EVIDENCE DOSSIER

Ambu® aScope™ 4 Cysto

Ambu

September 2021, 3rd edition

This document includes published peer-reviewed studies on health economics, organisational impact and infection control related to the aScope 4 Cysto single-use cystoscope.

CONTENTS

ABBREVIATIONS

CA: Clinical consultation appointment

CFU: Colony forming unit

DTC: Direct to cystoscopy

ED: Emergency department

JJ stent: Double-J stent

OR: Operating room

UTI: Urinary tract infection

PREFACE

This dossier gives you an overview of the evidence-based landscape related to aScope™ 4 Cysto, a single-use cystoscope. The introduction explains the clinical performance of aScope 4 Cysto and the market readiness of single-use cystoscopes, according to urologists worldwide.

The main section comprises all studies published from January 2015 to June 2021 related to workflow, procedure relocation, health economics, and contamination of reusable cystoscopes compared to fully disposable cystoscopes. The last section presents the benefits of aScope 4 Cysto.

While each study summary is true to the original publication, the original copies can be made available upon request. Should you wish to discuss any publication in this dossier in more detail, do not hesitate to send an inquiry to our Global Health Economist, Dinah Rindorf (dihr@ambu.com).

In an effort to include all known data irrespective of the outcome, a systematic literature search on cystoscopes has been conducted to generate the Evidence Dossier, giving the reader every opportunity to obtain a balanced overview of the data that exists relevant to disposable cystoscopes such as the aScope 4 Cysto. The study titles are taken from the publications as they appear in their original form, allowing the reader to make an accurate internet search should they wish to find out more.

We hope this evidence dossier provides you with an understanding of the overall clinical landscape concerning aScope 4 Cysto and assists you in your day-to-day evidence-based practice.

While every effort has been made to provide accurate information, we will be pleased to correct any errors or omissions brought to our notice in subsequent editions.

A HISTORY OF BREAKTHROUGH IDEAS

Ambu has been bringing the solutions of the future to life since 1937. Today, millions of patients and healthcare professionals worldwide depend on the efficiency, safety and performance of our single-use endoscopy, anaesthesia, and patient-monitoring and diagnostics solutions. The manifestations of our efforts have ranged from early innovations like the Ambu® Bag™ resuscitator and the Ambu® BlueSensor™ electrodes to our newest landmark solutions like Ambu® aScope™ – the world's first single-use flexible endoscope. Moreover, we continuously look to the future with a commitment to deliver innovative quality products, like Ambu® aScope™ 4 Cysto, which have a positive impact on your work.

Headquartered near Copenhagen, Denmark, Ambu employs approximately 4,600 people in Europe, North America and the Asia-Pacific region.

For more information, please visit ambu.com.

CLINICAL PERFORMANCE OF THE AMBU® ASCOPE™ 4 CYSTO[1]

The flexible cystoscope is an indispensable tool when diagnosing and treating disorders in the lower urinary tract. For this reason, uncompromised quality and satisfactory performance of the flexible cystoscope are prerequisites when used for cystoscopy procedures.

A recently published whitepaper from Ambu describes the results from 380 evaluation forms evaluating the performance of the aScope 4 Cysto after using the cystoscope for a cystoscopy procedure. The evaluation forms were filled in by urologists in Europe, Australia and Hong Kong. They rated the overall performance of the aScope™ 4 Cysto system, as well as the navigation, manoeuvrability, image quality, and bending capability with and without a tool in the working channel on a 5-point Likert scale (from "very poor" [1] to "very good" [5], or from "very difficult" [1] to "very easy" [5]).

