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What is This?
Urinary tract infection following flexible cystoscopy: a comparison between sterilised cystoscopes and disposable sterile sheaths

Steve P McCombie, Jack P Carmichael, Srijit Banerjee and Sarah J Wood

Abstract

Objective: The objective of this article is to compare the incidence of post-cystoscopy urinary tract infections (UTIs) between cystoscopes sterilised between patients and cystoscopes that use removable sterile sheath technology.

Patients and methods: A total of 200 patients undergoing flexible cystoscopy at the Norfolk and Norwich Hospital (Norwich, UK) between November 2011 and March 2012 were identified prospectively as part of an ongoing audit of the department’s services. One hundred patients were recruited from day procedure lists, using KeyMed® cystoscopes sterilised between patients (sterilised scope, SS); 100 patients were recruited from a ‘one-stop’ urology clinic, using a Vision Sciences® CST-5000 cystoscope with disposable sterile Endosheath® technology (removable sheath, RS). Mid-stream urine (MSUs) samples and patient symptoms were recorded prior to the cystoscopy and at least three days following the cystoscopy.

Results: No significant difference was found in the incidence of new MSU-confirmed UTI (2.7% (SS) vs. 2.0% (RS)). In those undergoing their first cystoscopy, no significant differences were found in either new symptoms (34.1% (SS) vs. 36.7% (RS)) or requirement for antibiotics (13.6% (SS) vs. 13.0% (RS)).

Conclusion: Flexible cystoscopy using removable sterile sheath technology does not have a higher incidence of UTI compared to a cystoscope sterilised between patients. The introduction of cystoscopes using this technology can therefore safely transform flexible cystoscopy into an outpatient clinic procedure.

Keywords
cystoscopes, cystoscopy, urinary tract infections, signs and symptoms

Introduction

Flexible cystoscopy has traditionally been performed with a sterilised cystoscope in a designated theatre or endoscopy suite setting; however, there are many disadvantages with this. Multiple cystoscopes are needed for one list, and the sterilisation of cystoscopes is time consuming, expensive, exposes staff to harmful chemicals and can damage the cystoscopes. The reported incidence of urinary tract infection (UTI) following flexible cystoscopy with a sterilised cystoscope varies greatly between studies, with incidences of between 21% and 0.85% being recorded.

In recent years an alternative to this has emerged with the introduction of cystoscopes with removable sterile sheaths. Cystoscopes using this technology are often decontaminated between lists, but only wiped clean between patients; a new removable sheath is then used for each patient and then disposed of. This process avoids many of the problems associated with traditional sterilisation and lends itself to use in the outpatient clinic or community
environments. The sheaths’ integrity is reliably resistant to high-pressure leak testing and proven to effectively barrier against micro-organisms as small as 27 nanometres. Whilst no directly comparative data is available, similar patient-ready scope contamination rates have been found in scopes using removable sheath technology (22%) and those that have been traditionally sterilised (14–18%). Cystoscopes using sterile sheaths have been reported to be straightforward to use and comparable to traditional cystoscopes in terms of patient comfort, flexibility, visual quality and costs. There has been relatively little work on the incidence of UTI following cystoscopy with a cystoscope utilising removable sterile sheath technology.

Methods

Patients undergoing flexible cystoscopy at the Norfolk and Norwich Hospital (Norwich, UK) between November 2011 and March 2012 were identified prospectively and invited to take part in this audit. One hundred patients were recruited from a well-established day procedure unit flexible cystoscopy service that used KeyMed® cystoscopes undergoing traditional sterilisation procedures in between patients (sterilised scope, SS). One hundred patients were also recruited from a newly developed ‘one-stop’ urology clinic, wherein patients requiring cystoscopy are offered it in the same clinic appointment as their consultation. This clinic occurred in an outpatient department, and cystoscopy was performed with a Vision Sciences® CST-5000 flexible cystoscope using disposable sterile Endosheath® technology (removable sheath, RS). This cystoscope was decontaminated using the Tristel® Wipes System before the beginning of a clinic, but only wiped clean with a Sani-Cloth® 70% alcohol wipe before replacement of a new sterile sheath between patients. There was no randomisation and patients simply had the procedure they would have had even if the audit had not been ongoing. Antibiotic prophylaxis for the procedure was at the discretion of the urologist performing the cystoscopy.

