

Disposable sheaths use versus instruments reprocessing for nasopharyngolaryngoscopy in ENT-clinic: a cost-minimization analysis

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Abstract

Background. Nasopharyngolaryngoscopes reprocessing is often suboptimal and breaches in reprocessing protocols are commonly reported. Single-use sheaths help in reducing endoscope contamination. The aim of the study is to compare costs related to disposable instruments reprocessing and the single-use sheaths alternative.

Research design and methods. A cost-minimization analysis to compare fiberoptic nasopharyngolaryngoscopy instruments reprocessing with disposable sheaths use was performed through the micro-costing approach with data from teaching hospital and costs in euros referred to 2022, following the Consolidated Health Economic Evaluation Reporting Standards.

Results. In the base-case scenario, using disposable sheaths costs € 2,600 less than using cleaning and sterilization procedures. The analysis of direct medical costs, which included personnel, equipment and operating costs, and consumables, revealed higher costs related to personnel for the cleaning and sterilization alternative. Sensitivity analysis further supported the robustness of the cost-saving findings, with variations in disposable sheaths cost and sterilization kits demonstrating significant impacts on the cost difference between the two alternatives.

Conclusions. Based on the study findings, this economic analysis shows that using disposable sheaths covering nasopharyngolaryngoscopes is an appropriate cost-saving strategy. Further studies on a larger scale are needed to confirm these encouraging results.

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Introduction

The nasopharyngolaryngoscope (NPL) is an instrument widely used within the field of otolaryngology and allows the operator the ability to fully evaluate the Upper aerodigestive tract (UADT). It is an essential tool in the diagnosis of voice disorders, locating foreign bodies, diagnosis of head and neck cancers, evaluation of the acute airway distress and evaluation of many other UADT disorders (1).

NPLs are used both in the clinic setting and within the hospital for inpatient and emergency department consultations. In between uses, NPL requires reprocessing - given its exposure to blood, body fluids, and microorganisms - to avoid cross-contamination and this process requires time and resources (2). Endoscope reprocessing often is suboptimal and serious breaches in reprocessing protocols are commonly reported (3). Residues may build up on endoscope surfaces when reprocessing steps are skipped or performed incorrectly. Disinfectants or sterilizers are not so effective when residual soil remains on endoscopes. Endoscope reprocessing guidelines describe single-use sheaths as a potential method for reducing or preventing endoscope contamination. Sheaths are generally made of polyurethane-based materials. They create a physical barrier on the endoscopes to cover reusable components (e.g., insertion tubes, control handles). While some sheaths are just tight fitting covers for exterior surfaces, others have more intricate designs that include disposable passageways (4). After a procedure is completed, personnel discard the sheaths, clean, and disinfect the endoscope components. When sheaths remain intact during a procedure, endoscope components do not require high-level disinfection (HLD) or sterilization. This reduces reprocessing time and may prolong the life of the endoscope components (5). Given the current COVID-19 pandemic context, it becomes even more important to be able to perform NPL as safely as possible, respecting the most accurate cleaning and safety standards and avoiding delays that may cause distress as well as inadequate queueing conditions with regards to physical distancing requirements (6-8). Patients often decide not to go to the hospital for fear of COVID-19 infection, especially in the context of an NPL because the UADT represents the gateway for the SARS-COV-2 virus (9). Recently disposable sheath use during NPL has been produced and implemented at several institutions within the United States and Europe (10). The progressive adoption of this technology cannot proceed without appropriate

feasibility and economic evaluations. There is growing interest in this area in the literature (1-5).

Cost-minimization analyses have already been successfully applied to this (1,11) and other ENT sub-fields (12,13). The aim of the study is to perform and to compare disposable sheaths use with the cleaning and sterilization alternative for the NPL, from the payer perspective.

Materials and Methods

The economic evaluation was designed as a cost-minimization analysis to compare the use, in fiberoptic nasopharyngolaryngoscopy, of disposable sheaths use to cleaning and sterilization.

The analysis adhered to the reporting guideline Consolidated Health Economic Evaluation Reporting Standards (CHEERS). Aggregated and anonymized data were used, in alignment with the ethical principles outlined in the Helsinki Declaration, as well as in compliance with Italian regulations (Law 196/03) and international data protection standards (EC/2016/679). Due to these considerations, there were no requirements for informed consent.

Target population

Target population included individuals of any age presenting with symptoms and conditions such as respiratory problems, nasal obstruction, chronic cough, vocal cords problem, suspected presence of gastroesophageal reflux, recurrent epistaxis, globus sensation, and suspected presence of polyps, cysts, or other tumours in the nasopharyngeal, pharyngeal, or laryngeal region.

Data sources, setting, and study perspective

The study took place at the Campus Bio-Medico University, located in Rome, Local Health Unit 2 (i.e., ASL RM 2) and ran from June 2022 to December 2023.

Cost data were derived from the teaching hospital's 2022 accounting files, and information on the hourly wage and working hours was collected from the documents archives (14). The cost analysis was performed from the payer perspective (i.e., University hospital). In health economic evaluations, the perspective determines which costs and outcomes are to be considered in the analysis. Common perspectives include societal, patient, provider, and payer. The payer perspective focuses on the costs incurred by the entity responsible for financing the healthcare

intervention. Therefore, in our analysis, we considered all costs directly incurred by the university hospital in delivering such interventions.

Intervention and comparator

The intervention consists in NPL with disposable sheaths, followed by cleaning and disinfecting the endoscope components. Sheathed endoscopes do not require high-level disinfection (HLD) or sterilization when sheaths remain intact. The comparator is NPL with a reusable endoscope, subjected to HLD or sterilization between uses.

Effectiveness

Evidence indicates that disposable sheaths effectively provide a sterile barrier without compromising the quality of endoscopic procedures. As reported by a recent systematic review (10), no breaches were detected in the sheaths, and both sheathed and unsheathed endoscopes exhibited minimal microbial growth. Studies demonstrated comparable diagnostic and therapeutic efficacy between the two techniques (15-18).

Silberman et al. (19) highlighted the superior performance of non-latex disposable sheaths in maintaining sterility, with excellent optical qualities and compatibility with topical anaesthetics and lubricants.

A detailed assessment of nine parameters, including image clarity, illumination, and manoeuvrability, showed the sheath's usability. A study by Gupta et al. (20) showed that, across 75 patient uses, no sheath breaches occurred, and installation/removal times averaged 15 and 5 seconds, respectively (20). The slight reduction in success rate for first-attempt procedures (83%) was only attributed to the performance of less experienced residents.

Costs estimation

The costs considered in the analysis were estimated through the micro-costing approach (21). Only direct medical costs were included and then grouped into the following categories: personnel, equipment and operating, and consumables. Table 1 shows the unit cost for the main cost components.

Personnel costs for the fiberoptic laryngoscopy were computed observing in detail all the basic tasks required for the provision of a fiberoptic laryngoscopic examination and measuring the effective work time of the personnel involved (i.e., one physician, one nurse, one health assistant). Staff worked 47 weeks a year, 4 days a week, that is, around 187 days (or 1,426 hours) a year.

Equipment and operating costs, related only to the cleaning and sterilization alternative, included

Table 1 - List of cost items and unit costs for each alternative

Cost Component	Disposable sheaths use (number of visits: 4,140)	Cleaning and Sterilization (number of visits: 4,140)
	Cost (€)	Cost (€)
Consumables		
Sterilization kits (per week)	–	16
Disposable sheaths (per visit)	7	–
Tongue depressors (per visit)	0.05	–
Enzymatic detergent (per liter)	6.19	–
70% alcohol solution (per liter)	12.5	–
Equipment and Operating		
Depreciation and taxes (per year)	–	2,800
Electricity (per day)	–	1
Envelopes (per visit)	–	0.15
Solvents (per week)	–	300
Personnel ^{a,b}		
Medical doctor (per hour)	75.25	75.25
Nurse (per hour)	28.28	28.28
Health assistant (per hour)	–	21.80

^a The fiberoptic laryngoscopy, adopting disposable sheaths, required the presence of one otolaryngologist and one nurse.

