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Quality assurance in breast cancer surgery in France – Recommendations of the French Senologic Society (Société Française de Sénologie et de Pathologie Mammaire – SFSPM)

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In France, regional breast cancer screening programmes have been implemented since 1989 and a national protocol started in 1994. The national extension was effective in January 2004. During this period major improvements in terms of professional practice have been achieved. Quality control procedures were initially implemented for radiologists, thanks to the national breast cancer screening programme. Our first guidelines based on the "European guidelines for quality assurance in mammography screening" initially involved screening and diagnosis but surgery and breast cancer treatment were not yet considered. Being concerned by the quality of the whole process, from the diagnosis to the treatment, the SFSPM worked on quality assurance together with the national agency for accreditation to develop guidelines for the treatment of breast cancer with a particular effort on surgery.

In the vast majority of cases, surgery is the first treatment applied. Surgery also plays a decisive role in a patient's cure. An insufficient technical environment or inadequate individual care may lead to serious consequences for the future of the patient. We suggested that the experience of the surgeon is, amongst other factors, related to his/her activity (number of cases annually operated). This criterion has to be considered when choosing specialists for breast cancer surgery, but the present conditions of medical practice in France must also be taken into account. Considering the high number of breast cancer women (42,000 new cases per year) an abrupt stop of the activity of the surgeons who would not be immediately in accordance with the new guidelines could disrupt national senologic activity.

In France, breast surgery is performed in numerous public and private institutions by specialists coming from different specialities: mainly gynaecologists, general or visceral surgeons, surgical oncologists, or more rarely plastic surgeons with an oncologic specificity. Our goal was to ensure that all these surgeons would have a homogeneous approach, to ensure equal quality of care to breast cancer patients throughout the country.

Breast surgery requires a double multidisciplinary organisation: non palpable lesions require close collaboration with both the radiologists and the pathologists (this activity is growing with the national extension of mass screening). On the other hand, taking care and treating invasive lesions require a close collaboration with radiation oncologists and medical oncologists. For breast cancer care, each step of the ladder, from diagnosis to treatment, can be a subject for improvement: breast cancer surgery is one of those steps.

Quality assurance criteria for hospitals are based on:

- Adequate specific equipment.
- Written procedures that must outline the organisation of every step required for the quality of the surgery (preoperative, the surgery itself, and postoperative care).
- These procedures secure the care of the patient in the hospital from his/her admission to the moment they are allowed home.
- The hospital has to be able to give the surgeon's activity to the authority's representatives.
- The hospital has to sign a convention with a regional network for cancer treatment.

Quality assurance criteria for the surgeon himself focus on:

- The training: surgical specialisation (gynaecologic surgery, general surgery) with a specific training in breast surgery.
- Regular participation in a multidisciplinary breast cancer meeting. The surgeon has to personally present his/her patients records to a clearly identified team.
- The surgeon has to be a member of a known regional network of oncology.
- The patient's medical record has to contain all the data related to the surgery.
- The time allowed between each step of the process has to be in accordance with national recommendations, particularly in case of invasive cancers.
- The surgeon has to be able to demonstrate his/her annual activity in breast surgery in case the representatives of the national authority require it.
- If a minimum level of surgical breast activity was to be considered as a quality criterion, the useful and acceptable level proposed would be between 20 and 30 breast cancer operations annually after 2 to 4 years of practice.

In 2006, these recommendations will be included in a national ministerial order and we hope that they will contribute to a more equal access for women to high quality breast cancer care

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Outcomes of breast conserving surgery in early onset breast cancer: Omission vrs. delivery of adjuvant radiotherapy

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Introduction: Early onset breast cancer (stage I/II) is associated with good prognosis and low local recurrence rates. Breast conserving surgery plus adjuvant radiotherapy is accepted treatment for stage I/II disease. Evidence increasingly demonstrates the deleterious long-term consequences of radiotherapy. The purpose of this study is to investigate whether or not the omission of adjuvant radiotherapy in this specific cohort of (stage I/II) breast cancer patients has any measurable consequence on local recurrence rates, disease free survival and overall survival.

Method: Clinical case notes were reviewed retrospectively on 190 patients treated with breast conserving surgery (BCS) at a single institution from January 1990 to December 2004. The cohort was divided into two matched treatment groups: BCS with or without adjuvant radiotherapy. The groups were matched by age and date of presentation. Parameters recorded included: histo- pathological features, adjuvant therapy received, follow- up, local relapse rates, disease free and overall survival.

Results (provisional): In group I (with adjuvant radiotherapy) there were 112 women of median age 57 (38–80 years). The median tumour size was 9 mm (1–10 mm) and median follow-up was 74 (15–110) months. There were no local recurrences. In group II (without adjuvant radiotherapy) the median age at presentation was 59 (48–81) years. The median tumour size was 7 (9–10)mm and median follow- up was 47 (14–93) months. There were three non-breast cancer related deaths and three local recurrences (6%).

