The Infection Issue: Transurethral “Foley” Catheters

Clinical evidence suggests it’s time to change the approach, not just the catheter.
Superiority of Suprapubic vs. Transurethral Catheterization:

Suprapubic catheterization can effectively reduce transurethral Catheter Associated Urinary Tract Infections (CAUTI) by as much as 86.6%\textsuperscript{15, 33}

- Significantly lower infection rates (up to 87% reduction)\textsuperscript{2, 29}
- Fewer complications & improved outcomes\textsuperscript{22}
- Higher patient preference (89%)\textsuperscript{5}
- No ACA payment penalties due to CAUTI\textsuperscript{4}
- $5,914 average payment reduction per transurethral catheter CAUTI episode\textsuperscript{4, 8, 4}

<table>
<thead>
<tr>
<th>Complication/Issue</th>
<th>Urethral Catheter</th>
<th>Suprapubic Catheter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection Rate</td>
<td>Up to 87% Higher\textsuperscript{17}</td>
<td>Lower\textsuperscript{18, 2}</td>
</tr>
<tr>
<td>Urethral Trauma - False Passage/Perforation\textsuperscript{18}</td>
<td>✓</td>
<td>N/A</td>
</tr>
<tr>
<td>Urethral Lesions/Strictures (scarring)\textsuperscript{20}</td>
<td>✓</td>
<td>N/A</td>
</tr>
<tr>
<td>Erosion of Urethra\textsuperscript{21}</td>
<td>✓</td>
<td>N/A</td>
</tr>
<tr>
<td>Return to Normal Voiding\textsuperscript{22}</td>
<td>Slow</td>
<td>Rapid</td>
</tr>
<tr>
<td>Voiding Trials - Early Discharge\textsuperscript{23}</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Requires Office Visit for Catheter Change\textsuperscript{9}</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Risk of Bladder Cancer\textsuperscript{25}</td>
<td>Higher</td>
<td>Lower</td>
</tr>
<tr>
<td>Nursing Costs\textsuperscript{14, 15, 24}</td>
<td>Higher</td>
<td>Lower</td>
</tr>
<tr>
<td>Re-catheterization Rate\textsuperscript{17}</td>
<td>Higher</td>
<td>Lower</td>
</tr>
<tr>
<td>Residual Urine\textsuperscript{19, 24}</td>
<td>Higher</td>
<td>Lower</td>
</tr>
<tr>
<td>Economics - Cost of Catheterization\textsuperscript{12, 13, 14, 15}</td>
<td>Higher</td>
<td>Lower</td>
</tr>
<tr>
<td>Quality of Life - Patient Preferred</td>
<td>“Hurts like hell.”\textsuperscript{16}</td>
<td>89% patient preferred\textsuperscript{5}</td>
</tr>
</tbody>
</table>

Urinary tract infections are the second most common type of infection in the body, accounting for about 8.1 million occurrences each year in the U.S.\textsuperscript{3}
Suprapubic Catheterization is Associated with Significantly Lower Infection and Complication Rates:

86.6% CAUTI Reduction:
Prospective randomized controlled trial of urethral versus suprapubic catheterization.
"We propose that, when catheterization is required during a general surgical procedure, the suprapubic route is to be preferred."

77.8% CAUTI Reduction:
Suprapubic or urethral catheter: what is the optimal method of bladder drainage after radical hysterectomy?
"...suprapubic catheterization is associated with a lower rate of UTI and an earlier trial of voiding..."

73% CAUTI Reduction:
Suprapubic Percutaneous Cystostomy versus Urethral Catheterisation in Abdominal Surgery: A Prospective Randomised Controlled Study.
"It allows prompt re-establishment of normal micturition, is better tolerated by the patients and has a lower risk of complications." Botisios, Demetriades, Goulmamis, Kanellos, Dadoukis. 4th Surgical Department, Aristotelian University of Thessaloni, G. Papanicolaou General Hospital, Thessalon, Greece, Dig Surg 1997;14:404–408 (DOI:10.1159/000172583)

65% CAUTI Reduction:
Suprapubic Bladder Drainage in General Surgery.
"The results reported favor suprapubic over urethral catheterization in that urinary tract infections are reduced. 35% incidence of bacteriuria (100% for urethral catheters inserted an equal length of time)."

55% CAUTI Reduction:
Acute urinary retention. Comparison of suprapubic and urethral catheterisation.

54% CAUTI Reduction:
"SPC is a valuable option of urinary management for quadriplegic patients..."

