A PROSPECTIVE EVALUATION OF A NURSE-LED STENT REMOVAL SERVICE USING THE SINGLE-USE ISIRIS® IN A TERTIARY REFERRAL STONE UNIT AND ITS IMPACT ON PATIENT WAITING TIMES

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ABSTRACT

Background and Objective
Double J (JJ) ureteric stenting represents one of the most significant causes of patient discomfort and dissatisfaction following endourological procedures. At our institution, a large tertiary referral centre for complex stones, standard JJ stent removal was previously undertaken with a flexible cystoscope (FC) in the endoscopy department by a doctor. The pathway was prone to delays through capacity constraints and prioritization being given to cancer investigations. The Isiris® is a single-use stent removal system consisting of a ‘camera on chip’ disposable FC with an integrated grasper. We examine the feasibility of a nurse-led stent removal service using Isiris®, performed as an office-based procedure, and its effect on waiting times.

Material and Methods
A specialist stone nurse undertook training in FC approved by the British Association of Urological Surgeons (BAUS) and the British Association of Urological Nurses (BAUN). Once competency was reached, a nurse-led service was offered to patients in the outpatient setting. A prospective database from April 2018 to March 2020 was maintained to include patient data for stent removals in the nurse-led clinic using Isiris®. This was compared to a retrospective dataset of FC and stent removal between July 2016 and December 2016, performed by a doctor in the endoscopy department. The delays in stent removal compared to the ‘ideal’ stent removal date (planned date plus or minus 3 days tolerance allowed) were compared between the two pathways.

Results
The specialist nurse undertook BAUS theory training and competency was reached using an approved BAUS/BAUN competency package. 414 stent removals were booked in the nurse group, of which 395 were undertaken. 291 of 395 (74%) patients in the nurse removal Isiris® group had their stent removed on time, whereas only 16 of 54 (30%) patients had their stents removed on time in the FC stent removal group. A delay of more than 21 days was seen in 22% of FC group vs only 2% in the nurse-led Isiris® group. Both planned removal and actual stent dwell time were longer in the FC group compared to Isiris® group (p < 0.0001). There were no major complications with the use of Isiris® for stent removal in the nurse-led clinic.

Conclusion
This study has demonstrated that it is feasible to introduce a nurse-led stent removal service. The introduction of this service using the Isiris® system has led to a reduction in delays of stent removal, which is likely to translate into significant quality of life improvement for patients and economic benefits for the healthcare system.

Key Words: Isiris®, nurse-led, single-use, stent removal, flexible cystoscopy
INTRODUCTION

Insertion of an indwelling JJ stent is commonly performed after endourological procedures, including ureteroscopy (URS). While EAU guidelines\(^1\) suggest that routine stenting need not be performed in uncomplicated cases, there is no consensus on the definition of a complicated URS or the associated risks. UK-based multicentre audits have shown that post-URS stenting was performed in 65–68% of patients\(^2\),\(^3\). Furthermore, there is a lack of evidence on the optimal stent dwell time and, in practice, depending on the healthcare system, logistics often determine when a stent can be removed.

The standard pathway for stent removal includes placement on a flexible cystoscopy list which commonly is consultant or urology trainee led. These lists are generally prioritized to meet cancer diagnostics targets resulting in increasing pressures on service provision. In a high output stone centre, the volume of cases awaiting flexible cystoscopy and removal of ureteric stents may lead to delays in removal due to capacity issues. As a consequence, patients are at risk of prolonged morbidity including pain and discomfort, reduced quality of life, urinary tract infection, stent encrustation and migration, and in the worst-case scenario, a forgotten stent.

An alternative pathway, to remove these bottlenecks, is to train additional staff, such as a urology clinic nurse specialist (CNS), and remove this service from the endoscopy department where there are capacity constraints. Nurse-led cystoscopy bladder cancer surveillance and one-stop clinics have become the standard of care in many urology units. The role of specialist nurses in undertaking independent flexible cystoscopy clinics has been well-established. BAUS and BAUN have published guidelines for training and assessment of nurse cystoscopists.\(^4\) The accuracy and diagnostic ability of specialist nurses conducting cystoscopy is proven to be equivalent to urology trainees.\(^5\) Additionally, the advantages of nurse-led cystoscopy clinics include continuity of care and availability of a consistent responsible health professional.\(^6\) Instituting a nurse-led dedicated clinic for removal of ureteric stents is a pragmatic approach towards ensuring continuity of patient care and a reduction of delays in stent removal.

