

A PROSPECTIVE AUDIT OF URINARY TRACT INFECTION INCIDENCE FOLLOWING THE USE OF ENDOSHEATH® FOR FLEXIBLE CYSTOSCOPY

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ABSTRACT

Objectives

To assess the incidence of bacteriuria and urinary tract infection following use of Endosheath®, and to assess patient comfort and satisfaction post-procedure.

Patients and Methods

One hundred thirty-five patients undergoing Endosheath® flexible cystoscopy (FC) were prospectively identified. Patients were excluded if pre-procedure urinalysis or symptoms suggested infection. Those who underwent FC were asked to provide a urine sample 72 hours post-procedure, assessing for bacterial culture and sensitivity. Patients completed a questionnaire assessing comfort, pain and whether they would recommend the procedure to others if required.

Results

Of the 135 patients, 117 patients returned their post-procedure samples for processing. Thirteen (11.1%) of the urine cultures samples were positive. Four (3.4%) of 13 patients had symptoms of urinary tract infection (UTI) and were treated with antibiotics. One hundred and seven (79%) patients found the procedure comfortable and 104 (77%) patients would recommend the procedure to others.

Conclusions

Flexible Cystoscopy utilizing Endosheath® appears to have comparable incidence of bacteriuria and UTI post procedure compared with standard FC, and is well tolerated by most patients.

Flexible cystoscopy (FC) is a commonly performed procedure in Urological practice for diagnosis, follow up and for double J stent removal.^{1,2} It is not without risk, as urinary tract instrumentation is associated with an incidence of approximately 2.8 to 21% for bacteriuria and 3.5 to 5.5% for urinary tract infection (UTI).^{3,4} While cystoscopes have been traditionally processed and disinfected in between cases to prevent infection, few Urology departments have employed disposable sheath technology (Endosheath®) which can be applied to the same fiberoptic cystoscope in between cases. This technique became more popular over the last decade and has been widely observed in different regions. Individually sterilising FC is a laboursome and time consuming process requiring multiple scopes, large capital investment, specialised sterilization equipment, facilities and staff. While this technology was introduced in our department in 2014,

few publications have demonstrated the possible benefit of disposable sheath in FC.^{5–10} But not much literature evidence on the post procedure infection rates available for this novel technology. The objectives of this audit were to assess the incidence of bacteriuria and UTI following the use of Endosheath®, and to assess patient comfort and satisfaction post-procedure.

PATIENTS AND METHODS

Ethical approval for the study was obtained from the East Lancashire Clinical Audit & Effectiveness Department. Between June and August 2015, patients in the Urology Investigation Unit at Burnley General Hospital, UK, undergoing Endosheath® FC were prospectively enrolled for the study. In this unit only Endosheath® FC is utilized from 2014. Hence, all patients may have had the same procedure even if this study was not done. The Endosheath® FC was done for various diagnostic indications during this period. As per the trust policy, it was ensured that none of the patients posed any risk of Creutzfeldt-Jakob Disease (CJD) or variant CJD to the best of their knowledge.

Endosheath® Flexible Cystoscopy was undertaken with the Vision Sciences Fiber Cystoscope Model CST-4000 (Figure 1 and 2) from Genesis Medical Limited. It's unique D shaped structure compliments well with the disposable working channel in the Endosheath® creating a smooth circular cross section (Figure 3). Prior to undertaking FC, the scope is wiped with enzymatic sponges and then dried with gauze. It is then wiped with Sanicloth 70% wipes and allowed to dry as recommended by the National Institute for Health and Care Excellence (NICE) guidelines. The FC will then slide and be placed inside a new Endosheath® (Figure 4) from Cogentix Medical built specifically for the CST-4000 cystoscope following the standard protocol. The Endosheath® will cover the cystoscope completely and will isolate it from patient contact. The disposable Endosheath® is for single-use only.

All patients had a pre-procedure urinalysis, and those with a positive finding and/or patients with symptoms suggestive of cystitis were excluded. Those with a Foley catheter or doing intermittent self catheterization were also excluded due to possible bacterial colonization.

After Endosheath® FC was undertaken, patients were asked to complete a questionnaire assessing patient comfort, pain (on a visual analog linear scale of 0–10), and whether they would recommend the procedure to others if required (Yes, may be or No). Also, all patients were asked to provide a mid-stream urine sample 72 hours post-procedure, to be analyzed later for microscopy, culture and sensitivity. If positive for growth, the organism identified on urine culture was documented as well as the corresponding indication for FC then each individual patient was contacted to assess for symptoms of UTI and treated if necessary.

