EVIDENCE DOSSIER

Ambu® aScope™ 4 Cysto

Ambu

February 2021, 2nd edition

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

CONTENTS

ABBREVIATIONS

ED: Emergency department

JJ: Double-J stent

OR: Operating room

UTI: Urinary tract infection

DTC: Direct to cystoscopy

CA: Clinical consultation appointment

PREFACE

This dossier gives you an overview of the clinical landscape related to Ambu® aScope™ 4 Cysto, a single-use cystoscope. The introduction summarizes the most frequent adverse events associated with cystoscopies reported to the U.S. Food and Drug Administration (FDA). The introduction underlines the increased awareness around the challenges of working with reusable cystoscopes, including sterility, a lack of availability of the scopes, and the hassle of reprocessing.

The main section is comprised of all studies published from January 2010 to November 2020 related to the organizational impact, contamination, infection control and clinical performance of reusable cystoscopes and fully disposable cystoscopes used for specific procedures (e.g. Isiris™ - Coloplast). 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 drop 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 Clinical Evidence Dossier, giving the reader every opportunity to obtain a balanced overview of the data that exists relevant for disposable cystoscopes like 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 & 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 4,000 people in Europe, North America and the Asia-Pacific region.

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MANUFACTURER AND USER FACILITY DEVICE EXPERIENCE (MAUDE) REPORTS

Each year, several Manufacturer and User Facility Device Experience (MAUDE) reports are submitted to the U.S. Food and Drug Administration (FDA) containing data on suspected device-associated deaths, serious injuries, and malfunctions.

In the period from 1 January 2010 to 4 May 2020, 393 cystoscope-related reports were submitted to the MAUDE database. An analysis of all the cystoscope-related MAUDE reports showed that the most common adverse events are patient infections and positive microbiological tests. Patient infections are associated with higher morbidity in patients and increased cost for the healthcare system, and the results underline the importance of identifying and eliminating the causes of infections following cystoscopy.

HOW WAS THE ANALYSIS CARRIED OUT?

Reports were categorised as follows: patient infection (post-procedural), scope malfunction, positive microbiological tests and image defects. Of the 393 reports, 18 reports were not covered by the identified categories and thereby excluded. Of the remaining 375 reports, 188 (50%) reported on patient infection, 94 (25%) reported on positive microbiological test, 84 (22.5%) reported on scope malfunctions and 9 (2.5%) reported on image defects (see Figure 1).

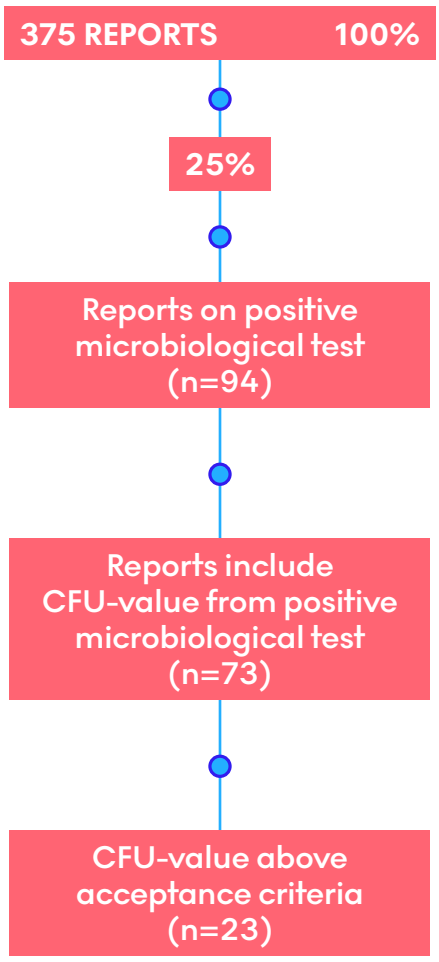


Figure 1. CFU levels among positive microbiological test reports

Among positive microbiological test reports, 73 (78%) included the CFU level, revealing that 23 (32%) of the tests contained unacceptable CFU levels (above 25 CFU/scope, 10 CFU/mL or 10 CFU/channel). 14 (15%) reported on microbiological tests containing pathogenic bacteria above the acceptance criteria.

