

TUESDAY 16 SEPTEMBER 1997

Teaching Lectures

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Axillary dissection – How and when do I do it?

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When I do axillary dissection: complete (three levels) axillary dissection has been routinely performed in any case of primarily operable invasive cancer. Since the indication of axillary dissection has been discussed, in the frame of two controlled studies, for T1NO tumours, traditional surgery has been compared to wide resection without axillary dissection. The study slightly differ in that the first considers women over 65 years, whereas the second one has been focused on patients under 65 years. The women of the experimental arm (no axillary dissection), for whom nodal status is unknown, will receive adjuvant therapy on the basis of biologic prognostic factors, as determined on primary tumour.

How I do axillary dissection: the technique of axillary dissection cannot be described in detail here. It will be shown during the presentation. Generally speaking, axillary dissection has been always performed in continuity or in discontinuity, with separate incisions, depending on tumour size. The dissection is complete, up to the apex of the axilla, removing the nodes of the axilla, removing the nodes of the three levels. Minor pectoral muscle is usually preserved.

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Adjuvant systemic therapy (AST) for breast cancer: Facts and open questions 1997

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AST reduces relapses and prolongs survival of women with operable breast cancer. This is true for all studied subpopulations (i.e., N+ and N– disease, pre- and post-menopausal ages). The overall effect of the adjuvant systemic therapies is modest but clinically and humanly relevant. Adjuvant endocrine therapies include tamoxifen and, for premenopausal patients, ovarian ablation. Adjuvant chemotherapy regimens mainly include CMF or anthracycline-containing regimens. In postmenopausal women, the use of the two modalities (endocrine and cytotoxic) together has proven to be more beneficial than each modality alone, but optimal combinations are still in trial. Examples for issues under current investigation are:

- (a) Novel chemotherapies (e.g., taxanes) and endocrine therapies (e.g., GnRH analogs, use of aromatase inhibitors)
 - (b) High-dose chemotherapy with marrow support
 - (c) Integrating pre- and postoperative systemic treatments
- The selection of adjuvant systemic therapies outside trials include:
- (a) Determination of risk of relapse
 - (b) Extrapolating relevant data from results of clinical trials
 - (c) Integrating patient's preference with physician's "best bet"

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Design and regulations of clinical trials

P. Therasse. *EORTC Data Center, Brussels, Belgium*

There haven't been any profound changes with regards to the methodology of clinical trials over the last decade. However in the particular area of oncology some new concepts have emerged. A lot of work has been done to better investigate the socio-economical aspects of cancer treatment in clinical trials. Biases of selection in late phase II studies can be eliminated by the introduction of control groups and the speed of development of new treatment strategies has been improved with intergroup studies and also with an innovative approach for phase II–III trials based on early stopping rules. From a regulatory point of view a major step forward has been initiated with the implementation of the European Good Clinical Practice (GCP) guidelines and more recently with the acceptance of the

International Conference on Harmonization (ICH) GCP guidelines. Most European countries have now implemented specific and constraining rules for conducting clinical trials which have an heavy impact on academic programs. The official European guidelines for the testing of new anticancer agents has been revised and under specific conditions "response rate" has been confirmed as an acceptable evaluation criteria for registration purposes. All these aspects will be discussed during the oral presentation.

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Surgery for metastatic disease

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From the stage of the appearance of a subpopulation of cells within the primary tumor to the formation of a secondary tumor The metastatic cell has to survive a complex cascade of events at the target organ. Once a metastases or a recurrence develops the chances for cure are markedly diminished. Surgery however carries the best chance for cure, palliation or adjuvant therapy. Selection of proper therapy requires; knowledge of the tumor biology, host tumor interactions, the accurate stage of the disease, knowledge of prior treatment and their implication, understanding the strength and weakness of the surgical procedure, asses the patient's expectations and understanding of the risks involved. Once the goals are realistically defined curative surgery utilizing major resection, palliative or adjuvant surgery can be applied. The combination of surgery with new technologies may increase the efficiency of this procedure. Surgery can also assist in the application of new treatment modalities such as; the use of biological modifiers with or without high dose chemotherapy and genetic therapy. The various surgical possibilities and procedures that can be utilized will be discussed.

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Current status and treatment of endometrial cancer

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Endometrial cancer is the fourth most common malignancy in women, accounting for about 34,000 new cases and 6,000 deaths every year in the USA. The 5 year survival rate in women who develop endometrial cancer is around 80%, which is higher than cervical (70%) and ovarian (45%) cancers, but it is still disappointing mainly because most patients present early with disease. It is only 10 years that FIGO moved the clinical staging of this disease to a surgical one, thus impacting upon a better definition of prognosis and saving unnecessary overtreatment, or allowing further therapy. Surgical staging permits additional knowledge regarding the true virulence of this tumor which may be important for accurate prognostic stratification and decisions in treatment approaches. Radiation therapy has played the prime role in adjuvant therapy for many years, but the role of adjuvant chemotherapy is receiving increasing attention. Salvage chemotherapy for the patient with recurrent or metastatic disease remains predominantly palliative. Some gynecologic oncologists advocate the use of laparoscopy combined with vaginal hysterectomy to perform complete surgical staging of endometrial cancer. Pelvic and para-aortic laparoscopic lymphadenectomies have been performed successfully both in animal models and humans. However, some issues are to be discussed, regarding women with endometrial cancers: 1) the feasibility of laparoscopic node dissection; 2) the role of vaginal hysterectomy; 3) the laparoscopic technique; 4) indications or applications; and 5) cost and benefit to the patient.