

First evaluation of the ASL of Lecce mammographic screening program results by using Surgical Pathology's indicators of quality in diagnosis and treatment

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Abstract

The aim is to highlight the progress of earliness and quality of diagnosis and breast cancer cure in the Province of Lecce by surveying a number of indicators obtainable from surgical pathologist's evaluation. The study, conducted with the software SQTm (www.qtweb.it), is based on breast cancer of women 50-69 years old residing in the Province of Lecce who undergone breast surgery in the years 2003, 2004, 2010, 2011 and 2012 at the "V. Fazzi" Hospital, which is reference center for diagnosis and treatment of breast cancer within the Breast Cancer Screening Program of the ASL of Lecce, active since 2008. Compared to the prescreening period, results of all the indicators showed an almost progressive and significant improvement along the years, highlighting the first beneficial effects, primarily the improvement of early diagnosis, resulting from the impact of screening on the female target population. However, the study has emphasized some important problems arising from persistent and systematic deficiencies in the organizational and multidisciplinary approach, on which we must concentrate efforts to further improve the screening program results.

Keywords: Breast Cancer, Diagnosis Quality, Mammographic Screening

Introduction

The Planned Mammographic Screening (PMS) for breast cancer, with the uterine cervix cancer screening and the colon-rectum one's, is part of LEA (Essential Assistance Levels) in Italy from several years, implying the national and regional sanitary service assure all the women from the target population (50-69 year old) of active measures for early diagnosis, based on mammography as the first level test carried out after a call once every two years. The planned screening's first aim is to reduce mortality for all the neoplasias is addressed to, with an acceptable cost/benefit ratio. The second aim is to improve the diagnostic and therapeutic course quality. So a planned screening program is not limited to appropriate organizational

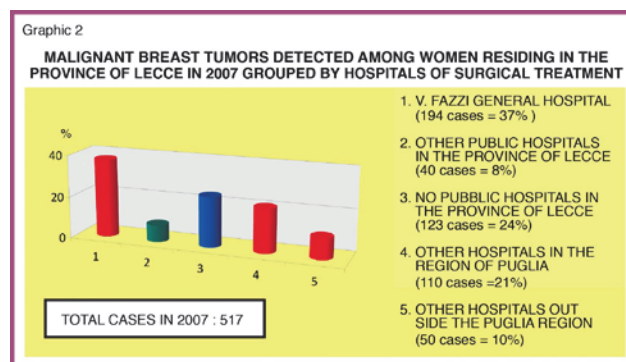
measures for a good coverage and compliance of the target population in first level testing, it provides also a good management of a right diagnostic and therapeutic course, a control system and checking the results and a continuous action to straighten the shot of screening organizational machine. From 2006 is available the SQTm (computerized Schedule for Quality in Treatment of Mammary carcinoma) dedicated software developed by Piedmont's CPO (regional Oncological Prevention Center) with European funds from the "Europe against cancer" Program and under the auspices of EUSOMA. SQTm is used from several years by GISMa (Mammographic Screening Italian Group) to do year's surveys on mammographic screening results in Italy, based on monitoring

many quality's indicators of diagnosis and treatment.

Objective

The aim of this study is to evaluate, by some GISMa's indicators, the quality trend of diagnosis and treatment of the mammary carcinoma in Salento over a period of ten years during which the PMS was introduced in Lecce's district (800.000 residents). The study is based on cases of breast pathology observed in resident women operated at "Vito Fazzi" General Hospital of Lecce, the biggest one in the district, that is home to breast unit and also reference center for diagnosis and for treatment of screen-detected cases of breast carcinoma in the PMS of the ASL of Lecce (local health authority). PMS in Lecce's district is active from 2008. The cases falling in the study were observed during the years 2003, 2004, 2010, 2011 and 2012 and were registered with SQTm. Their files have been analyzed in partnership with Piedmont's CPO. This work is part of a collaboration in monitoring program for mammographic screening in Italy, in which Lecce's team is so far the only one from Southern Italy. Preliminary data for the years 2003, 2004 and 2010 only were presented at the GISMa's National Meeting of Palermo in 2011 (Delos, Tarantino, Olla Atzeni et al. 2011) . The years 2003 and 2004 were evaluated for prescreening results. On the other side the years from 2010 were examined for any positive impact of the local PMS on the target population. With this work we hope provide useful informations to solve any critical issues of local PMS. From Cancer Registry of Lecce's district we can notice an incidence of about 500 breast malignant neoplasias a year in women (Melcarne, Rashid, Quarta 2010) .

In the Graphic 1 we can observe breast malignant tumors, distributed by age groups, in the 2007, most recent year published available.