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 document will not go into depth with the different levels of evidence, but 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 January 1, 2021. Articles published in the English language within the areas of infection control, performance and health economics were included. Commentaries, letters to 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 2014.

This Clinical Evidence Dossier includes summaries of eight published peer-reviewed studies, two case reports and two conference abstracts related to cystoscopy procedures.

This clinical evidence dossier includes summaries of 6 published peer-reviewed studies, 2 abstracts and 1 outbreak report related to cystoscopes and cystoscopy procedures.

PEER-REVIEWED STUDIES

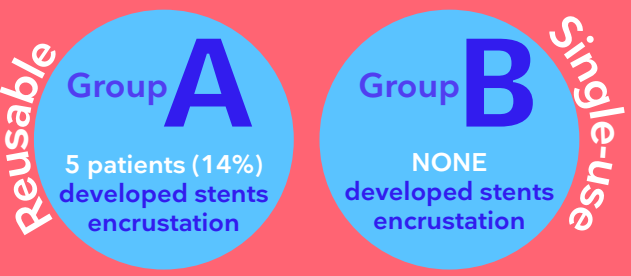
★★★ Cost Open access

TAKE AWAY

This study shows that single-use cystoscopes (Isiris™) significantly reduced stent dwell time and procedural time. It allowed the procedures to be done in the outpatient setting thereby reducing the organizational pressure on endoscopy related diagnostic procedures, and the cost associated to 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 group A and B, respectively (p <0.001).**
- **The stent indwelling time was 26.8 and 15.4 days for group A and B, respectively (p <0.001).**



- **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 reduced from 21 days to 3 days.**
- **Looking at the cost per procedure between group A and group B, it was £365.40 and £252.62 (p <0.001) if the costs of managing complications were considered.**

Comparison of ureteric stent removal procedures using reusable and single-use flexible cystoscopes: a micro cost analysis, Cent Eur J Urol.[1]

Pietropaolo et al. 2020

STUDY AIM

Once ureteral stents are placed, it is commonplace for it to be removed via a flexible cystoscopy in operating room (OR) or an endoscopy room-based outpatient setting. This requires access to reusable flexible cystoscopes, endoscopy room and staff. The availability of these resources affects the organizational capacity, that can delay the stent removal with the prolongment of the hospital endoscopy waiting time. Introducing the single-use cystoscope Isiris™ for JJ stent removals might help ease the workflow for these procedures by its features regarding availability and portability. The aim of this study was to compare the indwelling stent time, cost, stent-related complications and organizational impact for standard cystoscopic stent removal in endoscopy room versus out-patient clinic based stent removal with the single-use cystoscopes.

METHODS

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

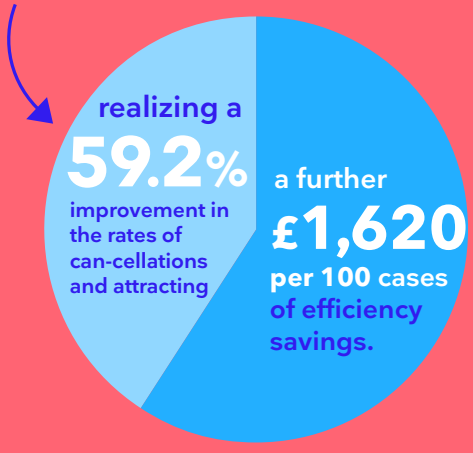
★★★ Organizational benefits Open access

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 reduction in complications.

KEY FINDINGS

- The excess dwell time was significantly reduced in the Isiris group compared with the Standard group.
- The rate of ED attendance whilst the stent was in situ was reduced by 33.5% in the Isiris 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 Isiris 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 Isiris group compared with the Standard group...



