1184

TOLERANCE OF SMALL BOWEL ANASTOMOSES IN RABBITS TO PHOTODYNAMIC THERAPY(PDT) WITH DIHEMATOPORPHYRIN ETHERS(DHE) AND 630 NM RED LIGHT

TF DeLaney[1], WF Sindelar[2], GF Thomas[1], AM DeLuca[1], JK Taubenberger[3]
[1]Radiation Oncology Branch, [2]Surgery Branch, [3]Laboratory of Pathology, National Cancer Institute, Bethesda, MD 20892 USA

PDT is being evaluated in experimental clinical trials in patients with peritoneal malignancies. Some patients require partial small bowel resection with re-anastomosis prior to PDT because of bulky tumor or focal involvement of small bowel by tumor. To assess the safety of PDT in this setting, the tolerance of small bowel anastomoses in New Zealand white rabbits to PDT with DHE and 630 nm light was studied. With conventional DHE doses of 1.5-2.5 mg/kg given 24 hours prior to surgery and light doses of 0-20 J/cm^2 of 630 nm light, no adverse effects were seen on the healing of small bowel anastomoses. Higher photosensitizer doses of 10 mg/kg and 20 mg/kg in conjunction with 20 J/cm^2 , however, induced failure and breakdown of fresh anastomoses in 2/3 and 4/4 animals respectively. These data will help to define tolerable PDT doses in clinical trials of abdominal PDT.

1185

PHOTODYNAMIC THERAPY IN SQUAMOUS CELL LUNG CANCER

T Sutedja & P Postmus.
Pulmonary Department Free University Hospital Amsterdam, the Netherlands.

Photodynamic therapy (PDT) was performed in 6 patients (pts) with CT-scan negative, <2cm^2 intraluminal squamous cell lung cancer. Pts. were inoperable due to limited pulmonary function. Photofrin II was injected 2 mg/kg 48 hours prior to illumination with 630 nm. wavelength light from a tunable dye laser. Cylindrical diffusers were used for illumination. Follow-up has been 3-7 months. No complication occurred, one pt. developed mild skin photosensitivity. In 2 pts. intraluminal tumor recurred 4 and 6 months post-PDT and pts. were then treated with small volume radiotherapy. In the 4 remaining pts. repeated bronchoscopy and CT-scan did not show tumor recurrence. This prospective study confirms our earlier experience that PDT with curative intent is only justifiable in the treatment of small lesions. Frequent follow-up is indicated because of possible recurrences. The major limitations of PDT remains the limited penetration of red laser light and the lack of in vivo dosimetry.

1186

PHOTODYNAMIC THERAPY (PDT) FOR SUPERFICIAL SKIN MALIGNANCIES USING TOPICAL 5-AMINO-LEVULINIC ACID.

Meijnders PJN[1], Star WM[2], Wijthoff SJM[3], Naafs B[4] & Levendag PC[1]
Departments of Radiation Oncology[1] and Physics[2], Plastic Surgery[3], Daniel den Hoed Cancer Centre; Dep. of Dermatology[4], University Hospital Dijkzigt; Rotterdam, the Netherlands.

Exogenously administered 5-amino-levulinic acid (ALA) can result in an accumulation of protoporphyrin IX (PpIX) in several cell types. PpIX is a heme precursor which is an effective photosensitizer. Kennedy reported on PDT of superficial skin cancer with 79% complete remissions (CR) after 1 and 95% after 2 treatments. ALA was dissolved in a water/oil based cream, which was applied to the lesion and covered with thin gauze and a plastic film. Three hours later the lesions were irradiated with 50-100 J/cm^2 of red or green light. The treatment is self-limiting due to complete photobleaching of the PpIX. Until now 8 patients have been treated in our institute, most of them having basal cell carcinomas (bcc). The first patient with extensive disease was treated since january 1990 on more than 120 fields with areas up to about 50 cm^2. Superficial lesions often showed a CR (clinically and/or histologically). Treatment of 3 patients with 6 small primary bcc's resulted in 5/6 CR (follow up 4, 7, 22 mths). Two patients had extensive recurrent disease in heavily treated areas on the scalp, resulting in 1 failure after 2 months and 1 CR (>15 mths), but with persisting erosion of the skin. One patient showed extensive actinic keratosis and ulceration in the scalp, not responding to conservative treatment, but responded very well to ALA-PDT.
In conclusion, ALA-PDT is a simple and quick treatment for patients with bcc's which does not cause skin phototoxicity. Until now curative results are comparable with standard treatment and good to excellent cosmesis has been achieved without indication of late toxicity. A clinical trial has been started to determine the possibilities of this new modality.

