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Performance and Cost of Disposable Biopsy Forceps in Upper Gastrointestinal Endoscopy: Comparison with Reusable Biopsy Forceps

Chul-Hyun Lim, Myung-Gyu Choi, Won Chul Kim, Jin Soo Kim, Yu Kyung Cho, Jae Myung Park, In Seok Lee, Sang Woo Kim, Kyu Yong Choi and In-Sik Chung

Department of Internal Medicine, The Catholic University of Korea College of Medicine, Seoul, Korea

Background/Aims: It is believed that disposable biopsy forceps are more costly than reusable biopsy forceps. In this study, we evaluated performance and cost of disposable forceps versus reusable forceps in esophagogastroduodenoscopic biopsy.

Methods: Between October 2009 and July 2010, we enrolled 200 patients undergoing esophagogastroduodenoscopic biopsy at Seoul St. Mary's Hospital. Biopsies were performed with 100 disposable or 5 reusable forceps by random assignment. Seventy-five additional patients were studied to estimate durability of reusable forceps. The assisting nurses estimated the performance of the forceps. The evaluation of costs included purchase prices and reprocessing costs. The adequacy of the sample was estimated according to the diameter of the ob-

Results: Performance of disposable forceps was estimated as excellent in 97.0%, good in 2.0% and adequate in 1.0%. Reusable forceps were estimated as excellent in 36.0%, good in 36.0%, adequate in 25.1% and inadequate in 2.9%. The performance of reusable forceps declined with the number of uses. The reprocessing cost of reusable forceps for one biopsy session was calculated as \W8,021. The adequacy of the sample was excellent for both forceps.

Conclusions: Disposable forceps showed excellent performance. Considering the reprocessing costs of reusable forceps, usage of disposable forceps with a low price should be considered.

Key Words: Endoscopy; Biopsy; Disposable equipment; Costs and cost analysis

INTRODUCTION

Ideal endoscopic biopsy forceps should be able to obtain adequate tissues for pathologic examination, operate without mechanical failure, easy to use, and not expose patients or practitioners to cross-contamination or transmission of infection. Since endoscopic biopsy causes damage to mucosal barrier, there is high risk of transmitting infection. As with other medical expendables, disposable biopsy forceps may preclude cross-

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Correspondence: Myung-Gyu Choi

Department of Internal Medicine, The Catholic University of Korea College of Medicine, 222 Banpo-daero, Seocho-gu, Seoul 137-701, Korea Tel: +82-2-2258-6017, Fax: +82-2-2258-2038, E-mail: choim@catholic.ac.kr

@ This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (http://creativecommons.org/ licenses/by-nc/3.0) which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited. contamination and transmission of infection.¹⁻⁵ Currently, reusable biopsy forceps are used most often since disposable biopsy forceps are considered more costly than the reusable ones in South Korea. Reusable biopsy forceps are more likely to harbor microorganisms due to the high possibility of the remnant organic adherent materials, 1,6,7 which might cause significant reprocessing cost for rigorous washing, disinfection, or sterilization. Given the reprocessing cost and the high price of reusable biopsy forceps, disposable forceps may be a good candidate for clinical use. Another barrier against using reusable forceps is the current medical insurance system, which covers only the cost of therapeutic disposable forceps, not of sterilization and reprocessing of reusable biopsy forceps. Recently, lowpriced disposable biopsy forceps are introduced in the market, calling for cost-effectiveness comparison with reusable biopsy forceps. This study was aimed to evaluate whether disposable biopsy forceps are more beneficial than reusable biopsy forceps,

in terms of performance and cost, in a tertiary hospital setting.

