A Cost-Effectiveness Analysis of Exalt Model D Single-Use Duodenoscope Versus Current Duodenoscope Reprocessing Methods

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Abstract

BACKGROUND AND AIMS: The spread of duodenoscope-related infections has led to the recognition that reprocessing of duodenoscopes using high-level disinfection (HLD), if done perfectly, narrowly meets the advised thresholds of endoscope decontamination. In 2019, the US Food and Drug Administration (FDA) recommended a transition to duodenoscopes designed to pose less risk, including the use of disposable duodenoscopes. The Exalt Model D (Boston Scientific Corp, Marlborough, MA) single-use duodenoscope (EXALT) has been shown to be substantially equivalent to reusable duodenoscopes for clinical use. The aim of this study was to estimate the cost-effectiveness of EXALT in the United States healthcare system.

METHODS: A cost-effectiveness model was developed comparing HLD, culture-and-quarantine (CQ), Ethylene oxide sterilization (ETO), and EXALT in a simulated cohort undergoing Endoscopic Retrograde Cholangiopancreatography (ERCP) for choledocholithiasis. Published information was leveraged describing clinical estimates, infectious outbreaks, and hospital costs.

RESULTS: In a base analysis, HLD was the least costly ($962), and EXALT was the costliest ($3000), but yielded the most QALYs (0.0172 incremental QALYs). The incremental cost-effectiveness ratio was $38,461 for ETO gas sterilization and $62,185 for EXALT. However, with the availability of device-specific reimbursement for EXALT in the US in the form of transitional pass-through payment (TPT) and new technology add-on payment (NTAP), EXALT provided the highest cost-savings to the hospital versus alternative strategies by maintaining QALY gains while decreasing estimated net costs. Probabilistic sensitivity analyses showed EXALT to be preferred compared to HLD over a range of willingness-to-pay.

CONCLUSION: EXALT is a viable and cost-effective strategy that should be strongly considered for ERCP.

Keywords: Single-use duodenoscope; Duodenoscopes/microbiology; Economic analysis; Endoscopic Retrograde Cholangiopancreatography (ERCP); Equipment contamination; Equipment reuse.

Background and Introduction

Duodenoscopes are essential to performing Endoscopic Retrograde Cholangiopancreatography (ERCP) and facilitate the management of pancreaticobiliary disorders; more than half a million ERCPs are performed annually in the US alone.[1] Duodenoscope contamination has been linked to outbreaks of Carbapenem–Resistant Enterobacteriaceae (CRE) and infections caused by other multidrug resistant organisms (MDROs).[2-6] Regulatory authorities such as the US Food and Drug Administration (FDA), the US Centers for Disease Control (CDC), and professional societies have published reprocessing guidelines to minimize the risk of transmitting serious infections. However, multiple factors contribute to device contamination and may remain unaddressed.[2,7-10] Despite hospitals' adoption of best practices related to high-level disinfection (HLD) protocols, concerns about infection have led many healthcare facilities to use supplemental or alternative reprocessing method(s). These measures include double high-level disinfection (HLD), microbiological culturing, and ethylene oxide (ETO) gas sterilization.[8,11] Nevertheless, in the latest report by the US FDA, depending on the specific model of duodenoscope used, 1.9% to 22% of all samples from specific

Abbreviations: ERCP, endoscopic retrograde cholangiopancreatography; ETO, ethylene oxide sterilization; EXALT, Exalt Model D single-use duodenoscope; HLD, high-level disinfection; NTAP, new technology add-on payment; TPT, transitional pass-through payment

Most current article

2590-0307

https://doi.org/10.1016/j.tige.2021.09.007

What You Need to Know

Background

Given concerns regarding possible contamination of reusable duodenoscopes, which solutions are economically viable for hospitals? Is the Exalt Model D single-use duodenoscope a cost-effective solution?

Findings

The results suggest the Exalt Model D single-use duodenoscope is a cost-effective solution. Given single-use duodenoscopes are additionally reimbursed through Medicare Outpatient Transitional Pass-Through Payment, single use duodenoscopes provide value to hospitals through saving costs and increasing QALYs.

