Value-based pathology: a cost-benefit analysis of the examination of routine and nonroutine tonsil and adenoid specimens

Netser J C, Robinson R A, Smith R J, Raab S S

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
Histologic examination of routine and nonroutine tonsils and adenoids (T&A) specimens.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with routine and non-routine T&A specimens. Patients with routine specimens were defined as those who underwent bilateral tonsillectomy, bilateral tonsillectomy and adenoidectomy, or adenoidectomy alone. Excluded patients were those who had their procedures as part of a multiple biopsy panendoscopy procedure. Patients with non-routine specimens were defined as those who underwent unilateral tonsillectomy or a tonsillar biopsy that was not performed as part of a panendoscopy procedure.

Setting
Hospital. The economic study was carried out in Iowa City, USA.

Dates to which data relate
Effectiveness and resource use data corresponded to the patients examined between 1 January 1985 and 1 September 1995. The price year was 1996.

Source of effectiveness data
The evidence for final outcomes was based on a single study.

Link between effectiveness and cost data
The costing was undertaken retrospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. The study review covered the histologic diagnoses for all routine (n=2700) and non-routine (n=71) T&A specimens during a period of 10 years and 8 months. The age distribution was determined based on the review of pathology reports for the first 20 to 25 cases accessioned during each calendar year (270 cases). The mean age for the patients with routine specimens was 24.2 (range: 2 - 66; median 19.5) years compared to 48.6 (range: 6 - 87; median 46.5) years for the non-routine specimens. The histologic slides of
2% (54 cases) of the cases with a diagnosis of normal, tonsillitis, or hyperplasia were randomly reviewed to determine the percentage of potentially misdiagnosed routine cases.

**Study design**

This was a retrospective cohort study, carried out in hospitals and clinics affiliated to a university. The duration of the follow-up appears to be different for each study patient, and based on the presentation provided in the paper, ranged from zero to six years. Loss to follow-up was not reported. The diagnosis from the pathology report was compared with the diagnosis on retrospective histologic review, and the number of discrepancies was recorded. One of the authors who was unaware of the original diagnosis and history reviewed the slides.

**Analysis of effectiveness**

The principle used in the analysis of effectiveness was not explicitly specified. The main clinical outcome was a potential, or actual, effect on patient care as a result of pathologic examination. The following conditions for the existence of a potential effect on patient care were considered:

1. the pathologic diagnosis was not normal, tonsillitis, or hyperplasia;
2. the clinical history was significant (a reported clinical diagnosis other than normal, tonsillitis, or hyperplasia); and
3. the pathologic diagnosis was consequential (for example, granulomatous disease, which could affect patient care).

The discordant rate was also reported.

**Effectiveness results**

The number of cases with a diagnosis other than normal, tonsillitis, or hyperplasia were: routine, 27 (1%); and non routine, 56 (79%). 12 out of 67 routine cases did not have a significant clinical history; only 6 cases had a potentially significant pathologic diagnosis. Chart review of these 6 patients showed that in none of them did the pathologic diagnosis affect the actual patient care. In all non-routine cases, the pathologic diagnosis affected patient care. In routine cases, the concordance rate was 100% based on the comparison between the retrospective histologic review of the 27 cases and the original histologic diagnoses. In 54 randomly selected cases, with a pathologic diagnosis of normal, tonsillitis, or hyperplasia, the corresponding rate was also 100%. In non-routine specimens, the overall concordance rate between the clinical and pathologic diagnoses was 89%. A concordance rate of 100% was achieved when the retrospective histologic diagnoses were compared with the original histologic diagnoses.

**Clinical conclusions**

For routine T&A specimens, the incidence of clinically significant disease was remarkably low. In only 1% (27 out of 2700) of cases from a period somewhat longer than 10 years was the pathologic diagnosis something other than benign, tonsillitis, or hyperplasia. Pathologic diagnoses did not affect actual patient care in any cases. For non-routine specimens, the incidence of malignancy was 39%. However, even in cases in which the pathologic diagnosis was not cancer, the pathologic diagnosis still affected patient care.

**Measure of benefits used in the economic analysis**

A potential or an actual effect on patient care as a result of pathologic examination (unexpected diagnosis).

