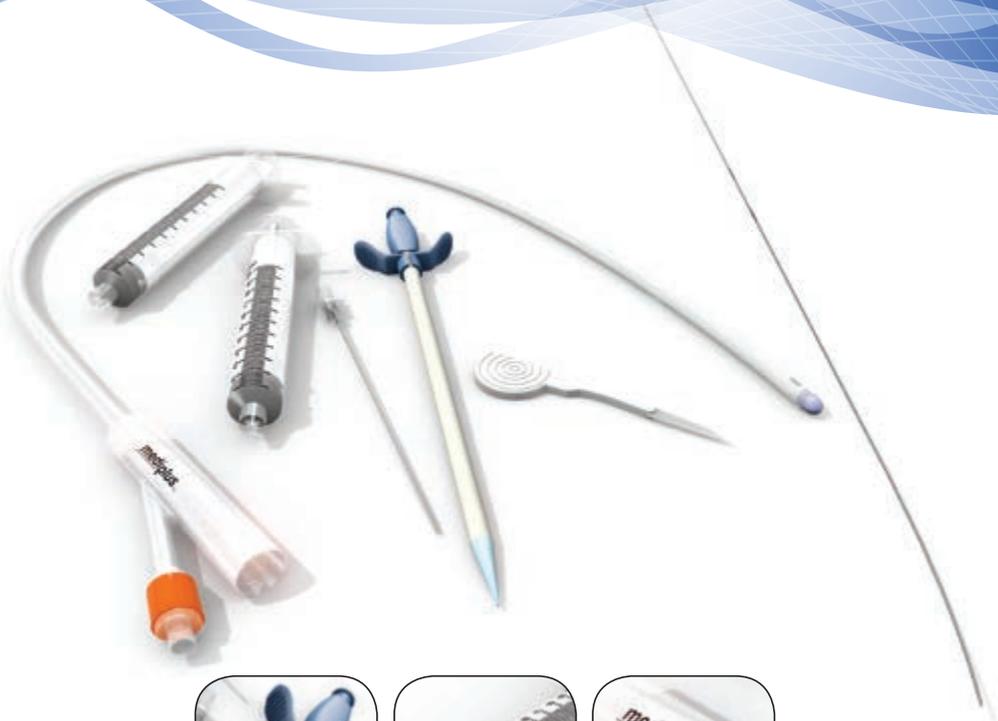


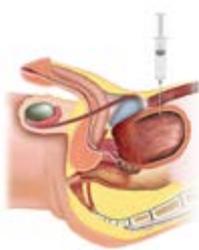
Clinical Summary



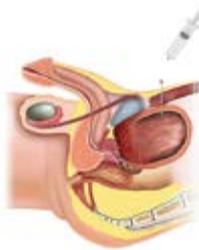
S-Cath™ System

*medi*plus

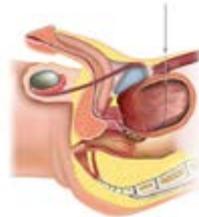
Seldinger Suprapubic Foley Catheter Introducing System



Inject local anaesthetic along a track from the skin incision down to the bladder



Remove syringe of anaesthetic from needle



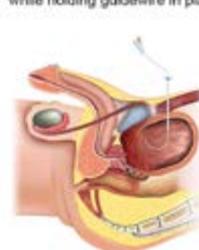
Insert guidewire through needle, floppy end first, up to first black mark; remove needle while holding guidewire in place



Insert trocar into bladder along guidewire to second black mark



Remove trocar and guidewire from outer sheath. Occlude outlet of sheath with thumb to avoid excessive release of fluid from bladder



Insert foley catheter down sheath to mid-point of catheter length. If using paediatric size (code 5758*), remove internal guidewire from catheter before proceeding to next step



Inflate balloon with 10ml sterile water



Slide outer sheath back along catheter shaft until external to abdomen. Pull sheath apart and remove from catheter

*5758 not available in the USA

Benefits of using S-Cath™ System

Utilising the seldinger technique, this patented system facilitates a one tract entry for a more controlled, accurate and precise entry, decreasing the risks associated with standard blind methods.

Why Compromise?

Benefits

- Smaller diameter trocar when compared to standard trocar diameter, thus reducing trauma for a smooth, penetrative entry.
- 7 all inclusive components, saving time.
- 100% silicone Foley catheter with integrated balloon.
- 3 stage guidewire ensuring accurate placement along one anaesthetised tract. ^{5,7,8,9,10}
- Decrease the risk of posterior bladder wall perforations and bowel injuries. ^{5,7,8,9,10,13}
- Facilitate use in an outpatient or sub acute setting. ^{5,7,8,9,11}
- Greater confidence for the user. ^{12,14}

Mediplus

Mediplus was established in the United Kingdom in 1986. The Company's focus is the research, development, manufacture and marketing of innovative medical devices that meet the needs of patients and clinicians worldwide.

