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Prospective, Randomized, Pathologist-Blinded Study of Disposable Alligator-Jaw Biopsy Forceps for Gastric Mucosal Biopsy

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Abstract

Background—Endoscopic biopsy forceps differ in the size and shape of the biopsy cup and the presence or absence of a needle.

Methods—We compared 4 different “large cup” forceps (3 with needles designed for 2.8 mm biopsy channels. A gastric antral and corpus biopsy were obtained with each. Parameters examined included: weight (mg), length (mm), orientation (poor, good), intactness (1, 2, or 3 pieces), depth (superficial, above muscularis mucosae, included muscularis mucosae), crush artifact (yes, no), and overall adequacy (inadequate, suboptimal, adequate).

Results—24 patients were enrolled (191 biopsies). The median length was approximately 5 mm (range 1.1 to 8.2 mm). Histologically inadequate specimens were present in 4% with the forceps without needle compared to 16% of those with needles ($P = 0.061$) and there were significantly fewer specimens in 3 or more pieces than did the forceps with needles 2.1% vs. 12.6% ($P < 0.05$).

Conclusions—Current alligator style forceps provide a high proportion of acceptable specimens with only minor differences between brands. Forceps from one source were least preferred by endoscopy assistants and had the highest rates of inadequate biopsies and biopsies with crush artifact. Forceps without needles provide histologically acceptable samples slightly more frequently than those with needles.

Keywords

gastric biopsy; endoscopy; forceps; depth; adequacy

Introduction

The practice of gastroenterology was revolutionized by the advent of fiberoptic endoscopy which for the first time allowed physicians the ability to identify, localize, and sample the gastrointestinal mucosa as a safe, rapid, and routine procedure. This ability to obtain directed biopsies allowed clinician to directly confirm their clinical and/or endoscopic suspicions of the presence of a benign or malignant process. Instruments have continued to evolve and in 1995 Tytgat and Ignacio proposed 24 “improvements” to forceps design (1). The more toward routine use of disposable biopsy forceps accelerated the introduction of new forceps designs in part because biopsy forceps have almost become commodities forcing the manufacturers to compete on price as well as function. Currently there are a large variety of forceps available

that differ in terms of size and shape of the cups, the presence or absence of serrations, fenestrations, and needles and new versions are regularly introduced.

An adequate tissue sample (eg, size, depth, undamaged) is required for the gastrointestinal pathologist to be able to provide an accurate assessment of the status of the gastric mucosa (eg, normal, atrophic, inflamed, infected, neoplastic, etc); both the Sydney and OLGA systems for grading and reporting biopsies are predicated on adequate sampling (2,3). The information obtained from biopsy specimens is often critical to patient care such that the overriding factor when selecting the a forceps should be the adequacy of the tissues for histologic diagnosis. Prior studies have shown that in general “larger is better” (ie, the specimens obtained with large bite size forceps are superior to small size forceps) and that alligator style cups provide better samples than oval shaped cups of the same size (4–8). In addition, small specimens are discouraged because of their tendency to fragment and are thus more difficult for the histology technical to orient properly.

This study evaluated three large cup forceps designed for a standard 2.8 mm biopsy channel. Three different forceps with needles and one without a needle were compared for use in obtaining gastric mucosal biopsies. The null hypothesis was that there was no difference in the forceps with regard to adequacy of the mucosal samples obtained.

Methods

This was a prospective pathologist blinded study of disposable forceps for biopsy of the gastric antral and corpus mucosa. Adult patients of either sex scheduled to have an esophagogastroduodenoscopy (EGD) with gastric biopsies were invited to participate. All procedures were done by the same experienced endoscopist (DYG) and all biopsy samples were scored by the same gastrointestinal pathologist (H El-Z).

Four different disposable biopsy forceps “large cup” were used in this study; three contained needles and one did not. The forceps were chosen as the newest largest alligator type cup available. All forceps were designed for 2.8 mm channels and included: Radial Jaw 3, large capacity with needle (Boston Scientific; 2.2 mm OD, M00515972), Alligator Jaw with needle (ConMed; 2.3 mm O.D., 00386), Endojaw (Olympus; 2.45 mm O.D., FB-220 K with needle), and Endojaw (Olympus; FB-210 K without needle) (Figures 1 and 2). The Olympus forceps were identical except for presence or absence of the needle. All the forceps had fenestrated cups and sheath-coated shafts designed for smooth insertion.

All specimens were taken from normal appearing gastric mucosa. The first set of four biopsies were taken from the lesser curvature of the mid gastric antrum with each of the different forceps. After the antral biopsies were taken, the corpus biopsies was taken from the posterior wall of the greater curve in the mid body. The sequence with which the forceps were used was randomized using a random sequence defined prior to the start of the study. The same order was used for both the antral and corpus biopsies. After withdrawal of the forceps the biopsy specimen was “shaken off” into separate vials of 10% buffered formalin.

