This case study presents findings from one subject enrolled in a research study evaluating an experimental device called the Cath-Assist (see Figure 1). The Cath-Assist (Physician Technologies Incorporated, Reno, NV) is designed to facilitate female urethral catheterization by exposing the vulvar vestibule, isolating the urethral opening, and blocking the entrance to the vagina. The product is made of a material called Voridian, which is an FDA-approved Class VI polymer already utilized in other medical products. Devices for this research study were sterilized using gamma radiation, individually packaged, and sent to the research team for use according to the research protocol. Currently, the device is not available to clinicians.

This case study is the first publication about this device. A randomized, controlled, clinical trial study was chosen to evaluate the Cath-Assist. Female patients admitted to a general surgical unit who require urethral catheterization, were over the age of 18, and could read and speak English were invited to participate. In the control group, urethral catheters were inserted using the hospital’s current policy and procedure (Reilly, 2001). In the intervention group, this same policy and procedure were followed, and the Cath-Assist device was used to assist with catheter insertion. A research nurse was present during the catheterization procedure, which was performed by the patient’s bedside nurse, to collect variables of interest. Variables collected include qualitative and quantitative data from the patients as well as the nurses performing the procedure. The study was approved by the institutional review board.

The primary aim of the larger study is to evaluate whether the Cath-Assist device might decrease the time required to insert a urethral catheter and improve the accuracy of insertion attempts. This case study presents data from one patient enrolled in the early phase of the ongoing clinical trial. Overall study findings will be published at the completion of the study.

Clinical Interactions

The subject presented in this case study was a 50-year-old female admitted to the general surgical unit with gangrene of the foot requiring a below-the-knee amputation and several surgical debridement procedures throughout a 6-month admission. The patient had a history of obesity (admit weight >600 pounds), peripheral vascular disease, and type 2 diabetes. She required an indwelling urinary catheter due to immobility and to monitor urine output.

The patient was enrolled into the study on two separate occasions because the urinary catheter required replacement as a result of patient discomfort. For the first enrollment, the subject was randomly assigned to the intervention group, during which the Cath-Assist was used. As per protocol, repeat subjects were assigned to the opposite group for the second procedure. Hence, for the second catheterization procedure the traditional catheterization procedure was used, without the Cath-Assist device.

Results of Clinical Interaction

The results from both catheterization procedures are summarized in Table 1. The nurses and patient made additional comments following the procedure. The patient stated she “liked using that device so much better than the usual way.” When
the subject required a third catheter insertion, she requested that the nurses use the Cath-Assist device. The nurses stated that the device “really made a difference.”

Clinical Implications

Identification of the urethra is challenging in average-size women. This challenge is accentuated in obese women. For example, in order to visualize the urethra and maintain sterile technique in obese patients, the nurse performing the procedure needs other nursing personnel to assist with positioning the patient. In this case study, several nurses were used to assist with the procedure (standard = 5; Cath-Assist = 3).

The increased demand for human resources to provide care for obese patients has significant implications for hospitals. While it cannot be concluded from this case study that the Cath-Assist would reduce the number of nurses required to perform a catheterization procedure in all obese female patients, the use of fewer nurses for the Cath-Assist catheterization procedure is an interesting finding that requires further study. Use of the Cath-Assist device in this patient allowed the procedure to be completed substantially faster, at a lower price, with less difficulty for the nurse performing the catheterization and with less discomfort for the patient.

How the Cath-Assist device might benefit obese female patients as well as the nurses caring for them should be evaluated in future studies. The results of the case study must be replicated in a large clinical trial before the results can be applied to the population of obese female patients.

Conclusions

Urethral catheterization in this case study was facilitated in an obese patient with the Cath-Assist device. These findings are potentially important since obesity is a major public health problem in the United States. In a recent report, Ogden and colleagues (2006) reported that the current prevalence of obesity in women over the age of 20 years is 33%. A potentially large proportion of these women will enter hospitals for bariatric care or other health problems associated with obesity. Many of these hospitalized women will require urethral catheters. This case study illustrates a potentially useful device that might assist nurses to successfully perform catheterization procedures in obese women.

Table 1.

Results of Control and Intervention Group Catheterizations in an Obese Patient

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control Group (Standard Catheterization)</th>
<th>Intervention Group (Cath-Assist Device)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of attempts</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Time to urine flow (minutes:seconds)</td>
<td>5:11</td>
<td>0:10</td>
</tr>
<tr>
<td>Patient discomfort rating</td>
<td>“Severe”</td>
<td>“Minimal”</td>
</tr>
<tr>
<td>Nurse difficulty rating</td>
<td>“Very Difficult”</td>
<td>“Moderately Difficult”</td>
</tr>
<tr>
<td>Total material costs</td>
<td>$170.00</td>
<td>$85.00</td>
</tr>
<tr>
<td>Number of additional personnel required to perform procedure (Due to patient factor = obesity)</td>
<td>5</td>
<td>3</td>
</tr>
</tbody>
</table>

Figure 1.

Cath-Assist Device in Relation to a Key

This figure shows the Cath-Assist device in relation to a key (left = side view; right = forward view). The Cath-Assist is designed to facilitate urethral catheterization in women by: (1) exposing the vulvar vestibule, (2) blocking the entrance of the vagina so that insertion of the catheter into the vagina is not possible, and (3) isolating the opening of the urethra. When the device is applied to the vaginal opening (#2), the labia are retracted laterally (#1), allowing for visualization of the urethra. An alignment hole (#3), sufficiently large enough to pass a standard catheter through, is positioned at the entrance of the urethra.

References
