Invasive cervical carcinoma: role of MR imaging in pretreatment work-up - cost minimization and diagnostic efficacy analysis

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
Magnetic resonance imaging (MRI) in pretreatment work up for invasive cervical cancer patients.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with the histologic diagnosis of invasive cervical cancer.

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

Dates to which data relate
The effectiveness data were obtained from studies published in 1980-1995, and a single study, the data for which were collected between 1989 and 1993. The resource use data corresponded to patients admitted to an institution between 1989 and 1993. The price year was 1995.

Source of effectiveness data
Effectiveness data were derived from a single study and a synthesis of previously completed studies.

Link between effectiveness and cost data
Costing was retrospectively performed on the same patient sample as that used in the effectiveness analysis based on the single study.

Study sample
Power calculations were not used to determine the sample size. From a total of 258 patients available for inclusion in the study, 246 were finally included. 105 patients were included in the MRI group with an average (SD) age of 51 (15), and 141 were included in the control group with an average (SD) age of 47 (14).

Study design
This was a retrospective cohort study carried out in a single centre. The allocation of patients groups was based on the
first-line diagnostic strategy performed. The duration of the follow-up was 4 months after the diagnosis. No loss to follow-up was reported. The final diagnoses (reference test or 'gold standard') were obtained from surgery findings.

Analysis of effectiveness
The intention to treat principle applied to the analysis of effectiveness. The primary health outcome was overall staging accuracy. The groups were shown to be comparable in terms of race, histologic tumour characteristics, stage of disease, and treatment received, but not in terms of age at diagnosis (the non-MRI group was significantly younger on average).

Effectiveness results
In the MRI group 52.4% of the total were stage Ib disease patients, whereas in the non-MRI group those patients made up 40.4% of the total. The overall staging accuracy for the MRI and non-MRI groups was 95% and 89%, (p=0.41).

Clinical conclusions
There was no comorbid factor influencing the choice of diagnostic tests and there was no difference in the choice of treatment or staging accuracy between the two patient groups. MR imaging obviates a number of "routine procedures", thereby replacing a lengthy work-up with one examination.

Outcomes assessed in the review
The efficacy of the tests as measured by the likelihood ratio of positive and negative findings (using sensitivity and specificity values) of each diagnostic strategy was assessed by a review of the literature.

Study designs and other criteria for inclusion in the review
The study designs selected were not reported. Only studies published in the English language between January 1965 and March 1995 were searched. Studies with sample sizes of at least 20 patients and data permitting calculations of likelihood ratios were included in the analysis. Review articles, letters and comments were excluded.

Sources searched to identify primary studies
Not reported.

Criteria used to ensure the validity of primary studies
Not reported.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
A total of twenty-five studies was included in the review. For the calculation of likelihood ratios in diagnosis of parametrial invasion, data related to MRI from ten studies were used whereas for CT and clinical examination, data from eight and three studies were used. The association of nodal metastasis with positive and negative test results, expressed as likelihood ratios for each strategy, was obtained from nine studies for MRI and 11 studies for CT.

Methods of combining primary studies
The outcome data from the primary studies, expressed in terms of specificity and sensitivity results, were combined by weighting each value by its corresponding sample size.
Investigation of differences between primary studies
Not reported.

Results of the review
For the evaluation of parametrial invasion, the likelihood ratio for the MRI for positive and negative test results was 11.2 and 0.3; the corresponding CT values were 2.6 and 0.61 and for clinical examination were 2.7 and 0.65.

The evaluation of nodal disease had the following positive and negative values:

MRI, 10.0 and 0.53;

CT, 5.4 and 0.66.

Since a 0% probability of bladder and rectal invasion in stage Ib cervical cancer was found, the routine use of barium enema examination, cystoscopy, or proctoscopy was not justified. Since cross sectional imaging (i.e. CT, and MRI ) allows evaluation of the renal obstruction with an equivalent accuracy to that of intravenous urography, while improving the staging accuracy, it is unnecessary to perform the latter test whenever the former is available. Although there was no data to allow the calculation of likelihood ratios for urography and CT, the authors did state that the literature supported the hypothesis of equal accuracy of intravenous urography, CT and MRI.

Measure of benefits used in the economic analysis
‘Clinical usefulness’ as expressed by the change in positive predictive value for each test was the measure used in the analysis.

Direct costs
Costs were not required to be discounted due to the short period of follow-up. Quantities of resource use were reported separately from costs. The costs measured were charges for diagnostic tests performed. The source of these cost data was Medicare charges from 1995. The quantities of resource use were obtained from actual data from patients admitted to the study site in San Francisco, California, between 1989 and 1993. Costs for stage Ib disease patients were reported separately from those for all patients. The date of the price data was 1995.

Statistical analysis of costs
Student’s t test was performed and confidence intervals (CI) were reported.

Indirect Costs
Not considered.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
For patients in the disease stage Ib only, the increase in positive and negative predictive values (differences between posttest and pretests positive predictive values) for parametrial invasion were, as follows:
MRI, 48%;
CT, 14%;
clinical examination, 15%.

The corresponding results for the evaluation of nodal disease were:

MRI, 52%;
CT, 39%.

When all patients were considered, the corresponding figures for MRI, CT, and clinical examination, for the evaluation of parametrial invasion, were 52%, 17%, and 18% for the change in positive predictive value. The evaluation of nodal disease showed that MRI and CT had positive changes of 52% and 40%, respectively.

**Cost results**
The mean cost per patient (SD) for the MRI group including all patients was $988 (405), and for the non-MRI group was $1,389 (586), (95% CI: $277 - $525). When only stage Ib disease patients were included, the respective figures were $887 (366) and $1,336 (438), (95% CI: $299 - $598).

**Synthesis of costs and benefits**
Since MRI was shown to be the dominant strategy, the cost and benefits were not combined.

**Authors' conclusions**
Guidelines for the pretreatment work-up of clinical stage Ib cervical cancer need revision. MRI should be used as an adjunct to clinical evaluation.

**CRD COMMENTARY - Selection of comparators**
The reason for the choice of the comparators is clear.

**Validity of estimate of measure of benefit**
As acknowledged by the authors, the validity of the study results cannot be guaranteed due to the retrospective nature of the study itself, the non-randomised design of the single study, and the lack of a systematic analysis in the review of the literature.

**Validity of estimate of costs**
The cost analysis only included costs associated with diagnostic test procedures. The costs were approximated by Medicare charge data rather than true costs. The quantities of diagnostic tests performed were reported separately from the costs.

**Other issues**
In view of the lack of a prospective study design and sensitivity analysis, the results may need to be treated with some caution. The conclusions reached by the authors may not be fully justified given the uncertainties surrounding the data. The generalisability of the study results to other settings or countries was not addressed. The results were not presented selectively.

**Implications of the study**
As the authors noted, further studies are required with prospectively collected data on effectiveness and resource use and with a randomized design used to allocate patients between strategies.

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