There was a significant reduction in the number of UTIs between the end of the study and baseline among the patients in the hydrophilic catheter group, but not in the patients in the standard catheter group ($P = .012$ versus $P = .24$), but this difference may have been because patients in the hydrophilic catheter group had a higher baseline mean number of UTIs than did patients in the standard catheter group.

Another possible limitation of this study is that Vapnek et al. compared single-use to reusable catheters. However, since Vapnek et al. did not find a significant difference between the standard and the hydrophilic catheters, perhaps this is not an issue. If, on the other hand, there had been a significant difference in the number of UTIs favouring hydrophilic catheters, reusing the standard catheters might have been more of an issue.

Pachler et al., 1999

In the prospective crossover study by Pachler et al. (26) the primary outcome was patients' preferences regarding catheter usage comparing hydrophilic to standard catheters. Patients (N = 32) were given a questionnaire after using each of the 2 catheters for 3 weeks. They found that there was no significant between the groups in terms of the frequency of catheterization, discomfort associated with the catheters, opinion regarding the handling of the catheters, or the rate of infection (measured by the incidence of bacteriuria). It is unknown whether the sample size was sufficient to demonstrate an effect (i.e., it is possible there was a type II error).

Sutherland et al., 1996

Sutherland et al. (27) hypothesized that hydrophilic catheter would be associated with less urethral abrasion and improved comfort compared with standard catheters in boys with myelodysplasia, spinal cord injury, or Hinman syndrome (N = 33). This is the only RCT identified that investigated the use of hydrophilic catheters in a young male population. To measure these outcomes, the presence of blood and infection in the urine during weekly urinalyses were evaluated. To measure comfort, the participants completed a questionnaire at the initial and final visit regarding the ease of use, comfort of insertion, and overall opinion of the catheters. A VAS was used to record responses.

They did not report the rate of UTIs among the patients in their study; instead, they reported the incidence of bacteriuria. They found that after each of the patients had used the catheters for 8 weeks, there was not a significant difference in the incidence of bacteriuria (18.8% versus 28.6% for patients using the hydrophilic catheters and standard catheters, respectively).

The questionnaire measured participants' satisfaction with the catheters using a 10-point VAS, where 0 indicated the most satisfaction, and 10 indicated the least satisfaction. The participants using hydrophilic catheters reported significantly higher rates of satisfaction regarding the convenience and insertion of the catheter compared with participants using standard catheters ($P < .05$). There were no significant differences, however, in terms of overall opinion of the catheter and the handling of the 2 catheters.

Across studies, there was a lot of variation in terms of the reason for catheterization, inclusion criteria, and type of catheter used. For example, the studies by Vapnek et al. and Pachler et al. used reusable catheters in the control arm, while the other 3 RCTs used single-use catheters in the control arm (Table 3). All 5 RCTs focused mainly on males requiring intermittent catheterization (Table 4). Three RCTs (23;26;27) included only males Age varied considerably. The study by Sutherland et al. included young males (mean age 12 years), while the study by Pachler et al. included older males (mean age 71 years).

Table 3: Study Design of Studies Comparing Hydrophilic to Standard Intermittent Catheters*

Study, Year	Reason for Catheterization	Inclusion Criteria	Exclusion Criteria	Type of Catheter	Reused or Single-Use Catheters
De Ridder et al., 2005 (23)	Spinal cord injury	- Males only - >16 years - Injured < 6 months - Neurogenic bladder emptying disorder - Require ≥ 3 catheterizations/ day	- Symptomatic UTI - Urethral stenosis or fibrosis - Mentally unstable patients - Patients in other clinical trials	Hydrophilic	Single-use
				Uncoated PVC (lubricated manually)	Single-use
Cindolo et al., 2004 (24)	Patients undergoing immuno- or chemotherapy for bladder cancer	- Primary bladder cancer	- Allergy to anesthetics - Inability to cooperate with evaluations - History of UTI or urinary stones - Previous transurethral catheterization - Brittle diabetes - Post-void residual volume > 50mL	Hydrophilic	Single-use
				Standard PVC, lubricated	Single-use
Vapnek et al., 2003 (25)	Neurogenic bladder	- Adept at CIC	- History of vesicoureteral reflux, unexplained hematuria, bladder calculi - Require prophylactic antibiotics	Hydrophilic-coated	Single-use
				Standard PVC (unclear if they were lubricated)	Reused
Pachler et al., 1999 (26)	Urinary retention due to prostatic enlargement	- Prostatic enlargement	NR	Prelubricated, hydrophilic, disposable PVC	Single-use
				Non-hydrophilic PVC	Reused (several times within 24 hrs)
Sutherland et al., 1996 (27)	Myelodysplasia spinal cord injury, Hinman syndrome	- Adept at CIC - Willing to have weekly urinanalysis - Boys only	- History of urethral pathology	Hydrophilic	Single use
				Standard	Reused

* CIC refers to clean intermittent catheterization; NR, not reported; PVC, polyvinyl chloride; UTI, urinary tract infection.