^b The fiberoptic laryngoscopy, adopting cleaning and sterilization, required the presence of one otolaryngologist, one nurse and one health assistant.

depreciation and taxes of the medical equipment used to sterilize instruments, electricity, and supplementary expenditure as solvents and envelopes.

Consumables costs, related to the cleaning and sterilization alternative, included the sterilization kits.

In relation to the other alternative (i.e., use of disposable sheaths), consumables costs included the disposable sheaths for flexible NPLs and tongue depressors.

Currency, price date, and conversion

All costs were expressed at 2022 cost level. Cost analyses were performed in euros (€) for the year 2022. No conversion was needed.

Sensitivity analysis

Sensitivity analysis was created to deal with uncertainties in the input variables and parameters (22). A univariate deterministic sensitivity analysis was performed changing the cost of disposable sheaths by $\pm 25\%$ and keeping the cost of equipment unvaried since it is not reusable (i.e., depreciation and taxes €2,800). Furthermore, the cost of sterilization kits was varied by $\pm 25\%$ while the cost of personnel by $\pm 5\%$. All the analyses were conducted using Microsoft Excel version 16.82 (Microsoft Corporation, Redmond, WA).

Results

Base case scenario

Table 2 summarizes the costs associated with the adoption of disposable instruments compared to the cleaning and sterilization alternative for the nasopharyngolaryngoscopy examination.

In the base case, using disposable instruments costs €2,600 less than using cleaning and sterilization procedures. Having ascertained the exclusive costs of each alternative, the costs related to personnel were higher for the cleaning and sterilization alternative (Δ : €15,543).

Sensitivity analysis

Figure 1 shows the findings of the one-way deterministic sensitivity analyses. The base-case cost saving was most sensitive to changes in disposable sheaths cost, sterilization kits, and personnel, while it was not sensitive to changes in depreciation and other types of consumables.

Disposable sheaths cost had the largest impact on the base-case cost saving. Decreasing the costs by 25% raised the cost savings to - € 9,103 while an increase of the same percentage led to extra costs up to € 5,387.

Furthermore, halving the procedural time, associated with TF adoption, by 50% raised the cost savings to € 412 while an increase of 50% led to an

Table 2 - Summary of the costs for each alternative

Cost Component	Disposable Instruments (number of visits: 4,140)	Cleaning and Sterilization (number of visits: 4,140)
Consumables		
Sterilization kits (per week)	–	752
Disposable sheaths (per visit)	28,980	–
Tongue depressors (per visit)	207	–
Enzymatic detergent (per liter)	410.03	–
70% alcohol solution (per liter)	1,552.5	–
Equipment and Operating		
Depreciation and taxes (per year)	–	2,800
Electricity (per day)	–	187
Envelopes (per visit)	–	366.75
Solvents (per week)	–	14,100
Personnel^{a,b}		
Medical doctor (per hour)	107,306.5	107,306.5
Nurse (per hour)	40,327.28	40,327.28
Health assistant (per hour)	–	15,543.40
Total	178,783.31	181,382.93

