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TrueClr Active External Catheter White Paper

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Prospective Blinded Evaluation of the First External Catheter System that Actively Empties the Bladder (Ur24T / TrueClr)

Background

According to 2019 statistics from the Institute for Healthcare Improvement (IHI) and the US Centers for Disease Control (CDC), Catheter Associated Urinary Tract Infections (CAUTIs) acquired in a hospital setting may be in excess of 500k per year in the United States.[1,2] If nursing homes are considered along with acute care hospitals, it is estimated that there are more than one million cases of CAUTIs annually in the U.S. based on IHI statistics. Complications associated with CAUTIs include longer Length of Stay (LOS), patient discomfort, and overall increase in healthcare cost. The primary risk factor leading to a CAUTI is the presence of an internal catheter. The best way to eliminate CAUTIs is to reduce the use of internal catheters. Current devices, such as urinals, bedpans, and other external catheter devices, are passive meaning the patient must be able to void the bladder through muscle control and often allow urine to come into contact with the skin. Furthermore, the physical demands on nurses to help aid in voiding a patient's bladder leads to fatigue, potential falls, and injured backs related to lifting and moving their patients. The Ur24T TrueClr catheter represents a revolutionary new approach to urine elimination with active external removal. As an active device, it utilizes suction applied

either from hospital grade wall suction or an external suction device. The question of the effectiveness of the Ur24Technology TrueClr adult models on active elimination and if any tissue injury occurs was the purpose of this study.

Hypothesis

This review presents an evaluation of the Ur24T/TrueClr products in terms of their ability to eliminate the urinary bladder at pressure levels that do not cause pressure injuries in both male (TrueClr M/M+) and female (TrueClr F) patients. Patient satisfaction is also assessed.

Methods

This study involved 41 patients (21 male/20 female) who were between the ages of 20-82 years old. The durations of placement were 7 to 14 days. The participants completed a survey about their experience with the TrueClr External Catheter. The evaluation included assessments of urinary collection, duration of use, comfort level, and skin condition.

To assess skin condition, the following tools and methods were used:

1) Tools
   a) NPIAP Pressure Injury Stages (see appendix 1)
   b) Verified skin monitoring assessment was also performed

2) A subset of the patients had photos reviewed of the skin where the TrueClr was applied, randomized, and reviewed in a blinded fashion

3) 2 Independent Evaluations
   a) Dermatology review of randomized photos
   b) RN skin assessment expert review

Results

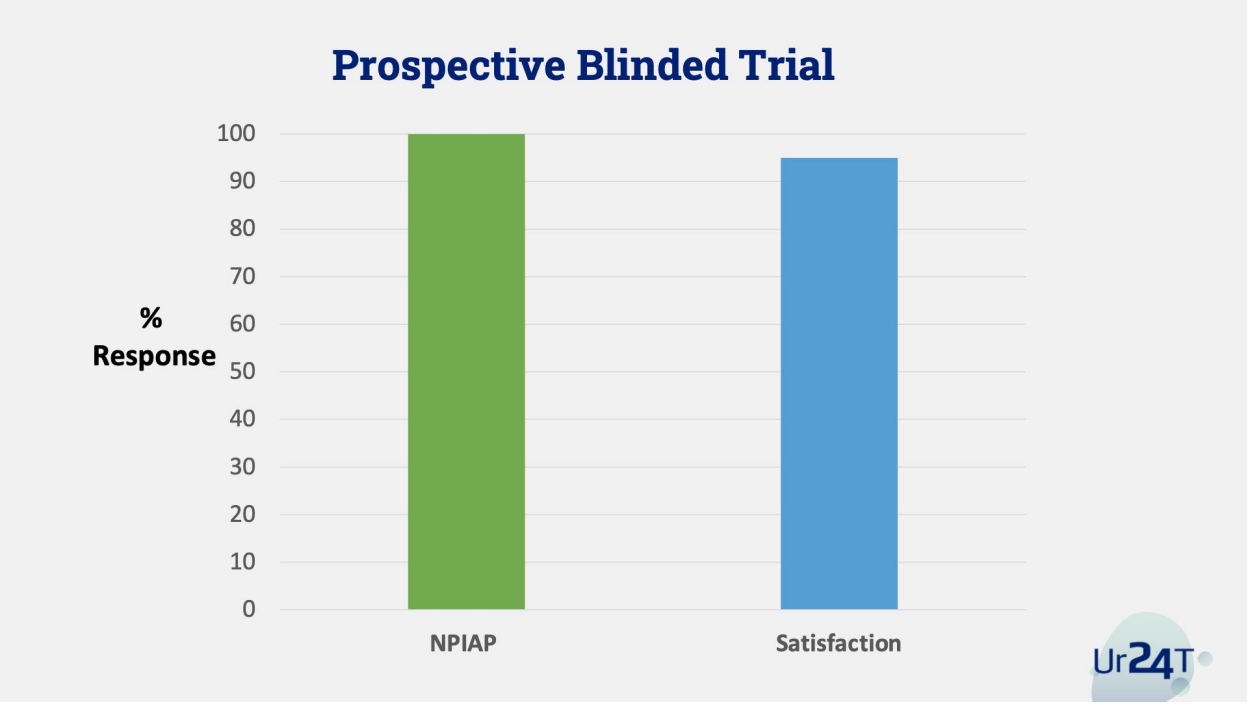
The Ur24T TrueClr catheter was proven to be highly effective as an active external catheter capable of removing a significant amount of urine from the bladder without tissue injury. On average, 650 mL of fluid was eliminated from the bladder, with a range of 550-1050 mL. As seen in the table graphs, survey responses indicated no evidence of pressure injuries (score = 100%) in the target areas of use and the comfort satisfaction score was high at 95%.