Isiris\(^*\) is an integrated system with a single-use digital cystoscope with a built-in light source, stent grasper, and a portable monitor. Its safety and efficacy have been evaluated in a prospective multicentre study, which showed good results in terms of image quality, maneuverability, and grasper functionality.\(^7\) Whereas a flexible cystoscopy procedure requires a dedicated endoscopy unit, Isiris\(^*\) can be used in an office-based or even ward-based set-up. The need for regular disinfection of conventional cystoscopes is eliminated and a separate assistant for stent grasper is not necessary. Except for a chaperone, there are no extra staffing requirements. All these factors can potentially increase the capacity for the number of stent removal procedures performed on a certain list thus reducing waiting times.

The study aims to evaluate the feasibility of a nurse-led ureteric stent removal clinic using Isiris\(^*\) and its impact on waiting times for ureteric stent removal. We compare the waiting times to the standard pathway, which involves flexible cystoscopy and stent removal by a urology doctor in the endoscopy unit.

METHODS

Nurse-Led Clinic

The urology department at Addenbrooke’s Hospital, Cambridge University Hospitals NHS Trust, provides a comprehensive stone service as a tertiary centre. A nurse-led stent removal clinic was set up in April 2018 under the leadership of our stone CNS (JC), who also assumed responsibility for all the nursing activity in the clinic. The operational policy involved Local Safety Standards for Invasive Procedures (LocSSIPs) based on National Safety Standards for Invasive Procedures (NatSSIPs).\(^8\) JC undertook a structured training program consisting of a theory study day and a formal competency package provided by BAUN and approved by BAUS.\(^9\) Additionally (a) Advanced clinical skills and assessment, (b) Non-medical prescribing training, and (c) Local competency assessments were achieved. Training was completed by the CNS before initiation of the service. Booking process involved electronic ordering by the surgeon immediately after the initial procedure. Patients undergoing stent placement were provided with written information and a contact number for the CNS on discharge from hospital. For
the location of the clinic, a day-case ward area, where outpatient stone procedures including shockwave lithotripsy are performed, was selected. Clinic capacity was five patients per list, and all were undertaken using the Isiris® stent removal system. Written consent was obtained in the clinic on the day of the procedure by the CNS after explaining the procedure and the risks. Patient safety measures included a team brief, use of WHO checklists, and de-briefing. A Band 3 health care assistant was assigned as a chaperone, to sign for checklists and to assist with the procedures if necessary. Apart from the Isiris® system, equipment made available in the clinic included (1) Fluid infusion stand, (2) Saline infusion, (3) Giving set, (4) Sterile swabs packs, (5) Chlorhexidine sachets, and (6) Sterile lubricating jelly. Infection control, sterilization, and governance protocols were instituted as per hospital policy.

Isiris® System
Developed by Coloplast®, the system is exclusively designed for removal of ureteric stents from the bladder via a urethral route in adults. It has an integrated grasper, with 2 prongs which are activated by a button on the handpiece. The disposable scope is connected by a cable to a reusable 9-inch portable LCD monitor. Image acquisition is digital with a complementary metal-oxide semiconductor sensor located at the tip of the scope. Although the image quality is comparable to other flexible cystoscopes (FC), it has not been licensed for diagnostic purposes. It provides a 0° view with 85° field of vision, with a deflection of 90° down and 80° up. An irrigation channel with a Luer lock connector can be connected via a given set to a fluid infusion bag. The scope has a 16Fr diameter with a working length of 390mm and has no working channel. Each scope is provided in a sterile pack and disposed of after use thus avoiding cross-contamination. Isiris® was introduced to the Department of Urology at Addenbrooke’s hospital in 2017. There are no reports of major complications attributed to the use of Isiris® for stent removal.

Study Design
This is a single centre study conducted within the Department of Urology at Addenbrooke’s hospital, Cambridge University Hospitals NHS Trust. Consent was obtained as per the trust policy.