Implications for Patient Care

Single-use duodenoscopes are a viable and cost-effective strategy that should be considered for ERCP to address concerns regarding reusable duodenoscope contamination.

duodenoscope models tested positive for "high concern" bacteria (eg, pathogens such as *E. coli* or *Staphylococcus aureus*).[13] It is currently recognized by experts that evidence is inadequate to conclude that proper cleaning and reprocessing can thus adequately eliminate bacterial residue from reprocessed duodenoscopes. Some experts in recent publications have proposed to improve patient safety, we should move from HLD to use of sterilized or disposable sterile endoscopes.[14-16]

Recently, a novel single-use duodenoscope (Exalt Model D, Boston Scientific Corp, Marlborough, MA) (EXALT) has been made commercially available and a clinical study has shown its performance characteristics to be substantially equivalent to standard reusable duodenoscopes.[17] We performed a cost-effective analysis of EXALT using a Markov-model to compare this new device with other approaches to reduce reprocessed duodenoscope-contamination risk. We hypothesized the use of EXALT, because of its ability to eliminate duodenoscope-transmitted infections from reprocessing failures, would be cost-effective when considering all direct costs of potential infections.

Methods

Decision Analysis Model

We followed the guidelines of the Second Panel on Cost-Effectiveness in Health and Medicine[18] and constructed a patient-level model in a hypothetical cohort of patients undergoing ERCP (Figure 1). We evaluated approaches to reducing infection related to duodenoscope use: (1) use of EXALT, or (2) different reusable duodenoscope reprocessing techniques. We constructed the decision tree model to project the procedure and the potential use of a contaminated scope, terminating in a Markov model to simulate colonizations, infections, and the course of treatment of infection.[19] We used a patient lifetime post index ERCP procedure time horizon in the model and compared the following approaches:

1. *Standard ERCP: ERCP performed using reusable duodenoscopes and following FDA recommended reprocessing:*

We used this as the reference approach for this analysis; the probability of contamination post-HLD was informed by a recent FDA postmarket '522' study.[12]

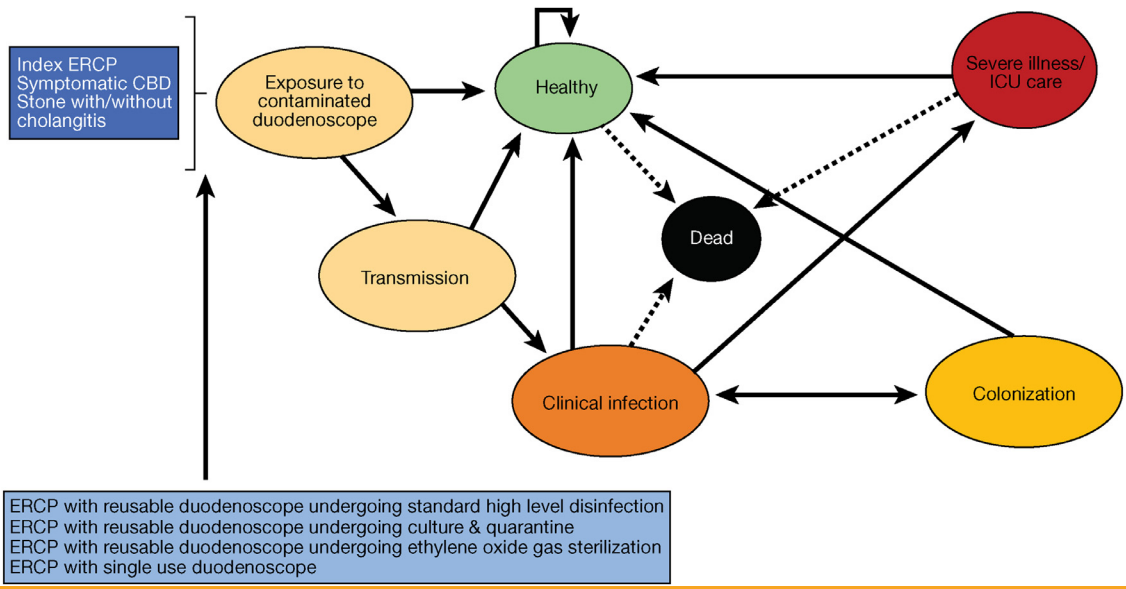

Figure 1. Figure showing the different Markov states in the decision model.