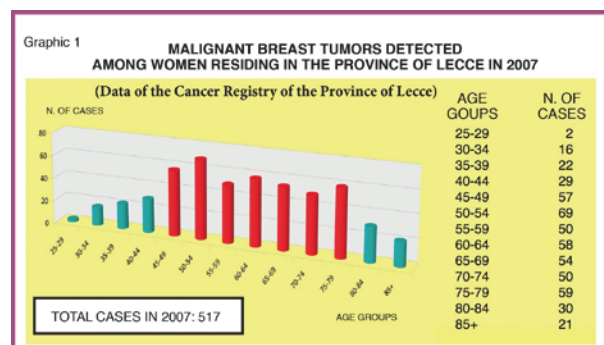


In the Graphic 2, reporting the same cases distributed by hospitals of surgical treatment, we can observe that 37% of malignant breast tumors was operated at "Vito Fazzi" General Hospital of Lecce.

Materials and methods

This study concerns malignant and benign disease cases of the breast regarding women operated in the years 2003, 2004, 2010, 2011 and 2012 at Vito Fazzi General Hospital, where are treated surgically about 200 breast carcinoma cases for year, that is 37% of all breast malignant tumors cases incident in women of Lecce's district. All the cases were registered in SQTm by Surgical Pathology Unit of "Vito Fazzi" Hospital. For this first evaluation we haven't taken in to account all the indicators of the GISMa's surveys, but only those that usually can be deduced by the Surgical Pathology's diagnostic report. In particular for this study we have calculated with SQTm the values of the following indicators:

- 1) Pre-operative diagnosis in cancer (C5/B5)
- 2) Completeness of diagnostic and prognostic data in surgical pathology's report of invasive cancer cases (histotype, grading, pTNM)
- 3) Only one operation after pre-operative diagnosis of invasive cancer
- 4) Only one operation after pre-operative diagnosis of non-invasive cancer (in situ carcinoma)

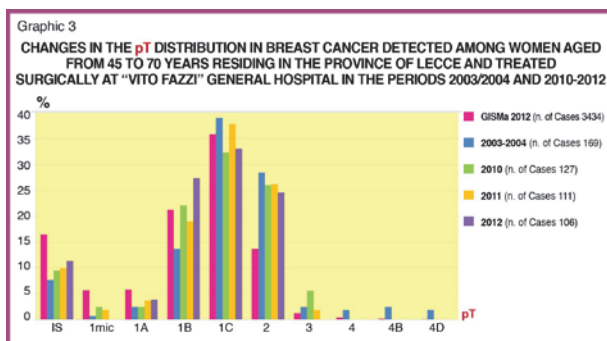


- 5) Axillary staging by Sentinel Lymph Node (SLN) only in pN0
- 6) No axillary dissection in Ductal Carcinoma in Situ (DCIS)
- 7) Conservative surgery (quadrantectomy) in invasive cancers ≤ 30 mm
- 8) Immediate plastic reconstruction in invasive carcinoma cases treated with total mastectomy
- 9) pN0 in invasive cancer cases
- 10) Early diagnosis (pTis + pT1mc + pT1a + pT1b) in all cancer cases
- 11) Benign/Malignant ratio (B/M) in surgically treated cases

Indicators from 1 to 8 are GISMa's ones (Mano, Ponti, Angiolini et al 2013). Indicators from 9 to 11 usually are not reported in GISMa's Surveys, but they are anyway calculated for this study and compared with the corresponding values achieved from data of GISMa's Survey 2012 (Ponti, Mano, Tomatis et al. 2015).

Results

We can find in Table 1 the obtained values, reported as cases number and percentages distributed by years of treatment, for all the different indicators considered. The years 2003 and 2004 are reported together. In the same table are reported the corresponding values of the national GISMa's Survey 2012.



In Graphic 3 we reported changes over time in the pT distribution in breast cancer detected among women aged between 45 and 70 years, who are the ones that benefit most from the PMS.

Indicator n. 1 increases from 17,2% of the prescreening period to the 29% for 2011 and to 23% for 2012. Indicator n. 2 increases from 31% to 74,7% in 2012. Indicator n. 3 remained nearly the same only with little variations over time. Indicator n. 4 gets better, from 61,5% of 2003-2004 to 87,5% of 2012. Indicator n. 5 increases from 29,5% to 63,6%. Indicator n. 6 doesn't improve so much, but it has little variations (from 76,9% to 80%). Indicator n. 7 has improved only slightly over time (from 63,8% to 66,7%). Indicator n. 8 increased by 10% over time, but started from 0 in the prescreening period. Both indicators n. 9 and n. 10 improved a little, from 54,9% to 58,2% the first, from 31,3% to 37,2% the second. But in Graphic 3 you can see that pT distribution highlighted changes indicative of an earlier diagnosis in the years of PMS. In particular they are increased cases of carcinoma in situ, microinvasive carcinomas and carcinoma within 1 cm and decreased cases of carcinoma above 2 cm. Indicator n. 11, expressed as a ratio, has gotten a lot better, gradually improving from 1,41 of the prescreening period to 0,56 of 2012.

