

Prospective Analysis of Versatility and User Satisfaction with a Novel Single-Use Cystoscope with Working Channel

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Keywords

Cystoscopy · Novel single-use cystoscope · Endoscopic treatment

Abstract

Introduction: In the present study, a prospective systematic assessment of the clinical utility of the Ambu® aScope™ 4 Cysto Reverse Deflection with regard to image quality, maneuverability, and navigation in an outpatient and inpatient setting was performed. **Materials and Methods:** A prospective multicenter study was performed for evaluation of the instrument during routine cystoscopy. We evaluated the clinical performance of the instruments using a standardized user questionnaire in different categories including image quality, treatment success, imaging of all areas of the urinary bladder, quality of navigation, flexibility of the endoscope, and satisfaction with the device. Statistical analyses were performed by SPSS using the Kruskal-Wallis and Wilcoxon-Mann-Whitney tests. A p value of $p \leq 0.05$ was defined as statistically significant. **Results:** A total of 200 cystoscopies were performed, and the questionnaire response rate was 100%. The image quality was rated as very good in 65.5% ($n = 131$), good in 30.5% ($n = 61$), and neutral in 4% ($n = 8$) of cases. The criteria for poor or very poor were not mentioned. The characteristic “treatment success based on image quality” was also evaluated

as very good in 49% ($n = 98$) and good in 50.5% ($n = 101$). The analysis revealed a very good or good overall impression of the examiners in all cases. Replacement of the cystoscope was not necessary during any of the examinations. However, in 3 cases, technical difficulties were documented. Further analysis of the data showed that physicians with less professional experience rated the visualization of the urinary bladder ($p = 0.007$) and the treatment success with regard to image quality significantly worse ($p = 0.007$). **Conclusion:** The Ambu® aScope™ 4 Cysto Reverse Deflection shows high satisfaction values among users in clinical routine. In analogy to other studies with flexible endoscopes, urologists with more professional experience show higher satisfaction values than examiners with less training in flexible endoscopy.

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Introduction

Cystoscopy is the most common endoscopic examination in urology. It is used for diagnostic purposes, e.g., for evaluation of the bladder mucosa in case of tumors of the bladder and urethra, as well as for interventional

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purposes, e.g., for forceps biopsies or for removal of inserted ureteral stents. Good endoscopic visualization and device handling are essential for the examiner.

The Ambu® aScope™ 4 Cysto Reverse Deflection is a new flexible disposable cystoscope certified for diagnostic cystoscopy in November 2020. Clinical studies show that the use of disposable endoscopes is more cost-effective compared to reusable endoscopes. Beebe et al. [1], Donato et al. [2], and Pietropaolo et al. [3] demonstrate a more favorable cost-effectiveness compared to conventional reusable cystoscopes [1–5]. The clinical advantages of single-use endoscopy also include the immediate availability of sterile disposable instruments. When using multiple endoscopes, hygienic aspects, a possibly limited number of available devices, and the time of reprocessing between two examinations must be taken into account in hospitals and outpatient offices [6].

Currently, however, there is no comprehensive validation with regard to the satisfaction of users and examiners with the handling and the device characteristics of the Ambu® aScope™ Cysto Reverse Deflection in clinical routine. Multicenter studies with other single-use devices primarily describe their clinical possible indications, e.g., based on the success rate of the removal of inserted DJ splints [7]. Despite poor flexion due to an instrument inserted in the working channel, Scotland et al. [8] described in an observational study a satisfying image quality using a single-use cystoscope. While systematic prospective-randomized trials comparing single-use cystoscopes versus reusable cystoscopes remain methodologically challenging, user satisfaction appears as a measurable effect size to determine the product quality and clinical applicability of a novel instrument. Therefore, in the present study, a systematic assessment of the clinical usability of the Ambu® aScope™ 4 Cysto Reverse Deflection integrating image quality, maneuverability, and navigation was performed in both an outpatient and inpatient setting.

Methods

Study Population and Study Period

The evaluation was performed on a total collective of 200 patients who received a cystoscopy. Data collection took place between September 2021 and January 2022 at four centers (2 inpatient centers, 2 outpatient centers). A positive ethics vote for the observational study was granted by the Ethics Committee of the University of Tübingen under the number 387/2021B02.

Patients were included who had an indication for diagnostic cystoscopy, cystoscopic follow-up of previous urinary tract disease, biopsy of the urethral mucosa/bladder mucosa,

botulinum toxin injection into the urinary bladder muscles, removal of ureteral stents, as well as for bladder stone removal in the course of a routine presentation in the clinic/practice. The Ambu® aScope™ 4 Cysto Reverse Deflection was used instead of a flexible reusable cystoscope for diagnosis/intervention. After the examination, the users were asked about image quality, navigability, and maneuverability using a standardized questionnaire. Patient-related clinical and histological variables were not included in the study.