Survey

Survey data was collected using a 5-point Likert Scale (1 = Strongly disagree, 2 = Disagree, 3 = Neutral, 4 = Agree, 5 = Strongly agree).

Survey data demonstrated significant satisfaction with TrueClr and high ease of use:

- 100% Agreed that TrueClr was intuitive to use
- 86% Agreed that TrueClr was comfortable to wear
- 70% Strongly Agreed and 30% Agreed it was easy to use
- 100% Reported no skin irritation
- 100% Would recommend the TrueClr product to patients with similar clinical symptoms



Legend: NPIAP Pressure Injury Stages (left), 100% with negligible/no irritation. Satisfaction with TrueClr (right) was > 95%.

Representative Clinical Scenarios

Outpatient

This patient is a 72-year-old male who has urinary incontinence at night with frequent need to urinate and frequent accidents. This led to daytime tiredness.

Data Collected

- 12 days of data
- Duration from 7 to 9.5 hours
- Collection from 550 – 1050 ML
- Average collection of 647 ml/session.
- Comments: Comfortable. Amazing urine collection system easy to use
- NPIAP score = 0

Inpatient

This patient is an 85-year-old female who suffered Acute Respiratory Failure in the Intensive Care Unit after the indwelling catheter was removed. The TrueClr catheter was used to monitor Intake and Output (I&O's).

Data Collected

- 4 days of data
- Patient wore female catheter for 12 hours throughout the night shift and was disconnected throughout the day while working with physical therapy and occupational therapy
- Collection was 850mL-1.7 Liters
- Average collection was 1.15 Liters/session
- No evidence of skin breakdown nor irritation
- Comments per staff: "Easy to use, much better than the previous external catheters that our facility used."
- Comments per patient family: "I'm happy that my loved one was able to get away from using the catheter because of the inconvenience of having a catheter."

Outpatient: Muscular Dystrophy

This is a family that has 4 male children that suffer from Muscular Dystrophy. The ages are 16 (twins), 22, and 28. Three out of the four patients are wheelchair bound who do have control of their bladders while the fourth patient was bed ridden with tracheostomy and feeding tubes.

Data Collected

- Comments per family: “Needed TrueClr catheter for him because he was urinating in diaper often. Made easier so that the diaper does not have to be changed multiple times per day. No leakage, works well for urine collection.”

Conclusions

The Ur24T TrueClr prospective blinded evaluation has shown that the external catheter device did not cause any suction trauma and was effective at eliminating retained urine from the bladder. The male (TrueClr M/M+) and female (TrueClr F) external catheter empties the bladder best in the 100-130 mmHg pressure ranges. The external catheter was proven to be effective at draining the bladder and was well tolerated with high patient satisfaction. The recommendations to interchange or discontinue the external device after 15 days inpatient and 30 days outpatient appear to be valid and not result in infection or tissue injury.