Biopsy Scoring

Each biopsy was weighed by picking up the biopsy using a blunt forceps with serrated tips and blotting it against adsorbent paper to remove the excess formaldehyde. The biopsy was weighed (Denver Instrument Company XE-100A series) to the nearest 0.0001 gram. Samples were then reintroduced into formalin and routinely processed, embedded on edge and stained using the hematoxylin and eosin stain. Each specimen was then graded by the experienced gastrointestinal pathologist. The parameters evaluated included: a) length in mm, b) orientation scored as 0 to 2 where 0 = cut enface, 1 = half way in between 0 and 2, 2 = perfect orientation,

c) intactness scored as 0 to 2 where 0 = one piece, 1 = 2 pieces, and 2 = more than 2 pieces, d) depth scored from 0 to 2 where 0 = very superficial, 1 = just above the muscularis mucosae, 2 = muscularis mucosae present in the section, e) crush artifact scored as 0 = no and 1 = yes, and f) overall adequacy of the specimens for histological diagnosis as determined by the experienced gastrointestinal pathologist scored from 0 to 2 where 0 = inadequate, 1 = suboptimal, and 2 = adequate.

The study was approved by the local institutional review boards and all patients gave written informed consent prior to endoscopy.

Statistical analysis

The sample size was chosen based on an evaluation of prior published studies to help identify a sample to compare adequacy of sample for pathologic interpretation. The sample size chosen was 24 patients which was considered a feasible number to undertake, and with standard deviation unknown, validation is needed to show that a power at or above 80% is achieved using a reasonable range of standard deviations (20–40% of the reference mean) with the group sample size (N1) fixed at 12. In keeping with the complete balanced crossover design and the analysis to compare lengths of two forceps (Mean1 vs. Mean2) at a time, the total sample size (N1+N2) estimation would have to be evenly divisible by 24 (ie. each of the 24 sequences must have the same number of patients). We used a table of Bioequivalence Means Power Analysis showing the power calculations for both a group sample size of 12 and of 24 to identify the best sample size based on its relation to changes in power. The biopsy length is 8 mm with the reference forceps and is thought to range from 7.0 to 8.0 mm with the comparison forceps. We wished to show that the length is within 20% of the length of the reference forceps (= 1.6 mm). The significance level was 0.10.

The biopsy parameters were analyzed using Sigma Stat 3.5 (Systat Software, Inc.). The three different forceps with needles were compared using ANOVA (Kruskal-Wallis One Way) or Chi Square for categorical data. A P value of 0.05 or less was considered significant.

Results

Twenty four patients were enrolled. No adverse events or complications accrued with any of the study subjects throughout the study period. Overall, 1 of the planned 192 samples was not available for assessment leaving a total of 191 analyzable gastric mucosal biopsy specimens.

Biopsy length and weight

The median length of the fixed biopsy specimens was approximately 5 mm (range 1.1 to 8.2 mm) (Table 1). The length of tissue with the ConMed forceps was shorter than with the other forceps and was significantly shorter than that obtained with the Olympus forceps with a needle ($P = 0.019$) (Table 1). There was no significant difference between the three forceps with needles ($P = 0.188$) (Table 1).

The median weight of the specimens obtained with needles ranged between 8.4 and 9.1 mg (Table 1). The specimen obtained with the forceps without the needle was significantly heavier than those obtained with needles combined (9.2 ± 1.9 vs. 8.4 ± 1.8) ($P < 0.001$) and between Boston Scientific or ConMed forceps individually ($P < 0.003$) (Table 1). Among the forceps with needles, biopsy obtained with Olympus forceps was significantly heavier than with the ConMed forceps ($P = 0.008$) (Table 1). Overall, the ConMed forceps provided smaller and lighter biopsy samples compared to the other disposable forceps evaluated.

Embedded and stained biopsy specimens

Orientation is a function of the size of the specimen and the skill of the histology technician. The proportion deemed unacceptable orientation ranged from 4.1% to 14.6%; none of the comparisons were significant ($P>0.5$) (Table 2).

The majority of specimens were intact or in less than 3 pieces (Table 2). The forceps with no needle produced significantly fewer specimens with 3 or more pieces than did the forceps with needles 2.1% vs. 12.6% ($P<0.05$). There were no significant differences between the forceps with needles (Table 2)

The majority of samples either contained the muscularis mucosae or were just above it with less than 7% being scored as superficial (Table 2). There were no significant differences between forceps with regard to depth of the biopsy ($P = 1.0$) (Table 2). The presence of crush artifact was also similar with the different forceps ($P = 1.0$) (Table 2).

A score was given for overall adequacy for interpretation. Between 81 and 85% of specimens obtained with a needle forceps were scored as adequate vs. 95.8% of those taken with the Olympus forceps without a needle ($P = 0.061$) (Table 2).

