Out-patient flexible cystoscopy using a disposable slide-on™ endosheath system

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ABSTRACT

INTRODUCTION The aim of this study was to investigate the feasibility of out-patient flexible cystoscopy.

PATIENTS AND METHODS Twenty-seven patients awaiting diagnostic or check cystoscopy in Leeds, UK were invited to undergo out-patient flexible cystoscopy using a CST-2000 Flexible Cystoscope (Vision Sciences; Natick, MA, USA) using the sterile single-use slide-on™ disposable endosheath endoscope system (EndoSheath®; Vision Sciences). The performance of the cystoscope was evaluated, and the patients' experiences were documented using a questionnaire.

RESULTS The out-patient setting proved to be ideal for flexible cystoscopy. The cystoscope was rated highly for image quality, ease of use and handling. All patients complimented us on the service and preferred out-patients to a day-ward or theatre attendance.

CONCLUSIONS This study demonstrates that it is possible to perform out-patient flexible cystoscopy safely, economically and efficiently with the aid of a disposable endoscope system.

KEYWORDS

Flexible cystoscopy – Vision Sciences – Disposable endoscopy sheaths – Slide-on™ endosheath system

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Flexible cystoscopy is the most frequently performed urological procedure both as a diagnostic and surveillance tool. Freely available facilities to flexible cystoscopy is fundamental to modern urological practice but this is often limited by access to facilities, sterilisation and instrumentation resulting in significant waiting times for the procedure delaying diagnosis and treatment. Most units perform flexible cystoscopy in a day-ward theatre setting, others in purpose-built endoscopy units, few in the out-patient setting. Within our unit, flexible cystoscopy is performed in day-ward theatres, waiting times for non-urgent flexible cystoscopy has reached 9 months. Purchasing and servicing a large number of instruments was considered costly. Moving flexible cystoscopy into an out-patient setting with the implementation of the new Vision Sciences flexible cystoscope using slide-on™ endosheath system may overcome these difficulties and provide an opportunity to improve efficiency.

This paper reports our initial experience with this new device comparing it with standard flexible cystoscopy in an out-patient setting.

Patients and Methods

Twenty-seven patients on the day-case waiting list for diagnostic flexible cystoscopy were randomly chosen to be part of the pilot for the out-patient flexible cystoscopy list. Initially, small numbers were listed to establish the processes; the last list accommodated 10 patients comfortably. All patients were given an information sheet in the waiting area prior to the procedure. They were interviewed using a simplified assessment sheet and consented by the operator (Appendix 1). Patients did not fully change as in the day-ward setting but removed their lower half garments in the treatment room behind a screen.

The Vision Science CST-2000 flexible cystoscopy was used for all procedures. At first glance, the flexible cystoscope looks similar to existing instruments but closer inspection reveals several key differences (Fig. 1A–D). The cross-section of the instrument is crescentic and measures 13.8-F by 16.8-F. It has a lever to lock onto the disposable sheath and a depression valve for irrigation. The sheath incorporates a 6-F working channel for biopsy and ureteric stent removal.

Figure 1 CST-2000 Flexible cystoscope with the sterile, single-use slide-on disposable endosheath.

Figure 2 Crescent-shaped flexible cystoscope with (A) or without (B) an endosheath. (C) The lever that locks the cystoscope into the sheath. (D) The irrigation valve.

The cystoscope is sterilised at the beginning and end of the list with conventional techniques using peracetic acid. The single-use, slide-on sheath is employed between each patient. For each procedure, both the operator and the assistant wear double-layer, sterile gloves so as not to contaminate the instrument when re-sheathing. At the beginning of each procedure, the individually pre-packaged sheath is secured on a table-top fixed device. The instrument is inserted into the sheath and the two are locked together with a catch on the instrument (Fig. 2A–D). The sheath is pulled over to cover the rest of the cystoscope before attaching a camera. The instrument is introduced into the urethra in a standard fashion after cleaning and insertion of local anaesthetic jelly. At the end of the procedure, the assistant slides the sheath off the instrument, removes the outer gloves and inserts a new sterile sheath into the table-top holding device. The operator inserts the cystoscope into the new sheath, removes the outer gloves before pulling the sheath onto the rest of the instrument. The cystoscope is now ready for the next patient. The de-sheathing and re-sheathing process takes about 2 min. A standard catheterisation pack was used to provide the swabs and paper towel.

The assessment of the procedures was evaluated according to ease of use, flexibility and vision. Staffing ratios and patient flows were developed as the clinic progressed until the ideal levels were identified. The patients were asked to give feedback of the out-patient cystoscopy service.

Results

Out-patient setting

The out-patient setting proved to be ideal for flexible cystoscopy utilising a treatment room used for catheterisation and the main waiting area as pre-waiting and recovery area. The optimum staffing ratios were a receptionist, one trained (assistant) and one untrained nurse and the operator.

Instrumentation

EASE OF USE

Once the operator and assistant became familiar with the sheathing, the whole process of sheathing and re-sheathing became smooth and efficient. The whole process was more intricate than normal but the benefits outweighed the disadvantages. Care was taken not to put the instrument down after use until it was re-sheathed ready for use again. On four occasions, the sheath clung to the scope due to friction requiring the sheath to be cut off. Finally, there was no break in the integrity of the sheaths or damage to the instrument.

