rienced progressive disease (PD) at 6 months on subsequent endocrine therapy. Among the remaining 20 women who progressed at 6 months on fulvestrant, there were four with SD and 16 with PD at 6 months on subsequent endocrine therapy. Of these 27 women, 22% (n=6) therefore achieved OR/SD at 6 months of therapy using another (third- to sixth-line) endocrine agent (anastrozole = 4; exemestane = 1, megestrol acetate = 1). It can therefore be concluded that further endocrine response can be induced in a reasonable proportion of women after failure with fulvestrant.

Thursday, 21 March 2002 16:30–18:00

PROFFERED PAPERS

Surgery, including reconstructive surgery

226 ORAL

Efficacy of contralateral prophylactic mastectomy in BRCA1/2 mutation carriers with previous unilateral breast cancer

H. Meijers-Heijboer, M. Menke-Pluymers, C. Seynaeve, W. van Putten, M. Tilanus-Linthorst, E. Crepin, B. ven Geel, C. Brekelmans, J. Klijn.
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Introduction: Unilateral breast cancer (BC) patients with a BRCA1/2 gene mutation have a high risk of contralateral BC and frequently opt for contralateral prophylactic mastectomy (CPM). For this group of patients there are no data on the efficacy of this procedure in reducing the incidence of contralateral BC. Further, the effect on overall survival (OS) is unknown.

Patients and Methods: Included were BRCA1/2 gene mutation carriers with unilateral BC diagnosed after 1-1-1982. Excluded were patients with tumor stage IIIb or higher as well as patients with symptomatic synchronous bilateral BC or previous other invasive cancer. Follow-up started at 1-1-1992 or date of first BC if this was after 1-1-1992. In this way 117 affected carriers were selected, out of which 39 opted for CPM and 78 for surveillance (S). Kaplan-Meier survival curves were used to compare the incidence of contralateral BC between both groups.

Results: Mean age at diagnosis of the primary BC was 40 years (range 30-65) in the CPM group and 41 years (22-73) in the surveillance group (p=0.36). The median duration of follow-up after CPM was 3 years (0.4-9.4); for the surveillance group this was 5.2 years (0.6-9.6). 72% of the CPM group and 38% of the S group opted for prophylactic oophorectomy (PO) (p=0.001). Tumor stage distribution did not differ significantly between the groups. Unexpectedly, tweo invasive breast cancers (3 and 7 mm, resp.) were found at CPM. No incident contralateral BC cases occurred after CPM, whereas 19 cases (24%) of contralateral BC were found in the surveillance group, giving a yearly incidence of 4.3%. This difference was statistically significant (p=0.01). Multivariate analyses, correcting for the effect of PO and adjuvant treatment, on contralateral BC incidence and OS are ungoing and will be presented at the conference.

Conclusion: Contralateral prophylactic mastectomy significantly reduces the occurrence of contralateral BC in BRCA1/2 gene mutation carriers with previous unilateral BC.

227 ORAL

Surgical outcome in patients with nonpalpable breast malignancies detected in a screening program

F.D. Rahusen[1], M.J. Koppe[1], O. Visser[2], J. Benraadt[2], A. Labrie[2], S. Meijer[1]. *[1] Vrije Universiteit Medical Center, Surgical Oncology, Amsterdam, The Netherlands; [2] Comprehensive Cancer Center Amsterdam, IKCA, Amsterdam, The Netherlands*

This study was undertaken to investigate the surgical outcome in patients participating in a national screening program. In view of published guidelines for the management of nonpalpable breast tumors, particular focus of this study was on the use of a preoperative needle biopsy and the number of surgical procedures that patients had to undergo before completion of treatment.

Methods: Patients with nonpalpable breast malignancies detected during a two year screening period were subject of this retrospective study. Mammographic appearance, diagnostic interventions and tumor related variables were assessed in relation to radicality of the first tumor excision, the incidence of residual disease in the re-excision and the total number of surgical interventions.

Results: Of all resected nonpalpable tumors, 101 were pure' DCIS, 141 were invasive cancers with a DCIS component and 141 were invasive only. The presence of microcalcifications on mammography in 184 patients was indicative of the presence of DCIS in 169 resections (92%). The initial operation was a wire guided excision in 376 of 383 included patients. Clear margins were obtained in 58% of all patients. Factors independently related to the radicality of excision were: a preoperative diagnosis ($p = 0.01$), the presence of DCIS ($p = 0.04$) and tumor size ($p = 0.001$). A single surgical procedure was done in 88% of patients with a (pre-)operative histological diagnosis, in 45% of patients with positive cytology and in 13% of patients without a preoperative diagnosis. Residual disease upon re-excision was dependent on margin status ($p < 0.001$), multifocality of the primary tumor ($p = 0.001$) and the presence of DCIS ($p = 0.001$).

Conclusions: A preoperative histological diagnosis will greatly increase the likelihood of a one stage definitive surgical procedure for women with nonpalpable breast cancer. Margin clearance of nonpalpable breast cancer is dependent on both a preoperative diagnosis and primary tumor characteristics. A better compliance with guidelines concerning the use of a preoperative needle biopsy is likely to improve surgical outcome and decrease the number of surgical interventions.

228 ORAL

Ultrasound guided lumpectomy is superior to wire guided resection of nonpalpable breast cancer: a prospective randomised trial

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The wire guided excision of nonpalpable breast cancer often results in tumor resections with inadequate margins. The use of intraoperative ultrasound (US) is emerging as an alternative guiding tool for the resection of nonpalpable breast tumors. We investigated whether intraoperative US guidance enables a better margin clearance than the wire guided technique in the breast conserving treatment of nonpalpable breast cancers.

Methods: Patients with histologically confirmed nonpalpable breast cancers, that could be visualized with both US and mammography, were randomized to undergo either a wire guided or US guided excision. The US guided procedure was done with a 10Mhz, 3 cm probe in a sterile sheath. Adequate margins were defined as equal or more than 1 mm. Margin clearance, specimen weights and cost-effectiveness of both treatments were compared.

Results: After randomization, 26 patients were to undergo US guided resection and 23 to undergo wire guided resection. One patient underwent US guided excision after a wire dislocation in the operating room. Of 27 US guided excisions, 1 patient (4%) was found to have focally positive margins, 2 patients (7%) had close margins (< 1mm) and 24 patients (89%) had radical margins. Of the wire guided excisions, 4 patients (18%) had positive margins, 6 had close margins (27%) and 12 had radical margins (55%). From the outset radical margins were defined as 1 mm or more. Therefore, the US guided procedure resulted in significantly more patients with radical resections than the wire guided excision: 89% versus 55% respectively [p = 0,007 in chi-square analysis]. Mean tumor size and specimen weight were 1.36 cm and 53 gram respectively in the wire group versus 1,34 cm and 51 gram in the US group. The duration of operation was identical in both groups. The total cost of radiological procedures amounted to 206 Euro for the wire-guided procedure and 65 Euro for the ultrasound guidance.

Conclusions: For ultrasonographically identifiable nonpalpable breast cancer, US guided lumpectomy seems to be superior to wire guided excision with respect to margin clearance and cost-effectiveness. Another advantage of the US guided procedure is that patients do not have to undergo the unpleasant wire placement before surgery.

229 ORAL

Impact of surgery on outcome in early breast cancer

J.A. van der Hage[1,4], H. Putter[2], J. Bonnema[1], M.J. van de Vijver[3], C.J.H. van de Velde[1]. [1] *Leiden University Medical Center, Surgery, Leiden, The Netherlands;* [2] *Leiden University Medical Center, Medical Statistics, Leiden, The Netherlands;* [3] *Netherlands Cancer Institute, Pathology, Amsterdam, The Netherlands;* [4] *EORTC Data Center, Brussels, Belgium*

Background: It has long been accepted that adequate locoregional therapy can delay or prevent local or regional recurrence in women with early breast cancer. However, a central question about locoregional therapy, i.e. surgery and radiotherapy, for early breast cancer remains whether more-extensive treatment significantly reduces mortality from breast cancer. EORTC trial 10801, which randomised between mastectomy and breast-conserving surgery (BCS), demonstrated superior locoregional control rates in the MRM-group. However, this did not result into a difference in overall survival. It may be that the lack of difference in overall survival could be due to insufficient sample size.