Conclusions: Following breast conservation surgery in these select groups of patients there was an annualised rate of recurrence of approximately 1.5%. There were no significant different outcomes between the two groups. This provides further evidence to suggest patients with small invasive breast cancers could be adequately managed without the use of adjuvant radiotherapy.

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Multidisciplinary management of patients with BRCA1 and BRCA2 mutations in Institut Curie of Paris

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Five per cent of breast cancers are associated with a genetic predisposition. BRCA1 and BRCA2 genes and their mutations associated to breast cancer, respectively located on chromosomes 17q and 13q, have been identified in 1994 and 1995. The inheritance of BRCA1 and BRCA2 mutations is autosomal dominant. Identification of a mutation in a family neither explored before, usually takes a long time (about 9 months) and is particularly difficult as a result of the large sizes of BRCA1 and 2 genes and of the wide range of the various mutations (800 for BRCA1 and 200 for BRCA2). On opposite when a mutation is identified within a family, its detection can be obtained in few days.

Management of patients with mutated BRCA genes is complex; requiring usual mammary imaging as well as MRI scan. Different concurrent consultations are advisable: with the oncogenetician, breast surgeon, gynaecologist, plastic-surgeon and oncopsychologist. When the assessment is done the therapeutic schedule is decided by the medical team and the patient.

In summary 3 different situations can be encountered:

1. when no malignant breast lesion is present, a bilateral prophylactic mastectomy with areola ablation, skin cover preserving and breast reconstruction by implants is proposed. No axillary exploration of lymph nodes will be performed. On another hand, scientific pieces of information concerning the question of areola conservation are still lacking
2. when in situ carcinoma lesions are present, a mastectomy with areola ablation, skin cover preserving and immediate breast reconstruction is proposed an exploration of axillary lymph nodes either by sentinel lymph node procedure or limited axillary dissection will be performed. A contralateral prophylactic mastectomy will be concurrently proposed as described above. Similar procedures are proposed to patients with an

associated micro invasive component or with an invasive carcinoma of small size, however without any schedule of postoperative radiotherapy.
3. when an invasive carcinoma is present; the usual treatment according to the recommendations of our institute is proposed. In this case the contralateral prophylactic mastectomy as described above is performed the same day than the subsequent reconstruction of the ipsilateral breast.

We report here the preliminary results of our prospective registration in progress in Institut Curie.

The multidisciplinary management of patients with BRCA1 and BRCA2 mutations is particularly of great importance, requiring a specialised trained medical team It must be are particularly underlined that there is an increasing demand, concerning well-informed patients, therefore the given information and its traceability, as always in surgery consultation.

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Breast cancer surgery in day case setting: A systematic review

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Introduction: Is there enough evidence in the literature to demonstrate that day case surgery (DCS) for breast cancer is feasible, safe and well accepted by all patients and in all types of surgical procedures?

Brief description: A systematic literature search in five scientific databases (Medline, Embase, CINAHL, Psychinfo and Cochrane library) and in the reference lists of selected papers was performed for the terms breast, surgery, neoplasm, cancer, ambulatory, day case, outpatient, day care, day surgery, one day and early discharge. No restrictions were used concerning study design, age, gender or stage of breast cancer. Studies were selected if describing breast conserving surgery (BCS) with sentinel lymph node biopsy (SLNB), axillary lymph node dissection (ALND) with or without BCS, simple mastectomy (SM) or modified radical mastectomy (MRM) under general anaesthesia and in day case setting. The outcome of the study should describe one of the following aspects: the success rate of DCS, reasons for unplanned admissions, complication rate, patient satisfaction or costs.

Summary: No randomised clinical trials (RCT) on the subject were found. The included studies were mainly observational studies without a proper control group. Sixteen papers describing 18 studies were included. The percentage of patients treated with DCS in these studies ranges from 4 to 100%. This is mainly caused by differences in patient recruitment, surgical intervention performed and exclusion criteria used for DCS. Overall, no significantly increased risk of surgery in day case setting is seen. The major cause of (unplanned) admission is side effects from anaesthesia (postoperative nausea and vomiting). The MRM is less frequently performed in DCS than BCS with and without ALND. Despite the fact that authors report that patient and informal carers are satisfied and accept DCS well, no validated questionnaire was used to assess patients' acceptance or satisfaction. The range of hospital cost reduction varied between 50 and 85%.

Conclusion: This literature review describes that performing DCS in breast cancer is not supported by evidence from RCT's, but seems feasible in approximately 50–70% of the population depending on the distribution of the type of surgery performed, the hospital setting, health care system, and without an increase in surgery related complications. Similarly, patients' acceptance and satisfaction seems sufficient, but is not supported by evidence.

