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# Stage I Seminoma of the Testis. Adjuvant Radiotherapy or Surveillance?

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**Summary**—Lately the role of radiotherapy in stage I seminoma of the testis has been questioned by some authors who reported on a "surveillance" strategy for these patients. Since 1980, 124 patients with seminoma of the testis have been referred to this institution; 97 of 116 patients analysed presented with stage I disease and 10 of these had elevated levels of  $\beta$ HCG.

A total of 64 patients were given radiotherapy after orchiectomy and 33 entered a surveillance protocol. After a median follow-up of 48 months, 3 patients in the surveillance group relapsed after 5, 13 and 49 months and 2 of the irradiated patients did so after 25 and 33 months. Elevation of  $\beta$ HCG was not significant because none of these patients showed progression.

A low rate of progression and excellent survival are associated with standard treatment (orchiectomy and radiotherapy) and good results have been achieved with chemotherapy in cases of relapse. A surveillance policy is not recommended in stage I seminoma because of its slower growth compared with non-seminomatous germ cell tumours (NSGCT), the absence of a specific tumour marker, the 10% risk of occult metastases and the 3-fold higher progression rate compared with irradiated patients. We suggest the use of a reduced dosage and radiation field.

Testicular seminoma has proved to be extremely responsive to therapy. After standard therapy—infra-diaphragmatic lymph node irradiation—excellent cure rates have been reported, with survival rates of 85 to 90% in stage I tumours (Thomas *et al.*, 1982; Peckham 1988; Fossa *et al.*, 1989). In view of the low rate of occult metastases (in approximately 10% of cases) (Maier *et al.*, 1968) and the morbidity of radiation therapy (impaired spermatogenesis, peptic ulceration, bowel complications and second malignancies) (Hay *et al.*, 1984; Hamilton *et al.*, 1987; Coia and Hanks, 1988), it has been suggested that radiotherapy should be omitted.

To find out if it is possible to reduce therapy without compromising patients' safety, we evaluated the follow-up of patients with seminoma stage I who were treated either with adjuvant radiotherapy or surveillance after orchiectomy between 1980 and 1988 at Hannover Medical School.

## Patients and Methods

Since 1980, 124 patients with seminoma of the testis have been referred to this institution. Eight patients were lost to follow-up; 7 of these had stage I tumours—6 in the radiotherapy group and 1 in the surveillance group. Of the remaining 116 patients, 97 (83.6%) presented with stage I disease and thus could be analysed; 10 of these (10.5%) had elevated levels of  $\beta$ HCG. Sixty-four patients were given radiotherapy after orchiectomy and 33 were assigned to a surveillance protocol. The decision on treatment was made by the patient himself after being fully informed of the advantages and disadvantages of both strategies. The median ages of 32.5 years (range 18–67) in one group and 33 years (range 21–48) in the other group were comparable.

Stage I seminoma was defined by (1) verification of a histologically pure seminoma, (2)  $\beta$ HCG in the normal range or decreasing after orchiectomy (patients with elevated levels of alpha-fetoprotein (AFP) were treated as having non-seminomas) and (3) ultrasonography of the abdomen, CT of abdo-

men and chest and conventional chest X-ray without evidence of tumour spread.

Patients in the surveillance group were followed up closely with monthly examinations (AFP and  $\beta$ HCG, chest X-ray and either CT scan or sonography) in the first year, 2-monthly in the second year and every 3 months in the third to fifth years. Irradiated patients were followed-up every 3 months for the first 2 years and every 6 months for the third and fourth years, with annual visits thereafter.

**Results**

In all, 97 patients were followed up for a median of 48 months (range 4–110) and 5 patients (5.2%) relapsed; 3 (9.1%) of the 33 patients in the surveillance group showed progression after 5, 13 and 49 months and 2 of the irradiated patients (3.1%) did so after 25 and 33 months (Table 1). Details of relapse and treatment are summarised in Table 2. Of the 2 relapsing patients in the irradiated group, 1 developed isolated lung metastases and was treated with 4 cycles of chemotherapy (cisplatin vinblastine, bleomycin—PVB) and resection of

residual tumour. He has been disease-free for 65 months. The other patient, who had a prior herniorrhaphy, showed progression in the irradiated area, retroperitoneal and inguinal. He received 2 cycles of PVB and secondary retroperitoneal lymph node dissection (RPLND) and has been disease-free for 46 months. All of the 3 relapsing patients in the surveillance group showed retroperitoneal progression and were cured by different types of therapy; carboplatin and secondary RPLND and radiation or chemotherapy alone. No patient has died from his disease or from complications of treatment.

Ten of the 97 patients (10.5%) had elevated levels of  $\beta$ HCG prior to orchiectomy; 6 of them received adjuvant radiation therapy and 4 were entered into the surveillance protocol; none relapsed.

Histopathologically we found 95 cases of classical seminoma, 1 anaplastic and 1 spermatocytic seminoma.

