Pergamon

*European Journal of Cancer* Vol. 32A, No. 11, pp. 1866–1875, 1996

Printed in Great Britain
0959-8049/96 $15.00 + 0.00

PII: S0959-8049(96)00206-7

## Original Paper

# Comparison of the Surgical Procedures for Breast Conserving Treatment of Early Breast Cancer in Seven EORTC Centres

M.R. Christiaens,[1] L. Cataliotti,[2] I. Fentiman,[3] E. Rutgers,[4] M. Blichert-Toft,[5] J.E. DeVries,[6] H.P. Graversen,[7] K. Vantongelen[8] and R. Aerts[8]

[1]University Hospital, Leuven, Belgium; [2]University Hospital, Firenze, Italy; [3]Guy's Hospital, London, U.K.; 4[4]Antoni Van Leeuwenhoekhuis Hospital, Amsterdam, The Netherlands; [5]Rigshospitalet, Copenhagen, Denmark; [6]Sophia Hospital, Zwolle, The Netherlands; [7]University Hospital, Odense, Denmark; and [8]Clinical Trial Office, University Hospital, Leuven, Belgium

**The aim of this study was to develop a standardised surgical report for breast-conserving procedures, supporting the systematic documentation of the different aspects of the surgery. The surgical procedure for tumourectomy and axillary clearance was translated into a series of steps that could be quantitatively documented. This description was submitted twice to a group of surgeons from different departments to ensure that all steps that are considered to have relevance for outcome were included and that no superfluous data were collected. After two corrective phases, a first test format was developed. Between February 1993 and May 1994, seven surgical departments, participating in EORTC trials, completed this questionnaire for a number of their patients. The data collected related to general information on the department, the tumour excision itself, the axillary dissection and, in a later phase, on pathology. 269 questionnaires (264 tumour excisions, 259 axillary dissections and 189 pathology reports) were collected and analysed. Even though the participating departments were involved in a single trial on breast-conserving surgery and had previously developed regular contacts about the practical aspects of treatment, many differences were detected. In general, variations were found in the waiting time between treatment prescription and execution, experience of the surgeon, duration of the procedure, and the use of prophylactic antibiotics. Also, in the practical execution of the procedure, major variations in the type of incision, width of tumour excision, closure of the breast tissue and skin, the use of frozen sections and the extent of the axillary dissection were found. The most relevant differences and their possible consequences are discussed. It has been proven possible and feasible to document quantitatively a surgical procedure. The fact that within a group of surgeons participating in the same clinical trials, many differences in the surgical techniques are observed, stresses the need to reach a consensus on a stricter set of guidelines for breast-conserving procedures and their documentation, especially when conducting clinical trials.** 

**Key words: quality assessment, surgery, breast conservation, breast cancer**

*Eur J Cancer*, Vol. 32A, No. 11, pp. 1866–1875, 1996

## INTRODUCTION

ONE OF the main aims in monitoring the health care system is to ensure that all patients are referred for state-of-the-art treatment, at the time that they need it, and that they receive the correct therapy [1]. The monitoring of the correct technical execution of a treatment requires the definition of all elements of the process which are considered to be of importance. In radiotherapy [2, 3] and chemotherapy [4, 5], major efforts towards this aim have been carried over the past few years. Their prescription schedules carry quan-

Correspondence to M.R. Christiaens, Department of Surgery, Division of Senology, University Hospital K.U.L., Brusselsestraat 69, B-3000 Leuven, Belgium.
Received 4 Sep. 1995; revised 23 May 1996; accepted 23 May 1996.

titative indications and this was very helpful in setting criteria. For surgery, one is confronted with a paradoxical situation in which it is acknowledged that the "quality" of the surgeon is a predominant factor determining the outcome, while little or no efforts have been carried out to monitor the process. These two factors are probably related as the relative lack of quantification and absence of written procedures makes it difficult to measure objectively the process, while putting a larger responsibility on the individual surgeon, possibly resulting in wider ranges of performance.

The EORTC Breast Cancer Cooperative Group (BCCG) has set up a project in which procedures for the different parts of breast cancer treatment are worked out. These efforts were collected in a "Manual for Clinical Research in Breast Cancer" [6]. In one of the chapters, a number of surgical procedures are defined in general terms. As a further development, the presently reported pilot study has attempted to structure the whole procedure of tumour excision and axillary clearance in a number of steps which, individually, can be quantified.

The aim is to develop a consensus on a minimum data set that would be required to define as accurately as possible the technical conditions and steps that are taken during the surgical procedure. This should be of great help in transferring structured information to the other specialists' areas (pathology, radiotherapy) involved in the treatment of breast cancer. It should also help in producing a standardised report on the surgical procedure in such a way that assessment of treatment outcome, side-effects and complications can be better correlated with the surgical procedure. Finally, in the context of clinical research, such a systematic and structural approach should allow much better comparability of data between different centres [7].

## MATERIALS AND METHODS

As a first step, the procedure of tumour excision and axillary clearance was completely written out and translated into a series of questions with answers, which included all possible variations in technique. This questionnaire was circulated to five surgeons from different centres, all active in the EORTC BCCG, with the request to indicate which of the questions were considered by them to be of relevance in assessing outcome of the surgical procedure. A consensus was reached on the questions considered of minor importance and to be deleted, but also on a few items to be added. The questionnaire was transformed into a computerised checklist with multiple-choice answers without need for written formulations.

The questionnaire was initially divided into three subjects: the first part collecting general information (pre-operative staging, structure of the department dealing with treatment decision and prescription, experience of the surgeon and conditions of the surgical act). The second part was related to the excision of the tumour (type of incision, width of the excision, handling the specimen, closure of the breast). The third part contained information on the axillary clearance (incision, levels, neurovascular structures, closure).