RESULTS

A total of 135 patients were included in the study, comprising of 86 men (64%) and 49 women (36%). None of them had features of cystitis and everyone had normal pre-procedure urine dipstick. None of the patients received oral or intravenous pre-procedural antibiotic prophylaxis, but 7 (5%) patients were already on a low dose prophylaxis regimen for recurrent UTI.

The Endosheath® FCs were undertaken on 12 individual lists using 3 different scopes. Of the 135 patients identified and included in our audit, 120 (88.8%) of them returned a mid-stream urine for microscopy, culture and sensitivity. Three samples were rejected by the lab due to inadequate volume, leaving 117 samples (86.6%) which were processed. Thirteen (11.1%) of the cultures were positive, with 5 samples showing growth of *E. coli* and 4 samples showing mixed growth. On 4 of the 12 lists, there were at least 2 instances of infection. None of which grew the same organism, showing absence of cross infection.

Despite the negative urinalysis, three of the patients with *E. coli* had a documented similar infection within the last three months and were on nitrofurantoin prophylaxis as per sensitivity for recurrent infections prior to Endosheath® FC and one patient had mixed growth pre and post procedure. Of those investigated for recurrent infections, 57% patients did have positive cultures after the procedure.

Only 4 of the 13 patients contacted for positive growth were symptomatic for UTI and were treated with antibiotics as per sensitivity results (two *E. coli*, a

FIGS. 1 and 2 Images showing the Vision Science CST-4000 Flexible Cystoscopy and The Endosheath® before application.



coliform, and a *Pseudomonas* infection). The remaining eight patients were considered as having asymptomatic bacteriuria or contamination. None of the 13 patients required hospitalisation after the procedure. The indications for cystoscopy with the corresponding bacterial growth are presented in Table 1.

On the other hand, we had 132 (98%) questionnaires completed and returned, 104 (79%) of the patients found the procedure comfortable, 102 (77%) opted to recommend the procedure to others, and 95% of patients ($N=125$) would have the procedure repeated again if required. The mean and median pain scores were 2.55 and 2 respectively, with 29 (22%) patients scoring zero for pain. The pain score results are presented in Figure 5.

DISCUSSION

As technology has evolved, many specialties have developed their endoscopic instruments (e.g., nasendoscopy, gastroscopy, sigmoidoscopy, and bronchoscopy) for diagnostic and therapeutic purposes. In an attempt to limit the burden of sterilization processes and improve the efficiency of turn over between cases, these specialties have employed the use of Endosheath® technology similar to the one used for our flexible cystoscopes.^{11–14} The integrity of these endosheaths seems to be reliable and resistant to high pressure leak tests.¹⁵ One particular concern with Endosheath® technology is that the cystoscopes are not disinfected to the standard as traditional techniques, and patients may be at higher risk of developing urinary tract infections. This study aimed to assess the rates of bacteriuria and urinary tract infection, in patients undergoing Endosheath® cystoscopy. If similar to rates of bacteriuria and UTI in patients undergoing traditional cystoscopy, then Endosheath® cystoscopy may prove to be a more cost effective and efficient alternative at no increased adverse risk.

To evaluate the rates of bacteriuria and UTI, a cohort of 135 patients undergoing Endosheath® cystoscopy provided 120 follow up urine samples which were analysed post procedure. Three specimens were excluded from analysis due to inadequate sample. The main results were that 13 out of 117 (11.1%) showed evidence of bacteriuria. Of those with positive cultures, only 4 (3.4%) patients were treated for a post procedure UTI. In the remaining cohort, 4 (3.4%) patients had asymptomatic bacteriuria with no subsequent treatment needed and 5 (4.3%) were considered as contamination. This finding is in keeping with literature rate of UTI (3.7%) and bacteriuria (2.8–21%) post non-sheathed

FIG. 3A Tip of Endosheath® before application showing the working channel.

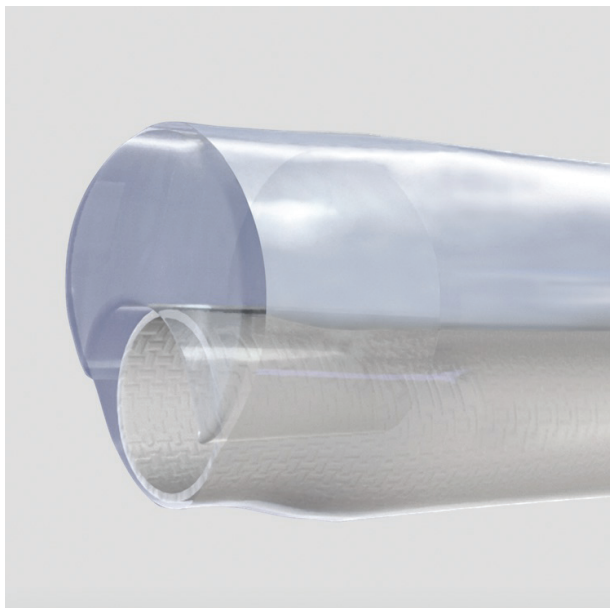


FIG. 3B Advancing the Vision Science CST-4000 Scope tip into the Endosheath®.

