Surveillance for stage I testicular germ cell tumours: results and cost benefit analysis of management options

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 health intervention examined in the study was a 10-year surveillance programme for both seminoma and non-seminomatous stage I testicular germ cell tumours. The outline of the programme included monthly visits and tests (computerised tomography scans, chest X-ray, and measurement of serum tumour makers), which became less frequent as the programme went on.

Type of intervention
Treatment (surveillance programme).

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised men with seminomas or non-seminomatous stage I testicular germ cell tumours, who had undergone orchidectomy and with tumour markers which were back to normal status and who displayed no evidence of metastases.

Setting
The setting was hospital. The study was carried out in the UK.

Dates to which data relate
Data on effectiveness were directly collected from 1979 to 1996 and were also derived from studies published between 1985 and 1996. No dates for resource use or the price year were reported.

Source of effectiveness data
The effectiveness evidence was based both on a single study and on published studies.

Study sample
Power calculations were not performed and the method of sample selection was not reported. Of the 195 eligible men with stage I NSGCT, 183 patients (94%) opted for surveillance (the remaining 12 received adjuvant chemotherapy) and, of the 137 eligible men with stage I seminoma, 120 patients (88%) opted for surveillance (the remaining 17 cases received adjuvant irradiation). As a result, a sample of 303 patients (183 NSGCT and 120 seminomas) was included in the analysis.

Study design
This was a prospective cohort study of two groups of patients undergoing the same intervention. A sample of 303 patients enrolled in the surveillance programme was followed for 10 years. Median follow-up was 5.8 years (range: 0.1 - 21.7 years) for patients with NSGCT and 4.6 years (range: 0.1 - 19 years) for those with seminoma. Details of the study centres were not reported. Loss to follow-up was not stated.

Analysis of effectiveness
The method of analysis (intention to treat or treatment completers only) was not stated, but all patients included in the study were accounted for in the analysis. The primary health outcomes assessed were survival (calculated using the Kaplan-Meier approach from the day of diagnosis until death or date of last follow-up), relapse rate, relapse-free survival at 5 years, and median time to relapse. Comparability of study groups was not reported as no comparison was carried out in the single study.

Effectiveness results
In the NSGCT group, survival was 100% at 5 years and 98.9% (95% CI: 96% - 100%) at 10 years; the relapse rate was 28%; the relapse-free survival at 5 years was 69% (95% CI: 61% - 76%); and the median time to relapse was 6 months (range: 1 months - 10.2 years).

In the seminoma group, survival was 100% at 5 years and 94.4% (95% CI: 86% - 100%) at 10 years; the relapse rate was 15%; the relapse-free survival at 5 years was 82% (95% CI: 74% - 90%); and the median time to relapse was 4 months (range: 1 months - 4.2 years).

Clinical conclusions
The authors concluded that the surveillance programme was effective in maintaining high survival rates in both groups of patients (those with NSGCT and those with seminomas).

Outcomes assessed in the review
The health outcomes assessed from published studies were survival and relapse rates with surveillance, nerve sparing RPLND, adjuvant chemotherapy, and adjuvant radiotherapy.

Study designs and other criteria for inclusion in the review
Not stated.

Sources searched to identify primary studies
Not stated.

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

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

Number of primary studies included
Twelve primary studies were used to derive the effectiveness data.

Methods of combining primary studies
Narrative methods were used to combine primary studies.

**Investigation of differences between primary studies**
Not carried out.

**Results of the review**
Survival and relapse rates were 98.4% and 25% with surveillance, 98% and 17% with nerve sparing RPLND, 98% and 5-11% with adjuvant chemotherapy, and 98.5% and 4-6% with adjuvant radiotherapy.

**Measure of benefits used in the economic analysis**
The benefit measure used in the economic analysis was the number of lives saved which was obtained by combining the data derived from the published studies. The calculation was made for a hypothetical population of 1,000 patients.

