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USER APPRECIATION OF THE CHARACTERISTICS AND PACKAGING OF THE VAPRO® INTERMITTENT CATHETER DESIGN

Hypothesis / aims of study

The aim of this study was to assess user appreciation of the characteristics of the VaPro Intermittent Catheter design and features to include ease of opening the package; ease of removing the catheter from the package; ease of ability to remove the cap; ease of advancing the catheter once the introducer tip is inserted into the meatus; and ease of catheter removal (after insertion and drainage of urine).

The secondary aim was to assess user appreciation of the characteristics of the VaPro Intermittent Catheter regarding insertion of the introducer tip into the urinary meatus and overall catheter preference compared to the catheter the subject regularly used.

Study design, materials and methods

Institutional Review Board approved this study in July, 2008. This is a non-blinded, multiple-site user assessment and user preference study of the VaPro Intermittent Catheter design. There was no hypothesis testing. Therefore this study is not statistically powered. Successful assessment of the catheter is defined by at least a 75% overall positive or neutral subject response related to packaging features and catheter use and attributes.

Fifty-seven (57) current users of hydrophilic catheters users were enrolled from three (3) study sites. Subjects were given fifteen (15) VaPro Intermittent Catheters to use in their normal manner over a four (4) day period. Subjects were instructed to return to the study site following use of all of the catheters or following the four (4) day study period which ever came first. Subjects completed a user assessment form following the use of each catheter and a user preference form was completed at the end of the study.

Results

Data was collected from fifty-seven (57) current users of hydrophilic catheters.

Feature	Positive or Neutral Response
Opening package	99%
Removing catheter from package	98%
Handling the catheter	87%
Removing the cap	97%
Advancing the catheter thru the introducer tip	95%
Removal of the catheter after catheterization	96%

Interpretation of results

Data analysis indicates subjects reported the VaPro Intermittent Catheter is easy to open (99%) and remove from the packaging (98%). Subjects found that the VaPro Intermittent Catheter easy to handle (87%). The protective cap was easy to remove (97%) while advancing the catheter through the introducer tip was also quite manageable (95%). Subjects found the removal of the catheter following catheterization was also found to be easy (96%). Finally, subjects found that the VaPro Intermittent Catheter is equal to or better than their usual catheter (70%).

Concluding message

The new VaPro Intermittent Catheter is easy to use and will assist patients to improve their intermittent self-catheterization procedure.

Key words: LUTS (lower urinary tract symptoms), VaPro Intermittent Catheter

Specify source of funding or grant	The support of Hollister Incorporate for this clinical study is gratefully acknowledged.
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Copernicus Group IRB for 2 sites and Shepherd Center Research & Review Committee for 1 site
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes