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The Total Cost of Reusable Duodenoscopes – Are Single-Use Duodenoscopes the Future of ERCP?

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Abstract

Multiple outbreaks have been reported due to contaminated patient-ready duodenoscopes used for endoscopic retrograde cholangiopancreatography (ERCP). These outbreaks have forced the Food & Drug Administration (FDA) to issue Safety Communications recommending healthcare facilities to transition to duodenoscopes with newer designs minimizing the risk of contamination and patient-to-patient infections. Sterile single-use duodenoscopes eliminates the risk of contamination and subsequent cross-infections and no reprocessing or repair is needed. This multicentre study found, the cost per ERCP including capital investments, repair/maintenance, reprocessing, and post-endoscopic infection ranges from $1,110.29 to $1,338.78 at high volume centres (>350 ERCPs/year) and from $1,220.58 to $2,685.76 at low-volume (<350 ERCP/year) centres using 1% and 1.2% infection rates, respectively. The weighted average per-procedure cost based on the annual number of ERCP procedures ranges between $1,283.93 and $1,378.29 using 1% and 1.2% infection rates, respectively. Costs were estimated using a micro-costing approach. Single-use duodenoscopes might be cost-effective at most facilities due to the risk of infection and costs associated with reprocessing and maintaining reusable duodenoscopes.

Keywords: Endoscopic retrograde cholangiopancreatography; Reusable duodenoscopes; Single-use duodenoscopes

Abbrevations: AER: Automated Endoscopic Reprocessor; ERCP: Endoscopic Retrograde Cholangiopancreatography; FDA: Food & Drug Administration; HICPAC: The Healthcare Infection Control Practices Advisory Committee; MDRO: Multi-Drug Resistant Organism; PPE: Personal Protective Equipment

Introduction

ERCP is a lifesaving procedure primarily used for treating diseases in the pancreatic and bile ducts [1]. However, the several outbreaks mainly caused by multi-drug resistant organisms (MDRO), transmitted via contaminated duodenoscopes, have led to concerns regarding patient safety. To overcome these challenges, single-use duodenoscopes are a new initiative seeking to eliminate any risk of duodenoscope-related infections. The purpose of this study was to assess whether single-use duodenoscopes will be feasible in clinical practice compared to reusable duodenoscopes. A micro-costing approach was used to estimate the per-procedure cost of ERCP, since this method is the most precise way of estimating economic costs [2]. The estimated per-procedure cost included capital costs (e.g., duodenoscopes and automatic endoscope reprocessors [AERs] etc.), costs associated with reprocessing, personnel, annual maintenance and repair, and post-procedural treatment due to duodenoscope-related infections.

Research Methodology

All data related to reusable duodenoscopes was collected at seven different endoscopy units with different volumes at AdventHealth Orlando, FL, USA. Data was collected over a three-week period and all cost data were collected by the same investigator to secure consistency. To make the cost data transferable to other settings, different scenarios with varying annual procedure volumes and number of duodenoscopes were created by extrapolating data from the seven units. Cost per-procedure was calculated for five different ERCP volume settings (50, 150, 350, 500, and 750) performed with two, four, five, six, and eight duodenoscopes ($45,000 per duodenoscope/ $9,967 per year), respectively (Table 1). The annual repair and service cost per duodenoscope was $2,500. Cost calculations for the AER assumed 1,500 uses annually ($35,400 per AER [$5.150/year]) [3]. Repair and maintenance of the AER is $5,000 annually. The same cost was assumed for the sterilization system. Based on published literature and recent outbreaks with MDRO the duodenoscope-related infection risk was estimated at 1% to 1.2% [4]. Cost of an infection caused by a MDRO was collected from HCUPnet [5]. The estimated cost for treating a duodenoscope-related infection is $47,181 leading to a per-procedure infection cost ranging from $471.81 to $566.17 depending on the infection risk. Costs of duodenoscopes and related equipment were amortized over a five-year period. Equipment used for reprocessing (e.g., AERs and storage cabinets) were amortized over an eight-year period. A discount rate of 3.5% was used. Based on published contamination rates, we assumed that 15% of all reprocessed duodenoscopes fail cleaning verification tests and therefore require re-cleaning. To capture costs related to training and education of personnel, time spent handling documentation for repair, re-training personnel to stay compliant with latest reprocessing guidelines, conducting internal audits etc., 20% overhead costs were added. Overhead costs were not added to the infection cost data. Cost for disposing a single-use duodenoscope was assumed equivalent to the cost of disposing of various disposables used during reprocessing (e.g., personal protective equipment [PPE], water, brushes, etc.) [3].

Results

This multicentre study only seeks to estimate the incremental costs, thus cost

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of tools or other costs directly linked to the ERCP procedure are assumed the same for both reusable and single-use duodenoscopes. Based on micro-costing data, the estimated per-procedure cost of reusable duodenoscopes ranges from $1,110.29 to $2,685.76 based on infection rates of 1%-1.2%, respectively. For centres performing <350 ERCPs annually the per-procedure cost ranges from $1,220.58 to $2,591.39 based on a 1% infection rate. For centres performing 500 or more ERCPs annually the per-procedure cost ranges from $1,110.29 to $1,244.42 assuming 1% infection risk. With a 1.2% infection risk, the per-procedure cost would increase $94.36. The per-procedure cost is highly dependent on the annual procedure volume, duodenoscopes available and the reprocessing setup. Time spent on manual reprocessing was on average 26 minutes per duodenoscope.