A

B

C

D

Figure 3 The installation stand attached onto a table (A) before securing the endosheath (B). The distal end of the cystoscope is inserted into the opening of the sheath (C) while the eye-piece is covered by the remainder of the sheath (D).

FLEXIBILITY

The instrument handled identically to conventional scopes with no restriction of movement (Fig. 3) or handling. The instrument is lighter than most, which is a distinct advantage when the camera was attached to the eyepiece. The working channel allowed passage of a biopsy forceps which, in one patient, facilitated retrieval of a foreign body (Fig. 4).

OPTICS

There was no noticeable reduction in quality of vision by looking through the transparent tip at the end of the scope.

Patient feedback

All patients complimented us on the service and preferred to come to out-patients rather than attend day-ward or day-theatre. They did have higher expectations of attending for

Figure 4 A foreign body retrieved from a patient.

an appointment whereas day-theatre patients seem to accept a longer wait for their procedure.

Discussion

Out-patient flexible cystoscopy is not a new concept but this requires either support with sterilisation units or several pre-packed scopes, which may limit the number of procedures that could be performed. The use of the re-sheathable, flexible cystoscopy overcomes most of these obstacles, potentially freeing up valuable day-theatre or endoscopy theatre time.

Vision Science also manufacture disposable sheaths for ENT instrumentation which have found favour in many centres including our own.¹ The disposable nasopharyngolaryngoscopy sheath has proven cost-effective and has resulted in large numbers of procedures being performed in the community setting rather than in secondary care.

The US FDA-approved sheath is a proven effective barrier to micro-organisms as small as 27 nm (equivalent to a polio virus particle size) and is designed to isolate the patient from the cystoscope. Current, high-level disinfection of flexible cystoscopes uses either glutaraldehyde or peracetic acid. The efficacy of glutaraldehyde relies on 'meticulous', manual pre-cleaning, although symptomatic iatrogenic infection rates are low, this is likely to be due to under-reporting² as previous studies have shown a 15–17% positive culture rate in 'patient-ready' scopes.^{3,4} Though more effective, peracetic acid disinfection is equally time-consuming, labour-intensive and, potentially, a costly process.⁵ There have been scares about cross-contamination between patients undergoing endoscopies. Three-thousand patients had to be contacted recently due to problems with decontamination.⁶

Out-patient flexible cystoscopy is not a new concept. Each urology unit provides flexible cystoscopy in differing

facilities with varying numbers of instruments and staffing levels. In Leeds, all flexible cystoscopies are performed within the day-theatre setting in four different hospitals with a total of eight lists per week. Transportation is needed before and after each list to move instruments around the city as well as the staff. This initiative has proven that all such lists could be moved into an out-patient setting. The cost of the Vision Science flexible cystoscopy is less than standard instrumentation; the cost of the disposable sheaths is £18 + VAT each from Dantec Dynamics Ltd.

All patients in our study preferred out-patient rather than day-case attendance. The next step would be to offer flexible cystoscopy at the time of out-patient attendance eliminating waiting times which can only improve the outcome of care. The flexible cystoscope could be pre-sterilised and ready for use; once used, it could be available for subsequent patients. This process could avoid costly installations of sterilising equipment. These lists were carried out in a treatment room in the out-patient department adjacent to the day-theatre. There was no significant impact on the sterilising turnover of the existing endoscopy lists in this unit.

Conclusions

We would commend urologists and managers to consider the investment in out-patient flexible cystoscopy provision for both diagnostic and surveillance endoscopy and that the Vision Science CST-2000 with slide-on™ endosheath system be part of the planning.

Acknowledgement

The authors have no financial involvement or interest with Dantec Dynamics Ltd, Garonor Way, Royal Portbury, Bristol BS20 7XE, UK.

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APPENDIX 1

The simplified assessment sheet used to assess patients before undergoing cystoscopy

Leeds Teaching Hospitals NHS Trust Flexible Cystoscopy

Date of admission -----

Name (addressograph) ----- Next of kin/carer -----

Contact No -----

GP -----

Transport home: Car, taxi, bus, ambulance. Accompanied or self

PAST MEDICAL HISTORY	MEDICATION
Heart disease, Heart murmur --- Yes/No	Warfarin -----Yes/No
Diabetes ----- Yes/No	Antibiotics -----Yes/No
Possibility of pregnancy ----- Yes/No	Allergies to drugs, antibiotics, latex, <i>etc.</i> ---Yes/No

URINALYSIS

Protein ----- Yes/No Blood -----Yes/No

INFORMATION FOR CONSENT

Verbal/written ----- Yes/No

PRE-OPERATIVE CHECK:

Signature -----

Identity band applied -----

Allergies noted -----

Relevant blood results present -----

Urine tested ----- Pulse ----- BP ---/---

OPERATIVE PROCEDURE -----

STERILISATION TRACKING

DISCHARGE CRITERIA

Passes urine	Clear/blood-stained
Has had something to eat/drink	Yes/No
GP discharge letter and information given	Yes/No Time of discharge

Print name of nurse ----- **Signature of nurse** -----