The Mediplus philosophy is to provide high quality products at fair prices supported by excellence in customer service. The Company sells direct to end-users in the United Kingdom and to more than forty countries internationally through a network of carefully selected distributors.

On the 22nd April 2013, Mediplus received The Queen's Award for Enterprise – International Trade. These awards are made annually by HM The Queen, and are only given for the highest levels of excellence



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BJUI, www.bjui.org, Atlas of Surgery, Mar 2008

Department of Health Briefing Pack: S-Cath™ System Suprapubic Foley Catheter Introduction Set



August 2012

The S-Cath™ System is a suprapubic catheter introduction set that is manufactured by Mediplus Ltd. The system helps to reduce the number of complications associated with suprapubic catheterisation, is safer for patients and can produce cost savings for NHS Trusts. The transfer of the procedure from an inpatient to an outpatient setting can benefit patients and can dramatically reduce the associated length of stay.

This Briefing Pack looks at the S-Cath™ System, how it works, the evidence available, the clinical and system benefits and the financial case. It also presents the findings of two trusts where the technology has been used.

Findings from the contributing Trusts, detailed in Section 10, include:

- The technology is safe in use, especially for more junior staff, and that it produces a clean and neat incision compared to the previously used system. Patients have responded positively to the technology and are, on the whole, pleased with the results.
- The Trust has seen a reduced length of stay, reduced complications, a reduction in healthcare associated infections and has benefited from realising savings.

Feedback from NHS Sites using S-Cath™ System

For the production of the briefing document, opinion was sought from two NHS Trusts, Sheffield Teaching Hospitals NHS Foundation Trust and Taunton and Somerset NHS Foundation Trust, who have used or who currently use this technology.

Sheffield Teaching Hospitals NHS Foundation Trust has used the S-Cath™ System for a number of years and it is fully embedded within their routine service. They use the system for patients who have chronic retention of urine, neurological problems or who require emergency catheterisation due to a bladder outlet obstruction. The Trust has found that the technology is safe in use, especially for more junior staff, and that it produces a clean and neat incision compared to the previously used system. Patients have responded positively to the technology and are, on the whole, pleased with the results.

Taunton and Somerset NHS Foundation Trust has used this product since 2007 and it is fully implemented and embedded within their service. They currently use the product for anybody requiring a suprapubic catheter. Specifically, this includes patients in acute retention of urine, neurological patients and those suffering with a bladder outlet obstruction. They currently run two specific suprapubic catheter clinics per month in outpatients. These clinics are staffed by a specialist nurse and a care assistant and they see approximately five patients per clinic. The implementation of these clinics has helped to reduce the patient's length of stay from up to three days down to an average of 37 minutes. Initially the Speciality Urology Nurse was trained to perform the procedure by the Consultant Urologist. Following many years of experience, the Specialist Nurse now undertakes the training of medical staff in the procedure. The Trust has seen a reduced length of stay, reduced complications, a reduction in healthcare associated infections and has benefited from realising savings. Angus MacCormick, Specialist Urology Nurse at the Trust says, **"The main thing is it gives you more confidence in knowing that there is a reduction in serious complications"**.



British Association of Urological Surgeons' Suprapubic Catheter Practice Guidelines



Simon C.W. Harrison*, William T. Lawrence†, Roland Morley‡, Ian Pearce and Joby Taylor§
*Pinderfields General Hospital, Wakefield, †Eastbourne District General Hospital,
Eastbourne, ‡Kingston Hospital, Kingston upon Thames, and §Manchester Royal
Infirmary, Manchester, UK. *BJU International*, Volume 107, Issue 1, pages 77–85, January 2011

Objectives

To report the British Association of Urological Surgeons' guidelines on the indications for, safe insertion of, and subsequent care for suprapubic catheters.

Methods

A comprehensive literature search was conducted to identify the evidence base. This was reviewed by a guideline development group (GDG), who then drew up the recommendations. Where there was no supporting evidence expert opinion of the GDG and a wider body of consultees was used.

Results

Suprapubic catheterisation is widely used, and generally considered a safe procedure. There is however a small risk of serious complications. Whilst the evidence base is small, the GDG has produced a consensus statement on SPC use with the aim of minimising risks and establishing best practice (Table 1). It should be of relevance to all those involved in the insertion and care of suprapubic catheters.