Table 4: Characteristics of Studies Comparing Hydrophilic to Standard Intermittent Catheters*

Study, Year	Type of Catheter	No. of Patients	Gender	Mean Age, Years (SD)	Duration of Catheter Use Before Study Entry	Duration of Study
De Ridder et al., 2005 (23)	Hydrophilic	61	100% male	37.5 (14.6)	NR (less than 6 months)	12 months
	Uncoated PVC	62		36.7 (14.6)		
Cindolo et al., 2004 (24)	Hydrophilic	50	78% male	67.4	NR	Mean 24 month follow-up
	Standard PVC, lubricated	50	82% male	62.3		
Vapnek et al., 2003 (25)	Hydrophilic	30	NR; equal balance in both groups	39.8 (12.9)	43.7 (1–161) months	12 months
	Standard plastic	31		39.6 (16.0)	56.0 (4–228) months	
Pachler et al., 1999 (26)	Prelubricated, hydrophilic, disposable PVC	32	100% male	71.3 (range 50–87)	Not reported	3 weeks with each catheter
	Non-hydrophilic PVC	32		71.3 (range 50–87)		
Sutherland et al., 1996 (27)	Hydrophilic	17	100% male	11.7 (3.8)	4.2 (SD 3.5) yrs	Boys evaluated weekly for 8 weeks
	Standard	16		12.1 (5.7)	4.4 (SD 3.7) yrs	

*NR refers to not reported; SD, standard deviation; UTI, urinary tract infection

In terms of outcomes, 3 of the RCTs reported the rate of UTIs, (23-25) while the other 2 reported the incidence of bacteria in the urine. (26;27) De Ridder et al. and Cindolo et al. reported a significant reduction in the rate of UTIs among patients using hydrophilic catheters; however, as mentioned previously in the descriptions of the studies, both of these trials had serious limitations. De Ridder et al. reported follow-up results for all patients, but more than one-half of the patients were lost to follow-up. The RCT by Cindolo et al. reported a significant difference in the rate of UTIs according to the number of catheterizations per group. However, when the Medical Advisory Secretariat calculated odds ratios for the number of patients in each group who suffered from 2 or more UTIs, there was no significant difference between the groups. None of the other studies detected a significant difference in UTIs or bacteriuria between patients using hydrophilic catheters and those using standard catheters.

Table 5: Outcomes for Infection and Bacteria Levels in Studies Comparing Hydrophilic Versus Standard Intermittent Catheters*

Study, Year	Type of Catheter	N	Rate of UTI	Incidence of Bacteriuria	Limitations
De Ridder et al., 2005 (23)	Hydrophilic	61	64%	NR	• More than one-half of the sample lost to follow-up (65/128) • Reported 12-month results for all patients despite high dropout rate; unclear how these results were collected for dropouts
	Uncoated PVC	62	82% *P* = .02		
Cindolo et al., 2004 (24)	Hydrophilic	50	Rate by no. of catheterizations 3.5%	NR	• Patients did not suffer from urinary retention; catheters used for treatment, not bladder drainage • Inconsistent results—significant for rate of UTI by number of catheterizations, not significant for the number of patients who suffered from 2 or more UTIs
	Standard PVC catheter	50	Rate by no. of catheterizations 7.4% *P* < .01		
Vapnek etal., 2003 (25)	Hydrophilic	30	Mean no. of UTIs per month 0.13 (SD 0.18)	"The number of patients with a positive culture did not change significantly during the study course"	• Groups not comparable at baseline; patients in hydrophilic group had higher mean number of UTIs per month at baseline • Inconsistent results—no significant difference in mean number of UTIs between groups; however, significant decrease in hydrophilic group between end of study and baseline, but not in standard catheter group
	Standard PVC	31	0.14 (SD 0.21) *P* > 0.3)		
Pachler et al., 1999 (26)	Prelubricated, hydrophilic, disposable PVC	32	NR	52%	• Likely a type II error due to the small sample size • Patients were only followed for 6 weeks
	Non-hydrophilic PVC	32		63% *P* = NS	
Sutherland et al., 1996 (27)	Hydrophilic	17	NR	18.8%	• Likely a type II error due to small sample size • Nongeneralizable population—boys only
	Standard	16		28.6 % *P* = NS	