MATERIALS AND METHODS

This study was designed as a randomized comparative trial of disposable biopsy forceps versus reusable biopsy forceps. Subjects included patients undergoing upper gastrointestinal endoscopy at Seoul St. Mary's Hospital between October 2009 and July 2010. The target numbers of endoscopic biopsies were 200 patients. 5 reusable biopsy forceps (FB-21K-1; Olympus Co., Ltd., Tokyo, Japan) and 100 disposable biopsy forceps (FB-A-1-1600; Jiangsu Kangyou Medical Instrument Co., Ltd., Changzhou, China) were prepared, meaning 20 biopsies per 1 reusable forceps. The study was approved by the Institutional Research Ethics Board of the Catholic University of Korea (KC09DISV0256) and was performed accordingly. Patients provided written informed consent before endoscopic examination. Patients with lesions requiring biopsy or rapid urease test [Campylobacter-like organism test] on endoscopic examination were randomly assigned to receive the biopsy using either disposable biopsy forceps or reusable biopsy forceps based on the table of random numbers. Additional 75 patients received biopsy to estimate durability of reusable biopsy forceps, resulting in 35 endoscopic biopsies per reusable biopsy forceps. An endoscopist performed all the endoscopic biopsies, and 3 nurses assisted the endoscopy in turn. Reusable biopsy forceps were used once a day, and then reprocessed by washing with detergent, physical cleaning, rinsing, ultrasonic treatment, packaging, and ethylene oxide gas sterilization for reuse. Disposable biopsy forceps were used in 1 patient and then discarded.

Primary variables included the general evaluation and costs of using biopsy forceps. For general evaluation of the biopsy forceps, the assisting nurses scored the ease of forceps opening and closing as well as the ease of tissue separation from the forceps from 5 scales (excellent, 5; good, 4; adequate, 3; inadequate, 2; and poor, 1). The cost of biopsies included the purchase price, washing, sterilization, packaging, and labor costs of washing staffs. Secondary variable was the adequacy of samples, scored (≥2 mm, 5; 1.5 to 2.0 mm, 4; 1.0 to 1.5 mm, 3; 0.5 to 1.0 mm, 2; and <0.5 mm, 1) by measuring the diameters of the obtained tissue samples attached to a ruler-installed cork board.

SPSS version 13.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analyses. Independent sample *t*-test was performed for analyses of continuous variables, and chi-square test for discrete variables. *p*-values of less than 0.05 were considered statistically significant.

RESULTS

Among 100 patients in disposable biopsy forceps group, bi-

opsies were performed at 12 esophageal lesions, 159 gastric lesions, 7 duodenal lesions and 16 rapid urease tests, and mean 2.51 (range, 1 to 12) tissues were obtained. Among 175 patients in reusable biopsy forceps group, biopsies were performed at 20 esophageal lesions, 235 gastric lesions, 3 duodenal lesions and 39 rapid urease tests, and mean 2.51 (range, 1 to 6) tissues were obtained (Table 1).

Disposable biopsy forceps were generally estimated as excellent in 97.0%, good in 2.0% and adequate in 1.0%. Reusable biopsy forceps were generally estimated as excellent in 36.0%, good in 36.0%, adequate in 25.1% and inadequate in 2.9% (Table 2). The performance of reusable forceps declined with the number of uses. Five reusable biopsy forceps were firstly assessed as adequate at 4, 10, 13, 18, and 24 times used (mean, 13.8), respectively, and 3 reusable forceps were firstly assessed

Table 1. Number and Site of Endoscopic Biopsies

Variable	Disposable biopsy	Reusable biopsy	p-
variable	forceps (n=100)	forceps (<i>n</i> =175)	value
No. of sample (range)	2.51 (1-12)	2.51 (1-6)	NS
Location, mean \pm SD			
Esophagus	0.12 ± 0.33	0.11 ± 0.34	NS
Stomach	1.59 ± 1.20	1.34 ± 0.95	0.08
Duodenum	0.07 ± 0.29	0.02 ± 0.13	0.09
CLO test	0.16 ± 0.37	0.22 ± 0.42	NS

NS, not significant; SD, standard deviation; CLO test, *Campylobacter*-like organism test.