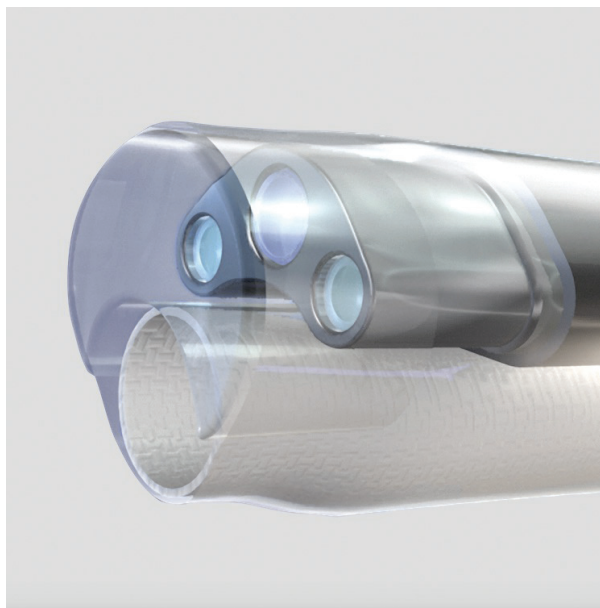


FIG. 3C The Endosheath® and Vision Science CST-4000 Scope fully engaged in correct position.

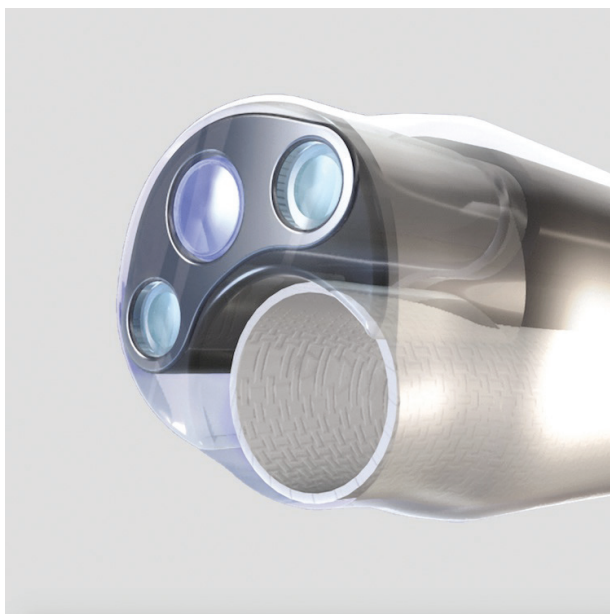


FIG. 4 The slide in application technique.



FIG. 5 Pain scores on a scale of 0-10 for patients undergoing FC with Endosheath®.

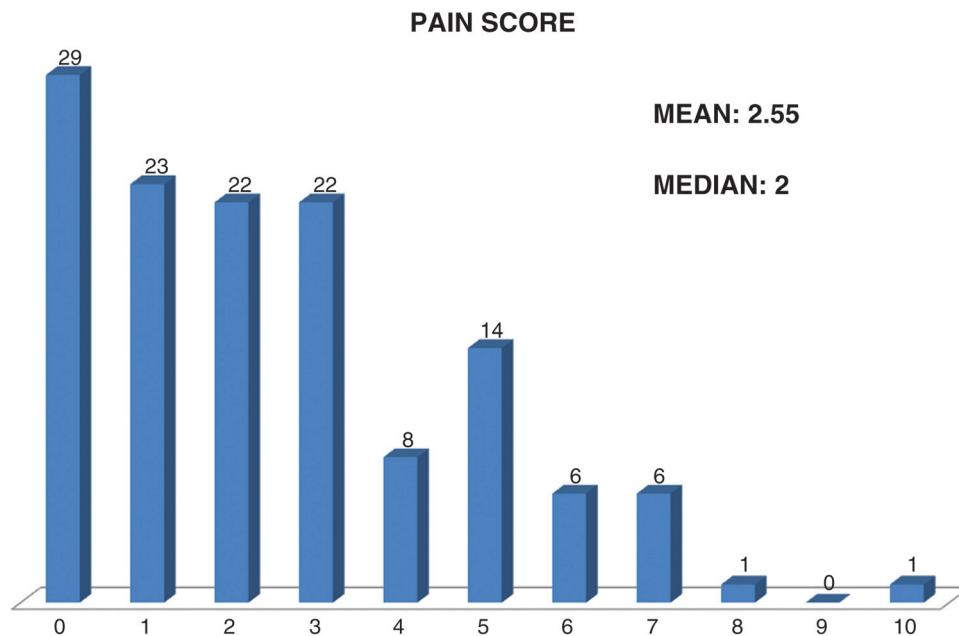


TABLE 1 Indications for FC and corresponding bacterial growth.

