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Monitoring surgical treatment of screen-detected breast lesions in Italy

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Abstract

The object of this study was to assess quality of care and adherence to treatment guidelines of screen-detected lesions in Italy using a new audit system. Data on screen-detected cases surgically treated in 1997 were collected using a system (QT 2.3) developed within the Italian Group for Planning and Evaluating Mammographic Screening Programmes (GISMa) and the European Breast Cancer Screening Network. Results of 18 performance parameters were considered compared with the reference standards. In 1997, 515 lesions (335 invasive, 60 *in situ* and 120 benign) in 496 patients were collected from 14 departments in the Central and Northern area of Italy. The 18 indicators were analysed and grouped according to six quality objectives. Some results were good and others were excellent, such as intraoperative identification, breast conservation surgery, adequate axillary procedures and completeness of pathology reports, but most of them failed: waiting times, preoperative diagnosis, employment of frozen section on small lesions and avoiding axillary procedures in ductal carcinoma-*in-situ*. This work is a first attempt in Italy to evaluate and uniform the criteria adopted for quality control of breast cancer treatment, using a standardised system. Some results are good or excellent, the overall level of compliance with quality indicators is not satisfactory and corrective actions should be undertaken for a number of issues. A continuous monitoring should be performed and appropriate action taken in order to verify the effectiveness of the corrective actions and to provide screen-detected patients with the best quality of care.

Keywords: Screening; Breast cancer; Breast lesion; Surgical treatment; Quality control; Audit system

1. Introduction

Recently, oncologists throughout Europe have been investigating the causes of regional variations in the survival of female patients with breast cancer [1]. A possible cause for these variations has been identified in the treatment (surgical and non-surgical) applied in different areas [2,3]. It has been shown that the surgical expertise and the volume of treated cases are important predictors of survival [4,5]. Treatment guidelines specifying quality objectives and outcome measures such as those from the British Association of Surgical Oncology [6], FONCaM (Italian Breast Cancer Task Force) [7], and the 'Europe Against Cancer Programme' [8–10] and EUSOMA [11,12] have been laid down to improve the quality of breast cancer care. Audit systems capable of monitoring these guidelines have also been devised [13]. In the present study on the quality of care for screen-detected lesions in Italy during 1997, we have employed one of these, i.e. the QT (Quality of breast cancer Treatment) [13], which has been developed by CPO-

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Piemonte within the Italian Group for Planning and Evaluating Mammographic Screening Programmes (GISMa) and the European Breast Cancer Screening Network. QT has been found consistent with the EUSOMA Guidelines and its use has been recommended for fulfilling the mandatory requirement of producing, at regular intervals, performance figures on precisely defined quality objectives and outcome measures [12,14]. Monitoring of screen-detected lesions is also important to keep to a minimum the potential drawbacks of the screening programmes such as useless biopsies and over-treatment. This is possible if the organisational, diagnostic and therapeutic aspects of the screening are monitored by quality-control procedures.

2. Methods

The project was launched within GISMa. Fourteen reference surgical departments from 10 screening programmes of four regions from the Centre-North of Italy (Piemonte, Lombardia, Emilia Romagna, Tuscany) agreed to participate.

Eligible lesions were all screen-detected, surgically treated, primary breast lesions. Data were recorded in QT retrospectively on the basis of clinical notes, operating theatre records, histology reports, and the screening unit's database. Afterwards, data were centralised for quality control and analysis. A number of quality checks were applied (such as consistency between pathological size and pT; between the summary on operating sessions and the number of operations recorded; temporal sequence of dates) and corrections were made after verifying the original case notes.

Indicators and reference standards derive mainly from the FONCaM protocol and other national and international consensus documents. The aim of these indicators is to verify adherence to these guidelines in the clinical practice and to verify their feasibility. Reference standards are not available or defined for all the indicators,