Systematic Questionnaire

Baseline variables recorded were the investigators' professional experience in two categories (1–10 and >10 professional years), the average number of cystoscopies performed by the investigators per week (1–2; 3–5; >5), the indication for performing cystoscopy, and any additional endoscopy accessories used. In addition, the following characteristics regarding examination quality were queried using a Likert scale (very good: 1, good: 2, neutral: 3, poor: 4, and very poor: 5): image quality, treatment success based on image quality, visualization of all areas of the urinary bladder, quality of navigation within the urinary bladder, quality of illumination, flexibility of the endoscope without endoscopy accessories, satisfaction with working channel size for biopsy, and flexibility of the endoscope with inserted endoscopy accessories. In addition, the image quality of the monitor, the menu navigation, data transfer options, and the 180° rotation possibility of the live image were evaluated. Finally, the question was asked about the overall impression regarding the image quality and functionality of the monitor as well as the overall impression regarding quality and functionality of the cystoscope (see Appendix 1: Questionnaire for users). If a change to another cystoscope was necessary during the procedure or if there were problems with the Ambu® aScope™ 4 Cysto, this was recorded.

The data were analyzed using SPSS Statistics version 28.0, and the scale levels were compared using the Kruskal-Wallis test and Wilcoxon-Mann-Whitney test. A significant difference was assumed at a value of ≤ 0.05 .

Results

Baseline Variables of the User Population

With 200 cystoscopies performed, the questionnaire response rate was 100%. Due to the anonymous questionnaire, the number of different investigators was not determined. In a total of 62.5% ($n = 125$) of responses, investigators reported professional experience of between 1 and 10 years, and 29.5% ($n = 59$) reported professional experience of more than 10 years. This information was missing from 16 questionnaires (8%). A total of 25.5% ($n = 51$) of respondents reported performing between 1 and 2 cystoscopies per week, 24.5% ($n = 49$) between 3 and 5 cystoscopies per week, and 44.5% ($n = 89$) more than 5 cystoscopies per week.

Table 1. Indication for cystoscopy

	Frequency	%
Initial examination of the bladder	94	47.0
Follow-up examination of the bladder	76	38.0
Biopsy of the bladder and/or bladder neck	7	3.5
Botox injection	5	2.5
Removal of ureteral stent	8	4.0
Removal of bladder stone	1	0.5
Other interventions	9	4.5
Total	200	100.0

Indication for Cystoscopy

Table 1 summarizes the indication for cystoscopy during the observation period. Ambu[®] aScope[™] 4 Cysto Reverse Deflection was used for the initial bladder examination in 47% ($n = 94$) of cases and for follow-up bladder examination in 38% ($n = 76$) of cases. Biopsies were performed in 3.5% ($n = 7$) of cases. Botox injections into the urinary bladder muscles were performed in 2.5% ($n = 5$) of cases. Urethral stents were removed in 4% ($n = 8$) of the examinations performed, and bladder stones were removed in 0.5% ($n = 1$) of the examinations.

Results of the User Survey

A detailed overview of the results of the user survey is shown in Table 2, and a summary is given in Table 3. The image quality was rated as “very good” in 65.5% ($n = 131$), “good” in 30.5% ($n = 61$), and “neutral” in 4% ($n = 8$) of cases. The criteria for poor or very poor were not mentioned. The characteristic “treatment success based on image quality” was also described as “very good” in 49% ($n = 98$) and “good” in 50.5% ($n = 101$). The visualization of all areas of the urinary bladder was “very good” in 48.5% ($n = 97$) of cases. The bending angle of the Ambu[®] aScope[™] 4 Cysto was described as “very good” in 123 cases (42.8%) and “good” in 68 (34.7%) of cases. With inserted endoscopy accessories, the value “very good” was achieved in 16.9% and the assessment “good” in 38 cases (64.4%). In three cases of ureteral stent removal, the categories “poor” or “very poor” were selected. The working channel size for performing a biopsy was described as “very good” in 8 cases (33.3%), “good” in 12 cases (50%), and “neutral” in 3 cases (12.5%) or poor in 4.2% of cases. Switching to another cystoscope was not necessary in any examination. In the documentation of three cases with technical difficulties, it was observed that the irrigation flow could not be controlled with inserted accessories. A second three-way stopcock became necessary for this purpose. In addition, insufficient

angulation of the instrument occurred during the removal of an inserted DJ splint with inserted endoscopy accessories. Another user described an insufficient inversion for evaluation of the bladder neck. The overall impression and functionality of the monitor and the single-use cystoscope were “very good” or “good” in all cases. A comparative analysis dividing the collective according to the professional years of the users showed that the visualization of all areas of the urinary bladder and the treatment success due to the image quality were rated lower in users with less professional experience (Table 4). The stratification according to the number of endoscopies performed per week shows a similar picture here: satisfaction with the Ambu[®] aScope[™] 4 Cysto was rated better among users with a higher number of endoscopies per week (Table 5).