INCLUSION CRITERIA
- Adults: Age 18 years and above
- Gender: Male and female
- Indication for stent insertion: Ureteroscopy including laser stone fragmentation for urolithiasis, diagnostic ureteroscopy, Percutaneous Nephrolithotomy (PCNL), pyeloplasty, trauma, reconstruction, and following surgical procedures including colectomy and gynecological procedures including hysterectomy
- Unilateral and bilateral stent removal

EXCLUSION CRITERIA:
- Indication for stent insertion: Renal transplant
- Patients who had stents on a string
- Patients who could not tolerate the local anesthetic procedure
- Patients with poor mobility who were deemed unsuitable for outpatient procedures

Data collection: A prospective database was created to include patients who attended the nurse-led stent removal clinic using the Isiris® system. Each episode of stent removal was recorded separately since April 2018.

The previously existing pathway involved flexible cystoscopy and removal of the stent with a grasper in the endoscopy department. The procedure was booked as a double slot on a generic flexible cystoscopy list in the endoscopy unit and performed by a urology doctor. Data for the FC pathway was collected retrospectively from the endoscopy lists and electronic patient records.

The following data parameters were recorded for the stent in each group:
1. Demographics: age and gender
2. Date of stent insertion
3. Indication for stent insertion
4. The planned stent removal date
5. The actual stent removal date
6. Delay* in stent removal in days
7. Failure of stent removal
8. Adverse events

*Delay was defined as a removal date which was overdue by more than 3 days after the planned date.
Outcomes: Primary outcome was a reduction in waiting times in the nurse-led clinic using Isiris® compared to the previously existing standard pathway. Secondary outcomes included the failure of stent removal and adverse events for Isiris®.

Statistics: Analyses were performed using IBM SPSS statistics software, version 26. Statistical tests included t-test, Mann-Whitney U test, Chi-Square test, and Fisher’s exact test to compare the findings between the two groups.

The study was registered as a service evaluation project with the Department of Clinical Governance, Cambridge University Hospitals NHS Trust (registration number – ID1521 PRN7521). As all patients signed an informed consent form and the principles of Declaration of Helsinki were followed, a formal ethics committee review was not deemed necessary.

RESULTS

The dedicated stone CNS in our department completed training in cystoscopy which included observing 14 FCs (recommended 10) and performing 78 FCs (recommended 40) under clinical supervision. A further 15 stent removals were performed using the Isiris® under supervision.

Between April 2018 and March 2020, a total of 414 episodes were recorded from the nurse-led stent removal clinic using Isiris®. Mean age was 59 years (median 60 years; range 18 to 94 years) and male: female ratio was 1.6:1; male: n = 253 vs female: n = 161 in the nurse-led clinic group. The data for the standard pathway using FC included 54 episodes between July 2016 and Dec 2016. For patients in the FC group, mean age was 61 years (median 66 years; range 24 to 94 years) and gender distribution was male = 28 and female = 26 (ratio 1.07:1). There was no statistically significant difference in the age distribution between the two groups (p = 0.37).

Out of 414 planned stent removals in the nurse-led clinic, 19 (4.5%) stents were not removed for the following reasons:

- Stent not visualized using Isiris® (n = 4); 2 stents were retracted into the ureter and were later removed by URS; 1 not removed due to poor bladder views and 1 not removed due to difficulty maneuvering the scope (via prostatic urethra) which were removed at a later date by a urology doctor
- Stent encrustation (n = 1); stent removed at a later date during elective PCNL
- X-ray on the day showed persistent stones and patient was listed for URS (n = 3)
- Patient death prior to stent removal (non-surgical cause; n = 1)
- Patient declined local anesthetic procedure on the day of the appointment (n = 5)
- Patient moved out of the area, cancellations due to administrative error or staff sickness (n = 5).

Thus true procedural failure using Isiris® was seen in only 2 (0.5%) cases in nurse-led clinic. Indications for stent insertion for patients seen in nurse-led stent removal clinic were classified as follows:

1. Ureteroscopy (including laser lithotripsy) for stones; n = 266 (67.3%)
2. Diagnostic Ureteroscopy +/- biopsy; n = 37 (9.4%)
3. PCNL +/- Combined procedure; n = 40 (10.1%)
4. Post-Pyeloplasty for PUJO; n = 11 (2.8%)
5. Reconstruction; n = 11 (2.8%)
6. Urological trauma; n = 4 (1%)
7. Surgical or Gynecological procedures; n = 6 (1.5%)
8. Other (including ureteric obstruction); n = 20 (5.1%)

Not surprisingly, the highest number of stent insertions was for endourological procedures. In comparison, indications for stent insertion in the FC group included (a) Ureteroscopy for stones (n = 48; 89%), (b) Diagnostic Ureteroscopy +/- biopsy (n = 2; 4%), and (c) PCNL +/- Combined procedure (n = 4; 7%). The discrepancy in indications between the two groups is likely due to the retrospective data capture process in FC group.