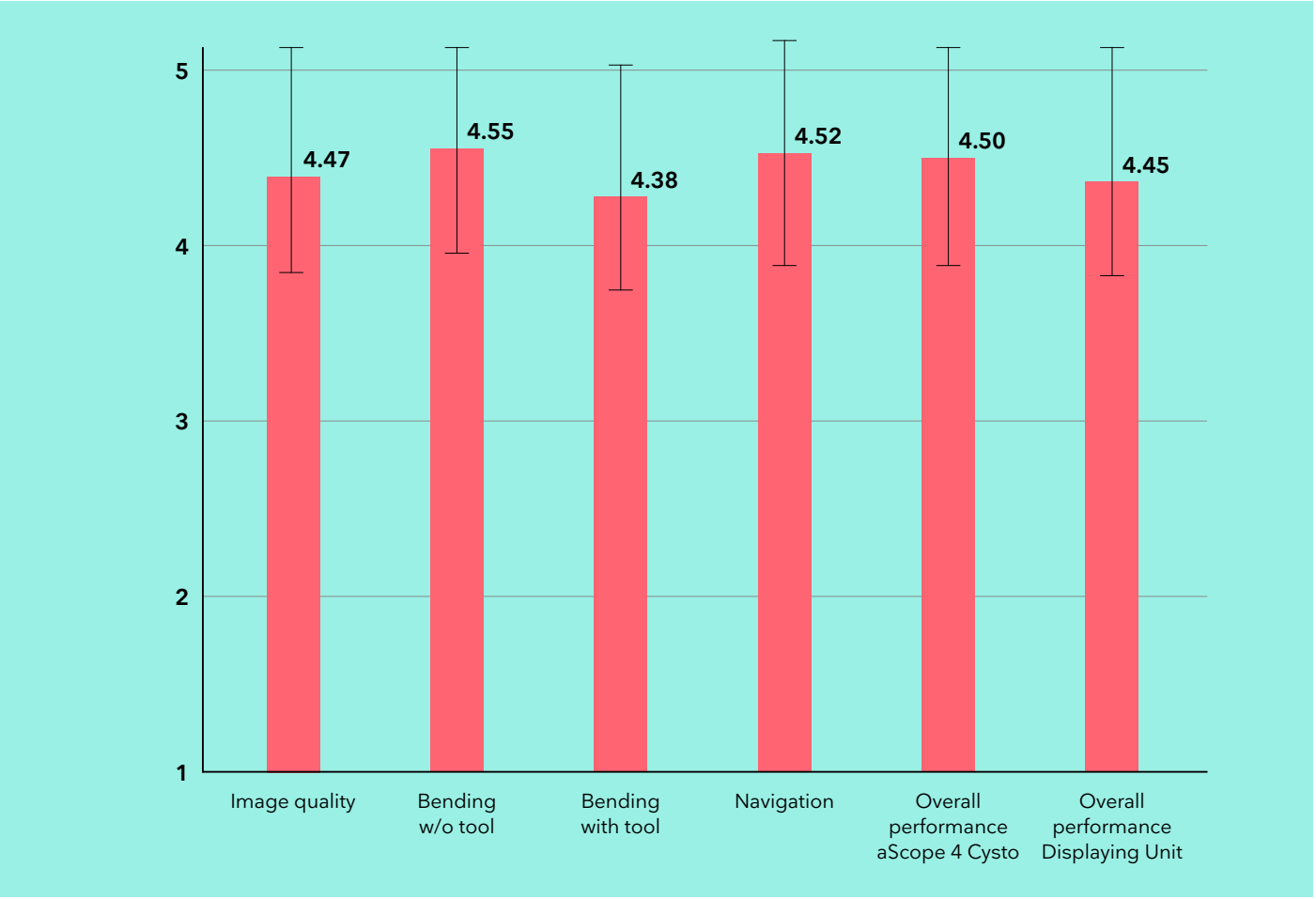


Figure 1: Average rating of performance (mean ± SD) on a 5-point Likert scale.

For performance parameters concerning image quality, bending (with and without tool) and overall performance (of the aScope 4 Cysto as well as the aView™ 2 Advance Displaying Unit), more than 90% reported "very good" or "good" performance. For ratings on navigation, 93.6% reported "very easy" or "easy" navigation.

These results indicate satisfaction with the aScope 4 Cysto system on the most important performance parameters such as image quality, bending capabilities and navigation. Based on these results, the single-use cystoscope aScope 4 Cysto is a highly useful device for daily urology practices, with uncompromising quality with every use. You can read the full white paper at ambu.com/urology.

ARE UROLOGISTS AND PROCUREMENT MANAGERS READY FOR SINGLE-USE CYSTOSCOPES?

Reusable flexible cystoscopes are often the cause of delays or cancellation of cystoscopy procedures, as cystoscopes become unavailable when out for reprocessing or repairs. Further, the U.S. Food and Drug Administration (FDA) recently announced an investigation of possible contamination issues associated with reprocessing urological endoscopes, after receiving 450 medical device reports describing post-procedure patient infections or other possible contamination issues between 1 January 1, 2017, and February 20, 2021. To avoid potential issues related to cystoscope availability or reprocessing, single-use cystoscopes like the Ambu® aScope™ 4 Cysto are entering the market, offering a sterile scope with consistent quality and no need for reprocessing.

In a recently published article, the market readiness for single-use cystoscopes was investigated by asking 415 urologists and procurement managers to indicate how many of their cystoscopy procedures they would consider using a single-use cystoscope for[1].

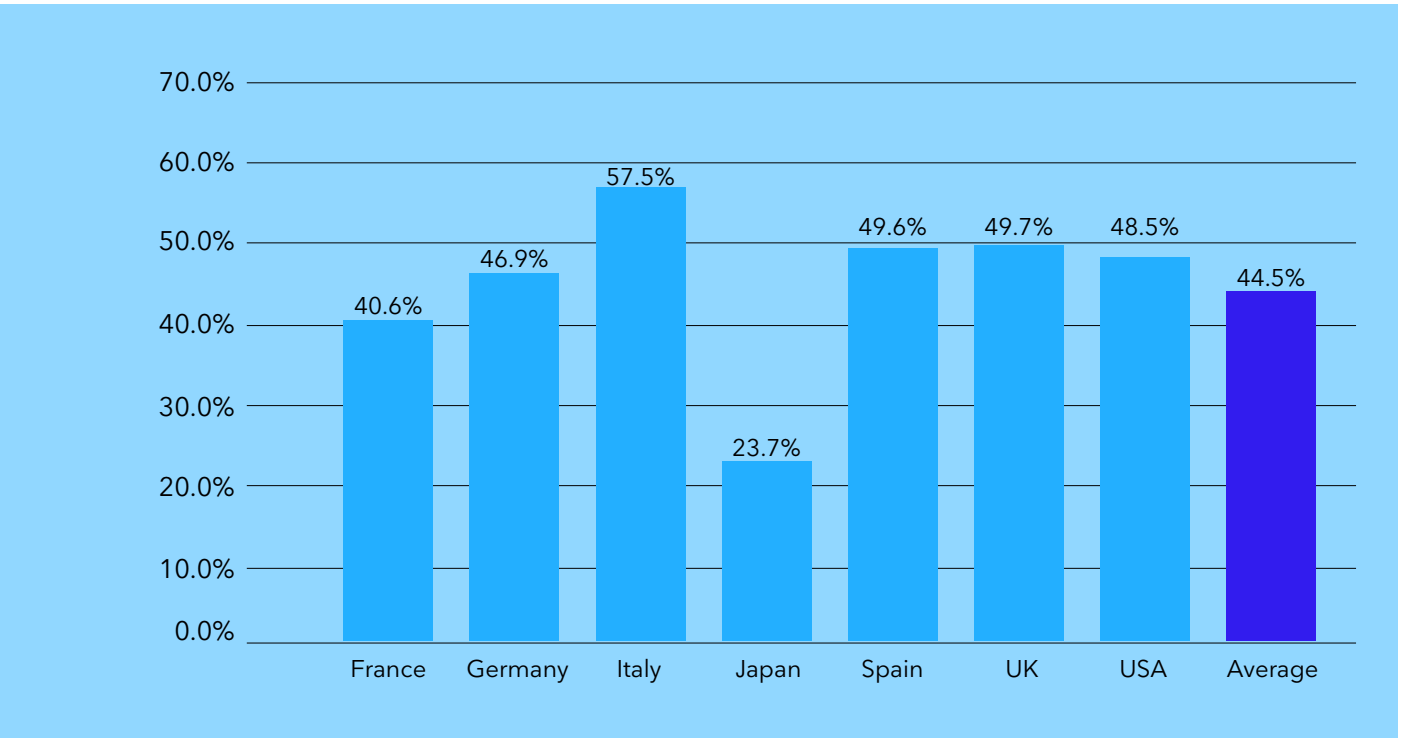


Figure 1: Average stated conversion rates from reusable to single-use cystoscopes by country

On average, the respondents indicated that they would consider converting to single-use in 44.5% of their cystoscopy procedures. Italian respondents reported the highest average conversion rate, at 57.5% of their procedures. Further, the results also showed that respondents indicated a significantly higher conversion rate when they [(1)] were concerned about cystoscopy-related infections as a result of contaminated cystoscope; [(2)] were members of their institution's value committee; [(3)] considered cost-transparency to be important when purchasing cystoscopes; or [(4)] used single-use ureteroscopes in their department.