Relapse occurred in 3% of patients with pT1 tumours, 7% with pT2 and 17% with pT3 lesions (Table 3). To ascertain if there was a rise in relapse probability with increasing pT stage the trend test (Armitage, 1955) was applied (using the StatXact package (Mehta *et al.*, 1988; Gajjar *et al.*, 1989). The exact one-sided *P* value for the observed trend was 0.08, so that the correlation was significant on the level of 10% but not 5%.

Delay in presentation was assessed in 67/97 patients, with 3 of these relapsing. The latter subgroup showed a preference for longer intervals (median 26 weeks) compared to the patients with no evidence of disease (NED) (median 3 weeks). The difference was statistically significant (log rank test, one-sided *P* value = 0.0387) (Kalbfleisch and Prentice, 1980).

Four patients (4.1%) developed a secondary malignancy after 14, 16, 72 and 84 months: in 1 a

**Table 1** Surveillance versus Adjuvant Radiotherapy

Surveillance		Radiotherapy	
No. = 33		No. = 64	
NED 30	Relapse 3 (9%)	NED 62	Relapse 2 (3%)
	Therapy		Therapy
	NED 3		NED 2

NED = No evidence of disease.

**Table 2** Details of Relapse

No. of patients	Radiotherapy	Time to relapse (months)	Site of relapse	Treatment	Status (months)
1	Yes	33	Retroperitoneal/inguinal	PVB + RPLND	NED 46
2	Yes	25	Pulmonary	PVB + L-Op	NED 65
3	No	49	Retroperitoneal	CP + RPLND	NED 33
4	No	5	Retroperitoneal	RPLND + RT	NED 43
5	No	13	Retroperitoneal/cervical	Cisplatin	NED 28

PVB = Cisplatin, vinblastine, bleomycin.  
 CP = Carboplatin.  
 RPLND = Retroperitoneal lymph node dissection.  
 L-Op = Resection of residual pulmonary tumour.  
 RT = Radiotherapy.  
 NED = No evidence of disease.

**Table 3** pT Stage

pT	No. of patients (%)	Relapses (%)
1	64	2 (3)
2	27	2 (7)
3	6	1 (17)

seminoma and in 3 a non-seminomatous germ cell tumour of the contralateral testis.

## Discussion

Many patients with seminoma of the testis have stage I disease at presentation, with percentages ranging between 69 and 84% (Calman *et al.*, 1979; Thomas *et al.*, 1982; Krag-Jacobsen *et al.*, 1984; Babaian and Zagars, 1988; Ellerbroek *et al.*, 1988). In the present study, 83.6% presented with stage I disease, which would seem to indicate a low metastatic potential. The historical data of Maier *et al.* (1968) showed a 10% incidence of occult metastases in patients presenting with stage I seminoma, but the methods of staging at that time were unsatisfactory and the more precise imaging systems used today may mean that the rate of occult metastases is even lower.

Excellent survival and low relapse rates have been reported in patients with seminoma of the testis stage I after orchietomy and adjuvant radiotherapy (Table 4). Furthermore, there is effective salvage treatment for patients who relapse (Thomas *et al.*, 1982; Loehrer *et al.*, 1987).

**Table 4** Relapse Rates after Orchietomy and Adjuvant Radiotherapy

	No. of patients	No. of relapses	Rate (%)
Ball <i>et al.</i> (1982)	232	4	3.0
Fossa <i>et al.</i> (1989)	365	13	3.5
Hamilton <i>et al.</i> (1986)	232	5	2.0
Thomas (1985)	150	2	1.0
Zagars (1988)	163	7	4.2

**Table 5** Relapse Rates after Surveillance

	No. of patients	Follow-up (months) Median (range)	Relapse	Rate (%)	Time (months) Median (range)
Horwich and Peckham (1988)	90	18 (4-40)	10	11.0	11 (7-24)
Peckham <i>et al.</i> (1987)	52	23 (12-41)	7	13.4	11 (6-23)
Thomas <i>et al.</i> (1989)	81	19 (3-43)	3	3.7	5 (3-18)
Present series	33	48 (4-110)	3	9.1	13 (5-51)

Successful results of a surveillance policy for stage I non-seminomatous germ cell tumours of the testis were reported by Peckham *et al.* (1982) and this raised the possibility of adopting a similar approach to stage I seminomas to avoid unnecessary additional therapy. Some initial results of the "wait and see" policy in testicular seminoma stage I revealed relapse rates of 3.7 to 13.4%, but follow-up was relatively short (Table 5).

Our relapse rate of 3.1% after adjuvant radiotherapy is similar to that of other series (Table 4). Patients in the surveillance group showed progression in 9.1%, thus recording a relapse rate 3 times higher than that of irradiated patients. This includes 1 patient with progression after 49 months and underlines the possibility of late recurrence in this group, as already described by other authors. Ellerbroek *et al.* (1988) reported a 30% relapse rate after 3 years, Calman *et al.* (1979) reported recurrence after 6 years, and Warhol *et al.* (1983) after 17 years.