Therefore we conducted a retrospective analysis combining the data of four trials which enrolled early breast cancer patients to study whether more-extensive locoregional treatment would result into better overall survival rates in a large set of early breast cancer patients.

Methods: The trials that were pooled are listed below:

EORTC trial 09771 (prolonged low-dose CMF vs. no CMF); 452 patients

EORTC trial 10801 (mastectomy vs. BCS); 902 patients

EORTC trial 10854 (1x peri-operative FAC vs. no FAC); 2795 patients

EORTC trial 10902 (4x neoadjuvant FEC vs. 4x FEC given postoperatively); 698 patients

Since the comparison of locoregional treatment in this series is non randomised, all analyses were adjusted for tumour size, nodal status, age, type of surgery, adjuvant chemotherapy, and radiotherapy.

Results: The combined data set comprised 4368 eligible early breast cancer patients. The median follow-up was 10 years. Patients who underwent BCS had poorer locoregional control rates compared to patients who underwent mastectomy (HR 2.08, $P < 0.001$). However, this did not result into a survival advantage for the mastectomy group (HR 0.97, $P = 0.63$).

In the mastectomy group, patients who received adjuvant radiotherapy had significantly better locoregional control (HR 1.82, $P < 0.001$) and overall survival rates (HR 1.37, $P < 0.001$) compared to patients who did not receive radiotherapy. Locoregional recurrence was associated with significantly worse overall survival rates in the BCS group (HR 6.17, $P < 0.001$) as well as in the mastectomy group (HR 5.00, $P < 0.001$).

Conclusions: This retrospective analysis in a large series of early breast cancer patients demonstrated superior locoregional control rates in patients who received more-extensive surgery. However, we could not demonstrate a survival benefit after more-extensive surgery. Locoregional recurrence was a powerful prognostic factor for poor overall survival after both BCS and mastectomy.

230 ORAL

Which is the contemporary need for axillary dissection to assign adjuvant treatment by means of St. Gallen direction in T1 clinically node negative breast cancer?

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We addressed the problem of the need for axillary staging in clinically node negative T1 Breast cancer by determining how the information provided by the dissection or sentinel node biopsy suggests a different treatment to that indicated by primary tumour characteristics and age alone.

We examined retrospectively 260 cases treated in 1996 at Istituto Nazionale Tumori of Milan for clinically node negative early breast cancer. Breast conserving treatment with complete axillary dissection was performed in all cases and fifty-six of them had nodal metastases. We adopted adjuvant therapy recommendations according to the Seventh International Conference on Adjuvant Therapy of Primary Breast Cancer, which was held in St Gallen, Switzerland, in February 2001. We assigned adjuvant therapy initially without considering information on node status (i.e. assuming all were pN0) and subsequently considering pathological nodal status. Based on the risk categories, treatments were reassigned and differences in proposed treatment were assessed to identify the influence of axillary staging in planning adjuvant therapy. We found that six patient with minimal-low risk, according to the age and tumour features, had involved axillary nodes; thus the change in indication for adjuvant therapy was 2.3%. When we adopted the guidelines of the previous St Gallen conference, which distinguished between younger and elderly patients, we didn't find any change in adjuvant chemotherapy indication in 44 cases over 65 years; while the change in indication for the remaining 216 cases was 18.5% to 6%, depending on whether none or all patients of the intermediate risk category (now abrogated) were assigned to chemotherapy. Therefore, if we compare our findings according to the guidelines of the Sixth with the ones according to the Seventh St Gallen International Conference recommendations, nodal status decreases his weight in conditioning adjuvant therapy since the trend is for a wider and wider application of adjuvant treatments even in node negative patients.

We conclude that satisfactory prognostic information, to stratify the risk in clinically node negative early breast cancer, can be obtained by consideration of primary tumour characteristics (by means of prognostic and predictive factors) and the information provided by axillary dissection is not necessary if guidelines recommending a wide application of systemic therapy are applied.

231 ORAL

Local relapse after breast conserving treatment for early breast cancer; impact on prognosis

M. Gennaro[1], P. Valagussa[2], C. Ferraris[1], A.R. Conti[1], M. Greco[1]. [1] *Istituto Nazionale Tumori, Breast Unit, Milan, Italy;* [2] *Istituto Nazionale Tumori, Scientific Direction, Milan, Italy*

Milan clinical trials showed that Quadrantectomy and axillary dissection followed by radiotherapy on the whole breast (QU.A.RT.) was equivalent to radical mastectomy in terms of Overall Survival (OS). When less extensive surgery was performed (Tumorectomy plus Radiotherapy) a greater incidence of local relapses as first event (LR) was observed; that however failed to affect OS. OS did not decreased even when radiotherapy after Quadrantectomy was omitted, although, compared with QU.A.RT, a greater incidence of LR was recorded. The evidence that such conservative approaches conditioning a higher risk of LR did not influence the OS, poses question about the relevance of this event. The aim of this study was to establish whether LR after breast conserving treatment for early breast cancer represents a failure of local control alone without affecting OS or if it is related with a worst prognosis and represent a failure of the treatment.

We analysed data from 2527 patients treated at Istituto Nazionale Tumori of Milan for early breast cancer from 1970 to 1989. Each of them underwent QU.A.RT and none of them had distant metastases at the time of diagnosis. Median follow up was 18 years. OS of 233 patients which developed a LR was compared with OS of the remaining 2294. OS was calculated from the date of primary surgery for both groups and included all cases of death. Differences on the occurrence of death within the two groups were assessed by means of log-rank test. All p values were two-sided.

We did not find any statistically significant difference between the two groups in terms of OS ($p<0.05$). Also subgroups analysis (i.e. age, nodal status and adjuvant systemic therapy) failed to show any significant difference between patients who recurred locally vs patients with no history of LR. However when patients in whom treatment failed locally have been considered alone with regard to time to LR (i.e. 0-24 and >24 months) a decrease in survival was observed for early events.

Long-term follow up highlights that LR is a local control failure, which did not entail a worse prognosis. Our results suggest that early LRs seem to be an expression of combined treatment resistance; therefore they require an aggressive rescue therapy. Combined treatment after LR should follow the guidelines adopted for primary breast cancer if the time to LR is longer than 24 months.

232 POSTER

Margin status in breast-conserving surgery: the problem of residual tumour burden

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Background Data and Objectives: Breast conserving surgery allows the same overall survival in the treatment of early breast cancer while preventing mutilation and quality of life impairment. As a matter of fact, limited surgery is defined by the clash of interests between the need to resect as much tissue as possible in order to get free margins and the goal of sparing tissue to preserve a good cosmesis. The study was designed to identify clinical and pathologic characteristics predictive of specimen margin involvement. Moreover the Authors aimed at assessing whether resection margin status might predict residual tumour burden.

Methods: In the period 1999-2000, 122 patients were operated on by quadrantectomy, defined as at least 2 cm of macroscopic free margins

around the tumour. Microscopic resection margins were prospectively defined as clear if the tumour was more than 10 mm from any margin of excision, close between 2 and 9 mm and involved if neoplastic cells were between 0 and 2 mm from the margins. Age at diagnosis, clinical palpability, mammographic pattern, preoperative work-up (needle biopsy or excisional biopsy), tumour size, histology, extensive intraductal component were evaluated by univariate analysis (chi2 test) in order to identify a correlation with positive margins. 99 tumorectomies, subsequently reexcised (mastectomy or quadrantectomy), were evaluated as to the presence of residual tumour in the reexcision specimen.

Results: 34 of 122 patients (27.9%) had positive margins, 12 of whom (35.3%) were reoperated on either by mastectomy or reexcision. Residual neoplastic foci were found in only 5 of them (41.7%). Only histology and the presence of an intraductal component were predictive of margin involvement ($p=0.01$, $p<0.0001$, respectively). The number and extension of involved lumpectomy margins were not correlated to tumour residual burden in the definitive specimen ($p=0.34$).

Conclusive Remarks: No conclusion can be drawn as to the influence of resection margin status on long-term survival and recurrences. Anyway, the assessment of a complete tumour excision, an integral part of breast conserving surgery, based on margin analysis, must be questioned if clear margins (more than 10 mm from the tumour edge) do not correspond to the absence of neoplastic foci in the remaining breast.

