These reports will appear on a monthly schedule whenever available. They are based on information provided by individuals or clinical and research groups pertinent to cancer research. More detailed information if needed may be obtained by writing to
EORTC Data Center
125 Boulevard de Waterloo
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Tel : (2)539.28.05 - Fax : (2)539.03.74

Guidelines for the preparation for publication of reports from EORTC Cooperative Groups

1. The chairman, convener or secretary of the Group is requested to mail the report to the office of the European Journal of Cancer & Clinical Oncology. The reports will be edited and published in the Journal within 6 to 8 weeks after reception in the office.
   Address : Institut Jules Bordet
   Rue Héger-Bordet, 1
   1000 Brussels (Belgium)

2. Please send the report typewritten on one side of page, triple spaced with a 5 cm left margin. Brevity is essential. Tables and figures are difficult to print and should be replaced by an appropriate text.

3. Please consult the reports published in the March 1989 issue of the Journal and consider them as models to be adopted for all reports with possible exceptional adaptations.

4. We request omission of list of names of attendants to the group meetings. Reports should be signed by either the chairman, convener, secretary of the group, or by all three ad libitum.

5. Please add as a conclusion to your report : "Additional information may be obtained by writing to the secretary of the group".

6. Protocols will be published at the request of the groups.

This office will be glad to receive your comments, criticism and suggestions on the edition and publication of your reports.

The Editor.

INFORMATION ON THE DATA CENTER OF EORTC

Telefax : (2)539.03.74

BOOKS

Multimodal Treatment of Ovarian Cancer
Editors : P.F. CONTE, R. ROSSO, N. RAGNI, J.B. VERMORKEN
Monograph Series of the EORTC (Volume 20)
Raven Press, New York, 1989
329 pages
ISBN 0-88167-476-1 (Order Code 1942)

Progress and Controversies in Oncological Urology II
Progress in Clinical and Biological Research Volume 269
Editors : F.H. SCHRÖDER, J.G.M. KLIJN, K.H. KURTH, H.M. PINEDO, T.A.W. SPLINTER, H.J. de VOOGT
EORTC Genitourinary Group Monograph 5
628 pages
ISBN 0-8451-5119-3

REPORT EORTC G.I. TRACT CANCER COOPERATIVE GROUP MEETING PARIS, OCTOBER 7-8, 1988

Chairman : U. METZGER

H. Bleiberg was elected as new Chairman of the Group ; J.C. Pector remains Secretary for one year.

1.0 Recently closed to patients' entry

1.1Rectum

40761 : **Preoperative radiotherapy as adjuvant treatment in operable rectal cancer** (Study coordinator : A. Gerard, Brussels)
Methods : Patients randomized to no adjuvant treatment or preoperative irradiation therapy administered in a dosage of 34.5 Gy divided into 15 daily doses of 2.3 Gy.
Results : Four hundred sixty six patients accrued between June 1976 and September 1981. Tolerance and side effects of preoperative irradiation found acceptable. Overall 5 year survivals similar in both groups. Local recurrence rates at 5 years were 30% and 15% in control group and the adjuvant radiotherapy group respectively (p = 0.003). Results to be published in "Annals of Surgery".

40811 : **Controlled trial of resectable (stage C1, C2, C3) rectal cancer to evaluate postoperative radiotherapy**
Methods : Patients randomised between no radiotherapy and radiotherapy after surgery (46 groups in 23 fractions given in 30 to 38 days).
Results : One hundred and seventy one patients registered until protocol closed in December 1986. Follow up excellent for all institutions, with the exception of 2 which have been excluded from the study. Patients and tumor characteristics similar in both groups. Radiotherapy given after a 34 day median duration after surgery but in 28/76 patients, radiotherapy began after 50 days or more. Four irradiated patients developed an intestinal occlusion. Follow up is continuing.

1.2 Colon

40812 (Study coordinator : U. Metzger, Zürich).
To determine if the use of 5FU through the portal vein improves survival of patients who received curative surgery for colorectal cancer.
Treatment schedule : patients who had curative resectable colon cancer (Dukes A-C) distributed in 3 groups : 1) no adjuvant therapy ; 2) portal vein perfusion with 5000 IU heparin/day for 7 days ; 3) portal vein perfusion with 500 mg/m^2 5FU + 5000 IU heparin for 7 days.
Results : Up to June 1987, 245 patients have been randomized. Due to a low accrual rate patient entry has been stopped. The treatment was well tolerated and toxicity was low. Data on disease free survival and survival not yet available.