Delays in Stent Removal

For the 395 successful Isiris® stent removals, 291 (74%) were removed on time (planned date +/- 3 days), 55 (14%) were delayed by 4 to 7 days, 40 (10%) were delayed by 8 to 21 days and a further 9 (2%) stents were removed after 22 days of the planned date. In the FC group, only 16 (30%) were removed within the planned date +/- 3 days. A delay

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of 4 to 7 days was seen in 5 (9%) stent removals, 8 to 21 days delay was seen in 21 (39%) and 12 (22%) were removed beyond 22 days. Table 1 illustrates the proportion of delays in the FC and Isiris® groups. Thus, waiting times and delays in stent removal were significantly lower in the nurse-led Isiris® clinic (p < 0.0001).

**Planned Removal Time vs. Dwell Time**

Median planned stent removal time in Isiris® group was 14 days (mean 17 +/- SD 9.7; range 3 to 120) and median dwell time was 18 days (mean 20 +/- 13.4; range 2 to 168). In the FC group median planned removal time was 21 days (mean 19 +/- SD 4.9; range 7 to 28) and median stent dwell time was 29 days (mean 31 +/- SD 14.2; range 5 to 69). The nurse-led clinic allowed stent removal to be planned at an earlier date. As a result, the stent dwell time was also proportionately lower. The FC group showed a longer duration for planned stent removal and prolonged dwell time as compared to Isiris® nurse-led clinic (p < 0.0001).

**Delay (days) FC Isiris®**

| Delay (days) | FC Number | Percentage | Isiris® Number | Percentage |
|--------------|-----------|------------|----------------|------------|
| 0–3          | 16        | 30%        | 291            | 74%        |
| 4–7          | 5         | 9%         | 55             | 14%        |
| 8–21         | 21        | 39%        | 40             | 10%        |
| 22 or more   | 12        | 22%        | 9              | 2%         |

**TABLE 1.** Delays in Stent Removal in FC vs. Nurse-led Isiris® Clinic

Table 2 shows a summary of planned removal times and dwell times for the various indications for stent removal in the nurse-led clinic. Median planned removal time for URS (diagnostic and laser lithotripsy for stones) and PCNL was 14 days, pyeloplasty, reconstruction and surgical or gynecological procedures, 42 days and urological trauma, 28 days. Overall, there was good conformity between planned removal and actual dwell time. It is interesting to note that stents inserted after diagnostic URS and for trauma had a longer median dwell time (19 days vs planned removal 14 days and 42 days vs planned removal 28 days respectively). One patient with URS and laser lithotripsy requested a later date and hence the dwell time was 54 days. A patient post bladder injury repair had delayed stent removal of 126 days over the planned 42 days (6 weeks) resulting in a dwell time of 168 days. Another patient with a history of retroperitoneal fibrosis was listed for planned stent removal in 4 months/120 days. Hence the dwell time was 120 days but there was no delay in the removal of the stent.

**TABLE 2.** Planned vs. Actual Dwell Time for Stent Removal in the Nurse-Led Isiris® Clinic

| Indications for Insertion     | No. | (%)  | Planned Removal in Days (Median) | Stent Dwell Time in Days (Median; Range) |
|-------------------------------|-----|------|----------------------------------|----------------------------------------|
| URS for stones                | 266 | 67.3 | 14                              | 14 (5–54)                              |
| Diagnostic URS                | 37  | 9.4  | 14                              | 19 (2–50)                              |
| PCNL                          | 40  | 10.1 | 14                              | 14 (7–53)                              |
| Pyeloplasty                   | 11  | 2.8  | 42                              | 42 (51–70)                             |
| Reconstruction                | 11  | 2.8  | 42                              | 42 (39–50)                             |
| Urological Trauma             | 4   | 1.0  | 28                              | 42 (42–168)                            |
| Surgical/Gynecological        | 6   | 1.5  | 42                              | 44 (19–49)                             |
| Other including obstruction   | 20  | 5.1  | 21                              | 21 (14–120)                            |
DELAYS VS INDICATION FOR STENTING IN ISIRIS® NURSE-LED CLINIC

