Cost-effective evaluation of indeterminate urinary cytology
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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
The performance of complete urological evaluations by cystoscopy and excretory urography (IVP) was examined in patients with indeterminate urinary cytology. Alternative methods (e.g. ultrasonography, retrograde pyelography or computerised tomography) were used for patients with an allergy to contrast media. Three strategies were considered:

the evaluation of patients with a history of bladder cancer or presenting with haematuria (strategy 1);

the evaluation of patients with a history of bladder cancer or presenting with haematuria or a history of smoking (strategy 2);

the evaluation of all patients with indeterminate urinary cytology (strategy 3).

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with indeterminate urinary cytology who could, potentially, be given a complete urological investigation.

Setting
The setting was a hospital. The economic study was carried out in Arizona, USA.

Dates to which data relate
The effectiveness and resource use data corresponded to patients who had undergone urine cytologies between March 1993 and July 1995. The price year was 1997.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was performed 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 sample was derived from a total of 9,763
cytologies that were performed at the study institution. Of these, 675 were indeterminate and 389 (83% males) underwent cystoscopy and IVP. The distribution of patients in terms of age was as follows: 25% were less than 66 years, 26% were between 67 and 72 years, 25% were between 73 and 77 years, and 24% were 78 years or older. The total number of patients qualified to be evaluated under strategy 1, 2 and 3 were 227, 330 and 389, respectively. The reasons for cytology were haematuria (28%), symptoms of dysuria, frequency and/or urgency (26%), history of bladder cancer (33%) and screening for high risk of bladder cancer (22%). Some patients had multiple indications for cytology and were counted more than once in these statistics.

Study design
This was a retrospective cohort study that was carried out in single centre. The duration of follow-up was to the point of diagnosis (or otherwise) of cancer.

Analysis of effectiveness
The principle used in the effectiveness analysis was treatment completers only. The clinical outcome measure was the number of cases of cancers detected. The features of patients associated with bladder cancer were investigated through step-wise multivariate logistic regression.

Effectiveness results
Fifty (22%) cancer cases were detected with strategy 1, 59 (18%) with strategy 2 and 60 with strategy 3.

From the multivariate analysis, the patients’ features associated with the detection of new cases of bladder cancer were history of bladder cancer, (p<0.001; odds ratio 5.57, 95% confidence interval, CI: 2.83 - 10.98) and presentation with haematuria, (p=0.001; odds ratio 3.21, 95% CI: 1.57 - 6.57).

Clinical conclusions
Patients with indeterminate urinary cytology who are non smokers and have neither haematuria, nor a history of urothelial cancer, are at low risk for malignancy.

Measure of benefits used in the economic analysis
The measure of benefits was the cases of cancer detected. This was derived directly from the effectiveness results.

Direct costs
The costs were not discounted, which was appropriate since they were incurred in less than one year. The quantities were not reported separately from the costs. The cost items were reported separately. The cost analysis covered the costs of cystoscopy and IVP from the perspective of Medicare and non Medicare payment. The price year was 1997.

Statistical analysis of costs
No statistical analysis of the costs was conducted.

Indirect Costs
The indirect costs were not considered.

Currency
US dollars ($).
Sensitivity analysis
No sensitivity analysis was conducted.

Estimated benefits used in the economic analysis
Fifty (22%) cancer cases were detected with strategy 1, 59 (18%) with strategy 2 and 60 with strategy 3.

Cost results
According to the Medicare reimbursement schedule, the total costs were $66,965 for strategy 1, $97,350 for strategy 2 and $114,755 for strategy 3.

The corresponding values for non Medicare patients were $214,742 (strategy 1), $312,180 (strategy 2) and $367,994 (strategy 3), respectively.

Synthesis of costs and benefits
The incremental cost-effectiveness ratio (ICER) was calculated as the additional cost per additional case detected. The ICER for strategy 1 relative to the strategy of no evaluation was $1,339 for Medicare and $4,295 for non Medicare patients. The ICER for strategy 2 relative to strategy 1 was $3,376 for Medicare patients and $10,862 for non Medicare patients. Finally, the ICER for strategy 3 relative to strategy 2 was $17,405 for Medicare patients and $55,814 for non Medicare patients.

Authors' conclusions
Patients with indeterminate urinary cytology who are non smokers, and have neither haematuria nor a history of urothelial cancer, are at low risk for malignancy and do not warrant complete evaluation.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator was clear. There is considerable doubt about how to evaluate patients with indeterminate cytology results, and the alternative strategies examined enabled an assessment of each approach in terms of the outcomes and costs. The authors also mentioned bladder tumour antigen markers as an alternative to predicting the presence of bladder cancer, but stated that large-scale studies are required fully to evaluate these. You should consider whether these approaches apply to your own setting.

Validity of estimate of measure of effectiveness
The study design was appropriate for the question being assessed. The sample of 389 patients with both indeterminate results and a full urological evaluation enabled the outcomes to be assessed. Hence, it was possible to determine the most appropriate way to treat them. There were 675 patients with indeterminate cytology at the institution, and it would have been interesting had the authors reported the long-term follow-up data for this group. The retrospective nature of the study design might be associated with a degree of selection bias and, therefore, may affect the validity of the results. However, the authors' approach was logical and appropriate. The authors stated that the study sample was representative of the population normally treated at their institute.

Validity of estimate of measure of benefit
The measure of benefit, the cases of cancer detected by each approach, was appropriate for the study question.

Validity of estimate of costs
The cost data had some limitations in that only the unit costs were provided and these were related to Medicare reimbursement and non Medicare schedules. The results are therefore not generalisable outside the USA, as they are based on charges and not on opportunity costs.
Other issues
The authors pointed out the issue of assessor subjectivity and skill in conducting urine cytology, which may explain much of the variation in the test results, in particular the indeterminate results. The authors compared their results with other studies in terms of the number of indeterminate results (4 - 32%) and emphasised the economic and clinical impact of dealing with non-emphatic results. The issue of generalisability to other settings or countries was not addressed.

Implications of the study
The findings supported the view that indeterminate urinary cytology for those who are non smokers, and who have neither haematuria nor a history of urothelial cancer, are at low risk for malignancy and do not warrant complete evaluation. The results from studies of bladder tumour markers as an alternative to urine cytology would help determine whether other more cost-effective tests would help in the treatment of patients with indeterminate cytology.

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