These results show that many urologists are open to using single-use instead of reusable cystoscopes for cystoscopy procedures. The Research and Reports in Urology journal offers open access to the full paper. You can find the link to the full paper at ambu.com/urology.

SUPPORTING EVIDENCE-BASED PRACTICE WITH BEST AVAILABLE EVIDENCE

Evidence-based decision-making is key when purchasing new devices. The core principle of evidence-based practice is the hierarchy of evidence, which identifies the best available evidence for a given clinical question. This Evidence Dossier will not go into depth with the different levels of evidence but will instead provide an easy overview that indicates the quality of the particular study based on the system below.

LOW QUALITY OF EVIDENCE

MEDIUM QUALITY OF EVIDENCE

HIGH QUALITY OF EVIDENCE

HOW WERE THE STUDIES IN THIS DOSSIER SELECTED?

Two major scientific online databases, PubMed (MEDLINE) and Embase, were searched for all relevant articles up to June 1, 2021. Articles published in the English language within the areas of infection control, workflow, procedure relocation and health economics were included. Commentaries, letters to the editor, book chapters, and publications with no clinical or economic relevance were excluded. In order to provide the reader with the most up-to-date studies, this document only includes studies published after 2015.

This Evidence Dossier includes summaries of twelve published peer-reviewed studies and two outbreak reports related to cystoscopy procedures.

HEALTH ECONOMICS

★★★ Cost Not open access

A micro-costing analysis of outpatient flexible cystoscopy: implications for adoption of single-use flexible cystoscopes, World J Urol[2]

Su et al. 2021

TAKE AWAY

The cost of reprocessing reusable cystoscopes represents a large fraction of the total cost per procedure, especially for high-volume facilities. The per-procedure cost is highly dependent on the number of cystoscopes available and the annual procedure volume. However, according to this study, it may be more economical to adopt single-use cystoscopes.

KEY FINDINGS

- **The cost of reusable flexible cystoscopes is highly dependent on the number of cystoscopes available and the annual procedural volume at individual urology practices. In a practice performing 1,000 cystoscopy procedures a year, the per-procedure cost ranges between $155 and $224.**
- **The total reprocessing cost per cycle was $48.90, covering the cost of supplies and the labour cost spent on manual cleaning used in reprocessing one reusable flexible cystoscope. Labour cost accounted for 48% of the total reprocessing cost.**

STUDY AIM

Micro-costing is a method that allows the precise valuation of the costs of health care interventions. To do a cost comparison of single-use vs reusable cystoscopes, this study employed micro-costing to evaluate the total potential costs and cost savings associated with the purchase, maintenance, and reprocessing of reusable flexible cystoscopes in urology practices.

METHODS

- All cost data regarding the purchasing, maintaining, and reprocessing of reusable flexible cystoscopes were obtained at a high-volume outpatient urology clinic (Johns Hopkins Outpatient Center, Baltimore, Maryland, United States).
- The total of all cost elements was used to calculate a per-procedure cost of reusable flexible cystoscopes with a range of annual procedures ranging from 1,000 to 3,000 procedures a year, performed with a fleet of cystoscopes ranging from 10 to 25 cystoscopes.

The per-procedure cost of reusable cystoscopes ranges between

$155 - $224

★★☆ Cost Open access

The first UK experience with single-use disposable flexible cystoscopes: An in-depth cost analysis, service delivery and patient satisfaction rate with Ambu® aScope™ 4 Cysto, The Journal of Endoluminal Endourology[3]

Wong et al. 2021

TAKE AWAY

According to this study, the aScope 4 Cysto is a safe and cost-efficient device for cystoscopy procedures. Due to its portability, it proves to be a simple and efficient way of performing a cystoscopy procedure in an inpatient, outpatient or emergency setting.

KEY FINDINGS

- **This study revealed that it costs £135.23 and £166.33 on average to perform a flexible cystoscopy using the aScope 4 Cysto and the traditional flexible cystoscopes, respectively.**
- **The mean satisfaction rate with use of reusable cystoscopes and single-use cystoscopes was 9.05 (range 6-10) and 9.65 (range 8-10), respectively (p=0.045). Further, 95% of patients preferred to have the procedure done with a single-use flexible cystoscope, whilst 5% had no preference.**

STUDY AIM

Hereford County Hospital was the first hospital in the UK to try the Ambu® aScope 4 Cysto. The aim of this study was to do a cost analysis and to evaluate the service delivery and patient satisfaction when using the aScope 4 Cysto compared to a traditional reusable cystoscope at this community hospital.

METHODS

- The cost of performing flexible cystoscopies using the aScope 4 Cysto in 20 patients was compared with 20 patients using traditional Olympus® CYF-240 flexible cystoscopies.
- All costs, excluding staffing cost, were accrued from sources within the endoscopy, pharmacy, and procurement departments within the hospital, and the organisations which have supplied the products to our department.
- A patient satisfaction questionnaire was also provided to the patients, comparing the use of reusable cystoscopes to the aScope 4 Cysto on a 10-point Likert rating scale.
- An unpaired t-test was used for statistical analysis of patient satisfaction, with a statistical significance set at $P < 0.05$.