Technical differences

There were no biopsy forceps failures during the study. We did not notice any difference with ease of insertion. The handle of the ConMed forceps differed from the others and was judged to be less convenient and more difficult to grip while obtaining the biopsy (Figure 3)

Discussion

Comparative studies of an earlier generation of disposable forceps did not discover a meaningful difference between offerings (9). However, the increased use of a single-use disposable forceps has created a large and potentially profitable market for instrument manufacturers making repeated testing mandatory. Overall, the quality and reliability of disposable forceps has been high making it difficult for manufactures of disposable forceps to market their forceps as the “best” one for a particular clinical use. The decision regarding which forceps to stock in an endoscopy unit may be decided by the owner of the unit or endoscopy supervisor with or without consultation with the physicians. Proof that a particular biopsy forceps obtained better diagnostic samples or was easier to use would help in patient care and marketability and dispel the notion that all forceps within a particular class are essentially the same. Thus, manufacturers continue to offer “improved” designs often with subtle changes in design, material (eg, brass vs. stainless steel), coating, cup shape, etc.

Generally, a single style of forceps is offered both with and without a needle. Needles were originally included to make taking of multiple specimens at one pass easier as well as to impale a particular site thus making directed biopsy more. Woods et al. reported that the absence of a needle resulted in deeper specimens (9). Bernstein et al. reported deeper specimens with forceps that contained needles but that difference was not significant when they confined their analysis to large cup forceps (4). Overall, our study confirmed that the presence of a needle results in a shorter and lighter specimen and an increase in the proportion of inadequate samples but the difference is small and does not generally affect interpretability provided several specimens are taken (5).

Generally, studies of disposable forceps have reported that the majority of biopsies obtained were suitable for histologic interpretation (10). Yang et al. defined the ideal forceps as one that 1) provided adequate tissue specimens for histologic evaluation, 2) had no mechanical problems, 3) be easy to use, 4) allowed no possibility of cross-contamination to either patients

or health care workers, and 5) be inexpensive (11). The only design feature that could promote cross contamination of health care workers is the presence of the needle which provides a sharp surface that could transmit patient material to endoscopy staff or those responsible for disposal of the used forceps. Needles have also been reported to puncture the biopsy channel (12) but that possibility appears remote with disposable forceps as it requires the presence of a bent needle. Studies by Yang et al., Deprez et al., Rizzo et al. and Kozarek et al. focused on costs (11,13–15) which was not considered here. Nonetheless, the conclusions of cost analysis have generally sided with disposable forceps being more cost effective when all the costs are taken into account (11,15). As noted above, the manufacturers have had to learn to compete on cost which helps control the cost to the endoscopy unit.

Practice Points

- Current alligator style forceps provide a high proportion of acceptable specimens with only minor differences between brands
- Forceps without needles provide histologically acceptable samples slightly more frequently than those with needles.
- Cost and operator perception of ease of use should govern choice of alligator style forceps. .

Research Agenda

- Disposable forceps should be evaluated based on the desired outcome (eg, for the ability to diagnose cancer, diagnose and stage gastritis, diagnose celiac disease, etc).
- Within manufacturers forceps should be compared in terms of different cup shape (eg, round, oval, alligator) as well as cup size (eg, length, width, depth).
- Standardized scoring methods would facilitate comparisons among studies.

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Figure 1.

Side view of the biopsy forceps used in the study are shown. A = Boston Scientific with needle, B = ConMed alligator jaw, C = Olympus with needle, D = Olympus without needle

Figure 2.
Handles of the forceps from the three different manufacturers. A = ConMed, B = Boston Scientific, C = Olympus.

Table 1

Characteristics of the gastric mucosal biopsy samples.

Forceps	Length	Weight
Boston needle	5.3 ± 0.2 (5.3) [^]	8.4 ± 0.2 (8.4)
ConMed needle	4.7 ± 0.1 (4.7) [*]	7.9 ± 0.2 (8.2)
Olympus needle	4.9 ± 0.2 (5.3)	8.9 ± 0.3 (9.1) [*]
Olympus no needle	5.1 ± 0.2 (5.3)	9.2 ± 0.3 (9.4) ^{**}

[^] Results of the antral and corpus specimens were averaged: mean ± SEM (Median)

^{*} Individual comparisons of the forceps with needle: the weight with the Olympus with needle was significantly greater than the ConMed forceps (P = 0.003).

^{**} Comparison of Olympus no needle with the combined results of the three forceps with needles (P<0.001)

Table 2

Results of the pathologist's scoring of the biopsy specimens after sectioning and staining

Forceps	Orientation *		Intactness 0-2 pieces	Depth ***		Crush ***	Interpretation	
	Perfect	Unacceptable		Full	Superficial		No	Inadequate
Boston: needle	37.5%	8.3%	89.6%	37.5%	4.2%		87.5%	14.6%
ConMed: needle	41.7%	14.6%	95.8%	70.8%	0.0%		70.8%	18.7%
Olympus: needle	27.6%	12.8%	76.6%	46.8%	6.4%		82.9%	14.9%
Olympus: no needle	39.6%	4.1%	97.9% **	62.5%	0.0%		66.7%	4.2% ****

* orientation reflects the interaction between the histologic technician and the specimen.

** P<0.05 for comparison of forceps with no needle forceps vs. all forceps with needles

*** no significant difference between forceps for parameter listed

**** P = 0.061 for proportion of inadequate specimens for no needle forcep vs. all forceps with needles