

2022 Best Research Poster Award



Clinical Utility of a Single-Use Flexible Cystoscope Compared with a Standard Reusable Device: A Randomized Non-Inferiority Study

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INTRODUCTION

Flexible cystoscopy is the cornerstone of investigation and surveillance of lower urinary tract pathologies. Present day reusable flexible cystoscopes have advanced greatly from their earlier predecessors possessing excellent lighting and optical specifications, coupled with precise and nimble maneuverability and have been shown to be reliable.(1)

The current study assesses the single-use cystoscope (Ambu® aScopeTM 4 Cysto System). Recent studies have suggested this novel device has comparable specifications, is well tolerated, and is more cost efficient compared to reusable devices.(2-3)

OBJECTIVES

The practical utility of the Ambu® aScopeTM 4 Cysto System, in terms of image quality, light quality, and maneuverability, has not been determined in an appropriate randomized non-inferiority study. We aim to compare with standard reusable FC for bladder cancer surveillance, and investigation of lower urinary tract symptoms.

METHOD

Patients requiring flexible cystoscopy who met inclusion criteria were randomly assigned to have their procedure performed using a single-use cystoscope (Ambu® aScopeTM 4 Cysto System) or a standard reusable scope (Olympus CYF-VH flexible video cystoscope). Primary outcomes were non-inferiority of the single-use scope, in terms of successful procedure completion rate, image quality, light quality, manoeuvrability. Secondary objectives compared safety, operative and perioperative time. The non-inferiority margin was set at -10%.

RESULTS

101 patients completed the study (n=50 trial, n=51 control). All primary outcomes demonstrated non-inferiority of the single-use scope, compared to standard reusable flexible cystoscope (Figure 1).

RESULTS (CONTINUED)

Successful completion rate, image quality, light quality, and maneuverability between single-use and reusable scopes were 100% and 98% (CI: -0.059 to 0.019); 96% and 100% (CI: -0.014 to 0.092); 98% and 100% (CI: -0.018 to 0.058); 98% and 100% (CI: -0.018 to 0.058).

There was no difference in operation time (p=0.415) or total theatre use time (p=0.441) between groups. Adverse event rates were 4.08% and 4.16% in the trial group and control groups, respectively. There were no post-operative urinary tract infections in either group.

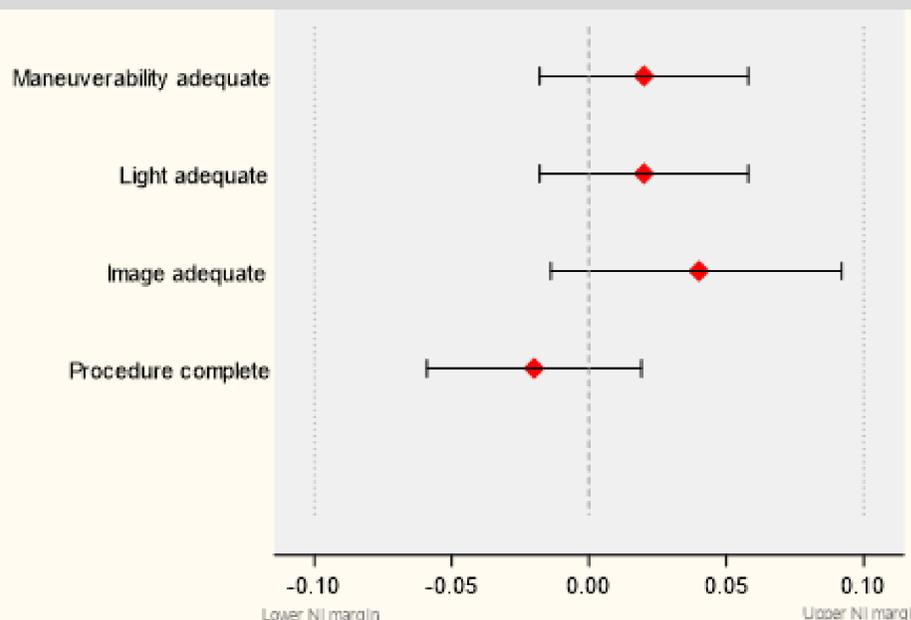


Figure 1. Primary outcomes. Single use flexible cystoscope shown to be non-inferior with confidence interval more than -10% in each of the four assessed domains.

CONCLUSION

Single-use flexible cystoscopes provide an alternative to reusable cystoscopes, and may provide advantages over reusable scopes in some settings, as they are easily portable, sterile, and do not require reprocessing. The single-use Ambu® flexible cystoscope is non-inferior to standard FC in terms of procedure completion and light quality, image quality and maneuverability. Single-use flexible cystoscopes are an effective and safe alternative to reusable flexible cystoscopes and may act as a suitable alternative or adjunct in the urologist’s armamentarium.

REFERENCES & ACKNOWLEDGEMENTS

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(1) Canales BK, Gleason JM, Hicks N et al. An independent analysis of flexible cystoscope repairs and cost. The Journal of urology. 2007 Nov;178(5):2098-102.

(2) Wong A, Phan Y, Thursby H et al. The First UK Experience with Single-use Disposable Flexible Cystoscopes: An In-depth Cost Analysis, Service Delivery and Patient Satisfaction Rate with Ambu® aScope™ 4 Cysto. Journal of Endoluminal Endourology 2021;4(1):e29-e44.

(3) Whelan P, Kim C, Tabib C et al. Evolution of single-use urologic endoscopy: benchtop and initial clinical assessment of a new single-use flexible cystoscope. Journal of endourology 2022;36(1):13-21.