QiVi™ Male External Urine Management

ABSTRACT

Urinary Incontinence (UI) is a common, distressing medical condition that affects more than 33 Million US adults each year. 43.8% of adults over the age of 65 experience some form of minor to moderate incontinence. In Critical Care settings across US, UI affects 45-79% adults. The true scale of this clinical challenge is magnified by the clinical complications such as IAD, HAPI, CAUTI etc. Existing solutions to incontinence containment and management are inadequate and may lead to complications such as CAUTI, Iatrogenic Injuries, MDRPI amongst other. This is a brief review of clinical problems associated with UI and the solutions to resolve them. This review begins with the conceptual definitions relevant to understanding the challenges associated with these clinical problems. Topics reviewed include epidemiology, clinical implications of the management of UI, and the burden upon healthcare recipients and caregivers within the larger healthcare delivery system. The conclusion poses a non-invasive solution to the clinical problem of UI, in a subset of immobilized individuals.

1.0 Introduction/Definition of Problem

This paper is intended as a brief overview of the problem of Urinary Incontinence (UI). It focuses on defining the scope of the problem, offering the epidemiological impact, while acknowledging best practice and the professional organizations which have led the way in developing guidance to impact quality patient outcomes. Current options are explored that have the potential to make a difference in care delivery and the potential to mitigate risk of infection for individuals who are experiencing UI.

1.1 Definition of Continence

Beginning with the normal physiological function, continence is defined as the ability to both store and empty urine, through coordination of the lower urinary tract and pelvic floor, orchestrated by intact neural pathways. Normal voiding function is cyclic and maintained, provided that the lower urinary tract (bladder, urethra and urethral sphincter) and pelvic floor is intact and under appropriate neural control of the cerebral cortex and mid-brain[1].

1.2 Definition of Urinary Incontinence (UI)

Alteration(s) in the control of either the voiding process or the ability to store urine, regardless of the source of the problem, are the result of dysfunction of the normal physiological mechanisms that contribute to continence. Thus, UI is defined as alteration(s) in the ability to store urine and to effectively control voiding, resulting in unintentional loss of urine[2].

UI is manifested along the entire continuum of care, from the community through the entire healthcare system. The problem exists in acute care and can be found within medical and surgical care units, the perioperative arena and within all specialty units, such as cardiovascular, oncology, neurology and pulmonary. Within extended care settings, UI exists in long term acute care, short and long term care for rehabilitation, palliative care, hospice and home care.

2.0 UI Incidence along the Healthcare Continuum

According to Center for Disease Control and Prevention (CDC), the Prevention's National Center for Health Statistics (NCHS) and the Center for Medicare & Medicaid Services (CMS), UI affects up to 43% within the community and within long term care, up to 70% patients[3]. Because UI is a 'hidden condition', not readily acknowledged by those who experience it, it often goes undetected until the problems associated with it drive the individual to seek solutions; thus, it is challenging to accurately source both prevalence and incidence in various care settings. UI which may be undetected in the community, becomes a known entity when individuals enter the healthcare system, at which point UI may eventually be captured as incidental, when individuals seek medical advice. Assessment and documentation are critical to uncovering and identifying the problem and mitigating other complications associated with UI.

3.0 Clinical Problems Associated with UI

Clinical problems associated with UI may involve both Healthcare associated infections and Hospital Acquired Complications.

3.1 Healthcare Associated Infections (HAIs):

HAIs are the most common cause of both morbidity and mortality in the United States. A HAI is defined as either a localized or systemic condition that results from an adverse reaction to an infectious agent, occurs during a hospital admission, and meets specific body site criteria [4]. Due to exposure of uncontained urine in the perineal area, the risk of urinary tract infections (UTIs) is high. Left to dwell on the skin, the urine becomes a vehicle for transmission of bacteria and pathogens to enter and migrate from the lower urinary tract proximal to the upper urinary tract.

One case-control study assessed a sample of 8,467 patients over one year and found hospital acquired UTI in 125 of those patients; the overall incidence rate was 14.8 cases/1000 admissions, with the most frequent organisms being Gram-positive bacteria[5].