233 POSTER

Further experiences with tram flap delay by pre-elevating the island

E. Towpik, S. Mazur, T. Witwicki, J. Jaworowski, R. Chmielewski, L. Sienko. *Maria Sklodowska-Curie Memorial Cancer Center, Department of Breast Cancer and Reconstr Surgery, Warsaw, Poland*

Objectives: Vascular compromise of pedicled TRAM flaps has been frequently reported. To prevent this complication we propose to delay the flap by pre-elevating the island 7-10 days prior to transfer.

Material and Methods: The skin island of TRAM flap is raised on the mastectomy side from the lateral tip to the midline, and on the contralateral side only to the lateral border of the rectus muscle sheath.. The island is then resutured and the final flap transfer is performed 7-10 days later. The method was used in 75 women, most of them were high risk (obese, smokers etc.).

Results: None of the flaps was totally lost. Partial necrosis requiring additional surgery, was observed in 2 cases (2.7%). Local fat necrosis was noted in 6 cases.

Discussion: The delay of pedicled TRAM flaps by ligation of the deep and superficial inferior epigastric vessels to enhance vascularity has been previously suggested. We present our experiences with an alternate method of delay: pre-elevating the skin island alone. All the inflow and outflow of blood, to and from the island is severed, other than through the paraumbilical perforators. The fact that the inferior epigastric pedicle remains intact until the moment of flap transfer (in contrast to other methods of delay) is of particular interest, as it allows the option of "supercharging" the flap, should that become necessary. The delay procedure performed in our series by pre-elevating the island, did not completely eliminate vascular compromise, since limited areas of skin necrosis were observed in two patients.

Conclusion: Pre-elevation of the skin island alone is a very simple and effective method of TRAM flap delay, alternate to ligation of the deep and superficial inferior epigastric vessels.

234 POSTER

Is ambulatory breast cancer surgery feasible?

C.N.A. Frotscher, M.H. Hebly, M.F. von Meyenfeldt, M.H.A. Bemelmans, G.H. Sie, W.A.J.J.H. Haagh, G.L. Beets. *University Hospital of Maastricht, Surgery, Maastricht, The Netherlands*

Introduction: Minor surgical procedures are often performed in an ambulatory setting, mainly because of economical incentives. Breast cancer surgery is generally performed in a clinical setting, as the medical, organizational and psycho-emotional issues are considered too complex for day care surgery. The aim of the study is to assess the feasibility of ambulatory breast cancer surgery.

Material and Methods: In January 2001 breast cancer surgery in ambulatory setting was started as a pilot study. All data were collected prospectively. The whole process of diagnosis, information and counseling, anesthetic assessment, surgical treatment and after care was continuously monitored. Problems were identified and the procedures adjusted when necessary.

Results: In the first six months of 2001 137 patients had surgery because of breast cancer. 70 patients (mean age 55; range 35-84) were planned as a day care procedure and 56 of these patients went home the day of operation. The operations performed in ambulatory setting varied from biopsy (6%) to lumpectomy and sentinel node procedures (58%), breast ablative procedures (13%) and axillary clearances (23%). The reasons for a clinical admission after a planned ambulatory procedure were: postoperative nausea (3), delay in operations schedule (4), change in planned operation (1), lack of preoperative information (2), lack of informal care (2), afraid to go home (2). There were no severe intra-operative surgical or anaesthesiological complications. There where no postoperative complications due to the ambulatory setting. No patient had to be readmitted after discharge because of early problems at home.

Essential in the organization of ambulatory breast care surgery is preoperative patient counseling, and a close cooperation between the departments of surgery, anesthesia, nuclear medicine and radiology. Relevant organizational issues will be demonstrated.

Conclusion: This pilot study shows that in a selected group of patients all types of breast cancer surgery can be performed in an ambulatory setting without an increase of complications. Whether or not ambulatory surgery is appropriate for every patient and every operation, will be the subject of an ongoing study.

235 POSTER

Bilateral autogenous breast reconstruction using perforator free flaps: retrospective review of one single center

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A single center's experience in bilateral breast reconstruction using perforator free flaps was presented. A series of 42 patients underwent this procedure between February 1996 and September 2001. The surgical procedures were performed for patients with bilateral breast cancer (10 patients) or as prophylactic mastectomy (30 patients) and after failed aesthetic breast augmentation (2 patients).

Prophylactic mastectomy was indicated in cases of history of cancer in the opposite breast (11 patients), of Recius disease (11 patients), of BRCA1(5 patients) and of a strong family history (3 patients). Primary and secondary bilateral breast reconstructions were done in 16 and 3 patients respectively. Fifteen patients, who had had breast reconstruction with implant, had a tertiary breast reconstruction. Combined reconstruction (primary with secondary and primary with tertiary reconstruction) was done in 8 patients. 76 Deep inferior epigastric perforator DIEP flaps and 8 superior gluteal artery perforator S-GAP flaps were used. Simultaneous bilateral breast reconstruction was performed in all patients with DIEP flap (38 patients) and in one patient with SGAP flap. In three patients, a differed breast reconstruction was done using S-GAP flap with 6 months interval. Average operative time was 10.5 hours (8-14.5 hours) for the simultaneous bilateral reconstruction. Total necrosis occurred in one case of DIEP flap and the reconstruction was salvaged with SGAP free flap 6 months later. Two pulmonary infections, one DVT and one cardiac arrhythmia were reported as postoperative complications. Mean hospital stay was 9 days (range 6-20 days). An abdominal bulging was reported in one patient. There were no recurrent disease or cancer manifestations, with an average follow-up of 3 years.

An assessment of quality of life, psychological benefit and patient satisfaction rate between the three modalities of reconstruction (primary, secondary and tertiary) will be discussed.

Bilateral autogenous primary breast reconstruction with perforator free flaps seemed to give the best rate of benefit. Decreasing the donor site morbidity and offering an excellent aesthetic and long term outcome by using this technique provides a high rate of patient satisfaction and is an adequate oncological alternative.

236 POSTER

Breast reconstruction with microvascularly supercharged pedicled tram flaps

T. Witwicki, E. Towpik, S. Mazur, R. Chmielewski, L. Sienko, J. Jaworowski. *Maria Sklodowska-Curie Memorial Cancer Center, Department of Breast Cancer and Reconstr. Surgery, Warsaw, Poland*

Objectives: Vascular compromise is a relatively frequent complication of breast reconstruction performed with the use of pedicled transverse rec-

tus abdominis myocutaneous (TRAM) flaps. We present our experiences in enhancing the flap vascularity by additional anastomoses of the inferior epigastric pedicle.

Material and Methods: The pedicled TRAM flap with additional anastomoses of the inferior epigastric vessels was used in 50 breast reconstructions. The anastomoses were performed to the thoracodorsal (6 cases) or internal mammary (44 cases) artery and vein.

A considerable percent of patients were assessed as "high risk".

Results: Good flap vascularity immediately after the operation was observed in all cases. Marginal flap necrosis developed in later days in 2 patients (they both were smokers).

Discussion: One of the means to improve the vascular supply is to raise a TRAM flap preserving it's superior pedicle, and - additionally - to perform microanastomoses of the inferior epigastric pedicle. This appears to be safer than a free flap, as it provides blood flow from both sources. Eventual inefficiency of the superior pedicle may be supported by the flow from the anastomosed inferior one. If, however, something goes wrong with the anastomoses, there is always a support from the superior pedicle.

In some cases of our series, after dissecting the flap and severing the inferior epigastric vessels, we observed the symptoms of venous congestion. They dissapeared after the successful microanastomoses were performed. Thus, our initial experiences show, that the major role for the microanastomoses is to improve the venous outflow from the flap island.

Conclusion: The pedicled TRAM flap with additional microanastomoses of the inferior epigastric vessels is a safe method of breast reconstruction with autogenous tissues.

237 POSTER

Endoscopic partial mastectomy for small breast cancer

Y. Sano, T. Saito, T. Shinoda, T. Yoshida, H. Ogihara. *Omiya red cross hospital, Surgery, Saitama, Japan*

Introduction: Recently endoscopic surgery has become increasingly popular. We introduced these surgical techniques into breast conservation surgery combined with sentinel node biopsy in order to improve cosmetic results.