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.[2]

Baston et al. 2018

STUDY AIM

Potential complications of indwelling stents include infection, encrustation, the risk of the 'forgotten' stent and the well-recognized stent-related symptoms of pain, strangury and haematuria. Patients often seek further contact with primary care or the emergency department (ED) and may need readmission. Recent evidence further highlights the need to minimize stent dwell time. The single-use cystoscope Isiris™ may help ensure that stents are removed when they are supposed to be, rather than their removal being deferred in favour of diagnostic cases in the endoscopy suites. Therefore, the study aimed to determine whether adoption of the 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 between August 2013 and December 2016 and received a stent were identified.
- In April 2016, in an attempt to standardize the procedure of stent removal, the process of cystoscopic stent removal was moved to the office/clinic environment, utilizing Isiris.
- 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.

★★★ Organizational benefits Open access

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).**

Direct to cystoscopy: A prospective quality assessment of patient preferences, Can Urol Assoc J.[3]

Assmus et al. 2020

STUDY AIM

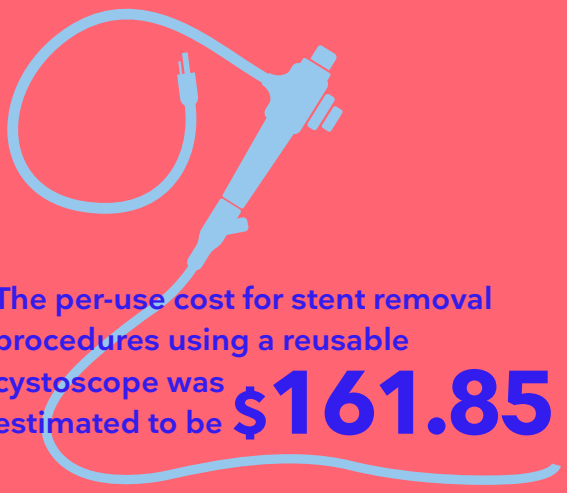
In many outpatient centres, patients need to schedule a follow-up appointment to have a cystoscopy after a clinical consultation, instead of going directly to cystoscopy (DTC). This is often due to the limited number of cystoscopes available for unplanned cystoscopies. Single-use cystoscopes are always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

★★★ 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.[4]

Beebe et al. 2020

STUDY AIM

Although removal of JJ stents only takes a few minutes to perform, the set-up of an office visit for a ureteral stent removal can be burdensome and labour-intensive. It often requires staff members with knowledge of the sterilization process, time to set up the room and periodic maintenance of the equipment. Single-use eliminates the need for reprocessing, and, with a rising trend in disposable scope usage in urologic surgeries, it is important to consider the cost ramifications to the health care system. Hence, 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 removal using a single-use cystoscope versus the Olympus® (CYF-VH) reusable flexible 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)
  - Sterilization equipment and the accompanying accessories, as well as the service contract for the sterilizing equipment

★★☆ Cost Not open access

TAKE AWAY

The single-use cystoscope for JJ stent removal, Isiris, 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 for procedure was estimated at €361 for in-office stent removal with Isiris, and €1,126.8 for OR stent removal with Storz™ reusable flexible cystoscope.**
- **Considering the 127 procedures 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, Urol J.[5]

Oderda et al. 2020

STUDY AIM

JJ stent removal is usually performed using a flexible cystoscope with a grasper. It requires an endoscopic room with video equipment and endoscopic instruments that need to be disinfected after each procedure, which might limit the number of procedures. 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. Hence, the aim of the study was to perform a cost-effectiveness analysis of a single-use cystoscope for JJ stent removal (Isiris™) in this institution.

METHODS

- A total of 127 consecutive patients undergoing in-office stent removal with Isiris 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 Isiris™ versus the traditional 16-Ch Storz™ reusable flexible cystoscope included:
  - A Storz™ flexible cystoscope plus grasper
  - OR occupancy
  - Medical personnel, including also the aid of a nurse
  - High-level cystoscope disinfection
  - Isiris cystoscope and Isiris™ monitor purchase
  - Repairs in the case of damages to reusable cystoscopes (included one serious damage each year).

★★☆ Cost Not open access

TAKE AWAY

The authors find, that the cost benefit for their department with the introduction of the single-use cystoscope has been a surplus of $104,434 (AUD), with an extra 65 elective spaces free for diagnostic flexible cystoscopy cases. 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.

