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NURSING PROTOCOL FOR EFFECTIVE ADMINISTRATION OF AMIFOSTINE

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Cisplatin is an effective cytostatic agent but has a number of potential side effects, including leuco- and thrombocytopenia, neuro-, oto- and nephrotoxicity. Amifostine (Ethyol®) is a radio-protective (and possible chemoprotective) drug developed by the US Army. In clinical trials amifostine appears to reduce cisplatin and carboplatin associated toxicity.

Amifostine has a number of side effects, the most important are nausea, vomiting and hypotension. These side effects are acute and most uncomfortable for the patient. With good nursing care and the use of adequate antiemetics nausea, vomiting and hypotension is well controlled. Based on our experience during the last 2 years (45 patients with either cisplatin or carboplatin with amifostine) we developed a nursing protocol so that amifostine can be given with maximum safety, ensuring comfort for the patient. Amifostine given according to a strict nursing protocol is well tolerated and easily administered. Complications are reduced to a minimum.

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REPORT OF A RESEARCH NURSES' EXPERIENCE IN IMMUNOTHERAPY COLLABORATION BETWEEN AN INTENSIVE CARE UNIT AND AN ONCOLOGY CENTER

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In recent years, the participation of the nurses in clinical trials has become necessary and a new role has developed.

In the Immunotherapy Unit, patients with metastatic renal cancer or metastatic melanoma receive Interleukin-2 or Interferon infusion following complex research protocols.

The clinical research nurse or clinical research assistant does the link between patients, principal investigators, medical doctors, nursing staff and all the other health care professionals.

She is responsible at 3 main levels: patients, protocol and staff.

(1) She has to welcome, inform, teach patients and family, obtain signature of informed consent, contribute to the improvement of the well being and quality of life of the patient during the treatment, as well as to give psychological support and comfort, then follow-up those patients.

(2) She is responsible for running the study following ethical aspects, the Good Clinical Practice, the written protocol obligations in order to ensure the quality of care and the security of patients, ensuring the availability of the biotherapy drugs, and management of stocks in relation with the chemistry unit, for organizing specific blood samples collection and try to reduce the amount of blood collection with the laboratory, for running specific nursing or medical protocols to deal with adverse events (vomiting, fever, venous catheter...) and report toxicity due to treatment, for collecting data and data management, for participating to the evaluation of results.

(3) Relations with health care professionals: with the nurses, she contributes to the information and teaching about follow up of patients, results of the study, specific care; with the medical doctors, she has to be the link between the Cancer Institute with the principal investigator responsible for the inclusion and follow up of patient, and the Intensive Care Unit responsible for the administration of treatment and care of the patients. In general, she tries to implement meetings between all participants of the study, to participate in decisions taken about protocols, for writing articles and developing new functions, to motivate the staff nurses.

As clinical research and clinical trials are becoming more and more complex, the role of the research nurse becomes critical and essential in order to improve the quality of care and quality of life of patients; and therefore to assure consistency and reliability of the study.

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NURSING MANAGEMENT OF PATIENTS WITH METASTATIC MELANOMA TREATED IN DAY HOSPITAL (D.H.) WITH: CIS-PLATIN (CDPP), DACARBAZINE (DTIC), INTERLEUKIN (IL-2), TAMOXIFEN (TAM)

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The goal of nursing care in this protocol is to improve the patients' (pts) quality of life during this treatment and to reduce the time of treatment in D.H.

Treatment: day 1: CDDP 100 mg/m² e.v.—DTIC 750 mg/m²—TAM per os. After CBC and biochemistry the patients started the treatment according to the following schedule: 5HT antagonist infusion (20 min), hydration with 500 ml normal saline plus furosemide (30 min), diuresis control (>300 ml) CDDP 50 mg/100 ml normal saline (45 min)—hydration 1500 ml (2 hours)—DTIC in 500 ml of normal saline (1 hour)—5HT antagonist infusion (30 min). The time necessary to complete the treatment and to educate the patients is about five hours. During the treatment the nurses give to the patients informations about the sequence and duration of treatment—reasons for antiemetic, diuretics and hydration—education and dietetics advices before, during and after treatment. Moreover the nurses educate the patients for home care on the use of antiemetic drugs for os, dietetics advices, anticipations of side effects (fatigue, nausea and vomiting, danger for infection and bleeding, alopecia, mucositis), check for the correct TAM schedule and side effects. From day 12 to day 23 the patients receive IL2 and the nurses control the blood pressure and the premedication with aspirin, indomethacin and torecan before IL2 administration; at the end of IL2 the nurses check the blood pressure and give information about the side effects (fever, myalgia, hypotension, nausea and vomiting, diarrhea, sleeplessness, chills, itching). With this intense nurses—patients relationship we have achieved the following results: (1) The waiting time before IL2 administration was reduced (2) The side effects of IL2 were significantly reduced because of a better management (3) The informations collected from the patients were more detailed and precise as we went on with this treatment. We feel that a good nurse/patient relationship can improve the wellbeing of the patients during this toxic treatment.

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ARE SIDE-EFFECTS OF ADJUVANT RADIOTHERAPY ACCEPTABLE?

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As the benefit of adjuvant radiotherapy is not clear-cut as regards gynecologic malignancies, side-effects should be kept at an acceptable level. Thus, nursing aspects are especially important. The aim of the study was therefore to study quality-of-life issues.

41 patients completed self-questionnaires (18 questions, mainly 4-point and 5-point Likert-like questions) before treatment, after 1 and 4 weeks of treatment and 6 weeks after treatment, respectively.