Materials and Methods: 25 early-stage breast cancer patients underwent endoscopy-assisted partial mastectomy and sentinel node biopsy. The mean age of the patients was 55.2 years old. The mean size of the tumor was 12.2 cm in a diameter. 10 of them underwent partial mastectomy via a 5cm skin incision on the middle axillary line and 15 of them underwent it via circumareolar line. Sentinel node biopsy was performed via 3 cm skin incision on the middle axillary line. When metastasis was found in a sentinel node by frozen section, complete axillary dissection was performed with the enlarged 5 cm skin incision. When node negative, endoscopy-assisted partial mastectomy was performed through a transaxillary or a circumareolar incision using a Visiport and a Harmonic Scalpel coagulator.

Results: The average operation time was 108 minutes, and the average blood loss was 48.3 g. Node positive rate was 32% (8/25). The surgical wounds through the middle axillary incision were completely invisible in the front view. The wounds through the circumareolar incision were almost satisfied. The post-operative shape of the breast was cosmetically satisfactory. Surgical margin was sufficient by specimen radiography.

Conclusion: This operation has a great advantage for clinical cosmesis and keeps the same oncological radicality as standard partial mastectomy.

238 POSTER

Nipple areola complex reconstruction: experience and development of an asymmetric trefoil (ATF) flap

L. Hayes, A.D. Baildam. *South Manchester University Hospitals NHS Trust, Breast Surgery, Manchester, United Kingdom*

Reconstruction of the nipple-areola complex (NAC) is the final stage of breast reconstruction. A satisfactory cosmetic result depends on many factors including symmetry of size, position, shape and projection. Achieving persisting nipple projection is the most common difficulty encountered and many approaches have been described. We present our experience with meeting the cosmetic demands of nipple reconstruction.

Initial practice in this unit was to perform "mushroom flaps" with skin grafts taken from the thigh. Within 12-18 months most of these nipples had flattened, the grafts had paled and patient satisfaction was low. As a result there was a reappraisal of our technique and this led to the development of the asymmetric trefoil (ATF) flap.

Technically the ATF flap is a geometric design based upon the diameter and projection of the natural nipple. The procedure is performed under local anaesthetia and followed 2 to 3 months later by tattooing of the areola.

Over the last 4 years we have performed 185 NACs. All procedures have been well tolerated and patient satisfaction is high. Shrinkage of about 20% is allowed for at the time of reconstruction and excessive shrinkage has not been a significant problem with only 2 cases of flattening necessitating further procedures. One case of nipple reduction was necessary due to lack of the expected shrinkage. Nipple projection is satisfactory and maintained in the majority of cases. Nipple diameter when compared to the contralateral nipple is equivalent within 1 to 2 mm in a series of cases where postoperative measurements have been taken. There has been one minor infection and one case of tip necrosis. This latter case was in a patient who had had previous radiotherapy.

In conclusion, the ATF flap fulfils the majority of criteria required for cosmetically satisfactory nipple reconstruction. Although some degree of flattening of projection does occur, this appears to be limited and predominantly affects NAC reconstructions performed on subjects who have had tissue expansion following mastectomy and therefore have attenuated skin and subdermal tissue planes. The high level of patient tolerability and satisfaction with this technique lead us to recommend it for wider usage.

239 POSTER

Mastectomy with breast reconstruction is more time-consuming and labour intensive than 'conventional' breast cancer surgery

J. Dace, U. Sridharan, C. Holcombe. *Breast Clinic, Linda McCartney Centre, Royal Liverpool University Hospital*

Introduction: In breast units that offer a full reconstructive service, it has become clear that oncoplastic surgery takes longer than simple mastectomy and axillary clearance, and necessitates extra outpatient work. It often also generates a need for additional surgery on the reconstructed and contralateral breast. The aim of this study was to quantify this extra workload in a small number of patients.

Materials and Methods: In a pilot study, charts were chosen at random from groups of women who had mastectomy alone, mastectomy plus expander reconstruction or mastectomy plus TRAM reconstruction (all patients had axillary surgery where indicated). Three groups of ten were compared with respect to duration of hospital stay, length of surgery, complications, follow-up and need for further surgery.

Results: Groups were age-matched and displayed similar tumour pathology. The mean lengths of inpatient stay for mastectomy, mastectomy+expander and mastectomy+TRAM were 7.1, 5.6 and 9.8 days respectively. It took 840 minutes (14hrs)to perform 10 mastectomies (mean=84min), 1400 min (23.3hrs) to perform 10 mastectomies with expanders (mean=140min) and 2485 minutes(41.4hrs) to carry out 10 mastectomies with TRAM reconstruction (mean=248min). Early complications (i.e. wound infection/ seroma) occurred in 2 of the mastectomy group, 2 of the expander group and 5 of the TRAM group. The mean number of follow-up appointments was 1.6(mastectomy), 4.5(expander) and 3.7(TRAM). No one in the mastectomy group had further surgery whereas 70% of the expander group and 50% of the TRAM group did.

Conclusions: Although the number of patients in the study is small, it is clear that extra clinic and operating time is needed for breast reconstruction. The crude figures above demonstrate that roughly three mastectomies can be done in the time it takes to perform a mastectomy with a TRAM reconstruction. This is often overlooked when unit performance figures are assessed and this issue needs to be addressed

240 POSTER

Margin status after breast conserving surgery (BCS) for breast cancer (BC): Can we improve the prediction of residual tumor in patients reoperated on for close or positive margins?

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Purpose: Microscopic complete excision is crucial for BCS, because this parameter is highly high correlated with the rate of recurrence and, for some BC patients, with overall survival. Many trials have shown that radiotherapy cannot compensate for involved margins. The optimal extent of the surgical excision and the method for margin evaluation are however controversial. No uniform definition has been established for the margin status. The exact width of the resection margin that will minimize the risk of recurrence is unknown and other parameters such as the extent of tumor at the margin,

the number of involved margins and the tumor type (invasive/in situ/mixed) may also influence this risk.

Methods: We retrospectively examined 132 tumors (invasive 42, in situ 18, mixed 72), submitted to local re-excision (n = 69) or total mastectomy (n = 63). All the pathology reports or the slides were reviewed by JMG. For each margin (6 directions), we assessed the width of normal tissue (mm), the tumor type (in situ/invasive/mixed) and extent (minimal/focal/extensive). A positive margin was defined at 0 mm in width.

Results: Residual tumor (RT) was found in 57% of cases (70% for mastectomy and 45% for local excision), with good spatial agreement between disease predicted and that found. A clear relation was found between RT (36 to 100%) and the number of positive margins (1 to 6). For margins $\geq$1 mm (24 pts), this relation disappeared. In the 8 pts in whom all margins were $\geq$2 mm, there was nonetheless 50% of residual tumor. There was no difference in RT between close (1 mm) and positive margins. For DCIS, the size of the lesion was highly predictive of RT (23 mm/43 mm, $p < 0.00001$). For invasive tumors (+/– in situ) there was no correlation with the size. Analysis of the type of margin positivity and extent was not statistically significant, probably due to the small sample size.

Conclusion: Several directions were found that can be explored to identify a subset of patients who do not need re-excision, based on the margin status (width of normal tissue, tumor type and extent). These preliminary results encourage us to continue this analysis on a larger series.

241 POSTER

The 'integrated care pathway' to audit the treatment for patients undergoing surgery for breast carcinoma - a year's review

A. Shepherd, R. Primrose, Z. Rayter. *Bristol Royal Infirmary, Breast Unit, Bristol, UK*

Integrated care pathways (ICP) have been developed by several clinical specialties to allow improvements in the provision and documentation of patient care. In our Breast Unit we have developed an ICP for patients undergoing elective breast operations. It is a convenient method of documenting an in-patient episode for each member of the multi-disciplinary team. The aim of this study was to assess the incorporation of the ICP into our department.

One hundred sets of notes were reviewed for patients undergoing mastectomy, with or without primary reconstruction, between August 2000 (when the ICP was introduced) & August 2001. Twelve criteria points were used to assess the standard of documentation ("good", "average" & "poor") in each pathway and the extent to which patient management matched the unit policy. An event not matching the pathway is recorded as a "variance".

