Follow-up of prostate cancer patients by on-demand contacts with a specialist nurse: a randomized study


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
On-demand follow-up of prostate cancer patients by a specialist nurse was compared to traditional follow-up by a urologist.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis (cost-consequences analysis).

Study population
Men with newly diagnosed or previously known prostate cancer in any stage were eligible for the study but the disease must have been judged to be clinically stable with an expected survival of more than three months. The exclusion criteria were: patients considered for curative treatment; patients participating in a trial that stipulated a specific follow-up protocol; or patients with psychiatric disorders or those whose general condition had deteriorated.

Setting
The study setting was secondary care in Sweden.

Dates to which data relate
The effectiveness evidence and resources used were collected between January 1991 and August 1992. The prices used related to 1993.

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

Link between effectiveness and cost data
Prospective costing was carried out on the same sample of patients as that used to collect the effectiveness evidence.

Study sample
No power calculations were reported. Consecutive patients with prostate cancer attending one of the three study sites were asked to participate in the study. Four hundred men took part in the study (200 in the urologist group and 200 in the nurse group) and ten patients did not give their consent to be randomised into the study. The authors did not report any evidence that the initial study sample was appropriate for the clinical study question.
Study design
The study was a multi-centre (three hospitals) randomised controlled trial. Randomisation was stratified for the three participating centres and was carried out using closed envelopes in each unit. No further details about randomisation were reported. Patients were followed-up for three years. One hundred and seventy nine patients died during the study period. Eight patients (seven in the urologist group and one in the nurse group) were lost to follow-up. No method was used to conceal the allocation group of patients for the assessment of outcomes.

Analysis of effectiveness
The analysis of the clinical study was based on treatment completers only.

The primary health outcomes used in the analysis were:

- anxiety and depression assessed using the Hospital Anxiety and Depression Scale (HADS);
- patient satisfaction (accessibility by phone, outpatient service and use of alternative medical facility) assessed using a questionnaire at baseline, 12 months, 24 months and 36 months.

Patients with newly diagnosed prostate cancer were excluded from the first questionnaire. A HADS score between 11 and 21 was defined as positive.

Safety was assessed using complication frequency and lag time from symptom to intervention.

The two groups were comparable in terms of the classification of malignant tumour, age group, presence of hormone resistant disease and treatment received prior to the start of the study.

Effectiveness results
The response rate for the questionnaire varied between 85 and 90% for the first year and decreased to 82% for the third year. No statistical difference between the two groups was found in terms of positive anxiety HADS scores:

- 4.3% for the urologist group and 3.2% for the nurse group (relative risk for nurse group (RR): 0.75 (95% CI: 0.24 to 2.29)) at baseline;
- 6.0% for the urologist group and 4.8% for the nurse group (RR: 0.79 (95% CI: 0.32 to 2.02) at 12 months;
- 3.9% for the urologist group and 6.0% for the nurse group (RR: 1.54 (95% CI: 0.52 to 4.59) at 24 months;
- 8.3% for the urologist group and 5.1% for the nurse group (RR: 0.62 (95% CI: 0.23 to 1.69) at 36 months.

No statistical difference between the two groups was found in terms of positive depression HADS scores:

- 3.1% for the urologist group and 1.9% for the nurse group (relative risk for nurse group (RR): 0.62 (95% CI: 0.15 to 2.56)) at baseline;
- 2.7% for the urologist group and 4.8% for the nurse group (RR: 1.79 (95% CI: 0.55 to 5.84) at 12 months;
- 2.3% for the urologist group and 5.2% for the nurse group (RR: 2.25 (95% CI: 0.59 to 8.50) at 24 months;
- 7.3% for the urologist group and 9.4% for the nurse group (RR: 1.28 (95% CI: 0.54 to 3.07) at 36 months.

There was no statistical difference in terms of patient satisfaction with accessibility by phone, outpatient service and use of alternative medical facilities at baseline, 12 months, 24 months and 36 months.

There was no statistical difference between the number of interventions due to symptoms related to prostate cancer, with the exception of a lower rate of uraemia in the nurse group (4 patients and 7 interventions) compared to the urologist group (12 patients and 16 interventions, p=0.03). No statistical difference in time from symptom to
intervention was observed.

**Clinical conclusions**
The authors concluded that men with prostate cancer can be safely followed-up by a specialist nurse.

**Modelling**
Kaplan-Meier survival curves were used to analyse the data on rate of symptoms and the time to intervention for symptoms to detect any delay in diagnosis in the nurse group or urologist group.