Elevation of serum  $\beta$ HCG is described in 10 to 21% of seminoma patients (Mann and Siddle, 1988), whereas morphological correlation (syncytiotrophoblastic cells) could be established in only 4 to 14.5% (Butcher *et al.*, 1985). Javadpour (1986) suggested a worse prognosis for patients with  $\beta$ HCG-positive seminoma, but the results in our study (no relapse in 10 patients with elevated levels of  $\beta$ HCG) corroborate the experience of other authors (Peckham *et al.*, 1987; Babaian and Zagars, 1988; Wilkinson *et al.*, 1988). Thus we would not recommend a change from the usual policy for these patients.

The side effects of adjuvant radiotherapy are relatively infrequent and usually affect the gastrointestinal tract (Peckham, 1988; Fossa *et al.*, 1989). Coia and Hanks (1988) reported about 4% of patients with severe complications requiring hospitalisation in a series of 883 patients who received radiotherapy for seminoma or Hodgkin's disease. With dosages below 35 Gy, Prosnitz (1988) observed only 1% of patients with major complications. The risk of infertility presents a special problem (Thomas *et al.*, 1977). Even with careful

scrotal shielding, either oligozoospermia or azoospermia persists in approximately 50% of irradiated men. However, it should be remembered that 22 to 53% (Jewett and Jarvi, 1986) of all men after unilateral orchiectomy and before further therapy exhibit azoospermia and 25% of all patients with testicular tumours remain subfertile, regardless of therapy. On the other hand, the recovery of spermatogenesis after radiation therapy is possible.

The problem of second malignancies after radiotherapy has not yet been solved. Evaluation of the South Thames Cancer Registry for the period 1961 to 1980 by Coleman *et al.* (1987) did not reveal an excessive incidence of second cancers among men with testicular cancer, apart from contralateral testicular neoplasms. For the latter the risk rose from 2.9 to 14.3 over the 2 decades, with relatively few men being treated by chemotherapy alone in either time period. Kaldor *et al.* (1987) reported a 2-fold higher chance of developing second malignancies in testicular cancer, but the study did not allow any differentiation with respect to the therapeutic approach previously selected. Hamilton *et al.* (1986) suggested that there was no increased risk compared with the normal population, but Hay *et al.* (1984) found a 9% incidence of second, non-testicular malignancies in patients irradiated between 1950 and 1969. Fossa *et al.* (1989) observed a 2-fold higher chance of developing second malignancies compared with the general population, though in this series tumours of the contralateral testis were included.

A relapse rate of 9 to 13% in a surveillance policy seems to be acceptable, even in comparison with 20 to 30% in NSGCT stage I. However, the time to relapse is usually longer than in NSGCT and it must be remembered that the follow-up in previous studies was relatively short. Furthermore, relapse is confined in most cases to the retroperitoneum, which is a more difficult area to assess by imaging techniques. Though all relapses have been salvaged, surveillance in seminoma patients might be considered more complicated and costly because a longer period of intensive follow-up is required. In addition, a satisfactory serum tumour marker has yet to be discovered. Placental alkaline phosphatase (PLAP) has been thought to be of value (Horwich *et al.*, 1985), but observations of elevated levels of PLAP in 55 to 90% of seminoma patients with active disease (Horwich *et al.*, 1985) would indicate a sensitivity lower than that required for reliable follow-up.

The difference between 3.1% and 9.1% in irradiated and surveillance patients does not attain

statistical significance, but in calculating the low number of overall relapses, about 20 000 probands are necessary to detect the proposed difference as significant with a power of 95% (Sachs, 1982). In spite of this, the 3-fold higher relapse rate must be emphasised, and so in our opinion radiotherapy remains an important and safe method of treatment for patients with seminoma stage I.

A more vexing question is whether dosage and radiation field can be optimised. Total dosage should not exceed 30 Gy (Hanks *et al.*, 1981) and satisfactory results have been obtained even with 25 Gy (Thomas, 1985). Fossa *et al.* (1989) require that the inguinal region be excluded even in patients with a past history of inguinal or scrotal surgery. Radiation of the ipsilateral iliac region may also be questioned, since iliac tumour growth is rare in patients with testicular cancer (Fossa *et al.*, 1989). Considering these restrictions, immediate and long-term morbidity can probably be reduced even further.

Another option seems to be the use of carboplatin: it has been established that seminoma, as well as being more radiosensitive than non-seminoma, is also more chemosensitive. This has been reflected by the observation that approximately 70% of patients can become disease-free with cisplatin alone (Oliver, 1987), compared with 10% of patients with NSGCT (Higby *et al.*, 1974). Two courses of adjuvant treatment provide a realistic alternative to radiotherapy and may well be less toxic (Peckham *et al.*, 1985; Oliver, 1987). It is probable that a prospective study comparing radiotherapy and carboplatin may be indicated in stage I seminoma.

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