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Sentinel node biopsy after neoadjuvant chemotherapy in breast cancer

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Background: to evaluate the accuracy and feasibility of sentinel node biopsy technique in patients with operable clinically node negative breast cancer after neoadjuvant chemotherapy irrespective of the initial stage.

Material and Methods: the subject of this study was 45 consecutive patients affected by T2N1M0 core biopsed breast cancer, treated at Istituto Nazionale Tumori, Milano. Age ranged from 24 to 58 years. They underwent neoadjuvant taxanes-antracyidine containing chemotherapy. Axillary mapping was performed in all patients using both lymphoscintigraphy with radioactive colloid and blue dye injection. After this a three-levels axillary dissection was performed after sentinel node biopsy at the time of definitive surgery. Breast conserving treatment was allowed in 21 patients; thew remaining received total mastectomy.

Results: The detection rate of sentinel node was 2/45 (95.5%) with a full concordance between the two methods (blue dye and hot). Nodal involvement was found in 14 (31%) patients in agreement with sentinel node status. The sentinel node was the only positive in 5 (11%) of these patients. In this series 20 patients was node negative and false negative rate was 4/45 (9%).

Conclusions: neoadjuvant chemotherapy downstages axillary lymph nodes and sentinel node biopsy seems to be as accurate and feasible to stage axilla as in case of sentinel node biopsy performed during primary surgery.

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Lymphovascular invasion and local recurrence

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Introduction: Lymphovascular invasion (LVI) is associated with an increased risk of local recurrence after breast conservation and mastectomy. We wished to study whether management of the primary tumour should be influenced by the presence of LVI.

Material and Methods: 347 patients treated under the care of a single surgeon between 1st Jan 1992 and 31st Dec 1995 were followed for a median of 68 months after surgery for breast cancer. Twenty three had suffered local relapse after mastectomy (18) or conservation (5). All patients had clear margins at primary surgery. LVI was present in the primary tumour in 4/23 (17.3%) of those who relapsed, compared with 42/324 of those who did not ($Chi^2 = 0.37$; $p = 0.55$, no significant correlation). LVI was included with tumour grade, tumour size and extent of nodal involvement in multivariate logistic regression analysis with local recurrence as the dependent variable. Tumour size greater than 3 cms (Odds ratio 2.67, $p = 0.06$) and involvement of 4 or more nodes (odds ratio 10.1, $p<0.0001$) were the only variables associated with local recurrence. LVI and tumour grade were not associated independently with local recurrence.

Conclusion: The presence of LVI should not determine the management of primary breast cancer.

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Endoscopic subcutaneous mastectomy and immediate reconstruction for breast cancer

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Background: A subcutaneous mastectomy has been proven to be oncologically safe for early breast cancer. Although a subcutaneous mastectomy and reconstruction are well established, most incisions are made directly on the breast. To improve the cosmetic outcome, an endoscopic subcutaneous mastectomy and immediate reconstruction was undertaken, which can be performed through minimal axillary and periareolar semicircular incisions.

Materials and Methods: Between October 2002 and September 2005, 31 patients with early breast cancer, whose tumors were less than 4 cm in size and more than 2 cm apart from the nipple-areolar complex, and who were clinically node negative without invasion to skin and pectoralis muscle, underwent endoscopic mastectomies with immediate reconstruction employing saline bag implants. Firstly, an endoscopic dye-guided sentinel node biopsy was performed through a low transverse axillary incision lateral to the pectoralis major. A subpectoral pocket was gently created under the view of endoscopic monitor by Vein Harvest. A periareolar semicircular incision was made to create the skin flap using Visiport and PowerStar Scissors. Frozen section biopsies were performed to rule out tumor invasion to the resection margin. After resection of the entire breast tissue, a saline bag prosthesis was inserted. The patients and tumor characteristics, operation time, amounts of bleeding, and cosmetic results were evaluated.

Results: The mean patient age was 45 years (25–64). The mean tumor size was 2.2 cm., ranging from 0.5 to 3.5 cm. The average operation time was 119 minutes (80–150). The mean amount of operative bleeding was 226ml (60–390ml). There was two cases of transient necrosis of the nipple-areolar complex. An early implant removal was performed in one patient due to a suspected microperforation. Excellent or good cosmetic results were obtained in 30 patients (96.8%).

Conclusion: An endoscopic subcutaneous mastectomy with immediate reconstruction, is a new technique that can minimize the direct operation scar on the breast skin following a classic operation. In properly selected cases, our results show maximized cosmetic satisfaction of breast cancer patients, so offers a promised alternative to a classic subcutaneous mastectomy with immediate reconstruction.