The Breast Unit
Update on advantages and the open issues

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Breast cancer is acknowledged as an international priority in health care. It is currently the most common cancer in women worldwide, with demographic trends indicating a continuous increase in incidence.
In the World, it is estimated that by 2020 there will be approximately 2,000,000 new cases of breast cancer per year. The enormous burden placed by this disease both on the population and on health care systems explains the increasing efforts and resources that have been devoted over the years to the search for a systematic and optimized strategy in breast cancer diagnosis and treatment.
Today, the Breast Unit model is identified as the gold-standard to ensure optimized patient-centered and research-based clinical services for breast cancer patients improving survival rates and patients' quality of life by a multidisciplinary approach in breast care.
The present work reviews the lines of development of this multidisciplinary model of breast cancer treatment and analyzes the requirements of a high quality Breast Unit, its potential advantages and the many open issues that still require proper definition and implementation.

KEY WORDS: Breast Unit, Breast cancer, Breast center, Multidisciplinary treatment

Introduction

Breast cancer is acknowledged as an international priority in health care. It is currently the most common cancer in women worldwide, with demographic trends indicating a continuous increase in incidence. Only in the European Union, it is estimated that by 2020 there will be approximately 394,000 new cases of breast cancer per year and 100,000 deaths [1].

The enormous burden placed by this disease both on the population and on health care systems explains the increasing efforts and resources that have been devoted over the years to the search for a systematic and optimized strategy in breast cancer diagnosis and treatment. The observation, confirmed in many studies, that being treated by coordinated teams of specialists from various fields of oncology, specifically trained in breast diseases may improve survival rates and patients' quality of life has progressively opened the way to a multidisciplinary approach in breast care [2-9]. Today, the Breast Unit model is identified as the gold-standard to ensure optimized patient-centered and research-based clinical services for breast cancer patients.
The present work reviews the lines of development of this multidisciplinary model of breast cancer care and analyzes the requirements of a high quality Breast Unit,

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The "History" of Breast Unit development

The concept of streamlining the evaluation and management of patients with diseases of the breast through a comprehensive program is not new.
In the USA, as early as 1931, Dr. Cusham D. Hagensen developed a clinical subspecialty in breast disease and in Europe, Charles-Marie Gros in Strasbourg in 1960 organized a medical clinic dedicated to breast diseases [10,11].
But it was not until 1979 that the first free-standing multidisciplinary facility – The Van Nuys Breast Center – was founded in California by Melvin J. Silverstein, opening the way to a "cultural change" in the management of breast diseases and initiating a worldwide debate on the importance of a collaborative approach in breast care [12].
At the First European Breast Cancer Conference in Florence in October 1998, a Statement was issued declaring that "all women across Europe should have access to fully equipped, dedicated Breast Units" [13]. Shortly after, a position paper was published by the European Society of Mastology (EUSOMA) on the standards required for the creation of high quality Breast Units across Europe [14,15].
The European Parliament (EP) issued two resolutions on breast cancer in the European Union (EU) in 2003 and 2006 respectively, calling on the EU member states for the establishment of a network of certified multidisciplinary breast centers essentially meeting the core criteria set by EUSOMA [15,16].
Similar efforts were initiated also in the United States by the American College of Surgeons that in 2006 developed the National Accreditation Program for Breast Centers (NAPBC) [17]and by the Senologic International Society (SIS) that also approved a voluntary accreditation program for its worldwide affiliated Societies [18].
In 2010, the EP adopted a further "Written Declaration on the Fight Against Breast Cancer in the European Union", calling for measures to ensure the provision of multidisciplinary specialist breast units and the development of a certification protocol in accordance with the EUSOMA guidelines by 2016 [19].
In Italy, a Senate Health Commission was established in 2010 to activate and certify Breast Units, as recommended by the EU and in 2012, the Italian Ministry of Health created a Working Group that is currently developing uniform guidelines to assist Regional governments in the creation of a proper network Of Breast Units [20,21].

The requirements of a Breast Unit

The EP has indicated that creation of breast units in all countries of Europe, including Italy, should refer to the EUSOMA guidelines [22].
Such guidelines indicate that a specialist multidisciplinary breast unit should serve a population of at least 250-300,000 citizens and recruit at least 150 newly diagnosed cases of primary breast cancer (at all ages and stages) each year. This is considered the minimum caseload sufficient to maintain expertise for each team member and to ensure cost-effectiveness.
The core team of the Breast Unit must be guided by a Clinical Director and include two or more breast surgeons, each personally performing primary surgery on at least 50 newly diagnosed cancers per year and regularly attending a weekly Multidisciplinary Meeting (MDM). These breast surgeons should be able to undertake basic reconstruction and there should be standard arrangements with one or two nominated Plastic Surgeons (non core team members) with special expertise in breast reconstructive techniques.
The core team should also include two or more fully trained radiologists, with continuing experience in all aspects of breast imaging, tissue sampling and image-guided localization procedures. They should read a minimum of 1000 mammograms per year (5000 for those involved in screening programs) and participate in a national or regional quality assurance program.
Other core team members must include a lead pathologist, a medical oncologist, a radiation oncologists, a breast diagnostic radiographer, a data manager and at least two breast care nurses.
The unit must possess suitable and up-to-date imaging equipment, and offer access to all services that even if provided in different locations must be supervised by the breast unit's core multidisciplinary team.
All core team members have the obligation to attend a MDM held at least weekly to discuss diagnosis, pathological findings following surgery and evaluate treatment options for every case treated in the Breast Unit.
The Units must have written protocols for diagnosis and for management of cancers at all stages, agreed upon by all core team members.
Units must record basic data on diagnosis, pathology, primary treatment and clinical outcomes. Regular audit meetings should take place, with annual production of performance and audit figures.

