Long term outcome and cost in the management of Stage I testicular seminoma

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 implementation of a surveillance programme for the management of patients with Stage I testicular seminoma after orchidectomy was examined. The surveillance programme consisted of examinations every 4 months during the first 3 years, every 6 months during years 4 to 7, and annually in years 8 to 10. A computed tomography (CT) scan of the abdomen and pelvis would be performed at each visit, chest X-rays would be taken at alternate visits, and serum tumour markers were estimated at each visit during the first two years.

Type of intervention
Surveillance and/or treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised postoperative patients with Stage I testicular seminoma.

Setting
The setting was a hospital. The economic study was performed in Toronto (ON), Canada.

Dates to which data relate
The effectiveness data were collected between January 1981 and December 1994. The cost data appear to have related to a study published in 1996. The price year was 1994.

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

Link between effectiveness and cost data
The costing was not performed prospectively. In addition, it was not carried out on the same sample population as that used in the effectiveness analysis (see 'Modelling' section).

Study sample
Power calculations, to assure a certain power, were not performed in the planning phase of the study. Patients treated at the Princess Margaret Hospital (Toronto, Canada) during the study period were considered for the effectiveness analysis. The total study sample comprised 471 patients, of which 245 were treated with adjuvant RT and 226 were managed by surveillance. Two of these patients were treated with post-orchidectomy RT followed by surveillance. Patients who expressed a preference for standard management with RT were excluded from the surveillance group. The
study sample was not shown to be representative of the study population.

**Study design**
This was a prospective cohort study that was performed at a single centre. The median duration of follow-up was 9.7 years (range: 1.8 - 15.0) for patients treated with adjuvant RT and 7.7 years (range: 1.8 - 15.0) for patients managed by surveillance. The authors did not report any loss to follow-up, neither did they report whether they used a blinding method to assess the outcomes.

**Analysis of effectiveness**
The patients managed with both RT and surveillance were not accounted for in the final effectiveness results. The primary health outcomes assessed were:

- overall 5-year survival,
- the cause-specific survival,
- the number of patients relapsed,
- the 5-year relapse-free rate,
- the median time to relapse,
- the type of treatment received by patients with relapse, and
- the number of deaths among patients managed either with RT or surveillance.

The patients were shown to be similar in terms of age, although there were differences in the histological type of testicular seminoma.

**Effectiveness results**
The 5-year survival was 97% for all patients.

The cause-specific survival was 99.8%.

The number of patients relapsed at 5 years was 14 (of 243) in the RT group and 37 (of 224) in the surveillance group.

The 5-year relapse-free rate was 94.4% among patients treated with RT versus 85.4% among surveillance patients.

The median time to relapse was 15.4 months among patients treated with RT versus 18 months (range: 3 - 108) among surveillance patients.

Patients who relapsed in the RT group were treated either with cisplatin-based combination therapy, local RT or local excision, according to their type of relapse. Surveillance patients that relapsed received either RT, chemotherapy, retroperitoneal lymphadenectomy, or VP-16 and cisplatin chemotherapy (in case of second relapse).

None of the RT patients, but one of the surveillance patients died during the study period.

**Clinical conclusions**
Compared with patients managed by surveillance, patients treated with RT presented better health outcomes (higher 5-year survival rates, lower number of patients with relapse, longer median time to relapse, and no deaths).
Modelling
The authors reported that modelling was used to estimate the costs, but the type of model used was not reported. It appears that the authors have estimated the costs by imputing unit costs to the estimated resources used, according to the current follow-up policies followed in the hospital where the study was carried out.

Measure of benefits used in the economic analysis
No summary measure of benefit was used in the economic analysis. The study was, in effect, a cost-consequences analysis.