Ninety-two pathways were rated as "good", 1 as "average", 3 as "poor" and 4 pathways were missing. The mean in-patient stay was 5.3 nights. Three patients did not receive pre-operative heparin and 2 did not have daily post-operative heparin (due to post-operative haematoma formation). All patients with prosthetic breast implants received antibiotics and all patients had post-operative pain relief prescribed. Tweleve wound problems were documented by the nursing staff, but only 2 required any action (1 wound haematoma & 1 wound dehiscence). Seventy-eight patients were discharged with a drain in-situ for district nurse removal and all others had the drains removed at day 9 or when draining <30mls/day.

After some initial minor difficulty the introduction of an integrated care pathway has proved to be a convenient and effective way of documenting a patient episode and making sure each patient receives the highest standard of care from the multi-disciplinary team in accordance with unit policy. We would commend the ICP to you.

242 POSTER

Breast carcinoma conservative treatment. Locoregional recurrences: Incidence, risk factors and prognosis

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Purpose: The aim of this study was to analyze our own experience concerning the breast conservative treatment (BCT) with regard to the incidence, the risk factors and the evolution of the patients with locoregional recurrences (LRR).

Methods: Surgery has been carried out for 693 breast cancer patients between the 1st of January 1993 and the 1st of August 2001 in our Gynecology Department. BCT (partial mastectomy and axillary dissection) was performed in 149 cases (21.50%). Radiotherapy, chemotherapy and hormonotherapy were administered within the Oncology Department.

Results: An obvious increase of the BCT incidence was recorded (from 6.97% in 1993 to over 35% during the last three years). LRR were suspected in 16 cases. Pathology validation was obtained in 6 cases (4.02%) and all were on the same side as the primary lesion. LRR were diagnosed after 2 years and 3 years and 9 months after initial surgery. The following parameters were identified as possible risk factors in the 6 patients with LRR: age (45–50 years old in 4 cases), tumor size (more than 2 cm in 3 cases), tumor free margins ("close" margins in 1 case), lymph node involvement (N1 in 3 cases), extensive ductal carcinoma (2 cases), tumor grading (G2 in 4 cases), vascular and lymphatic space invasion (in 2 cases). The following protocols were administered to the LRR patients: reexcision (4 cases), Madden operation (1 case), radiotherapy (3 cases), chemotherapy (1 case). As 2 cases only have more than 5 years since LRR diagnosis we could not evaluate the survival rate.

Conclusions: Accomplishing the BCT selection criteria remains crucial. The "tumor free margins" excision (that we perform guided by the frozen section examination) is essential. In most of the cases we recommend RT in order to decrease the LRR risk. Tumor size, lymph node involvement, excision margins, extensive ductal carcinoma, vascular and lymphatic space invasion, site of the LRR and age could be considered as risk factors for LRR even we had a low number of cases. Analysis of patients with LRR after BCT is useful for case selection, specific therapy assigning and increasing the overall survival.

243 POSTER

Cosmesis and satisfaction after breast conserving surgery (BCS) correlates with the percentage of breast volume lost

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Cosmesis after BCS is an important factor that correlates with psychosocial adjustment after surgery. Previous studies by our group have shown that it is dependent on breast size and specimen weight. This study assessed the cosmetic outcome in relation to the estimated percentage of breast volume lost (EPBVL).

The study group consisted of 151 women who had undergone BCS. All had previously completed a patient satisfaction questionnaire and been subjectively assessed by a panel for cosmetic outcome as part of previous studies. Preoperative mammograms were reviewed and breast volume estimated. A validation series of 40 patients who had skin-sparing mastectomy showed cone volume on the oblique mammogram to most accurately predict true breast weight (correlation 0.9).

Both subjective cosmetic assessment and patient satisfaction correlated strongly with EPBVL ($p<0.001$, table).

A prospective study will show if PBVL can be predicted preoperatively. This may provide better selection criteria for BCS and select those patients in whom breast reshaping or volume replacement should be considered.

244 POSTER

Immediate breast reconstruction - A six years experience in a DGH

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Aim: To evaluate the results of immediate breast reconstruction carried out by a single breast surgeon in a district general hospital.

Patients and Methods: 103 consecutive patients who underwent immediate breast reconstruction for breast cancer over a 6 year period (August 1995 to July 2001) were studied. Patient and tumour characteristics, surgical complications, local and regional recurrence, survival and patient satisfaction were assessed.

Results: 698 cases of operable breast cancer presented during study period, (275 mastectomies; Reconstruction rate = 37%)

Mean age of patients: 51 (range 32 - 79 years).

Type of reconstruction: Subpectoral expanders: 83, Latissimus dorsi: 20. Unilateral procedure 95, Bilateral: 4

Indications for mastectomy: Multifocality: 27, tumour size: 21, tumour position: 21, incomplete clearance after wide local excision (WLE): 13, extensive DCIS: 10, patient preference: 5, tumour recurrence after WLE: 4, Paget's disease: 2.

Type of mastectomy: Simple, node clearance: 64, simple, node sampling: 31, subcutaneous with sampling or clearance: 8.

Characteristic of primary tumour: Grade I: 13, grade II: 35, grade III: 33, lobular carcinoma: 9, DCIS: 10, Paget's disease: 2, Phylloides tumour: 1.

Type of prostheses: Siltex Becker: 70, McGhan Anatomical: 29, Nagor: 4.

Adjuvant Therapy: Radiotherapy: 39, chemotherapy: 43, Tamoxifen: 79.

Complications: Wound infection: 7, capsule formation: 5, superficial skin necrosis: 4, intraoperative pneumothorax: 2, filling port migration: 1, expander deflation: 1, inadequate expansion: 1, hot water bottle burns in post operative period: 2.

Follow-up: Loco-regional recurrence to date: 8 [mean Nottingham Prognostic Index = 5.5 (range 3.4 - 6.6), distant metastases: 6, deaths: 9.

Patient satisfaction:

a. Subpectoral tissue expanders: six died prior to postal survey, 77 questionnaires sent out, questionnaires returned = 72 (92.3%).

Adequate information received by patients before surgery: 65 (90.27%).

Expectations of final results met: fully 34(47.2%), partially 28 (39%), not at all 4 (5.5%), did not respond 6(8.3%).

Overall satisfaction: very good 28 (39%), good 23 (32%), satisfactory 13 (18%), poor 5 (7%), no response 3(4.1%).

b. Latissimus Dorsi: 20 Questionnaires sent out, 16 questionnaires returned (80%)

Adequate information received before operation: 15 (93.75%)

Expectations of final result met: fully 12(75%), partially 4(25%), not at all 0.

Overall satisfaction: very good 11 (68.75%), good 4 (25%), satisfactory 1(6.25%), poor 0.

Conclusion: Immediate breast reconstruction can be provided by a single handed breast surgeon in a district general hospital with acceptable results. In these circumstances Latissimus Dorsi reconstruction has been shown to provide superior results to tissue expanders in terms of patient satisfaction.

245 POSTER

Early discharge from hospital with an axillary drain in situ after breast cancer surgery

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The purpose of this study was to assess the feasibility and complication rate of early discharge from hospital with an axillary drain in situ after surgery for breast cancer. A questionnaire survey of patients views was also conducted and will be reported separately.

Forty eight patients about to undergo surgery for breast cancer were enrolled. They were counselled regarding early discharge by the surgeon and the breast care nurse and this information was supplemented with a leaflet. Patients were asked to fill in a questionnaire before and 6 weeks after the surgery for their views. Length of stay and complications were recorded.

Median length of stay for the whole group was only 3 days (range 1-9)despite the fact that only 81% were discharged with the drain in situ. The median duration for drain placement was 7 days (range 0-11). In 5 patients, the drain fell out before it was due to be removed, in 3 patients whilst in hospital and in 2 whilst at home. Of the 23 patients who still had a drain in situ at their first out patient visit (at 8 or 9 days postoperatively), 74% had the drain removed at this visit. Infection and haematoma occurred in 10% and 5% of patients respectively in the whole group. Seroma formation occurred in 28% of all patients. The median duration of drain placement in these patients was 6.9 days compared with 7.2 days in the 72% who did not develop a seroma. The median number of bed days saved was 4 per patient without any increase in complication rates.

In conclusion, early discharge with an axillary drain in situ is feasible, cost effective and is not associated with an increase in complications.

