

The treatment of intraperitoneal malignant disease with monoclonal antibody guided ^{131}I radiotherapy

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Summary Seven patients with small volume ovarian carcinoma, colorectal, distal oesophageal disease with lymph nodes and a primary oesophageal adenocarcinoma, were treated with intraperitoneal monoclonal antibody guided radiotherapy (^{131}I conjugated to 10 mg of monoclonal antibody) were injected i.p. in 2000 ml peritoneal saline fluid. Patients were evaluated 3 months later: 3 had clinical progressive disease while three had a response demonstrating progressive disease in 2 of the remaining 4 patients. The seventh patient did not have a third liver laparotomy and it cannot be concluded if a response.

Five patients with recurrent malignant disease not controlled by a second or repeated laparotomy were similarly treated with 7.5 mg of ^{131}I conjugated to 10 mg monoclonal antibody. In three patients the tumor was controlled for a mean of 4 months. One patient died two days to a toxic side effect of her laparotomy but tumour cells disappeared from the ascitic fluid after therapy. In the patient whose disease was not controlled, a subpopulation of antigen negative tumour cells was demonstrated. This study was unable to demonstrate a therapeutic benefit for i.p. injected monoclonal antibody guided radiotherapy for solid intraperitoneal tumours but suggests that it may be capable of controlling the administration of a 10 per cent positive response rate.

Ovarian carcinoma is the most common cause of death from gynaecological cancer and the third most common of all cancers in women. In England and Wales over 3,700 women die each year and 4,000 new cases are diagnosed (Toms *et al.*, 1981). The majority of patients with ovarian carcinoma, therefore, die of their disease. While mortality rates for carcinoma of the cervix and uterus have dropped over the last 30 years, the mortality rate for carcinoma of the ovary has risen (Osmond *et al.*, 1985).

The cornerstone of current therapy is surgery, as prognosis is more strongly related to volume of disease remaining after a debulking operation (Christie *et al.*, 1979). While high response rates in multidrug regimens have been reported (Slevin, 1986), no improvement in long term survival has yet been achieved. Patients with ovarian cancer may continue to relapse and die of disease many years after achieving complete remission (Neug *et al.*, 1986). When patients relapse after chemotherapy, the options are extremely limited. The prognosis of disease relapse in previously chemoresistant tumours has been well documented both *in vivo* (Friedlander *et al.*, 1983) and *in vivo* (Wilson & Neal, 1981) and so long term benefit is available from further chemotherapy. The place of abdominal-pelvic radiotherapy at this point is also unclear (Dombro *et al.*, 1979). There is a clear need for further effective therapeutic modalities in this disease.

The success of monoclonal antibodies, labelled with a radioisotope, to detect ovarian cancer by immunoscintigraphy (Parnovics *et al.*, 1980, 1981; Paticky *et al.*, 1985), suggested that monoclonal antibody targeted therapy could be possible. However studies of antibody uptake by tumour in rat intravenous injections, suggested that insufficient dissemination between tumour and blood as well as low absolute levels of uptake occurred (Epstein *et al.*, 1980). Therefore, a regional, intraperitoneal approach to ovarian cancer seemed logical for many tumours. While over 80% of patients have disease outside the pelvis at presentation, over 70% have disease confined to the peritoneal cavity (Shepherd, 1985). Large i.p. drug concentrations advantages have been demonstrated when chemotherapy has been given intraperitoneally rather than intravenously (Meyer & Collins, 1985) and it has been shown that i.p. injected albumin can penetrate tissue to a depth in excess of 1 cm (Theilick, 1985).

Early, empirical studies were encouraging, however, quantitative studies on the uptake of i.p. injected monoclonal antibodies into solid tumour and ascites were equivocal when solid tumour was considered (Hasson-Smith, Chouk, Cip. At. ICRP, 1984; Epstein, 1986; Ward *et al.*, 1987).

Uptake of i.p. injected monoclonal antibody conjugates into solid tumour was shown to vary markedly both within and between patients, however, when ascites cells were considered, consistently greater uptake and large tumour cell: normal tissue or blood ratios were demonstrated (Ward *et al.*, 1988; Lawson *et al.*, 1986).

It was therefore decided to perform separate studies of i.p. ^{131}I monoclonal antibody therapy in patients with ovarian cancer, recurrent or persistent after conventional therapy, and in patients with recurrent malignant ascites which was not controlled by paracentesis and/or diuresis.

Materials and methods

Patients

Patients with ovarian cancer without ascites had either conventional therapy consisting of radical debulking surgery and platinum containing chemotherapy. All patients were referred after second look laparotomy (Table 1) when further debulking to less than two centimetres disease and full documentation of site and size of tumour nodules was deemed vital.

Patients referred for treatment of recurrent ascites were a heterogeneous group. All patients had reaccumulation of ascites within 6 weeks of paracentesis and, in all but 2 (Cases 9 and 12), despite spiro-lactone orally (Table 1).

Patients were treated after full informed consent had been obtained and these studies were approved, in advance, by the Ethical Committee of St. Bartholomew's Hospital.

Monoclonal antibodies

H4HPC2 2H4HPC2 (Taylor-Papadimitriou *et al.*, 1981) is an IgG₁ source monoclonal antibody directed against an antigen found on a host monoclonal antibody hybridoma population differentially expressed by malignant cells. This antigen is found in the majority of ovarian carcinomas and also in breast, thyroid and gas adenocarcinomas and differentiated neuroblastomas.

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