Discussion

With the introduction of single-use endoscopes in urology, alternative systems to reusable cystoscopes are available, which are currently under scientific validation in terms of quality, cost-effectiveness, and ecology. Available studies with single-use cystoscopes (e.g., for the removal of ureteral stents) have demonstrated their clinical efficacy and cost-effectiveness compared with reusable cystoscopes [1–3]. The aim of our study was to investigate the satisfaction of users and examiners with the handling and features of the Ambu[®] aScope[™] 4 Cysto Reverse Deflection in everyday clinical practice. The evaluation of the results showed a very good or good overall impression of the examiners in 100% of the cases. In none of the examinations performed was it necessary to switch to an alternative system in order to complete the examination successfully. In 2022, Whelan et al. [9] showed that there was no technical or optical disadvantage between the Ambu[®] aScope[™] 4 Cysto Reverse Deflection and the sterilizable Olympus SD scope. With the exception of the 3 mm distance, where an optical advantage of the compared digital reusable cystoscope was observed. Scotland et al. [8] studied a single-use cystoscope (NeoScope) and found that flexion, image quality, and maneuverability were equivalent to the reusable cystoscopes. Disadvantageously, reduced flexion with instruments in the working channel was described for single-use cystoscopes.

In the present study, technical difficulties were noted in 3 of the 200 examinations performed. E.g., inversion was not sufficiently possible to assess the bladder neck in one case. In this case, the examination was performed by an

Table 2. Results from the user survey

	Very good		Good		Neutral		Bad		Very bad		Not specified	
Image quality	131	65.5%	61	30.5%	8	4.0%	0	0.0%	0	0.0%	0	0.0%
Treatment success due to image quality	98	49.2%	101	50.8%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Imaging of all areas of the bladder	97	49.0%	93	47.0%	6	3.0%	2	1.0%	0	0.0%	0	0.0%
Navigation inside the bladder	127	63.5%	61	30.5%	12	6.0%	0	0.0%	0	0.0%	0	0.0%
Lighting	135	67.8%	56	28.1%	8	4.0%	0	0.0%	0	0.0%	0	0.0%
Flexibility without endoscopy accessories	123	62.8%	68	34.7%	5	2.6%	0	0.0%	0	0.0%	0	0.0%
Working channel size for biopsy	8	33.3%	12	50.0%	3	12.5%	1	4.2%	0	0.0%	0	0.0%
Flexibility with endoscopy accessories	10	16.9%	38	64.4%	8	13.6%	2	3.4%	1	1.7%	0	0.0%
Image quality monitor	136	68.0%	48	24.0%	15	7.5%	1	0.5%	0	0.0%	0	0.0%
Menu navigation	82	41.2%	98	49.2%	19	9.5%	0	0.0%	0	0.0%	0	0.0%
Data transfer option	53	61.6%	27	31.4%	5	5.8%	1	1.2%	0	0.0%	0	0.0%
180° rotation option of the live image	31	53.4%	22	37.9%	3	5.2%	0	0.0%	0	0.0%	1	1.7%
Total impression quality + functionality Ambu aView 2 Advance	133	67.2%	64	32.3%	1	0.5%	0	0.0%	0	0.0%	0	0.0%
Total impression quality + functionality Ambu aScope 4 Cysto	132	66%	68	34%	0	0.0%	0	0.0%	0	0.0%	0	0.0%

Table 3. Summary of results from the user survey

	N	Minimum	Maximum	Average value	Standard deviation
Image quality	200	1	3	1.39	0.564
Treatment success due to image quality	199	1	2	1.51	0.501
Imaging of all areas of the bladder	198	1	4	1.56	0.608
Navigation within the bladder	200	1	3	1.42	0.605
Lighting	199	1	3	1.36	0.559
Flexibility without endoscopy accessories	196	1	3	1.40	0.540
Working channel size for biopsy	24	1	4	1.87	0.797
Flexibility with endoscopy accessories	59	1	5	2.08	0.772
Menu navigation	199	1	3	1.68	0.640
Data transfer option	86	1	4	1.47	0.663
180° rotation option of the live image	57	0	3	1.47	0.630
Total impression quality + functionality Ambu aView 2 Advance	198	1	3	1.33	0.483
Total impression quality + functionality Ambu aScope 4 Cysto	200	1	2	1.34	0.475

examiner with low professional experience (1–2 cystoscopies per week, professional experience less than 10 years).