Table 2. Performance of Biopsy Forceps

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Score	Disposable	Reusable biopsy	<i>p</i> -		
	biopsy forceps (n=100)	forceps $(n=175)$	value		
5	97 (97.0)	63 (36.0)			
4	2 (2.0)	63 (36.0)			
3	1 (1.0)	44 (25.1)	< 0.001		
2	0 (0)	5 (2.9)			
1	0 (0)	0 (0)			

Values are presented as number (%).

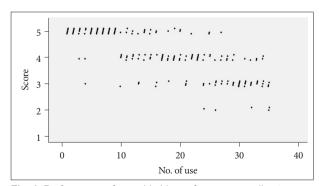


Fig. 1. Performance of reusable biopsy forceps according to number of uses.

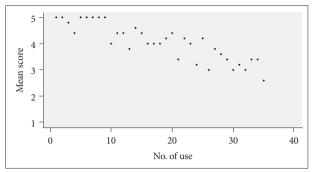


Fig. 2. Mean score of performance of the reusable biopsy forceps according to number of uses.

Table 3. Reusable Biopsy Forceps Processing Costs

Cost of supplies and processing (per biopsy forceps)	Cost, won (\mathbb{W})
I. Washing in fresh detergents	
1. Proteolytic enzyme (₩19,980/L, 8 mL/L, 146 cc)	140
2. Gloves (₩75, 1 pair)	150
3. Disposable gown (₩75, one)	77
4. Tap water (₩1,285/ton, 13 L)	17
5. Goggles (₩32,000, 240 time)	133
6. Disposable mask (₩70, one)	70
7. Disposable arm cover (₩150, 1 pair)	300
II. Mechanical cleaning	
1. Brush (₩12,100, 800 time)	15
2. Gauze (₩10, one)	10
3. Neutral detergent (₩1,692/L, 50 cc)	85
III. Rinsing	
1. Tap water (₩1,285/ton, 30 L)	39
2. Gloves (₩75, 1 pair)	150
IV. Ultrasonic treatment	
1. Electric power (₩100/kW, 30 min)	25
2. Proteolytic enzyme ($19,980/L$, 8 mL/L, 64 cc)	43
3. Tap water (₩1,285/ton, 8 L)	10
V. Rinsing	
1. Plastic gloves (₩7.5, 1 pair)	15
VI. Packaging	
1. Sterilizer pouch (₩62,700, 300 time)	209
VII. Ethylene oxide sterilization	
1. Cycle (₩500,000, 80 forceps in one cycle)	6,250
VIII. Labor costs	
1. Technician salary (\text{\tint{\text{\tint{\text{\tin}\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\tex{\tex	283
Total cost	8,021

as inadequate at 24, 26, and 32 times, respectively (Figs. 1, 2).

The reprocessing cost of reusable forceps for one biopsy session was calculated as ₩8,021 (Table 3). The purchase price of reusable biopsy forceps was \W353,000. The cost per use

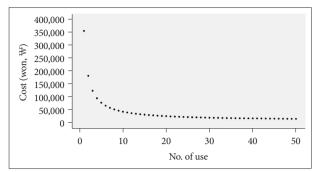


Fig. 3. Cost per use of reusable biopsy forceps with the number of uses

was calculated as ₩42,519, ₩25,270, ₩19,520, ₩16,645, and 44,921, if the forceps were used 10, 20, 30, 40, and 50 times (Fig. 3).

The mean adequacies of the samples were 4.98±0.09 and 4.93±0.21 in disposable forceps group and reusable forceps group, respectively, without significant difference between the 5 reusable forceps and disposable forceps (Fig. 4). The reusable biopsy forceps group did not show a change in adequacy of sample as the number of use increased.

DISCUSSION

This is the first study in South Korea to compare cost-effectiveness of reusable biopsy forceps and disposable biopsy forceps. The reprocessing cost of reusable biopsy forceps was ₩8,021 at Seoul St. Mary's Hospital. When the numbers of upper gastrointestinal endoscopic biopsies performed in 2008 are divided by the numbers of newly-purchased reusable biopsy forceps during the same period, the lifetime of reusable biopsy forceps is estimated to be 50 times of use, in which case the cost of one biopsy, including the purchase price of the forceps, mounts to as high as ₩14,921. The disposable forceps investigated in this study costs ₩13,200 with superior performance, indicating that the disposable forceps are clinically more beneficial.

