ORIGINAL ARTICLE

Cost-Utility Analysis of the Ambu® aScope™ 4 Broncho Single-Use Flexible Video Bronchoscope Compared to Reusable Flexible Video Bronchoscopes

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ABSTRACT

Background: Recent research has demonstrated higher than expected infection transmission following bronchoscopy with reusable flexible bronchoscopes (RFBs). Cost-effectiveness analyses of the Ambu® aScope™4 Broncho single-use flexible bronchoscope (aScope) demonstrated that it can be considered cost-effective. However, there has been no cost-utility analysis (CUA) of the aScope. Therefore, the objective of this study was to conduct a CUA of aScope vs RFB.

Methods: A decision tree model was developed to estimate the CUA of the aScope vs RFB from a third-party payer perspective within a 24-month time horizon. Procedure-related costs were sourced from the literature and unit costs of infections were estimated using UK National Health Service (NHS) tariffs. Infection rates, utilities, and model parameters were obtained using targeted literature reviews. Scenario and probabilistic sensitivity analyses (PSA) were conducted to explore parametric uncertainties around the base case analysis.

Results: Over a 24-month time horizon, aScope was the cost-effective (dominant) strategy compared to RFBs, with aScope being less costly (£220.00 vs £431.13) and more effective (1.59 vs 1.58 quality-adjusted life years [QALYs]). PSA indicated that aScope had a 100% probability of being cost-effective at a willingness-to-pay (WTP) threshold of £10,000/QALY. Scenario analyses supported these findings, with a net monetary benefit (NMB) ranging from £61.04 to £400.30 at a WTP threshold of £10,000/QALY.

Conclusion: This CUA demonstrates that aScope is cost-effective, in comparison to RFBs, and is associated with a cost saving £211.12 and a small gain in QALYs (0.0105). Sensitivity analyses demonstrated an NMB of £315.68 at a WTP threshold of £10,000/QALY.

Keywords: Bronchoscopes; cross-contamination, cross-infection, hospital accuired infections, nosocomial infections, health economics, single-use, disposable.

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INTRODUCTION

Flexible bronchoscopy of the airways is a valuable tool for evaluation and management of airway diseases. It provides healthcare professionals with both visualization of and access to affected tissues and can be used to evaluate many different pulmonary conditions including tumors, infectious and inflammatory conditions, airway stenosis, airway foreign bodies, and pulmonary hemorrhage [1,2].

Most bronchoscopy procedures are currently performed with a reusable flexible bronchoscope (RFB), though single-use alternatives are available and have been demonstrated to have equal efficacy for bronchoscopy procedures [1,3–6]. Although RFBs are generally considered safe and complications are usually minor, recent research has demonstrated higher than expected infection transmission following bronchoscopy with RFBs, even when appropriate decontamination procedures are complied with [7,8]. Further, the current coronavirus disease (COVID)-19 pandemic has increased the demand for single-use equipment to mitigate against infection risk. Ambu® aScope ™ 4 Broncho (aScope) is a single-use flexible bronchoscope delivered sterile straight from the package, thus minimizing the risk of infection transmission and device cross-contamination compared to RFB use [1,9–11]. Cost-effectiveness research has demonstrated that the aScope can be considered cost-effective compared to a RFBs and is associated with increased patient safety [12]. Additionally, a recent systematic literature review and cost-effectiveness study by Mouritsen et al. demonstrated a high (2.8%) post-bronchoscopy infection rate transmitted via RFBs [1].

Cost-effectiveness analyses are an important element for evaluating new technologies, providing guidance for payers, local authorities, and hospital administrators on the cost-effectiveness of new devices. Cost-utility analyses (CUAs) enable comparisons to be made across disease areas and are particularly useful for broad-based resource allocation and decision-making, and they are therefore frequently required for evaluation of devices by health technology assessment (HTA) agencies such as the National Institute for Health and Care Excellence (NICE) in the UK [13]. To date, no CUA comparing RFB with a single-use alternative, from a UK perspective, has been performed. Therefore, the objective of this study was to evaluate the cost-utility of the aScope compared to RFBs from a UK National Health Service (NHS) perspective.

MATERIALS AND METHODS

Model overview

We developed a simple decision tree model to estimate the cost-utility of aScope vs RFB for bronchoscopy procedures in intensive care units (ICUs) for elective care patients. The model included costs from a UK third-party payer perspective within a 24-month time horizon. The model provided estimates of costs (e.g. acquisition, repair, reprocessing, and infections) and quality-adjusted life years (QALYs). All costs and QALYs beyond the first year were discounted at 3.5% in line with the NICE reference case [14].