Schout et al. [10] evaluated beginners and advanced examiners with an endoscopy simulator and found that with increasing experience, the quality of flexible cystoscopy improves and the time required to perform a qualitative examination decreases. In order to perform a sufficient examination, a threshold of 122 cystoscopies to full quality in flexible cystoscopy was defined in another study [11]. The described difficulties in handling the equipment could therefore also be due to the low professional experience of the examiner. In the same context, examiners in the present study with higher professional

experience gave a significantly better overall evaluation of the disposable cystoscope than examiners with less experience.

Furthermore, a lack of flexion of the instrument with inserted grasping forceps for the removal of an inserted DJ was documented. In this case, the examiner cited that the available grasping forceps for flexible cystoscopy were too short for the disposable cystoscope. Despite the fundamentally high compatibility of single-use instruments with endoscopic aids, sufficient passage of the working channel forceps and baskets should be checked as part of the acquisition. Here, the working channel of the Ambu aScope 4 Cysto has a diameter of 6.6 Fr. and is thus comparable to available flexible urethrocystoscopes.

Table 4. Comparison of professional years

	Professional years	N	Average rank	p
Image quality	1–10	125	89.17	0.133
	>10	59	99.55	
	Total	184		
Treatment success due to image quality*	1–10	125	98.20	0.007*
	>10	58	78.63	
	Total	183		
Imaging of all areas of the bladder*	1–10	124	97.81	0.007*
	>10	58	78.00	
	Total	182		
Navigation within the bladder	1–10	125	92.06	0.847
	>10	59	93.43	
	Total	184		
Lighting	1–10	125	90.21	0.408
	>10	58	95.86	
	Total	183		
Flexibility without endoscopy accessories	1–10	123	87.30	0.150
	>10	57	97.41	
	Total	180		
Working channel size for biopsy	1–10	9	14.17	0.328
	>10	15	11.50	
	Total	24		
Flexibility without endoscopy accessories	1–10	42	31.46	0.227
	>10	17	26.38	
	Total	59		
Image quality monitor	1–10	125	88.94	0.104
	>10	59	100.03	
	Total	184		
Total impression quality + functionality Ambu aView 2 Advance	1–10	123	89.96	0.481
	>10	59	94.71	
	Total	182		
Total impression quality + functionality Ambu aScope 4 Cysto	1–10	125	89.97	0.250
	>10	59	97.86	
	Total	184		

Significant differences marked with *.

In an earlier study, Wong et al. [12] focused their analysis on patient satisfaction with the Ambu® aScope™ 4 Cysto Reverse Deflection. All patients had previous experience with a reusable cystoscope. The authors described that 95% of the subjects would prefer the single-use cystoscope over the reusable cystoscope due to the shorter procedure time.

Apart from the general aspects of using single-use cystoscopes or reusable endoscopes like logistic aspects and immediate availability of endoscopes [1–5], costs and cost-effectiveness of the procedures [13, 14], and hygienic aspects [15–17], increasing attention has recently been given to waste and environmental issues related to sterilizable systems and single-use instruments as part of sustainability efforts and “planetary health” in healthcare. Su et al. [4] reported costs for using reusable cystoscopes

to remove DJ splints in a range from \$165 to \$1,469 in dependence of the number of investigations performed. In comparison, the cost of single-use cystoscopy was reported between \$244 and \$420. The authors concluded that for facilities performing fewer than 700 cystoscopies annually with a total of 20 multiple cystoscopes available, greater cost-effectiveness can be achieved using single-use cystoscopes. Davies et al. [18] investigated the carbon footprints of single-use URS and reusable systems and surprisingly found no significant differences between the devices (4.43 vs. 4.47 kg CO₂ per device/use). However, the type of re-sterilization and the associated energy consumption for the reusable devices appear most relevant here. By contrast, the disposal of single-use devices is primarily responsible for the respective CO₂ emissions. It should be kept in mind that apart from reprocessing and