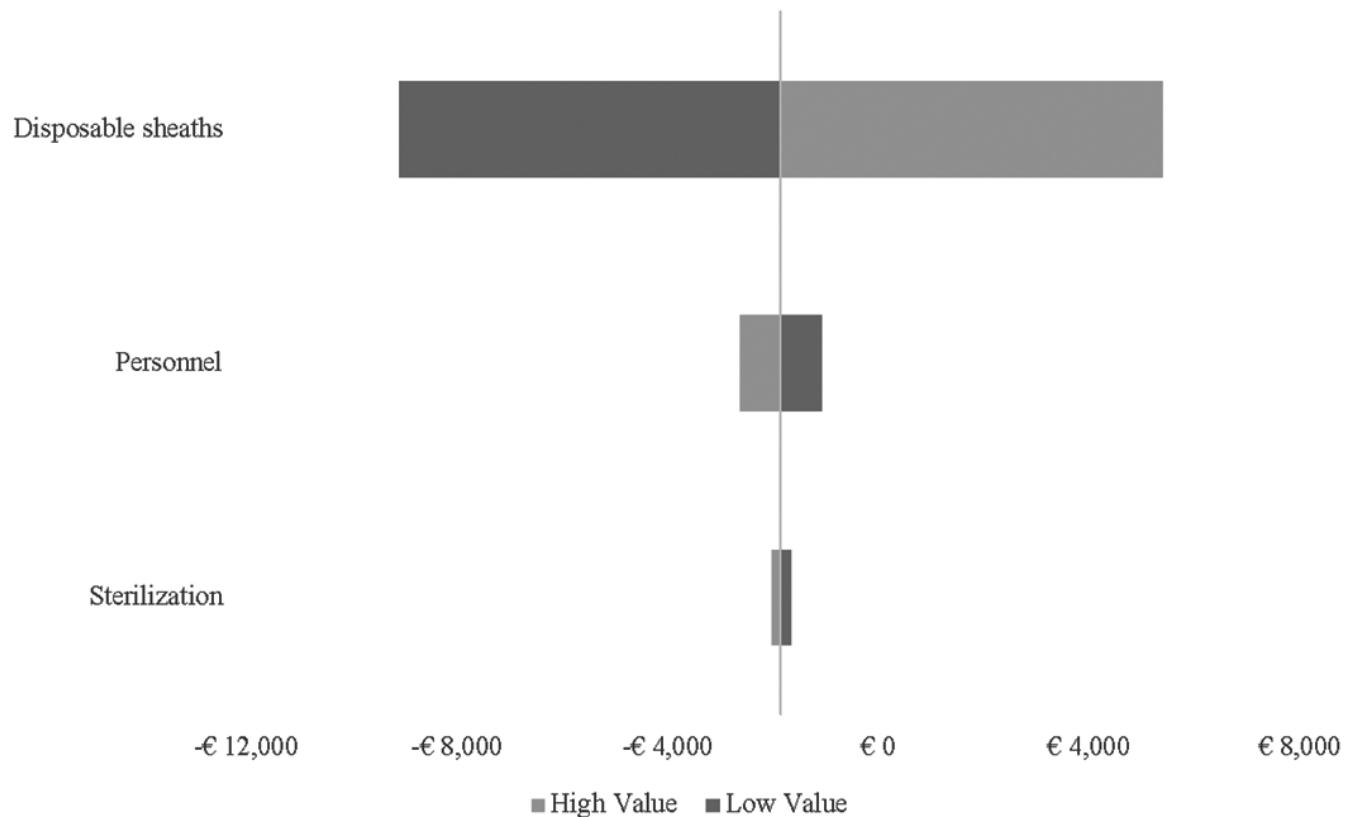


Figure 1 - Tornado diagram

extra cost of € 195. Changes in the cost of sterilization kits, associated with cleaning and sterilization alternative, were similar to the base-case estimate (–€ 1,670 to –€ 2,046).

Discussion

The findings of this cost-minimization analysis support the hypothesis that using disposable instruments for NPL is a cost-saving approach. The base-case analysis showed a cost difference of –€ 2,600, favouring disposable sheaths over cleaning and sterilization, and the deterministic sensitivity analysis confirmed the robustness of the results.

In the existing scientific literature, economic evaluations of nasopharyngolaryngoscopes, flexible ENT-endoscopes, and fiberoptic nasendoscopes present mixed findings regarding disposable versus reusable alternatives. Some studies, such as those of Walczak et al. (1), found disposable NPLs to be cost-effective, while Becker et al. (23) reported lower costs for reusable systems. Ellis et al. highlighted that