We assessed delays in the nurse-led clinic for the various indications for stenting and the results are summarized in Table 3. The majority of the stents (95%) inserted for ‘other’ indications including obstruction and post-resection of bladder tumour over the ureteric orifice were removed on time. Ureteroscopy with laser lithotripsy, PCNLs, and urological reconstruction had higher numbers of stents removed on time (74.8%, 75%, and 80% respectively). Delays were highest in the small proportions of surgical and gynecological surgery category (66% delayed).

Adverse Events

There were no major complications including post-stent removal urosepsis, hematuria, or readmissions for any other reason. A significant event occurred in a patient with bilateral ureteric stents who had a wrong side stent removed in the Isiris® nurse-led clinic. The views were clear at the time of the removal. However, no harm was caused, and she is awaiting a nephrectomy for a previously non-functioning kidney on the side of the stent that was removed.

DISCUSSION

The first case report of Isiris® use involved the removal of foreign bodies from the lower urinary tract as an ambulatory procedure.11 It recognized the utility of Isiris® as an accessible device for the removal of objects in an ambulatory setting, precluding the need for hospital admissions. Following this, it has been used widely for ureteric stent removal and its safety and efficacy were reported in the first European multicentre prospective evaluation.7 In another study,10 the image quality and functionality compared to four different FCs was favourable. Due to its narrow field of vision, the authors concluded that it was inferior for use as a diagnostic cystoscope. Cost-effectiveness studies12, 13 have indicated that although the Isiris® system itself is expensive, there is an overall cost-benefit if other hidden costs are taken into account. More recently, the use of Isiris® for office-based stent removal was evaluated in a retrospective study by comparing it to endoscopic JJ stent removal.14 There was a reduction in excess stent dwell time from 8 days in the standard group to 0.96 days in the Isiris® group. The outcome was reduced patient complications, improved diagnostic capacity, and cost-efficacy.

Our study is the first prospective evaluation of the use of Isiris® in a nurse-led ureteric stent removal clinic as an office-based procedure. Our findings are supported by robust data collected systematically. Institution of a nurse-led clinic is a feasible and safe practice when organized with appropriate governance policies. We have compared the waiting times to standard practice and demonstrated a significant reduction in delays in stent removal and overall stent dwell time.

The nurse-led clinic in our department was started by a dedicated stone CNS after completion of the recommended training. As this is a structured program, our CNS acquired the skill sets necessary for

| TABLE 3. Delays in Stent Removal for Various Indications in the Nurse-Led Isiris® Clinic |
|---------------------------------------------|-----------------|-----------------|-----------------|-----------------|-------------------|
| Indication                                 | 0 to 3 Days (Removed on Time) | 4 to 7 Days     | 8 to 21 Days    | 22 Days or More |
| URS for stones (n = 266)                   | 199 (74.8%)       | 41 (15.4%)     | 24 (9%)         | 2 (0.8%)        |
| Diagnostic URS (n = 37)                    | 23 (62.2%)        | 5 (13.5%)      | 8 (21.6%)       | 1 (2.7%)        |
| PCNL (n = 40)                              | 30 (75%)          | 4 (10%)        | 4 (10%)         | 2 (5%)          |
| Pyeloplasty (n = 11)                       | 7 (63.6%)         | 1 (9.1%)       | 2 (18.2%)       | 1 (9.1%)        |
| Reconstruction (n = 11)                    | 9 (80%)           | 1 (10%)        | 1 (10%)         | 0               |
| Urological Trauma (n = 4)                  | 2 (60%)           | 0              | 1 (20%)         | 1 (20%)         |
| Surgical/Gynecological (n = 6)             | 2 (33.3%)         | 3 (50%)        | 0              | 1 (16.7%)       |
| Other incl. obstruction (n = 20)           | 19 (95%)          | 0              | 0              | 1 (5%)          |