A simple decision tree model was developed in Microsoft Excel 365 to estimate the costs and QALYs associated with aScope vs RFB. The model evaluated aScope vs. RFB in two separate arms. Each arm had four possible and mutually exclusive outcomes: (1) no infection, (2) sepsis, (3) pneumonia, and (4) tuberculosis (TB). The probability of no infection was set to 1 minus the total probability of the three infection outcomes. All events occurred at entry into the model. The model only allowed patients to experience a single initial event. This approach was chosen as it reflects the direct outcome of the bronchoscopy procedure itself, and no data on subsequent infections following the initial procedure were available. All costs and QALYs were captured at the end of the model.

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As the aScope has demonstrated equal performance to RFBs for bronchoscopy procedures [3–5], we assumed that both cohort pathways are identical, with the only differences being the costs associated with the use of each device, costs of infections, risks of infections, and the associated utility scores, based on health-related quality of life (HRQoL) scores.

Model inputs

A targeted literature search was performed for each of the model inputs using the Cochrane Central Register of Controlled Trials (CENTRAL) database (via the Cochrane Library) and Medline database (via PubMed). The publications were assessed based on the title, abstract, and full-text reported. If a publication was found to be eligible by two independent assessors, it underwent data extraction. Data extraction from the eligible full-text publications was performed and validated by two independent assessors. Any disagreement regarding eligibility or data extraction was resolved by consensus between the pairs of assessors.

The search strategies and results of each targeted literature review were reported in Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagrams, which can be found in the Electronic Supplementary Materials.

Clinical inputs

The clinical inputs, i.e., the infection rates, were sourced from a recently published systematic literature review and cost-effectiveness analysis by Mouritsen et al., who reported on cross-contamination and infection rates related to RFBs [1]. The review identified three types of infections, all of which were included in our model: sepsis, pneumonia, and TB [1]. The review identified 16 studies with a total of 2351 patients who underwent 3120 bronchoscopy procedures performed with RFBs. Eighty-six (2.8%) of the patients were reported to have a bronchoscope-linked infection. Additionally, the cost-effectiveness analysis in the paper by Mouritsen et al. assumed an infection probability of zero for the aScope [1]. The aScope is sterilized using an ethylene oxide sterilization (ETO) process, which is approved for medical devices, and after aScope sterilization, the contamination rate can be guaranteed up to 1 in 1,000,000 [15]. This infection rate was applied to all the aScope outcomes. The infection rates for aScope and RFB use are shown in Table 1.

Cost inputs

The costs associated with the RFB procedure were stratified into capital, repair, and reprocessing costs, and were estimated from the perspective of the UK NHS. Only studies with UK data were considered eligible for this analysis.

Based on the targeted literature search on costs, we identified two UK studies, by McCahon et al. [16] and Mouritsen et al. [1], where costs associated with the RFB procedure were transparently calculated and stratified into capital, repair, and reprocessing costs. Mean costs based on both sources were used in the baseline analysis and reported in Table 2. The costs were inflated to 2019 costs using Hospital & Community Health Services/NHS inflation indices.

The mean cost per aScope procedure was derived from the study by Mouritsen et al., which reported a list price of £220 per procedure [1]. The procedures were assumed to be identical for aScope and RFB use, and they were therefore not included in the analysis.

Costs of infections

The costs of infections were estimated using the NHS reference costs from 2019/2020 [17]. For pneumonia, sepsis, and TB, a mean based on all the relevant Healthcare Resource Group (HRG) codes (Electronic Supplementary Material) was used, amounting to £4,494.65, £5,466.89, and £2938.25, respectively and reported in Table 3.

Utility inputs

To estimate the QALYs accrued in each of the two patient cohorts, a targeted literature review was conducted to identify utility scores for the population of interest. A targeted literature search was conducted for each type of infection included in the model. One article [18] was identified for pneumonia; however, our searches did not identify any sources with usable utility scores for sepsis or TB. The search strategies and flow diagrams for each type of infection are shown in the Electronic Supplementary Materials.