One cohort study in an academic teaching hospital included all adult admissions from 2013 through 2017 using active surveillance methods; tracking UTIs, both device related and non-device related. Among 97,485 unique patients, 1,273 cases of UTIs were identified, out of which 715 were Non-Device related-UTIs (ND-UTIs) and 558 were reported as Catheter Associated-UTIs (CAUTIs)[6]. The incidence rate of non-device related UTIs (ND-UTIs) remained relatively stable, yet the proportion of ND-UTIs increased from 52% to 72%. Myriad of factors such as gender, age, presence of peptic ulcer disease, paralysis, immunosuppression, trauma, urinary retention, suprapubic catheters and nephrostomy tubes may contribute to risk and increased incidence of ND-UTIs. Authors concluded future research may focus on prevention strategies.

Depending upon the method of containment and management of incontinence, the potential for skin breakdown exists, which is an avoidable adverse event (AE) with implications for the subsequent development of pressure injury (PI). Therefore, in addition to impacting the status of Hospital Acquired Infection (HAI), urinary incontinence can also impact the development of skin breakdown, one of the primary Hospital Acquired Conditions (HAC) Hospital Acquired Conditions | CMS .

3.2 Skin Breakdown

Moisture Associated Skin Damage (MASD), Incontinence Associated Dermatitis (IAD) and PIs are each potential complications of UI and are considered HACs. Despite the development of new technology surrounding absorptive products, the demand on nursing hours can impact the response time to each individual wetness event. Prolonged exposure of patients to UI with the associated moisture and chemical components of urine, can alter the pH level of the skin, while creating microclimate that increases host susceptibility to the clinical risk of skin breakdown.

A quasi-experimental post-test study was conducted, following a prevalence audit of IAD, to evaluate the effect of evidence based (EB) initiatives[7]. Implementation of a staff driven EB research protocol, using absorptive products, was able to narrow the gap between research and practice, to address a clinical problem.

Prevalence of IAD was investigated in four Norwegian hospitals, with a sample of 340 patients, using a modified PI Prevalence Minimum Data Set[8]. Using descriptive statistics, the analysis identified 16.5% (56 out of 340) of the sample patients were found to be incontinent. The prevalence rate of IAD was 29% (16 out of 56) among patients with either UI or FI (fecal incontinent)[9].

Like UI, IAD has historically been underreported as a healthcare condition[10]. In those cases where prevalence and incidence is documented, evidence supports a clinically significant association between IAD and the risk of developing PIs[7 or 8]. The investigators concluded that hospitals should determine protocols and implement measures to improve knowledge base of incontinence, IAD and PI practices.

A descriptive and correlational analysis of data from a large database of IAD and PIs was performed for use in a national quality improvement study[11]. The goal was to evaluate current prevention practice. The overall prevalence rate of IAD was 21.3%, while the prevalence of IAD among patients with incontinence was 45.7%. Multivariate analysis revealed that the presence of IAD and immobility was associated with an increased likelihood of developing a full-thickness sacral PI[11].

In addition to increasing the risk of skin breakdown, UI that is not contained, impacts care management of patients, due to the inability to measure output accurately. Many patients require documentation of their output to accurately calculate nutritional needs, determined by assessment. If urine is not contained and is lost to absorptive products or bed linen, that fluid cannot be accurately accounted for and precise supplementation of hydration cannot be determined.

3.3 Healthcare Associated Complication Reduction Program:

HACs may be potential problems associated with UI that are not managed appropriately. A brief overview of the skin breakdown that can occur demonstrates how these skin conditions impact patient outcomes and negatively contribute to patient's quality of life. They become an additional burden to the patient, the caregiver, and the greater healthcare delivery system. As part of a HAC Reduction Program, the United States began tying quality parameters and fiscal determinations associated with reimbursement to occurrence of specific HACs to facilitate reduction of those conditions. In 2015, that Program began to require Medicare payments to be adjusted according to ranking of quality measures, with a threshold of 75th percentile, making facilities with Total HAC Scores above that threshold, subject to a 1% payment reduction[12]. In addition, public reporting of Total HAC Scores is now mandatory and can be found online at the Medicare's website.

4.0 Available Solutions

Historically, there have been clinical solutions implemented to manage the problem of UI. Those solutions have included indwelling urinary catheters, absorptive products including body worn absorptive products and external sheath catheters.

4.1 Internal Urinary Catheters

The indwelling urethral catheter (IUC) was implemented as an early solution to UI. The medical device features of IUCs include a balloon, a catheter tip, catheter tubing (varying sizes) and the composite material of the catheter, which may include silicone, PVC, latex and antimicrobial[13]. Historically, they afforded a method to contain the urine output and served as a way to be able to measure the output efficiently and consistently. It appeared that they provided a solution to maintain the integrity of the perineal skin, while simultaneously, monitoring urine output for accurate documentation of fluid loss.