Discussion

Our results support previous studies indicating the per-procedure cost of reusable duodenoscopes is highly dependent on the annual procedure volume and amount of capital equipment available [6,7] (Table 2). The per procedure costs ranged from $2,591.39 to $2,685.76 for low-volume centres performing 50 ERCPs/year and from $1,244.42 to $1,338.78 for high-volume centre performing >750 ERCPs/year depending on the infection risk. Since capital investments are distributed over fewer procedures at low-volume centres, the per-procedure cost increases. In 2018, the FDA encouraged healthcare facilities to sample and culture duodenoscopes in addition to following

Table 1. Estimation of the per-procedure costs of reusable duodenoscopes by varying number of annual procedures and number of duodenoscopes. Costs are categorized based on The Healthcare Infection Control Practices Advisory Committee (HICPAC) reprocessing steps.

Annual ERCP procedures	50	150	350	500	750
Number of duodenoscopes	2	4	5	6	8
			Total per-procedure costs		
Capital	$1,713.00	$1,033.92	$560.76	$465.90	$610.03
Repair and maintenance	$304.00	$164.00	$85.43	$70.00	$ 60.00
PPE			$15.70		
Pre-cleaning including transport from OR to reprocessing room			$11.81		
Leak-testing, manual cleaning, and visual inspection			$71.87		
Storage			$3.20		
Documentation	Documentation of each step (e.g., personnel costs) is included as overhead costs in the listed per-procedure costs.				
Infection 1%			$471.81		
Infection 1.2%			$566.17		
Total per-procedure cost 1%	$2,591.39	$1,772.31	$1,220.58	$1,110.29	$1,244.42
Total per-procedure cost 1.2%	$2,685.76	$1,866.67	$1,314.94	$1,204.65	$1,338.78

Table 2. Total per-procedure cost of reusable duodenoscopes by varying the number of duodenoscopes and annual number of ERCP procedures based on a 1% infection risk.

		Annual number of procedures													
Number of duodenoscopes available		50	150	250	350	450	550	650	750	850	950	1050	1150	1250	1350
2	$3,140.49	$ 1,513.33	$ 1,187.90	$ 1,048.43	$ 970.94	$ 921.63	$ 887.50	$ 862.47	$ 843.32	$ 828.21	$ 815.98	$ 805.87	$ 797.38	$ 790.15
3	$4,086.14	$ 1,828.54	$ 1,377.03	$ 1,183.52	$ 1,076.01	$ 1,007.60	$ 960.24	$ 925.51	$ 898.95	$ 877.98	$ 861.01	$ 846.98	$ 835.20	$ 825.17
4	$5,031.78	$ 2,143.76	$ 1,566.16	$ 1,318.61	$ 1,181.09	$ 1,093.57	$ 1,032.98	$ 988.55	$ 954.57	$ 927.75	$ 906.04	$ 888.10	$ 873.03	$ 860.19
5	$5,977.43	$ 2,458.98	$ 1,755.29	$ 1,453.70	$ 1,286.16	$ 1,179.54	$ 1,105.72	$ 1,051.59	$ 1,010.20	$ 977.52	$ 951.07	$ 929.21	$ 910.86	$ 895.22
6	$6,923.08	$ 2,774.19	$ 1,944.41	$ 1,588.80	$ 1,391.23	$ 1,265.51	$ 1,178.47	$ 1,114.64	$ 1,065.83	$ 1,027.29	$ 996.10	$ 970.33	$ 948.68	$ 930.24
7	$7,868.72	$ 3,089.41	$ 2,133.54	$ 1,723.89	$ 1,496.30	$ 1,351.47	$ 1,251.21	$ 1,177.68	$ 1,121.45	$ 1,077.06	$ 1,041.13	$ 1,011.44	$ 986.51	$ 965.27
8	$8,814.37	$ 3,404.62	$ 2,322.67	$ 1,858.98	$ 1,601.37	$ 1,437.44	$ 1,323.95	$ 1,240.72	$ 1,177.08	$ 1,126.83	$ 1,086.16	$ 1,052.56	$ 1,024.33	$ 1,000.29
9	$9,760.02	$ 3,719.84	$ 2,511.80	$ 1,994.07	$ 1,706.45	$ 1,523.41	$ 1,396.69	$ 1,303.77	$ 1,232.71	$ 1,176.61	$ 1,131.19	$ 1,093.67	$ 1,062.16	$ 1,035.31
10	$10,705.66	$ 4,035.05	$ 2,700.93	$ 2,129.17	$ 1,811.52	$ 1,609.38	$ 1,469.43	$ 1,366.81	$ 1,288.33	$ 1,226.38	$ 1,176.22	$ 1,134.79	$ 1,099.99	$ 1,070.34
11	$11,651.31	$ 4,350.27	$ 2,890.06	$ 2,264.26	$ 1,916.59	$ 1,695.35	$ 1,542.18	$ 1,429.85	$ 1,343.96	$ 1,276.15	$ 1,221.25	$ 1,175.90	$ 1,137.81	$ 1,105.36
12	$12,596.96	$ 4,665.49	$ 3,079.19	$ 2,399.35	$ 2,021.66	$ 1,781.31	$ 1,614.92	$ 1,492.90	$ 1,399.58	$ 1,325.92	$ 1,266.28	$ 1,217.02	$ 1,175.64	$ 1,140.39
13	$13,542.60	$ 4,980.70	$ 3,268.32	$ 2,534.44	$ 2,126.73	$ 1,867.28	$ 1,687.66	$ 1,555.94	$ 1,455.21	$ 1,375.69	$ 1,311.31	$ 1,258.13	$ 1,213.46	$ 1,175.41
14	$14,488.25	$ 5,295.92	$ 3,457.45	$ 2,669.54	$ 2,231.80	$ 1,953.25	$ 1,760.40	$ 1,618.98	$ 1,510.84	$ 1,425.46	$ 1,356.34	$ 1,299.25	$ 1,251.29	$ 1,210.43
15	$15,433.90	$ 5,611.13	$ 3,646.58	$ 2,804.63	$ 2,336.88	$ 2,039.22	$ 1,833.15	$ 1,682.03	$ 1,566.46	$ 1,475.23	$ 1,401.38	$ 1,340.36	$ 1,289.12	$ 1,245.46
16	$16,379.54	$ 5,926.35	$ 3,835.71	$ 2,939.72	$ 2,441.95	$ 2,125.19	$ 1,905.89	$ 1,745.07	$ 1,622.09	$ 1,525.00	$ 1,446.41	$ 1,381.48	$ 1,326.94	$ 1,280.48