The base case utility scores for pneumonia were sourced from a nested matched-cohort study by Mangen et al. [18] This study was executed in parallel to the "Community-Acquired Pneumonia Immunization Trial in Adults" (CAPiTA), a placebo-controlled double-blinded randomized control trial that evaluated the effectiveness of a 13-valent pneumococcal conjugate vaccine in 84,496 elderly individuals in the Netherlands [19]. The data were based on patients hospitalized with a clinical suspicion of a pneumonia episode from the CAPiTA study population. The patients were prospectively followed, along with subjects without pneumonia, for 12 months after hospital discharge. A total of 562 participants were included in the study, of which 341 had radiologically confirmed community-acquired pneumonia (CAP), and 221 had radiologically non-confirmed CAP [18]. The participants completed the 3-level EuroQol 5 dimensions (EQ-5D-3L) survey at 0, 1, 6, and 12 months after hospital discharge following pneumonia. Baseline and 1-, 6-, and 12-month utility scores were used in our model for the base case analysis. The EQ-5D-3L health states were scored with the Dutch value set [20]. The utility scores are reported in Table 4.

Table 1: Infection rates.

Parameters	Proportion of patients (%)	
Type of infection	aScope	RFB
Sepsis	0.3×10^{-6}	0.16
Pneumonia	0.3×10^{-6}	2.34
Tuberculosis	0.3×10^{-6}	0.26

Table 2: Cost of the RFB procedure.

Type of cost and source	Source cost	Inflated to 2019 prices
Capital costs		
McCahon et al. (2015)	£137	£148.22
Mouritsen et al. (2019)	£116.4	£123.02
	Mean cost	£135.62
Repair costs		
McCahon et al. (2015)	£141	£152.55
Mouritsen et al. (2019)	£92.9	£98.19
	Mean cost	£125.37
Reprocessing costs		
McCahon et al. (2015)	£51	£55.18
Mouritsen et al. (2019)	£39.9	£42.17
	Mean cost	£48.67

Table 3: Total costs of infections.

Type of infections	Mean cost per infection
Sepsis	£5,466.89
Pneumonia	£5,466.89
Tuberculosis	£2,938.25

Table 4: Utility scores at baseline and follow-up points after a pneumonia infection.

Parameters	Description	Mean	SD	SE
Prior to Pneumonia	Baseline	0.81	0.23	0.01
Pneumonia	Admission	0.23	0.32	0.01
	Month 1	0.72	0.24	0.01
	Month 6	0.74	0.23	0.01
	Month 12	0.74	0.23	0.01

The utility scores were observed to rapidly decrease following the pneumonia episode and then returned to a level lower than the baseline utility at the 1-month follow-up. From months 6 to 12, a steady-state was observed. Utility scores at 12 months had not returned to the baseline level, indicating a prolonged utility loss. Consequently, a longer time horizon than 12 months was necessary to capture the QALY loss beyond 12 months. A conservative approach was selected, in which the utility level was assumed to linearly return to baseline from months 12 to 24. This assumption was tested in scenario analyses to investigate the impact on the results.

Scenario and sensitivity analyses

The results of cost-effectiveness models are always subject to uncertainty, which should be tested using scenario and sensitivity analyses [21]. Nine scenario analyses were performed to test the impact of changes in the time horizon, utility score assumptions, and cost inputs on the results. The cost inputs for the scenario analyses were sourced from research conducted outside of the UK, as the targeted literature search identified non-UK research with lower ranges of cost per RFB procedure [22]. Châteauvieux et al. conducted a micro-costing study of RFB at Georges Pompidou European Hospital in Paris, France [22]. The study estimated a significantly lower cost per RFB procedure compared to the cost in the base case analysis and that in European cost study [22]. To test the impact of a lower cost per RFB procedure, the estimates from the study by Châteauvieux et al. were applied to the model in one of the scenario analyses. The mean costs in the study by Châteauvieux et al. were £14.98, £35.51, and £36.38 for capital, repair, and reprocessing costs, respectively. All costs were inflated to 2019 prices and converted from euro (EUR) to pounds sterling (GBP) using a EUR to GBP conversion rate of 0.90.

A probabilistic sensitivity analysis (PSA) was undertaken to explore the joint uncertainty of all model parameters, and their impacts on the cost-utility results. To conduct the PSA, probabilistic distributions were assigned to each model input parameter. Distributions were sourced from the already included literature. For distributions where a standard error (SE) was not available or could not be calculated, an SE of 20% of the mean value was used. The parameters and distributions are reported in Table 5. The PSA involved a second-order Monte Carlo simulation with 1000 iterations of the mean incremental cost-effectiveness ratio (ICER). The results are presented in a scatterplot of incremental cost savings vs incremental QALYs gained.