43.3% CAUTI Reduction:
Suprapubic bladder drainage versus a transurethral catheter in patients following anterior colporrhaphy.
"The additional time required for placing the suprapubic catheter postoperatively is by far outweighed by the advantages of this system, such as shorter hospitalization and a lower incidence of urinary tract infections."

Less pain and discomfort with SPC:
Published evidence favors the use of suprapubic catheters in pelvic colorectal surgery.
"The results reported favor suprapubic over urethral catheterization in that urinary tract infections are reduced." Branagan, Moran. Published evidence favors the use of suprapublic catheters in pelvic colorectal surgery. Dis Colon Rectum. 2002;45(8):1104-8.

Coated catheters do not significantly reduce CAUTI:
Antimicrobial Catheters for Reduction of Symptomatic Urinary Tract Infection in Adults Requiring Short-term Catheterisation in Hospital: A Multicentre Randomised Controlled Trial.
"The reduction we noted in CAUTI associated with nitrofural-impregnated catheters was less than that regarded as clinically important." Pickard, Lam, MacLennan, Stnr, Kilomo, McPherson, Gillies, McDonald, Walton, Buckey, Bousie, Burt, Norrie, Vale, Grant, N'Dew. Institute of Cellular Medicine, Newcastle University, Newcastle upon Tyne, UK. 2012
CMS and the Affordable Care Act:
The U.S. Healthcare System is in the midst of unprecedented change that is affecting how hospitals are paid and how healthcare services are delivered.

Clinical and economic advantages of suprapubic catheterization (SPC)

CLINICAL STATISTICS — the focal point of healthcare reform:
- 80% of Hospital Acquired Infections (HAI) are Urinary Tract Infections (UTI) ¹⁰
- 32% of all HAI are due to CAUTI (transurethral catheter) ¹⁰
- 9,000 deaths are attributed to CAUTI each year ²⁸ ($1.8 billion*)
- 45 billion is spent annually in the treatment of HAI ²⁶
- 400% increase in multi-drug resistance to E. coli bacteria, a leading cause of UTI ¹¹

CLINICAL ADVANTAGES — with SPC approach:
- Significantly lower infection rates (up to 87% reduction) ²⁹,²
- Fewer complications*
- Higher patient preference (89%) ⁵
- Severe complications due to long-term usage eliminated ²⁷

COST ADVANTAGE — financial based incentives:
- Lower treatment cost ⁸
- No ACA payment penalties due to CAUTI ⁴
- $5,914 average payment reduction per transurethral catheter CAUTI episode ³,⁸,⁴
  (Not applicable to SPC)
- SPC infections are fully reimbursed under ACA rule ⁴
- SPC infections are not included in ACA CAUTI score ⁴

We have a simple, proven solution.

Change the approach, not just the catheter.™

* SEE CHART ON PAGE 2

HA-CAUTI reduction was not statistically significant over the first 3 years post implementation of ACA tracking with penalties for non-compliance. ²⁷

SPC is not included in ACA CAUTI rate reduction programs:
- SPC reimburseable for treatment
- SPC not included in CAUTI rate score ⁴

Consequences of Transparency:
Published infection rates of hospitals and physicians will influence patients and payers.

$5,914
Average payment reduction per CAUTI episode ³,⁸,⁴
(Not applicable to SPC)
Suprapubic cystostomy (SPC) is a common method for treating acute or chronic urinary retention and urinary incontinence as an alternative to transurethral catheterization. SPC is frequently used to provide drainage during and following common surgical procedures due to Post-Op Urinary Retention (POUR). Over twenty years of clinical studies have proven that patients with SPC have lower rates of urinary tract infection, lower pain and improved quality of life when compared to long-term indwelling and clean intermittent urethral catheterization. In addition, SPC eliminates potential injury to urethra and bladder sphincter from catheterization.

Despite clinical advantages and patient preference, SPC has not been widely used for transurethral catheterization. This is largely due to high rates of bowel injury and mortality associated with blind percutaneous “trocar punch” cystostomy and open cystostomy - the current “standards of practice” for placing suprapubic catheters.

**T-SPeC®**

**T7 · T14**

Taking complications out of suprapubic cystostomy

T-SPeC® has two models based on patient size. The T7 model will accommodate patient abdomen thickness up to 7 cm, the T14 model up to 14 cm — addressing the obese and morbidly obese patient.