Table 1
Summary of outcome-measure definitions

Outcome measure	Eligible cases
Waiting times	
<21 days to surgery	Operated breast lesions (synchronous lesions counted once)
Histology report within 10 days from biopsy	Breast cancers (synchronous lesions counted once) with open surgical biopsy followed by definitive breast surgery
Surgery within 10 days from biopsy	Breast cancers (synchronous lesions counted once) with open surgical biopsy followed by definitive breast surgery
Histology report within 20 days from surgery	Operated breast lesions (synchronous lesions counted once)
Oestrogen receptor status within 20 days from surgery	Operated breast cancer (synchronous lesions counted once)
Preoperative diagnosis	
Preoperative diagnosis	Operated breast cancers with preoperative diagnosis
Surgical breast procedures	
No failed biopsy	Impalpable operated breast lesions
Two-view specimen X-ray	Impalpable operated breast lesions
No frozen section (<10 mm)	Invasive breast carcinoma up to 10 mm of pathological diameter, excluding DCIS with microinvasion
Free margins <1 mm at last operation	Cancer operated with breast conservation surgery
No repeated surgery for incomplete excision	Operated breast cancer with preoperative diagnosis
Completeness of pathology report	
Histology grade performed	Operated invasive breast carcinoma
Estrogen receptors performed	Operated invasive breast carcinoma
Avoiding unnecessary radical or extensive procedures	
Breast conservation in pT1	pT1 invasive breast carcinoma without DCIS component or, when a DCIS component is present, with whole pathological size up to 20 mm Multiple tumours excluded Synchronous lesions in the same breast are counted once
Breast conservation in DCIS $\leqslant 20$ mm	DCIS with pathological size up to 20 mm Multiple and microinvasive tumours excluded Synchronous lesions in the same breast are counted once
No axillary procedure in DCIS	Operated DCIS; microinvasive tumours excluded Synchronous lesions in the same breast are counted once
Axillary surgical technique	
$\geqslant 10$ nodes in axillary clearance	Operated invasive breast carcinoma with axillary dissection (levels I–III) Synchronous lesions in the same breast are counted once

DCIS, ductal carcinoma-*in-situ*.

which are subjected to periodical updating with the evolution of scientific knowledge and changes in the clinical, cultural and organisational context. Definitions and algorithms to calculate each indicator are provided by the QT manual and in the European guidelines, and are briefly summarised in Table 1. Ten outcome measures and targets are from the minimum set recommended by European guidelines [13], while the remainder are GISMa indicators. Outcome measures have been grouped into six quality objectives: waiting times, preoperative diagnosis, surgical breast procedures, completeness of pathology report, avoiding unnecessary radical or extensive procedures, axillary surgical technique.

3. Results

From 1 January to 31 December 1997, participating centres operated on 515 screen-detected eligible lesions (335 invasive, 60 *in situ* without microinvasion and 120 benign) in 496 patients (Table 2). Ten of the invasive lesions had invasive component measuring less than 1 mm.

The 14 participating departments treated surgically an average of 160 breast cancer cases in 1997, ranging from 48 to 284. Three of these departments treated surgically fewer than 100 cases. The overall benign:malignant ratio was 0.42 (range 0.14–0.83). Screen-detected cases represented 18.2% (range 9.0–35.4%) of all breast cancers operated by these departments during the year. The 10 screening programmes referred on average 73% of screen-detected cases to participating departments, while the remaining screen-detected cases chose to be treated at non-reference surgical centres and are not included in this analysis.

The benign:malignant ratio in screen-detected lesions was 0.30 (range 0.0–0.86). Cancers classified as pTla or pTlb accounted for 143 (42.9%) of the 333 invasive cases with known pathological size. Node-positive cases were 24.5%. Two hundred and ninety-five invasive cases were of known grade: 29.5% of them were G1, 51.5% were G2 and 19.0% were G3. Overall hospitalisation time was on average 7.0 days. When an axillary procedure was performed, total length of stay (all hospitalisations included) was on average 9.3 days.

Table 2
Cases included in the study, by centre and pathological diagnosis

Centre code	Benign	*In situ*	Invasive	Total
1	8	1	16	25
2	30	11	57	98
3	19	13	29	61
4	5	6	29	40
5	19	2	20	41
6	12	4	21	37
7	0	3	16	19
8	1	1	14	16
9	3	2	21	26
10	3	5	23	31
11	0	0	14	14
12	11	4	44	59
13	3	6	15	24
14	6	2	16	24
	120	60	335	515

Table 3 shows the results of performance parameters. The second column of this table indicates, for each outcome measure, how many departments met the target out of the total number of departments that provided valid information. Conventionally, a department was defined as providing valid information if the proportion of missing values was lower than 30%. For each analysis, departments with missing values exceeding 30% have been excluded. The third column indicates the total number of eligible cases, of which the numbers of missing values are indicated in the fourth column.