95%

of patients preferred to have the procedure done with a single-use flexible cystoscope

★★★ Cost Not open access

TAKE AWAY

There is a considerable contribution of capital equipment, maintenance, labour and supplies to the cost of cystoscopy. When compared to the cost of single-use cystoscopes, the profitability is highly dependent on the procedure volume and the amount of capital equipment available.

KEY FINDINGS

- **A total of 3,739 flexible office cystoscopies were performed in 2019 with 9 reusable cystoscopes, equivalent to 415 procedures per cystoscope. Based on the micro-costing analysis, the total annual cost for reusable flexible cystoscopes was $600,484, which corresponds to a per-procedure cost of $161.**
- **An analysis of the urology clinic's use of reimbursement tariffs showed an average reimbursement rate of $296.**

The economics of cystoscopy: A microcost analysis, Urology[4]

Kenigsberg et al. 2021

STUDY AIM

The purpose of this study was to conduct a micro-costing analysis to estimate the per-procedure cost of reusable flexible cystoscopes and to compare this to reimbursement for procedures during the same time frame.

METHODS

- All costs were calculated using a micro-costing approach in an American urology clinic. The costs included:
  - Capital equipment: Reusable cystoscopes, storage supplies (e.g. scope hangers, cabinets, towers, etc.) and automated endoscope reprocessors.
  - Maintenance: Annual service contracts covering all reusable cystoscopes and automated endoscope reprocessors.
  - Reprocessing: Cleaning supplies (e.g. chemicals, syringes and personal protection equipment).
  - Labour cost: Labour time used for reprocessing and hourly rate.
- The per-procedure cost of reusable flexible cystoscopes was calculated by dividing the total costs from the micro-costing analysis with the number of procedures performed in 2019.

★★★ Cost Open access

TAKE AWAY

This study shows that the single-use cystoscope significantly reduced stent dwell time and procedural time. It allowed the procedures to be done in an outpatient setting, thereby reducing the organisational pressure on endoscopy-related diagnostic procedures, and the cost associated with the procedure.

KEY FINDINGS

- **A total of 72 patients (37 reusable cystoscopic stent removals, 35 single-use cystoscopic stent removals) were included in the study.**
- **The mean procedure time was 14.4 and 2.2 minutes for groups A and B, respectively (p <0.001).**
- **The stent indwelling time was 26.8 and 15.4 days for groups A and B, respectively (p <0.001).**
- **In group A, 5 patients (14%) developed stent encrustation, compared to none in group B.**
- **Using single-use cystoscopes for JJ stents released capacity in the endoscopy room to perform urgent diagnostic flexible cystoscopy or cancer surveillance. For this reason, the mean number of days patients waited for diagnostic cystoscopy was reduced from 21 days to 3 days.**
- **The cost per procedure for group A and group B was £365.40 and £252.62, respectively (p<0.001), if the cost of managing complications was considered.**

Comparison of ureteric stent removal procedures using reusable and single-use flexible cystoscopes: a micro cost analysis, Cent Eur J Urol[5]

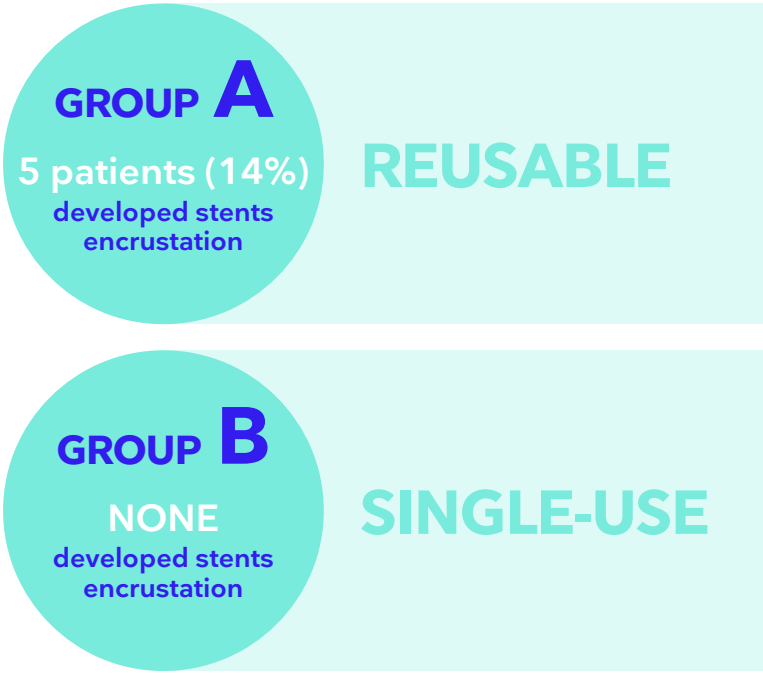
Pietropaolo et al. 2020

STUDY AIM

The aim of this study was to compare the indwelling stent time, cost, stent-related complications and organisational impact for standard cystoscopic stent removal in the endoscopy room versus out-patient clinic-based stent removal with the single-use cystoscope (Isiris™).

METHODS

- The JJ stent removals with reusable cystoscopes took place in the endoscopy room (group A), while the procedure with single-use cystoscopes was done in the outpatient clinic (group B).
- A micro-costing analysis was performed, evaluating the impact on costs, complications and organisational benefit.



★★★ Cost Not open access

TAKE AWAY

The per-use cost for stent removal procedures using a reusable cystoscope was estimated to be $161.85. If the number of stent pulls is less than 704, this cost analysis favours the single-use cystoscope over the reusable cystoscope.

KEY FINDINGS

- **A total of 1,775 cystoscopic procedures were performed, and the reusable cystoscope was used for stent removal in 871 (49%) cases.**
- **The per-use cost for stent removal procedures using the reusable cystoscope was estimated to be $161.85.**
- **Based on the current volume, the break-even point was calculated to be 704 stent pulls, when comparing to the cost of the single-use cystoscope ($200).**

Single-Use Grasper Integrated Flexible Cystoscope for Stent Removal: A Micro-Costing Analysis-Based Comparison, J Endourol[6]

Beebe et al. 2020

STUDY AIM

The aim of the study was to perform a micro-costing analysis comparing the cost of a single-use cystoscope for JJ stent removal (Isiris™) to the cost of using a reusable cystoscope.