Results: Before treatment, only a few patients had subjective symptoms. At the end of treatment the percentages of any problems/daily problems were as follows: fatigue 92%/34%; diarrhoea 89%/39%; flatulence 86%/43%; nausea 64%/23%; abdominal pain 38%/23%; bladder problems 43% gyn problems 39%. When medication was needed, a good or satisfactory effect was achieved in 100%, 94% and 78% as regards diarrhoea, nausea and flatulence, respectively. Despite the side-effects, 86% reported that radiotherapy was less burdensome than expected. Nursing aspects (diet, information, psychological support) were important.

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NEW HORIZONS AND NEW PERSPECTIVES IN CANCER NURSING: THE ROLE OF THE NURSE IN A GENETIC THERAPY UNIT

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A study, testing the feasibility of administering, intratumorally, a defective recombinant adenovirus containing the E. Coli Beta-Galactosidase gene, is ongoing at the Institut Gustave-Roussy in patients with inoperable lung cancer. Five patients have been included since September 1994

in the study phase 1 in which 3 patients are to be included at each dose level (3 levels).

In accordance with the recommendations of the commission for Genetic Engineering of the Ministry of Higher Education and Research, patients are to be isolated in type TL2 facilities during hospitalization.

The constraints imposed upon health care providers participating in the study and the practical implementation of the study itself:

- 1—Application of isolation measures
- 2—Protection of the environment
- 3—Measures for the protection of personnel and to ensure that they are continually informed
- 4—Preparation, transport and handling of the adenovirus
- 5—Administration of chemotherapy and fiberoptic endoscopy examinations at the patient's bedside
- 6—Handling and outcome of biological fluids
- 7—Transport, selection and renewal of material
- 8—Care from a psychological point of view, of the patients and families faced with isolation
- 9—Organizing daily surveillance of patients
- 10—Description of measures to be employed when faced with an emergency will be described.

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OUTPATIENT NURSING CARE OBVIATES HOSPITALIZATION OF CANCER PATIENTS TREATED WITH HIGH-DOSE CYCLOPHOSPHAMIDE (HD-CTX)

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HD-CTX (7 g/m²) is an effective anticancer treatment for lymphoma and breast cancer patients. The pancytopenia that follows HD-CTX can be substantially ameliorated by administration of hematopoietic growth factors (i.e., GM-CSF, G-CSF, or a combination of IL-3 and G-CSF). Until recently, we cared for HD-CTX-treated patients by protective isolation to avoid infectious complications. In order to eliminate isolation and to reduce days of hospitalization, we elected to discharge patients shortly after HD-CTX administration and care for them on an outpatient basis. Patients were readmitted in the hospital only for grade 4 febrile neutropenia and/or thrombocytopenia. We compared the outcome of two groups of patients similarly treated with HD-CTX and cytokine(s), nursed by protective isolation or followed in the outpatient clinic, respectively. Days in the hospital were in median 15 versus 8.5 ($P < 0.003$), and days of isolation were 8 versus 0, respectively. Treatment-related complications, days of neutropenia, transfusion requirements, days of antibiotic treatment, and days with fever $\geq 38.5^{\circ}\text{C}$ did not differ between the two groups. We conclude that outpatient nursing care of HD-CTX treated patients can obviate hospitalization and improve quality of life of these patients, and increase the treatment capabilities of transplant Units.

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SPECIAL INTEREST GROUP (SIG) FOR ONCOLOGY RESEARCH NURSES IN DENMARK

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In Nov. 1993 the Danish Oncology Nursing Society initiated the formation for a country-wide SIG for oncology research nurses (ORN). A group of ORNs first met in Feb. 1994. The goal of the SIG was to gather an expert group of ORNs providing opportunities for network within the field of clinical oncology research. The SIG has 4–5 meetings per year, activities within clinical research, education and publishes a news letter twice yearly. In Jan. 1995 the SIG launched the first multidisciplinary symposium for all research nurses in Denmark focusing on clinical research, ethical issues and GCP. As a result a country-wide, multidisciplinary SIG for research nurses has been formed in order to facilitate further development in the area. In the future the SIG will focus on new educational activities and cooperation with a possible European SIG for ORNs under EONS. The group has established a firm basis for a dynamic development in the area. Further details on objectives, organization, and key tasks will be presented.

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GENETICALLY-MODIFIED AUTOLOGOUS TUMOR CELLS IN PATIENTS WITH MELANOMA; A PHASE I STUDY

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The major end points of many phase I studies of immunotherapy are toxicity and the determination of the optimal biological response modifying dose. We are conducting a phase I study with Somatix Therapy Corporation in which patients with progressive, advanced melanoma are vaccinated three times with irradiated, autologous tumor cells transduced with the gene for granulocyte macrophage colony stimulating factor. The major goals of this study are to determine the safety and toxicity of this treatment and to evaluate the immune response.

The most important implications for nursing care are patient information and support as well as the assessment of toxicities. One of the problems is that despite extensive information about the experimental nature of the study, patients still have high expectations of a significant tumor response. Although patients have advanced melanoma and are incurable, many are without physical complaints making it difficult for them to accept the severity of their illness. It is therefore important that realistic expectations are emphasized without denying the patient hope. As signs of disease progression develop, it becomes easier for the patient and family to accept the physical and psychosocial aspects of advanced disease.

Genetically modified vaccines are likely to be an important development in the treatment of patients with cancer. Nurses, as members of the multidisciplinary team have an essential role in the development of this treatment modality as well as developing new ideas regarding the care and support of these patients.