Treatment of high grade cervical intraepithelial neoplasia by photodynamic therapy using hexylaminolevulinate may be cost-effective compared to conisation procedures due to decreased pregnancy-related morbidity
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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.

CRD summary
The objective was to evaluate the cost-effectiveness of photodynamic therapy (PDT) for high-grade cervical intraepithelial neoplasia (CIN). The authors concluded that PDT could be cost-effective, compared with conisation (cone biopsy), in Germany. There were a few limitations to the study and the methods and results could have been reported more clearly. The appropriateness of the authors’ conclusions is hard to assess and they should be considered with caution.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The objective was to evaluate the cost-effectiveness of photodynamic therapy (PDT) for high-grade cervical intraepithelial neoplasia (CIN).

Interventions
PDT using hexyl aminolevulinate was compared with the usual care, which was conisation (cone biopsy), by loop electrosurgical excision procedure, laser, or cold knife.

Location/setting
Germany/secondary care.

Methods
Analytical approach:
The authors developed a decision model of the possible treatment pathways, using clinical and economic data from published sources and medical insurance claims databases. They did not state the perspective.

Effectiveness data:
The effectiveness data were from relevant studies and a German insurance company (Techniker Insurance). The main clinical parameter was the response rate, which was the regression of high-grade CIN. For conisation, the estimates were from a published study and a recent Cochrane Review and, for PDT, they were from published phase II studies. The number of subsequent pregnancy complications, such as premature birth or lifelong disability after premature birth, were from published literature.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
The primary clinical outcomes were the number of conisations and the reduction in subsequent pregnancy complications.

Cost data:
The cost categories included the direct costs of gynaecological examination, testing and diagnosis, conisation
procedures, and anaesthesia, as well as the indirect costs of work disability. The direct costs were estimated using German payment guidance (Einheitlicher Bewertungsmassstab), and the indirect costs were based on the German gross domestic product, population, business days, and mean days of illness. Pregnancy complications following conisation were from two German databases and published literature. Assumptions were required for the unit cost of PDT as it had recently been introduced in Germany and the reimbursement rate had not been set. All costs were in Euros (EUR) and future costs were discounted at a rate of 3% per year over seven years.

Analysis of uncertainty:
Not considered.

Results
Per year in Germany, there were expected to be 760 newborns following conisation and 26 would die. Of the survivors, 18 were expected to have severe lifelong disability, 24 moderate lifelong disability, and 65 mild lifelong disability. With PDT, there were 70% fewer deaths or lifelong disabilities.

The total cost of conisation was EUR 1,473 compared with EUR 1,386 for PDT. It was assumed that 30% of PDT patients would need secondary conisation. The additional cost of pregnancy complications after conisation was estimated to be EUR 573 per patient, which increased the total cost to EUR 2,046 for conisation and EUR 1,558 for PDT.

Authors' conclusions
The authors concluded that PDT could be cost-effective, compared with conisation, for treatment of high-grade CIN in Germany.

CRD commentary
Interventions:
The reporting of the interventions was poor, but they appear to have been relevant to the setting and included most of the standard alternative treatments. It was unclear if laser conisation was included.

Effectiveness/benefits:
The methods used to identify and select the most relevant sources (for example, a systematic review) were not reported, and these sources were not fully described (study design, sample size, population, interventions, and comparators). This makes it difficult to assess if the best evidence was used. The sources appear to have been relevant to the setting and their references were given. It was not clear whether the estimates were from direct or indirect comparisons of the alternative treatments. The measures of benefit appear to have been appropriate as they assessed morbidity or mortality, but they might not be comparable with other disease interventions.

Costs:
The authors did not explicitly state the time horizon, but included the lifelong disability costs for newborns of mothers treated with each intervention, and discounted the costs over seven years to correspond with the time between conisation and giving birth. They did not state the perspective, but included those direct and indirect costs consistent with a societal perspective. The sources of these estimates were provided. The costs and resource quantities were mostly reported separately, which will allow the transfer of the analysis to other settings. The currency was reported. The price year was not explicitly stated, but appears to have been 2009 to 2010.

Analysis and results:
No summary measure of benefit was used and the costs were presented separately from the benefits; a cost-consequences analysis was carried out. The authors did not investigate the impact of parameter uncertainty, which makes it difficult to assess whether the results were robust. The reporting of the results was adequate, but a little confusing. The authors discussed some limitations of their study, such as the final efficacy results from phase III studies (of PDT for CIN) were not available at the time, and there was uncertainty about the procedure costs for PDT.

Concluding remarks:
There were a few limitations to the study and the methods and results could have been reported more clearly. The appropriateness of the authors' conclusions is hard to assess and they should be considered with caution.
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