Only a small percentage of surgical departments met the target for surgical waiting times, while the targets for histology reports were generally met. The medians were: 21 days from referral to operation (5.4% of women waited more than 2 months; 2.9% more than 3 months); 47 days from screening to operation (more than 2 months for 17.7% of the cases; more than 3 months for 8.6% of them); 7 days from biopsy to histology report; 28 days from biopsy to definitive operation, 8 days from definitive operation to histology report and 12 days from operation to oestrogen receptors' report.

Five of the 14 centres achieved the objective on preoperative diagnosis (overall result: 61.4%). Results on specimen orientation and on avoiding the dissection of specimens, although these are important to accurate histological assessment and biological characterisation, and to defining margins, were found unreliable because the information was rarely recorded in the pathology report. One centre did not collect the information on failed biopsies with sufficient completeness, while all the remainder met the target, with the exception of two, which only slightly missed it. The overall result was 99.0%. Conversely, only two departments met the target on specimen X-ray, none on frozen section and four on free margins. For the free-margin indicator, the overall result (87.6% free margins) was not very far from the target. Finally, 86.2% of the cases with a preoperative diagnosis of cancer (C4–C5) did not require a further operation for incomplete excision; 10 of 14 centres met the target.

Histology grade was available for 98.6% of invasive cancers and 12 of 13 centres met the target. Information of hormonal receptors was available in 98.3% of cases and 13 of 14 centres met the target. 90.6% of unifocal pT1 cases and 86.0% of ductal carcinoma-*in-situ* (DCIS) not greater than 20 mm had breast-conservation surgery. Two centres only did not meet these targets. 14.7% of the DCIS with no reported microinvasion

Table 3
Outcomes measures according to six quality objectives, 14 surgical departments 1997

Outcome measure	Departments above target/ total departments	No. of eligible cases	Missing values	Overall result (%)	Target (%)
Waiting times					
<21 days to surgery	1/13	462	19	**54.9**	⩾90
Histology report within 10 days from biopsy	5/6	43	0	86.0	⩾80
Surgery within 10 days from biopsy	0/6	43	0	**0.0**	⩾80
Histology report within 20 days from surgery	8/10	304	12	89.7	⩾80
Oestrogen receptor status within 20 days from surgery	7/11	306	18	**78.9**	⩾80
Preoperative diagnosis					
Preoperative diagnosis	5/14	395	1	**61.4**	⩾70
Surgical breast procedures					
No failed biopsy	11/13	302	0	99.0	⩾95
Two-view specimen X-ray	2/11	276	12	**55.7**	⩾95
No frozen section (<10 mm)	0/14	127	2	**37.6**	⩾95
Free margins >1 mm at last operation	4/13	306	4	**87.6**	⩾95
No repeated surgery	10/14	227	2	**86.2**	⩾90
Completeness of pathology report					
Histology grade	12/13	304	21	98.6	⩾95
Oestrogen receptors	13/14	325	27	98.3	⩾95
Avoiding unnecessary radical or extensive procedures					
Breast conservation in pT1	12/14	245	0	90.6	⩾80
Breast conservation in DCIS ⩽20 mm	NA/13	43	0	86.0	NA
No axillary procedure in DCIS	9/12	51	0	**86.3**	⩾95
Axillary surgical technique					
⩾10 nodes in axillary clearance	9/14	229	3	96.0	⩾95

DCIS, ductal carcinoma-*in-situ*; NA, not available.

underwent an axillary procedure. Three centres did not meet the target and were responsible for all the failures (the remaining centres had a result of 100%). 96% of patients with invasive breast cancer had a sufficient number of nodes examined after dissection of the axilla (nine of 14 centres met the target).

4. Discussion

Some of these results are excellent (breast conservation, completeness of pathology reports) or good (number of nodes in axillary dissection, operative identification of the lesion, no repeated surgery after C5 preoperative diagnosis). However, the overall level of compliance with quality indicators is not satisfactory and corrective action is needed on a number of issues in order to provide screen-detected patients with the best quality of care. These are: waiting times; preoperative diagnosis; the use of specimen X-ray; employment of frozen section on small lesions; the achievement of free margins; avoiding axillary procedures in DCIS.

4.1. Waiting times

The delay between referral for surgical treatment and hospitalisation was mainly due to the long waiting list in surgical departments. Surgical open biopsy of the lesion as a separate operating session was performed in 21% of the operated lesions. Although this procedure was rather variably undertaken among centres, it was often done in local anaesthesia (86.0% of 43 biopsied benign lesions and 73.8% of 65 cancers). Surgical biopsy was followed by a second operation in 69.2% of malignant lesions. When open biopsy was employed, the time from surgical referral to definitive surgery could be substantial: the median was 54 days (31.7% waited more than 2 months; 14.6% more than 3 months). Most of the delay was not due to the waiting time for histological reporting.