1187

PHOTODYNAMIC THERAPY (PDT) WITH CHLORINS

E. Zhavrid, G. Kostenich and I. Zhuravkin; Research Institute of Oncology and Medical Radiology, 223052 Minsk, Belarus

Chlorins belong to the group of promising photosensitizers with photophysical properties needed for use in PDT. A study of different chlorins was performed in vivo on rats with transplantable tumors. Chlorin e6 was chosen as a basic compound for drug production. We have studied toxicity, pharmacokinetics and photodynamic effect of this photosensitizer on mice and rats. A preferential retention of chlorin e6 in tumors it was found compared with muscules, spleen, liver and kidneys 24-73 h after i.p. or i.v. injection. PDT with chlorin e6 produced a vast tumor necrosis, inhibition of tumor growth rate and cure of the animals. High therapeutic effect was observed at low doses of the agent (3-5 mg/kg) and laser irradiation (45-90 J/sq.cm). For the time being, a drug form of the agent and a novel Nd : YA10 laser system (660 nm, 5 W) have been developed for use in phase I of clinical study

Psychosocial Oncology

1188

INFORMED CONSENT IN EUROPEAN MULTICENTRIC RANDOMISED CLINICAL TRIALS

M Zwitter, CJ Williams.
Institute of Oncology, Ljubljana, Slovenia and University Hospitals, Southampton, UK

An overview was done on the current practice of informed consent in European multi-centric randomised clinical trials. The participants of twelve such studies recently published by European Journal of Cancer were approached with a simple questionnaire, with a response rate of 51/87 (59%). According to the answers, a full information about all the treatment options and on the randomisation procedure had been given by 30 (59%) of the doctors; the rest informed the patient on the proposed treatment arm only, and sometimes also added information on the inclusion in a prospective clinical trial. The 24 doctors from France and Italy were less inclined to reveal to the patient all the information about the randomisation, when compared with the colleagues from non-Mediterranean countries (33% vs 81%). An unexpected, yet most interesting finding of our survey is that the participants in the studies on supportive treatment were much more strict in their adherence to the rules of informed consent, when compared with the colleagues randomising among various chemotherapy, radiotherapy, or surgical treatment options (full information, 87% vs 47%). Further discussion on the real position of informed consent in practice is needed.

1189

KNOWLEDGE OF DIAGNOSIS IN ITALIAN PATIENTS WITH ADVANCED CANCER

P.Pronzato, P.L.Losardo, E.Cantinotti, F.Colombo, D.Dal Mut, L.Pacolini, G.Scopsi, G.Bertelli. Ospedale S.Andrea, La Spezia, and National Institute for Cancer Research, Genova, Italy.

Most studies on the subject of the communication of the diagnosis of cancer come from anglo-saxon countries and could be scarcely relevant for caregivers working in different cultural contexts. We have submitted a questionnaire with 17 items, exploring the knowledge of diagnosis/ prognosis and satisfaction with received informations, to 100 adult italian patients (pts) with advanced neoplasms treated in a general hospital. Despite the fact that most pts were receiving chemotherapy, only 38% were aware of having a malignant cancer. Older pts and males had an even lower level of awareness. On the other hand, 83% of pts express desire to know 'all the truth'. The role of nurses and social workers in this cultural setting will be discussed.