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Original article

Formal analysis of the surgical pathway and development of a new software tool to assist surgeons in the decision making in primary breast surgery

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ABSTRACT

Background: The increased complexity of the decisional process in breast cancer surgery is well documented. With this study we aimed to create a software tool able to assist patients and surgeons in taking proper decisions.
Methodology: We hypothesized that the endpoints of breast cancer surgery could be addressed combining a set of decisional drivers. We created a decision support system software tool (DSS) and an interactive decision tree. A formal analysis estimated the information gain derived from each feature in the process. We tested the DSS on 52 patients and we analyzed the concordance of decisions obtained by different users and between the DSS suggestions and the actual surgery. We also tested the ability of the system to prevent post breast conservation deformities.
Results: The information gain revealed that patients preferences are the root of our decision tree. An observed concordance respectively of 0.98 and 0.88 was reported when the DSS was used twice by an expert operator or by a newly trained operator vs. an expert one. The observed concordance between the DSS suggestion and the actual decision was 0.69. A significantly higher incidence of post breast conservation defects was reported among patients who did not follow the DSS decision (Type III of Fitoussi, $N = 4$; 33.3%, $p = 0.004$).
Conclusion: The DSS decisions can be reproduced by operators with different experience. The concordance between suggestions and actual decision is quite low, however the DSS is able to prevent post-breast conservation deformities.

Introduction

Prior to the historical trials on breast conservation, a mastectomy was the only surgical choice for primary treatment of breast cancer. Once the safety of glandular preservation had been established at the beginning of the 1980s, a second possible treatment could be offered to patients [1–6].

Initially, partial mastectomies appeared to guarantee integrity, but quite soon it became clear that breast conservation in some cases may not yield satisfying results [7,8].

Sometimes the cosmetic appearance after these operations was rather poor with visible scarring and severe deformities of the mammary shape. Several studies confirmed unsatisfactory results, even for breast-conserving surgery, in up to 20% of cases [9,10].

These failures initiated some reports regarding techniques derived from cosmetic surgery (breast reductions, mastopexies) to remove breast tumors without deformities [11–13].

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The advent of primary systemic therapies has also increased the number of possible therapeutic choices in the hands of surgeons [14,15].

Post-mastectomy radiation therapy (PMRT), which has recently shown increased indications, may also interfere with the pathway of breast reconstruction [18–23].

This information regarding the possible failures of breast conservation and good outcomes of mastectomy and reconstruction, coupled with an increase in patients' awareness, has generated a very complex and multifactorial decisional pathway [24–33].

With this study, we aimed at creating a prototype software tool capable of assisting patients and surgeons in making proper decisions. We tested it in a short cohort of patients in order to provide a preliminary validation of this instrument. We assessed the reproducibility and repeatability of the clinical procedure, the actual applicability of the proposed decisions, and the effects on postoperative residual defects.

Methods

Endpoints, decisional drivers, creation of subcategories of disease

In order to analyze the decision process, we created a set of possible endpoints of the surgical treatment of breast cancer. These were identified as safe removal of breast cancers on negative margins, avoiding disfiguring cosmetic results, and preserving good quality of life, thus putting the patient at the center of the decision process.

We hypothesized that these endpoints could be addressed by combining a set of decisional drivers that include morphological elements (breast shape and size) and topographic aspects related to cancer location, size, and stage in association with patients' preferences regarding surgical techniques as described in Table 1. We created four subcategories for volume according to bra size. Breast ptosis was classified into three subgroups using a modification of the classification of Regnault [23]. We also included in the "moderate ptosis" group patients with pseudo-ptosis and glandular ptosis to reduce the number of possible combinations. The breast was subdivided into seven subunits to locate the lump. Cases for which a mastectomy was the only possible choice did not include the assessment of tumor size, location, and risk of positive margins.

For patients affected by early-stage invasive cancer that can be treated with breast-preserving surgery, we decided to convey also the information on the risk of positive margins derived from a validated software tool named *breastconservation!* [17]. However, a high risk of positive margins was not per se an indication to perform wider excisions or mastectomies. The use of this tool was valid only for patients with invasive cancer.

Patients' preferences were investigated by doctors and breast care nurses during pre-op sessions using specific leaflets and multimedia tools [34]. We subcategorized patients' wishes according to three subcategories: "minimal aggressiveness," "maximum reshape," and "mastectomy."

At the end of this process, we identified four subgroups named as "ESBC" (localized invasive cancers with or without a minor ductal carcinoma in situ (DCIS) component), "DCIS localized" (small DCIS suitable for breast conservation), "MULTICENTRIC" (early-stage disease widespread in the breast, including DCIS), and "LABC" (locally advanced cancers requiring multimodality treatment, including radiation).

The decisional elements were combined manually in an electronic spreadsheet; each combination was considered as a single clinical case and associated with the most suitable surgical option by a panel of experienced oncoplastic surgeons. The final surgical suggestion was established according to current standard practice and previous observation reported by the senior authors of the paper [21,27,35–40].

Formal analysis and design of the decision tree

The decisional process was analyzed according to the Iterative Dichotomiser 3 (ID3) algorithm. This allowed the creation of a navigable decision tree and a prototype decision-support system software (DSS) tool [41]. The information gain IG (A,S) measures how much uncertainty in S was reduced after splitting set S on an attribute A. It was calculated taking into consideration the subtraction between the information entropy of a specific subset of records and the sum of the entropies related to each value of one single attribute. Using this method, we choose iteratively the attribute that minimizes the amount of entropy of a specific subset of records as a node of the decision tree. In each subgroup, the highest value identifies the decisional driver providing the highest amount of information to the decisional pathway.

Preliminary clinical testing

Once the DSS was available, we tested it on 52 patients to verify its clinical usability in a single unit in Catania-Ospedale Cannizzaro from November 2013. Patients affected by non-metastatic disease and candidates of any kind of surgical treatment (excluding secondary procedures, delayed reconstructions, surgery for local control in patients with disseminated disease) were admitted to this study. Current standard guidelines for treatment of breast cancer in our unit were strictly followed for either surgery and radiotherapy or other adjuvant treatments. All patients involved in this study signed a proper informed consent.

First of all, we investigated the repeatability of the suggestion produced by the DSS. We verified the concordance between the decision produced by an expert operator at two different times (during the last consultation and the night before the operation). Afterwards, we compared the output obtained by a newly trained surgeon with that of an expert one. Finally, we assessed the number

Table 1
List of decisional drivers.

T-Stage or Multicentric disease	Location[a]	Volume	Ptosis	Risk of positive margins[b]	Pt wishes
T > 2 cm	Central	Minimal	Nil	High	Mastectomy
T < 2 cm	Upper	Medium	Moderate	Intermediate	Max. reshape
LABC	Lower	Large	Severe	Low	Min. Aggressiveness
DCIS<4 cm	Upper outer	Very Large			
Multicentric Invasive/Extensive DCIS	Upper inner				
	Lower outer				
	Lower inner				

[a] Not assessed for LABC Multicentric/extensive DCIS.
[b] Not assessed for LABC Multicentric/extensive DCIS and localized DCIS.