Low-cost technology for screening uterine cervical cancer
Parashari A, Singh V, Sehgal A, Satyanarayana L, Sodhani P, Gupta M M

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
The use of a diagnostic instrument, an illuminated magnifying device (Magnivisualizer), for the detection of uterine cervical cancer. The device, which is portable, easily manipulated and can be operated using a dry-cell battery (12 V, 8 - 10 Ah), was used for visual inspection of the cervix.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women attending the gynaecologist with symptoms such as abnormal vaginal discharge, contact bleeding and irregular vaginal bleeding.

Setting
The setting was a maternal and child health care clinic. The economic study was carried out at the Sucheta Kriplani Hospital in New Delhi, India.

Dates to which data relate
The dates during which the data were gathered were not reported. The price year was not given.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on a different patient sample from that used in the effectiveness analysis.

Study sample
Power calculations to determine the sample size were not performed. All eligible patients attending the maternal and child care health care clinic at the Sucheta Kriplani Hospital in New Delhi were selected for the analysis. Overall, a sample of 403 women was included in the analysis. With the exception of one woman, the same cohort of patients undergoing both visual examination and cytological investigation also underwent colposcopically directed biopsy and/or histological investigation. Thus, the final sample comprised 402 women.
Study design
This was a prospective, cross-sectional, diagnostic test evaluation study, which was carried out in a single centre. Those patients testing positive were followed until a definite diagnosis was achieved using colposcopy and/or histology. No loss to follow-up was reported in the final sample of 402 women.

Analysis of effectiveness
All patients included in the study were accounted for in the analysis. The primary health outcomes assessed in the analysis were sensitivity, specificity, and the positive or negative predictive values of visual examination and cytological investigation, compared with assessment by colposcopy and/or histology. Comparability of the study groups was not required since a single cohort of patients provided the effectiveness data for both screening interventions.

Effectiveness results
Out of 194 women found negative by biopsy and/or histological investigation, the specificity was 94.3% (183 women) with the Magnivisualizer and 99% (192 women) with cytological investigation.

Out of 73 women found positive for low-grade dysplasias by biopsy and/or histological investigation, the sensitivity was 57.5% (42 women) with the Magnivisualizer and 75.3% (55 women) with cytological investigation.

Out of 76 women found positive for high-grade dysplasias by biopsy and/or histological investigation, the sensitivity was 82.9% (63 women) with the Magnivisualizer and 78.9% (60 women) with cytological investigation.

Out of 59 women found positive for carcinoma in-situ or early invasive cancers by biopsy and/or histological investigation, the sensitivity was 94.9% (56 women) with the Magnivisualizer and 94.9% (56 women) with cytological investigation.

Out of 208 women found positive by biopsy and/or histological investigation, the overall sensitivity was 77.4% (161 women) with the Magnivisualizer and 82.2% (171 women) with cytological investigation. Consequently, the positive predictive value with the Magnivisualizer was 93.6% (161 out of 172 women) and the negative predictive value was 79.6% (183 out of 230 women). The corresponding values for cytological examination were 98.8% (171 out of 173 women; positive value) and 83.8% (192 out of 229 women; negative value).

Clinical conclusions
The authors stated that visual examination performed with the Magnivisualizer resulted in high sensitivity and specificity values, which were similar to those of cytological screening.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the analysis. A cost-consequences analysis was therefore carried out.

Direct costs
Discounting was not carried out as the time horizon of the analysis was relatively short. Only the cost of screening (visual examination or cytological investigation) was included in the analysis, and the unit costs were provided. The cost/resource boundary adopted in the analysis was not explicitly reported. The source of the cost data was not reported. The quantities of resources used were derived from the study and then assessed for a hypothetical population of 100,000 women. The price year was not given.

Statistical analysis of costs
No statistical analysis of the costs was carried out.
Indirect Costs
The indirect costs were not included in the analysis.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were not performed.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The authors stated that the cost of one screening was $0.55 for the Magnivisualizer and $1.10 with cytological investigation.

Synthesis of costs and benefits
Irrelevant since a cost-consequences analysis was conducted.

Authors' conclusions
Screening on the basis of visual examination (Magnivisualizer) was as effective as cytological investigation in the detection of uterine cervical cancer. The cost of screening with the Magnivisualizer was lower than that associated with cytological examination.

CRD COMMENTARY - Selection of comparators
The authors explained their choice of the comparators. The cytological examination represented the currently implemented diagnostic procedure at the study centre, although not feasible as a nationwide screening strategy. Colposcopy and/or histology was considered to be the 'gold' standard for the diagnosis of uterine cervical cancer. You should decide whether it represents a widely used diagnostic intervention in your own setting.

Validity of estimate of measure of effectiveness
The analysis of effectiveness used a single group of patients who underwent both tests, thus limiting the potential role played by confounding and selection bias. The use of a prospective cohort study appears to have been appropriate for the study question and there was no statistical analysis. The sample was fairly large, but power calculations were not performed. The study sample appears to have been representative of the study population. The period during which the effectiveness data were collected was not reported.

Validity of estimate of measure of benefit
The health outcomes were left disaggregated and no summary benefit measure was used. Thus, a cost-consequences analysis was performed. Unfortunately, although overall the Magnivisualizer was less sensitive than cytology, the authors claimed that the results were similar. In fact, there was no statistical test of the difference. Also, the value of any loss in accuracy, particularly in missing cases, was not accounted for in terms of mortality or quality of life.

Validity of estimate of costs
There were few details on the analysis of the costs. The unit costs were reported, whereas the source of the cost data
and the price year were not. The cost/resource boundary was not explicitly stated. The costs were treated
deterministically. The costing was carried out on a sample of patients different from that used in the effectiveness
analysis. These issues may affect the validity of the estimated costs. As mentioned in the ‘Validity of measure of
benefit’ section, there is a lack of accounting for the cost of missing cases, which could affect a decision relating to this
technology.

Other issues
The authors did not compare their findings with those from other studies. The issue of the generalisability of the study
results to other settings and countries was not addressed, as no sensitivity analyses were performed and no price year
was given. Moreover, the setting of the study was fairly specific and reflected issues typical of developing countries.
Consequently, caution should be exercised when extrapolating the conclusions of the analysis to other contexts. A
sample of women at risk for uterine cervical cancer was enrolled in the study, and this was reflected in the conclusions
of the study.

Implications of the study
The use of the Magnivisualizer should be recommended due to the difficulty of performing a nationwide screening on
the basis of cytological investigation, for the detection of uterine cervical cancer. The characteristics of the device make
it particularly suitable for use in rural areas of India where there is no electricity. It may also performed in primary care
settings, the only additional requirement being the availability of an examination table. These recommendations should
be viewed in the context of the caveats described.

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