Patients provided a mid-stream urine (MSU) sample prior to their cystoscopy, and a urine dipstick and microscopy, culture and sensitivity analysis was performed on this sample. Details of the procedure, indication and symptoms prior to the procedure were recorded from discussion with the patient and review of their clinical records. Patients were instructed to submit a second MSU sample for laboratory analysis following the procedure and post-procedure MSU samples for laboratory analysis are not part of the normal practice. These additional processes were approved by the audit department and microbiology department for the purposes of this audit.

Exclusion criteria included patients who were catheterised, performed intermittent self-catheterisation or who were both unable to be contacted following the cystoscopy and failed to submit a post-cystoscopy urine sample. High-risk patients (e.g. human immunodeficiency virus (HIV) or hepatitis) were not excluded from the study, although there were none in either group. The hospital infection control team have written guidance on how such cases would be managed. This would be the same in each group with patients going last on the list, appropriate disposal of all consumables and sterilisation of the scopes after use with either traditional sterilisation procedures or the Tristel® Wipes System.

For the purposes of this audit UTI was defined as a pure growth of $\geq 10^5$ colony-forming units/ml with a pyuria of $\geq 10$ white cells per high-power microscopy field. Fisher’s exact test and the unpaired $t$ test were used to statistically analyse the results of the study.

Results

Demographics

One hundred patients were recruited for both the sterilised scope (SS) arm and removable sheath (RS) arm of the audit. Sixty-nine per cent of the SS arm patients were male, compared to 56% in the RS arm ($p = 0.08$). The mean age of patients in the SS arm was 70.2 years (range 23–93), as compared with 59.2 years (range 22–88) in the RS arm ($p < 0.0001$).

Indication

The differences in indications for cystoscopy between the two sides of the audit can be seen in Figure 1. Check cystoscopies were performed only in the SS arm of the audit because those in the RS arm were all new referrals. Consequently, there were significantly more cystoscopies being performed in the RS arm of the audit for haematuria ($p = 0.0003$) and recurrent UTIs ($p = 0.0005$).

Urine dipstick

Ninety-seven per cent of those in the SS group and 83% of those in the RS group had a urine dipstick result recorded prior to their cystoscopy. The remaining patients usually had a urine dipstick test performed; however, often the urine was discarded without documentation of the result. There was no significant difference between the two groups in either the number of patients testing positive for nitrates and costs.
Pre-procedure Table.

(2.1% (SS) vs. 3.6% (RS)) or blood (50.5% (SS) vs. 53.0% (RS)). Thirty-four per cent of those in the SS group and 14.5% of patients in the RS group tested positive for leukocytes \((p = 0.0006)\).

Of the five patients testing positive to nitrites in both arms combined, only one patient had a pure-growth with significant pyuria on their pre-procedure MSU and they were completely asymptomatic following cystoscopy.

Procedure

Antibiotic prophylaxis for the procedure was considered to include oral antibiotics, long-term low-dose prophylaxis or gentamycin injection. In the SS arm 19% of patients received antibiotic prophylaxis, as compared with 21% in the RS arm \((p = \text{not significant (ns)})\). Twelve patients in the SS group had a procedure (seven biopsies, five stent removals) at the time of their cystoscopy as compared with one patient (urethral dilatation) in the RS group \((p = 0.003)\). Of the 200 cystoscopies performed in total, eight bladder tumours were identified, four from each arm of the audit.

MSU results

A positive MSU was defined as a pure growth of \(\geq 10^5\) colony-forming units/ml with \(< 10\) white cells per high-power microscopy field. Colonised urine was defined as a pure growth of \(\geq 10^5\) colony-forming units/ml with \(< 10\) white cells per high-power microscopy field. Contaminated urine was always suggested on the MSU report based on a heavy mixed growth (12), growth of co-agulase-negative staphylococcus (one) or lots of epithelial cells in the sample suggesting poorly voided urine (two).

The number and results of patients having pre-procedure and post-procedure MSUs sent for microscopy, culture and sensitivity can be seen in the Table. There was no significant difference in the number of positive, colonised or contaminated MSUs between the two groups, either before or after the procedure. The mean length of time between cystoscopy and returning a post-procedure MSU was 6.5 days (range one to 23) in the SS arm and 7.4 days (range two to 22) in the RS arm \((p = \text{ns})\). Of seven positive pre-procedure and eight positive post-procedure MSUs in both groups combined, 87% (13/15) grew Coliforms and 13% (2/15) grew Enterococci.