Given the paucity of evidence, areas for future research and development are also highlighted. This review has been commissioned and approved by BAUS and the Section of Female, Neurological and Urodynamic Urology.

Conclusions

It is hoped that these guidelines will assist in minimising morbidity associated with SPC usage. Insight message Trocar systems are in widespread use and, relatively recently, a modified trocar system has been introduced that utilizes the Seldinger principle¹. The use of a Seldinger guidewire may allow a more controlled insertion of a trocar and sleeve than may be achieved using a standard trocar.

¹ NHS Technology Adoption Centre. The Seldinger suprapubic catheter kit. Available at:
<http://www.technologyadoptionhub.nhs.uk/the-suprapubic-foley-catheter-kit/executive-summary.html>
Accessed 19 September 2010

A dedicated Specialist Nurse led Suprapubic Catheterisation Clinic: The Taunton Experience

J.Jelski, Xi Cheng, Faith McMeekin, A. MacCormick, R. Macdonagh, Musgrove Park Hospital, Taunton, UK

Introduction

The purpose of this audit is to show how a dedicated Nurse led suprapubic catheterisation clinic has fundamentally changed the practice in our Hospital whilst improving safety and providing ample training opportunities and increased patient satisfaction.

Method

Retrospective review of our specialist nurse led SPC service using USS guided Seldinger technique 2007- 2013.

Results

- 402 SPCs inserted in period audited including emergencies.
- Of those inserted via Trocar 90% were under GA with average LOS 2.25 days.
- Of those inserted via the Seldinger technique 100% were under LA with average LOS 28 minutes.
- No LA SPC mortalities and <1% risk of Visceral injury.

Conclusion

- Reduced hospital stay and use of GA lists
- Below quoted risks for mortality and visceral injury
- Improved local training and experience

Introducing a new technique for suprapubic catheterisation

McMeekin F, MacCormick A, MacDonagh R
Musgrove Park Hospital, Taunton, UK
Continence UK, 2010, Vol 4, No 1

Take home message

- Conventional suprapubic catheterisation insertion using kits with a trocar can be daunting to the user, as well as the patient.
- The Seldinger technique allows controlled entry of the trocar into the bladder over a guidewire and is designed to reduce the potential hazards of the blind technique.
- The equipment consists of a long needle, guide-wire, trocar with outer sheath and a silicone catheter.
- The MediPlus guide-wire is the key to success of this technique.
- Introducing the Seldinger MediPlus suprapubic catheter has allowed the authors to offer an outpatient suprapubic catheterisation service.
- This technique has proved so effective that it has been advocated by the NHS Technology Adoption Hub.

Table 1 Comparison of conventional SPC and Seldinger System

	Conventional SPC	Seldinger MediPlus SPC
General anaesthetic (%)	90	3
Duration of stay (%)	2.3 days	28 mins
Insertion in theatre (%)	91	11
Insertion in OP clinic (%)	0	75

Table 1 shows the comparison of traditional trocar only based products with S-Cath™ System. The two key messages are:

1. The procedure can now be carried out in an outpatient setting removing the need for General Anaesthesia.
2. The associated morbidity is reduced using S-Cath™ System, hence the reduction in length of stay.

Optimising safety of catheterisation

The Clinical Services Journal, October 2009

Objectives

- Unlike traditional suprapubic catheterisation procedures performed in the operating theatre, the Seldinger SPC kit allows trained staff to insert the catheter accurately into the bladder under local anaesthetic in an outpatient setting
- Suprapubic catheterisation using the Seldinger technique offers a safer alternative to the traditional procedure
- The technique lets non-consultant grade clinical staff and suitably trained nurse practitioners perform the procedure after training, meaning consultants have more time, while suitably trained staff can safely insert catheters during out of hours
- One of the largest benefits to Trusts is that the new procedure reduces hospital stay and therefore frees up staff and theatre time
- Benefits of the Seldinger SPC technique:
 - Low risk of complications and trauma
 - Avoids urethral catheterisations out of hours where contraindicated or undesirable
 - Promotes patient dignity and sexual function
 - Reduces demand on theatre capacity – allow insertion in the day case/outpatient setting
 - High clinician confidence to undertake procedure safely
 - Reduced length of hospital stay
 - Income generation from additional activity in released bed and theatre capacity



How to Why to Guide - The Seldinger Suprapubic Catheter Kit



NHS National Technology Adoption Centre (NTAC), April 2009

NTAC

NTAC's original remit was to enable adoption of healthcare technologies which were under utilised within the NHS. The outcome of this work was the production of a How to Why to Guide™.

