Catheter Evolution Prevents Injury and CAUTI

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Disruption in Catheter Associated Urinary Tract Infections (CAUTIs)

The indwelling single-balloon urethral (Foley) catheter has not changed in more than 80 years. Urinary single-balloon catheters are used widely in hospitals and in long-term care facilities. However, they carry inherent risks of complications, including infections and even death.

Typically, innovation occurs once there is a disruptive issue or event. In the case of indwelling catheters, that issue became critical when the Centers for Medicare & Medicaid Services (CMS), stopped reimbursing hospitals for avoidable CAUTIs.

CMS had set a catheter-associated urinary tract infection (CAUTI) reduction goal of 25% by 2020 and a benchmark goal of 1 CAUTI per 1,000 catheter days. The scope of the gap between the CMS goal and what has been achieved can be illustrated by an example. The published NHSN CAUTI rate for neuroscience intensive care units in hospitals is currently 5.3 CAUTIs per 1,000 catheter days. A 25% reduction results in 3.975 CAUTI per 1,000 catheter days, which is still four times higher than the CMS bench-mark. Clearly, hospitals need better solutions to successfully reduce CAUTI than what has been tried to date.

There has been little success in developing CAUTI prevention strategies that work. The US Department of Health and Human Services (HHS) stated, "These target goals for reduction of health care-associated infection (HAIs) are ambitious but achievable," indicating that they expected it would be difficult to achieve the 25% reduction. Programs such as Team Stepps, ON-THE-CUSP (Keystone Project), and the "Catheter-Out" program each failed to show meaningful reductions, and neither have shown sustained reduction rates. The following data reinforces the urgency of this long-standing and poorly addressed health issue:

- Approximately 75% of hospital-acquired UTIs are associated with a urinary catheter; and 15-25% of hospitalized patients receive urinary catheters during their hospital stay.[15]
- From 60–80% of hospitalized patients with an indwelling catheter receive antimicrobial. This intense antimicrobial use contributes to the development of resistant organisms, which are frequently isolated from the urine of catheterized individuals.[16]
- CDC reports 17% of patients with a catheter-associated urinary tract infection (CAUTI) will be diagnosed with sepsis and 10% will die from it. 15% of patients with CAUTI related bacteremia die within 30 days. 13,000 deaths are directly attributable to CAUTIs each year.[17]
- The CDC National and State Healthcare-Associated Infections Progress Report stated that there was "No change in overall CAUTI [rates] between 2009 and 2016."[18]
- The CAUTI bundle in widespread use in hospitals today has not changed since 2009.
- Costs associated with CAUTI: Expenses include treatment costs, extended hospital stays, and use of physician and nursing time. Many sources place the per-incident cost or CAUTIs in the range of $900 to $1,000.[2] APIC places the cost at about $5,900 per incident, and overall US cost at more than $3 billion annually.[3] One multi-site healthcare system, in a published analysis, calculated its per-incident cost to be about $11,417.[4]
- In addition, the Affordable Care Act penalizes hospitals for high CAUTI rates. Rates range between 1-3% of the total Medicare hospital reimbursement.

Clinicians Recognize the Problem

A recent national survey on clinicians' attitudes about catheter-associated urinary tract infections (CAUTIs) yielded the following findings (CoreRx paper on file at Poiesis Medical*)

- Most respondents said that their hospital administrators are strongly emphasizing the importance of CAUTI reduction.
- Most respondents were also concerned that their hospital's nurses are not adequately complying with CAUTI protocols.
- Nearly 80% of respondents believed that Foley catheters can cause trauma to the wall/lining of the bladder.
- More than 80% stated that bladder wall/lining trauma increases CAUTI risk.

"We all know that a healthier, less traumatized tissue will probably be more able to resist clinical infection when exposed to bacteria, as compared to a more diseased and less healthy tissue."

-Rabih Darouiche, MD, Baylor College of Medicine.

