

ASSESSMENT OF THE EFFECTIVENESS AND EASE OF USE
OF DIRECTVISION[®] - A DIRECT VISUALIZATION SYSTEM
FOR URINARY CATHETERIZATION: RESULTS OF A
SINGLE-CENTER PROSPECTIVE STUDY

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List of Abbreviations:

CDC	Center for Disease Control and Prevention
BPH	Benign prostatic hyperplasia
DUC	Difficult urinary catheterization
FDA	Food and Drug Administration
VGCD	Visually-guided catheterization device

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1. Research Synopsis

The Center for Disease Control and Prevention (CDC) reports that one in four patients hospitalized in the United States is catheterized to void the bladder or monitor urinary output. In the male population, Dr. Singh, an urologist estimates that about 20% of catheterizations are difficult. Driving a catheter blindly, guessing whether to push the catheter forward or manipulate it to get around a point of resistance leads to the risk of injury which increases the more the catheter is manipulated. Additional adverse events include: urosepsis, UTI and bladder perforation. The standard of care treatment for patients with difficult urinary catheterization (DUC) is to proceed with a cystoscopic catheter placement or suprapubic tube placement.

PercuVision has the only Foley catheter with a micro-endoscope for visualization and navigation of the urethra for nurses and other qualified health care professionals.

Moreover, it allows urologists to place a guidewire under direct vision rather than calling for a flexible cystoscope which is considered a minor procedure.

In this study, we plan on assessing the effectiveness and ease of use of the PercuVision DirectVision[®] System device.

1.1 Study Title

Assessment of the effectiveness and ease of use of the DirectVision System - A catheter-based direct visualization system for urinary catheterization: results of a single-center prospective study.

1.2 Study Population

We will prospectively enroll any patient over 18 years old with a standard indication for difficult urinary catheterization from March 6th, 2017 (if approved by IRB) to December 6th, 2017.

1.3 Study Design

This is a prospective unblinded randomized study where we will prospectively enroll any patient over the age of 18 years (except pregnant patients) with a Urology consult for a standard indication for difficult urinary catheterization from March 6th, 2017 to December 6th, 2017. The prospective subjects will be randomized to either catheter placement via DirectVision or catheter placement via cystoscope. We will gather details such as name, age of patient, address, sex of patient, urological history of patient, indication for Foley catheter placement, number of attempts by referring service and level of training of the person who tried placing the catheter, time to place catheter via DirectVision/cystoscope, ancillary tools used (Coude catheter, guidewires, dilators, suprapubic tube, cystoscope, etc), findings (false passage, stricture, bladder neck

contracture, obesity, mental impairment, BPH, etc), adverse outcome, degree of difficulty, presence of pain and hematuria.

1.4 Sample Size

We hope to enroll a total number of 75-100 subjects. We usually receive about 10-20 consults a month for difficult Foley catheter placement.

1.5 Study Duration

We estimate that the study duration will be 9 months. We plan on enrolling patients until December 6th, 2017.

1.6 Primary Objective

To assess the effectiveness of using DirectVision for all cases of difficult urinary catheterization prior to proceeding cystoscopically. The following outcomes will be measured (Set up time/total procedure time to place catheter placed via DirectVision/cystoscope, ancillary tools used, findings, adverse outcome, degree of difficulty, presence of pain and hematuria).

1.7 Secondary Objectives

To evaluate the cost to place a catheter using DirectVision versus via flexible cystoscope.

2. Background and Significance

Difficult urinary catheter (DUC) insertion is one of the most common reasons for urological consultation in hospitals. Despite the prevalence of consultation, literature regarding DUC is extremely limited and focuses predominantly on techniques of successful catheter placement, rather than understanding the clinical situations associated with difficult catheterization consults.

Although the incidence of DUC is unknown, many causes have been identified, including anxiety, poor technique, urethral stricture, phimosis, anasarca, bladder neck contracture, false passages, benign prostatic hyperplasia, unfavorable body habitus and patient positioning¹.

Routine placement of transurethral catheters can be challenging in some situations, such as urethral strictures, severe phimosis and false passages. Intravaginal retraction of the urethral meatus can complicate Foley placement in postmenopausal females. In men, blind urethral procedures with mechanical or metal sounds without visual guidance or guidewire assistance are now discouraged due to the increased risk of urethral trauma and false passages².

Complications of DUC can include urethral abscess, necrotizing infection, rectal injury, urethral stricture, urinary tract infection, urosepsis, hematuria requiring transfusion, as well as extreme physical and emotional distress to the patient¹.

All health care professionals and staff, who are authorized to place urinary catheters, should be instructed in proper techniques and encouraged to call for help if they encounter difficulties beyond their ability to resolve².

Since ancient Greece, urinary catheters have been placed blindly. Urinary catheterization is considered an essential skill for physicians and, in the past, required surgery when blinded attempts failed. The last major advancement in urinary catheterization occurred when rubber catheters were introduced in the 18th century⁴.

