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THE QUALITY OF SURGERY AS A PREREQUISITE FOR BREAST CONSERVATION

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The main innovation in the treatment of primary breast cancer has been the substitution of the radical mastectomy by a limited breast surgery, removing only a portion of the mammary gland. Different definitions were introduced to describe the new techniques: wide resection, segmental mastectomy, quadrantectomy, lumpectomy, sector resection. How much normal tissue must be removed around the margins of primary carcinoma remains to be defined, all studies showing however that the larger is the resection the lower is the incidence of local recurrences. One of the reference points considered in the past an important one in deciding the extension of the excision is the histological involvement of the resection margins: recent studies have however shown that the predictive value of negative or positive margins is very limited. An important variable is the extensive intraductal component (EIC) of the excised tumor; in cases with EIC the risk of local recurrences is much higher than in cases without EIC, likely due to the fact that in EIC positive cases an extensive invasion of the ductal tree may be present around the primary carcinoma. Finally, an important factor is the age of the patient, being the risk of local recurrences progressively reduced with the increase of the age

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QUALITY ASSURANCE IN BREAST CANCER RADIOTHERAPY.

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The success of radiotherapy in the overall management of primary breast cancer depends upon the quality and accuracy of treatment. Treatment techniques are relatively complex and require accurate planning and precise set-up in order to achieve homogeneous dose distribution within the target volume while only minimally irradiating heart and lung tissue.
A comprehensive QA program which establishes and documents the operating policies and procedures of an institution has an essential role in the delivery of optimal treatment. Such a program involves objective, systematic monitoring of the quality and appropriateness of patient care both in routine practice and within the framework of either single or multi-institutional clinical trials. The QA program should encompass structure (staff, facility, equipment), process (pre-and post treatment evaluation, actual treatment application), and outcome (survival, tumor control, complications).
A well-implemented QA program will help to avoid protocol deviations, particularly in multi-institutional clinical studies, and to quantify inevitable intra- and interdepartmental variations in treatment parameters. The QA activities of the EORTC Radiotherapy Group are models of this type of program, and include a dummy run procedure, an immediate review of case report forms, an individual case review, in vivo dosimetry studies with independent verification of mailed TLDs, and a phantom dosimetry study.

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PATIENT DOCUMENTATION AS AN ESSENTIAL TOOL FOR QUALITY ASSURANCE IN THE MANAGEMENT OF BREAST CANCER

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Quality assurance (QA) in breast cancer management is concerned with determining whether the most effective and efficient strategies of care are selected and implemented in a correct way in all patients. Within the QA triad (Donabedian's structure, process and outcome) the measurement of process (the treatment actually delivered to patients) has been the most frequently used procedure.
Since patient documentation plays a crucial role in determining whether optimum management has been achieved, minimum criteria for the documentation of staging and diagnosis (clinical, radiological and pathological), as well as guidelines for the documentation of the treatment process (surgery, radiotherapy, chemotherapy) and outcome (tumor effect and toxicity) need to be developed in order to provide the clinician with essential information that will guarantee and support the safety, accuracy and quality of treatments.
The discussion will concentrate on QA activities in the field of breast-conservation where the efficacy and effectiveness are greatly influenced by the precision of both surgical and radiotherapeutic techniques. QA studies in radiotherapy have highlighted several weak points in the treatment procedure which relate to the level of accuracy of patient documentation, transfer of information between the different disciplines involved, treatment prescription and the practical aspects of the execution of the therapy. Surgery depends to a greater degree on the experience, skill and technique of individuals. This makes it more difficult to score the results of the surgical intervention on a multi-institutional level. A QA programme of surgical breast-conservation techniques (breast and axilla) has been activated which should enable the analysis of treatments delivered while highlighting the variations and identifying the surgical parameters which may have a major impact on the outcome. This will allow a.o. the production of surgical reports with all the required predetermined information. These reports will be correlated with a similar reporting procedure that will be established for pathology.

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THE CORRECT PATHOLOGICAL EVALUATION OF THE SPECIMEN AFTER BREAST CONSERVATION SURGERY

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About 60% of invasive breast cancers are multifocal, of which approximately 15% have a very high multifocal tumor burden, usually of the intraductal type (extensive intraductal component; EIC), outside the invasive mass. On the other hand, about 40% of invasive breast cancers are unifocal, having no tumor foci beyond the index tumor. Optimal therapy may vary for these groups of cancers from breast-conserving surgery with or without local radiotherapy to mastectomy. This therapeutic choice is largely based on the expected amount of residual tumor left behind after an excisional biopsy. Optimum pathology supported by specimen X-ray and high quality mammography is capable to predict the type and amount of potential residual tumor in most of the cases. In a recent study on a series of 149 patients, the amount of DCIS within 1 cm from the invasive edge of the primary, and the size of margin-width around the primary turned out to be the most important factors in the assessment of residual tumor after an excisional biopsy. An adequate pathologic evaluation of the margins requires a proper orientation and the inking of the entire surface of the specimen. Subsequently the specimen should be X-rayed, first intact to permit comparison of the lesion with that of the preoperative mammograms, and then after sectioning at 4 to 5 mm intervals to allow the assessment of the margins in 3 dimension. A tissue margin of 1 to 2 cm around the index tumor is necessary to enable the identification of the highly important and less important multifocal tumors and their unifocal counterpart.

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COSTS AND BENEFITS OF CHEMO-ENDOCRINE TREATMENTS FOR OPERABLE BREAST CANCER.

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Clinical trials of adjuvant therapies usually measure the effectiveness of treatments by comparing disease-free survival or overall survival. These take into consideration only indirectly the quality of life experienced by the patients. Some approaches have been developed to assess the impact of adjuvant therapy on the quality of life of breast cancer patients. Other methods were created to compare treatments based on time spent without symptoms of disease and toxicity (TWiST). Considerations of early effects of chemotherapy, late effects of chemotherapy and endocrine manipulations are component of an evaluation using such methods. The integration of quality of life assessment (patients' perception) and comparison of the duration of times spent with or without events influencing such perception will provide a new tool for evaluating benefits from treatments given in the adjuvant setting.

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DESIGN AND CONDUCT OF CLINICAL TRIALS IN BREAST CANCER. REPORTING OF THE RESULTS