KEY FINDINGS

- **In the 12 months prior to introducing the single-use cystoscope, 13 reusable cystoscopes were damaged, costing $4888 (AUD) in repairs and replacements per month.**
- **In the period after introducing the single-use cystoscope, one scope has been damaged at a cost of $920 (AUD) per month.**

This resulted in a cost savings of approximately $23,809 on repairs and replacement over this six-month period.

- **Considering the 127 procedures performed in-office rather than in the OR, 64 hours of OR time was saved.**

Prospective trial of single-use, flexible cystoscope for ureteric double-J stent removal: Cost and utility analysis, J Clin Urol.[6]

Donato et al. 2019

STUDY AIM

Since their invention, JJ stents have been a critical tool in urological practice and their insertion and removal is one of the most common procedures performed. Removal of JJ stents requires significant resource allocation and given the costs associated with additional staffing, sterilisation process and repairing of damaged scopes, the authors introduced a single-use cystoscope (Isiris™) into their hospital. After completing a thorough procurement process, the authors prospectively studied the benefits of the single-use system to their patients, examined its effect on productivity and endoscopy use, and performed a cost-benefit analysis.

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, repair costs of reusable scopes over the 12 months prior to introducing single-use cystoscopes and 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.

★★★ Cost Open access

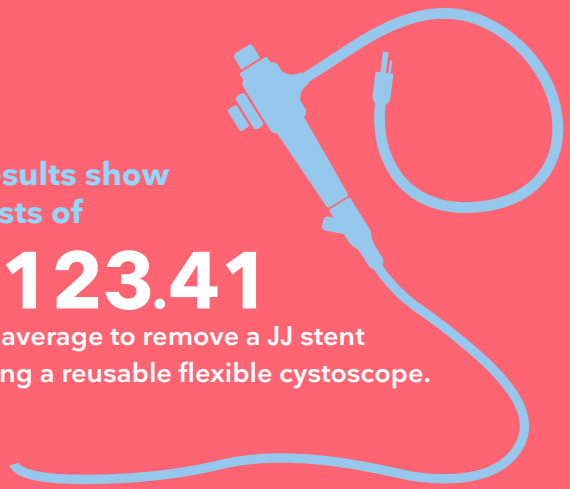
Cost analysis and service delivery on using Isiris α™ to remove ureteric stents, J Endoluminal Endourol.[7]

Phan et al. 2018

TAKE AWAY

The single-use cystoscope provides clinicians with flexibility and ease in removing JJ stents in the outpatient clinic, reducing the pressure and demand for dedicated flexible cystoscopy slots in the endoscopy department. This flexibility in the use of the single-use cystoscope may prevent unnecessarily long journeys for patients in remote areas.

KEY FINDINGS



Results show costs of

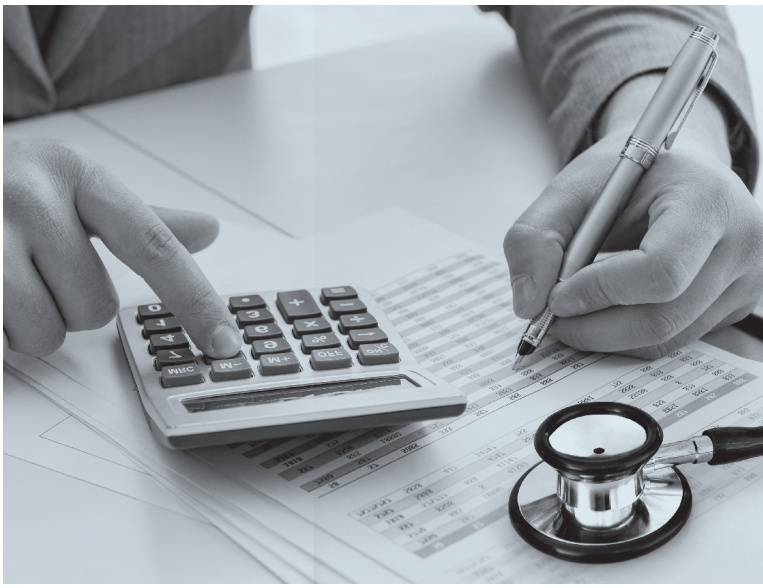
£123.41

on average to remove a JJ stent using a reusable flexible cystoscope.