"The presence of a catheter further predisposes the patient to CAUTI by provoking inflammation and traumatizing the mucosa. Inflammation and mechanical damage to the urinary epithelium not only increases the risk of UTI but also compromises the patient's ability to mount an effective immune response to bacteria in the bladder."

-Reducing Catheter-Associated Urinary Tract Infection in the Critical Care Unit. Mikel Gray, Professor and Nurse Practitioner, Department of Urology and School of Nursing, University of Virginia.

Although physicians, nurses, infection preventionists and other clinicians understand many of the potential risks and complications associated with urinary catheterization, they have not been able to consistently prevent these consequences. They have employed standard precautions based on industry and regulatory guidance, such as: using the catheter only when clinically indicated; leaving the catheter in place only for as long as deemed necessary; enforcing safe standards for catheter insertion and maintenance; and using alternatives where possible. Despite these efforts, it has been difficult to meet the primary medical mandate to "do no harm" when using a single-balloon catheter as a therapeutic tool.

How Catheter-Caused Complications Happen

Many of the complications associated with urinary catheterization are due to inherent flaws in the design of the most commonly used single-balloon urinary catheter -- the "Foley." This catheter was first introduced in 1937. While Foley catheters provide crucial clinical benefits for appropriate patients, they are also one of the leading causes of nosocomial infections in the intensive care unit (ICU).[6] In recent years, extensive research has confirmed that the Foley catheter's design interferes with the bladder's natural innate defenses against infection.

To understand how Foley catheterization leads to complications like CAUTI, it's necessary to understand the body's own means of preventing urinary tract infections, and how Foley catheters break down those defenses.

The bladder has two innate defense mechanisms: urination, and the bladder's mucosal lining. Urination removes 99.9% of bacteria from the bladder. However, the remaining 0.1% can still be sufficient to cause an infection under certain circumstances. The mucosal lining defends against these remaining bacteria by acting as a barrier to bacterial adherence.[7,8]

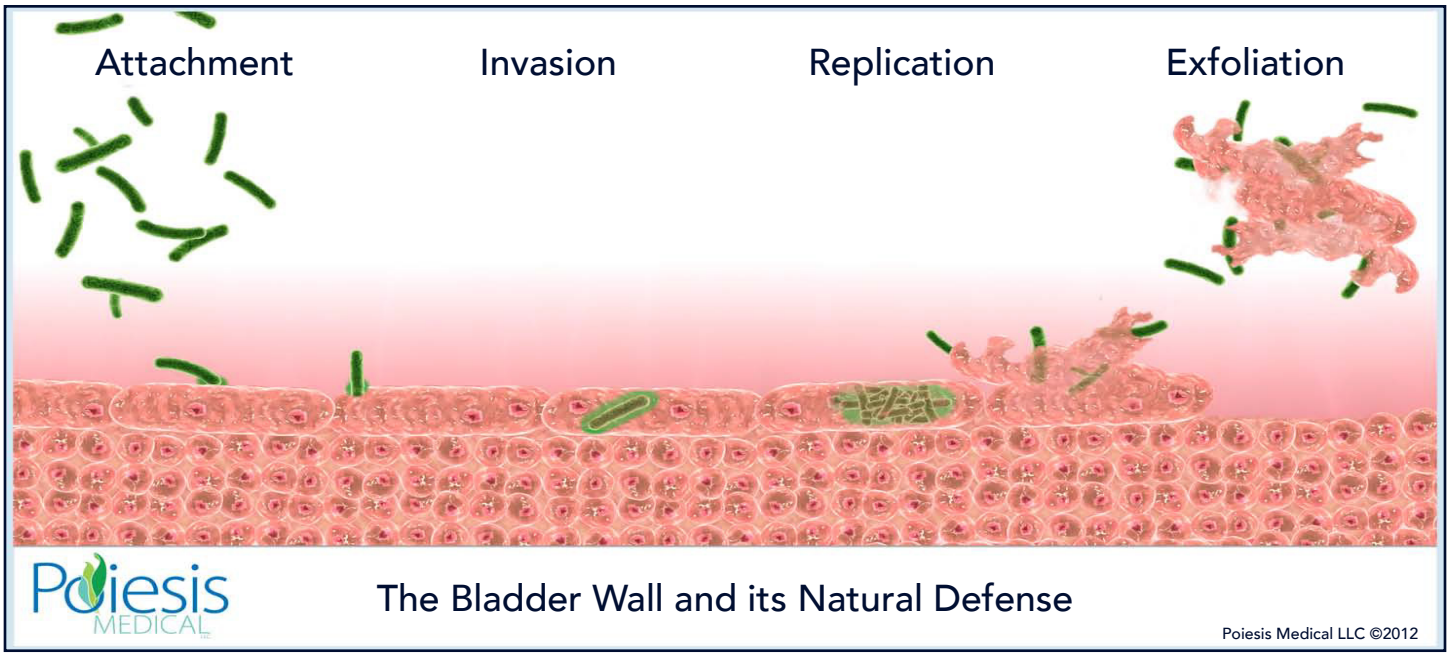
Once bacteria attach to the bladder wall, they can form colonies, which then form the basis for infection.