Seven centres agreed to complete the questionnaire in a number of their breast-conserving interventions performed, starting in February 1993. All data were collected by the Clinical Trial office in Leuven, Belgium. After 4 months, the first information collected was analysed and discussed between the surgeons involved. Some questions on procedure, and a fourth part concerning the pathology, were added. As the first round was considered positive, all centres agreed to continue documentation of some of their breast-conserving procedures. By the end of May 1994, a total of 269 questionnaires were entered in the computer giving information on 264 tumour excisions, 259 axillary clearances and 183 pathology reports (Table 1). All data were considered for analysis, including the data collected before the change of the first questionnaire. Since some questions on procedure were added in June 1993, fewer answers were available for some items.

Four of the major participating centres have been site-visited by the first and third author, to check whether the actually performed procedures were executed as they were reported in the checklists. No major deviations were noted. Coefficients of variation are calculated using the root mean square error.

## RESULTS

General information is available on 269 cases. Breast-conserving treatment for early breast cancer is a joint venture of surgeon and radiotherapist in the first place. It has been stressed that to obtain high-quality performance a multidisciplinary approach is advisable [8, 9]. In our data collection file, decision on treatment could either be taken by the surgeon alone or in a "joint clinic". Two possible options of multidisciplinary behaviour have been taken into account. Either the surgeon and the radiotherapist discuss the patient's file and make up a treatment proposal, or the patient is present at this multidisciplinary meeting. In the latter case, the patient is re-examined by the surgeon and the radiotherapist, the patient's history and technical investigation are reviewed, the decision on treatment is taken by the team and discussed with the patient. Of the seven centres involved (Table 1), four plan their decisions for 92–100% of the patients in "joint clinics". Two centres report joint-clinic decisions for less than 10% of their patients and one centre treats about half of the patients in a joint clinic. Only one of the centres (D), having a multidisciplinary approach, always sees the patient at the time of the treatment decision.

*Table 1. Number of questionnaires completed (February 1993–May 1994) for each centre and procedure*

| | Total number | | | | |
|---|---|---|---|---|---|
| Centre | Breast 264 | Axilla 259 | Pathology 183 | General 269 | Decisions* in "Joint Clinic" |
| A | 17 | 15 | 6 | 18 | 44% |
| B | 18 | 18 | 12 | 18 | 100% |
| C | 65 | 60 | 34 | 65 | 9% |
| D | 101 | 105 | 77 | 105 | 100% |
| E | 36 | 36 | 35 | 36 | 100% |
| F | 14 | 13 | 7 | 14 | 0% |
| G | 13 | 12 | 12 | 13 | 92% |

* Decisions taken with a multidisciplinary approach.

As for other types of surgery, the workload [10] and the surgeons' experience [11, 12] in breast cancer surgery may influence the result of standard surgical treatment. For the participating centres, the workloads during 1993 and 1994 were almost comparable; Centres A, C, D, E and F had more than 200 (range 195–311) new breast cancer patients a year. In Centre B, 88 (1993) and 66 (1994) breast-conservation procedures were performed. Centre G had 104 (in 1993) and 123 (in 1994) new patients during the study period. It should be stressed that only some of the breast-conservation procedures, and for each centre a different percentage of the total amount of surgical procedures for breast cancer, were documented. In the participating centres, breast-conserving procedures are most often performed by staff members with extensive experience (>50 operations/year) in this kind of surgery. In five of the centres, more than 85% of the patients are operated on by a staff member carrying out more than 50 breast procedures per year. In Centre C, there is greater variation in experience between the operating staff members and in centre G, 45% of operations are carried out by a staff member who performs 40 procedures a year and 31% by residents having less experience (<10–20 operations/year), but who are assisted by more experienced staff members. For all other centres, residents are responsible for only 2–8% of the operations.

Since there is no major reason that differences in workload and experience of the surgeon may influence the evaluation of this documentation study, no further grouping according to those factors has been done.

The time between treatment decision making and the surgical procedure was calculated. For breast and axillary surgery carried out in one operation period, this delay varied from 5 to 110 days. Most patients were operated on in the first 15 days after treatment planning. Figure 1 shows the same analysis for the three major contributing centres. In Centre D, almost all patients were operated on in the first 2 weeks. In Centres C and E, a larger delay and greater variation was noted. When the breast and axillary procedures were performed on different dates, the time period between the first event (breast surgery or decision making) and the completion of the surgery showed a more marked variation. For these patients, the whole surgical period took beween 5 and 85 days, with surgery completed within 40 days in 80% of the patients. The variation is almost equal for the three centres mentioned above.

The duration of the breast and axilla procedure was strongly dependent on whether frozen sections or specimen X-rays were carried out. The mean overall surgical time was 90 min (range 40–170). If the time that the surgeon waits for outcome of the control procedures is deducted, the mean duration was 60–70 min. When looking at the individual centres (Figure 2), the distributions reflect the fact that Centres C and D carry out frozen sections on a regular basis, which translates into a wider range of times. Centre E, which does not carry out frozen sections, has a much narrower distribution with the vast majority of overall times between 50 and 70 min. When deducting the "waiting times", it becomes apparent that the main range for actual surgical time for Centres D and E are exactly the same, while Centre C has a slightly wider range. It is also this centre that has the greatest variation in experience of the surgeon.

In one centre (C) antibiotic prophylaxis was always used while this is not, or rarely, the case in the other centres. After the first audit meeting, the surgeons of this centre discussed the matter and decided to change their procedure, eliminating the routine administration of antibiotics. In all but one centre (C) the forms, reporting the performed surgery, were completed personally by the surgeon.