Table 1. Cost Estimates

Variables *High-concern organisms denotes multidrug (including carbapenem) resistant Enterobacteriaceae and other gut-derived organisms.	Base-case (range) 2020 USD	References
Cost of standard high-level disinfection per duodenoscope Cost of double high-level disinfection per duodenoscope Cost includes staff time and wages paid to complete basic reprocessing activities, cost of purchase and maintenance of automated endoscope reprocessor (AER), cost of storage and cost of personal protective equipment for personnel.	$200 ($80-$300) $215 ($90-$320)	10,20,34,35
Cost of culture and quarantine per duodenoscope Cost includes cost of reprocessing, cultures, surveillance, EtO sterilization for duodenoscopes with 2 successive positive cultures, and cost of purchasing additional duodenoscopes to maintain work-flow given need for quarantine and for replacing duodenoscopes damaged by incidental EtO.	$480 ($200-$500)	10,20,34,35
Cost of EtO gas sterilization per duodenoscope Cost includes the cost of reprocessing, ETO sterilization, and cost of purchasing additional duodenoscope considering turn-around time for EtO sterilization and also, for replacing duodenoscopes damaged by EtO.	$1,180 ($400-$1500)	10,20,34,35
Approximated Cost of Exalt Model D disposable duodenoscope	$3000 ($2000-$5000)	34, Estimate
Cost of providing care for management of uncomplicated choledocholithiasis requiring ERCP and CBD stone extraction Cost based on weighted national estimate for MS-DRG 446.	$6900 ($3000-$13,000)	23
Cost of treatment of high-concern organisms* related infection by type of infection • Cholangitis • Pneumonia • Misc. infection (soft tissue, skin, surgical site, abscess, etc.) • Sepsis • UTI Cost data were derived from Premier Research database, an electronic laboratory, pharmacy and billing data repository, for years 2009 through 2013, which contains approximately 15% of all hospitalizations in the US.	 $40,000 ($20,000-$60,000) $30,432 ($10,000–$50,000) $38,494 ($25,000-$50,000) $50,038 ($35,000-$75,000) $33,400 ($15,000-$50,000)	10,23,24,46,47
Additional cost of care for ICU stay for those patients requiring ICU based management	$9322 ($5000-$25,000)	10,38
Total institutional cost for control of high-concern organisms* related hospital outbreak averaged per patient Costs included microbiological diagnostics/surveillance and decolonization costs; missed revenue due to closed beds; additional cleaning costs; additional personnel (infection prevention, nursing staff and clinicians); costs made for contact or strict isolation of patients, including cost of personnel protective equipment.	$30,000 ($20,000-$50,000)	30-32,39-41
Estimated Willingness to pay for calculation of Net Health Benefit and incremental cost-effectiveness ratio	$100,000 ($50,000-$200,000)	18,21
Discounting rate for both cost and effectiveness	0.02 (0.01-0.03)	18,21

2. *ERCP with culture and quarantine:*

In this approach, after high-level disinfection following the FDA recommended reprocessing guidelines, duodenoscopes were cultured and quarantined for 48 hours. Some duodenoscopes were quarantined and unavailable to perform procedures. To maintain workflow, we assumed additional capital cost would be required to purchase additional reusable duodenoscopes.[20] We defined culture sensitivity as 80% based on peer-reviewed literature[15,16] and conservatively assumed cultures would be 100% specific to potential infections of interest.

3. *ERCP with ethylene oxide (ETO) sterilization:*

In this approach, after initial FDA recommended HLD, the duodenoscopes were exposed to ETO gas, which requires the duodenoscopes be processed at an outside facility with at least a 48-hour turnaround time and the purchase of additional duodenoscopes. Due to ETO gas exposure, we used a replacement interval of 4.5 years compared to a standard replacement period of 5 years.[20]

4. *ERCP using Exalt Model D single-use duodenoscope:*

In this approach, EXALT was used for typical ERCP procedures. We modeled that all duodenoscope contamination-related infectious complications would be prevented by using the EXALT with zero scope reprocessing costs.

Outcomes Compared and Statistical Methods

The primary outcomes we used to compare the net costs and quality of life among the competing strategies were incremental cost-effectiveness ratio (ICER) and the net health benefit (NHB) (definitions included in the supplemental materials).