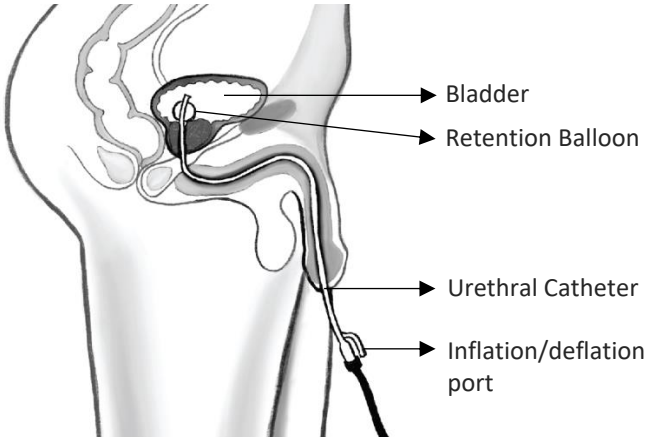

Illustration 1 - Indwelling Urinary Catheter

Unfortunately, while providing a containment solution, IUCs also have demonstrated that they are subject to clinical complications, if overused, without appropriate indications. Evidence exists to confirm that IUCs, although a necessary adjunct to care within specific parameters, have become a source for hospital acquired infections (HAIs)[14].

4.2 Complications Associated with IUCs: Catheter Associated Urinary Tract Infection (CAUTI)

When a foreign body such as an IUC connects a normally sterile, hydrated body site to the outside world, it will inevitably become colonized with microorganisms. If the burden of microbial colonization associated with the implementation of the medical device (IUC) is low and remains non symptomatic, the colonization is termed asymptomatic bacteriuria (ASB) and may be experienced as the normal body defense to the insertion of a foreign body. If the bacterial burden increases and becomes symptomatic, due to the duration of catherization and quality of catheter care, the microenvironment is altered[13]. It can provide a prime growth medium for the development of an established community of biofilm, which represents a variable linked to the difficulty in the prevention of infection[15]. The host may subsequently become symptomatic with a variety of signs such as, fever, chills, pain, and hematuria. Evidence suggests the risk of UTI increases by 3-7% with each day of catheterization. The problem of IUC and the associated bioburden can be approached in two ways, by adhering to a protocol that limits initial placement, and by minimizing duration of placement[16]. Evidence shows

that 21% to 38% of initial urinary catheterizations are not justified, while one-third to one-half of the days of continued catheterization are not justified[16].

4.2.1 CAUTI: Occurrence and Impact

IUCs are widely used and the rate of catheterization is estimated at approximately 15-25% of hospitalized patients[17].

CAUTIs represent the majority of UTIs (67%) in all hospital patients[18], while in the population of critical care patients, CAUTIs account for up to 97% of all UTIs[19]. One multistate (10) prevalence survey in 183 hospitals (11,282 patients) found that 452 patients had one or more HAIs (4.0%). Device related infections, including CAUTI accounted for 25.6% of infections[18].

Another cross-sectional study of adult patient-visits to the Emergency Department (ED) was performed, using the National Hospital Ambulatory Medical Care Survey (NHAMCS) ED Component, which reviewed annual surveys, 1995 to 2010[20]. Demographic and presenting characteristics were collected, one variable identified was the outcome measure of placement of a IUC or a potentially avoidable urinary catheter (PAUC). PAUC was defined using the CDC Guidelines for appropriate catheter use[40]. Annual rate of ED placed IUC use varied between 2.2 to 3.3 per 100 adult ED visits. Among admitted patients, 8.4% received IUCs and 64.9% of those were Potentially Avoidable Urinary Catheters [20].

4.2.2 Other Complications Associated with IUCs

In addition to being a root cause of CAUTI due to their inappropriate use, IUCs can also be a cause of urethral erosion, bladder neck injury, bladder calculi, urinary leakage, and epididymitis or orchitis. A prospective audit review of inpatients with an IUC included surveillance of associated bacteremia and trauma[21]. Among 6513 IUC days, urinalysis and culture identified 116 UTIs (1.8% of IUC days), while 100 incidents of urinary trauma were identified (1.5% of IUC days), demonstrating trauma was as common as symptomatic UTI[21].