*NR refers to not reported; NS, not significant; SD, standard deviation; UTI, urinary tract infection

In the RCT by De Ridder et al., (23) patients completed a questionnaire at 6 and 12 months subjectively assessing the experience of the introduction and withdrawal of the catheter, time spent catheterizing and the satisfaction with the catheter. Patients rated the components on a 4-point scale. They reported that the time spent catheterizing was similar in both groups. In terms of the introduction and withdrawal of the hydrophilic catheter, it was very easy or easy compared with the standard catheter group (no statistical calculations provided). Patients seemed more satisfied with the hydrophilic catheter (33% and 36% satisfied at 6 and 12 months, respectively) than the standard catheter (15% and 22% satisfied at 6 and 12 months, respectively); however, this difference was not significant.

In the study by Cindolo et al., (24) after each catheterization, patients were asked to rate their discomfort on a 5-point VAS, where 0 indicates no discomfort and 5 indicates unbearable discomfort. The mean VAS score for discomfort was significantly lower for patients using the hydrophilic catheters compared with those using the standard catheters (1.3 [SD, 0.1] vs. 2.1 [SD, 0.2]; $P < .001$). Cindolo et al. did not report any other measures of patient satisfaction or quality of life.

The study by Vapnek et al. (25) did not include any measures of patient satisfaction or quality of life.

The crossover study by Pachler et al. (26) asked patients 6 questions after the patients had used each

catheter for 3 weeks. Table 6 shows the questions and the responses. There were no significant differences between the 2 groups on any of the questions. There is a possibility of a type II error because of the small sample size.

Table 6: Patient Satisfaction Questions and Responses in Study by Pachler et al.*

Question	Response	Hydrophilic Catheter	Standard Catheter
Problems in introducing the catheter			
	None	31	30
	Some	1	2
	Many	0	0
Burning sensation when introducing the catheter			
	None	30	31
	Some	2	1
	Many	0	0
Pain when introducing the catheter			
	None	29	30
	Some	3	2
	Many	0	0
Burning sensation or pain after removal of the catheter			
	None	30	30
	Some	2	2
	Many	0	0
Handling of catheter before introduction			
	Easy	30	25
	Tolerable	1	6
	Troublesome	1	1
Handling of catheter after use			
	Easy	30	27
	Tolerable	2	3
	Troublesome	0	2

*Pachler et al. (26)

In the RCT by Sutherland et al., (27) patients and their guardians completed a satisfaction VAS questionnaire (0 most favourable; 10 least favourable) at baseline and then at the end of the study. Questions included convenience of performing clean intermittent catheterization, ease of handling of the catheter, comfort of insertion, and general overall opinion of the catheter used. Sutherland et al. reported a significant difference between the catheters in the convenience and comfort of insertion, both favouring hydrophilic catheters ($P < .05$). However, there was no significant difference between groups for ease of handling or the general overall opinion of the catheters.

In summary, the studies by De Ridder et al. (23) and Pachler et al. (26) did not find significant differences in patient satisfaction between the hydrophilic and standard catheter groups. Sutherland et al. (27) reported conflicting results; however, the overall opinion of the catheters was not significantly different between the treatment groups. Cindolo et al. (24) found that the hydrophilic catheters were significantly more comfortable than the standard catheters. Similar to the results for effectiveness, it is not possible to establish clearly that there is a significant difference in patient satisfaction between the patients using hydrophilic catheters and those using standard catheters.

Economic Analysis

Literature Review: Objectives and Methods

The Medical Advisory Secretariat did a literature review by searching the Cochrane Library, MEDLINE, and EMBASE. No economic analyses were identified that investigated the costs of hydrophilic intermittent catheters.

Ontario-Based Economic Analysis

Notes & Disclaimer

The Medical Advisory Secretariat uses a standardized costing methodology for all of its economic analyses of technologies. The main cost categories and the associated methodology from the province's perspective are as follows:

Hospital: Ontario Case Costing Initiative (OCCI) cost data is used for all program costs when there are 10 or more hospital separations, or one-third or more of hospital separations in the ministry's data warehouse are for the designated International Classification of Diseases-10 diagnosis codes and Canadian Classification of Health Interventions procedure codes. Where appropriate, costs are adjusted for hospital-specific or peer-specific effects. In cases where the technology under review falls outside the hospitals that report to the OCCI, PAC-10 weights converted into monetary units are used. Adjustments may need to be made to ensure the relevant case mix group is reflective of the diagnosis and procedures under consideration. Due to the difficulties of estimating indirect costs in hospitals associated with a particular diagnosis or procedure, the Medical Advisory Secretariat normally defaults to considering direct treatment costs only. Historical costs have been adjusted upward by 3% per annum, representing a 5% inflation rate assumption less a 2% implicit expectation of efficiency gains by hospitals.