Table 5. Comparison cystoscopies/week

	Number of cystoscopies per week	N	Average rank	p
Image quality*	a. 1–2/week	51	110.39	(c)
	b. 3–5/week	49	122.33	(c)
	c. >5/week	89	71.13	(a) (b)
	Total	189		<0.001*
Treatment success due to image quality	a. 1–2/week	51	87.05	0.316
	b. 3–5/week	48	101.33	
	c. >5/week	89	95.08	
	Total	188		
Imaging of all areas of the bladder*	a. 1–2/week	50	78.48	(a)
	b. 3–5/week	48	109.17	(b)
	c. >5/week	89	94.54	
	Total	187		0.006*
Navigation within the bladder*	a. 1–2/week	51	92.26	(b)
	b. 3–5/week	49	117.56	(a) (c)
	c. >5/week	89	84.15	(b)
	Total	189		<0.001*
Lighting*	a. 1–2/week	51	108.03	(c)
	b. 3–5/week	48	121.37	(c)
	c. >5/week	89	72.25	(a) (b)
	Total	188		<0.001*
Flexibility without endoscopy accessories*	a. 1–2/week	47	117.66	(c)
	b. 3–5/week	49	120.64	(c)
	c. >5/week	89	67.90	(a) (b)
	Total	185		<0.001*
Working channel size for biopsy	a. 1–2/week	11	14.00	0.070
	b. 3–5/week	10	13.25	
	c. >5/week	3	4.50	
	Total	24		
Flexibility with endoscopy accessories	a. 1–2/week	14	31.68	0.282
	b. 3–5/week	13	34.65	
	c. >5/week	32	27.38	
	Total	59		
Image quality monitor*	a. 1–2/week	51	110.59	(c)
	b. 3–5/week	49	118.83	(c)
	c. >5/week	89	72.95	(a) (b)
	Total	189		<0.001*
Total impression quality + functionality Ambu aView 2 Advance*	a. 1–2/week	50	111.10	(c)
	b. 3–5/week	48	122.13	(c)
	c. >5/week	89	69.22	(a) (b)
	Total	187		<0.001*
Total impression quality + functionality Ambu aScope 4 Cysto*	a. 1–2/week	51	113.53	(c)
	b. 3–5/week	49	121.36	(c)
	c. >5/week	89	69.87	(a) (b)
	Total	189		<0.001*

Significant differences marked with *.

disposal of the medical products, transportation and logistic efforts represent highly relevant parameters for CO₂ emissions in urological endoscopy.

Despite its prospective design, the present study is not without limitations. A main limitation of the present approach to user quality assessment is the lack of a control group, so that no comparative results with

reusable endoscopes could be obtained. Noteworthy, a comparative study of reusable and single-use instruments is challenging in the context of a multicenter study given a diverse distribution of reusable endoscopes from different manufacturers, different imaging technologies (chip on tip or classic), and investigator experience in the respective centers.

While the analysis of single-use versus reusable endoscopy in urology is an open scientific field with ongoing research and discussion, the clinical data here demonstrate the clinical feasibility of single-use endoscopy using the Ambu® aScope™ 4 Cysto Reverse Deflection based on an extensive user survey.

Conclusion

The Ambu® aScope™ 4 Cysto Reverse Deflection shows high satisfaction values among users in clinical routine. In analogy to examinations with other flexible devices, examiners with more professional experience show higher satisfaction values than colleagues with less experience. A change to an alternative system was not necessary during the study.

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Statement of Ethics

All procedures performed in studies involving human participants were in accordance with the ethical standards of the Institutional and/or National Research Committee and with the 1964 Helsinki Declaration and its later amendments. The study was approved and consented by the Local Ethical Committee of the University of Tübingen, Germany (project number: 387/2021B02). Written informed consent was not required in accordance with local guidelines.

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Conflict of Interest Statement

S.R.: consultant/speaker honoraria for Advanced Accelerator Applications Germany GmbH, MDxHealth, Astellas Pharma, Pfizer Oncology, Bayer Oncology, Merck Pharma, Desitin, Ambu A/S, BMS Pharma, Eisai Pharma, and MSD Sharp & Dohme GmbH; A.N.: consultant/speaker honoraria for MSD, Janssen, AstraZeneca, Ipsen, Amgen, Roche, GlaxoSmithKline, and Boston Scientific. T.K. and J.S.: consultant/speaker honoraria for LISA Laser, OptiMed, Ambu A/S, Boston Scientific, Olympus, Mediate, Dr. Schwabe, and Omega Pharma. T.L. has no conflicts of interest to declare.

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Author Contributions

Thomas Lütfrank (T.L.) and Steffen Rausch (S.R.): project development, data collection, data analysis, and manuscript writing/editing. Andreas Neisius (A.N.), Johannes Salem (J.S.), and Timur H. Kuru (T.H.K.): data collection and manuscript writing/editing. All authors critically revised the manuscript and approved the final version. They agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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