"Urinary bladder appeared capable of synthesizing a glycosaminoglycan (GAG), which [helped] prevent bacterial adherence to the mucosal cells. Adherence has been reported to play a role in bacterial virulence at many mucous surfaces including the gastrointestinal tract, the genitourinary tract, and the oral cavity, the main theme being a [microbe's] ability to infect a surface is directly proportional to its ability to adhere."

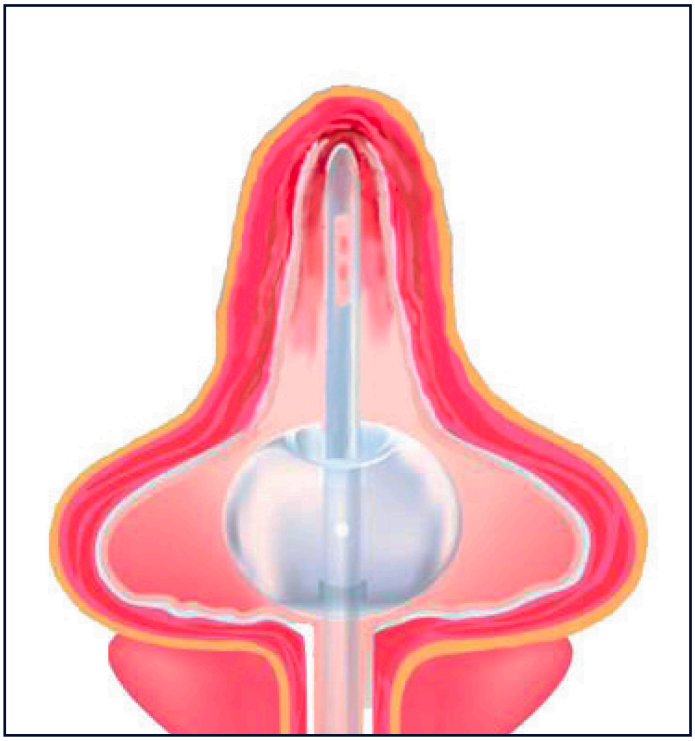
-A new perspective on the elusive glycosaminoglycan layer. J. C. Nickel and J. Cornish.

Meanwhile, new facet cells are growing continually to replace the ones that are exfoliated.[7,8] If this layer of facet cells is damaged, then the sequence of adherence, colonization, and infection can follow.[9]

This image illustrates the process by which a healthy bladder's mucosal lining prevents infection:



The natural defensive structure of the bladder wall works very well – but it was "built" to fight bacteria, not withstand physical assaults from a mechanical device. Unfortunately, the bladder's defense mechanisms were not fully understood when the Foley catheter was developed. As a result, the design of the Foley catheter violates the transitional cell lining, directly causing infection and other complications.