These Guides provide comprehensive and relevant information for clinicians, managers, key decision makers and other stakeholders on how to implement specific technologies. These Guides provide NHS organisations with the key information they need to use to "adopt" these life-changing technologies in order to sustainably deliver improved outcomes.

Key benefits of the technology

The Seldinger Suprapubic Catheter Kit offers a number of benefits for both clinical staff and patients:

- Greater control and accuracy. A high degree of control allows accurate placement.
- Reduced risk. Low risk of trauma and tissue damage for the patient. The catheter rarely needs to be inserted under general anaesthetic - reducing the associated risks in an elderly at risk group of patients.
- Greater confidence. The bladder may be located with an 18G hypodermic needle, giving more confidence in inserting the trocar into the bladder, as the track has already been secured by the guide wire.
- Improved insertion and removal. The safety guide wire improves insertion and removal, guaranteeing insertion of the trocar along the anaesthetised track.
- Reduces costs and hospital stay. The procedure rarely needs to be undertaken as an inpatient, under general anaesthetic or in an operating theatre - reducing hospital stay, as well as reducing overall costs.
- Frees up consultants time and enhances out of hours services. Enables non-consultant grade clinical staff and suitably trained nurse practitioners to perform the procedure after training, thereby freeing up consultant time and allowing suitably trained staff to safely insert catheters during out of hours

Suprapubic catheter insertion is an outpatient procedure: cost savings resultant on closing an audit loop

Khan A, Abrams P

Bristol Urological Institute, Southmead Hospital, Bristol, UK

BJU Int. 2009 Mar;103(5):640-4. Epub 2008 Oct 24.

Objectives

To explore, by an audit, the regional practice of inserting a suprapubic catheter (SPC), and to prospectively determine the proportion of patients that can be successfully managed on an outpatient basis in one department.

Methods

Both local and regional practice were determined by a retrospective analysis of the hospital database for all cases of SPC insertion between April 2005 and March 2006. In addition, a questionnaire was e-mailed to each of 11 urology departments. Locally, from August 2006 onwards, all patients scheduled for SPC insertion were referred to a new clinic, where the SPC was inserted using a new SPC kit and the Seldinger technique.

Results

Locally, 66 patients (mean age 70 years, range 26-93) had a SPC inserted between April 2005 and March 2006; 49 had an elective procedure while 17 were emergency admissions. The median (range) hospital stay was 3.5 (1-85) days. Within the region, 480 SPCs were inserted in theatre during the same period, of which 52% (249) were inserted as elective inpatients, 11% (52) were inserted as a day case, and 37% (179) had SPCs as emergency admissions. A nurse-led outpatient service was available in two hospitals, where 89% of patients seen in the clinic had successful insertion under local anaesthesia, and only 11% were referred for insertion under general anaesthesia. Between August 2006 and July 2007, 50 of 54 patients had a SPC inserted successfully in the new SPC clinic. There were no major complications. The cost benefits of adopting an outpatient management strategy were significant, at approximately GB 100,000 pounds/year in our hospital, 790,000 pounds/year in the region and 9,500,000 pounds/year for the UK.

Conclusion

An outpatient procedure for a SPC is safe and feasible in most patients, and its widespread use would produce considerable cost savings.



Suprapubic bladder catheterisation using the Seldinger technique



Vasdev V, Kachroo N, Mathur S, Pickard R

Department of Urology, Freeman Hospital, Newcastle upon Tyne, UK; BioMed Centre, Bristol Urological Institute, Bristol, UK

The Internet Journal of Urology™ ISSN: 1528-8390, Feb 09

Background

Suprapubic catheterisation is normally performed blindly or ultrasound guided. We present an evaluation of a new Seldinger technique for suprapubic catheterisation in our department describing the technique and post procedure results.

Methods

6 patients had suprapubic catheters introduced via the Seldinger technique using a suprapubic Foley catheter introduction set, Mediplus Ltd, High Wycombe, UK. All clinicians completed a questionnaire at the end of the procedure rating their confidence in the new device compared to the standard technique across 5 domains using a simple scale.

Conclusion

Overall users of the device expressed greater confidence in application, patient comfort and safety of the new device compared to standard trocar placement. Given the current drive to minimise risk these devices appear to represent a significant advance over standard methods and merit consideration for routine use.

A new model for suprapubic catheterization: the MediPlus Seldinger suprapubic catheter

Mohammed A, Khan A, Shergill IS, Gujral SS.

ST1 in Surgery/Urology, King George Hospital, Ilford, London, IG3 8QY, UK
Expert Rev Med Devices. 2008 Nov;5(6):705-7.