Bladder trauma may occur as a consequence of blunt abdominopelvic trauma cases. The American Urological Association (AUA) publishes guidelines on management of urogenital trauma, that include urethral catheter drainage as the standard of care for bladder rupture yet offer no recommendations regarding duration of indwelling catheter. One 10-year retrospective review of bladder trauma patients at a tertiary care facility, found that length of catheterization beyond 14 days yielded a sustained complication rate of 21%, while removal of catheter prior to 14 days yielded no complications[22].

4.3 Complications with Other Solutions, External Options

4.3.1 Absorptive products

Absorptive products which are a common method of containment for incontinence, have been addressed earlier and have their own inherent set of complications. IAD, categorized as a MASD, is a clinical problem and a potential outcome of UI, secondary to incontinence, if urine is not managed appropriately and moisture remains in contact at the interface with the surface of the skin. The perineal area extending to the buttocks and gluteal clefts, is especially prone to skin breakdown. Nested within the larger domain of MASD, a growing body of evidence demonstrates that IAD is a risk factor for further development of PI.

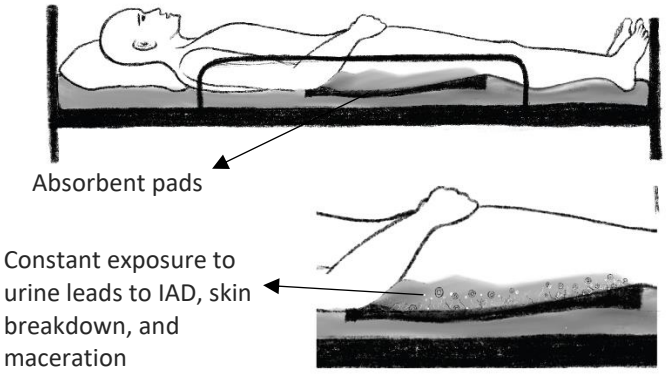

Illustration 2 - Absorbent Pads

There has been an expansion of existing technology in the field of absorptive products within the last decade, and they provide one method of containing moisture, but exposure to urine still occurs, despite wicking, with the potential for skin damage. Extended periods of skin exposure to chemical irritants provides a medium for growth of bacteria which subsequently leads to increased risk of HAI. Implementation of absorptive products for UI is less than optimal method of management, can impact user's quality of life, is a burden of labor for healthcare recipients and for caregivers, and has significant healthcare cost in

addition to inability of providing output measurement[23].

4.3.2 External sheath catheters

In addition to the internal options for UI, lately there have been external devices available for containment and management. Male options include external male catheters or condom catheters, which come with their own set of complications. These complications may include a negative impact on skin integrity, design inadequacy, inadequate adhesion and issues with packaging and quality of devices[24].

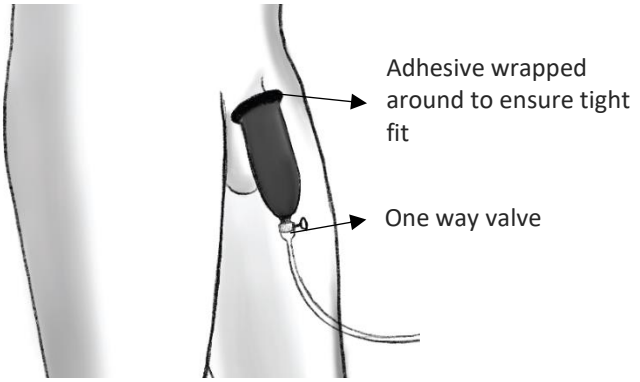

Illustration 3 - Condom/Sheath Catheters

External urinary collection devices are less invasive than IUCs, but they remain a source of risk for potential complications. Skin irritations, lesions and dermatitis have been documented, especially at the interface with the penile shaft. Problems such as PIs, disruption of drainage and dislodgement of sheaths have occurred, each exhibiting its own challenges for both the healthcare recipient and the caregiver[25].

Sheath catheters are associated with problems related to fitting and management. Correct sizing poses difficulties for the healthcare recipient and the caregiver. To avoid leakage, which can potentially be embarrassing and may lead to skin breakdown, availability of multiple sizes and a method for determining the appropriate size, is necessary. That poses logistical problems that can impact healthcare supply and demand. Quality of life may be impacted, depending upon assessment and implementation and considerations of maintaining dignity of the user is clinically important. Another consideration is the dexterity of the user[26]. Even If properly fitted, the sheath may restrict recipient's movement. Allergic reactions have also been experienced and documented, secondary to the materials used in the manufacture of the sheath devices.