Data Collection

We performed a literature search of the MEDLINE, EMBASE and Cochrane Databases (July 2010 to January 2020) using predefined search criteria (keywords included in the supplemental materials). Abstracts from major gastroenterology meetings were searched for all relevant abstracts published from 2010 to 2019. Manual searches of the bibliography of selected publications were also performed.

Clinical Probabilities and Utilities

Clinical probabilities, including transitional probabilities between different health states and performance characteristics of different duodenoscope disinfection protocols, were derived from published information. When specific published information was not available, expert clinical opinion was used (AD, RM).

Quality-adjusted life-years (QALYs) were estimated by adjusting the life expectancy of each health state by utility, which reflects patient preferences for that health state. Utility values were obtained from published literature.[18,19] (Table 2)

Cost Estimates

Costs in the analysis represent costs from a United States healthcare system perspective. We included costs related to infectious complications, reprocessing, capital, inventory, labor, and surveillance. We considered only direct costs, and adjusted all costs adjusted to 2020 US dollars. We did not consider indirect costs, such as time spent by the patient and immediate family members for caregiving. We did not include costs related to physician services.

In the baseline analysis, we based hospital costs related to medical, surgical, and diagnostic services related to the management of choledocholithiasis and post-ERCP contaminated scope related complications on the 2018 weighted national estimated hospital cost of care for relevant inpatient diagnoses.[23] We used cost data for the management of infectious complications resulting from duodenoscopes contaminated with high-concern organisms from previously published literature.[24]

In our baseline analysis, under the strategy of EXALT based management, the hospital was assumed to incur the cost of the device. In a subanalysis, we offset the cost of EXALT, estimated at $3000, by using an estimated reimbursement for the SUD of $3000 based on the newly established Medicare Outpatient Transitional Pass–-Through (TPT) payment and an estimated reimbursement for the SUD of up to $1715 for the New Technology Add-on Payment (NTAP). (Boston Scientific applied for these payments – additional information included in supplemental materials) (Table 1).

Sensitivity Analyses

We performed one way and multiway sensitivity analyses of important clinical variables, costs, and QOL estimates. In a hypothetical cohort of 10,000 patients undergoing ERCP, we performed a Monte Carlo simulation for a probabilistic sensitivity analysis (PSA).[19,22] In this method, sampling probability values quantify the total impact of uncertainty on the model. We performed threshold analyses to understand the impact of key clinical and cost estimates and the various threshold points, if any, in which variables would meaningfully change results.

Results

Base Case Results

In the baseline analysis, point-estimates project the standard HLD approach would generate the fewest QALYs, and the EXALT based approach was projected to generate the most QALYs over the lifetime of the model cohort (Table 2). The Incremental Cost–Effectiveness ratio (ICER; the ratio of incremental costs to incremental effectiveness, measured in quality adjusted life-years) was $38,461 for ETO gas sterilization and $62,185 for EXALT over standard high-level disinfection. The culture and quarantine approach was dominated; which denote a therapy more costly but not more effective. In this case, the culture and quarantine approach was more costly than EXALT and was not estimated to produce additional quality of life benefits beyond the benefits generated by EXALT (Table 3).

Subanalysis Using the Transitional Pass-Through Reimbursement for SUD

To reflect the impact of the recently approved TPT and NTAP, we performed a subanalysis for ERCP performed for Medicare patients in both the hospital outpatient (HOPD) setting for TPT reimbursement, and the hospital inpatient (HIPD) setting for NTAP reimbursement. In the TPT scenario, EXALT was a cost-saving approach with zero cost (ie, cost less device specific reimbursement) per patient treated with a net saving of $962 compared to standard HLD reprocessing while generating 21.92 QALYs – an increase of 0.033 QALYs (0.15%). All other approaches were more expensive and less effective than TPT-reimbursed EXALT. For the NTAP scenario, EXALT was a very cost-effective approach, with net costs of only $323 versus HLD while maintaining similar QALY benefits. TPT payments for Medicare outpatient cases using EXALT and NTAP for Medicare inpatient cases using EXALT are anticipated to continue to be paid from CMS until June 30, 2023 and at least September 30, 2022, respectively.