The technical aspects of tumour excision reveal that five centres perform more than 70% of the tumour excisions in one step, which means that only one intervention in the breast was necessary to resect the tumour grossly. In two centres (B, F), 58 and 62% of the procedures were completed in one step. Only Centre E reported a significant number of tumour excisions under local anaesthesia (11%). The location of the incision (Table 2) was almost invariably above the tumour. Incisions distant to the tumour were used in less than 5% of the cases. The policy to excise the overlying skin (Table 2) was different between centres. In two centres, this was infrequently (Centre D: 21%) or rarely (Centre E: 3%) done. In Centre C, this was nearly always (91%) done and in the four other centres the overlying skin was excised in approximately 30–64% of the cases. The length (Table 2) of the resulting scar varied considerably. At Centre E the incisions were always less than 5 cm, while for the other centres small scars ($\leq 5$ cm) were produced in approximately 20–75% of the cases. Incisions of more than 10 cm occurred in 10–20% of the cases except for Centre F in which 79% of incisions were more than 10 cm without a reasonable explanation. Centre C had incisions of more than 5 cm in 86% of cases. This correlates with the fact that the same centre frequently conducted overlying skin excisions (91%) and tumour excisions in continuity (42%) with the axillary clearance (Table 3). Other centres use continuous incisions in a maximum of 8% of their cases. The expected tumour-free margins showed an interesting difference. While in six of the seven centres, the surgeon stated that, in the vast majority of cases, he aims at a minimal tumour-free macroscopic margin of 1–2 cm, at Centre E a macroscopic margin of less than 1 cm was achieved in 80% of the cases.

When localisation procedures are carried out, nearly all centres used a hooked wire, with only Centre C routinely using the carbon injection technique.

A striking difference was seen in the policy of using frozen sections. Centres C and D use this almost routinely as 80–90% of the interventions were under guidance of frozen section. Centre E never performed frozen sections in the reported cases and the others use them on an incidental basis ranging from 10 to 40%. This different policy is reflected in the duration of the operation, as already described before (Figure 2). In Centre D, it was usual practice to incise the tumour at a side-table to take a sample for receptors determination. During the pilot study, the surgeon changed this practice and personally performed the inking of the specimen before incision.

All centres sent "fresh" specimens to the pathologist. All centres, except Centre G where the specimen is placed in an ice box, delivered the specimen at room temperature. The time to deliver the specimen to the pathology department was between 5 and 10 min in Centres A, B, C, D and E. In Centre F, it took between 5 and 30 min and in Centre G usually 30 min. As already described above, the

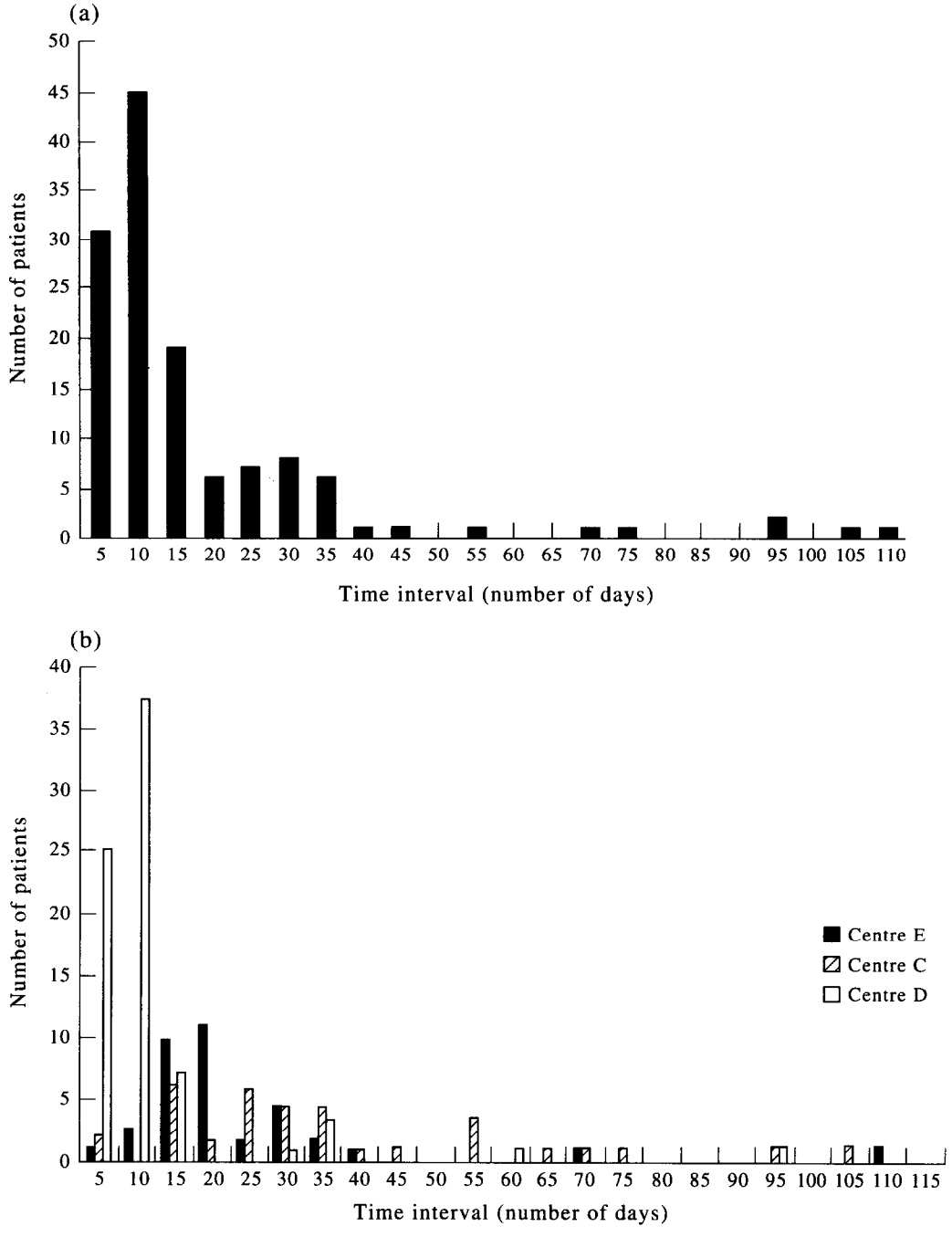


**Figure 1. Time between treatment decision and execution of the surgical procedure for all patients (a) and for the three major participating centres (b).**

surgeon at Centre D samples tissue immediately after excision to have enough fresh frozen material for further examination without impairing the possibility of evaluating the margins.

