Out with the old and in with the new: a comparison of rectal suction biopsies with traditional and modern biopsy forceps

Hall N J, Kufeji D, Keshtgar A

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.

CRD summary
This aim was to assess the adequacy of rectal suction biopsy (RSB), performed using the Noblett biopsy forceps compared with the rbi2 device, for the diagnosis of Hirschsprung's disease. The authors concluded that the rbi2 offered superior RSB performance and was likely to be cost-effective compared with the "old" Noblett forceps, although a prospective study was required to confirm these findings. Although the clinical aspects of the study were reasonably well reported, the reliability of the findings is questionable.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The aim was to compare the adequacy of rectal suction biopsy (RSB) specimens, when performed using the widely used Noblett biopsy forceps, compared with a novel forceps device rbi2 (Aus Systems, Allenby Gardens, South Australia), for the diagnosis of Hirschsprung's disease (HD).

Interventions
The proposed advantage of the "new" device over the "old" one included the consistency of the specimen. This was attributed to the fact it used a single-use disposable sharp blade, which, as a result, could reduce the need for a repeat biopsy.

Location/setting
UK/university hospital.

Methods
Analytical approach:
This economic evaluation was based on a single retrospective clinical study with a cross sectional time horizon. During the first 2.5 years the Noblett forceps were used and during the last 1.5 years the rbi2 forceps were used. The study perspective was not stated by the authors.

Effectiveness data:
The evidence came from a single-centred, clinical study, with a historical case series design. During the four year study, 88 infants under one year old underwent RSB. A total of 238 specimens were obtained, during 102 biopsies (62 with Noblett and 40 with rbi2). The reported clinical and demographic variables were not statistically different between the two groups. The primary outcome was the adequacy of the sample. A specimen was defined as inadequate if it was too small or contained inadequate submucosa for histological diagnosis. A biopsy episode was considered inadequate if all the specimens taken within that episode were inadequate. If this occurred, a repeat biopsy was recommended.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
The primary outcome appears to have been inadequate biopsy and specimen episodes.
Cost data:
The authors attempted to determine the costs for each biopsy episode by incorporating the cost of the equipment purchase and sterilisation, biopsy processing, and patient admission. The source was the hospital information department. The currency was UK pounds sterling (£) and the price year was not stated.

Analysis of uncertainty:
Not relevant.

Results
A total of 13 inadequate episodes, which resulted in either a repeat RSB (which was included in the analysis) or open rectal biopsy (which was not included in the analysis) were reported. A significantly higher proportion of specimens taken with the Noblett forceps were inadequate compared with the rbi2. For Noblett, 30 out of 153 (20%) were inadequate compared with 6 out of 85 (7%), for rbi2, (relative risk, RR: 2.8, 95% confidence interval, CI: 1.2 to 6.3, p=0.01). There were no differences in the complication rates.

There was a non-significant higher incidence of inadequate biopsy episode, with the Noblett forceps, compared with the rbi2. For the Noblett 10 out of 62 (16%) were inadequate, compared with 3 out of 40 (7%) for the rbi2 (RR: 2.2, 95% CI: 0.6 to 7.3, p=0.24).

The authors reported the purchase price of the Noblett biopsy forceps (£750) and the rbi2 forceps (£299), the cost per biopsy episode for cleaning and sterilisation, histological processing, and analysis, which was the same for both processes (£28.76), the additional cost for each rbi2 biopsy episode, which related to the pack of disposable biopsy capsules (£44.50), and the hospital stay for inadequate RSB (paediatric ward £250, and special care baby unit £286).

The authors stated that it was not possible to determine accurately the additional costs relating to repeat biopsy for each instrument.

Authors' conclusions
The authors concluded that the rbi2 offered superior RSB performance and was likely to be cost-effective compared with the "old" Noblett forceps. They stated that a prospective study comparing their relative performance was needed.

CRD commentary
Interventions:
The two techniques for undertaking RSB were well reported. However, it was not clear if they were the main ones for diagnosing HD or if there were any other relevant techniques.

Effectiveness/benefits:
The retrospective study design (as the authors acknowledged) does not allow any strong conclusions regarding the real differences between the two methods. Also, although the two groups appeared to be comparable, no adjustment was made for potential confounding factors. A prospective design (also acknowledged by the authors) could confirm these findings.

Costs:
The authors reported the individual costs without combining them, so the mean total cost for each biopsy or specimen was not directly reported. Also, a comparison of the additional days in hospital, which was an important issue, was not possible. The authors suggested that the cost of performing an RSB with the new device was greater than with the old device, and that this additional cost was low compared with the costs of repeated biopsies. It is not clear however that this statement was supported by their analysis.

Analysis and results:
Although the two groups appeared comparable, no adjustment for potential confounding factors was explored. The authors also highlighted another weakness of their analysis, which was the inability to adjust for individual expertise when performing the procedure. Whilst the reporting was clear, the costing was limited and the analysis was subject to a number of limitations, many of which were highlighted and acknowledged by the authors.
Concluding remarks:
Although the clinical aspects of the study were reasonably well reported, the reliability of the findings is questionable.

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