The performance of biopsy forceps in this study was estimated by assisting nurses based on the general evaluation and the size of the obtained tissues. Disposable biopsy forceps received generally excellent grade, without any trouble in obtaining maximum 12 tissues per biopsy. Reusable biopsy forceps, on the contrary, were graded adequate or inadequate, in the general estimation, with the increasing number of use. The nurses pointed out that the reusable biopsy forceps did not open and close smoothly as the number of use increased.

Reusable biopsy forceps were used up to 35 times for durability evaluation and were not found as poor in the general evaluation, did not cause any functional disturbance, and the adequacy of the obtained samples were good. It was apparent,

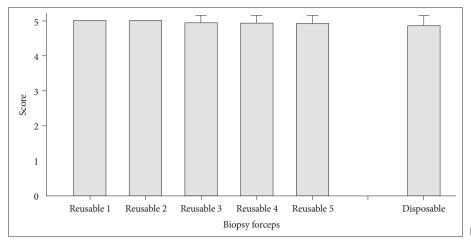


Fig. 4. Size of obtained samples.

however, that the performance of reusable biopsy forceps decreased as the number of use increased, which is comparable to previous studies reporting reduced performance of reusable biopsy forceps as the number of use increased.⁸ Some studies even reported malfunction.⁹

The reprocessing cost of reusable biopsy forceps were estimated at \(\forall 8,021 \) at Seoul St. Mary's Hospital. The previous studies using similar method for cost analysis reported higher (\\$11.77 \text{ and } \\$16.56) reprocessing cost per use.\(^{8,9}\) Another studies analyzing annual total cost reported \\$3.25 \text{ and } \\$4.39 for reprocessing cost per use.\(^{10,11}\) Reusable biopsy forceps require a significant cost for reprocessing, which might be influenced by multiple factors such as the number of biopsy, expendables, method of sterilization, labor cost and method of calculation. In this study, the ethylene oxide gas sterilization accounted the largest portion of the reprocessing cost, which is also the case for a previous study.\(^9\) In addition, the work load of biopsy forceps reprocessing for the washing staff accounted for about 15% of the total work load, suggesting that disposable biopsy forceps might lower some of the labor cost.

Various pathogens, such as *Salmonella* species, *Pseudomonas aeruginosa*, *Helicobacter pylori*, *Strongyloides stercoralis*, hepatitis B virus and hepatitis C virus, may be transmitted through endoscopy. ^{1,5,12-15} Since endoscopic biopsy causes damage to mucosal barrier, there is high risk of transmitting infection. It is important, therefore, to remove all the organic adherent materials on biopsy forceps for adequate reprocessing. ^{6,7} These organic adherent materials are likely to remain on biopsy forceps, due to mechanical properties, and survive even after reprocessing. ¹ There were reports of remnant tissue materials and scratches found by scanning electron microscope on the surface of biopsy forceps reused for more than 20 times, and isolation of Escherichia coli from sterilized biopsy forceps. ¹⁶ It is recommended, by the guidelines of endoscopy disinfection to sterilize or disinfect endoscope components, and if possible

use steam sterilization. Given that endoscopy is performed in primary healthcare institutions where sterilization is more difficult, use of disposable forceps should be approved considering the survivability of microorganisms on reusable forceps. It seems reasonable to use disposable biopsy forceps or at least sterilize, rather than disinfect, reusable forceps, for patients with AIDS, hepatitis B or hepatitis C.

In conclusion, disposable biopsy forceps, with its superior performance and less cost than reusable biopsy forceps, need to be considered for clinical use. It is reasonable, in terms of cost-effectiveness, to use disposable forceps for high risk patients of infection through biopsy forceps.

Conflicts of Interest

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