40781 : **Double blind phase III clinical trial of adjuvant levamisole versus control in resectable Duke's C colon cancer** (Study Coordinator : J.P. Arnaud, Strasbourg).
Objective : determine the effect of levamisole on survival of patients who received curative surgery for colorectal cancer.
Treatment schedule : two to five tablets of 50 mg levamisole versus placebo daily, depending on body weight, for one year.
Results : from 1978 to 1987 297 patients were entered. Levamisole was generally well tolerated, with only four reversible cases of agranulocytosis reported among 129 patients. There was no benefit from levamisole on disease-free survival or on survival. The final results will be published in the "British Journal of Surgery".

40833 : **Randomized phase II study of a combination of cisplatin (DDP), 5-fluorouracil (5FU) and allopurinol (HPP) versus 5FU in advanced colorectal carcinoma** (Study Coordinator : H. Bleiberg, Brussels).
Objective : Improve the therapeutic index of fluorouracil by combination with cisplatin as enhancing agent and to allopurinol as toxicity modulator.
Treatment : Patients with measurable colorectal carcinoma, previously untreated by chemotherapy were randomised to receive either 5FU alone 500 mg/m^2 push IV d 1-5 or allopurinol 3x300 mg p.o., d 1-5, 5FU 800 mg/m^2 push IV, d 3-5 and DDP 50 mg/m^2 d 6. Treatment was repeated every 4 weeks.
Results : Six partial responses seen in each treatment group (15%) and the median survival was 7 months. Hematologic toxicities comparable in both treatment groups. Patients in the allopurinol group had less diarrhea (33 vs 43%) and stomatitis (10 vs 43%).

2.0 Active trials

2.1 Colon

40872 : **Randomised phase II study of low dose methotrexate (LD-MTX) plus high dose 5-fluorouracil (HD-FU) versus HD-FU in advanced or metastatic colorectal carcinoma** (Study Coordinator : G. Blijham, Maastricht).
Objective : To assess the response rate of high dose 5FU combined with low dose MTX.
Treatment : Patients randomised to receive 5FU 60 mg/kg IV as a continuous 48 h infusion every week for a total of 4 doses, then every other week for another 4 doses with or without MTX, 40 mg/m^2 IV push before and 48 hrs infusion with 5FU.
Results : Up to September 1988, 66 patients have entered the trial. Toxicity grade 3 was noted in 2 patients in the high dose arm and in 3 patients in the low dose arm. No data available yet concerning response rates.

40863 : **Pilot study on the regional treatment of colorectal liver metastases by intermittent arterial ischaemia with degradable starch microspheres (DSM) and arterial and portal infusion with mitomycin-C plus 5FU** (Study Coordinator : Civalleri).

Objective : Evaluate the therapeutic value of combination arterial and portal chemotherapy with mitomycin C bolus infusion plus 5FU continuous infusion associated with arterial embolization with DSM.
Treatment : Before starting chemotherapy the arterial catheter perfusion of the liver and the vascularity of metastases are evaluated by an intraarterial perfusion scan.
DSM administration is monitored using a sodium-iodine detector connected to a one-channel analyzer and the pulses collected are further processed using a computer with a printer.
Mitomycin C 10 mg/m^2 is given on day 1 2/3 by arterial route mixed with DSM, 1/3 by portal route. 5FU 500 mg/m^2 to be given as a continuous infusion from day 1 to 5.
Results : Fourty patients entered in this study. Major difficulty due to portal catheter mobilisation occurred. A new study excluding the portal route will be designed.

2.2 Hepatocarcinoma

40861 : Double blind clinical trial of an antiandrogen therapy versus a placebo in unresectable hepatocellular carcinoma (Study Coordinator : H. Bleiberg).
Objectives : To test the activity of anti-androgen therapy in terms of tumor response and survival.
Treatment : Patients to be randomised to receive Ananandron + placebo or Zoladex + placebo, which will all be administered with the same schedule.
Results : Up to September 1988, 49 patients have been randomised. No major side effects were reported.