A recent review and analysis of the MAUDE Database (FDA), included a report of 401 incidents associated with external urinary catheters. The primary categories of harm included clinical complications (152), impact on skin integrity (131), design inadequacy (122), adhesive based events (95) and events related to quality/packaging (25). Clinical complications encompass events related to bleeding, C Difficile Infections (CDI), kidney infections, pain, sepsis and UTIs. Events associated with skin integrity included allergic reactions, infection, Medical Device Related Pressure Injuries (MDRPIs), skin damage and irritation. Design inadequacy events involved dislodgement, device malfunction, leakage, obstruction, and sizing misfit. The issues associated with adhesives included

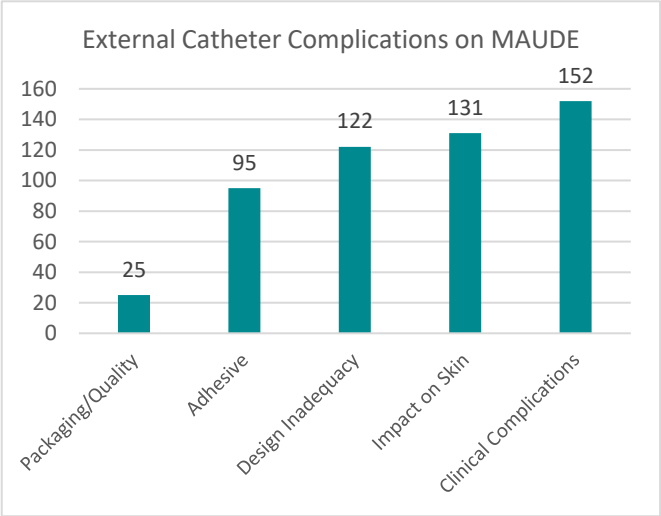

Chart 1 - FDA MAUDE Analysis

complaints related to difficulties with device removal. Packaging and quality concerns were related to harms with missing components[24].

Specific characteristics may cause sheath catheters to be unsuitable for targeted individuals[27]. Those who may not be good candidates for them include individuals with a retracted penis, those who have existing skin breakdown, anyone who is disoriented and may try to remove the sheath, individuals with urinary retention or those with a history of recurrent UTI. Therefore, assessment, training and clinical assessment are required on the part of the clinician.

5.0 Professional Implications of UI on Patient Outcomes

5.1 Best Practice Guidelines

Despite the strong link between urinary catheters and subsequent UTI, one national study found no strategy that appeared to be widely used to prevent hospital-acquired UTI[28]. Best practice is driven by evidence, which lays the foundational structure of quality healthcare delivery. Two professional organizations have contributed to the evidence-based guidelines surrounding the management of urinary incontinence; Healthcare Infection Control Practices Advisory Committee (HICPAC) and The Wound Ostomy and Continence Nurse (WOCN) Society.

HICPAC, a federal advisory committee appointed to provide advice and guidance to the Department of Health and Human Services (DHHS) and the Centers for Disease Control and Prevention (CDC), has published a Guideline for Prevention of CAUTIs which can be found at CAUTI Guidelines | Guidelines Library | Infection Control | CDC[29]. Nested within the Guideline Library, key questions drove the search for evidence such as, who should be the recipients of catheters, what is the best practice in those cases and how best to prevent CAUTI in that population. Regarding appropriate urinary catheter use, Category 1B (strong recommendation supported by low quality evidence), recommends placement only for appropriate indications such as urinary retention or bladder outlet obstruction. The recommendations advise for the catheters to be removed as soon as possible. Recommendations also advice to avoid implementation of catheters for management of incontinence. Due to paucity of high-quality evidence, the recommendations are based primarily upon expert opinion and or accepted practice[29].

In 2020, the WOCN Society, whose triad of specialties include continence care, developed, and published an algorithm for interventions post catheter removal WOCN IPCaRe. A Clinical Resource Guide in the Care and Management of Patients with Urinary Catheters (2015) was developed by the Clinical Practice Continence Subcommittee, to support best practice. They also recommend the primary Indications for Use as severe urine retention and obstruction of urine outflow. Mere Urinary Incontinence was again deemed inadmissible for the use of IUCs.