...enabling transition from other cystostomy options and from transurethral catheterization.
THE INABILITY TO PRECISELY LOCATE THE PUBIC BONE AND CONTROL THE CORRECT ANGLE OF NEEDLE/TROCAR CONTRIBUTE TO INACCURATE PLACEMENT, PUNCTURE OF PERITONEAL CAVITY AND/OR SMALL BOWEL. 7

OPEN CYSTOSTOMY IS HIGHLY INVASIVE, REQUIRING A LARGE INCISION, LONG PROCEDURE, AND EXTENDED INPATIENT RECOVERY TIME.

Clinical Procedure Outcomes

<table>
<thead>
<tr>
<th>Percutaneous Trocar Punch</th>
<th>Open Cystostomy</th>
<th>T-SPeC®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimally Invasive</td>
<td>Highly Invasive</td>
<td>Minimally Invasive</td>
</tr>
<tr>
<td>15 Minute Procedure*</td>
<td>1-2 Hour Procedure Time</td>
<td>5 Minute Procedure</td>
</tr>
<tr>
<td>Small Catheter Size (unreliable drainage)</td>
<td>Long Recovery - Post-Op Hospitalization</td>
<td>Large-bore 18 Fr. Catheter (reliable drainage)</td>
</tr>
<tr>
<td>Unpredictable Surgical Tract</td>
<td>Large Open Incision</td>
<td>Small Surgical Tract (5mm)</td>
</tr>
<tr>
<td>High Complication Rate - 45.5%</td>
<td>High Complication Rate - 30.3% 1</td>
<td>Low Complication Rate - 3.5% 6</td>
</tr>
<tr>
<td>High Mortality - 4.4% 10</td>
<td>High Mortality - 1.83% 1</td>
<td>No Mortality - 0% 6</td>
</tr>
</tbody>
</table>

* 30+ minutes when placed by interventional radiologist.

BAUS Suprapubic Catheter Guidelines

The British Association of Urological Surgeons (BAUS) has created SPC practice guidelines based on a 2010 audit directed by the National Patient Safety Agency. The audit was initiated due to the number of adverse events and studies confirming high morbidity and mortality rates relating to percutaneous trocar puncture techniques. As a result, the guidelines recommend ultrasonography by individuals who have received specific training and are experienced with the SPC procedure. The full BAUS report can be reviewed on-line at: swanvalleymedical.com/clinical/baus.
The T-SPeC® works amazingly well and was simple to use. I found the T-SPeC® created a faster, easier, and safer tract for suprapubic cystostomy catheter placement. It required less anesthesia when compared to other cystostomy kits I have used for more than 10 years. I had a lot of optimism for the T-SPeC® device when I first heard about an ‘inside-to-out’ cystostomy kit — T-SPeC® exceeded my expectations. The device will play an important role in my practice to allow a safe and minimally invasive procedure to place a suprapubic catheter in my patients with urinary retention and incontinence. The current cystostomy kits use an ‘outside-to-in’ technique that does not always allow accurate placement of the catheter and has been shown to cause rare but serious complications such as small bowel perforation that can result in sepsis and even death. The T-SPeC® utilizes the safer and innovative passageway, ‘inside-to-out’ technique, allowing reliable catheter placement and equally important — virtually eliminates the risk of small bowel injury.

DR. BRIAN FLYNN
DIRECTOR OF FEMALE PELVIC MEDICINE AND RECONSTRUCTIVE SURGERY
ASSOCIATE PROFESSOR OF UROLOGY
UNIVERSITY OF COLORADO HEALTH SCIENCE CENTER

The T-SPeC® (Transurethral Suprapubic endo-Cystostomy) Clinical advantages of precise inside-to-out technology

Bladder Management Indications:
(Incontinence & Retention)

Neurologic Diseases/Patient Conditions
- Alzheimer’s Disease
- Cerebral Palsy
- Encephalitis
- End-stage Bladder
- Multiple Sclerosis
- Obesity
- Parkinson’s Disease
- Spinal Cord Injury
- Stroke

Post Operative Urinary Retention (POUR)
- Bladder Cancer
- Bladder Stones
- Brachytherapy
- Colorectal Surgery
- Female Surgery (Prolapse, Sling)
- General Surgery
- Hifu
- Prostate Surgery
- Urethroplasty

Mortality rate: 0% vs. 4.4% Complication rate: 3.5% vs. 45.5%

For more information on T-SPeC®, visit: www.swanvalleymedical.com.
Clinical References


* Applicable to hospitals not meeting established CMS performance goals.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Caution: Refer to package insert provided with the product for complete Instructions for Use, Contraindications, Warnings and Precautions prior to using this product.

Clinical document files: http://www.swanvalleymedical.com/references/clinical-papers

Applicable to hospitals not meeting established CMS performance goals.