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Cost Utility Analysis Comparing Duodenoscope Reprocessing/Sterilization, Novel Duodenoscopes with Disposable Endcaps and Fully Disposable Duodenoscopes

Author(s): Monique Barakat*[2] , Swarnadip Ghosh[2] , Subhas Banerjee[1]
1 Stanford University Medical Center Division of Gastroenterology & Hepatology, Stanford, CA
2 Stanford University Department of Statistics, Stanford, CA
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Background: Transmission of multi-drug resistant organisms by duodenoscopes used during ERCP is problematical. The FDA (Food & Drug Administration) recently issued a communique recommending transition away from reusable fixed endcap duodenoscopes to those with newer design features that facilitate or eliminate the need for reprocessing. Duodenoscopes with disposable endcap and fully disposable duodenoscopes have now been developed. This analysis evaluates the relative cost of different approaches to minimizing infection risk, taking into account the cost associated with duodenoscope-transmitted infection.

Methods: We developed a Monte Carlo analysis model in R to assess the cost-effectiveness of various approaches: (1) Single High Level Disinfection (HLD), (2) Double HLD, (3) Ethylene oxide (EtO) sterilization, (4) Culture & hold, (5) Duodenoscope with disposable endcap and (6) Disposable duodenoscope. This model utilizes a multi-state trial framework and institutional cost estimates (Table 1). We assumed a triangular distribution with 3 parameters: minimum, maximum and most probable infection rate (MPIR), which vary across the six options. Using these values, we simulated quality adjusted life years (QALY) lost by duodenoscope-transmitted infection and factored this into the average cost for each approach. Our model's simulated cost for each approach at variable rates of MPIR is depicted in Figure 1.

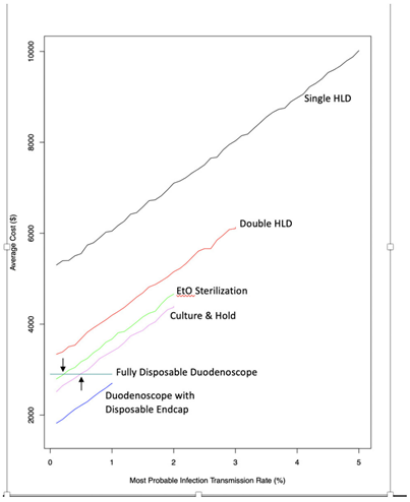
Results: At all rates of infection transmission below 1%, the duodenoscope with disposable endcap was the most cost-effective approach (Figure 1). The fully disposable duodenoscope eliminates the potential for infection transmission and is more cost effective than single/double HLD at all infection transmission rates, more cost effective than EtO for MPIR <0.22%, and more cost effective than culture & hold for MPIR <0.49%. Single and double HLD are the two most costly approaches at all potential infection transmission rates. The next two most costly approaches: EtO and culture & hold, require more duodenoscopes and costly transport/institutional infrastructure.

Conclusions: Our model indicates that novel duodenoscopes with a disposable endcap represent the most cost-effective option performing ERCP, with an anticipated very low infection transmission rate and disposable element costing approximately 1/5 that of the fully disposable duodenoscope. Limitations of this model include necessary assumptions and the potential lack of generalizability to lower volume community facilities. These data underscore the importance of cost calculations which account for the potential for infection transmission and associated patient morbidity/mortality associated with each approach. Institution-specific cost analyses will become increasingly relevant as the FDA recommendation for transitioning to duodenoscopes with newer design features gains momentum.

To read the abstract, visit:
https://www.giejournal.org/article/S0016-5107(20)30839-7/fulltext

Duodenoscope-transmitted infection minimization approach	Estimated 'Per Use' Cost (Materials & Labor)	Infection Transmission Rate (Estimated Range)	# Reusable Duodenoscopes Needed
Single Reprocessing	130.92	0.1-5%	5
Double Reprocessing	188.32	0.1-3%	7
EtO	643.68	0.1-2%	12
Culture & Hold	386.67	0.1-2%	12
Disposable Endcap	654.00	0.1-1%	5
Disposable Duodenoscope	2,903.50	0%	0

Model Assumptions & Justification Parameter/Assumption	Value	Basis for Assumption/Value
Annual ERCP Volume	800	Annual ERCP volume at our tertiary care center
Tertiary Care Overall MDRO Infection Carrier/Infection Rate	11%	Derived from tertiary care infection control data.
MDRO Transmission Rate after ERCP performed with MDRO-infected duodenoscope	30%	Infectious disease consultation/literature based.
Rate of Clinical Symptom Development in MDRO Infected Patient	50%	Infectious disease consultation/literature based.
Cost of management of cholangitis (2-day ICU stay, 1 day stepdown)	$375,000	Derived from our tertiary care center.
Rate of Survival after MDRO Infection	70%	Infectious disease consultation/literature based.
Average Age of Patients undergoing ERCP	60 (range 18-99)	Derived from our tertiary care center data.
Estimated Post-ERCP Lifespan	7 years	Derived from our tertiary care center data.
Value of Quality Adjusted Life Years	$100,000/year	Standard value within accepted QALY range.



WHY IT'S RELEVANT

There is much concern o er the challenges associated with ro erly cleaning duodenosco es and the risks of possible CRE infection to patients if an improperly cleaned duodenoscope is used in a procedure. This study provides a view of the costs associated with the different options for cleaning duodenoscopes as well as the cost of using a fully disposable duodenoscope. By including different cleaning methods, it provides the ability to see how the costs and effectiveness of these different methods impact healthcare processes.

Key Takeaways:

1. This study indicates that Duodenoscopes with disposable endcaps are more cost effective than fully disposable duodenoscopes up to a most probable infection transmission rate of 1%.
2. Facilities are encouraged to assess their duodenoscope and reprocessing methods to identify underlying risk and costs associated with their current practice as well as anticipated changes to their practice.

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