A quality assessment survey (96 questions) for infection preventionists was implemented throughout a well-known integrated health system in the mid-west to evaluate prevention measures associated with various hospital acquired infections, including CAUTI[30]. There was 100% completion of surveys, which found that 78.6% had established policies for urinary catheter placement and maintenance[30], yet variation in practice and evaluation of competencies and outcomes was found, bringing into question compliance with sound policies. Device need was initiated and driven by nurse evaluation (77.5%), yet only 26.8% of hospitals maintained annual nursing competencies[30]. This review led to recommendations for review of policies and implementation of evidence-based practice with educational initiatives.

A quality improvement project utilizing pre- and post-intervention data, assessed implementation of education to increase awareness of catheter use, with the primary endpoint being duration of catheterization. During the total study period, 149 patients (18.3%) were catheterized during their hospital stay. There was a statistically significant decrease in the duration of catheterization (median 7 vs 5 days; $p<0.01$), LOS (medium 13 vs 9 days) and the number of CAUTIs (4 vs 0, $p=0.04$)[31]. The authors conclude that awareness of risks of inappropriate catheterization has the potential to decrease the duration of catheterization, in addition to LOS and the incidence of CAUTI.

There appears to be a consensus of expert opinion that the primary indications for insertion of a urinary catheter are urinary retention and urinary output obstruction. Other indications for use, as per the ANA Streamlined Evidence-Based RN Tool: CAUTI Prevention, include comfort measures at end-of-life care, presence of difficult to heal wounds in the perineal, sacral or buttocks region, certain perioperative case use and prolonged immobilization[32]. These indications reference the CDC (2009) Criteria for IUC Insertion CAUTI 104 (cdc.gov)[33].

6.0 Fiscal Implications of UI

A review of the literature on patients who have IUCs for a period of from 2 to 10 days, found that bacteriuria is expected to develop in 26% (95% confidence interval [CI], 23% to 29%)[33]. Among patients with bacteriuria, symptoms of UTI will develop in 24%, (95% CI, 16% to 32%), and bacteremia from a urinary tract source will

develop in 3.6% (95% CI, 3.4% to 3.8%). Each episode of symptomatic UTI is expected to cost an additional $676, and catheter-related bacteremia is likely to cost at least $2836[33]. The fiscal implications of additional treatment compound the regulatory impact of these events. A systematic review of patient-level cost data, focusing on studies conducted in the United States between 2000 and 2017 revealed that the prevailing notion of a CAUTI costing approximately $1,000 is an underestimate and an oversimplification of its true economic burden. Using the data gathered, it was found that CAUTI costs ranged from $876 to $10,197 when inflation-adjusted into the equivalent of 2016 dollars[35]. The low end of that range came from a study of adult patients in an inpatient setting, with costs calculated from the hospital's perspective. The high end came from a study of ICU patients, with costs calculated from Medicare's perspective.

As many as 65%-70% of cases of CAUTI may be preventable with evidence-based strategies, while CAUTI may be the most preventable HAI[36]. The authors' findings suggest that 100% prevention of HAIs may not be attainable with current evidence-based prevention strategies; however, comprehensive implementation of such strategies could prevent hundreds of thousands of HAIs and save tens of thousands of lives and billions of dollars.

Prolonged exposure of uncontained urine in contact with the epidermal surface of the skin may increase the risk of problems associated with UI, beyond the primary outcome/complication of CAUTI. In addition to infection, MASD, IAD and subsequently PIs, that affect millions of patients annually, impacting cost-of-management across the care continuum.

'The national cost of hospital-acquired pressure injuries in the United States' by William V Padula averages the expected cost of HAPI to be $10,708 which represents the incremental cost incurred because of extended LOS while the total national burden is estimated at $26.8 Billion for 2.5 million reported cases in the United States.

7.0 QiVi - A novel solution

7.1 Value proposition

A new external device for management of urinary output has become available for male bedridden patients experiencing UI. External Urine Management Device- 'QiVi', is an effective solution to the most common problems associated with the available internal management devices. With an innovative design, the QiVi contains urinary output, while simultaneously eliminating the complications associated with incontinence, absorbent pads, IUC's, and many external catheters including CAUTI, skin breakdown, urethral erosion, bladder neck injury, bladder calculi, and urinary leakage.