DirectVision is a new visually-guided catheterization device (VGCD) that uses a camera visual guide / microendoscope within a triple lumen flexible urinary catheter with an angled tip, essentially combining the functionality of a urinary catheter with a cystoscope. DirectVision uses fiber-optic bundle of 6,000 integrated fibers to provide illumination and transmit real-time video. This pilot study suggests that the VGCD is feasible and safe to use in the clinical setting³.

Flexible cystoscopy is currently the national/international standard of care for placement of complex Foley catheter. DirectVision has been FDA-approved for difficult urinary catheterization.

All investigators performing urinary catheterization either via flexible cystoscope or via DirectVision have adequate training and experience if both procedures are being compared.

Procedures done via flexible cystoscopy or DirectVision will be covered by insurance (including Medicaid/Medicare).

In this prospective study, we plan on assessing the effectiveness and ease of use of DirectVision - A direct visualization system for urinary catheterization.

3. Objectives

Our objectives are to assess the effectiveness of using DirectVision for all cases of difficult urinary catheterization prior to proceeding cystoscopically and additionally to

assess the cost difference between catheter placement via flexible cystoscope versus DirectVision.

3.1 Primary Objective

To assess the effectiveness of using DirectVision for all cases of difficult urinary catheterization prior to proceeding cystoscopically.

Outcomes such as Set up time/total procedure time to place catheter placed via DirectVision/cystoscope, ancillary tools used, findings, adverse outcome, degree of difficulty, presence of pain and hematuria will be measured.

3.2 Secondary Objectives

To evaluate the cost difference to place a catheter using DirectVision versus via flexible cystoscope.

4. Study design/methodology

This is a prospective unblinded randomized (alternating assignment) study where we will prospectively enroll any patient over the age of 18 years (except pregnant patients) with a Urology consult for a standard indication for difficult urinary catheterization from March 6th, 2017 (if approved by IRB) to December 6th, 2017.

Nurses and providers will be asked to call Urology for any patient who was found to have a DUC. A DUC in this study will be characterized as any catheterization that was not successful after one attempt. Then the prospective subjects will be randomized to either catheter placement via DirectVision or catheter placement via cystoscope by Dr Calixte, Dr Parekattil or Dr Brahmhatt. We will gather details such as name, age of patient, address, sex of patient, urological history of patient, indication for Foley catheter placement, number of attempts by referring service and level of training of the person who tried placing the catheter, time to place catheter via DirectVision/cystoscope, ancillary tools used (Coude catheter, guidewires, dilators, suprapubic tube, cystoscope, etc), findings (false passage, stricture, bladder neck contracture, obesity, mental impairment, BPH, etc), adverse outcome, degree of difficulty, presence of pain and hematuria.

Normally a 16Fr flexible cystoscope with a light source is used when difficult urinary catheterization are encountered.

After successful catheterization via cystoscopy or DirectVision, we will follow the patient for 1-3 days as needed to ensure adequate Foley drainage.

DirectVision is an innovative device from DirectVision System; Westerville, Ohio which consists of a microendoscope that inserts into 1 lumen of a 3-way/trilumen Foley catheter. The microendoscope is connected to a camera and LED (light emitting diode), transporting light to the catheter tip and an image back to the LCD (liquid crystal display) monitor for real time visualization of the urethra during catheter placement. Irrigation is used during catheter placement to assist in expanding the urethra, activating the lubricious coating of the catheter, and preventing debris from covering the lens at the distal tip of the catheter. A curved (Coude') tip assists in navigating the normal S-shaped curve of the bulbous urethra. The procedure may be performed by any health professional (surgeon, physician, nurse, or allied health staff) trained to insert Foley catheters. The

minimal training required to learn equipment may be incorporated into existing nursing or residency training.

PercuVision (sponsor) will offer a grant to the PUR Clinic. Part of the grant will be used to gift the hospital with a cystoscopy cart which will hold disposable supplies to help make access to supplies easier (\$1733). \$1000-1200 will be taken from the grant to provide a 30 minutes presentation about DirectVision to the nurses at South Lake. The sessions will go during one week span. We will provide a continental service (\$3/person) for the early day session and a lunch session (\$5/person). The food will be catered from our South Lake Cafeteria. The target would be 200 RNs who work during the hours of 0800 – 1700. Physicians will be compensated \$100 for completion of each research form. PercuVision will also pay the Hospital overhead ~3000\$ and the IRB fees (\$2375 for the initial fee for a sponsored study is \$2375 and \$900 for the annual continuing fee).

5. Study Population

We will prospectively enroll any patient over 18 years with a standard indication for difficult urinary catheterization (failed catheterization after one attempt) from March 6th, 2017 (if approved by IRB) to December 6th, 2017.