Abstract

Insertion of a suprapubic catheter is one of the essential skills that all surgeons should master. It provides an alternative way to drain the bladder in cases where urethral catheterization is contraindicated or deemed difficult. It also has a role in elective cases where long-term drainage of the bladder is required. In this article, we discuss the MediPlus suprapubic catheter kit, which offers a new and potentially promising technique for safe introduction of the catheter into the bladder.

Take home message

- A suprapubic catheter is a common method for urinary bladder drainage when using a urethral catheter is not possible or contraindicated
- Blind suprapubic catheter insertion with the use of trocar is associated with posterior bladder wall and bowel injury
- Mediplus suprapubic catheter uses the Seldinger technique for suprapubic catheter insertion
- The design of Mediplus suprapubic catheter has the theoretical advantage of avoiding bladder and bowel injury
- The Mediplus SPC kit is a new and potentially promising technique for safe introduction of the catheter into the bladder
- It has the potential to replace existing suprapubic catheter kits owing to the ease of insertion and patient safety, if confirmed in future studies.



Suprapubic catheter insertion using the Seldinger technique, with the Mediplus SPC kit



*D.M. Gulur, F. Housami, M.J. Drake
Bristol Urological Institute, Bristol, UK
BJUI, www.bjui.org, Atlas of Surgery, Mar 2008*

Abstract

Suprapubic catheter (SPC) placement is routinely used in Urology to decompress the bladder in patients who present as an emergency with Bladder Outlet Obstruction (BOO) and a urethral catheterization is unsuccessful because of an enlarged prostate or urethral strictures. It is electively indicated in patients unable to tolerate a long-term urethral catheter due to bladder spasm/discomfort/bypassing and in patients with neurological diseases like MS and Spina bifida.

Conventional SPC insertion using kits with a trocar can be daunting to the surgeon, as well as the patient, due to the risks involved 1. Mediplus Ltd, High Wycombe has introduced a new kit using the Seldinger technique 2. Seldinger technique is routinely used by anaesthetists for central line insertion. The kit consists of a long needle, guidewire, trocar with an outer sheath and a 14 French silicone catheter. We regularly use the Mediplus SPC kit in our hospital for emergencies and electively in the catheter clinic.

S-Cath™ System testimonials

Mr Ruaraidh MacDonagh,

Consultant Urological Surgeon, Taunton and Somerset NHS Foundation Trust.

"Suprapubic catheterisation employing the Seldinger technique makes catheter insertion technically easier and safer and consequently facilitates the training of junior clinical staff."

Prof Christopher Chapple, BSc, MD, FRCS (Urol), FEBU

Royal Hallamshire Hospital, Sheffield

"Having used it I would prefer it over all of the alternatives and we have switched over to using it"

Angus MacCormick

Nurse Practitioner, Taunton and Somerset NHS Foundation Trust

"Suprapubic catheterisation using the Seldinger technique offers a safer alternative to the traditional procedure. The suprapubic catheter insertion clinic allows patients the opportunity to have the procedure undertaken under local anaesthetic, thus preventing the risks associated with general anaesthesia in a relaxed out-patient environment".

Odunayo Kalejaiye

Specialist Registrar, Taunton and Somerset NHS Foundation Trust

"Finally SPC insertion has caught up with other blind procedures using the Seldinger approach. This is easy to use for all levels."

Vivek Kumar

Specialist Registrar, Royal Hallamshire Hospital, Sheffield

"Safe and easy to use"

Altaf Mangera

SHO, Royal Hallamshire Hospital, Sheffield

"Less daunting for an inexperienced person such as myself"

Mr Ian Dickinson

Urology Consultant at Darent Valley Hospital

"I was never really satisfied with the previous catheters as we were using them 'blindly' and was attracted to the Seldinger SPC because of the three-stage guide-wire. It allows for controlled entry into the bladder and removes any guesswork.

In trials, it was easy to use. Its implementation was unanimously supported by my colleagues as they could be more confident knowing a higher degree of accuracy is involved. I believe patients also benefited from a more comfortable procedure and I would strongly encourage other hospitals to adopt this technique."

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Pacific Surgical Specialties

10 N. Post St, Suite 615
Spokane, WA 99201
Ph. 855.447.3222

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Mediplus Ltd

Unit 7 The Gateway Centre,
Coronation Road, Cressex Business Park,
High Wycombe, Bucks, HP12 3SU UK

Tel: +44 (0)1494 551200 | Fax: +44 (0)1494 536333

Email: help@mediplus.co.uk | Web: www.mediplus.co.uk

