The treatment of cervical intra-epithelial neoplasia: when could we "see and loop"?

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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
Using one of three designed strategies in the management of cervical intra-epithelial neoplasia (CIN) in order to find the optimal role of the loop electrosurgical excision procedure (LEEP) in the diagnosis and treatment of high grade CIN. The strategies considered were as follows:

1. Biopsy following abnormal colposcopy findings, succeeded by LEEP in the case of biopsy revealing CIN II or more;
2. Biopsy following abnormal colposcopy findings less than CIN II and LEEP in the case of CIN II or more;
3. Biopsy following abnormal colposcopy findings less than CIN III and LEEP in the case of CIN III or more.

Type of intervention
Diagnosis; treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients undergoing LEEP treatment for suspected or proven CIN lesions.

Setting
Hospital. The economic study was carried out in Hong Kong.

Dates to which data relate
The effectiveness data were gathered from May to October 1994. No date was specified for the resource and price data.

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

Link between effectiveness and cost data
It was not stated whether or not the costing was carried out on the same sample as that used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. The study sample consisted of 95 patients who underwent colposcopy, punch biopsy and LEEP.
Study design
The study was a retrospective cohort study performed in one centre.

Analysis of effectiveness
It was not stated whether the analysis of the clinical study was based on intention to treat or on treatment completers only. The health outcome measures consisted of the level of agreement (k) between the two histologicalexaminations, namely punch biopsy and LEEP, and between colposcopic and histological (a combination of LEEP and punch biopsy) diagnosis as well as undercall and overcall rates, and the sensitivity and false positive rate of colposcopy. Spearman's rank and Wilcoxon matched pairs signed ranks test were utilized to estimate the correlation coefficient and the significance of differences.

Effectiveness results
The level of disagreement between LEEP and punch biopsy diagnosis was k=0.35. The punch biopsy had undercall and overcall rates of 23.0% and 42.5%, respectively. According to Spearman's rank, the correlation between punch biopsy and LEEP diagnosis was 0.48 (P<0.0001). The Wilcoxon test revealed that the severity of abnormalities found on punch biopsy was significantly higher than on LEEP specimens of the same patients (two-tailed P<0.01). Comparing colposcopic and histological diagnosis resulted in a level of disagreement of k=0.58; theundercall and overcall rates of colposcopy were 11% and 31%, respectively; the Spearman's rank coefficient was0.61 (P<0.000001); and the Wilcoxon test P=0.06. The colposcopy had a sensitivity of 75% and a false positive rate of 11.4% (in the diagnosis of CIN III or more). The corresponding false positive rate in the case of CIN II lesions being classified as high grade was 36.8%.

Clinical conclusions
The study confirmed the findings of other studies regarding the disagreement between the two biopsy methods, namely punch biopsy and LEEP. Furthermore, the study revealed a considerable disagreement between colposcopic and histological diagnoses.

Modelling
A decision analytic model was constructed to estimate the cost of the three designed strategies utilizing the clinical probabilities produced by the effectiveness analysis section of the study.

Measure of benefits used in the economic analysis
The authors did not produce a summary measure of benefit within the economic evaluation.

Direct costs
The resource quantities were not reported separately. The cost component of each branch of the decision tree was reported separately. The costs calculations included staff salaries and time per procedure including pathological examination. The costs per patient of the three strategies were estimated, setting a monetary value of zero for the disutility (a proxy for unknown long term effects of over-treatment by LEEP on fertility and pregnancy in low grade cases) of inappropriate LEEP in low grade cases. It was not stated from whose point of view the cost estimation was performed. No details were given about the sources of the cost data and the corresponding price data. A comprehensive list of cost components included in the cost calculations of colposcopic and histological examinations was not given.

Indirect Costs
Not reported.

Currency
Hong Kong dollars (HK$). A conversion to US dollars was carried out.
Sensitivity analysis
A one-way sensitivity analysis was conducted to investigate the impact of altering the assumption regarding the disutility of performing inappropriate LEEP for patients with low grade lesions (CIN I or less) on the cost relationship of the three strategies.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The estimated cost per patient of strategy 1 was HK$1,390, for strategy 2 was HK$891 and for strategy 3 was HK$1,024.

Synthesis of costs and benefits
A synthesis of costs and benefits was not performed since strategy 2 was a dominant strategy relative to the standard management of CIN (strategy 1). Sensitivity analysis revealed that strategy 3 became the cheapest when the monetary value of the disutility of inappropriate LEEP exceeded HK$4,200. If the monetary value of the disutility of inappropriate LEEP exceeded HK$18,000, strategy 1 would have become dominant.

Authors’ conclusions
The authors concluded that selective "see and loop" approach for high grade CIN III lesions suspected on colposcopy would not over-treat but would reduce the number of colposcopy appointments, waiting list for colposcopy and subsequent expenses.

CRD COMMENTARY - Selection of comparators
A justification was given for the choice of the comparator. Strategy 1 was considered as the comparator since it represented the standard management approach in the treatment of CIN. You should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of benefit
Lack of randomisation casts some doubt on the internal validity of the effectiveness results.

Validity of estimate of costs
Resource quantities were not reported separately from the costs. Adequate details of the sources of cost data and methods of cost estimation were not given. Since a comprehensive list of cost components included in the cost calculations of colposcopic and histological examinations were not given, it is difficult to judge on the internal validity of cost estimation.

Other issues
Given the lack of randomisation, a comprehensive set of sensitivity analyses, and statistical analysis of the costs, the results need to be treated with some caution. The issue of generalisability to other settings or countries was not addressed.

Source of funding
None stated.
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