Advantages of the Breast Unit model

Breast units can provide a facilitated access, in one place and at one time, to high-quality diagnosis and treatment. Patients have shown to greatly appreciate the opportunity to receive high-quality health and psychosocial care by a broad-based interdisciplinary team of specialists of all areas and of all necessary expertise, in a technically competent manner, with good communication, shared decision-making and cultural sensitivity that can significantly improve the continuum of care [23-27].
Patients are also starting to acknowledge that being treat-

ed in a specialized Breast Unit can offer improved oncological outcomes. A significant number of studies support the evidence that multidisciplinarity, specialization and higher caseload can be associated with better survival.

Kesson et al. [2] have documented an 18% lower breast cancer mortality rate and an 11% lower all-cause mortality rate at five years, in women receiving multidisciplinary breast cancer care as compared to similar patients treated in neighbouring hospitals over the same time period [2].

Sainsbury et al. examined differences in survival in 12,861 women with breast cancer in Yorkshire as a function of consultant caseload showing that the 5-year breast cancer survival was significantly better for surgical caseloads >30 cases/year in conjunction with availability of full range treatment options [3]. Similar evidence was provided by Stefoski Mikeljevic and associates [4] that documented a 4% lower survival at 5 years and a 10% increase in the relative risk of death in patients managed by surgeons with workloads < than 30 new cases per year as compared to surgeons with a workload > than 50 new cases year [4]. Skinner et al. studied the effect of surgeon and hospital specialization on survival after breast cancer treatment in 29,666 patients from the Los Angeles County Cancer Surveillance Program database. Surgeon specialization appeared as an independent predictor of survival on multivariate analysis, with a 33% reduction in the risk of death at 5 years when treatment was provided by a surgical oncologists accredited by the Society for Surgical Oncology [5].

Chen et al. in a study that examined outcomes in 13,360 breast cancer patients treated by surgery in various hospitals in Taiwan showed that 5-year survival rates by hospital volume in their setting were 77.3% for high-volume (>585 cases), 74.5% for medium-volume (259-585) and 72.1% for low-volume hospitals (< 258) [9].

Guller and colleagues, in a review of 233,247 patients that received either breast-conserving surgery or mastectomy for localized breast cancer, showed that patients operated at low-volume hospitals were significantly more likely to die or develop postoperative complications and were less likely to undergo breast conserving surgery as compared to patients treated in high-volume hospitals [28].

Barriers to Breast Unit development

Even though significant efforts have been devoted to the creation of multidisciplinary units throughout the world, the process is still challenged by many controversies [29]. In Italy, as in most European countries, there are at least three major barriers that limit the proper development of the Breast Unit model:

FINANCIAL BARRIERS

The establishment of specialized breast unit carries substantial expenditures. Breast oncology often requires the use of expensive technologies and the certification and specialization processes also imply additional costs. This can be a quite relevant problem if one considers the continuous reduction in resources that health care system has to face. To justify the economic investment a minimum caseload of 150-200 newly diagnosed cases per years is required [30-32].

At present, reimbursements for breast cancer-specific surgical interventions in almost all European countries are regulated by the DRG system, that does not take into account disease severity, the type of used technology, quality outcomes and the complexity of the treatment. As a result, average DRG-reimbursements for breast cancer patients appear largely inappropriate for the quality care provided by a breast unit.

Wagner et al. investigated the expenditure and income structures of an EUSOMA certified breast center in Germany, separating costs into fixed and variable components. After stepwise deduction of all relevant costs, and taking into account income for the individual remuneration areas, it was calculated that to cover real costs additional revenue of euro 1,288 per calculated case would have been needed [33]. The validity of these data was confirmed by Köckemann et al. who calculated that an additional sum of euro 1,646 per patient with a first diagnosis of breast carcinoma would be needed to cover costs [34].

Moreover European DRG systems vary consistently from country to country. The reimbursements for an index case treated with partial mastectomy may range from €577 in Poland to €5780 in the Netherlands [35]. In Italy, there are major inconsistencies in the DRG system. At present, no additional reimbursement is provided for breast reconstruction after mastectomy or for the concurrent treatment of bilateral cancers. With the current DRG-system, reimbursement is the same for a patient with unilateral cancer that undergoes a unilateral mastectomy with no reconstruction as well as for a patient with bilateral cancer that undergoes a bilateral mastectomy with immediate bilateral reconstruction. In other words, same reimbursement for a simple operation that lasts one hour as for a highly-complex operation that can last many hours and that carries considerable additional costs for the implants [36].