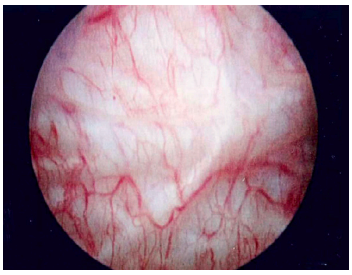


The Foley catheter breaches the bladder wall's defenses in several ways:

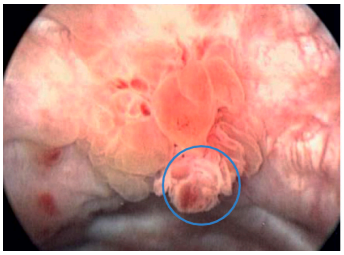
- Pressure damage from the catheter tip: as the bladder drains, it collapses around the tip of the Foley catheter. Most of the pressure created as the bladder pushes against the tip is focused on a small area of the bladder wall. The pressure of the tip pressed against the bladder wall, combined with motion friction, can strip away the protective mucosal lining.[10,11,12,13]
- Bladder spasms from tip trauma: these spasms can disturb the position of the anchor balloon, allowing bacteria to flow into the bladder. The trauma and greater presence of bacteria increase the risk of bacterial attachment and proliferation.
- Suction aspiration damage from drainage eyes: The bladder wall wraps around the catheter tube and be aspirated into its exposed drainage eyes. This suction action strips away the bladder's protective lining and blocks urine from draining through the catheter.[10,11,12,13]

The following photographs show actual tip and aspiration injuries caused by the traditional Foley catheter inside the bladder. These photos, taken using a cystoscope, document both tip and aspiration damage to the bladder caused by Foley catheterization. All photos were taken just 24 to 72 hours after catheterization.

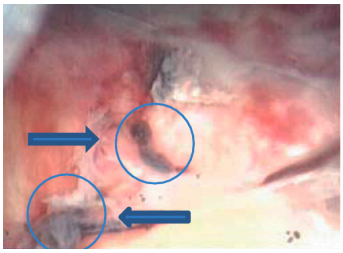
A non-catheterized bladder with a healthy mucosa exhibits no signs of trauma.



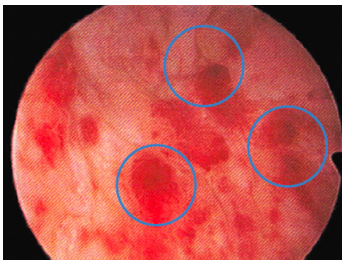
Compare these four photos to the photo of the healthy bladder above.