Sensitivity Analysis

Sensitivity analyses were performed by varying important cost estimates and clinical probabilities. The tornado diagram (Figure 2A) shows the results of 1-way sensitivity analyses. When comparing EXALT to HLD, the model was most sensitive to important clinical variables such as

Table 2. Clinical Probabilities and Utility Estimates

Variables *High-concern organisms denotes multi-drug (including carbapenem) resistant Enterobacteriaceae and other gut derived organisms.	Base-case (range)	References
Age at entry in the model	50 (20-90)	Estimate
Probability of contaminated duodenoscope with high-concern organism* after standard high-level disinfection The probability of contaminated duodenoscope with high-concern organisms is dependent on the model of the duodenoscope used; it was assumed that most of the ERCPs in the US are performed using the Olympus TJF160F/VF model.	0.06 (0.03-0.17)	10,42,43
Probability of contaminated duodenoscope with high-concern organism* after ETO gas sterilization	0.03 (0.02-0.1)	7,10,15,16,34,43
Probability of transmission of infection after exposure to contaminated duodenoscope scope with high-concern organism* Based on expert opinion. To account for variability, uncertainty analysis was performed using PSA using the range as a triangular distribution.	0.4 (0.1-0.6)	Estimate
Probability of clinical infection requiring hospitalization after transmission of high-concern organisms* associated with a contaminated duodenoscope	0.5 (0.1-0.7)	10,41-43, Estimate
Probability of different types of clinical infections from high-concern organisms* Pneumonia Sepsis UTI	 0.3 (0.1-0.5) 0.2 (0.1-0.5) 0.2 (0.1-0.6)	24,45
Probability of high-concern organisms* related severe illness requiring ICU admission	0.1 (0.05-0.2)	46
Probability of mortality of high-concern organisms* related severe illness requiring ICU admission Age <65 years Age 65-85 years Age >85 years	 (0.05-0.2) 0.15 (0.1-25) 0.3 (0.2-0.5)	10,36,45
Probability of long-term colonization with high-concern organisms* after exposure to contaminated duodenoscope and/or clinical infection	0.4 (0.2-0.5)	10,42-44, Estimate
Annualized probability of persistence of long-term colonization with high-concern organisms* (stage dependent) <1 year 1-2 years 2-3 years >3 years	 0.52 (0.2-0.8) 0.15 (0.03-0.2) 0.03 (0-0.05) none	37,47,48
Annualized probability of transition to active clinical infection from a state of long-term colonization with high-concern organisms* (limited to initial 3 years of model entry)	0.25 (0.1-0.5)	37,45,47
Probability of a (contaminated) duodenoscope associated hospital outbreak of illness related to high-concern organisms*	0.000015 (0-0.00001)	2,3,7,49
The average number of cases involved in a duodenoscope associated hospital outbreak	20 (2-135)	Estimate, 2,3,7,49
Utility value when healthy	1 (0.9-1.0)	18
Utility value with long term colonization with high-concern organisms	0.9 (0.85-1.0)	10,30,37,41,45,47
Disutility value of hospitalization for clinical infection	-0.06 (-0.02, -0.15)	18,50
Disutility value of ICU admission	-0.11 (-0.06, -0.34)	18,50
The sensitivity of duodenoscope culture for high-concern organisms* under the culture and quarantine approach (for Bayesian analysis; specificity modeled as 1.0)	0.8 (0.6-1.0)	10,44

the probability of transmission of high-concern organisms after exposure to contaminated duodenoscopes (threshold value of 0.29), probability of developing clinical infections after exposure (threshold value of 0.42), probability of long-term colonization with high-concern organisms after exposure (threshold value of 0.32), and cost of EXALT (threshold value of $3,281).

Figure 3 and Supplemental Figure show the results of 2-way sensitivity analyses. Unless the cost of EXALT exceeds specific thresholds, the approach of EXALT was preferred in terms of net health benefit across the considered range of probability of contaminated duodenoscopes and risk of transmission after exposure.