In Centre E, 83% of the specimens are sent to the pathologist without orientation. Centres C, D and F always orientate the specimen, and the others orientate the specimen in 24, 38 and 70% of the cases. Of the three centres who usually use markers to orientate the specimen, one centre describes that they do so in one direction, one in four directions and the third in either two or three directions. At the audit discussion meeting, it seems that most of them did not take into account resected skin as an additional, important orientation for the pathologist, and only counted the markers they put on the specimen themselves.

Only four of the seven centres regularly use clips (Table 2) for the localisation of the excision site (frequencies ranging from 64–83%) to enable the radiotherapist better orientation of boost volumes.

In Centre D, the resection cavity is never routinely drained (Table 2), in Centres B and F no drains are used in about 90% of the cases. In the four others a suction drain is used in 36–100% of cases. After tumour excision, the cavity is not routinely closed in Centres B and F and in 19% of

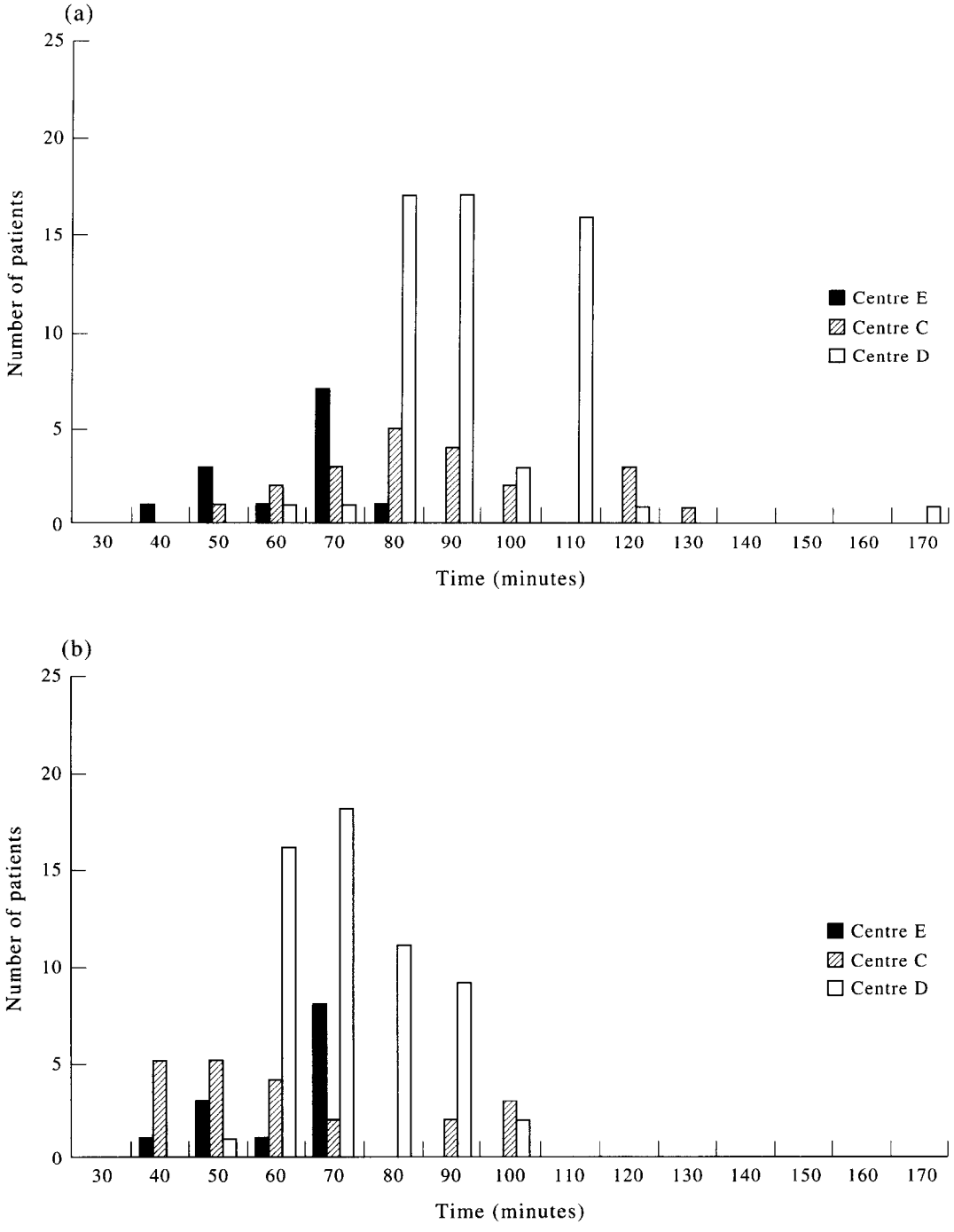


**Figure 2. Time to perform the whole procedure (a) and minus waiting time (b) in three major participating centres.**

the cases in Centre E. In the other centres, 50–100% of the cavities are closed. When closing the cavity, one of the centres (C) usually applies radial closure, while the others frequently use concentric closure or a breast tissue mobilisation procedure.

For the closure of the skin, one of the centres (E) usually applies interrupted stitches, five use a mixture of interrupted, running or intradermal sutures and one (D) always uses an intradermal running suture and applies steristrips. Only Centre D uses absorbable material for closure of the skin while the others use non-absorbable material.