Analysis was conducted of only those patients who had both a negative pre-procedure mid-stream urine sample (MSU) and a submitted post-procedure MSU \((n = 123; 73\) (sterilised scope (SS)) + 50 (removable sheath (RS))). This showed an incidence of de novo urinary tract infection (UTI) of 2.7% (two of 73) for the SS group and 2.0% (one of 50) for the RS group \((p = \text{ns})\).

Symptoms

Ninety-eight patients in each arm of the audit were contacted following their cystoscopy. The mean length of time between the cystoscopy and being contacted was 7.0 days (range four to 18) in the SS arm and 8.0 days in the RS arm (range four to 29) \((p = 0.03)\). Sub-analysis was also carried out on patients in the SS group who were not having check cystoscopies and for whom adequate data were available (SS(sub), \(n = 44\)).

In the SS group 25.5% of patients developed at least one new symptom following the cystoscopy, compared with 34.1% in the SS(sub) group and 36.7% in the RS group \((p = \text{ns})\). The mean number of new symptoms per patient was 0.41 in the SS group, 0.59 in the SS(sub) group and 0.68 in the RS group \((p = \text{ns})\). The incidence of individual symptoms following cystoscopy for all groups can be seen in Figure 2; no significant differences were found between the groups for any individual symptom.

Table. Pre-procedure and post-procedure MSU results.

<table>
<thead>
<tr>
<th>Pre-procedure</th>
<th>Number</th>
<th>Negative</th>
<th>Positive</th>
<th>Colonised*</th>
<th>Contaminated**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilised scope</td>
<td>98</td>
<td>90 (91.8%)</td>
<td>4 (4.1%)</td>
<td>2 (2.0%)</td>
<td>2 (2.0%)</td>
</tr>
<tr>
<td>Removable sheath</td>
<td>78</td>
<td>68 (87.2%)</td>
<td>3 (3.8%)</td>
<td>4 (5.1%)</td>
<td>3 (3.8%)</td>
</tr>
<tr>
<td>Sterilised scope</td>
<td>89</td>
<td>75 (84.3%)</td>
<td>5 (5.6%)</td>
<td>3 (3.4%)</td>
<td>6 (6.7%)</td>
</tr>
<tr>
<td>Removable sheath</td>
<td>84</td>
<td>75 (89.3%)</td>
<td>3 (3.6%)</td>
<td>2 (2.4%)</td>
<td>4 (4.8%)</td>
</tr>
</tbody>
</table>

MSU: mid-stream urine samples; * Pure growth of \(\geq 10^5\) colony forming units/ml with \(< 10\) white cells per high-power microscopy field; ** Suggested on the MSU report based on a heavy mixed growth, growth of co-agulase negative staphylococcus or lots of epithelial cells in the sample suggesting poorly voided urine.
Antibiotic usage and complications

In the SS group 7.1% of patients were given antibiotics for a suspected new UTI following their cystoscopy, compared with 13.6% in the SS(sub) group and 13.3% in the RS group ($p = \text{ns}$). In the SS group this treatment was initiated by the authors (four), a general practitioner (two) or a hospital doctor (one, treated for prostatitis). In the RS group treatment was initiated by a general practitioner (seven), the authors (three), the patient (two) or a hospital doctor (one, pyelonephritis). Duration of the course of antibiotics prescribed was not assessed.

Of the 20 patients thought to have a new UTI in both groups combined, 14 of them returned post-procedure MSUs, and 57% (eight of 14) of these were positive; most patients were treated purely on the basis of their symptoms. Two patients in the SS group presented to hospital in the immediate period following their cystoscopy. One patient presented with urinary retention and stayed in hospital one night. The other patient was a man with a previous history of prostatitis who presented 23 days following the procedure with symptoms of prostatitis, and was discharged the same day with oral antibiotics. One patient in the RS group presented to hospital following cystoscopy; they were discharged the same day with oral antibiotics for suspected pyelonephritis.

Cost comparison

The focus of this paper was not to compare costs between these two methods of cystoscopy. However, as this is of relevance to any unit considering commencing or changing a cystoscopy service, the costings to our department have been considered here.