Indications for Cystoscopy	No. of Patients	Mid-Stream Urine Culture and Sensitivity (No. of Patients)
Check flexible cystoscopy	5	<i>E.coli</i> (1) Pseudomonas (1) Mixed growth (2) Coagulase negative staph (1)
Recurrent urinary tract infections	4	<i>E.coli</i> (3) Mixed growth (1)
Lower urinary tract symptoms	2	<i>E coli</i> (1) Beta haemolytic strep (1)
Haematuria	2	Coliform (1) Mixed growth (1)

cystoscopy and with rates of UTI (2.0%) post resheathable cystoscopy.^{4,6} Another non-randomized study was conducted by McCombie SP et al⁶ examined the rates of UTI and bacteriuria after resheathable cystoscopy in 200 patients in 2012. They found no significant difference between the incidence of UTI with traditional sterilization (2.7%) or resheathable cystoscopy (2.0%).

Approximately 20% of their patients received pre-procedural antibiotic prophylaxis while none of our patients had an pre-procedural antibiotic prophylaxis given but we had similar results. The similarity in rates of UTI post resheathable and traditional cystoscopy demonstrate that Endosheath® cystoscopy provides a safe alternative to traditional sterilization processes.

Another aspect that our study looked at was the comfort during the procedure. One randomized control trial evaluating the efficiency of both forms of cystoscopy found that, despite Endosheath® cystoscopy being more time-efficient, it was more difficult in inserting and handling the FC when using the Endosheath®. Most users commented that the deflection of the scope was slightly stiffer compared to the standard non-sheathed scope and this may contribute to discomfort during the procedure.⁵ Therefore patients were asked to complete a self-reported questionnaire post procedure, one element of which was reporting periprocedural pain on a linear visual analog scale of 0 to 10. In our study, the median pain score was 2 and mean pain score was 2.55. Our pain scores appear to be similar to the mean pain score for traditional cystoscopy of 2.48 reported by others.¹⁶ While this study did not evaluate ease of insertion or instrument handling, the comparable rates of pain during cystoscopy indicate that, Endosheath® cystoscopy provides a comfortable alternative.

The Vision Sciences Fiber Cystoscope CST-4000 from Genesis Medical Limited is priced around £8,250 and each sheath cost £30. Only one scope is needed with usually another scope kept in the department as a standby in case of a break, breach of integrity or any adverse event. Fewer number of scopes are needed in total compared to the traditional non-sheathed flexible cystoscopes which rotates at least four to six scopes each list with the need to process them quickly to accommodate the 10-15 patients on each list. The handling will include transfer, washing and disinfection. In general, Endosheath® will favour a lower capital expenditure. It has a less labour-intensive process with less handling and eventually less need for repairs.¹⁷

There are some limitations to this study. The level of clinical experience and clinical role of individual cystoscope operators was not documented, and thus clinical and technical experience could not be evaluated as a variable in the analysis. Furthermore, our study examined only a single cohort of patients, and future work should focus on developing a multi-centre randomised control trial evaluating the rates of UTI, bacteriuria and pain in patients undergoing Endosheath® cystoscopy in comparison with patients undergoing traditionally non-sheathed cystoscopy. Finally, we did not look into the financial cost of using

the Endosheath® but we managed, in average, to accommodate an extra two patients on each list, given the time saved from the need to transfer, process and sterilise non-sheathed flexible cystoscope.

CONCLUSIONS

Endosheath® cystoscopy is a safe alternative to traditionally non-sheathed cystoscopy, with comparable rates of both bacteriuria and UTI post procedure, and self-reported pain scores. This diagnostic tool utilising Endosheath® technology has the potential to increase efficiency and provide cost savings. Its use can be easily deployed as a simple office-based procedure at local primary health centres and community based hospitals should the service be needed to reduce the burden on busy trusts.

CONFLICT OF INTEREST

None to declare. No funding or financial support was provided from any source. The images were obtained from Genesis Med Ltd. after concluding this study, only for this publication need. Full permission was granted to publish the images.

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