**Measure of benefits used in the economic analysis**
No measure of benefit was reported in this study and, hence, a cost-consequences analysis was conducted.

**Direct costs**
Quantities and costs were reported but not analysed separately. Direct costs included the resource use associated with contact with the healthcare system, interventions and drugs prescribed relating to prostate cancer, which was confirmed by checking the patient's medical records. The categories of direct costs listed by the authors were outpatient costs, pharmaceutical costs and institutional care costs. The cost of medication was calculated using FASS (not defined) prices. The estimation of the quantities and costs was based on actual data. The quantity of resource use was measured during January 1991 and August 1993. The constituents of these categories were not described in detail by the authors. The study perspective was not reported explicitly.

The costs of all medical interventions were calculated using the estimates of costs used in budgeting for healthcare in Orebro County, Sweden. The cost of medication was calculated using FASS (not defined) prices. The estimation of the quantities and costs was based on actual data. The quantity of resource use was measured during January 1991 and August 1993. The price year was 1993. The time horizon for the study was not reported. Discounting was not carried out. Average costs were reported for all patients and a sub-group of patients without verified bone metastases at study inclusion.

**Statistical analysis of costs**
No statistical analysis of costs was reported.

**Indirect Costs**
Indirect costs were not reported.

**Currency**
Swedish kroner (SEK). Currency conversion rates for 100 SEK were reported (11.6 ECU and 12.3 US$). No date for the currency conversion was reported.

**Sensitivity analysis**
No sensitivity analysis was reported.

**Estimated benefits used in the economic analysis**
The reader is referred to the effectiveness results reported above.

**Cost results**
The total costs for the urologist group were SEK 19,454 per year per patient (SEK 15,198 for patients without verified metastases).

The total costs for the nurse group were SEK 17,033 per year per patient (SEK 10,731 for patients without verified metastases).

**Synthesis of costs and benefits**
Costs and benefits were not combined.

**Authors' conclusions**
The authors concluded that a specialist nurse can safely follow up men with prostate cancer not suited for curative treatment and that this alternative is cost-effective, especially in men without metastases.

**CRD COMMENTARY - Selection of comparators**
The selection of comparators, follow-up of patients with prostate cancer by a specialist nurse compared to a urologist, seemed appropriate for the Swedish healthcare system. You, as a user of this database, must decide whether these alternatives reflect clinical practice in your own healthcare setting.

**Validity of estimate of measure of effectiveness**
The study used a multi-centre, randomised trial design, which was appropriate for the aims of the evaluation. The study sample appeared to be representative of the study population of men with stable disease. The authors did not state which of the outcome measures used was the primary outcome and did not report power calculations. It is therefore not possible to assess whether the absence of a statistical difference between the two study groups is due to chance or to true equivalence between the two groups. The authors suggested that the two groups were similar at baseline. However, they did not report the results of any statistical analysis to determine the comparability of the groups. The analysis of data was based on treatment completers rather than on intention to treat. In addition, the actual number of patients who were dead, who did not respond These factors could potentially bias the results.

**Validity of estimate of measure of benefit**
No summary measure of benefit was reported. It was not possible to use the values from the HADS in the economic analysis because the scale comprised two domains (anxiety and depression). These domains could not be summarised into a single index representing an overall measure of benefit from the patients' perspective.

**Validity of estimate of costs**
The study perspective and time horizon were not reported explicitly. Therefore it is not possible to assess whether the appropriate direct costs were included in the analysis. Furthermore, it is not possible to determine whether the omission of indirect costs from the analysis was appropriate to the chosen study perspective. Costs were valued over a three-year time-period, which means that discounting should have been carried out. However, discounting was not included in the analysis of the cost data.

**Other issues**
The authors did not report calculations to assess the power to detect statistically significant differences, the study perspective, time horizon or a sensitivity analysis. This limits the internal validity of the study and its generalisability to other health care settings in different countries.

**Implications of the study**
The authors suggested that follow-up, by a specialist nurse, of prostate cancer patients not suited for curative treatment
is a safe and cost-effective option compared to follow-up by a urologist. The authors caution that on-demand follow-up by nurses cannot be recommended when detection of asymptomatic local progression would benefit patients. It has not been clearly demonstrated that early detection and treatment of non-symptomatic local progression in patients not eligible for curative treatment would result in prolonged survival or other benefits. The authors suggest that further studies are required before a recommendation is made to change routine follow-up practice.

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