Direct costs
The direct costs included in the analysis were those of the Ontario Ministry of Health. These were for RT (including costs associated with equipment, personnel and maintenance), chemotherapy, follow-up visits, follow-up CTs, chest X-rays, serum markers and overheads (e.g. security, heating, utilities). The authors reported that the costs common to both strategies (tumour marker estimation and salvage chemotherapy) were not estimated. The costs were estimated from a published study (Warde and Murphy, see Other Publications of Related Interest), although some authors' assumptions also appear to have been used. The costs were derived through modelling, which appears to have been based on current data and authors' assumptions. The authors reported the estimated percentage of patients using the treatments and tests considered in the economic analysis, although neither the amount of resources used nor the unit costs applied to resource use were reported. Discounting was not reported to have been performed, although it would have been appropriate as the period considered for the estimation of costs was 10 years. The price year was 1994. The authors reported the costs per patient.

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

Indirect Costs
The indirect costs were not estimated.

Currency
Canadian dollars (Can$). The exchange rate was Can$1 = US$0.66.

Sensitivity analysis
Sensitivity analyses were not performed.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The estimated costs per patient were:

Can$5,720 for patients treated with adjuvant RT (Can$3,120 associated with RT and Can$2,600 associated with follow-up visits and chest X-rays); and

Can$8,228 for patients managed with surveillance (Can$415 associated with RT, Can$2,210 associated with follow-up visits and chest X-rays, and Can$5,600 for follow-up CTs).

The additional cost per patient managed with surveillance was Can$2,508 over 10 years.
Synthesis of costs and benefits
The estimated benefits and costs were not combined as a cost-consequences analysis was undertaken.

Authors' conclusions
Both surveillance and radiotherapy (RT) gave excellent results for patients with Stage I seminoma, although surveillance was more expensive than RT.

CRD COMMENTARY - Selection of comparators
The choice of adjuvant postoperative RT as the comparator was justified because it was standard management for patients with Stage I testicular seminoma. You must decide whether this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The authors did not report the criteria used in the hospital to manage patients either with adjuvant RT or surveillance. It would have been more appropriate to have performed a randomised controlled trial, instead of a prospective cohort study, to reduce the potential for bias. The authors did not justify their choice of the study design. The further treatments received by patients who experienced relapse differed according to their type of relapse, and this might have influenced the health outcomes obtained. The study sample was not shown to be representative of the study population. No statistical analyses of the effectiveness results were reported. This introduces uncertainty into the reliability of the conclusions.

Validity of estimate of measure of benefit
No summary measure of benefit was used in the economic analysis. Thus, the study was, in effect, a cost-consequences analysis. It would have been possible to have estimated a measure of health benefit such as the number of quality-adjusted life-years gained during the study period. This measure would have been useful for comparing the results with those of other interventions.

Validity of estimate of costs
The perspective adopted was that of the Ontario Ministry of Health. Most, but not all, of the relevant costs related to this perspective were reported. Although the authors excluded the costs of salvage chemotherapy, arguing that the same proportion of patients would require it, the patients received different types of salvage chemotherapy and these might have been associated with different costs. Moreover, the adoption of a societal perspective might have been more appropriate, as there were relevant indirect costs (i.e. productivity loss) related to the interventions. The length of the periods considered for the estimations of effectiveness and costs differed, which makes it difficult to interpret the study findings. The resource quantities and the unit costs were not reported separately, which hinders reflation exercises in other settings. Further, no statistical or sensitivity analyses of the costs were reported, which introduces uncertainty into the reliability of the cost results.

Other issues
The authors made appropriate comparisons of the study findings with those from other studies. The survival rates and disease-related rates associated with surveillance were shown to be similar to other studies. However, the risk of developing a second malignancy, which has been shown to be higher for patients receiving RT in long-term studies, was not found in this study, perhaps because of the shorter follow-up period considered. The issue of the generalisability of the results was not addressed.

Implications of the study
Since no statistical or sensitivity analysis of effectiveness or costs was performed, and there were several other caveats
to this study, the results should be interpreted with caution. The authors suggested that, to account for patient preference, the use of RT should be reconsidered and a surveillance programme should be offered to all patients as an alternative management option. As they stated, there are pros and cons associated with the implementation of a surveillance programme. RT has a higher relative risk of developing a second malignancy (which was not shown in this study), while surveillance requires many CT scans and other examinations. The authors recommended further research to better determine the follow-up schedule for patients under surveillance, based on their prognostic factors for relapse.

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Other publications of related interest


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