Wound dressing was achieved using a compressive bandage in four of the seven centres and usually a non-compressive bandage in the other three. When the tumour excision and axillary clearance procedures were carried out in the same operation time, gloves, instruments and towels were nearly always (>90%) changed in Centre D and hardly ever in Centres E and G. The others change gloves and instruments in 50–80% of the cases.

To perform the axillary dissection (Table 3), a longitudinal incision was usually made in three (C, D, E) of the centres, a transverse incision in three (B, F, G) and in Centre A both procedures were used. As already mentioned,

*Table 2. Variations in the procedure for the tumourectomy*

| Centre | A | B | C | D | E | F | G |
|---|---|---|---|---|---|---|---|
| Total number | 17 | 18 | 65 | 101 | 36 | 14 | 13 |
| Length of the incision | | | | | | | |
| < 5 cm | 3 (18%) | 3 (17%) | 7 (11%) | 77 (76%) | 36 (100%) | — | 6 (46%) |
| 5–10 cm | 11 | 13 | 43 | 20 | — | 3 | 7 |
| >10 cm | 3 (18%) | 2 (11%) | 13 (20%) | 2 (2%) | — | 11 (79%) | — |
| Unknown | — | — | 2 | 2 | — | — | — |
| Type of incision | | | | | | | |
| Semicircular | 11 | 18 | 4 | 97 | 32 | 13 | 9 |
| Radial | 3 | — | 30 | 3 | 4 | 1 | 4 |
| Unknown | 3 | — | 31 | 1 | — | — | — |
| Incision over the tumour | 16 | 15 | 64 | 94 | 36 | 14 | 13 |
| Skin excision | 7 (41%) | 8 (44%) | 59 (91%) | 21 (21%) | 1 (3%) | 9(64%) | 4 (31%) |
| Orientation of the cavity with clips | — | 15 (83%) | — | 73 (72%) | — | 9 (64%) | 9 (69%) |
| Closure of the breast tissue | 9(53%) | — | 64 (98%) | 81 (80%) | 7 (19%) | — | 11 (85%) |
| Drain | | | | | | | |
| No | 4 | 16 (89%) | 39 (60%) | 100 (99%) | 23 | 13 (93%) | — |
| Suction | 13 (76%) | 2 (11%) | 21 (32%) | 1 (1%) | 13 (36%) | 1 (7%) | 13 (100%) |
| Penrose | — | — | 4 | — | — | — | — |
| Unknown | — | — | 1 | — | — | — | — |

centre C used a continuous incision from the breast to the axilla in 42% of the cases. In the other centres, the vast majority of the axillary dissections were performed through a separate incision. All continuous incisions were applied for tumours located in the outer quadrants. Except in Centres B and F, the first intercostobrachial nerve was routinely cut. In rare cases, the thoracodorsal and long thoracic nerve was cut. In all centres, the pectoralis minor muscle was left intact. There was some variation in the axillary dissection technique, with Centres A (87%), E (92%), C (98%) and D (99%) usually performing a Level I, II and III resection, while Centres B, F and G performed Level I and II resections, in respectively, 84%, 100% and 67% of their cases. Centres A and B sometimes (20 and 28%) resected tissue located in the interpectoral space. Rotter's space was cleared in 94% of the cases in Centre D, but the other participating centres did not explore Rotter's space.

The resected specimen was oriented (Table 3) in more than 90% of the cases in Centres A, D and E. Orientation was never done in Centre B and only sometimes in Centre C (78%), Centre F (31%) and Centre G (75%).

For haemostasis, all centres used cautery, Centre E even used cautery exclusively. Two centres (A, D) used both clips and cautery and Centres B, C, F and G used ligatures and cautery. Before closure, the axillary cavity was rinsed with warm water in two centres, with an antiseptic solution in one and three centres never rinsed the axillary. All centres routinely used one suction drain in the axilla. The skin closure had the same distribution as the closure of the breast incision, namely intradermal running sutures for Centre D, interrupted stitches in three centres, running sutures in two and a variation of running and interrupted sutures in one centre. Only Centre D used absorbable material and steristrips. Wound dressing was compressive in two of the centres, non-compressive in most cases in three of the centres, and various types of wound dressing in the last two centres were used. Postoperatively, Centre D did immobilise the arm in adduction, while all other centres did not immobilise the arm. During this evaluation, Centre D stopped immobilisation in view of the policy of the other centres. In all centres, patients were advised not to use the arm during the first 3–4 postoperative days.

Information about pathology was only requested in the second half of the study. 183 pathology reports were available to make correlations with performed procedures. Only 5 of the breast specimens weighed less than 10 g. The majority had a distribution of 10–49 g. Only Centre C has 16 out of its 34 specimens with a known weight over 100 g.

*Table 3. Variations in the axillary dissection procedure*

| Centre | A | B | C | D | E | F | G |
|---|---|---|---|---|---|---|---|
| Total number | 15 | 18 | 60 | 105 | 36 | 13 | 12 |
| Incision | | | | | | | |
| In continuity | 1 (7%) | — | 25 (42%) | 4 (4%) | 3 (8%) | 1 (8%) | — |
| Separate | | | | | | | |
| Transverse | 5 | 17 | — | 3 | 4 | 12 | 12 |
| Longitudinal | 7 | 1 | 35 | 98 | 29 | — | — |
| Combined | 2 | — | — | — | — | — | — |
| Extent of dissection | | | | | | | |
| Level I + II + III | 13 (87%) | — | 59 (98%) | 104 (99%) | 33 (92%) | — | 2 (18%) |
| Level I + II | — | 17 (94%) | — | — | — | 13 (100%) | 8 (67%) |
| Unknown | 2 | 1 | 1 | 1 | 3 | — | 2 |
| (+Rotter's Space) | 3 | 5 | — | 99 (94%) | — | — | — |
| Orientation of the major specimen | 14 (93%) | — | 47 (78%) | 104 (99%) | 36 (100%) | 4 (31%) | 9 (75%) |

There was a correlation between the weight of the fresh specimen resected from the breast and the length of the incision (Figure 3), but very surprisingly, there was no correlation between the maximum size of the resected specimen and the maximum size of the tumour (Figure 3). The surgeons excised almost the same amount of breast tissue for all kinds of tumour diameters. The location of the tumour did not seem to alter their policy.