**Direct costs**
Discounting was not reported although it would have been relevant as the time horizon of the analysis was 10 years. Unit costs were reported for some cost items. The economic analysis included visits, computerised tomography scans, chest X-ray, and measurement of serum tumour makers for the surveillance programme; chemotherapy hospital stay and drugs (such as antiemetics, antibiotics, etc.) for adjuvant chemotherapy; surgery for RPLND; and cycles of treatments for adjuvant radiotherapy. Salvage chemotherapy and salvage RPLND was included in the other options when required. The cost/resource boundary was that of the hospital. The estimation of costs and quantities of resources used was based on actual data derived from the Charing Cross Hospital in London. No price year was reported.

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

**Indirect Costs**
Indirect costs were not included in the analysis.

**Currency**
UK pounds sterling (€).

**Sensitivity analysis**
Sensitivity analyses were not conducted.

**Estimated benefits used in the economic analysis**
The number of lives saved in a population of 1,000 patients was 984 with surveillance, 980 with nerve sparing RPLND, 978 with adjuvant chemotherapy, and 985 with adjuvant radiotherapy.

**Cost results**
Total costs in a population of 1,000 patients were 6,028,500 with surveillance, 7,518,500 with nerve sparing RPLND, 5,722,000 with adjuvant chemotherapy, and 4,323,500 with adjuvant radiotherapy.

**Synthesis of costs and benefits**
An average cost-effectiveness analysis was conducted to combine costs and benefits of the interventions. No
incremental analysis was performed, although it was relevant. The cost per life saved was 6,126 with surveillance, 7,672 with nerve sparing RPLND, 5,851 with adjuvant chemotherapy, and 4,389 with adjuvant radiotherapy. The latter was the dominant strategy as it was associated with less costs and more benefits than the other interventions.

Authors’ conclusions
The authors concluded that the surveillance programme in both stage I seminoma and NSGCT patients was highly effective in providing high survival rates with minimal morbidity. The economic analysis showed that the surveillance programme was not more expensive than other procedures for the management of patients with seminoma and NSGCT and its cost-effectiveness was comparable to that of the other options.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparators was clear. The authors selected the interventions which represented actual options for the management of patients with seminoma and NSGCT. You, as a user of this database, should decide whether they represent widely used strategies in your own setting.

Validity of estimate of measure of effectiveness
Two distinct effectiveness analyses were performed. In the first analysis, a single study was conducted with a sample of patients followed with the surveillance programme; patient demographics were not reported, and no details of the assessment of the outcomes were reported.

In the second analysis (whose results were used in the cost-effectiveness analysis), effectiveness outcomes were derived from published studies, but a formal review of the literature was not carried out. No detail was provided on the comparability and validity of the primary studies or on the method of combination of primary data.

Validity of estimate of measure of benefit
The benefit measure was the number of lives saved, which appears appropriate for the comparability of the benefits of other interventions implemented in the health care system. It was derived from data obtained from published studies. However, when benefits were combined with costs, an average analysis was performed, although an incremental analysis would have been more appropriate.

Validity of estimate of costs
The analysis of costs was performed from the perspective of the hospital and it appears that all relevant categories of costs were included in the analysis. Unit costs were reported for most items. The estimated costs were based on actual data derived from a hospital in London. Some limitations to the validity of the cost analysis should be noted. First, costs were treated deterministically as no statistical analysis was conducted. Second, discounting was not reported although it would have been relevant given that the time horizon of the analysis was 10 years. And finally, no price year was given, making reflation exercises to other settings difficult.

Other issues
The authors did not compare their findings with those from other studies. The issue of the generalisability of the study results to other settings was not addressed as sensitivity analyses were not carried out. The authors stated that costs may vary between centres. The study enrolled a sample of patients with seminoma and NSGCT and this was reflected in the conclusions of the study.

Implications of the study
The authors suggest that a surveillance policy should be recommended for the management of patients with seminoma and NSGCT. However, other options, such as adjuvant chemotherapy and radiotherapy offer a more convenient cost-effectiveness ratio and similar survival rates. Finally, a key variable for the success of the surveillance programme may
be the high motivation of both patients and physicians.

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