- **Stent removal in the endoscopy department was delayed in 60% of patients, on average 6.4 days, compared to 0% of patients using the single-use cystoscope.**

STUDY AIM

Traditional reusable endoscopes are often associated with high maintenance costs, an expensive sterilization process, and the risk of transmitting diseases such as Creutzfeldt-Jakob. Single-use cystoscopes eliminate the risk of cross-contamination and the need for reprocessing after use. The study aimed to evaluate cost analysis and service delivery on using a reusable digital flexible cystoscope versus a single-use cystoscope for JJ stent removal (Isiris™) in a district general hospital in the UK.



METHODS

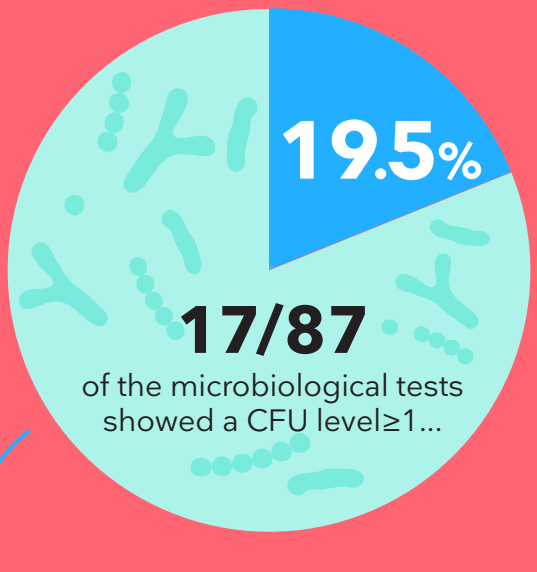
- The authors compared the cost of removing JJ stents using the single-use cystoscope in 10 patients prospectively versus 10 patients using the Olympus® (CYF-240) reusable flexible cystoscope retrospectively.
- Costs, excluding staffing, were accrued from sources within the endoscopy, pharmacy and procurement departments within the hospital, and from organizations that provided the products to the department.

★★☆ Infection Control Not open access

TAKE AWAY

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

KEY FINDINGS



Indicating that the cystoscopes were conta-minated. 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.**

Évaluation microbiologique de la désinfection des cystoscopes souples au CHRU de Brest de janvier 2007 à décembre 2014, Prog en Urol.[8]

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 present study aimed to provide epidemiological data on the monitoring of the microbiological quality of cystoscopes used in a hospital. The aim 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 the ministerial recommendations after indications that a cystoscope was con-taminated at CFU level≥1.

CONFERENCE ABSTRACTS & OUTBREAK REPORTS

★☆☆ Organizational impact Open access

What are the organizational impacts of the new single use solution for the DJ stent removal procedures? Eur Urol Open Sci.[9]

Campanario et al. 2020

TAKE AWAY

This data analysis revealed that the single-use cystoscope for JJ stent removal (Isiris) has a significant positive organizational impact compared to the traditional procedure with reusable cystoscopes. This impacts staff availability positively, increases the capacity of the department and decreases the patient's time in the unit.

KEY FINDINGS

The total number of removals performed increased by

37.8%

from 74 (group A) to 102 (group B). The number of staff required decreased from 4 to 3, and the time spent by each staff, room occupation and patient's time decreased significantly by 21% to 35% p<0.001. The mean dwell time was 20 days in both groups, as defined by our protocol. One UTI was noticed in reusable group versus zero in Isiris (NS).

STUDY AIM

The authors of this study had experienced a growing number of endoscopy procedures in their urology department. The increase in JJ stent removal procedures impacted the organization of the unit due to the complex set-up supporting the increase in procedures (e.g. periodic maintenance, repairs due to the use of grasper in the working channel, scope reprocessing with risky chemicals, etc.). To overcome this, the department implemented the single-use cystoscope for JJ stent removal (Isiris™). The aim of this study was to assess the organizational impact of implementing the single-use cystoscope for JJ stent removal procedures.