Therefore, it is evident that a thorough review of the DRG system to ensure fair and appropriate reimbursement for breast cancer treatments is a mandatory condition for the effective development of a network of breast units.

LACK OF A CORE CURRICULUM IN BREAST SURGERY

Even though specialist training in breast cancer is one of the key mandatory requirements of the Eusoma guide-

lines, to date there is no residency program in breast disease in any country of the world. Training in breast oncology has been guided more by common sense than by specifically structured programs [37-43].
As concerns surgeons, in United Kingdom only, general surgery residents have the choice to specialize in Breast Surgery, after 3 years of general training, by attending Breast Units at designated university centers [41]. In Italy, starting from 2012, some Postgraduate Schools in general surgery have established an elective course in breast surgery that residents may choose to attend during the last year of their training program.
The Italian Association of Hospital Surgeons (A.C.O.I.) has organized a "Special School of Breast Surgery", structured as a collaborative teaching effort of multiple specialized hospitals [44]. ACOI offers two annual courses (basic and advanced) that provide opportunities of multidisciplinary learning and professional development in the field of breast surgery through "hands on" interactive programs and direct participation in clinics and surgical activities.
The Italian School of Senology (S.I.S.) has offered more traditional training activities (residential courses, seminars, masters, consensus conferences, workshops etc) dedicated also to nurses, radiographers, psychologists and volunteers [45].
Similar or even greater challenges exist with regard to the training of breast care nurses (BCNs) [46-52]. EUSOMA acknowledges the key role of BCNs in assisting the patient and providing psycho-social support from the moment of diagnosis throughout the entire process of oncological treatment.
Even though the European Oncology Nursing Society has recently taken on board a project to build an international curriculum for training of BCNs [50], at present specialist education is licensed only in the United Kingdom with a university master's degree, while in Germany the requirements for oncology-specialized nurses are integrated into the certification guidelines of the German Society of Senology [46].
In Italy, as in many European countries, even if the need of nursing staff with specialized training has become clearly evident, measures for creating a well-defined and uniform BCNs curriculum are still in their infancy.

CONTROVERSIES IN THE ACCREDITATION PROCESS

Significant efforts have been devoted to the development of a a well structured certification process for breast units. In the United States, the NAPBC process grants "Full Accreditation" to those centers that comply with 90 percent or more of its accreditation standards, "Contingency Accreditation" to centers that meet less than 90 percent but more than 75 percent of the standards and "Accreditation Deferred" to centers that meet less than 75 percent of the standards at the time of survey. To maintain accreditation, centers must undergo an on-site review every three years [52,53].
In Europe, the EUSOMA process grants two levels of accreditation: "Initial" and "Full" accreditation. Initial accreditation can be requested by Units that declare to comply with the standars indicated in the Guidelines [54]. Full accreditation may be applied for when a Unit has 5 years of audit data, which may include cases treated prior to Initial Accreditation.
Even though the EP has invited member States to comply to the EUSOMA process, to date the accreditation landscape in Europe remains quite heterogeneous. In some countries, Breast Units are not requested to undergo any certification or auditing process and in the others there are no common policies with regard to who should do the certifying and how.
Taran and associates collected data on the certification process in 9 European countries, confirming consistent variations in the planning and performance of the certification process (carried out by public organizations in 5 countries and by private companies in the others) as well as in the auditing modalities and frequencies of different European countries [55].
Uniformly accepted global accreditation standards for breast unit are much needed in order to avoid that hospitals without the proper specialization or that do not provide the high-quality services requested by accreditation standards, claiming to have breast units [56,57].

Conclusions

The Breast Unit model, centered on a team of specialists from various fields of oncology, specifically trained in breast diseases and working together in a collaborative fashion, is unanimously viewed as the gold-standard to offer optimized care to all women with breast cancer.
Fourteen years after the EUSOMA position paper and eleven years after the first call to action on breast cancer by the EP, huge disparities in breast cancer treatment still exist across the EU and the landscape of European breast units remains quite heterogeneous.
Consistent action is needed toward the goal of establishing an adequate network of certified breast centers in all European countries by 2016. This action should be focused on the approval of proper modalities for a standard certification process, definition of specific training curricula for all core team members and a global improvement of reimbursement policies for breast unit.

Riassunto

Il tumore del seno rappresenta un problema di grande rilevanza sociale e sanitaria: Si stima che entro il 2020, nel mondo, vi saranno ogni anno oltre 2.000.000 di nuovi casi di carcinona della mammella.

Il modello "Breast Unit" è oggi unanimamente considerato come il gold-standard per garantire un trattamento ottimale alle pazienti affette da neoplasia mammaria. La normativa europea prevede pertanto che dal primo gennaio 2016 nei Paesi della Comunità Europea i tumori del seno siano trattati nel contesto di Centri di Senologia multidisciplinari e certificati dall'EUSOMA (European Society of Breast Cancer Specialists).
Il presente lavoro analizza i requisiti necessari di una Breast Unit, i potenziali vantaggi del trattamento multidisciplinare e le questioni ancora aperte che caratterizzano questo modello di cura, con particolare attenzione alla realtà italiana.

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