The KeyMed® cystoscopes used in the SS group cost our department approximately £18,000 each, plus the cost of a light source. The Vision Sciences® CST-5000 cystoscope used in the RS group cost our department approximately £8000 each, plus £10,000 for a video stack. Traditional sterilisation of scopes as performed in the SS group costs our department £20 per patient, whereas each removable sheath used for the RS group costs £25.

These costs are comparable but several other factors also need to be considered when assessing costs. Firstly, the lists studied in the SS arm required at least four scopes to run smoothly; however, those in the RS arm ran smoothly on one scope (with a second scope available in case of breakages). Secondly, the lists studied in the SS arm required three personnel in addition to the urologist, as compared with two additional personnel for the lists in the RS arm. The additional person was required for the lists in the SS arm to carry out the sterilisation of scopes. Finally, the cost saving associated with patients not needing to return to hospital another day for their cystoscopy must be considered. Considering these additional factors, the authors feel that cystoscopy with RS technology is at least equal in cost efficiency, if not more cost efficient, than cystoscopy with scopes undergoing traditional sterilisation procedures between patients.

Discussion

The main finding of this audit was that cystoscopy with a removable sterile sheath has an equivalent rate of post-procedure UTI to cystoscopy with a sterilised cystoscope. This was regardless of whether a diagnosis of UTI was based on MSU or symptoms.

The MSU data showed low rates of de novo UTI for both groups (2.7% (SS) vs. 2.0% (RS)), and the difference between the groups was not statistically significant. These incidences of new UTI are comparable to those found by Burke (2.7%), but much lower than those found by Almallah (4.5%), Clark (7.5%) and Rané (5% with gentamycin, 21% without gentamycin).4–8

Although patients in the SS group seemed to develop fewer symptoms than those in the RS group, these differences...
were not statistically significant and were very much reduced by removing patients who underwent check cystoscopy from the analysis. This was performed to provide a fairer comparison between the groups, as it meant only patients experiencing cystoscopy for the first time were included. It seems intuitive that these patients are more likely to report symptoms of UTI following cystoscopy than those who have had cystoscopies before, as they are less accustomed to normal post-cystoscopy symptoms. This is supported by the fact that when this sub-analysis was performed, the difference in antibiotic usage between the groups (7.1% (SS) vs. 13.3% (RS)) was completely removed (13.6% (SS(sub)) vs. 13.3% (RS)).

As a consequence of the design of the audit, and the fact that this was not a randomised controlled trial, there were significant differences between the two groups being compared. The patients in the RS group were younger and had a higher percentage of female patients; in addition they were more likely to be being investigated for recurrent UTIs or haematuria, and less likely to undergo a procedure. Most of these differences are probably a consequence of the fact that 55% of the patients in the SS arm were follow-up patients attending for a check cystoscopy, whereas those in the RS arm were all new referrals. In order to remove bias this difference created in symptom reporting, sub-analysis was carried out after removing patients attending for check cystoscopy from the analysis. The difference in length of time between cystoscopy and telephone follow-up between the two groups was probably a consequence of there being a higher proportion of younger patients in the RS arm, whom the authors found it more difficult to contact.

The finding of comparable rates of post-procedure UTI in this audit is in keeping with the findings of Arumuham et al. in 2010. Further work was needed on the subject though as this study did not include pre-procedure MSU analysis, meaning they could not be certain that all of their positive post-procedure MSUs were as a direct result of the cystoscopy. Additionally, they did not control for antibiotic usage, and used an interstitial cystitis symptom questionnaire to assess for symptoms of UTI that fails to assess for several important symptoms.

The findings of this audit are important as there is a growing movement towards RS technology internationally, largely because it allows flexible cystoscopy to be transformed into an outpatient or community-based procedure. At the Norfolk and Norwich Hospital (Norwich, UK) the introduction of a flexible cystoscope that uses removable sterile sheath technology has allowed us to introduce a ‘one-stop’ urology outpatient clinic, wherein patients receive a clinical consult as well as necessary investigations such as flexible cystoscopy in the same clinic appointment. This allows them to be reassured and discharged or booked for necessary treatment without the need to re-attend hospital for further investigation, thus avoiding unnecessary delays, reducing costs and improving patient satisfaction.

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Conflict of interest
The authors declare that there are no conflicts of interest.

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