RESULTS

Base case analysis

In the base case analysis, the total cost and QALYs gained (discounted) regarding the aScope and RFBs were estimated to be £220.00 and 1.59 QALYs, and £431.13 and 1.58 QALYs, respectively. This resulted in an incremental cost of -£211.12 (i.e., a saving) and an incremental QALY gain of 0.0105 QALYs for the aScope, indicating that the aScope was dominant in the base case analysis. A summary of the discounted costs and QALYs from the model is provided in Table 6.

PSA

The PSA scatterplot (Figure 1) demonstrates that the aScope was dominant in all iterations. The incremental costs ranged from -£22 up to -£424 per bronchoscopy procedure (i.e., the aScope procedure was less costly than the RFB procedure). The net monetary benefit (NMB) was £211.12, using a willingness-to-pay (WTP) threshold of £0. Changing the WTP threshold to £10,000/QALY resulted in an NMB of £315.68.

Scenario analysis

Nine scenario analyses were conducted to estimate the impact of changing the model time horizons, utility score assumptions, and cost

Table 5: Distributions of parameters used in the model.

Parameters description	Cell value	Distribution	SE
Model settings			
Time horizon	24	Not Included	
Discount (initial) – costs	0.04	Not Included	
Discount (initial) – QALYs	0.04	Not Included	
Costs of use			
aScope	£220	Gamma	44
RFB – capital	£14.98	Gamma	3
RFB – repair	£35.51	Gamma	7.10
RFB – reprocessing	£36.38	Gamma	7.27
Costs of infections			
Sepsis	£5,466.89	Gamma	1,093.38
Tuberculosis	£2,938.25	Gamma	587.65
Pneumonia	£4,494.65	Gamma	898.93
Risks of infections associated with RFB			
Sepsis	2×10^{-2}	Beta	
Pneumonia	2.3×10^{-1}	Beta	
Tuberculosis	3×10^{-2}	Beta	
Risks of infections associated with aScope			
Sepsis	3×10^{-6}	Beta	
Pneumonia	3×10^{-6}	Beta	
Tuberculosis	3×10^{-6}	Beta	
Utility scores[18]			
Baseline,	0.81	Beta	0.01
Pneumonia	0.23	Beta	0.01
Pneumonia, at month 1	0.72	Beta	0.01
Pneumonia, at month 6	0.74	Beta	0.01
Pneumonia, at month 12	0.74	Beta	0.01

Table 6: Summary of costs and QALYs (discounted) for the aScope and RFBs.

Parameters	aScope	RFB	Incremental cost or incremental QALY gain
Cost per procedure	£220.00	£309.67	-£89.67
Cost of sepsis per procedure	£0.00	£8.76	-£8.76
Cost of pneumonia per procedure	£0.00	£105.16	-£105.16
Cost of TB per procedure	£0.00	£7.53	-£7.53
Total cost per procedure	£220.00	£431.13	-£211.12
QALYs	1.59	1.58	0.01