When comparing the clinical and pathological tumour sizes (Figure 4), we found a clinical overestimation of the tumour, with larger differences between clinical estimate and pathological size as the tumour size increased. However, for approximately 20 cases, a clinical underestimation was found. This underestimation was not correlated with one centre, but was found in the three major contributing centres in equal proportion.

Most of the axillary specimens weighed between 50 and 199 g. In five centres, a minimum of 10 nodes were found in each specimen. The maximal count for each specimen varied between 16 and 46 nodes. The mean number of nodes found ranged from 11 to 24.

There was no correlation between the number of nodes examined and the weight of the axillary specimen. In Centres C and D, pathologists found the same number of nodes in specimens of different weights (Figure 5). In Centre E, there was a greater variation in number of nodes for the same weight of axillary specimen.

The percentage of positive nodes did vary from 1 to 25% of the counted nodes per centre; this could mean that different selection criteria for breast-conservative treatment were used. In Centres B, C and F, the total number and the amount of positive nodes was not available for each level

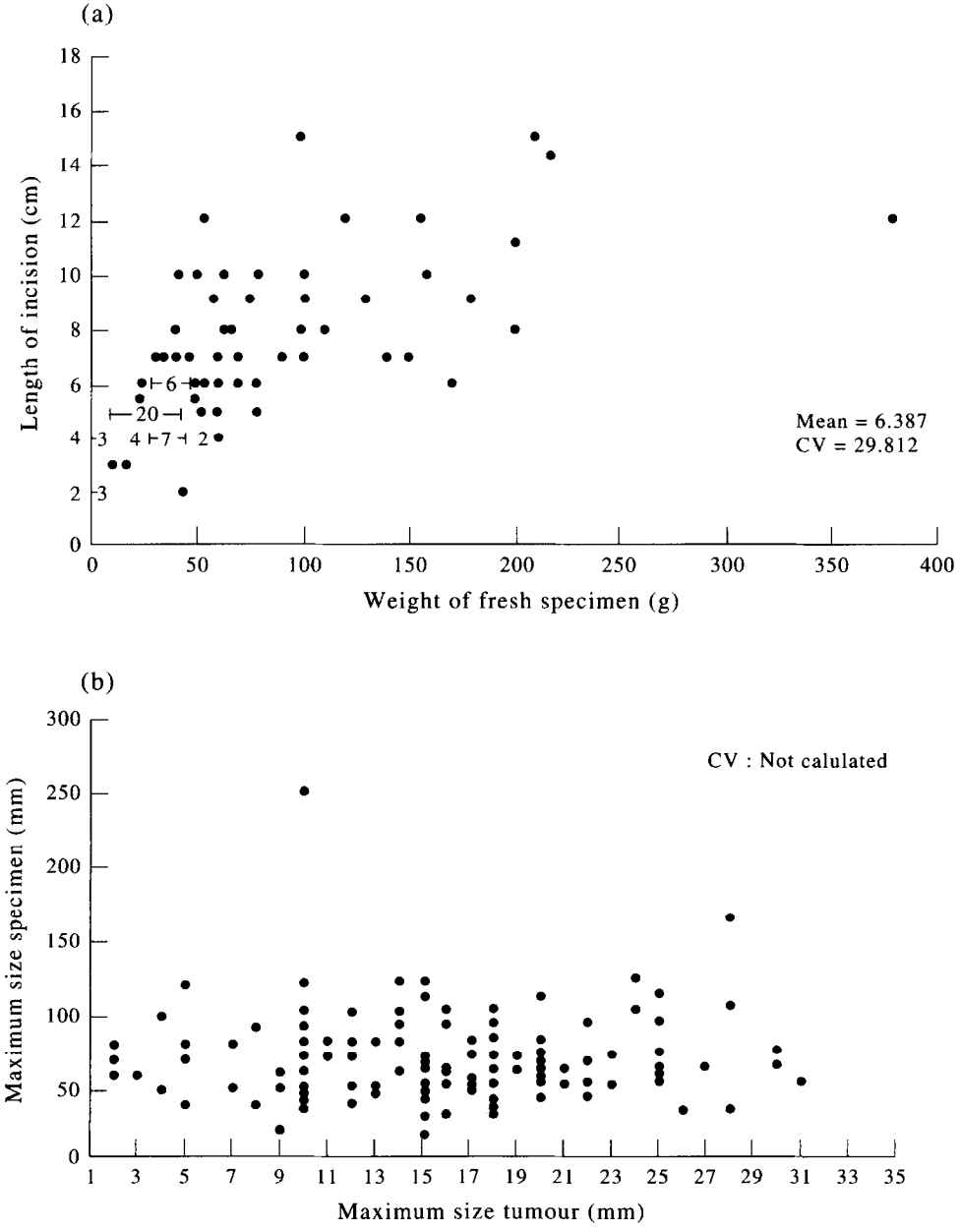


**Figure 3. (a) Correlation between the weight of the breast specimen and the length of the incision. (b) Correlation between maximum size of the specimen and size of the tumour. CV, coefficient of variation.**

