



User Appreciation of the VaPro Intermittent Catheter Characteristics and Packaging

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INTRODUCTION

- Intermittent catheterization (IC) is the insertion and removal of a catheter into the bladder several times a day to improve bladder emptying¹
- Two methods of IC are noted in the literature: Clean intermittent catheterization (CIC) and sterile IC²
- CIC is most practical and is the standard of care for persons with spinal cord injuries (SCI) with poor bladder emptying³
- Currently in the US there are over 200,000 people with SCI⁴
- 10,000 additional cases are expected yearly⁴

OBJECTIVES

The primary objective of this study was to assess user appreciation of the characteristics of the hydrophilic VaPro intermittent catheter design and features to include:

- Ease of opening and removing the catheter from the package
- Ease of handling the catheter, including the ability to remove the cap
- Ease of advancing the catheter once the introducer tip is inserted into the urinary meatus (reported as “inserted into the urethra”)
- Ease of catheter removal (after insertion and drainage of urine)

The secondary objective of this study was to assess user appreciation of the characteristics of the VaPro intermittent catheter regarding:

- Insertion of the introducer tip into the meatus
- Overall preference as compared to the subject’s usual catheter

It is important to note this was not a statistically powered study, therefore, no hypothesis testing was performed.

METHODS

- Multiple-site, non-blinded user assessment and user preference study of the VaPro intermittent catheter
- Performed by 3 investigators who recruited and enrolled current users of hydrophilic catheters from their patient database
- Institutional Review Board approval was granted and all subjects signed informed consent forms
- The study consisted of 2 visits and the subjects:
 - Were given 15 VaPro intermittent catheters to use in their normal manner
 - Returned after using all of the catheters or after a 4-day period (whichever came first)
- Assessment Forms were completed after each catheter use
- Overall preference form was filled out upon completion of the study

RESULTS

Demographic Profile

- Fifty-seven subjects (50 Males and 7 Females) currently using hydrophilic catheters were enrolled in the study
- Age = Mean 41.4 years, standard deviation 12.1

Present Conditions of Subjects (could select multiple options)

- Spinal Cord Injury: 46
- Diabetes: 4
- Neurogenic Bladder: 4
- Spina Bifida: 3
- Multiple Sclerosis: 2
- Other: 5

Subject's Usual Catheter Manufacturer

- Coloplast®
- AstraTech®
- Rüsçh®
- Rochester®
- Hollister
- Multiple catheter manufacturers

VaPro Intermittent Catheter Ease of Use Assessment

- Very Easy or Easy
- Neither Easy nor Difficult
- Difficult or Very Difficult

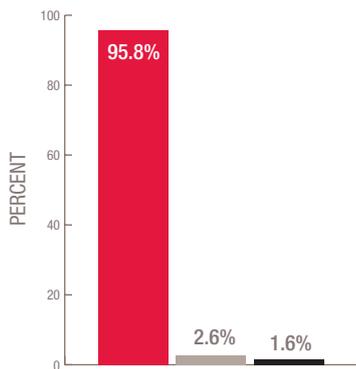


FIG. 1 Opening the catheter package

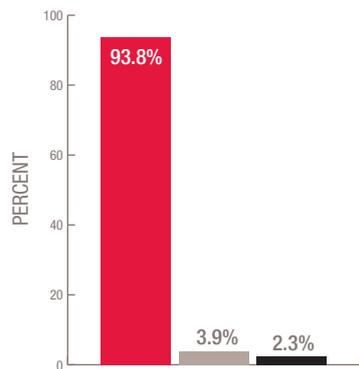


FIG. 2 Removing the catheter from the package

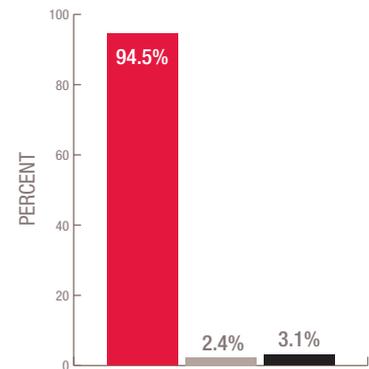


FIG. 3 Removing the cap from the catheter

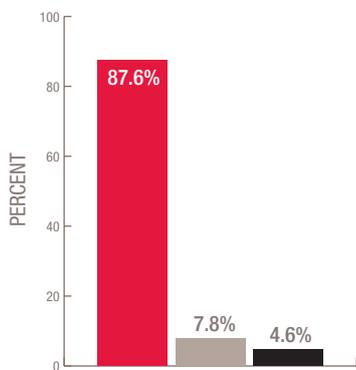


FIG. 4 Advancing the catheter through introducer tip

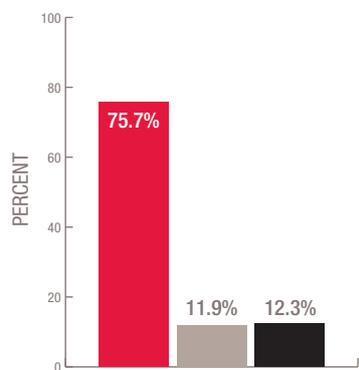


FIG. 5 Handling the catheter during the procedure

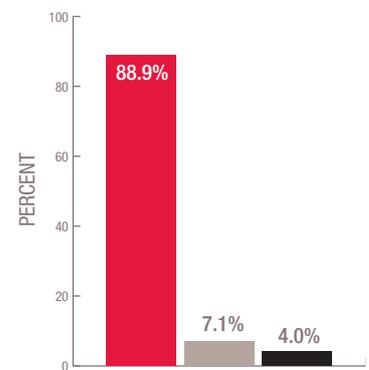


FIG. 6 Removing the catheter after urine was drained

VaPro Intermittent Catheter Ease of Use Assessment

- Strongly Agree or Agree
- Neither Agree nor Disagree
- Disagree or Strongly Disagree