METHODS

- The number of stent removal procedures at the hospital was recorded as a proportion of all cystoscopic procedures performed between February 2016 and February 2017.
- Costs involved in JJ stent removal using the Olympus® (CYF-VH) reusable flexible cystoscope versus a single-use cystoscope include:
  - Original purchasing price of an Olympus digital reusable cystoscope
  - Servicing contract for repairs (per scope, per annum)
  - Reprocessing costs, including all materials to properly decontaminate and repackage the scope and associated equipment
  - Personnel performing the reprocessing (labour cost based on the time and salary)
  - Sterilisation equipment and the accompanying accessories, as well as the service contract for the sterilising equipment

Cost per use for reusable cystoscopes was estimated to be

$161.85

OPTIMISATION OF PROCEDURE LOCATION

★★☆ Portability Not open access

TAKE AWAY

This study shows that single-use cystoscopes can provide financial benefits and enable JJ stent removals to be moved to the outpatient setting. This makes it possible to move patient care closer to patients in a time with increasing centralisation of health care delivery associated with negative patient experiences due to increased travel times.

KEY FINDINGS

- **147 JJ stent removal attempts using the single-use cystoscope were successful.**
- **One patient developed UTI following JJ stent removal. There were no other complications noted and no admissions required post-procedure.**
- **Substantial cost savings (£63,480 in savings for this cohort compared to conventional practice) were associated with the use of single-use cystoscopes. This was due to the increased income from reimbursement tariffs associated with moving this procedure to the outpatient setting.**

Isiris™ for Ureteric Stent Removal in Renal Transplantation: An Initial Single-Centre Experience of 150 Cases, Surg Innov[7]

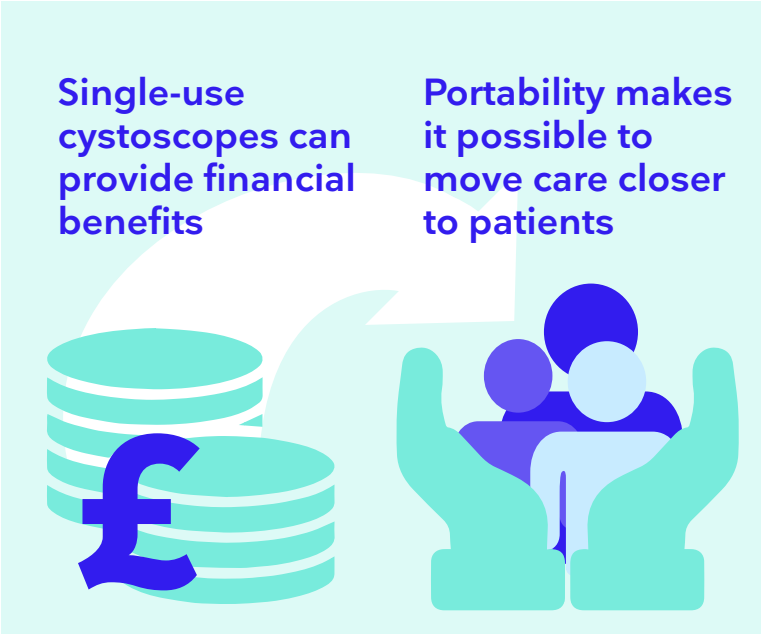
Doherty et al. 2021

STUDY AIM

Historically, JJ stent removal has been performed via flexible cystoscopy as an inpatient procedure in the operating room. Performing this procedure in the operating room is resource-intensive and has significant costs associated with room occupation time and subsequent instrument reprocessing. The aim of this study was to report initial experiences with utilising a single-use cystoscope (Isiris™) and to do a cost comparison of single-use vs reusable cystoscopes.

METHODS

- Transplant ureteric stent removal was performed by transplant surgical trainees with the assistance of a single nurse assistant in the outpatient clinic or at the bedside (in inpatients) between October 2017 and September 2018, utilising the single-use cystoscope (Isiris™).
- The presence of UTI was defined as the presence of elevated white blood cell count on microscopy, with confirmed bacterial growth on microbiological culture.



★★☆ Portability Not open access

TAKE AWAY

The single-use cystoscope for JJ stent removal represents an efficient and versatile instrument to perform JJ stent removal or other cystoscopic procedures in different hospital settings. The cost-effectiveness of such instruments becomes particularly evident in institutions where JJ stent removal is performed in the OR, leading to a significant advantage in terms of money saved per procedure and OR time gained.

KEY FINDINGS

- **The mean cost per procedure was estimated at €361 for in-office stent removal with the single-use cystoscope, and €1,126.80 for OR stent removal with Storz™ reusable flexible cystoscope.**
- **Due to 127 procedures being performed in-office rather than in the OR, 64 hours of OR time was saved.**

Cost-effectiveness analysis of a single-use digital flexible cystoscope for double J removal, Urologia[8]

Oderda et al. 2020

STUDY AIM

In the absence of an endoscopy room, the institution performs all cystoscopy procedures in the OR, with obvious consequences in terms of OR occupancy and overbooking. After implementing single-use cystoscopes (Isiris™) the department was able to perform JJ stent removals in an in-office setting instead of in the OR. The aim of the study was to do a cost comparison of single-use cystoscopes vs. reusable cystoscopes for JJ stent removal in this institution.

METHODS

- A total of 127 consecutive patients undergoing in-office stent removal with a single-use cystoscope from March to December 2017 were prospectively included in the study.
- A questionnaire was filled in after each procedure: the urologist filled in the section concerning the efficiency of the device, whereas the patient filled in the section concerning the invasiveness and tolerability of the procedure.
- Costs involved in JJ stent removal using the single-use cystoscope versus the traditional 16-Ch Storz™ reusable flexible cystoscope included:
  - A Storz™ flexible cystoscope plus grasper
  - OR occupancy
  - Medical personnel, including the aid of a nurse
  - High-level cystoscope disinfection
  - Isiris™ cystoscope and Isiris™ monitor purchase
  - Repairs in the case of damage to reusable cystoscopes (including one repair order each year)

★★☆ Portability Not open access

TAKE AWAY

The results demonstrate that introducing the single-use cystoscope for JJ stent removal helps reduce the strain on elective waiting lists, while also being financially beneficial. Besides the cost savings associated with single-use cystoscopes, the system freed up an extra 65 elective spaces for diagnostic flexible cystoscopy cases.