40871 : A simple large scale, randomised phase III trial on hepatic perfusion of 5FU and heparin in resectable cancer of the colon and rectum
Objectives : To determine if adjuvant therapy with portal vein perfusion of 5FU + heparin improves survival and/or time to disease recurrence in patients with colorectal cancer after potentially curative surgery. The treatment hopes to detect an improvement of 70 to 80% over surgery alone.
Treatment : Patients randomised to the control group will receive no further treatment after surgery. Patients randomised to the treatment group will receive 500 mg 5FU/m^2 + 5000 IU of heparin per 24 hrs for a total of 7 consecutive days.
Results : Up to September 30, 1988, 209 patients were registered. Contacts were taken with other groups which could enter patients in this trial.

3. New protocols

Dr. J. Jeekel (Rotterdam) presented a draft protocol for patients with pancreatic cancer who underwent a pancreatectomy with a curative aim. Patients to be randomized after surgery between a control arm and an arm combining radiotherapy (2x 20 Gy with an interval of 2 weeks) and 5-FU (25 mg/kg/day during days 1 to 4 of radiotherapy). The final version of this protocol will be submitted to the next session of the PRC.

REPORT EORTC HEAD AND NECK CANCER COOPERATIVE GROUP MEETING
PARIS, SEPTEMBER 28, 1988

Chairman : G. Snow (Amsterdam)

1. Review of ongoing studies

24842 : Phase II trial of cisplatin, methotrexate, bleomycin and vincristine (CABO) vs cisplatin and 5-fluorouracil (CF) v s cisplatin alone (C) in patients with advanced squamous cell carcinoma of the head and neck (Study Coordinator : M. Clavel).
Three hundred eighty two patients entered the trial up to the last EORTC Head and Neck meeting when the study was closed for accrual. Three hundred sixty nine patients were reviewed ; 18 not eligible. Thirty not evaluable for response. Three hundred twenty one patients fully evaluable. Fourty five patients were not pretreated. No patient received prior chemotherapy. The overall response is summarized :

%	CABO	CF	C
CR	11% C1* (5-18)	1% (8-4)	4% (0-8)
PR + CR	37% (27-47)	33% (22-43)	14% (6-21)

C1* is the 95% confident interval.

The comparison between the 3 arms shows a significant difference. CABO and CF are significantly better than C for the overall response. There is a trend in favour of CABO versus CF in regard to CR rate. No difference was found in either hematological or non hematological toxicity.

24844 : Randomized trial of 5-fluorouracil/cisplatin as induction chemotherapy followed by surgery and postoperative irradiation versus surgery and postoperative irradiation alone in the treatment of advanced squamous cell carcinoma of the lateral oropharynx and the lateral posterior oral cavity, a phase III study (Study Coordinator : G.B. Snow).
Until now nearly 80 patients have been entered. The study coordinator will prepare an interim report early next year to be presented at the Spring meeting of the group. On quite a few patients, however, data are still missing and the participating institutions are once more requested to send the missing data to the Data Center at their earliest convenience.

24851 : Phase II study of 4'-epidoxorubicin in recurrent or metastatic adenoid cystic carcinoma of the head, and neck (Study Coordinator : J.B. Vermorken).
Seventeen patients have now been entered of whom 16 are evaluable. Complete or partial responses were not noted, so that according to WHO criteria epirubicin is not active in this disease. However, 3 patients had symptomatic improvement, one of whom is now without symptoms for more than 2 years. This study is now closed (see for next study on adenoid cystic carcinoma under report of subcommittee on chemotherapy).

24871/08871 : EUROSCAN : intensive screening and/or chemoprevention, with vitamin A and/or N-acetylcysteine, of second primary cancer in patients curatively treated for carcinomas of the larynx, oral cavity and lung (Study Coordinators : U. Pastorino, N. de Vries, N. van Zandwijk).
Until now 25 patients have been entered, although 30 institutions in the European countries have been provided with medication. Ethical committees, regulations and initial organization within the participating centers are the main causes of the delay in accrual. By this time most of these problems have been solved and it is hoped that many patients will be entered in 1989.