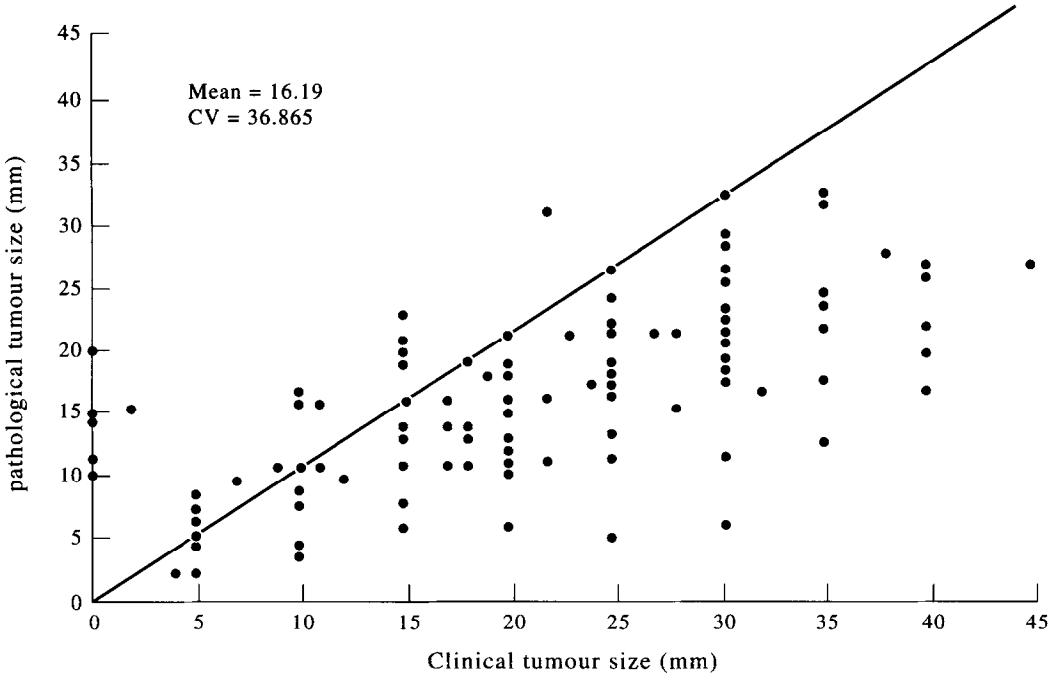


**Figure 4. Correlation between clinical and pathological tumour size. CV, coefficient of variation.**

separately. Centres B and F do not orientate the axillary specimen in the majority of cases, which makes it difficult to locate the positive nodes. Only in Centre D did the pathologist report on nodes in Rotter's space: 36 nodes were examined of which six showed tumour, although this did not change the pathological staging.

## DISCUSSION

From this study on the standardisation of reporting the surgical procedure for breast-conserving treatment of early breast cancer, we have information on three different levels. First, it has proven possible and feasible in daily practice to document quantitatively a surgical procedure. Secondly, it appears that there are strategical differences between the different centres concerning a number of fundamental decisions in planning and executing the treatment. Thirdly, significant differences in the surgical procedure exist and can be documented. These divergences in strategy and technique have been traced within a group of surgeons who meet regularly to discuss therapeutic modalities and who treat many of their patients in the frame of the same clinical trials that give a number of directives for the process. It is obvious that, in the general practice, even wider differences will be found.

The documentation of an operation takes the surgeon a few minutes immediately after the operation to register or enter the data into a computer. It offers the great advantage that, for each patient, the same set of data is always collected. The correlation with the information preceding the surgery (physical examination and radiology) and with the information following the resection (pathology) can facilitate a more rational decision for postoperative management and a more precise planning of, for example, radiotherapy.

A number of points involving strategy of treatment planning show interesting differences. Although a multidisciplinary approach to breast cancer is recommended [8, 9, 13], half the treatment decisions are not taken in a joint clinic and only one of the involved centres always examines the patient at the time of the multidiscipinary treatment decision. At the same time, the patient has the opportunity to discuss treatment options with the different specialists involved. Most centres state that treatment decisions are taken according to a local, multidisciplinary-discussed protocol, which makes it superfluous to discuss every patients' file when no difficulties are encountered.

The use of frozen sections during surgery is varied with some centres always using it, even with positive cytology, one never and the others sometimes. Obviously, this is a decision on principle that is dictated by the safeguards one would feel necessary to build in against the possibility of missing a pre-operative diagnosis by considering a benign lesion as malignant and thus carrying out an axillary clearance in a patient where there is no need for it. Even if this is a rare event, it would be of interest to come to a more structural approach, in order to define the patient group where frozen section could be deleted and those where there would still be an indication for it. The pressure to delete frozen sections is illustrated by the fact that, because of this procedure, the length of the surgical intervention is increased by about half an hour, which has clear economic repercussions.

Even though recommendations for the tumour-free margins of the resection are described [14–16], it appears that there is a difference in one of the centres, deliberately aiming at macroscopic margins of less than 1 cm while all the others aim at a margin of 1–2 cm. Also, the orientation of the specimen, for the breast and the axillary specimen, is not comparable since some do not orientate the specimen at all and others do it in various, sometimes insufficient ways even if skin has been excised. This information may be of great importance when secondary resections are considered if the obtained margins are insufficient. Indeed, only when the original specimen is orientated, can positive margins be orientated and re-excisions guided. Furthermore, the plan-