246 POSTER

Aesthetic evaluation of conservative breast cancer treatment: trying to optimize results

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Introduction: After testing inter-observer agreement in the evaluation of the aesthetic result of breast cancer treatment, by the patient and three doctors, even when objective parameters are used, the results are neither brilliant nor reproducible. We aim at a new quantitative computer method that measures differences objectively and also integrates the information of qualitative assessment obtaining likewise a better agreement.

Material and Methods: Pictures were taken from 33 women submitted to conservative breast cancer treatment. The patient's opinion about the aesthetic result was recorded. Subsequently three physicians from different specialities (a surgeon, a radiation oncologist and a gynaecologist), not involved in the treatment process, analysed the images. Previously four degrees of evaluation were established (bad, medium, good and excellent). Considering evaluation degrees as a score, the difference between global classifications was calculated with Kendall and Wilcoxon signed rank tests. The individual agreement (case by case) between doctors was evaluated by the proportions of agreement (pa) and the kappa statistic (k), with 95% confidence intervals (95% CI). Finally a consensus among the three doctors was obtained and compared with the patient's opinion.

Results: There were no significative differences between the doctor's global score (p=0,95) or between the three doctor's consensus and the patient's opinion (p=0,25). In the case-by-case analysis the initial agreement among doctors was only sufficient (pa= 0,59; CI95% 0,49-0,69 e k=0,42; CI95% 0,29-0,54) and between doctor's consensus and the patient's opinion was even worse (pa=0,51; CI95% 0,34-0,68 e k=0,24; CI95% 0,01-0,47).

Conclusions: When analysed as a score, there were no major differences in opinion between the three doctors neither between the consensus and the patient in the evaluation of the aesthetic result of conservative treatment for breast cancer. Major disagreement existed however when we applied case-by-case analysis, even when objective criteria were used. Trying to optimise these results led us to the development of an objective method of qualitative parameter evaluation using digital images and computer analysis and eventually integrating also the qualitative assessment previously defined.

247 POSTER

Use of harmonic scalpel in mastectomy and axillary dissection for breast cancer

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Objective:To assess the feasibility of using a harmonic scalpel compared to a conventional cold scalpel in mastectomy and axillary dissection for breast cancer. Patients and Methods: A total of 192 patients received surgical treatment for breast cancer between January 1999 and December 2000. The age distribution ranged from 28-78 years with meanof 63 years. Mastectomy and axillary dissection was the preferred option in sixty five percent of patients. A total of 56 patients having mastectomy and axillary surgery were included in this pilot study, of whom twenty-eight patients underwent dissection of mastectomy flaps and axilla using a harmonic scalpel. Dissection was carried out in the remainder 28 patients using a conventional scalpel. In the harmonic scalpel group the hook shear (SH105) was used in first sixteen patients and a 10 cm curved blade (HF105) was used for the remainder. Information regarding operative time, estimated blood loss, post operative wound drainage, seroma formation, hospital stay and early wound complications was recorded prospectively in both groups and analysed. Two suction drains were used in all patients. Results: The mean operative time was 100 minutes (range 80-120)in the harmonic scalpel group compared to 80 minutes(range 60-100) in the conventional scalpel group. The mean intra-operative blood loss was 107ml(range 60-200) in the harmonic scalpel group compared to 385ml(range 230-900) in the conventional scalpel group. Wound drainage in harmonic scalpel group was 454 mls(range 150-800) compared to 693 mls (range 200- 1200). Seroma formation was significantly less in the harmonic scalpel assisted patients. There was no significant difference in wound infection and healing in both groups. There was no significant difference in analgesic requirement in either groups. Conclusion:In our experience a harmonic scalpel is a feasible alternative to conventional scalpel dissection in mastectomy patients. Initial results are encouraging with less intra-operative blood loss, post operative wound drainage and seroma formation but not at the expense of increased surgical time. Further larger randomised studies are required before its routine use in breast surgery.

248 POSTER

Recurrences following 386 cases of breast conserving surgery in KCCH

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Background: BCT (breast conserving therapy) is now accepted as one of the standard therapeutic options for stage I, II breast cancers. However, especially in Korean breast cancer patients, many questions still remain to be answered in terms of the optimal indication, the extent of resection and the frequency and proper management of recurrence due to the lack of studies involving large numbers of patients. The aims of this study were to examine the pattern and the frequency of recurrence following BCT and to identify the risk factors of local recurrence and systemic relapse. In addition, the outcomes for the patients treated with a quadrantectomy and with a lumpectomy were compared with particular emphasis on the rate of local recurrence.

Methods: The medical records of 386 patients who underwent a BCT at Korea Cancer Center Hospital during the period from January 1986 to December 1996 were reviewed.

Results: Among the 386 patients, 269 (69.7%) patients underwent a quadrantectomy and 117 (30.3%) patients underwent a lumpectomy with microscopic confirmation of margin status. Level I, II axillary dissection and whole breast irradiation, including electron beam boost to tumor site, were performed routinely. The axillar and supraclavicular areas were included in the irradiation field when 4 or more positive nodes were found. Systemic treatment (CMF or CAF + tamoxifen) was done depending on the pathological stage and the hormone receptor status of the disease. During the period of follow up (median 66 months), 9 cases (2.3%) of local recurrence and 18 cases (4.7%) of systemic relapse were identified in 24 (6.2%) patients. Between the quadrantectomy and the lumpectomy groups, there were no significant differences in the frequencies of local recurrence (p=0.179) and systemic relapse (p=0.266). Young age (< 40) (p=0.01) and lymph node metastasis (p=0.0001) were proven to be risk factors of local recurrence. Large tumor size (>2cm) (p=0.03) and lymph node metastasis (p=0.003) were risk factors of systemic relapse.

Conclusion: The rates of local recurrence were very low in both the quadrantectomy and the lumpectomy group compared with those in a Western series. These results show that a quadrantectomy or a lumpectomy with confirmation of margin status followed by rediation therapy can provide excellent results in terms of local control and survival in Korean breast cancer patients.

249 POSTER

Therapeutic options for stage I breast cancer and the long term effect on survival: a Geneva Cancer Registry study

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Introduction: Early-stage breast cancer offers women and their clinicians different treatment options. We studied putative survival differences between women with breast-conserving surgery (BCS) versus mastectomy and the effect of adjuvant radiotherapy.

Patients and Methods: The current study included all women with primary invasive stage I (≤2 cm, N0)breast cancer diagnosed between 1989-1999 among the population of the Swiss canton of Geneva(400'000 inhabitants). Patients with previous malignancies(except in situ cancer other than breast and skin cancer other than melanoma), breast lymphoma or sarcoma were excluded. Only women who underwent putative, curative surgery (clear margin) were included (n=1046).The following treatments are considered: breast conservative surgery (BCS)plus radiotherapy(RX), BCS without RX, mastectomy plus RX, mastectomy without RX. The 10-year survival was estimated by the actuarial method(intervals in months and standard error according to Greenwood). The effect of treatment on observed mortality was evaluated by the Cox proportional hazards model accounting for age (in continuous), social class(high, medium,low, unknown), period (in continuous), breast quadrant(upper, lower, central, other), T1 sub stage (T1a, T1b-c), histology (ductal, lobular, other carcinoma)and grade (I,II,III,unknown), chemotherapy use (yes,no), and tamoxifen use (yes,no).

Results: The use of BCS increased during the period. Overall, 771 (73%) women had BCS plus RX, 70(7%)had BCS and 205 (20%) mastectomy. During the studied period, 113 women died, 38 from breast cancer and 75 from other causes. Ten-year observed survival was 79%(95% CI:75-83%) for all types of treatment, 85% (95% CI: 81-89%) for BCS plus RX, 60% (95% CI: 45-75%) for BCS, 69% (95% CI: 60-78%) for mastectomy. After accounting for putative prognostic factors, the effect of BCS on mortality rates was similar to that of mastectomy (Hazard ratio: 1.19, 95% CI:0.64-2.22). Only radiotherapy significantly decreased mortality rates (Hazard ration: 0.48, 95% CI:0.26-0.88) with similar benefits regardless of the type of surgery.

Conclusion: As expected, BCS and mastectomy for stage I breast cancer provide almost identical results in term of survival in routine practice in Geneva as described in the literature. Radiotherapy significantly increases the prognosis, whatever the surgical intervention used.