KEY FINDINGS

- **During the study period, 75 patients had their JJ stent removed with the single-use cystoscope.**
- **In the 12 months prior to introducing the single-use cystoscope, 13 reusable cystoscopes were damaged, costing $4,888 (AUD) in repairs and replacements per month.**
- **In the period after introducing the single-use cystoscope, one scope was damaged at a cost of $920 (AUD) per month. This resulted in cost savings of approximately $23,809 on repairs and replacement over this six-month period.**
- **The introduction of the single-used cystoscope produced a surplus of $104,434 (AUD).**

Prospective trial of single-use, flexible cystoscope for ureteric double-J stent removal: Cost and utility analysis, J Clin Urol[9]

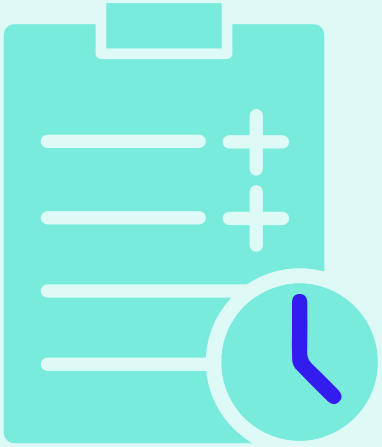
Donato et al. 2019

STUDY AIM

Given the costs associated with additional staffing, the sterilisation process and the repairing of damaged scopes, the authors of this study introduced a single-use cystoscope (Isiris™) into their hospital. The introduction of single-use cystoscopes in their department enabled them to move JJ stent removals out from endoscopy rooms to consultation rooms. The aim of this study was to compare the cost of single-use vs. reusable cystoscopes and to investigate the benefits of the single-use system to patients and its effect on the workflow in the department.

METHODS

- A prospective analysis of all JJ stent removals with the single-use cystoscopes was performed between April and September 2017.
- Data assessed included intended and actual stent indwelling time, successful removal rate, duration of the delay to stent removal, location of procedure and rates of reusable scope damage over the period.
- The cost of the single-use cystoscope and the repair costs of reusable scopes over the 12 months prior to introducing single-use cystoscopes and the six months following introduction were calculated.
- Whilst performing cystoscopies with reusable cystoscopes in their endoscopy room, they used a small consulting room to remove the majority of the stents with the single-use cystoscopes.



The single-use system freed up an extra

65 ELECTIVE SPACES

★★★ Portability Open access

TAKE AWAY

Performing the JJ stent removal in a consultation room instead of the OR or endoscopic room would lead to cost savings of €45 or €140, respectively. Hence, hospitals should consider the option of single-use cystoscopes for JJ stent removal, as single-use cystoscopes do not require a dedicated place and can therefore enable cost savings. Furthermore, moving procedures such as JJ stent removals to a consultation room will enable time for other activities in the endoscopic room and OR and decrease the risk of UTI.

KEY FINDINGS

- **During the year 2016, 603 JJ stent removals were performed in the endoscopic room and 6 in the OR. Total occupancy times were 301.5 hours for the endoscopic room and 3.0 hours for the OR.**
- **Total cost per JJ stent removal in the endoscopic room, OR and consultation room was €330, €425 and €285, respectively.**

Impact of double-J stent removal with a single-use cystoscope dedicated to this procedure: A cost analysis, World J Urol[10]

Doizi et al. 2018

STUDY AIM

In many institutions, JJ stent removal is performed in an endoscopic room or OR and requires video equipment and reusable cystoscopes that need to be disinfected after each procedure. The aim of this study was to compare the cost of a JJ stent removal in the endoscopic room or OR with reusable instruments to the cost of a JJ stent removal with a single-use cystoscope (Isiris™) in a consultation room.

METHODS

- This retrospective monocentric study included all the JJ stent removals performed in 2016 in a French academic institution.
- The cost analysis of JJ stent removals included: costs of reusable cystoscope and grasper (including material purchase, maintenance, reprocessing by disinfection or sterilisation), cost of video equipment (including material purchase, maintenance and light cable reprocessing), and cost of endoscopic room or OR occupancy for 30 minutes.
- The cost of JJ stent removals in an endoscopic room or OR was compared to the cost of a JJ stent removal performed in an outpatient consultation room with the single-use cystoscope, including its purchase, waste process, and room occupancy for 30 minutes.

Hospitals should consider the option of single-use cystoscopes for JJ stent removal, as single-use cystoscopes do not require a dedicated place and can therefore enable cost savings.

IMPROVED WORKFLOW

★★☆ Patient preferences Open access

Direct to cystoscopy: A prospective quality assessment of patient preferences, Can Urol Assoc J[11]

Assmus et al. 2020

TAKE AWAY

The study identifies a patient preference for DTC among cystoscopy patients. Hence, single-use cystoscopes can be a good alternative in situations where DTC would otherwise be impossible due to a limited number of cystoscopes being available.

KEY FINDINGS

- **Overall, most patients (85%) who responded to this question preferred DTC (8.4% omitted a response).**
- **According to univariate and multivariate logistic regressions analysis, there was no difference in age, gender, whether it was their first-time cystoscopy, or what the indication for cystoscopy was when comparing those who preferred DTC vs. clinical consultation appointment prior to cystoscopy (p>0.05).**

STUDY AIM

In many outpatient centres, patients need to schedule a follow-up appointment to have a cystoscopy after a clinical consultation, instead of going directly to cystoscopy (DTC). This is often due to the limited number of cystoscopes available for unplanned cystoscopies. Single-use cystoscopes are always available, enabling the possibility of going directly to cystoscopy at any time. But what do patients prefer? The aim of this study was to identify whether patients preferred to be seen DTC or after a clinical consultation appointment prior to cystoscopy.