The range in results by department is very large: from 5.6% to 100.0% of patients were operated within 3 weeks from referral. The five departments doing relatively better (result >70%) had a smaller average volume of cases: 87.6 versus 159.5 for all centres combined. Quality indicators for waiting time are very poor, and this is less evident, as expected, for cases treated in less specialised centres. Delays at any stage of the process may cause intolerable distress for the woman. Furthermore, delayed presentation of symptomatic breast cancer of 3 months or more is associated with lower survival rates [15]. The significant delay between diagnosis and treatment can be resolved only by creating specialised breast units with dedicated surgeons and by

providing surgical departments with dedicated operating sessions. Surgeons should be aware that performing a surgical biopsy substantially increases the total waiting time. Furthermore, the presence of a specialised pathologist would further reduce the time required for the histological and biological characterisation of the lesion. Diagnosis would also be improved by using fine-needle aspiration (FNA) or needle histology in order to reduce the number of surgical biopsies.

4.2. Preoperative diagnosis

Preoperative diagnosis is an important indicator since it affects other outcomes [16]. At the time of this study, cytology was predominantly used, while the employment of microhistological procedures has since been growing for microcalcifications and in general for non-palpable lesions.

Failure with this indicator can have three possible causes: a preoperative diagnosis may not have been made; a preoperative diagnosis may have been reached but with inadequate results; or with false negative or 'false dubious' results. The first reason was responsible for 47.4% out of the 152 failures, the second for 23.7% (unsatisfactory results accounted for 11.2% of the tests) and the third for 28.9% (false negatives were 23, or 7.1%, of the tests). The majority of the centres enrolled in the study routinely performed FNA cytology as part of the screening work-up. Three centres were an exception, rarely performing the procedure. For another two departments the problem was mainly related to an inadequate rate, approaching or exceeding 25%. In one centre, FNA was always performed with adequate results but many results were negative or dubious. A mixture of the different problems affected the remaining four centres not meeting the standard.

In Table 4, some outcome measures are represented according to the classification of the departments by proficiency in the preoperative diagnosis. The benign: malignant biopsy ratios in the three centres that rated very poorly on preoperative diagnosis are indeed the highest in our series (average 0.66). In the same centres, 35.9% of the benign lesions underwent quadrantectomy, compared to 15.4% in all others combined. Table 4 also shows that their performance is worse in avoiding axillary dissection for DCIS, but poor or good performance for preoperative diagnosis does not seem to affect indicators of the number of operations, the employment of frozen sections and margins.

Furthermore, according to the third edition of the *European Guidelines for Mammography Screening* [17], successes should include only definite preoperative cancer diagnoses (CS or B5). Only one out of the 14 centres would meet the target if the outcome measure were so defined and the overall result would be 40.6%. In our series, 14.9% of the C4 were false positive, and there was one (0.6%) benign with a C5 preoperative diagnosis. One centre, which used the C4 category extensively (31 cases or 63.3% of all cytological diagnoses vs. 18.9% in all remaining centres), was responsible for the majority of false positives. If this centre were excluded from the analysis, false-positive C4 would be only four out of 63 (6.3%).

According to the specific problems outlined above, either the dissemination or review of diagnostic protocols and/or training in sampling and reading would be necessary. This could be best done in multidisciplinary breast units.

4.3. Surgical breast procedures

Even if the operative identification of impalpable lesions had a satisfactory result, the lower than expected performance of the specimen X-ray in the same lesions may cast some doubt on the procedures followed for assuring, in the theatre, the correctness of excision. A reason for the poor performance of the indicator on radiography may derive from the fact that some clinically impalpable lesions may not be so in the theatre. However, the results for of this indicator do not change if we take into account only impalpable cancers smaller than 10 mm.