METHODS

- Retrospective data collection of organizational indicators was made. These included number of removals, number of staff involved, procedure durations, dwell time, infection and sick leave.
- JJ stent removal procedures were compared in period A (Feb-Sept 2017), using a reusable scope, to period B (Feb-Sept 2018), using the single-use cystoscope for JJ stent removal (Isiris).

★☆☆ Infection Control Not open access

TAKE AWAY

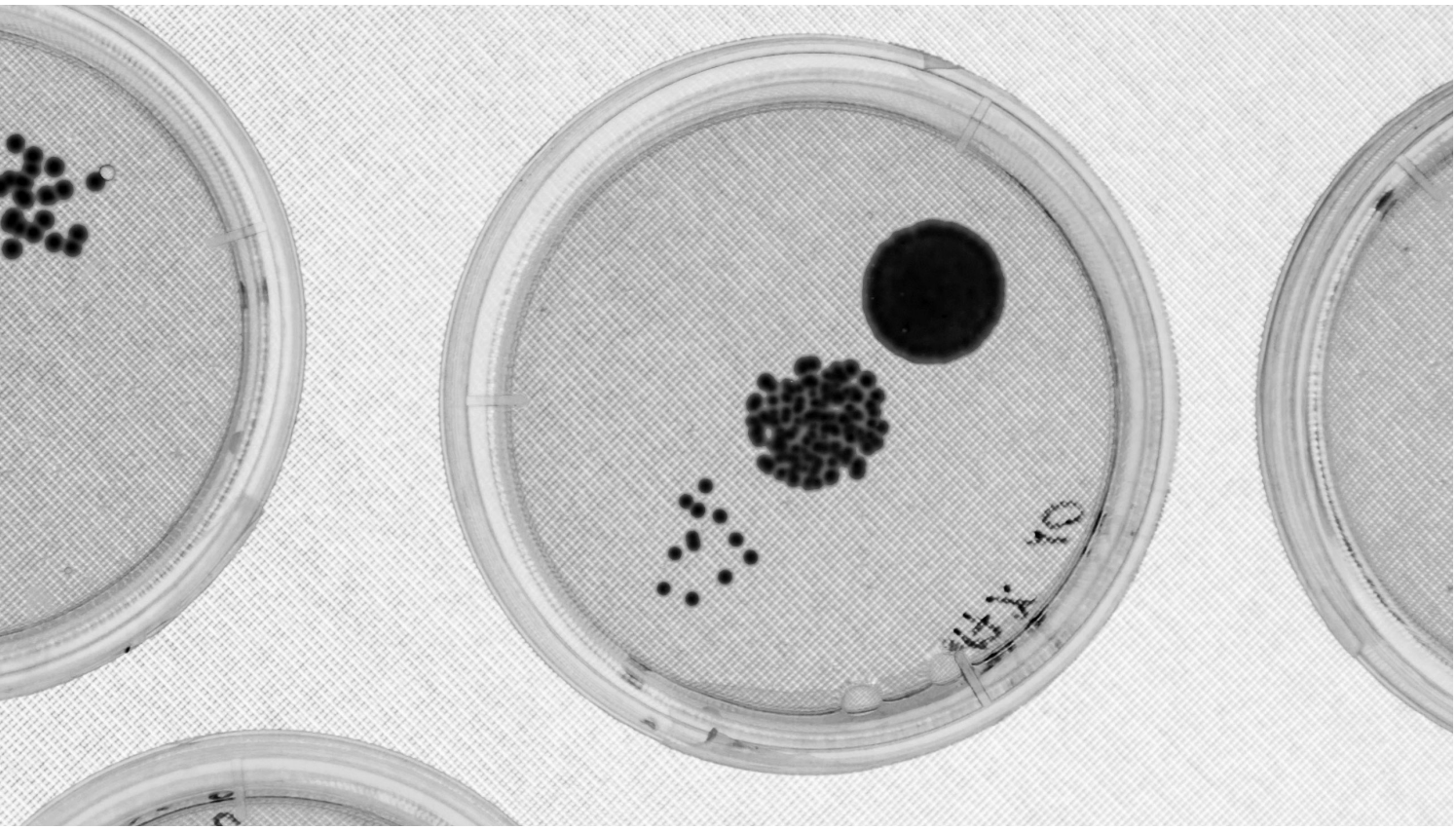
This outbreak strongly suggests that we should not trivialize UTIs occurring after an elective cystoscopy. Patients should be advised to signal the occurrence of urologic symptoms after urologic exploration. In the case of concomitant infections caused by P aeruginosa, the cystoscope should be suspected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