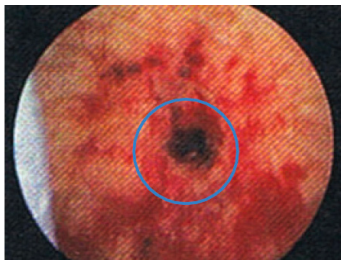
Polypoid cystitis



Hemorrhage in under-layers of the bladder



Damage to the bladder wall



Tip and aspiration after only 24 to 48 hours of catheterization

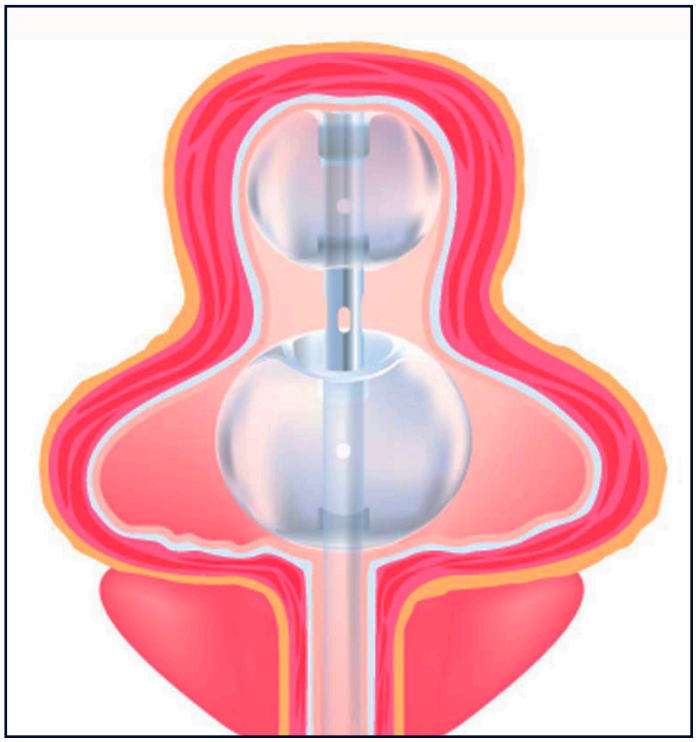
The catheter usually hurts the bladder mucosa and submucosa to various degrees. The aim of this study was to show pathological changes observed during a time period of one to 30 days of catheter treatment. Polypous cystitis was revealed in 29 cases (70%), and various mucosal defects in 12 cases (29%). A predominance of fibroblasts was observed in the reactive stromal cells of the bladder wall. Polypous cystitis develops already in the first days after permanent catheter insertion. The recent polyps present an inflammation caused by mechanical injury.

-PMID: 18724530 [PubMed - indexed for MEDLINE]

Evolutionary Catheter Design Presents a Viable Solution

Since the issue of CAUTI and its many consequences had come to a head in recent years, it was time for a disruptive redesign of traditional urinary catheters. Poiesis Medical, LLC (Jupiter, Fla.) undertook the challenge. Their new catheter, the Duette™* Urinary Drainage System, has directly contributed to improved patient outcomes. The Duette™ system in now in use in dozens of healthcare facilities, and initial clinical trials of the device have resulted in substantial reductions in CAUTI rates.

Designed to replace the Foley catheter, it is a practical alternative that eliminates the mechanical issues and harmonizes the body's innate immune system against bacteria entry and attachment to the bladder wall outlined above.



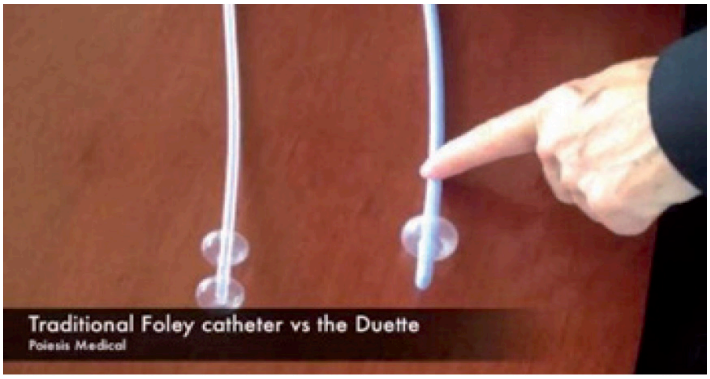
Duette™

Urinary Drainage System

Specifically:

1. The catheter has two balloons instead of the single balloon of the Foley device. The tip is enclosed in the second balloon, which serves as a cushion to prevent damage to the mucosal lining and bladder wall.
2. The drainage eyes are situated between the two balloons. This prevents the bladder wall from being aspirated into the eyes, thereby preventing the damage to the mucosal lining and wall from the resulting suction. Additionally this design maintain more continuous fluid removal.
3. The device is inserted and removed like a standard Foley, and therefore requires minimal new training for clinical staff.
4. The cost of the device is comparable to the price of 100% silicone Foley catheters, so there's no financial barrier to adoption.

This photo illustrates the differences between *the Duette™* Urinary Drainage System and the traditional Foley catheter.



