Urinary proteome analysis for prostate cancer diagnosis: cost-effective application in routine clinical practice in Germany

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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 study assessed the cost-effectiveness of applying urinary proteome analysis for the detection of prostate cancer in patients with suspicious prostate-specific antigen levels and/or digital rectal examination results. The authors concluded that the addition of non-invasive urinary proteome analysis for prostate cancer diagnosis was effective and reduced costs compared with conventional diagnostic approaches. The study methodology presented some potential limitations that should be taken into account when considering the validity of the authors’ conclusions.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The cost-effectiveness of applying urinary proteome analysis for the detection of prostate cancer in patients with suspicious prostate-specific antigen values and/or digital rectal examination results was assessed.

Interventions
Capillary electrophoresis coupled mass spectrometry urinary proteome analysis plus prostate biopsy was compared with biopsy alone.

Location/setting
Germany/secondary care.

Methods
Analytical approach:
The analysis was based on a Markov model with a one-year time horizon. The perspective adopted in the study was that of the compulsory health insurance.

Effectiveness data:
Clinical inputs were taken from a prospective within-group comparison study, which enrolled 211 patients between January 2007 and April 2008 at a single outpatient urological centre. The length of follow-up was one-year. The primary endpoint was accuracy (sensitivity and specificity) of urinary proteome analysis, which was assessed in 184 patients with conclusive test results. The urinary proteome analysis test results were evaluated using a combination of prostate biopsy, imaging procedures, prostate-specific antigen monitoring and transrectal ultrasound as the reference standards.

Monetary benefit and utility valuations:
Not considered.

Measure of benefit:
No summary benefit measure was used. The sensitivity and specificity of the diagnostic tests were the main endpoints of the clinical analysis.

Cost data:
The costs included diagnostic tests (prostate-specific antigen, urinary proteome analysis, biopsy and ultrasound). Costs

NHS Economic Evaluation Database (NHS EED)
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were based on standard German medical fee schedules and were provided by different German urological clinics. These fees were divided by a factor of 2.3 (the standard rate for private invoices) to approximate true costs for patients of compulsory health insurances. Costs were in Euros (EUR).

Analysis of uncertainty:
The robustness of estimated diagnostic costs was tested in a deterministic sensitivity analysis, where individual inputs of the model were varied using plausible ranges of values.

Results
Among 184 patients undergoing biopsy, prostate cancer was detected in 49 men. The urinary proteome analysis test sensitivity was 86% (95% CI 73 to 94) and specificity was 59% (95% CI 50 to 66).

There was a statistically significant difference (p=0.023) for urinary proteome analysis (area under the curve 72%) compared with prostate-specific antigen testing (area under the curve 60%). The urinary proteome analysis test results agreed 65.7% with follow-up reference results, while prostate-specific antigen achieved only 33.3% agreement.

In comparison with a strategy of direct biopsy, urinary proteome analysis before biopsy reduced the number of necessary biopsy sessions by 49% and the number of necessary control prostate-specific antigen tests by 38%. The total expected diagnosis costs were decreased by 19% (EUR 1,303.11 ± EUR 893 versus EUR 1,600.41 ± EUR 606).

When urinary proteome analysis was used to replace biopsy in subsequent follow-up, there was an increase of 4% of total diagnostic costs compared with biopsy.

The sensitivity analyses found that the results were robust.

Authors' conclusions
The authors concluded that the addition of non-invasive urinary proteome analysis for prostate cancer diagnosis was effective and reduced costs compared with conventional diagnostic approaches.

CRD commentary
Interventions:
The selection of the comparators was appropriate. The diagnostic options were generalisable to other health care settings.

Effectiveness/benefits:
The clinical data was based on a single cohort of patients from whom the accuracy of the various diagnostic tests was estimated. The use of a within-group comparison study did not require the enrolment of an external control group. Patient characteristics and details of the study design were provided; the results appeared to be valid. Most patients initially enrolled provided conclusive results for test accuracy. Standard statistical analyses were conducted. The study was based on a cost-consequences analysis. No outcome measure was considered.

Costs:
The focus was on costs reimbursed by the health insurers. Appropriate cost categories were included, although those related to the consequences of more accurate diagnoses were not taken into account, even though relevant. Unit costs of diagnostic tests were clearly reported. Data sources were presented. Details were given of the approach used to calculate costs reflecting the viewpoint of the analysis. The price year was not stated, which limited the possibility of conducting reflaction exercises in other time periods. Unit costs of tests were varied in the sensitivity analyses.

Analysis and results:
Cost-effectiveness ratios were not calculated because of the cost-consequences design of the analysis. Uncertainty was only partially investigated as the analysis considered the impact of selected inputs on total costs of the various diagnostic strategies. Results were presented for each diagnostic strategy assessed. The results appear to be specific to the authors’ context, so the external validity of the study seemed to be low. The authors acknowledged that some key assumptions were made in the Markov model.
Concluding remarks:
The study methods presented some potential limitations which should be taken into account when considering the validity of the authors' conclusions.

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