An outbreak of Pseudomonas aeruginosa urinary tract infections following outpatient flexible cystoscopy, Am J Infect Control.[10]

Sorbets et al. 2019

EVENT DESCRIPTION:

Between July 7, 2015, and 31 May 2016, 389 patients underwent cystoscopies, including 104 patients using the cystoscope number 419. In the meantime, 151 samples were positive for Pseudomonas aeruginosa in the 4 relevant units, including 98 urine samples. Four of the 104 patients exposed to the cystoscope number 419 had a Pseudomonas aeruginosa positive sample after cystoscopy. None of the 285 patients exposed to the 3 other cystoscopes were contaminated with Pseudomonas aeruginosa. Between May and October 2016, the urologists reported 4 further cases, all exposed to cystoscope number 419. Altogether, 11 patients presented with a Pseudomonas aeruginosa UTI after cystoscopy with the cystoscope number 419, and the outbreak lasted 9 months.



★☆☆ Cost Open access

TAKE AWAY

Performing the JJ 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 options such as single-use cystoscopes for JJ stents 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 to other activities in the endoscopic room and OR and decrease 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 occupational 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, J Urol.[11]

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. By using a single use flexible cystoscope (Isiris™) with integrated grasper dedicated to JJ stent removal, the institution has been able to perform JJ stent removals in a consultation room instead. Hence, the aim of this study was to compare the cost of a JJ removal in the endoscopic room and/or OR with reusable instruments to the cost of JJ removal with the single-use cystoscope 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 sterilization), cost of video equipment (including material purchase, maintenance and light cable reprocessing), and cost of endoscopic room or OR occupancy for 30 minutes.
- The costs of JJ stent removals in and endoscopic room or OR were compared to the cost of a JJ removal performed in an outpatient consultation room with the single-use cystoscope, including its purchase, waste process, and room occupancy for 30 minutes.