The many therapeutic benefits of this dual-balloon system support and help harmonize the body's own natural innate defenses against bacteria. In addition, by maintaining the inherent function and integrity of the bladder rather than injuring it, this solution offers a much broader contribution to health and wellness: it synchronizes with the new CDC National Prevention Strategy, which "helps move the Nation away from a health care system focused on sickness and disease to one focused on wellness and prevention." The reason for this National focus: "Prevention policies and programs can be cost-effective, reduce health care costs, and improve productivity."[20]

Evidence Over Time

How an indwelling urinary catheter performs during a pilot or trial is less important than how it performs over time. A clinical study (Tampa General Hospital in concert with the University of South Florida Morsani College of Medicine Division of Urology) demonstrated conclusively that it led to full adoption at Tampa General Hospital. There is now more than three years of Poiesis (Duette™) catheter use data at Tampa General Hospital. Tampa General has stated from the infection control department since house wide adoption they have experienced a 13:1 ratio in favor of Dual Balloon technology over the single balloon Foley, respectful to CAUTI reduction. Currently, 31 facilities are using the Duette™ catheter with similar results. This sustained improvement is important because existing CAUTI reduction protocols, bundles and toolkits have not shown meaningful results.

Duette™ System and CAUTI Quality Metrics

National Patient Safety Goals for reducing CAUTI include measures rated at three quality levels; 1 (I) being the highest quality supportive evidence, and 3 (III) being the measures with the lowest quality evidence to support them. Measures such as: "Use as small a catheter as possible … to minimize urethral trauma," or, "Maintain unobstructed urine flow…" are classified as Level III quality. They are common-sense guidance based on general knowledge, but are not at a specificity level to offer direct, repeatable results.

In contrast, use of the Poiesis Duette™ catheter achieves the equivalent of at least a Level II patient safety quality standard. Because of the significance, repeatability and duration of its CAUTI reduction results, it could potentially meet a Level I quality standard for its evidence-based, clinically validated results.

In our frightening new world of healthcare-acquired pathogenic infections, hospital decision-makers must look beyond their human interventions and actively seek innovative tools, develop guidance based on maintaining healthy organs rather than accepting injuries, and put together better evidence-based bundles to help them successfully reduce high CAUTI rates. They now have a unique new medical device, the Duette™ catheter, to help them. This innovation has performed consistently to eliminate injury and maintain bladder integrity and health, and thus reduce infection risk In addition, since governmental and professional organizations lead the way in determining best practices, they can also be leaders at investigating and encouraging evidence-based innovative technologies that can improve health and wellness, and to revise their guidance to adopt them once robust clinical data are available.

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*As of December 28, 2023, Poiesis Medical, LLC entered into an Exclusive Commercial Agreement with HR HealthCare. Under the terms of the agreement, HR HealthCare has exclusive commercialization rights to the "Duette™" Dual-Balloon Urinary Catheter in North America. The dual-balloon product ("Duette") is now marketed by HR HealthCare under the trade name "TruCath® Duo."

About Poiesis Medical, LLC

Poiesis Medical, LLC was incorporated in 2009 to investigate and present a solution for clinically identified urinary catheter-related health issues. One of Poiesis Medical's founders, a 30-plus year practicing urologist, had repeatedly noticed bladder lining damage in patients with indwelling single-balloon catheters. There had to be a way to prevent injury, and thereby prevent the known potential complications for patients. The new company focused on the catheter itself, to find a better solution. The development and success of their new catheter design was based on three key beliefs: clinically innovative devices will outperform human infection prevention protocols, especially when consistency is important; reducing damage/trauma is always a best practice for optimizing patient health; and applying root-cause metrics is a key to major changes in care.

About HR HealthCare

HR HealthCare, formerly HR Pharmaceuticals, Inc., is a leading manufacturer and supplier of healthcare consumables based in York, PA. As a professionally managed, family-owned business, HR HealthCare combines the agility of a private company with the expertise of an industry leader. The organization is unified and driven by its purpose of "Positively Impacting People's Lives," striving to enhance the quality of care through its diverse range of products and services across the United States.

Poiesis Medical: WP 09-20-17
HR HealthCare: REC-0030 Rev. 0 (08/2024)