5.1 Inclusion Criteria

Any patient over 18 years with a standard indication for difficult urinary catheterization from March 6th, 2017 (if approved by IRB) to December 6th, 2017 between the hours of 8AM and 5PM.

5.2 Exclusion Criteria

Any patient younger than 18 years of age, pregnant patients, patients who present between 5PM and 8AM.

6. Study Duration/ Study Timeline

We estimate that the study duration will be 9 months. We plan on starting to enroll subjects once approved by IRB around March 6th, 2017 (if approved by IRB) to December 6th, 2017

- Stage 1 Enrollment of subjects 6 months
- Stage 2 Data analysis and presentation and publication 3 months

7. Statistical Analysis Plan

Due to the lack of data in the comparison between DirectVision and flexible cystoscopy, we are creating this prospective study to assess the effectiveness and ease of use of DirectVision. This is an initial study to obtain preliminary data and likely only descriptive data will be gathered. We will subdivide the data into groups such as set up time/total procedure time to place catheter placed via DirectVision/cystoscope, ancillary tools used, findings, adverse outcome, degree of difficulty, presence of pain and

hematuria etc. The outcomes data will be collected in a data collection sheet. The outcomes data will then be analyzed and compared using ANOVA. We hope to enroll a total number of 75-100 subjects in both arms (DirectVision versus Flexible cystoscopy). We usually receive about 10-20 consults a month for difficult Foley catheter placement. There will likely be 50 subjects from each arm.

8. Informed Consent Process

An informed consent will be obtained. The subjects will be patient over 18 years who have a consult for difficult urinary catheterization.

9. Privacy and Confidentiality

The records of this study will be kept private and will be protected to the fullest extent provided by law. The data collection sheet will be stored in computers that are password protected to safeguard confidentiality. These Orlando Health computers are located in our Urology offices at South Lake hospital which are in locked room and require authorized access.

The consents will be stored in file cabinets located in a locked room in our PUR clinic office.

The consents and datasheet will be stored in a locked office of the investigators and maintained for a minimum of three years after the completion of the study.

Human subjects' names will be kept on a password protected file and will be linked only with a study identification number for this research. The study identification number will be kept separate from the data collected, and will be destroyed according to Orlando Health policy after three years.

Only the investigators Dr Etafy, Dr Parekattil and Dr Brahmhatt will have access to the data. No portable storage will be used for research data. The data will only be stored in the Orlando Health computers.

This research presents no greater than minimal risks to the patients and will not affect the rights and welfare of any of the subjects.

10. Risk/Benefit

10.1 Risk to participants:

Risks of cystoscopy (standard of care): subjects may subsequently experience blood in the urine, abdominal pain and burning sensation when urinating, infection from germs introduced in the urinary tract.

Risks of DirectVision are the same as the risks of cystoscopy.

Breach of confidentiality is a possible risk in this prospective study which will be mitigated by the use of password-protected computers.

10.2 Benefits to Participants:

We are hoping that the benefits to the patient will be decrease risk of infection, pain, bleeding, or risk of stricture formation from several tries of blind catheter placements. Moreover, the study will provide an opportunity to gain a better understanding of which

treatment options confer the best results for patients suffering with difficult urinary catheterization.

11. Safety Monitoring, Interim Analysis, and Stopping Rules

Breach of confidentiality is a possible risk in this prospective study which will be mitigated by the use of password-protected computers. There are also the usual risks that come with procedures such as infection, bleeding and pain. There are no other risks foreseen to the patients in this study.

There will be no interim review because known risks do not pose a threat of serious adverse events and the risks for both procedures are the same.

We do not anticipate any safety issue that will result in the suspension of this prospective study. The patient identifiable information will be deleted from the list at the earliest convenience after the completion of the study and the rest of the data which will only contained non-identifiable information will be kept indefinitely.

Additionally, any event or finding resulting in a temporary or permanent suspension of the study will be reported to the IRB and to the Corporate Office of Research Operations (CORO) in a timely fashion.

12. Conflict of Interest

There will be a grant provided to PUR clinic to gift the hospital with a cystoscopy cart, to pay for food during educational sessions and for research forms completion by the physicians as mentioned above.

13. Publication and Presentation Plans

We are planning on publishing when all the data have been gathered.

14. References

1. Bacsu et al. A prospective analysis of consultation for difficult urinary catheter insertion at tertiary care centres in Northern Alberta. *Can Urol Ass J*. Sept-Oct 2013; 7(9-10): 343-347.
2. Ghaffary et al. A practical approach to difficult urinary catheterizations. *Cur Urol Rep*. 2013 Dec;14(6):565-79.
3. Banks et al. Feasibility study of a visually guided male urinary catheterization device. *Journal of Urology*. 2009; 181(4): p454.
4. Willette et al. Best practices for blind catheterizations and algorithm to manage difficult urinary catheterization, including direct visualization of the urethra during placement. *West J Emerg Med* 2012.

15. Appendices

Data sheet collection