In the Monte Carlo analysis, by adopting EXALT instead of HLD, the relative risk reduction (RRR) and NNT (95% CI) for ICU admission and death related to duodenoscope associated infections over a patient's lifetime was: ICU admission: RRR, 0.996 (0.936-1.0); NNT:79 (67-95); Death: RRR, 0.973(0.552-0.998); NNT: 556 (350-997). The acceptability curve shows the probability of the results over a range of willingness-to-pay estimates, showing in 0.01% of trials the approach based on EXALT was dominant and in 67.28% of the trials EXALT was cost-effective with ICER of less than $100,000 per QALYs. (Figure 2B) Even in most conversative scenarios without

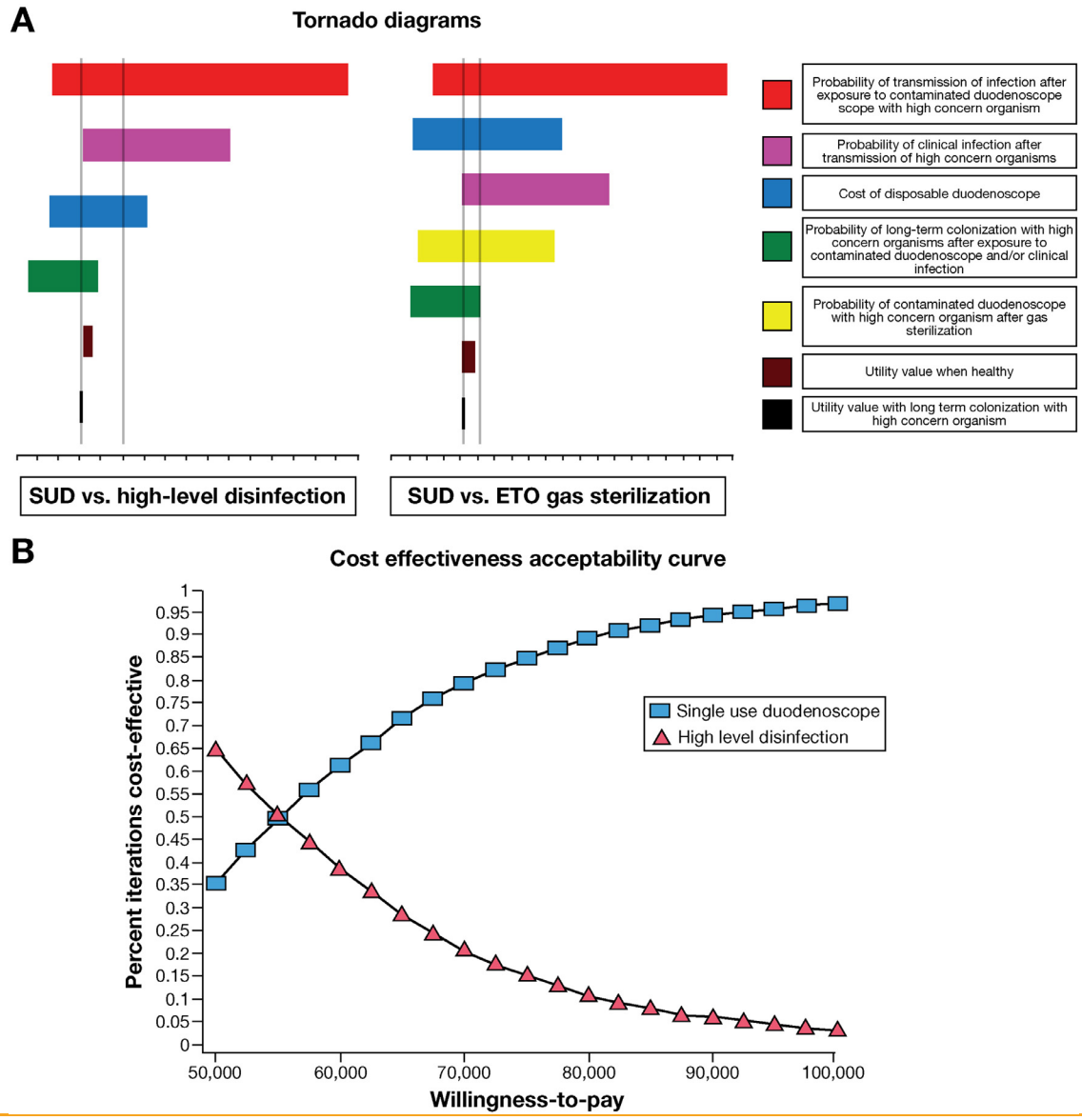

Figure 2. (A) The Tornado diagram shows the results of 1-way sensitivity analyses using important variables and the range of change of ICER with each variable with respect to the WTP. The left panel compares with HLD, and the right panel compares with ETO. (B) Acceptability graph summarizes the results of the Monte Carlo simulations; above a WTP of approximately $55,000 the majority of the iterations favor the approach of EXALT over high-level disinfection.

considering the transitional pass-through payment and simultaneously considering uncertainties associated with some of the inputs, EXALT is cost-effective when compared to other approaches in up to two-thirds of outcomes.