Recommendations

Based on the high satisfaction, low risk profile and successful elimination of urine from the bladder, TrueClr has demonstrated that it can successfully be used in a variety of clinical situations where either external catheters or indwelling catheters are currently used. We recommend considering the use of these catheters in both the inpatient and outpatient settings in cases where external or internal catheters are currently being used.

Limitations

One limitation of this study while it was performed on some immunocompromised patients, more patients will help gain insight in the tolerance in this group. The initial data however is encouraging.

Appendix 1: National Pressure Injury Advisory Panel “NPIAP” Pressure Injury Stages

The updated staging system includes the following definitions:

Pressure Injury: A pressure injury is localized damage to the skin and underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue.

Stage 1 Pressure Injury: Non-blanchable erythema of intact skin

Intact skin with a localized area of non-blanchable erythema, which may appear differently in darkly pigmented skin. Presence of blanchable erythema or changes in sensation, temperature, or firmness may precede visual changes. Color changes do not include purple or maroon discoloration; these may indicate deep tissue pressure injury.

Stage 2 Pressure Injury: Partial-thickness skin loss with exposed dermis

Partial-thickness loss of skin with exposed dermis. The wound bed is viable, pink or red, moist, and may also present as an intact or ruptured serum-filled blister. Adipose (fat) is not visible and deeper tissues are not visible. Granulation tissue, slough and eschar are not present. These injuries commonly result from adverse microclimate and shear in the skin over the pelvis and shear in the heel. This stage should not be used to describe moisture associated skin damage (MASD) including incontinence associated dermatitis (IAD), intertriginous dermatitis (ITD), medical adhesive related skin injury (MARSI), or traumatic wounds (skin tears, burns, abrasions).

Stage 3 Pressure Injury: Full-thickness skin loss

Full-thickness loss of skin, in which adipose (fat) is visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.

Stage 4 Pressure Injury: Full-thickness skin and tissue loss

Full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer. Slough and/or eschar may be visible. Epibole (rolled edges), undermining and/or tunneling often occur. Depth varies by

anatomical location. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.

Unstageable Pressure Injury: Obscured full-thickness skin and tissue loss

Full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed. Stable eschar (i.e. dry, adherent, intact without erythema or fluctuance) on the heel or ischemic limb should not be softened or removed.

Deep Tissue Pressure Injury: Persistent non-blanchable deep red, maroon or purple discoloration

Intact or non-intact skin with localized area of persistent non-blanchable deep red, maroon, purple discoloration or epidermal separation revealing a dark wound bed or blood-filled blister. Pain and temperature change often precede skin color changes. Discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury, or may resolve without tissue loss. If necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle or other underlying structures are visible, this indicates a full thickness pressure injury (Unstageable, Stage 3 or Stage 4).

This stage should not be used to describe moisture associated skin damage (MASD) including incontinence associated dermatitis (IAD), intertriginous dermatitis (ITD), medical adhesive related skin injury (MARSI), or traumatic wounds (skin tears, burns, abrasions).

Medical Device Related Pressure Injury

Medical device related pressure injuries result from the use of devices designed and applied for diagnostic or therapeutic purposes. The resultant pressure injury generally conforms to the pattern or shape of the device. The injury should be staged using the staging system.

Mucosal Membrane Pressure Injury

Mucosal membrane pressure injury is found on mucous membranes with a history of a medical device in use at the location of the injury. Due to the anatomy of the tissue these ulcers cannot be staged.

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Appendix 2: Citations

1. “How-to Guide: Prevent Catheter-Associated Urinary Tract Infection: IHI.” Institute for Healthcare Improvement, http://www.ihi.org/resources/Pages/Tools/HowtoGuidePreventCatheterAssociatedUrinaryTractInfection.aspx.

2. R. Douglas Scott II. The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention - Centers for Disease Control, Mar. 2009, https://www.cdc.gov/HAI/pdfs/hai/Scott_CostPaper.pdf.

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