**Direct costs**

Costs were not discounted due to the short time frame of the cost analysis. Quantities were reported separately from the costs only in terms of the average number of blocks submitted per case and the number of ancillary studies performed. Cost items were reported separately. The cost analysis covered the costs of technical and professional services, and ancillary studies such as immunoperoxidase, direct immunofluorescence, gene rearrangement, and other special stain
services. The perspective adopted in the cost analysis (intention to treat or treatment completers) was not explicitly specified. Charge data were used instead of true costs. The institutional billing office was the source of charge data. 1996 price data were used.

**Indirect Costs**
Not included.

**Currency**
US dollars ($).

**Estimated benefits used in the economic analysis**
There were only six routine cases in which pathologic diagnosis had the potential to affect patient care, and in none of these did the pathologic diagnosis affect the actual patient care. In all non-routine cases, the pathologic diagnosis did affect patient care.

**Cost results**
The total pathology charge for all routine T&A specimens was $390,482, or $36,608 per year, culminating in an average charge of $145. The total pathology charge for all non-routine T&A specimens was $37,269, yielding an average charge of $525.

**Synthesis of costs and benefits**
The charge per unexpected diagnosis (n=27) was $14,462 in routine specimens. The average charge to detect potentially clinically significant diseases among routine specimens was $64,718 per case and the charge per consequential pathologic diagnosis per year was $6,067. The charge per case to detect potentially clinically significant disease in non-routine specimens was $525.

**Authors' conclusions**
The authors concluded that histologic examination of non-routine cases is cost-effective, whereas in most routine cases with adequate clinical history, histologic examination is not cost-effective.

**CRD COMMENTARY - Selection of comparators**
The reason for the choice of the comparator (the policy of not performing histologic examination or gross examination) is clear. This allowed the active value of the histologic examination to be evaluated.

**Validity of estimate of measure of effectiveness**
The internal validity of the effectiveness results can not be guaranteed due to the retrospective nature of the study design. The study sample appears to be representative of the study population. The authors conjectured that theoretically the study sample may not have been large enough to allow for the effects of the histologic examination to be detected in a statistically credible way, but this was deemed to be extremely unlikely in practice. The positive effects of the intervention in terms of quality assurance and teaching were not included in the analysis since these effects were deemed to be achievable without examination of all routine T&A tissues.

**Validity of estimate of measure of benefit**
The estimation of benefits was obtained directly from the effectiveness analysis. The choice of estimate was justified.
Validity of estimate of costs
Some quantities were reported separately from the costs. Adequate details of the methods of cost estimation were given. Using charge data instead of true costs may have adversely affected the external validity of the cost analysis. The authors used charges only to provide a reference by which to compare test utility. The price date was given. The perspective adopted in the cost analysis was not explicitly specified. No statistical analysis was performed on either the resource use data or the cost data. The possible impact of the alternative health technologies on indirect costs (productivity loss or gain) was not discussed.

Other issues
In view of the retrospective nature of the study design, lack of sensitivity analysis and statistical analysis of resources used and costs, the study results may need to be interpreted with some degree of caution. The issue of generalisability to other settings or countries was not addressed. Appropriate comparisons were made with other studies. The study covered only the T&A specimens (as an example) and this appears to be reflected in the generalisations made in the authors' comments. The authors stated that they performed a cost-benefit analysis, but, as health outcomes were not measured in monetary terms, the study could be more correctly regarded as a cost-effectiveness study.

Implications of the study
When routine T&A specimens are removed because of repeated infection or enlargement, a gross-only examination or no examination should be performed. Any atypical clinical history, such as the possibility of a lymphoproliferative disease should result in a histologic examination even of routine specimens. A careful clinical examination of the patient is equally important. The data also indicate that there is no specific age cut-off beyond which histologic examination should always be performed.

Source of funding
None stated.

Bibliographic details

PubMedID
9260756

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Adenoidectomy /economics; Adenoids /pathology /surgery; Adolescent; Adult; Aged; Child; Child, Preschool; Cost-Benefit Analysis; Diagnostic Tests, Routine /economics; Female; Humans; Infant; Male; Middle Aged; Palatine Tonsil /pathology /surgery; Pathology, Surgical /economics; Tonsillectomy /economics

AccessionNumber
21997001123

Date bibliographic record published
30/09/2000
Date abstract record published
30/09/2000