Discussion

There have been only a few studies published that have examined the cost-effectiveness of different strategies of reprocessing duodenoscopes. In a cost-utility analysis, Almario et al. found both culture and quarantine and ETO gas sterilization-based strategies were not cost-effective with an unacceptable level of incremental cost per QALY. Although they concluded HLD was most cost-effective, they did not consider the approach of using EXALT, which was not FDA cleared at that time.[10] In another cost model, Bang et al. calculated the per-procedure cost of a disposable duodenoscope in the United States can vary from $797-$1,547 for centers performing at the 75th percentile of ERCP procedure volume. This study examined costs without considering effectiveness as an outcome and did not use uncertainty analysis.[34]

This analysis is based on a simulated model with estimates obtained from studies of varying quality. Specific information on the natural history of duodenoscope associated infectious complications is limited and was modeled from the natural history of hospital acquired infections with CRE/MDRO unrelated to endoscopy

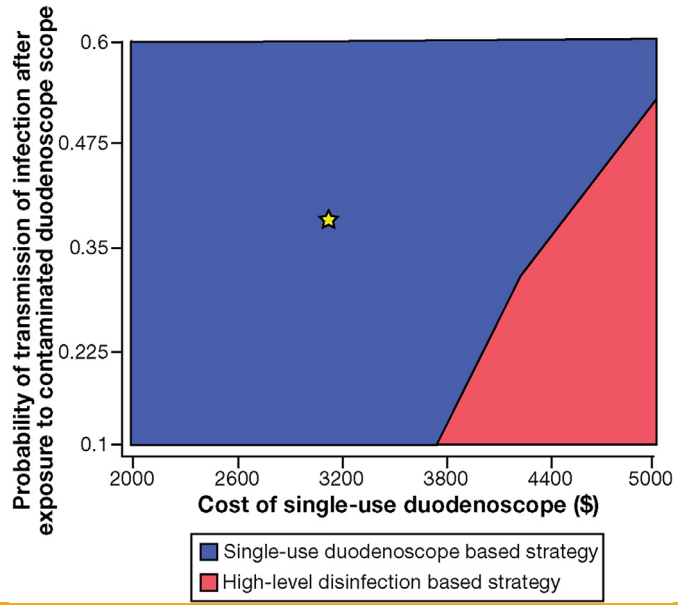

Figure 3. A 2-way sensitivity analysis with the cost of EXALT along the X-axis and probability of duodenoscope being contaminated with high-concern organisms after HLD along the Y-axis. The star represents the point estimates in the baseline analysis.

related infectious outbreaks. Some parameters were based on expert opinion. Definitive data on these variables populated by clinical opinion are unlikely to be available without large prospective trials. However, to account for clinical uncertainties, techniques of uncertainty analysis were used. These analyses were robust and the conclusions are valid over a wide range of potential values. Moreover, the NNT analysis suggests if a clinician were to treat approximately 79 random patients with EXALT, an ICU admission would potentially be avoided over this cohort of treated patients' lifetimes.

This study has several important limitations. In a recent trial, EXALT was evaluated by a group of expert endoscopists for feasibility, preliminary safety, and performance across all American Society for Gastrointestinal Endoscopy (ASGE) grade complexity ERCPs and this study showed its performance characteristics to be substantially equivalent to standard reusable duodenoscopes.[17] In the current analysis, a reference case of ERCP performed for the extraction of stone(s) from the common bile duct was considered. While in the recent trial, 3.3% of cases required a crossover from the single-use duodenoscope to a reusable duodenoscope, this crossover rate was not statistically significant and therefore that potential cost was not considered in the current analysis.