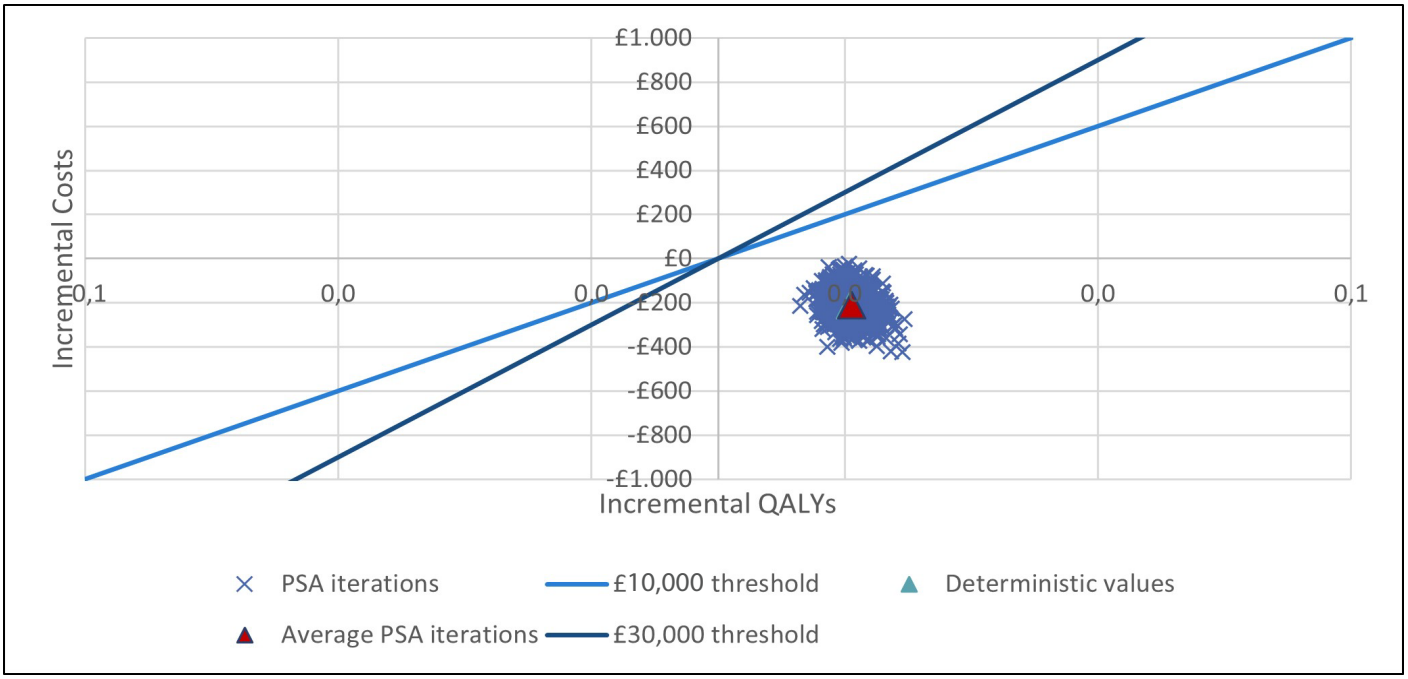

Figure 1: Probabilistic sensitivity analysis (PSA) scatterplot.

Table 7: Changing the time horizon, utility score assumptions, and cost inputs resulted in at a willingness to pay of £10.000 per QALY.

Scenario label	Device	Total costs	Total QALYs	Incremental costs	Incremental QALYs	ICER	NMB
Base case							
	aScope	£220.00	1.59				
	RFB	£431.13	1.58	-£211.12	0.01	Dominant	£315.68
Time horizon of 12 months							
	aScope	£220.00	0.81				
	RFB	£431.13	0.80	-£211.12	0.01	Dominant	£283.85
2. Time horizon of 36 months – utility gradually returns to baseline							
	aScope	£220.00	2.35				
	RFB	£431.13	2.34	-£211.12	0.01	Dominant	£344.53
3. Time horizon of 60 months – utility gradually returns to baseline							
	aScope	£220.00	3.79				
	RFB	£431.13	3.77	-£211.12	0.01	Dominant	£400.30
4. Time horizon of 36 months – utility at 12 months continues							
	aScope	£220.00	2.35				
	RFB	£431.13	2.33	-£211.12	0.02	Dominant	£288.75
5. Time horizon of 60 months – utility at 12 months continues							
	aScope	£220.00	3.79				
	RFB	£431.13	3.76	-£211.12	0.03	Dominant	£288.75
6. Time horizon of 24 months – cost inputs based on McCahon et al. (2015)							
	aScope	£220.00	1.59				
	RFB	£477.41	1.58	-£257.41	0.01	Dominant	£261.97
7. Time horizon of 24 months – cost inputs based on Mouritsen et al. (2019)							
	aScope	£220.00	1.59				
	RFB	£384.84	1.58	-£164.84	0.01	Dominant	£269.40
8. Time horizon of 24 months – cost inputs based on Châteauvieux et al. (2018)							
	aScope	£220.00	1.59				
	RFB	£208.32	1.58	£11.68	0.01	£1117.25	£92.88
9. Time horizon of 12 months – cost inputs based on Châteauvieux et al. (2018)							
	aScope	£220.00	0.81				
	RFB	£208.32	0.80	£11.68	0.01	£1606.34	£61.04

inputs. The results of the analyses are reported in Table 7. Changing the time horizon, utility score assumptions, and cost inputs resulted in NMBs ranging from £61.04 to £400.30 at a WTP threshold of £10,000/QALY

DISCUSSION

The CUA showed that the aScope is cost-effective compared to RFBs. Total cost and QALYs gained (discounted) showed that the aScope procedure was less costly (£220.00 vs £431.13) and more effective (1.59 vs 1.58 QALYs gained) compared to the RFB procedure. The incremental cost and incremental QALY gain were -£211.12 and 0.0105 QALY, respectively, resulting in an NMB of £315.68 at a WTP threshold of £10,000/QALY. The sensitivity analyses supported these findings. The PSA demonstrated that the aScope was dominant in all iterations. The NMB was £210.86 given a WTP threshold of £0.