Non-Hospital: These include physician services costs obtained from the Provider Services Branch of the Ontario Ministry of Health and Long-Term Care, device costs from the perspective of local health care institutions, and drug costs from the Ontario Drug Benefit formulary list price.

Discounting: For all cost-effective analyses, discount rates of 5% and 3% are used as per the Canadian Coordinating Office for Health Technology Assessment and the Washington Panel of Cost-Effectiveness, respectively.

Downstream cost savings: All cost avoidance and cost savings are based on assumptions of utilization, care patterns, funding, and other factors. These may or may not be realized by the system or individual institutions.

In cases where a deviation from this standard is used, an explanation has been given as to the reasons, the assumptions and the revised approach.

The economic analysis represents an estimate only, based on assumptions and costing methods that have been explicitly stated above. These estimates will change if different assumptions and costing methods are applied for the purpose of developing implementation plans for the technology.

Ontario Costs

Patients requiring intermittent catheterization use, on average, 4 to 5 intermittent catheters per day. Patients admitted to hospitals using intermittent catheters typically do not reuse catheters, owing to the potential increased risk of infection in hospital. Patients self-catheterizing at home are more likely to reuse catheters. Standard catheters cost about $1.00 to $1.50 each. Hydrophilic catheters cost between $2.00 and $5.00 each (figures from an Ontario-based medical supply distributor), depending on the type and whether they have been impregnated with antibiotics. All hydrophilic catheters are single-use.

Table 7 provides a breakdown of the costs of the catheters and the cost of using the catheters over the course of 1 year. It costs twice as much to use hydrophilic catheters. Over 1 year, this could cost as much as $4,500. Reusing standard catheters is the least expensive option; however, this option is not available to health care settings because of the increased risk of infection. One rehabilitation hospital that was contacted for this review estimated that 80% to 90% of its patients were being catheterized (either intermittent or indwelling) (Personal communication, March 2006).

Table 7: Cost of Intermittent Catheters: Per Patient

Type of Catheter	No. of Catheters Used Per Day	Cost Per Catheter ($Cdn)	Cost of Catheter Use Per Day ($Cdn)	Cost of Catheter Use Per Year ($Cdn)
Hydrophilic catheter	4–5	2.00–5.00	8.00–25.00	2,920–9,125
Single-use standard, manual lubricant, intermittent catheter	4–5	1.00–1.50	4.00–7.50	1,460–2,738
Reusable standard, manual lubricant, intermittent catheter*	1	1.00–1.50	1.00–1.50	365–548

*Reusable catheters are not recommended for in-hospital use. For the reusable catheters, it is assumed that a patient uses 1 catheter per day; however, it has been noted that patients may use 1 catheter for up to 1 week.

Existing Guidelines for Use of Technology

AETNA, (28) a private health insurance company in the United States, has published a Clinical Policy Bulletin on the use of urological supplies. The report indicates that AETNA will cover the cost of one replacement clean, intermittent catheter per week, unless more frequent replacement is medically necessary. They will also cover the cost of 8 ounces of catheter lubricant per month. In some specific instances they will cover the cost of sterile, single-use catheters, such as for patients residing in long-term care nursing facilities or patients who are immunosuppressed (e.g., patients who are HIV positive). The report does not indicate that it will or will not cover the cost of hydrophilic catheters.

Policy Development

Implications

It is difficult to estimate the number of people in Ontario who use intermittent catheterization. It is also challenging to ascertain how many patients suffer from UTIs due to intermittent catheter usage in Ontario.

Different health care sectors were contacted to attempt to learn more about intermittent catheter usage in Ontario and the rate of UTIs associated with catheter use.

In the Community

The Community Care Access Centres (CCAC) do not keep provincial records of the rate of UTIs or the number of patients requiring intermittent catheterization. Based on information regarding the purchasing of medical supplies by the CCACs, the Medical Advisory Secretariat estimated that the CCACs in Ontario purchased 46,000 intermittent catheters in 2004/2005. These catheters were likely reusable catheters used for periods up to 1 week or more; thus, it is difficult to determine the number of patients using intermittent catheters in the community based on these figures.

The Victoria Order of Nurses is a frequently contracted resource used by the CCACs to make home visits. However, they do not track the rate of UTIs for catheterized patients. Moreover, if a patient has a UTI, it is difficult to know if he or she developed the infection while in hospital or while being treated through the CCACs.

