Screening del carcinoma prostatico in pazienti disurici: protocolli diagnostici e rapporto costi/benefici [Screening for prostatic carcinoma in dysuric patients: diagnostic protocols and cost-benefit analysis]
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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
Different screening methods (either single or combined with other methods) for prostate carcinoma in dysuric patients: rectal-digital examination (EDR), haematic dosage of PSA (cut-off 4 ng/ml and cut-off 10 ng/ml) and transrectal echotomography.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
Male and female patients suffering from dysuria and undergoing EDR, hematic dosage of PSA and transrectal echotomography.

Setting
Hospital.

Dates to which data relate
The main effectiveness data were obtained from a single study conducted between 1991 and 1995. Resource and cost data were taken from 1991-1995 sources. The price year was not stated.

Source of effectiveness data
The estimates of the results of histological examinations, diagnostic sensitivity, specificity and accuracy and number of biopsies which would have been necessary if only two methods of screening had been implemented, were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken on the same patient sample as that used in the effectiveness study although it was not stated whether it was undertaken prospectively or retrospectively.

Study sample
Overall, 1,185 patients suffering from dysuria (mean age:67 years, range:41-63 years) underwent EDR, hematic dosage of PSA and transrectal echotomography. Of the 1,185 patients, 306 (25.8%) underwent prostate biopsy by means of
transperineal echograph with gauge 18 needles as in Hodge’s technique. Power calculations to determine the sample size were not undertaken.

**Study design**
The study was a case series. The duration of follow-up was not stated. There was no loss to follow-up.

**Analysis of effectiveness**
The analysis of effectiveness was based on treatment completers only. The primary health outcomes were the results of histological examinations, diagnostic sensitivity, specificity and accuracy and number of biopsies which would have been necessary if only two methods of screening had been implemented.

**Effectiveness results**
The histologic examination revealed prostate adenocarcinoma in 26.5% of cases, benign prostate hypertrophy in 64% of cases, acute and/or chronic phlogosis in 8.5% of cases and granulomatosis prostatitis in 1% of cases. The diagnostic sensitivity, specificity and accuracy were 92.5%, 78.3%, 79.3% respectively for the EDR. The corresponding figures for PSA with cut-off 4 ng/ml were 91%, 78.3% and 90%, respectively. The corresponding figures for PSA with cut-off 10 ng/ml were 80.2%, 93.3% and 90% respectively. The corresponding figures for echography were 100%, 30.3% and 48.6%, respectively.

When the different methods were combined, the sensitivity, specificity and accuracy were, respectively: 98.8%, 60% and 77%, for EDR + PSA (cut-off 4 ng/ml),

98.8%, 65.8% and 79.9% for EDR + PSA (cut-off 10 ng/ml),

100%, 22% and 64.2% for EDR + echograph,

100%, 20% and 62.9% for echograph + PSA (cut-off 4 ng/ml),

100%, 26.6% and 64.9% for echograph + PSA (cut-off 10 ng/ml).

The number of biopsies which would have been necessary if only two methods of screening had been implemented was 251 with EDR and echograph, 246 with EDR and PSA (cut-off 4 ng/ml) and 158 with EDR and PSA (cut-off 10 ng/ml).

**Clinical conclusions**
The study reveals that echography has a high number of false positive results. Furthermore, fixing the cut-off either to 4 ng/ml or 10 ng/ml does not change the accuracy of the different screening methods.

**Measure of benefits used in the economic analysis**
The benefit measure was the number of biopsies avoided by excluding echography from the screening.

**Direct costs**
Costs for the screening using the three different methods (either single or combined with other methods) were included in the analysis. Resource and cost data were not reported separately. Discounting was not undertaken. The quantity/cost boundary adopted was the patient. The price year was not stated.

**Statistical analysis of costs**
Not undertaken.
Indirect Costs
Not included.

Currency
Italian Lira (L).

Sensitivity analysis
Not undertaken.

Estimated benefits used in the economic analysis
The average number of biopsies avoided by excluding echography from the screening was 141 (46.2%).

Cost results
A programme using the three methods cost L207,000 - L437,000 per patient for a total of L245,295,000 - L517,845,000. An echo-guided prostate biopsy with a histologic examination cost L250,000 -L500,000 per patient with a total cost of L76,500,000 - L153,000,000.

Synthesis of costs and benefits
The total cost avoided by excluding echography from the screening was 62.1% of the health expenditure.

Authors' conclusions
The study shows that EDR and the serum dosage of PSA are necessary and adequate methods in the programme of early diagnosis and screening of prostate neoplasms. Prostate echography should be reserved for cases of doubt and for the exclusion of needle biopsy. These measures also result in an optimisation of health expenditure.

CRD COMMENTARY - Selection of comparators
The reason for the choice of comparator is clear. The programme of early diagnosis of prostate cancer is based on a combination of different methods: EDR, haematic dosage of PSA and echotomography. You, as a user of this database, should consider whether these are widely used health technologies in your own setting.

Validity of estimate of measure of benefit
The estimate of measure of benefit (biopsies avoided) used in the economic analysis is likely to be internally valid and the data do not appear to have been used selectively.

Validity of estimate of costs
Resource quantities were not reported separately from the prices. The costing methodology lacked some details, particularly regarding the price data. No statistical analysis was conducted.

Other issues
The authors' conclusions are likely to be justified given the uncertainties in the data. The issue of generalisability to other settings or countries was not addressed. However, some comparisons with other studies, supporting the clinical and economic results from the present investigation, were reported. Results do not appear to have been presented selectively.

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