The findings in this study are in line with previous cost-effectiveness studies on the aScope. Terjesen et al. investigated the cost-effectiveness of the aScope in a typical ICU setting in the USA [12]. They found that the aScope may be considered cost-effective, demonstrating a mean saving per procedure of approximately £95 and a 0.7% decrease in the infection risk. Further, the UK NICE has evaluated the use of aScope for unexpected difficult airways (UDA) and percutaneous dilatory tracheostomy (PDT) and concluded that in isolated hospital units, obstetric units, operating theatres, and ICUs, the aScope, in general, was likely to be cost-effective and could potentially be associated with significant cost savings when used in these settings [6].

There are two main strengths of this study, the first being that this is the first CUA comparing single-use flexible bronchoscopy with reusable flexible bronchoscopy. By using a common unit of measure, the findings in this study allow comparison across different health services and policies, which is useful for payers and hospital administrators when they are deciding on relative priorities regarding appropriate treatments for health conditions. Consequently, cost-effectiveness and cost-utility analyses are the preferred form of analysis among HTA bodies in Europe when evaluating medical devices [13,23]. Unlike in our study, most previous CUAs of medical devices submitted to the UK NICE demonstrate that the devices are associated with an increased cost along with a QALY gain [13]. In this study's base case, the cost per aScope procedure was lower than the cost per RFB procedure, which contributed to the positive results.

The other main strength is that the infection rates used in the model were based on a large number of observations included in a systematic literature review by Mouritsen et al. [1]: 2351 patients undergoing 3120 bronchoscopies. The infection identification methods used in the studies in the review involved traditional typing systems (based on phenotypes) or newer methods that examine the relatedness of isolates at a molecular level (such as polymerase chain reaction or pulse-field gel electrophoresis techniques). This ensures that there were verified biological links from the RFBs to actual patient infections in the studies included in the review [1] and increases the validity of the RFB-related infection rate data used in our model.

This study has several limitations. We were only able to identify two studies from the UK estimating to estimate the cost per RFB procedure [1,16]. Studies from outside the UK have demonstrated considerable variations regarding the cost per RFB procedure [24–27], indicating that cost is highly dependent on the local clinical setting and the calculation method. The scenario analyses demonstrated that the results depended on the cost per RFB procedure. However, even when the cost per procedure was considerably lowered, the ICER (£1606.34) still demonstrated cost-effectiveness in relation to the NICE ICER threshold ranges [28].

In our analysis, we assumed full conversion from RFB to the aScope. However, a mix of single-use and reusable equipment may be a more realistic alternative, which could further influence the CUA outcome in favor of RFB. Further research should be conducted to investigate the cost-effectiveness of a mixed usage strategy involving single-use and RFB equipment.

We were unable to identify utility scores from the UK, so utility scores from the Netherlands were used [18]. Using UK-based utility scores would increase the specificity of the data and may influence the results. However, as the infections are always expected to be associated with a QALY loss independent of the country, this would not change the conclusions in the base case analysis, as the aScope is associated with a lower infection risk than RFBs. Additionally, we were unable to identify utility scores for sepsis and TB, which could have an impact on the results, e.g., sepsis can have significant clinical implications for patients [29]. However, sepsis and TB accounted for the minority of the infections in the model.

Our model solely included cross-infection as a clinical input. There might be other relevant effect measures to include in a model comparing the aScope to RFBs in a CUA. However, we were unable to find any studies comparing other clinical effectiveness measurements of the aScope in comparison to RFBs.

Environmental aspects of new technologies are also increasingly important in HTAs, and these were not included in our evaluation. However, a newly published study in the American Journal of Environmental Protection comparing the environmental impact of the aScope and RFBs concluded that there are no differences regarding environmental impacts between the two technologies [30]. This is because RFBs must go through a complex and comprehensive reprocessing process between each use.

CONCLUSION

In conclusion, this CUA demonstrated that the use of the aScope is cost-effective and associated with both a cost saving -£211.12 and a small QALY gain (0.0105) in comparison to RFB use. The sensitivity analyses demonstrated an NMB of £315.68, at a WTP threshold of £10,000/QALY.

FUNDING

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CONFLICTS OF INTEREST

Anders Mærkedahl, Asger Lindvig and Andreas Pagh declare no conflicts of interest. Rasmus Russell is employed by Ambu A/S.

Availability of data and materials

The datasets analysed during the current study are from publicly available sources.

Code availability

The mode used for data analysis during the current study is available as supplementary material.

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