manufacturer reprocessing instructions to further reduce the risk of patient-to-patient infection [8]. The cost of culturing is not included in the per-procedure costs in this study. The cost of culturing duodenoscopes including labour costs and materials is estimated at $220 per procedure [9].

Limited data is available concerning the costs associated with treating a duodenoscope-related MDRO infection. However, the cost might depend highly on length of stay, type of antibiotic treatment, and whether the patients should be quarantined during their hospitalization [10]. With single-use duodenoscopes entering the market resources used to reprocess and maintain duodenoscopes can be used elsewhere, and more patients can potentially be treated. However, a full conversion into single-use will take time as old capital equipment will have to be replaced with single-use duodenoscopes. Therefore, there will inevitably be a transition period until the potential benefits of converting to single-use will be realized. The aim of our study was similar to the study by Bang et al. who also assessed the per-procedure cost of reusable duodenoscopes [6]. However, our study uses a more detailed approach by collecting micro-costing data and by extrapolating data to increase transparency. A significant difference from the study by Bang et al. is the cost of infection. Our study is using a general cost contrary to Bang et al. who used an infection cost specific for one hospital. The infection rates used in this study are similar to the ones stated by Bang et al., however the lack of evidence quantifying a duodenoscope-related infection risk constitutes a limitation of our study. Additionally, the infection cost is difficult to determine and is highly depend on the specific patient and disease, thus the infection cost in this study can either by overestimated or underestimated compared to real-life settings [6]. It is doubtless that infection risk is a big concern when discussing reusable duodenoscopes, and more studies should seek to address this matter. Hospitals are already using single-use equipment in critical cases where infections are life-threatening. For the critical cases the single-use duodenoscopes might be the most cost-effective choice, since these patients are at greater risk of acquiring an MDRO. Furthermore, our study illustrates that hospitals with few annual procedures has greater cost per procedure performed. This makes it significantly cheaper for low-volume hospitals to convert to single-use duodenoscopes over a shorter period compared to high-volume hospitals. The duodenoscope has a complex composition, why correct handling is necessary and involves proper cleaning including high-level disinfection (HLD) and drying before storage [11,12]. The mechanical characteristics and complex design of the duodenoscopes makes it difficult to sterilize using heat as this will destroy the multiple small mechanical mechanisms [13-15] (Supplementary Data).

Conclusion

Recent evidence has highlighted that reprocessing of reusable duodenoscopes is a challenge for many endoscopy facilities, and with new single-use endoscopes entering the market, this would help overcome these challenges. However, it is crucial that these new devices perform equivalent to the current reusable duodenoscopes in order to maintain patient safety. Therefore, the exact impact of single-use duodenoscopes on infection and complication rates, cost-effectiveness, and overall functionality will have to be assessed more thoroughly compared to reusable duodenoscopes. Single-use duodenoscopes appear to be feasible at most centres assuming the cost of single-use duodenoscopes will range between $1,400 to $3,000.

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Author Contributions

Data collection, data analysis, and manuscript writing was performed by Helena Strømstad Travis. Revision of manuscript for important intellectual content was performed by all authors.

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Conflict of Interest

Helena Strømstad Travis has received travel support from Ambu A/S, Ballerup, Denmark in order to collect data at Advent Health Orlando, FL, USA.

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