The new single-use Ambu® aScope™ 4 Cysto: evaluation of successful flexible cystoscopies and patient experience in direct visualization of the urethra and bladder

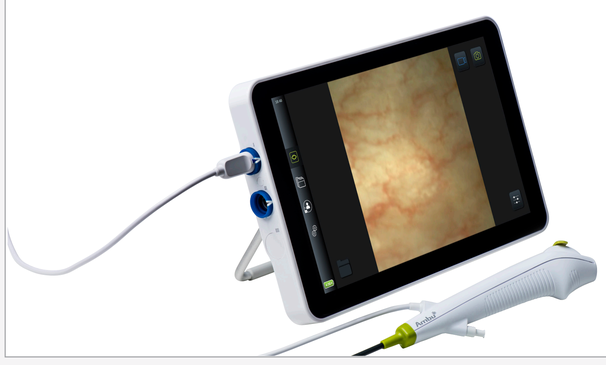
A.B. Stillebroer[1], P. Amping[2], B.F.M. Blok[1]

[1]Erasmus Medical Center Rotterdam, The Netherlands, a.stillebroer@erasmusmc.nl, [2]Ambu aScope Ballerup, Denmark

Aims of the study

Single-use cystoscopes mitigate several limitations of reusable cystoscopes, including high manufacturing and repair cost, requirement for skilled personnel for cleaning and processing, environmental impact of cleaning chemicals and risk of cross-contamination since it is delivered sterile. In this study we evaluate the application of the single-use Ambu® aScope™ 4 Cysto in flexible cystoscopies and patient experience in direct visualization of the urethra and bladder.

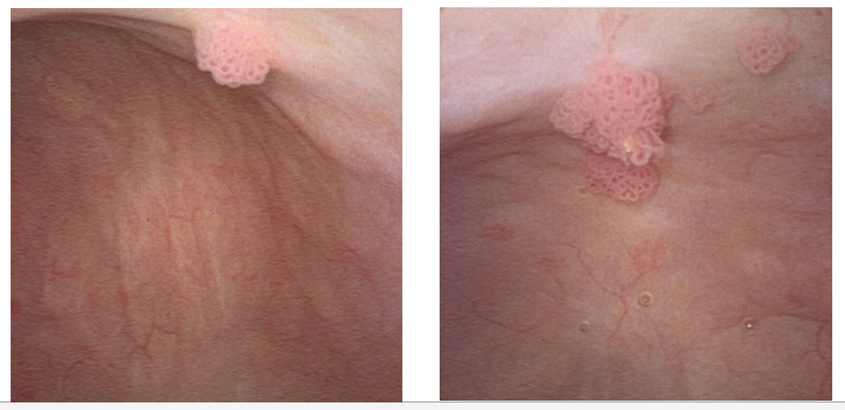
The primary aim was to determine the rate of completion of procedures in patients undergoing outpatient diagnostic and therapeutic flexible cystoscopy.



Materials and methods

This prospective, multinational, multicentre, open-label single-arm clinical investigation included 81 adult patients undergoing cystoscopy for examination/surveillance (diagnostic group) or with endoscopic accessories for therapeutic purposes (therapeutic group). All patients were treated with Ambu® aScope™ 4 Cysto, and were divided into two cohorts, with the intent of having 40 patients in each, either undergoing flexible diagnostic cystoscopy or flexible therapeutic cystoscopy with endoscopic accessories (biopsy forceps, stent removal forceps or botulinum needles). Four urologists with experience up to 25 years performed the examinations.