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safe practice. BAUS recommendations ensure safe competence-based care by delivering CNS training which involves a curriculum in line with the minimum standards required to perform the procedure. Several studies have proved that nurse cystoscopists are extremely efficient in performing FC, especially in bladder surveillance clinics.\(^5\)\(^,\)\(^12\) We have shown that it is possible to introduce independent nurse-led lists for stent removal. The main advantage of a nurse-led clinic is increased capacity by sharing the workload and a reduction in waiting times. It also releases medical staff thus allowing them to undertake the additional alternative activity and, in the case of trainees or residents, more training-oriented rather than service-oriented activity. Since a dedicated CNS is responsible for patient care, it ensures continuity with the stone team. Diagnostic flexible cystoscopy lists can be freed from these therapeutic procedures thus permitting more diagnostic capacity and helping the service to meet the requirements of cancer waiting times.

Our success rate for nurse-led stent removal using Isiris\(^8\) is comparable to the previously quoted success rates of 94% by Doizi et al.\(^7\) There were no cases of equipment malfunction during stent removal in our study and there is only 1 case of previously reported grasper failure.\(^13\) Use of Isiris\(^8\) instead of FC eliminates the need for endoscopy equipment such as a stack, light source and a separate grasper for stent removal. Isiris\(^8\) can be easily transported from one area to another and there is no need for special storage facilities. Similarly, there are cost savings related to disinfection, repair, and maintenance supported by data on single-use ureteroscopes.\(^16\)

We have shown a significant improvement in waiting times specifically for the subset of patients who waited for more than 21 days (2% in Isiris\(^8\) vs 22% in FC group). It would be ideal to see no delays as reported in the study of 10 patients by Phan et al.\(^12\) However, our larger dataset, with the inclusion of varied indications, shows good adherence between planned and actual dwell time. As per practice, we used an arbitrary planned date, which cannot be ideal but optimal time for stent removal is not known, hence dwell times are higher than previously reported.\(^14\) For similar indications, the planned stent removal date and hence the dwell time was much longer in the FC group. The previous pathway did not allow for earlier removal of stents as it was a tendency amongst clinicians to delay it to adjust for the existing logistics and capacity constraints. Our improved practice gives surgeons the confidence to keep the stent duration as short as possible. Prolongation of stent indwell time has risks including encrustation, UTIs, migration, and forgotten stents.\(^17\) All this associated morbidity is certainly avoidable if dwell time is kept to a minimum. Besides, it has an impact on health-related quality of life particularly due to loss of workdays and a longer period of return to daily activities.\(^18\) The economic impact of stent-related problems is well-documented.\(^19\) Recurrent admissions to the hospital incur costs to the department which are not reimbursed. Considering these disadvantages, it is logical that earlier stent removal has health and cost benefits to patients and the healthcare system.

It is important to note that even with our close follow up, there was a considerable delay for one patient with a stent inserted following repair of bladder trauma as an emergency procedure. This group of patients poses a potential risk regarding continuity of care as they are more likely to be lost in a system where shared accountability becomes a matter of concern. Placement of a stent on a string is an alternate option and a more certain way to protect against ‘forgotten stents’ but it has its shortcomings including stent dislodgement and inadvertent earlier removal.\(^20\)

We acknowledge the limitations of our study design as the compare group was a retrospective cohort of smaller size. The study is not randomized, however, we contemplate an RCT would be impractical in this scenario as it would not fulfil ethical considerations. Patient feedback data was not systematically collected in our study; however, Oderda et al\(^13\) have previously demonstrated that Isiris\(^8\) stent removal is well-tolerated by patients. Ultimately, assessment of patients quality of life preoperatively would be a very interesting aspect to study, and this could be done using one of the specifically designed quality of life measures such as the Cambridge Ureteral Stone PROM (CUSP)\(^21\) or the Cambridge Renal Stone PROM (CReSP)\(^22\) for ureteric and renal stone treatments respectively, and then asking the patients to complete the questionnaires
CONCLUSIONS

In our experience, Isiris® is a safe and versatile tool which can be used to ease the burden of capacity issues for ureteric stent removal and ensure timely removal. Based on the above findings, we propose that a nurse-led service using Isiris® should be the standard of care for stent removal. By reducing delays and waiting times significantly, this novel approach shows substantial benefits on a wider scale, including cost-effectiveness. The introduction of such a streamlined service will translate to better patient care and the provision of a better service.

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