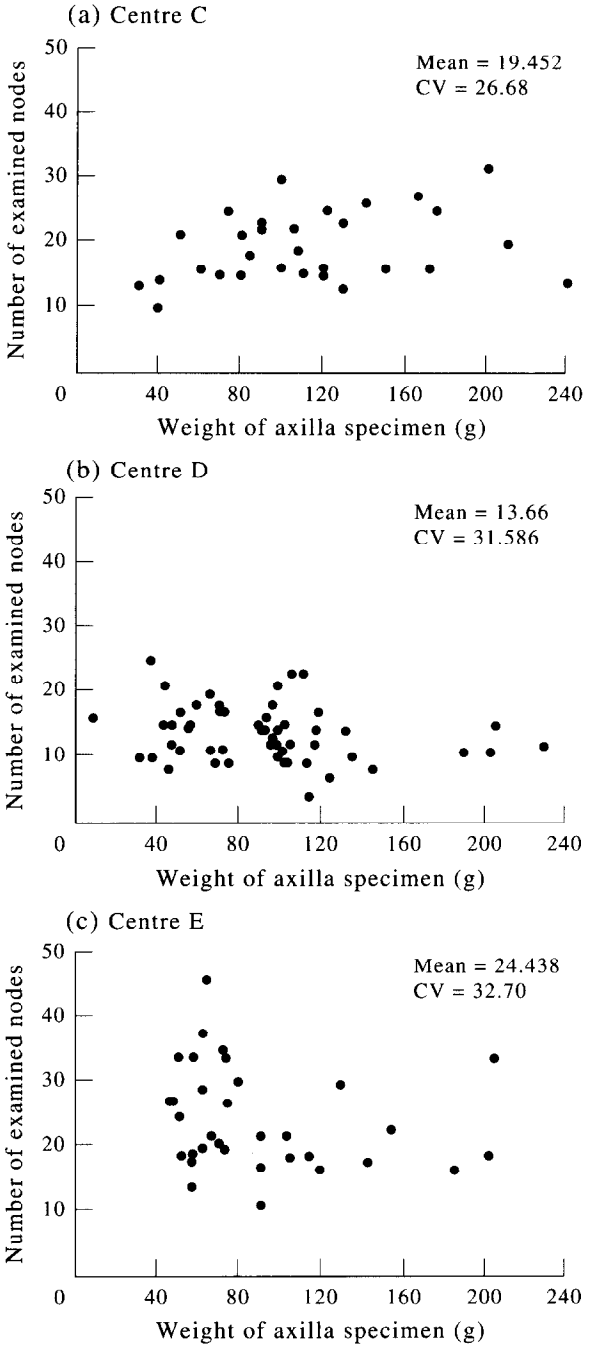


**Figure 5. Correlation between the number of nodes and the weight of the axillary specimens. CV, coefficient of variation.**

ning of radiotherapy could potentially be influenced by exact information of the margins, by pinpointing sites where tumour volume coverage should be generous. This is a problem similar to the differences in using localisation clips. The effectiveness of using limited-volume radiotherapy boosts [17] will be directly dependent on the precision of its localisation, and this can only be achieved by using such localisation clips [18]. Again, this is a matter of philosophy and belief, which are presently already influencing decisions without always being clearly formulated. It could prove useful in the future to try to quantify this.

The change of gloves, instruments and towels between the tumour excision and the axillary clearance is also a decision of principle that is applied very differently in the centres involved and which again has considerable economic repercussions.

Finally, the use of prophylactic antibiotics in clean operations without concomitant risk factors has always been discouraged [19]. The only centre giving pre-operative antibiotics in this study discontinued its use during the auditing process.

Clear differences in the surgical technique were also documented. The place, direction and the length of the incision varied greatly. The policy of excising overlying skin is applied very differently in the centres involved. In the Milan studies [20], wide skin excisions and continuous incisions to the axilla were routinely used. Others [21, 22] claim they obtained the same local control rates, but probably with better cosmetic results [23] by selectively performing less extensive excisions. The volume resected and the margins aimed for were different in the participating centres, although all purport to perform the same "wide excision". As the literature does not give clear directions whether to leave the breast cavity open [21] or to close [24, 25], the decision on whether or not to suture the breast tissue and how to do it, varied between the centres. Also, the use of drains in the breast is still a matter of controversy [21, 25], which is reflected in the variety encountered in the study. The way the skin is closed is probably of importance for cosmesis, but here differences are also noted. As these elements were not routinely provided in previous published reports, the impact of these differences can not yet be investigated.

The extent of the axillary dissection is obviously also a matter of debate. Whether Level III should be resected or not is still left open [26–30]. Again, the possible consequences for side-effects, diagnostic relevance and local control have not been studied extensively. This is reflected in the fact that some of the participating centres in this pilot study only resect Level I and II and others always perform a full axillary dissection. Furthermore, although the relative importance of the Rotter nodes has been demonstrated [31, 32], this is not at all reflected by this pilot study: only one centre does clear the interpectoral space and has a pathology report on the resected nodes. The decision on whether or not the axilla should be rinsed and what solution should be used, is an independent decision of the centres without clear scientific background.

Most interestingly, there is no correlation between the size of the resected volume and the pathological size of the tumour indicating that the surgeon is more influenced by his opinion on the volume which can easily be excised [33–35], and preserve acceptable cosmesis, rather than by fixed margins around the tumour to achieve acceptable local control [14–16], which would have led to a correlation between excised volume and tumour volume. Also, in the axilla, there was no correlation between the number of nodes found and the weight of the resected specimen. However, this correlation is obviously influenced by the obesity of the patient, individual differences in the number of nodes present and by the eagerness with which the pathologist is searching for the nodes.

This mutual audit of the strategy and technique in breast-conserving surgery through a standardised documentation process has been rewarding in so far, that it proves to be

feasible to collect the information needed. The differences that have been identified create a situation in which it will be necessary to reach a consensus as to which of the involved elements are considered to be of sufficient importance to be documented or even standardised. For these elements, the procedure will have to be determined and the margins of acceptable deviations will have to be identified. This may be of special importance when running clinical trials where surgery has to be "standard". In this way, a stricter set of guidelines for a breast-conserving procedure will have to be developed allowing for more accurate monitoring of minimum quality criteria.


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**Acknowledgements**—The authors are especially grateful to the EORTC Board for the grant received to accomplish this pilot study and to Prof. Dr E. van der Schueren, Head of the Department of Radiotherapy and Oncology of the University Hospital Leuven, for his interest and support. We also wish to thank Mrs Swinnen Hilde for her great help in data management.