Two images of bladder cancer

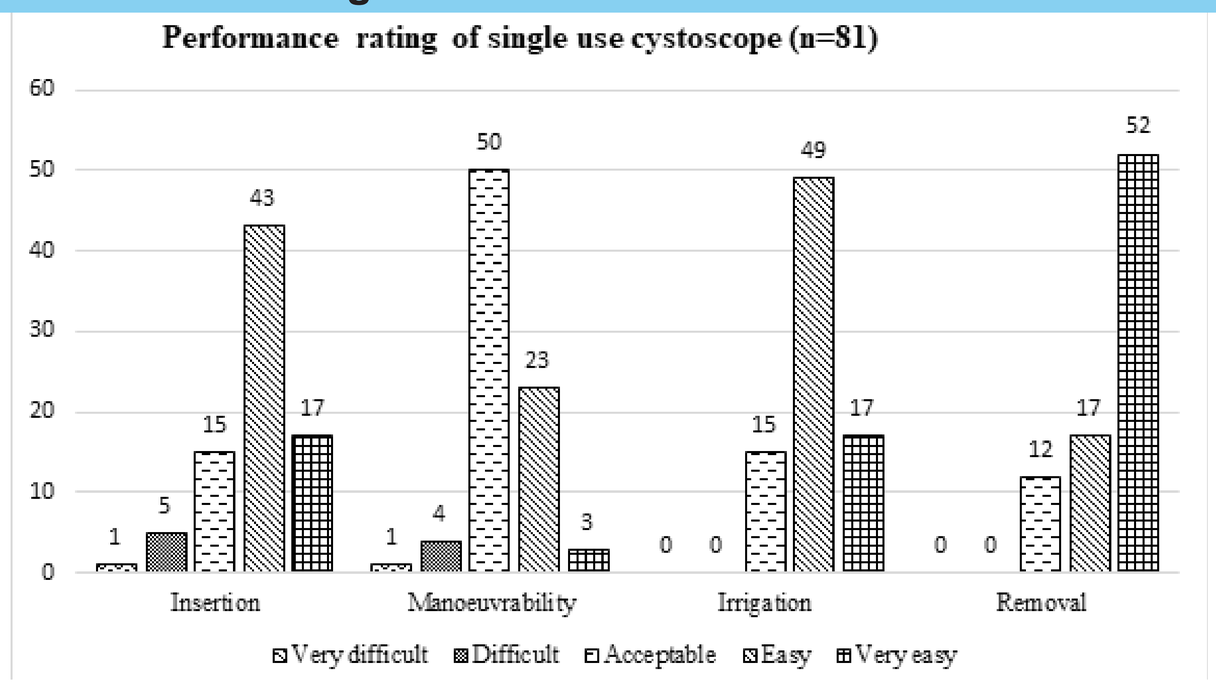


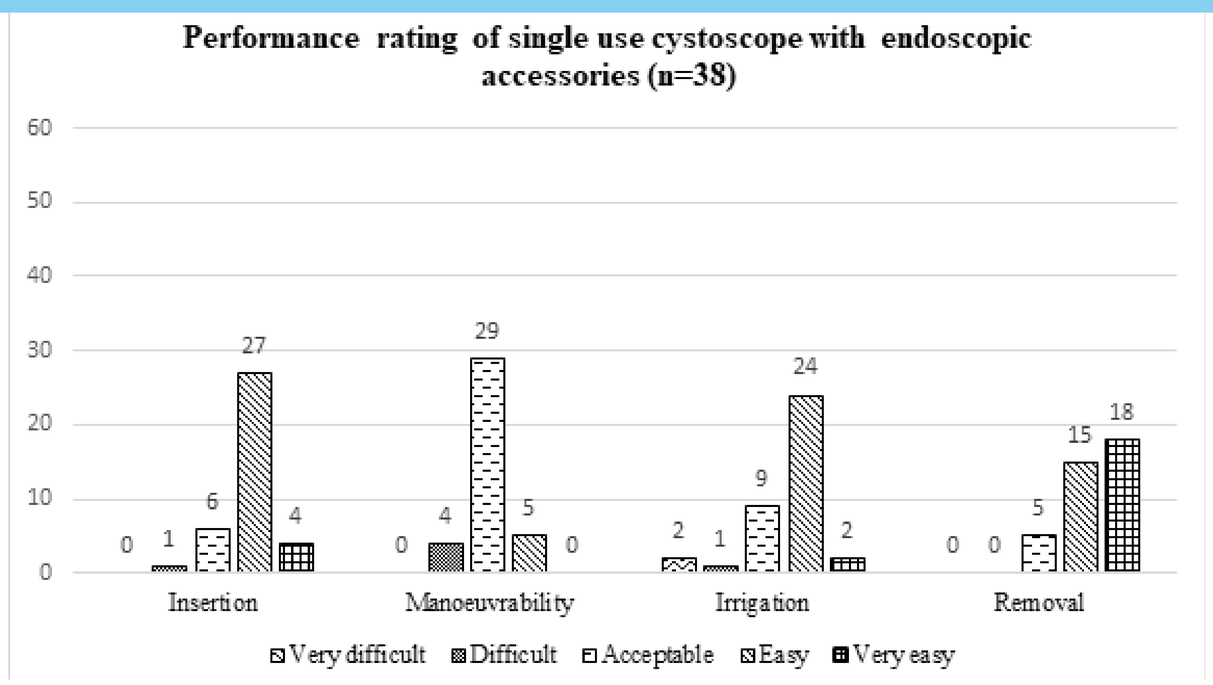
Results

Descriptive results

The investigation sample comprised 35 males (43%) and 46 females (57%) with a mean age of 62.00 years and 61.89 years, respectively. Ambu® aScope™ 4 Cysto cystoscopy was successful in 79/81 (98%; 95% CI: 94–100) procedures. Two procedures were converted to a reusable cystoscope due to poor vision. In one of these patients, converting did not help in completing the procedure. Bleeding during insertion of the cystoscope was reported in 2/81 cases (2%), whereas, during removal, no injuries, bleedings, or damage to the cystoscope were reported. At 7-day Follow up (FU), pain when urinating was reported as no pain or mild pain by 88% of the patients. 10% of the patients reported increase in urination frequency during the day and 9% reported increase in urination frequency during the night.Three out of the six reported AEs were possibly related to the procedure (two cases of UTI and one case of a small scratch during insertion of the cystoscope causing erythema and soreness). All three adverse events are general risks in cystoscopy procedures, and one was reported to be serious due to hospitalization for intravenous antibiotics.

Performance rating





The figures summarize performance ratings for Ambu® aScope™ 4 Cysto with and without accessories. Overall, insertion, manoeuvrability, irrigation and removal were mostly scored acceptable to very easy in both diagnostic and therapeutic procedures by the investigators. The mean procedure time was 3.37 ± 0.90 minutes for diagnostic cystoscopies and 9.84 ± 3.79 minutes for therapeutic cystoscopies. These are consistent with the mean procedure times for most routine cystoscopy procedures.

Conclusions

- The Ambu® aScope™ 4 Cysto was found to perform well for the diagnostic and therapeutic procedures assessed
- Results indicate that the risk for complication was low and pain levels were comparable with results for reusable cystoscopes based on existing literature
- At 7 days FU, patients appear to experience less pain during urination. Increase in urination frequency during day and night was less than reported in literature