★☆☆ Infection Control Open access

TAKE AWAY

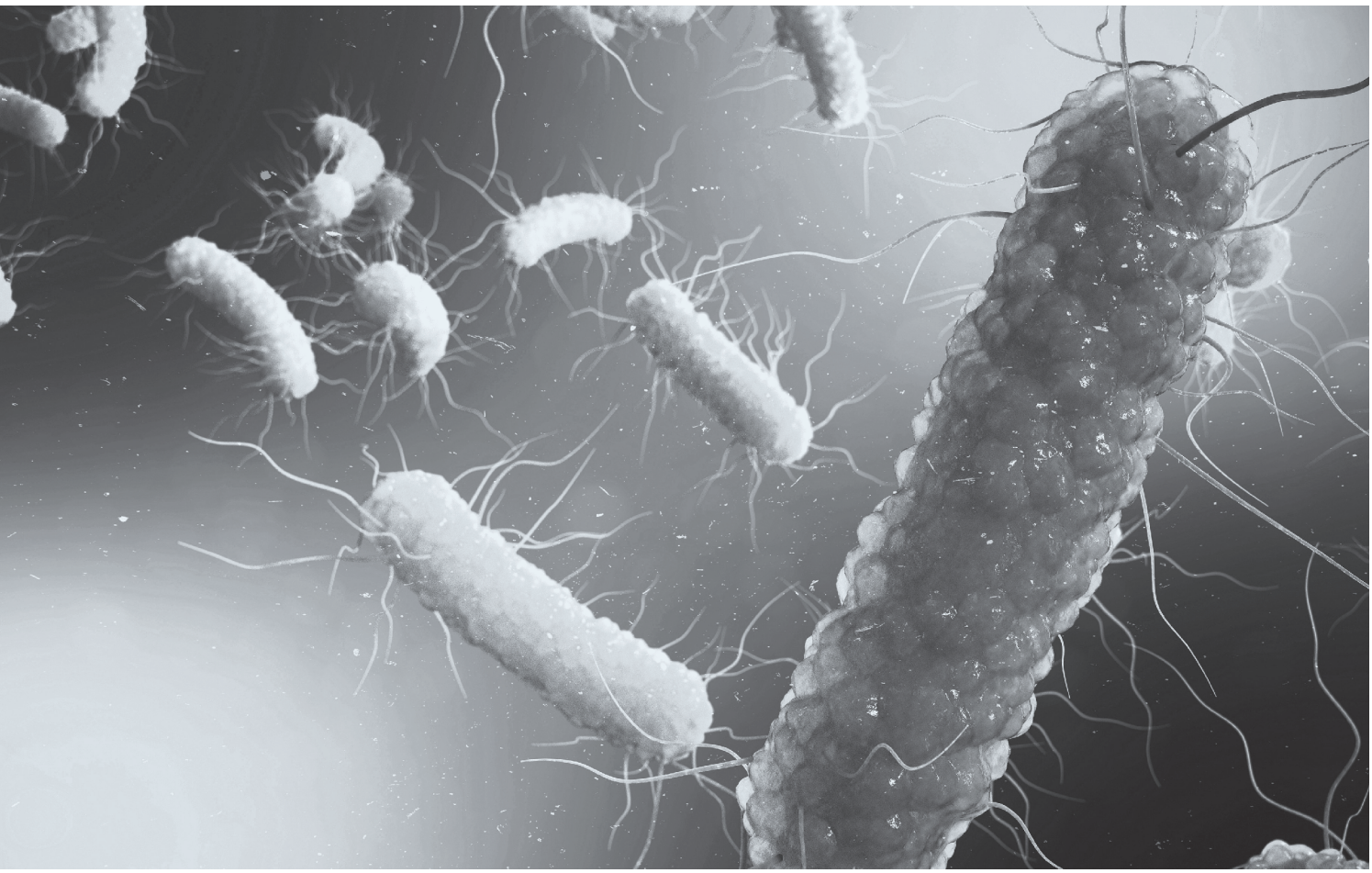
Strict control of cleaning and disinfection of the instruments should be carried out to avoid transmission of infections related to the use of devices.

Outbreak of Urinary Tract Infections by Salmonella Spp. after Cystoscopic Manipulation, Actas Urol Esp.[12]

Jimeno et al. 2016

EVENT DESCRIPTION:

Between October and November 2014, microbiology reports noted the unusual grouping of several isolates of Salmonella spp. (N = 4) in urine culture, indicating the possible existence of an outbreak. A retrospective collection of epidemiological, clinical, and microbiological data of cases was developed, showing that all patients had once undergone a cystoscopy. The cystoscopes were thoroughly cleaned, changing the antiseptic solution in advance. None of the environmental samples collected for culture was positive. In the outbreak, the index patient presented gastrointestinal symptoms along with urinary incontinence, so there is the possibility that urethral colonization occurred due to contiguity.



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, 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 are done, they simply dispose of it; there is no more hassle with cleaning.

EXCELLENT IMAGING AND MANOEUVRABILITY
With aScope 4 Cysto, physicians can count on clear, sharp images, which 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, eliminating the risk of patient cross-contamination.
- No need for post-procedure cleaning or repair, which eliminates various steps in order to optimize 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. No long-term service contracts or leasing agreements.
- Brand new every time, with excellent imaging and manoeuvrability.
- The single-use concept frees up resources by eliminat-ing reprocessing and costly repairs. Resources can be used for more cystoscopies and other procedures.

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