Visually Guided Male Urinary Catheterization: A Feasibility Study

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Introduction: Ten percent to 15% of urinary catheterizations involve complications. New techniques to reduce risks and pain are indicated. This study examines the feasibility and safety of male urinary catheterization by nursing personnel using a visually guided device in a clinical setting.

Methods: The device, a 0.6-mm fiber-optic bundle inside a 14F triple-lumen flexible urinary catheter with a lubricious coating, irrigation port, and angled tip, connects to a camera, allowing real-time viewing of progress on a color monitor. Two emergency nurses were trained to use the device. Male patients 18 years or older presenting to the emergency department with an indication for urinary catheterization using a standard Foley or Coudé catheter were eligible to participate in the study. Exclusion criteria were a current suprapubic tube or gross hematuria prior to the procedure. Twenty-five patients were enrolled. Data collected included success of placement, total procedure time, pre-procedure pain and maximum pain during the procedure, gross hematuria, abnormalities or injuries identified if catheterization failed, occurrence of and reason for equipment failures, and number of passes required for placement.

Results: All catheters were successfully placed. The median number of passes required was 1. For all but one patient, procedure time was ≤ 17 minutes. A median increase in pain scores of 1 point from baseline to the maximum was reported. Gross hematuria was observed in 2 patients.

Discussion: The success rate for placement of a Foley catheter with the visually guided device was 100%, indicating its safety, accuracy, and feasibility in a clinical setting. Minimal pain was associated with the procedure.

Key words: Urinary catheterization; Iatrogenic injury; Medical device safety; Urinary tract infections; Secondary prevention

Urinary catheterization is a commonplace procedure, with approximately 24 million catheters placed each year in the United States.[1] Although most catheterizations proceed without incident, approximately 10% to 15% involve complications, resulting in patient suffering and escalation of resources and personnel (Mayo Clinic Urinary Catheterization Team, oral communication, November, 2007). Injuries include tissue tears and false passage.[2] The risk of infection is approximately 3% to 10% per day of catheterization.[3] The more problematic the catheterization and the more attempts that are made, the greater the likelihood of bacterial contamination and subsequent urinary tract infection (UTI).[4] Even when omitting complicated catheterizations, insertion of a urinary catheter has been found to be the fourth most painful procedure in the emergency department and is significantly more painful in men than in women.[5]

Given the frequency and potential consequences of complications, new techniques to reduce not only the risks but the discomfort associated with urethral catheterization are clearly indicated.[5] The National Quality Forum recommends developing technology that allows direct visualization of the urethra during catheterization as part of a comprehensive strategy to reduce catheter-associated UTIs.[6] An innovative visually guided urinary catheterization device that addresses this problem recently has been developed.

The device is composed of a visual guide consisting of a 0.6-mm fiber-optic bundle inside a 14F triple-lumen flexible urinary catheter with an angled tip, which connects to a camera (Figure 1). The silicone catheter has a lubricious coating and an irrigation port. The angled tip allows flexible navigation under direct visualization. Progress can be viewed in real time on a color monitor.

Use of such a device may decrease iatrogenic urethral trauma, pain experienced by the patient, the number of health care providers involved, additional medical proce-

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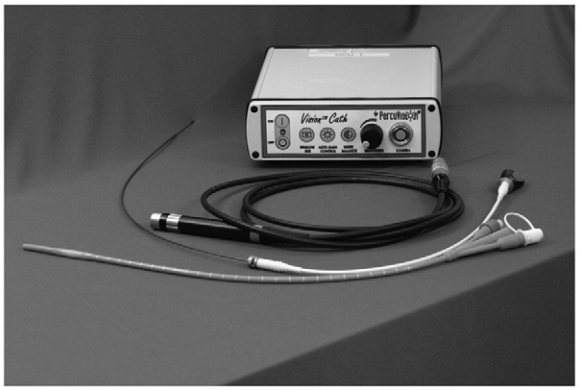

FIGURE 1
The visually guided urinary catheter device.

dures and supplies needed, and the time required for successful urinary catheterization. The goal of this pilot study was to examine the feasibility and safety of male urinary catheterization by nursing personnel using the visually guided device in a clinical setting.

Methods

STUDY DESIGN

This prospective study assessed the use of the visually guided device in male patients who were admitted to the emergency department and required catheterization. The study was approved by our hospital's Institutional Review Board.

STUDY SETTING AND POPULATION

The hospital in which this study took place is a large teaching community hospital. It has 1000 licensed beds, is a level II trauma center, and admits approximately 25,000 patients through the emergency department each year.

Two emergency nurses were trained to use the device via a pelvic trainer (Limbs & Things, Savannah, GA) in the hospital's simulation center. A didactic program was developed including lectures on male anatomy, indications and contraindications for urinary catheter placement, and complications that may occur. Criteria for proficiency included 5 practice procedures followed by 5 successful catheterizations as determined by one of the physician investigators.

Male patients aged 18 years and older who presented to the emergency department were eligible if they had a standard indication for urinary catheterization using a standard Foley or Coudé catheter. Exclusion criteria were having a current suprapubic tube or gross hematuria prior to the procedure. Stopping criteria previously developed for the protocol were based on injuries to the urethra, technical failures of the equipment, and the upper limit of the 95% confidence interval for the success rate of the device falling below 70%. None of the stopping criteria was met. Therefore 25 patients were enrolled, a number considered sufficient for a small feasibility study. In this initial feasibility study, it was not necessary for patients to be experiencing a difficult catheterization. During enrollment, a research coordinator obtained written consent from eligible patients and then recorded real-time data during the procedure.

STUDY PROTOCOL

The catheterization procedure consisted of the following steps:

1. Assembling the visually guided urinary catheterization equipment (ie, turning on and connecting the device's camera and monitor)
2. Preparing the patient for the procedure (ie, swabbing the genitalia with Betadine, instilling lidocaine gel, and retaining it for 5 minutes with use of a penile clamp)
3. Preparing the catheter for insertion (ie, inserting the visual guide into the guide port, connecting it to the camera light source, and commencing irrigation with sterile fluid)
4. Catheterization: advancing the catheter to the bladder
5. After the procedure: removing the visual guide and cap port, turning off the equipment, and transporting it for sterilization

If a catheter placement required multiple pullbacks and advancements and a second health care provider would normally attempt the catheterization or a urologist would have been consulted, a similar practice was followed when using the new device. The visual guide component is reusable and was resterilized in the hospital's reprocessing center using STERRAD low-temperature hydrogen peroxide gas plasma sterilization (Advanced Sterilization Products, Irvine, CA). In this study, the visual guide remained operative for approximately 10 catheterizations.

MEASUREMENTS AND KEY OUTCOME MEASURES

Primary outcomes of the study included whether the catheter was successfully placed. The total procedure time, defined from when the urinary kit was opened to balloon inflation, was measured via a stopwatch by the research coordinator, who did not perform the procedure. During the procedure, the coordinator queried patients about their pre-procedure and maximum pain, based on a 0 to 10 point pain scale. The report of pre-procedure pain was obtained just prior to the beginning of the catheterization procedure, and the report of maximum pain was obtained immediately after the Foley catheter was placed. Whether gross hematuria resulting from catheter insertion was pre-