Medicolegal issues related to duodenoscope associated infections have become a major concern for providers and institutions. We did not consider the cost of administrative sanctions, litigation, and negative publicity related to contaminated duodenoscopes and associated infectious outbreaks in this analysis, which may underestimate the overall cost-effectiveness of EXALT.

Table 3. Cost-Effectiveness Analysis Results

Approach	Cost	QALYs	ICER vs HLD	ICER vs next less-costly option
Standard high-level disinfection Double high-level disinfection	$962 $977	21.8938 21.8938	-	-
Culture and quarantine	$1279	21.8904	Dominated Dominated denotes more costly and no more effective (fewer QALYs)	Dominated
ETO gas sterilization	$1561	21.9093	$38,461	$38,461
Exalt Model D	$3000	21.9265	$62,185	$83,664
Exalt Model D in HIPD setting with NTAP estimated to offset $1,715 of SUD cost	$1285	21.9265	$9877	$166
Exalt Model D in HOPD setting with TPT payment offsetting 100% of SUD cost	$0	21.9265	Dominant Save $962 Dominant denotes less costly and at least as effective (more QALYs)	Dominant Least costly and most effective option

All patients who acquired clinical infection after exposure to contaminated duodenoscopes were assumed to require inpatient treatment, regardless of setting of care of the original ERCP. The natural history of the clinical course related to long term colonization and duration of the colonization was modeled using published information on infections caused by multidrug resistant Enterobacteriaceae. Because long-term effectiveness of decolonization remains uncertain and these practices are not common, costs and effects related to such strategies were not considered.[29,30]

The literature describing total cost of a hospital outbreak related to a contaminated duodenoscope is limited. The cost per patient involved in hospital outbreaks was based on the available published information.[31,32] The average number of patients involved in a contaminated duodenoscope associated hospital outbreak was estimated based on the number of reported patients per outbreak in Europe and the United States since 2012. Although the cost of administrative sanctions, litigation, and negative publicity related to outbreaks of duodenoscopes to hospitals are reported to be in the range of tens to hundreds of million dollars, these costs were not incorporated in the main economic analysis because of lack of consistent and public data.[33]

When evaluating technologies based on cost-effectiveness and additionally in the context of TPT or NTAP, the EXALT approach meets typically used cost-effectiveness thresholds compared to all other evaluated strategies and should be considered for standard practice. ERCP performed in countries outside the United States would not be eligible for TPT or NTAP and the base case scenario analysis may not apply.

Conclusion

The recent availability of a single-use duodenoscope eliminates the need for reprocessing and associated risk of patient to patient transmitted infection. In this era of increasing awareness and concern related to duodenoscope associated infections, the availability of single-use duodenoscopes has brought about a shift in the approach toward endoscopic infection control. The FDA recommendations for duodenoscopes strongly advise hospitals remediate and reduce the risk of cross-contamination, which compels hospitals to consider viable options and choose an approach that is cost-effective to achieve their own risk reduction goal. While more research is needed to understand and quantify the determinants of the natural history after exposure to contaminated duodenoscopes, such as the risk of transmission and the subsequent development of serious clinical infections, this economic analysis demonstrates an approach using Exalt Model D is cost-effective in the US healthcare system when compared to the currently utilized strategies of duodenoscope reprocessing.

Cited in Supplemental Materials

25,26,27,28,51,52,53

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.tige.2021.09.007.

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Article History
Received July 8, 2021. Accepted September 29, 2021.

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Conflicts of Interest
AD presented an abstract of this study at Digestive Disease Week Virtual held in Chicago, IL in May 2020. MC is an employee and stockholder of Boston Scientific Corp, which manufacturers the Exalt Model D single-use duodenoscope. AD and RM have been consultants to Boston Scientific Corp.

Funding
None.

Author Contributions
AD: Provided research oversight and clinical input; with MJC, designed analytic model, reviewed literature, drafted manuscript. MJC: Managed research project; with AD, designed analytic model, reviewed literature, drafted and revised manuscript. RM: Provided clinical input, reviewed literature, reviewed and codrafted manuscript.
All authors have reviewed and approved this manuscript prior to submission.

Ethical Statement
The corresponding author, on behalf of all authors, jointly and severally, certifies that their institution has approved the protocol for any investigation involving humans or animals and that all experimentation was conducted in conformity with ethical and humane principles of research.