250 POSTER

The outcome of conservative treatment of breast cancer

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Conservative treatment of breast cancer is an accepted alternative to mastectomy for the early stages of the disease. The purpose of the paper is to asses the outcome of conservative treatment of breast cancer.

It is a prospective study that compares the results of mastectomy to conservative treatment of breast cancer. Four groups of patients with stage I and II of breast cancer, treated by the same medical team at the Institute of Oncology "Prof. Dr. Al. Trestioreanu" Bucharest were followed:

Group A: 123 patients who underwent conservative treatment as they met the selection criteria for this type of therapy; Group B1: 30 patients who underwent conservative treatment because they had refused mastectomy; Group B2: 40 patients who underwent conservative treatment because of medical contraindication for extended surgery; Group M: 150 patients by whom mastectomy was performed, although they would have fulfilled the selection criteria for conservative treatment.

The most important selection criteria for conservative treatment have been: unilateral, unicentric breast cancer, T<2,5cm, N0-N1, tumor/breast ratio that would allow proper excision with a convenient cosmetic outcome, and patient desire.

Surgery consisted of limited mammary resection, defined as excision of the tumor together with at least 2 cm of peritumoural mammary tissue and axillary dissection. In all the cases postoperative radiotherapy was used, chemo- and/or hormonal therapy were associated depending on the prognostic factors of the disease.

Statistical test (X2) was performed in order to compare the results. Local recurrence rate at 5 years was: 6.9% in Group A, 25% in Group B1, 12.5% in Group B2, 1.3% in Group M (A-M=p>0,39). Overall survival rate at 5 years was: 91.37% in Group A, 70.83% in Group B1, 62.50% in Group B2, 88.60% in Group M (A-M=p>0,56). The cosmetic result after conservative treatment was good in over 70% of the cases.

Tumor size, tumor grading, axillary lymph node invasion and patient's age are the most important prognostic factors for local recurrence and survival.

Results confirmed that conservative therapy, with due observance of selection criteria and of the therapeutical protocol, is an appropriate therapy for a category of patients with early breast cancer.

251 POSTER

Breast conserving surgery by immediate repair of partial mastectomy defects

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Purpose: On the basis of results of retrospective studies and randomized clinical trials conducted during the 1980s, the 1990 National Institutes of Health Consensus Conference recommended breast-conserving surgery (BCS) as an appropriate therapy for most women with stage I and Stage II breast cancer. We evaluate the effect and prognosis of Breast-conserving Surgery(BCS).

Patients and Methods: A retrospective review of 215 patients who had undergone immediate volume replacement or mammoreduction between 1995 and 2000. We performed 2 approaches to repair of the breast deformity after BCS. In one approach, the missing tissue is replaced using either local or distant tissue. In the other approach, the missing breast tissue is not replaced, but the breast is reshaped so theat it is smaller-but has a more normal form-than is was preoperatively.

Results: We performed 317 BCS (59.25%) of all the 535 patients who underwent breast cancer operation from 1995 to 2000. The stage distribution for the IBR patients was as follows: stage 0 0.47%(1 out of 215 patients), I 56.74%(122 out of 215 patients), IIA 26.98%(58 out of 215 patients), IIB 9.30%(20 out of 215 patients), IIIA 6.51%(14 out of 215 patients). The types of IBR were as follow: 50 cases received mammoreduction pattern(23.25%),3 cases received local flap(1.40%), and 162 cases received distant flap(75.35%) among 215 patients. According to the tumor size, the type of IBR in diameter of smaller than 2.0 cm, between 2.0 and 5.0 cm, and larger than 5.0 cm, the type of IBR was mammoreduction(20.40%, 1.40%, 1.40%)), local flap(1.40%, 0.00%, 0.00%), distant flap(47.44%, 16.74%. 10.23%), respectively. In the cases of the early breast cancer (stage 0, stage I, and stage II), the recurrence rates of BCS especially decreased much more than the cases of MRM or RM (BCS: MR or RM = 5/317: 9/198, $p<0.05$). In the cosmetic results of BCS with IBR, good and excellent were 93.49% all together.

Conclusion: According to our report, the recurrence rate was low in the case of BCS. The increasing trend toward use of BCS is an indication that this important advance in the treatment of breast cancer is progressively gaining acceptance.

252 POSTER

Wire-guided breast surgery in the era of preoperative large needle image guided biopsy

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Vacuum-assisted stereotactic biopsy (VASB) and US-guided core-biopsy have become routine tools for assessment of nonpalpable breast lesions. Adoption of these methods has changed the practice of breast surgery. The aim of this retrospective study was to analyze the indication of 107 consecutive cases after needle-localization in our clinic.

We reviewed mammograms, breast ultrasound and pathology reports of 107 women that undergone wire-guided breast surgery from January 2000 to February 2001. In 65 cases wire-guided lumpectomy was performed. In all of them preoperative diagnosis of malignancy was obtained by image-guided breast biopsy (IGBB). In 7 cases premalignant pathology was diagnosed by IGBB and pathologist recommended surgical excision. In 3 cases discordance between imaging features and IGBB results lead to open biopsy. In 12 women preoperative IGBB was not performed because technical limitations or suspected radial scar. In 5 lesions diagnosed as papilloma by IGBB, excisional biopsy confirmed the benign pathology. We separately analyzed the subgroup of the lesions that presented mammographically as architectural distortion without obvious lesion at sonography. In 4 cases the final diagnosis was fibrocystic changes and in 4 cases radial scar without associated malignancy was found.

Altogether, 75 malignant, 7 radial scar, and 25 benign lesions were excised. We concluded that IGBB significantly decreased the number of benign lesions that were excised surgically.

253 POSTER

Pedicled TRAM flap reconstruction after mastectomy: results from a series of 86 patients

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Introduction: We describe the progress and outcome of patients who had either immediate or delayed TRAM reconstruction performed by the same surgical team during the period December 1993 to September 2001.

Materials and Methods: Patient details were analysed using a prospectively maintained computerised database, and the results tabulated as below.

Results: Eighty six patients were identified on whom a total of 95 TRAMs were performed.This series included 31 skin-sparing mastectomies. Sixty-six patients had immediate reconstruction and 19 were delayed procedures. The mean age was 46 years (range 25-58). The mean length of operation was 271 minutes (range 148-420) and the average hospital stay was 8.3 days (range 5-23). The mean tumour size was 2.9cm with median grade II. Thirty-seven patients had node positive tumours and adjuvant therapy was given in 73 cases.

Partial flap loss was noted in 12 instances (12.6%). One woman developed an incisional hermia and another had an abscess in the same area. There were no complete flap losses using this technique.

After a mean follow-up period of 35 months there have been 3 cancer-specific deaths. Six patients have developed metastatic disease and there is one diagnosed case of local recurrence within the mastectomy wound.

Conclusions: TRAM reconstruction after mastectomy does not compromise the oncological management of breast cancer. Although it is a lengthy procedure, the time spent in hospital is not excessive and complications are relatively infrequent. We commend this technique for immediate and delayed breast reconstruction.

254 POSTER

Axillary lymph node dissection in T1a and T1b breast cancer

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Background and Aims: Lymph node (LN) involvement in T1a (* 5 mm) and T1b (6-10 mm) breast cancer patients is low, and the need of axillary LN dissection (ALND) in the management of early breast cancer remains a controversial issue. ALND probably has not effect on the overall survival and is only useful for local control in patients with positive nodes. The aims of this study were to evaluate incidence of LN involvement in our series and to examine the correlation between the axillary LN status and the primary tumor characteristics in order to develop a panel predictive for axillary LN metastases.

Patients and Methods: This is a retrospective analysis of 158 T1a-T1b breast cancer patients who underwent either quadrantectomy or mastectomy with complete ALND from 1991 to 2000. Forty-seven patients had T1a and 111 T1b tumor. Each medical record was reviewed and axillary LN status was related to the following pathobiologic parameters of the primary tumor: tumor size, grading (G), hormone receptors (Estrogen [ER] and progesterone [PR]) status, proliferative index (Mib-1). Logistic regression model was applied to determine the set of variables that best predict LN involvement.