7.2 Innovation in Design

The QiVi is a solution to the problem of UI in the male population, while minimizing the risks associated with the currently available solutions. The external collection device is safe and efficacious in its method of application. It offers a reliable, consistent method for fluid collection and for measurement of the accurate urine output for documentation to calculate accurate fluid replacement. Furthermore, QiVi is a closed system which keeps the skin dry while acting as a two-way shield against the spread of infection.

QiVi adheres securely to the male anatomy with a novel silicone-based adhesive patch. The patch conforms around a wide range of anatomical sizes, provides a secure seal, and maintains a balanced microclimate at the interface with the urogenital area of skin. The patch has a customized shape that is designed to prevent any stress built up on the adhesive when the patient is being maneuvered in bed. More importantly the QiVi device is designed to be one size fits all, thus eliminating the need for stocking devices of multiple sized in the ICU. Comprehensive functional testing was performed to determine safety and efficacy. Results indicate that the adhesive patch maintains skin integrity while it shows no instance of dermal irritation upon repeated use[37]. Additional laboratory testing on the silicone-based adhesive employed demonstrates that the secure seal at the interface of skin and patch performs well even in the presence of hair follicles

while offering level of individual user comfort, even with repetitive application[39].

QiVi is designed to divert male urinary output into a collection cannister using negative pressure suction. It minimizes the complications caused by other types of urinary management systems, while providing accurate urinary output measurements for essential clinical documentation to meet patient needs. In-vitro simulation was conducted for comparative analysis of urinary output diverted by QiVi and IUC in a defined time period. The test was performed in a clinical laboratory with a silicone anatomical model, while maintaining consistent output flow rate, volume, and recommended suction pressure, in a controlled environment. The QiVi was able to divert the fluid 99.60% (400 ml) in 90 second[38]. The QiVi has a proprietary flow enhancing internal surface, which supports the diversion of fluid 48% faster than an IUC[38].

QiVi device is optimized for flow and does not have any absorbent or bulking materials in it. Singular focus of this design feature ensures the patients skin remains dry. The use of air-inlet ports in conjunction with vacuum suction creates a positive micro-climate in the pouch that remains void of any fluid or excessive moisture. The microclimate minimizes the risk associated with reportable clinical complications, damage to skin integrity, previous/currently available design inadequacy, adhesive problems, and quality concerns. It offers a method to contain UI in male population, that is safe and efficacious.

Besides accurate urine measurement and keeping the skin dry, another clinical problem the QiVi product solves is the creation of any air-lock or vacuum lock in the entire system. Flexible pouches often buckle (folds over) when filled with fluids or get entangled with patient's apparel or bedding. A folded pouch creates an obstruction that inhibits flow of urine. This obstruction leads to leakage of the pouch and requires a care provider to remove the air/vacuum lock from the suction line while avoiding any spilling of collected output. To address these benign yet important clinical challenges, the QiVi device comes with a peripheral frame where the tensile strength of the frame is modulated to provide both a shape memory as well as resiliency to the QiVi pouch. The other clinical advantage of a frame like structure is that the patients can now rest in a lateral or a semi-seated position and urinate in the pouch without causing any leakage.

Lastly, Medical Device Related Pressure Injuries are a growing phenomenon across the continuum of care. The National Pressure Injury Advisory Panel (NPIAP) has designated a specific category of PI associated with medical devices, called the Medical Device Related Pressure Injury (MDRPI) and have developed Guidelines for prevention MDPRI Posters | National Pressure Ulcer Advisory Panel (npiap.com) . The novel QiVi device was designed such that the urine output gets suctioned in the cranial direction, to minimize risk of MDRPIs. This approach, may seem counter-intuitive to most gravity enabled fluid collection devices, but it helps in avoiding any device related pressure injuries by eliminating tubing that could cause positional pressure injuries of the lower extremities. A suction tube that comes out over the supra-pubic and abdominal region, improves care provider efficiency and is well below the chest of the patient incase that space is needed for immediate cardio-pulmonary management.

Conclusion

The challenges and complications of UI management impact patient outcomes. Until now, solutions for UI have posed their own set of barriers to facilitating quality care. The QiVi has been designed to resolve the problems associated with management of male urinary incontinence, in a select subset of immobilized individuals, with benefits for both healthcare recipients and healthcare professionals. Through the analysis of clinical experience matched with the desire to learn from the past while eliciting feedback from clinicians, an innovative technology is now presented as a viable option. QiVi design facilitates quality of care and provides solutions associated with UI. Technology is leveraged for optimal patient outcomes.

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