METHODS

- A six-part patient questionnaire was distributed to adult (>18 years old) patients after their cystoscopies to evaluate their preferences. The questionnaires were provided to the patient by healthcare aids and cystoscopy nursing staff. Completion of the questionnaire occurred in a private room at the completion of their clinical interaction with the urological team.
- Prospective survey collection continued over a four-week period from September to October 2017, until 500 consecutive completed questionnaires were obtained.

Most patients (85%) preferred going direct to cystoscopy after a clinical consultation

★★★ Organisational benefits Open access

TAKE AWAY

Removal of stents in an office environment is both feasible and safe and appears to be associated with a significant potential cost saving. Patient experience has been enhanced, as evidenced by the timelier removal of stents and the reduction in complications.

KEY FINDINGS

- **The excess dwell time was significantly reduced in the single-use group compared with the Standard group.**
- **The rate of ED attendance whilst the stent was in situ was reduced by 33.5% in the single-use group (equating to approximately £1,110 cost saving per 100 stent removals) compared with the Standard group (14.7% vs. 22.1%, p = 0.47).**
- **Fewer patients from the single-use group (11% vs. 14%) were readmitted to hospital, a reduction of 22% (p = 0.78) (equating to approximately £750 cost saving per 100 stent removals).**
- **The rate of stent removal procedures cancelled on the appointed day was lower in the single-use group compared with the Standard group, realising a 59.2% improvement in the rate of cancellations and attracting a further £1,620 per 100 cases of efficiency savings.**

Office-based ureteric stent removal is achievable, improves clinical flexibility and quality of care, whilst also keeping surgeons close to their patients, Cent Eur J Urol[12]

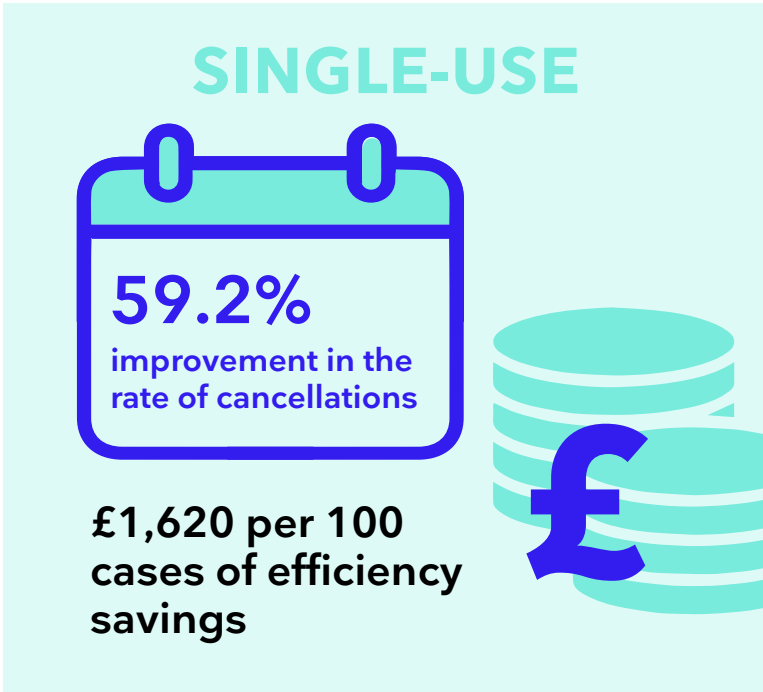
Baston et al. 2018

STUDY AIM

The aim of this study was to determine whether adoption of a single-use cystoscope (Isiris™) had shortened the dwell time of stents and whether this subsequently improved the rates of post-procedure-related events observed.

METHODS

- All patients that had undergone a rigid or flexible ureteroscopy or percutaneous nephrolithotomy and received a stent between August 2013 and December 2016 were identified.
- In April 2016, in an attempt to standardise the procedure of stent removal, the process of cystoscopic stent removal was moved to the office/clinic environment, utilising the single-use cystoscope.
- Blinded to the method of stent removal employed, the operating surgeon retrospectively reviewed the operation note and recorded an ideal dwell time for that particular patient's stent.



CONTAMINATED CYSTOSCOPES

★☆☆ Infection Control Not open access

TAKE AWAY

This outbreak strongly suggests that we should not trivialise UTIs occurring after an elective cystoscopy. Patients should be advised to signal the occurrence of urologic symptoms after urologic exploration. In the case of concomitant infections caused by P aeruginosa, the cystoscope should be suspected as a potential reservoir.

KEY FINDINGS

- **Between July 7, 2015, and May 31, 2016, 389 patients underwent cystoscopies, including 104 patients using the cystoscope number 419. Four of the 104 patients exposed to the cystoscope number 419 had a P aeruginosa positive sample after cystoscopy.**
- **None of the 285 patients exposed to the three other cystoscopes were contaminated with P aeruginosa. Between May and October 2016, the urologists reported four further cases, all exposed to cystoscope number 419. After returning cystoscope number 419 to the manufacturer, a scratch in the cystoscope channel was identified.**
- **Altogether, 11 patients contracted a P aeruginosa UTI after cystoscopy with the cystoscope number 419, and the outbreak lasted 9 months.**

An outbreak of Pseudomonas aeruginosa urinary tract infections following outpatient flexible cystoscopy, Am J Infect Control[13]

Sorbets et al. 2019

STUDY AIM

The most frequent microorganisms involved in UTIs after flexible cystoscopy are Escherichia coli, enterococci and staphylococci, whereas Pseudomonas aeruginosa (P aeruginosa) is one of the rarer microorganisms involved in UTIs. This study reports an outbreak of P aeruginosa UTIs after ambulatory cystoscopies.

METHODS

- The four reusable cystoscopes used in urology consultation were hand-cleaned and disinfected according to the national recommendations in France.
- The patients who developed P aeruginosa UTIs between 9 July 2015 and 30 June 2016 were identified by searching data from several relevant units in the hospital. The list of identified cases of P aeruginosa was then compared with the list of patients who underwent a cystoscopy between 7 July 2015 and 31 May 2016.