Discussion

The results of this investigation highlight an almost progressive and significant improvement of all the indicators over time from the prescreening period, that is years 2003 and 2004, when in the Lecce's district the early diagnosis for mammary tumors wasn't planned or organized but it only depended on women themselves. In details we want to underline, first of all, that the improvement of indicators 9 and 10 is expression of a meaningful, although initial, effect of PMS in diagnostic earliness. Over time, in effect, in years of PMS we diagnosed more mammary neoplasias of little dimensions and that doesn't affect axillary lymph nodes than in the prescreening period. Anyway the recorded improvement of these two indicators is not satisfactory yet, being their values distant from GISMa's values of 2012 (72,6 and 49,7 respectively), although during 2011 they got nearer (70,2 and 38,8). But we have to pay attention to the fact that GISMa's values are representative of geographic areas of Northern Italy where PMS, in activity from 90's, are the re-

sult of decades of experience and organization that allows higher levels of coverage and compliance, as well as a quality of diagnostic and therapeutic courses certainly superiors than in Lecce's experience that was just starting in the years of this study. We think however that this first result of PMS in Salento, talking about more precocious diagnosis, as highlighted by moderate improvement of indicators 9 and 10, is important and indicative about what potential can be developed over time with an implementation of screening activities. Particularly positive was the result of indicator n. 2, typical process indicator, that recorded progressive growing values until it goes over the medium GISMa's survey value (74,7% versus 62,6%). This result attests the elevated level reached in the ASL of Lecce by the breast surgical pathology, that is essential base for appropriateness and quality of medical care. About the appropriateness for the surgery treatment, we have used the indicators from number 3 to 7. Their monitoring is useful to pursue a double objective, on the one hand, of avoiding useless and more invasive surgery in favor of the patients and, on the other, of saving costs and operating room resources. The results regarding the surgical appropriateness were contradictory. If for the indicators 3, 4 and 6 we had remarkable values, that improved significantly on time, aligning in 2011 to GISMa's values, indicators n. 5 and 7 were disappointing (63,6 and 66,7 respectively), remaining far below of the GISMa's values (91,7 and 83,5). Essentially it seems like the conservative surgery is still inadequately applied, in particular, regarding quadrantectomy instead of total mastectomy, as in effect is highlighted by indicator 7, which improved a little during years of PMS. Regarding the saving of axillary dissection in pN0 cases (indicator n. 5), the sentinel lymph node technique was still underused, although this parameter significantly improved if compared with the value (29,5%) of prescreening period. But the most critical aspects are those remarked by indicators n. 1, 8 and 11. Very negative is the result of indicator n. 1, for the systemic implications on all the diagnostic and therapeutic course and, in particular, for its adverse effect on appropriateness of surgical treatment. The value of this indicator improved very little, from 17,2% to 23%, remaining far below of the GISMa's value

(82,3%). Despite this negative result we had positive values of indicators 3, 4, 6, as mentioned above, but this implies a systematic trend to bypass the pre-operative diagnosis by fine needle aspiration and/or needle biopsy, in favor of intra-operative diagnosis based on frozen sections. This practice is inadequate for several reasons and seems to be the heritage of the past when the surgeon was the only and almost exclusive reference for the breast pathology treatment. This practice should be abandoned in favor of the current good clinical practice recommendations because it causes the following negative consequences:

- 1) Increased costs due to overuse of intra-operative diagnosis, more expensive than the pre-operative one, as it lengthens the operating room time, requires the commitment of the medical and technical staff of surgical pathology during operations, brings to the operating table, as the indicator 11 remarks, many benign lesions, with a further consumption of resources and exposition to risk and discomfort the women unnecessarily operated;
- 2) lowering of the quality and appropriateness of the treatment plan due to bypassing the multidisciplinary assessment in pre-operative phase, leaving every decision to surgeon;
- 3) Exclusion of woman/patient from a decision regarding the treatment because she is under anesthesia when a decision is taken after a intra-operative diagnosis: the consequent implications, also talking about legal validity of consent to the treatment, can be easily understood.

About the very low value of indicator n. 8, regarding the plastic reconstruction of breast after total mastectomy, in part it's due to the multidisciplinary planning deficits of the diagnostic-therapeutic courses and to underuse of the pre-operative diagnosis.

Conclusions

From the results described above, albeit relative to a still initial period of introduction of the PMS in the district of the ASL of Lecce, with

the consequent and deducible limits both in terms of effective coverage of the target population and compliance of the invited women who appeared to be low (around the 40%), emerges already the capacity of this important early diagnosis planning tool. But also they emerge several critical issues that are attributable mainly to a deficit with regard to the approach and organization of multidisciplinary preoperative diagnostic and therapeutic planning process. These problems must be resolved through the efforts of medical teams involved, the Breast Unit, the body of the local PMS coordination and the management of the local health institutions. As the persistence over time of these critical issues, and still others in this study were not examined, produces the effect of devaluing the screening program, it is important to implement a systematic monitoring of the results with appropriate tools, to constantly correct the shooting of PMS and improve the quality of diagnostic and therapeutic path of breast cancer in the ASL of Lecce district.

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