For Complex Continuing Care

One complex continuing care facility estimated that 80% to 90% of its residents use some form of catheterization (Personal communication, March 2006). In 2004, the Canadian Institute for Health Information (29) reported that 19% of the residents in complex continuing care facilities use indwelling catheters, but they did not state how many use intermittent catheters. This report indicated that in 2004, 37% of the residents were using a "toileting plan," which may or may not have involved intermittent catheterization. Rates of UTIs in complex continuing care facilities are not routinely tracked. These facilities generally use standard, single-use catheters while patients are in hospital; however, they teach patients how to reuse catheters if they are discharged to home. One complex continuing care facility in the province indicated that they were starting a trial on the use of hydrophilic catheters in the spring of 2006.

For Long-Term Care Homes

Based on data from the Ministry of Health and Long-Term Care, 2.53% of residents in long-term care homes required catheters in 2004. (Personal communication, Ministry of Health and Long-Term Care 2005) This figure includes residents using any type of urinary catheter (indwelling, suprapubic, intermittent, and external condom drainage), not just intermittent catheterization. Many long-term care homes in the province will not accept residents if they are using catheters (Personal communication, September 2005). In 2004, 2.59% of residents suffered from UTIs. It is not possible to know whether those using catheters suffered from the UTIs reported at the long term care homes.

Patient Outcomes – Medical, Clinical

It is unclear if hydrophilic catheters reduce the risk of UTIs or improve the quality of life of patients requiring intermittent catheterization.

Demographics

People of any age can require catheterization. Intermittent catheterization is used in patients with urinary retention for various reasons, including in patients postsurgically, in patients with spinal cord injuries or other physical difficulties, or in men with benign prostate enlargement.

Diffusion

There is no review of the evidence available at this time to indicate that hydrophilic catheters are better than standard catheters at reducing the risk of infection and improving patient comfort.

Catheters are used in acute care, long-term care, complex continuing care, and community care settings. The cost of hydrophilic catheters is covered by some private health insurance providers in Ontario.

Less than 3% of patients are using catheters in long-term care homes. (Personal communication, Ministry of Health and Long-Term Care 2005) This is most likely because many long-term care homes will not accept patients who are being catheterized. About 90% of residents in long-term care homes in Ontario require continence care.

Cost

Hydrophilic catheters cost about twice as much as standard catheters.

Conclusions

At this time there is insufficient evidence to indicate that hydrophilic catheters are associated with a lower rate of UTIs and improved patient satisfaction among people requiring intermittent catheterization.

Appendices

Appendix 1: Literature Search Strategy

Database: Ovid MEDLINE(R) <1966 to November Week 3 2005>
Search Strategy:
---
1 exp Urinary Catheterization/ (9925)
2 ((intermittent or temporary or hydrophilic or coated or impregnated or silver or silicon$ or antibiotic or antiseptic or minocycline or rifampin or introducer-tip) adj3 catheter$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (3729)
3 1 and 2 (1102)
4 (catheter$ and (flocath or lofric or easicath or easycath or aquacath or urocath-gel or silky)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (18)
5 3 or 4 (1105)
6 limit 5 to (humans and english language and yr="2000 - 2006") (224)
7 limit 6 to (meta analysis or review, academic or review, tutorial) (31)
8 (systematic review$ or metaanalysis or meta-analysis).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (21596)
9 6 and (7 or 8) (32)
10 6 (224)
11 limit 10 to (case reports or comment or editorial or letter or "review" or "review literature" or review, multicase or "review of reported cases") (64)
12 10 not 11 (160)
13 9 or 12 (191)
14 from 13 keep 1-191 (191)

Database: EMBASE <1996 to 2005 Week 49>
Search Strategy:
---
1 exp urine catheter/ (960)
2 exp bladder catheterization/ or exp intermittent catheterization/ (1544)
3 ((intermittent or temporary or hydrophilic or coated or impregnated or silver or silicon$ or antibiotic or antiseptic or minocycline or rifampin or introducer-tip) adj3 catheter$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (2074)
4 3 and (1 or 2) (772)
5 (catheter$ and (flocath or lofric or easicath or easycath or aquacath or urocath-gel or silky)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (12)
6 4 or 5 (776)
7 limit 6 to (human and english language and yr="2000 - 2006") (418)
8 exp "Systematic Review"/ (7110)
9 Meta Analysis/ (20481)
10 (systematic review$ or metaanalysis or meta-analysis).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (30576)
11 7 and (8 or 9 or 10) (3)
12 7 (418)
13 limit 12 to (editorial or letter or note or "review") (103)

14 Case Report/ (378578)
15 12 not (13 or 14) (263)
16 11 or 15 (266)

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