11 PATIENTS
contracted a P aeruginosa UTI after cystoscopy with the same reusable cystoscope

The outbreak lasted 9 months

★★☆ Infection Control Not open access

TAKE AWAY

The rate of microbiological tests performed on cystoscopes with unacceptable CFU (colony forming unit) levels is relatively high (19.5%). Cystoscopes returning from the manufacturer following maintenance or repair are sometimes contaminated. Hidden microorganisms are present in small quantities, and identified germs are not known to be responsible for UTIs.

KEY FINDINGS

- **19.5% (17/87) of the microbiological tests showed a CFU level ≥1, indicating that the cystoscopes were contaminated. This rate reached 24.5% (12/49) of the programmed controls.**
- **The microorganisms identified were present in small amounts, corresponding mainly to bacteria from the environment.**

Microbiological evaluation of cystoscope reprocessing at Brest university hospital from January 2007 through December 2014[14]

Saliou et al. 2016

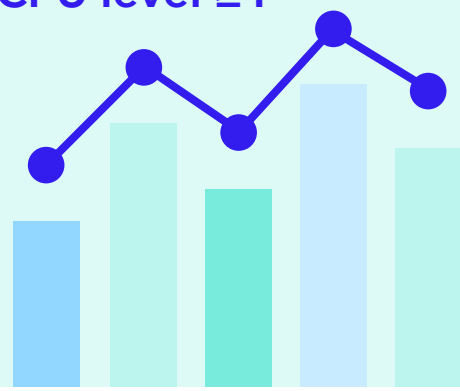
STUDY AIM

Flexible cystoscopes are relatively simple devices with an internal channel in which mineral and organic soils can accumulate in the form of biofilm. Hence, microbiological tests of cystoscopes must be carried out to ensure the effectiveness of the disinfection process. The aim of this study was to determine the success rate of disinfection and to describe the main microorganisms identified.

METHODS

- Prospective study of all the results of microbiological samples taken over an eight-year period at the Brest teaching hospital: a total of 87 microbiological tests.
- The analysis results were interpreted according to ministerial recommendations, after indications that a cystoscope was contaminated at CFU level ≥1.

19.5% (17/87) of the microbiological tests showed a CFU level ≥1



★☆☆ Infection Control Not open access

TAKE AWAY

Infectious outbreaks have previously been associated with reusable cystoscopes; however, this is the first study to report an infectious outbreak caused by Salmonella spp. Strict control of cleaning and disinfection of reusable cystoscopes should be carried out to avoid transmission of infections related to the use of these devices.

KEY FINDINGS

- **A total of 4 patients contracted a Salmonella spp. UTI after cystoscopy within a period of 3 weeks between October and November 2014.**
- **The index patient was subsequently i dentified as a faecal carrier of Salmonella spp., suggesting that urethral colonisation may be due to contiguity.**
- **After reinforcing the cleaning and disinfection of all reprocessing equipment and cystoscopes, no additional cases were identified up until December 2014.**

Outbreak of Urinary Tract Infections by Salmonella Spp. after Cystoscopic Manipulation, Actas Urol Esp[15]

Jimeno et al. 2016

STUDY AIM

Over a few months, a university hospital in Spain identified a worrying increase in urine cultures positive for Salmonella spp. This study reports an outbreak of Salmonella spp. UTIs after cystoscopy procedures at their hospital.

METHODS

- The cystoscopes were cleaned first by soaking the cystoscope in enzymatic detergent (Enzym®) and second in highly disinfecting solution (Instrunet®). Finally, the system was rinsed with saline.
- The presence of an infectious outbreak was considered after experiencing a worrying increase in urine cultures positive for Salmonella spp. in the period between October and November 2014. All patients that developed Salmonella spp. UTIs were identified, and their records showed that all these patients had once undergone a cystoscopy.

> **Strict control of cleaning and disinfection of reusable cystoscopes should be carried out to avoid transmission of infections related to the use of these devices.**

Ambu® aScope™ 4 Cysto

Ambu® aScope™ 4 Cysto is a single-use flexible endoscope solution that gives you a way to take control of your schedule and be more productive – without compromising on the quality of your work.

It offers consistent quality because you get a brand-new cystoscope for every procedure. It has the image quality and bending performance you need to perform your cystoscopies confidently. In addition, it is always available and portable, making it easier to manage your schedule and deal with in-house consult procedures. Finally, it eliminates the need for reprocessing, costly repairs and the risk of cross-contamination. As a result, the aScope 4 Cysto simplifies workflow, frees up resources and enables you to treat more patients.

ALWAYS AVAILABLE AND PORTABLE

aScope 4 Cysto is always available and portable, making it easy for physicians to manage their schedule and deal with in-house consult procedures.

SIMPLE SET-UP

aScope 4 Cysto makes it easy for the physician to plan and manage the day. From the outpatient clinic to inpatient consult procedures, physicians can take the lightweight single-use cystoscope and portable monitor with them under their arm. And when they finish the procedure, they simply dispose of the scope, so there is no more hassle with cleaning.

EXCELLENT IMAGING AND MANOEUVRABILITY

With aScope 4 Cysto, physicians can count on clear, sharp images that make it easy to identify anatomical structures. High bending angles of 210°/120° enable the physician to manoeuvre and navigate smoothly in the urethra and bladder. The physician can advance and completely retroflex the cystoscope to inspect the bladder neck with or without forceps inserted. aScope 4 Cysto offers consistent quality without any deterioration of image or bending quality, because the physician gets a brand-new cystoscope for every procedure.

KEY FINDINGS

- **Sterile straight from the pack** – eliminates the risk of patient cross-contamination.
- **No need for post-procedure cleaning or repair** – eliminates various steps in order to optimise daily workflow.
- **Ready when you are** – hassle-free portable solution makes it easy to manage your schedule and deal with in-house consult procedures.
- **Offers cost transparency** – one cystoscope, one price and no long-term service contracts or leasing agreements.
- **Brand new every time** – ensures excellent imaging and smooth manoeuvrability with every cystoscope.
- **Frees up resources** – eliminates reprocessing and costly repairs because it is single-use. Resources can be used for other purposes.

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