A performance, safety and cost comparison of reusable and disposable endoscopic biopsy forceps: a prospective, randomized trial

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Use of disposable or reusable biopsy forceps during upper and lower endoscopy. Reusable forceps were used once per day and reused on subsequent days after appropriate cleaning and sterilization until mechanical failure. Disposable forceps were used once and discarded.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Patients requiring upper or lower endoscopic procedures and biopsies.

Setting
Hospital. The economic study was carried out in the USA.

Dates to which data relate
Not dates were given.

Source of effectiveness data
The evidence for the final clinical outcomes was derived from a single study.

Link between effectiveness and cost data
Costing was undertaken on the same patient sample as that used in the effectiveness analysis, and appears to have been prospective.

Study sample
Power calculations were not used to determine the sample size. The study sample consisted of 48 reusable biopsy forceps and 51 disposable forceps randomly assigned for use during endoscopic procedures requiring biopsies: in total, 99 biopsy sessions were performed. For upper endoscopy, 28 sessions were with disposable forceps and 32 with reusable forceps. For lower endoscopy, 23 sessions were with disposable forceps and 16 sessions were with reusable forceps.
Study design
This was a prospective, randomised, blinded study, carried out in a single centre. The duration of the follow-up appears to have been until the end of the 2-month study period. Loss to follow-up was not reported. Experienced endoscopists performed all biopsies during regularly scheduled upper and lower endoscopies and were blinded to the choice of forceps. At the conclusion of the study, each reusable forceps was dismantled and examined under light microscopy for the presence of contamination.

Analysis of effectiveness
The principle used in the analysis of effectiveness appears to have been intention to treat. The performance of forceps was evaluated for ease of passage through the endoscope (EOP), ease of forceps opening and closing (EOC), adequacy of sample (AS), and overall evaluation (OE) by the endoscopist immediately after each endoscopy using an ordinal scale ranging from 1 (unacceptable) to 5 (excellent). A dependent variable named MEANOF3 was constructed as follows: (EOP+EOC+AS)/3. This result was compared with the OE given for each biopsy session to verify consistency in scoring by the endoscopist. Procedural complications were also noted. The presence of contamination in each reusable forceps was examined under light microscopy at the conclusion of the study. The effects of types of forceps, doctors performing the biopsies, and biopsies taken in the retroflexed position were investigated.

Effectiveness results
The mean (SD) ratings for both disposable and reusable forceps, respectively, were as follows: Ease of passage (EOP), 4.8 (0.5) and 3.6 (0.9);
Ease of opening and closing (EOC), 4.9 (0.4) and 3.9 (0.8);
Adequacy of sample (AS), 4.8 (0.4) and 3.9 (0.6);
Overall evaluation (OE), 4.8 (0.45) and 3.8 (0.8);
and MEANOF3, 4.8 (0.4) and 3.8 (0.7).
p<0.0001 for all comparisons. Procedural difficulties were reported in 5 of 48 (10%) biopsy sessions with reusable forceps, (p=0.009). Examination of reusable forceps revealed residual patient debris despite "adequate" cleansing.

Clinical conclusions
Disposable biopsy forceps were superior to reusable forceps in all categories assessed. The reusable forceps used in this study were cleaned and sterilised according to established guidelines. Residual patient debris were revealed despite adequate cleaning and sterilisation. These findings suggest that reusable forceps may pose a risk for the transmission of infectious agents.

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic analysis, and only separate clinical outcomes were reported.

Direct costs
Costs were not discounted due to the short time frame of the cost analysis. Some quantities were reported separately from the costs. Some cost items were reported separately. Cost analysis covered the costs of acquisition and reprocessing. Reprocessing costs included labour (to mechanically scrub, rinse and ultrasonically clean the forceps), cleaning supplies (gloves, impervious gowns, mask/face shields, gauze pads, enzymatic cleaner, water consumption, and steam autoclave), and implementation of hospital infection control policies (protocol implementation and validation). There were no processing costs for disposable forceps. The perspective adopted in the cost analysis appears to have been that of the hospital. The details of how the reprocessing costs were calculated were not given (for example, the
sources of cost data were not presented). The price year was not given.

**Indirect Costs**
Not included.

**Currency**
US dollars ($).

**Sensitivity analysis**
Not conducted.

**Estimated benefits used in the economic analysis**
Not applicable.

**Cost results**
The total cost per use of reusable forceps was $40.94 compared to $35 for disposable forceps (initial acquisition cost), resulting in an average saving of $5.94 per biopsy session associated with the use of disposable forceps.

**Synthesis of costs and benefits**
Costs and benefits were not combined since the use of disposable forceps was the dominant strategy.

**Authors' conclusions**
Disposable forceps outperformed reusable forceps and were found to be more cost-effective. Residual patient debris on reusable forceps may pose a risk of cross contamination and the spread of infection.

**CRD COMMENTARY - Selection of comparators**
No specific strategy was regarded as the comparator since both types of forceps are widely available for use in GI endoscopy units.

**Validity of estimate of measure of effectiveness**
The effectiveness results are likely to be internally valid given the randomised nature of the study design plus the assessments made for the effects of some of the potential confounders. However, no power calculations were performed and, consequently, it is not clear whether the sample size was large enough fully to address the study question.

**Validity of estimate of measure of benefit**
The authors did not derive a measure of health benefit. The study may therefore be regarded as a cost-consequences analysis.

**Validity of estimate of costs**
Insufficient details of the methods of cost estimation were given. Some quantities were reported separately from the costs. The price year was not given. The effects of different procedures on indirect costs (productivity loss) were not addressed. Cost results may not be generalisable to other settings or countries.
Other issues
The authors’ conclusion appears to be justified given uncertainties in the data. The issue of generalisability to other settings or countries was not addressed. Some comparisons were made with other studies. The degree to which the study sample was representative of the study population was not discussed.

Implications of the study
The study results show an inverse correlation between usage and performance of reusable forceps, although this was not statistically significant. According to the authors, this correlation may gain statistical significance with evaluation of a larger group of reusable forceps and should be further investigated. Further investigation in a larger study is warranted to investigate the incidence of instrumental complications.

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