Results: LN involvement was documented in 17.1% of the entire group. Two patients with T1a tumors (1,25%) and 25 with T1b (22,5%) had at least 1 LN positive for malignancy. A significant association with nodal metastases was found via bivariate analysis for PR- (OR 2.6), G2 vs G1 (OR 3.4), G3 vs G1 (OR 11.0), Mib-1 >20 vs <20 (OR 2.7). The association between ER status and LN positivity was not significant. After multivariate analysis, only the Grading significantly predicted for the presence of metastases in the axillary LN basin ($p<0.05$).

Discussion and Conclusions: Axillary LN dissection is largely performed for staging purposes. Several authors have argued that the incidence of node positivity in T1a tumors is so low that ALND could be safely omitted. Based on our results we feel that both patients with T1a and T1b should continue to have an histological assessment of axillary LN status, possibly with the sentinel node biopsy, that is widely accepted as a suitable alternative to ALND for staging purposes. Results of our series were no able to find a panel of pathobiologic characteristics with predictive value on nodal involvement. The finding of a relationship between PR negativity and axillary LN positivity should be confirmed in larger data sets.

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Conservative treatment of breast cancer and axillary dissection using a periareolar approach

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Surgery have to be considered, up today, as two steps of the same operation. Both in demolitive than in conservative treatment surgeon must try to combine a correct oncologic treatment with the better aesthetic result.WE introduce a surgical technique for the breast cancer conserving therapy by a total periareolar approach. This allow large glandular resection without living breast deformities as in breast shape as in nipple-areola complex and in the same time allows us to perform the sentinel node biopsy or a complete three levels lymphophoadenectomy. A periareolar reduction mammoplasty of the contralateral breast can be performed.

Since 1999 we have performed 60 BCT with this technique.Selected patients presented a T1 breast cancer without skin retraction or infiltration, distant more than 1 cm from the surface (eco-mammographic and spiral ct scan evaluation

Technique: Periareolar incision can be at 180° or 360° Preoperative marking can be total periareolar incision or an elliptical disepiteliazed pe-

riareolar area. First surgical step is to largely prepare glandular tissue, detaching breast from the skin, and separate breast from the muscular fascia.At this point half breast is taken out from the periareolar incision and we decide the resection extent according with tumor size. Before starting breast reshaping, axillary dissection has to be performed. This periareolar approach allows us to perform a complete three levels axillary dissection without adding an incision in the axilla. Than we have to reshape the breast according with the superior or inferior pedicle technique depending by which part of the breast we have resected).Nipple-areola complex now can be settled in a new position, its central vascular support is save and it is adjusted to the central skin incision avoiding any deformities.Contralateral mastopexy by the same technique is performed.In this way we obtain two symmetrical breasts rounder, no more ptosic and more projected with only a periareolar scar

Conclusions: (1) Periareolar approach allows large glandular resection even larger than a traditional quadrantectomy.

(2) It allows a complete axillary lymphophoadenectomy

(3) It allows a good breast simmetry with a good ptosis

(4) No nipple-areolar complex ischemic failure has been recorded

(5) No local relapse are still now recorded (median follo-up 12 month ranging 24-2 mt)

(6) All patients are satisfied of the result

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PROFFERED PAPERS

Predictive and prognostic factors

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Detection of persisting isolated tumor cells in the bone marrow as possible surrogate marker for the failure of systemic treatment of breast cancer

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Background: To date, there is no surogate marker available, to evaluate the therapeutic efficacy of adjuvant treatment in individual breast cancer patients before subsequent distant relapse. Detecting the persistence of disseminated tumor cells in the bone marrow (BM) may help to identify patients with increased risk for recurrence after the completion of primary treatment.

Method: We analyzed bone marrow aspirates of 156 patients without evidence of recurrence at the time of primary diagnosis and a median interval of 19.8 months thereafter. Carcinoma cells were detected using a standardized immunoassay with monoclonal antibody A45-B/B3 directed against cytokeratin (CK).

Results: At the time of primary diagnosis, 44 of 156 patients (28%) had a positive BM finding, while 37 (24%) had a positive BM finding at the time of the second BM analysis. Among those patients with an initially negative BM finding, 19 patients (12%) had a positive BM finding at the second aspiration, while 18 patients (11%) were BM-positive in both examinations. Of the 44 patients with ITC at the time of primary diagnosis, 26 patients (59%) received adjuvant chemotherapy, 7 patients (16%) received endocrine therapy and 11 (25%) patients had no systemic treatment at all. 55% of the patients without systemic therapy (n = 6) converted to a negative BM status at time of follow-up examination, while 60% of the patients, with endocrine (n = 4) or cytostatic (n = 16) therapy became negative (P = 0.79). Patients with a negative BM status at the time of follow-up examination (n = 119) had a significantly better overall survival than patients with a positive BM status at the time of the second BM aspiration (n = 37), both by univariate analysis (P = 0.0014. Log-rank) and multivariate analysis (P = 0.003, Cox Regression).

Conclusion: Indpendently of systemic therapy, a considerable number of patients remain BM-positive suggesting failure of therapy and risk of subsequent development of distant disease.

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Clinical response after two cycles is superior to HER2, Ki-67, p53, and bcl-2 in independently predicting a pathological complete response after preoperative chemotherapy in patients with operable carcinoma of the breast

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Purpose: To investigate the predictive value of clinical and biological markers for a pathological complete remission (pCR) after a preoperative dose-dense regimen of doxorubicin and docetaxel (AT), with or without tamoxifen, in primary operable breast cancer.

Patients and Methods: Patients with a histologically confirmed diagnosis of previously untreated, operable, and measurable primary breast cancer (T2-3($\geq$3 cm)N0-2M0) were treated in a prospectively randomized trial with four cycles of biweekly AT chemotherapy, with or without tamoxifen, prior to surgery. Clinical and pathological parameters (menopausal status, clinical tumor size and nodal status, grade, and clinical response after two cycles) and a panel of biomarkers (estrogen and progesterone receptors, Ki-67, HER2, p53, bcl-2, all detected by immunohistochemistry) were correlated with the detection of a pCR.

Results: A pCR was observed in 9.7% in 248 randomized patients and in 8.6% in the subset of 197 patients with available tumor tissue. Clinically negative axillary lymph nodes, poor tumor differentiation, clinically complete or partial response after two cycles, negative estrogen receptor status, negative progesterone receptor status, high percentage of Ki-67 positive cells, and loss of bcl-2 were significantly predictive of a pCR in a univariate logistic regression model, whereas in a multivariate analysis only the clinical response after two cycles provided significantly independent information. Backward stepwise logistic regression revealed a response after two cycles, with progesterone receptor status and lymph-node status as significant predictors. Patients with a low percentage of cells stained positive for Ki-67 showed a better response when treated with tamoxifen, whereas patients with a high percentage of Ki-67 positive cells benefited more when treated without tamoxifen. Tumors over-expressing HER2 showed a similar response to that in HER2-negative patients when treated without tamoxifen, but when HER2-positive tumors were treated with tamoxifen, no pCR was observed.

Conclusions: Reliable prediction of a pathological complete response after preoperative chemotherapy is not possible with clinical and biological factors routinely determined before start of treatment. The response after two cycles of chemotherapy is so far the strongest independent predictor, and can be used to save patients from further ineffective and toxic chemotherapy.

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TP53 mutation and/or overexpression of the HER2 receptor are strong indicators of poor prognosis in both node-negative and node-positive early breast cancer

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Purpose: Mutation in TP53 and overexpression of the HER2 receptor have been described to have prognostic importance for the outcome of breast cancer. The present study was performed to evaluate if TP53 mutation, HER2 expression, or a combination of these would be feasible prognostic markers in the routine diagnostic evaluation of early breast cancer, and especially in node negative patients.

Materials and Methods: Tumour material were obtained from women with sporadic early breast cancer. TP53 gene mutations in exon 2-11 were identified using DGGE and characterized by sequencing (Clin Cancer Res. 2000; 6:3923). Tumours were counted as HER2 overexpressing when a strong staining of the entire membrane (using the c-erbB-2 antibody from DAKO) was observed in more than 10% of the tumour cells ('3+' in the HercepTest guidelines). All patients were treated according to the Danish Breast Cancer Cooperative Groups guidelines for the DBCG 89 protocols.

Results: The study included 456 patients, 222 node-negative and 236 node-positive. TP53 mutation was found in 24%, HER2 overexpression in