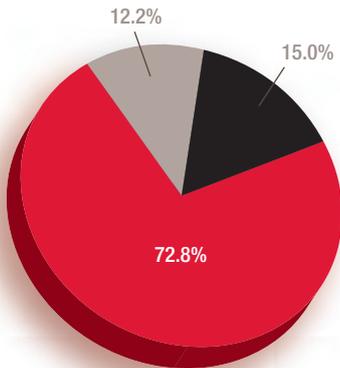


FIG. 7 Inserting the catheter is easy

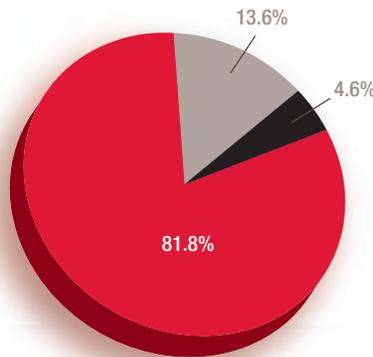


FIG. 8 No discomfort felt while the catheter is in place

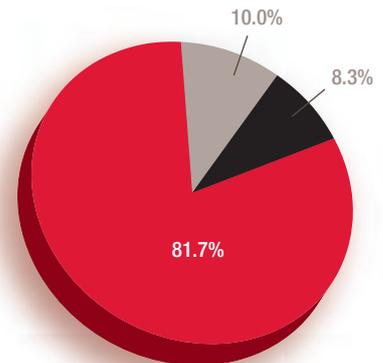


FIG. 9 Adequate amount of lubrication

Compared to the Subject's Usual Catheter, Subject Reported:

	Much Easier or a Little Easier	About the Same	A Little or Much More Difficult
Opening the catheter package is	59.6%	28.1%	12.3%
Removing the catheter from the package is	57.9%	24.6%	17.5%
Inserting the catheter is	66.7%	19.3%	14.1%
Ease of advancing the catheter through the urethra is	69.6%	21.4%	9.0%
Ease of removing the catheter is	66.1%	23.2%	10.7%

Compared to the Subject's Usual Catheter:

- 85.8% said the VaPro intermittent catheter's ability to drain the bladder is much better, better, or about the same
- 71.9% said the VaPro intermittent catheter overall is much better, better, or about the same
- 94.3% said overall, the comfort of the VaPro intermittent catheter while it was inserted was very comfortable, comfortable, or neutral

Protective Tip

How important is the VaPro intermittent catheter protective tip feature that prevents the catheter from coming in contact with bacteria in the urinary meatus?

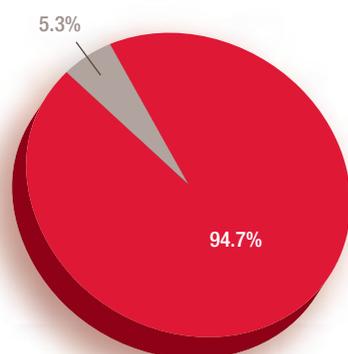
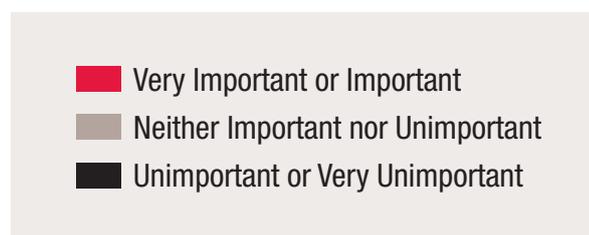


FIG. 10 Importance of VaPro intermittent catheter protective tip

CONCLUSION

The User Appreciation Study indicates the majority of the 57 catheter users, who use a variety of hydrophilic brands, found the VaPro intermittent catheter easy to use.

Features of the VaPro intermittent catheter that increase the ease of use may help patients adhere to a consistent intermittent self-catheterization schedule, which could lead to overall improved bladder health.

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WARNING: To help reduce the potential for infection and/or other complications, do not reuse. If discomfort or any sign of trauma occurs, discontinue use immediately and consult your healthcare practitioner.

- Ready-to-use, single-use intermittent catheter
- Hydrophilic-coated PVC catheter
- Protective tip and sleeve supports no-touch insertion technique
- 2 smooth catheter eyelets
- Color-coded funnel
- Adhesive tab for adhering packaging to a surface

This intermittent catheter is a flexible tubular device that is inserted through the urethra by male, female, and pediatric patients who need to drain urine from the bladder.

PRECAUTION: Please consult a medical professional before using this product if any of the following conditions are present: Severed urethra, unexplained urethral bleeding, pronounced stricture, false passage, urethritis – inflammation of the urethra, prostatitis – inflammation of the prostate gland, epididymitis – inflammation of the epididymis (testicle tube). Self-catheterization should follow the plan of care and advice given by your healthcare practitioner and be carried out only in accordance with the instructions for use provided. Because catheterization frequency varies by person, the recommended frequency of your catheterization should be provided by your healthcare practitioner. For any other questions about your catheterization, please contact your healthcare practitioner.

CAUTION: Rx Only. Federal (USA) Law restricts this device to sale by or on the order of a physician or other healthcare practitioner licensed under state law to order this product. Prior to use of this device, be sure to read (i) the complete information on how to use this device including Warnings, Cautions, and Instructions for Use, and (ii) all other package inserts and labels supplied with the product.

Note:

Store boxes in a flat position and at normal room temperature.

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