reusable scopes were less expensive in outpatient settings, with smaller cost differences in inpatient settings (24). Similarly, Jegatheeswaran et al. (25) concluded that reusable fiberoptic nasendoscopes had lower costs over 5- and 10-year periods but acknowledged the omission of raw material and energy costs in their analysis, which could favour disposables. These contrasting findings underscore the need for nuanced economic evaluations. Another point to be considered regarding costs is how inadequate disinfection of nasopharyngolaryngoscopes (NPLs) significantly contributes to healthcare-associated infections (HAIs), resulting in considerable financial and clinical burdens. These HAIs often necessitate prolonged hospital stays, intensive pharmacological treatments, and additional interventions, also considering potential legal ramifications, substantially increasing healthcare costs. A study conducted in an Italian university hospital revealed that patients with HAIs incurred an additional €4,988 cost, representing a 59.7% increase compared to non-infected patients (26). These findings suggest the urgent need for appropriate disposable technologies and standardized

effective disinfection protocols, and advanced cleaning technologies. Environmental sustainability is another key dimension to be considered. Transitioning to single-use endoscopes may reduce reprocessing waste but significantly increase overall waste, potentially quadrupling net waste due to ancillary supplies and disposal requirements (27). This raises critical questions about the environmental trade-offs of disposable solutions.

Strengths and limitations

The results of this study must be considered in light of its weaknesses and strengths. The use of administrative databases and accounting studies may not detect all significant nuance and heterogeneity.

While sensitivity analyses were conducted, micro-costing methods involve operator-dependent assessments and cannot be applied systematically. Additionally, environmental and repair costs were not included in the analysis, although a wide range of direct and indirect costs were considered to ensure robust estimates (28). Despite these limitations, this study contributes meaningfully to an underexplored area in the literature. Future research should incorporate environmental costs and repair costs to provide comprehensive evaluations. Given the low contamination rates of sheathed endoscopes and concerns about the adequacy of current reprocessing techniques, disposable sheaths offer a promising solution to reduce infection outbreaks linked to endoscopic procedures. Considering sheathed endoscopes have low contamination rates and current reprocessing techniques for endoscopes are often inadequate, disposable sheaths could be a viable solution to the concerning number of infection outbreaks associated with endoscopic procedures.

Conclusions

This economic analysis shows that using disposable sheaths covered NPLs is an equally effective and cost-saving strategy compared to instruments reprocessing. Larger-scale studies are necessary to confirm these encouraging findings. Economic evaluations play a crucial role in guiding decisions between reusable and disposable medical devices. Balancing resource management with high-quality service remains vital, especially considering the challenge represented by the COVID-19 pandemic.

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Riassunto

Utilizzo di guaine monouso rispetto al ritrattamento degli strumenti per la nasofaringolaringoscopia in otorinolaringoiatria: un'analisi di minimizzazione dei costi

Premessa. Il trattamento dei nasofaringolaringoscopi è spesso subottimale e vengono comunemente segnalate violazioni dei protocolli per il reprocessing. Le guaine monouso contribuiscono a ridurre la loro contaminazione degli endoscopi. Lo scopo dello studio è confrontare i costi relativi al trattamento degli strumenti monouso e l'alternativa delle guaine monouso.

Disegno di ricerca e metodi. Un'analisi di minimizzazione dei costi per confrontare il trattamento degli endoscopi per rinofaringolaringoscopia a fibre ottiche con l'uso di guaine monouso è stata eseguita attraverso l'approccio del microcosting con dati provenienti da un ospedale universitario e costi in euro riferiti al 2022, secondo i Consolidated Health Economic Evaluation Reporting Standards.

Risultati. Nello scenario di base, l'utilizzo di guaine monouso costa 2.600 euro in meno rispetto alle procedure di pulizia e sterilizzazione. L'analisi dei costi medici diretti, che includevano il personale, le attrezzature, i costi operativi e i materiali di consumo, ha rivelato costi più elevati legati al personale per l'alternativa di pulizia e sterilizzazione. L'analisi di sensibilità ha ulteriormente confermato la solidità dei risultati in termini di risparmio, con variazioni del costo delle guaine monouso e dei kit di sterilizzazione che hanno avuto un impatto significativo sulla differenza di costo tra le due alternative.

Conclusioni. Sulla base dei risultati dello studio, questa analisi economica dimostra che l'uso di guaine monouso per coprire i nasofaringolaringoscopi è una strategia di risparmio appropriata. Sono necessari ulteriori studi su scala più ampia per confermare questi risultati incoraggianti.

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