Intraoperative histology of the specimen by frozen section is often related to the surgeon's wish to perform a single operation. However, centres performing worse in this indicator (eight of the 14 centres have a result below the average) did only slightly better in avoiding

Table 4
Proficiency in preoperative diagnosis

	Benign: malignant ratio	Quadrant benign (%)	>1 operation (%)	No frozen section >10 mm (%)	Margins >1 mm (%)	No dissection in DCIS (%)
Centres meeting the target for preoperative diagnosis ($n=5$)	0.27	9.7	21.4	32.6	92.7	100.0
Intermediate (6 centres)	0.23	19.1	19.8	43.1	81.9	90.0
Centres performing no or very little preoperative diagnosis ($n=3$, outcome measures <40.0%)	0.61	35.9	19.4	29.4	96.3	33.3

DCIS, ductal carcinoma-*in-situ*.

repeated operations (89.1% vs. 86.2% for all centres combined, see below). It should be noted that, at the time of this study, the Italian recommendations were to avoid frozen section on lesions below or equal to 5 mm. If this standard were applied, the outcome would still be a failure, with an overall result of 50.0% and four out of 11 centres meeting the target.

The goal of breast-conservative treatment is to obtain a 1 cm free margin. The surgeon should perform a wide excision in one complete specimen in order to achieve a better pathological assessment of the margin. In the EUSOMA consensus document on quality control in the locoregional treatment of breast cancer, the surgical excision should aim at microscopically free margins, not defining the minimal distance of the tumour from the wedge specimen [13]. The interpretation of reviews of clinical outcomes based on surgical-margin status is difficult because of the lack of uniformity in surgical approaches and in the pathological methods, and the criteria used to assess margins may vary in different institutions and in the same centre across time. Recent reports [18] have shown that close margins (1 or 2 mm) have a higher risk of late recurrences even with a major dose of postoperative radiotherapy. The working standard suggested by the European screening guidelines to distinguish cases likely not to have been adequately excised (>1 mm) is employed here. If a larger width of margin were required (>5 mm), the overall result would be 81.1%. Conversely, if only transected margins were considered a failure, 95.6% of cases would have had free margins after the last operation. Clear margins depend on the width of the local excision and are inversely correlated with the aesthetic result.

None of 225 patients with preoperative diagnoses (77 C4, 148 C5) had more than two operations (including breast and axillary procedures). Forty-six (20.4%) of these cases had mastectomy, 35 at the first operation and the remaining 11 cases at the second operation. Thirteen cases had quadrantectomy as definitive surgery after they had had open biopsy or wide excision as a first operation. If mastectomies at the first operation were excluded, the overall result (83.7%) would not change much. However, if only C5 preoperative diagnosis were considered eligible only seven repeated operations for incomplete excision would be counted, with an overall result of 95.3%, well above the target (12/14 centres met this).

4.4. Avoiding unnecessary radical or extensive procedures

Axillary surgery is contraindicated in carcinoma-*in-situ*. This procedure may be performed after the inaccurate or mistaken interpretation of frozen sections. In fact, if only cases for which frozen sections were taken were to be included in the analysis, the result for this indicator would be much poorer ($12/17 = 70.6\%$) compared with cases with no frozen section ($32/34 = 94.1\%$). The belief that some DCIS of large diameter could have multiple invasive foci and represent an indication for axillary lymphadenectomy may also be involved. However, out of the seven failures, three are recorded as multifocal but only one was larger than 30 mm. Four out of the seven failures had mastectomy. Lobular carcinoma-*in-situ* ($n = 5$) has been excluded from this indicator. None had an axillary procedure.

This multicentre study is the first in Italy to employ the monitoring of standardised outcome measures with extensive data-quality control. These indicators were planned to evaluate if clinical practice follows the guidelines; their respect is related to a highly satisfactory level of oncological therapy [19]. Such monitoring has only recently been introduced and, therefore, the completeness of data collection is not satisfactory for some of the adopted outcome measures. However, in such instances, only data from centres providing sufficiently complete information were employed in the analysis.

Further work, such as follow up for recurrences, is needed to verify the adequacy of the indicators used and the standards suggested. Indicators should be kept updated with new surgical techniques (e.g. sentinel node), and any dimensions of care currently missing, such as aesthetic outcome [20], should be covered.

Despite these limitations, this study did clearly show important inadequacies in the care of screen-detected lesions, among which are unacceptable waiting times and inadequate preoperative diagnosis. The results have been discussed within the participating surgical departments and screening programmes in order to remove these deficiencies. The establishment of specialist breast units [12] linked with the screening programmes would be likely to provide the environment for substantial improvement, but the adoption of this organisational standard has so far rarely been possible. Monitoring is continuing so that surgical units can measure the quality of care provided and assess the impact of actions taken.

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Appendix

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