



## Review

# Primary systemic therapy for breast cancer: Does the patient's involvement in decision-making create a new future?



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## ABSTRACT

**Objective:** Primary systemic therapy (PST) followed by surgery is the standard initial treatment for locally advanced breast cancer (LABC). However, some patients are averse to mastectomy or breast-conserving surgery and do not consent to these procedures. The reasons for this controversial decision, the factors influencing the decision-making and optimal solutions for decision aiding need to be investigated.

**Methods:** We addressed these questions by a review of literature on the possibilities associated with different patient choices and subsequent treatment options in relation to LABC.

**Results:** A total of 5 reviews and 22 clinical studies were summarized in relation to decision making and the most successful decision aids. A discussion is given of the issues of those few patients who cannot be convinced to undergo surgery.

**Conclusion:** Currently there is no guideline for the treatment of patients who reject the surgical procedures after PST. Medical oncologists should be able to apply decision aid modalities in a personalized manner to give all needed information to their patients thereby ensuring a deliberate decision-making process, facilitating acceptance of a need for surgery, and thus improving the chances of prolonged survival.

**Practice implications:** Currently multidisciplinary tumor boards are the most suitable decision aids in oncological practice.

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## 1. Introduction

Primary systemic therapy (PST) for breast cancer was introduced in the late 1980s and early 1990s in an effort to improve life expectancy while increasing the chance of curative surgery in patients with primarily non-resectable breast malignancy or inflammatory breast cancer [1–4]. Broadwater et al. initially proved that aggressive preoperative chemotherapy and mastectomy did not adversely affect postoperative recovery compared with patients who underwent mastectomy alone [5]. Furthermore PST can be regarded as an *in vivo* test of the therapeutic efficacy of a chemotherapy regimen, as it allows evaluation of the tumor's response while it is still in its original position and condition, before definitive surgery. Lack of response to PST allows clinicians to change the dosage or agent employed in the regimen at the earliest opportunity in the treatment course, which could improve the clinical outcome [1–3,6–8].

Although comparisons in large randomized trials have shown no difference in overall survival (OS) between pre- and postoperative chemotherapy regimens, they do reveal that more patients become eligible for breast-conserving surgery (BCS) with PST [6,9–13]. BCS is one of the most important goals for patients and can help to preserve the patient's self-concept and body-image. Moreover, better recovery from BCS compared with mastectomy can help in compliance with later adjuvant therapy and remission control [14–16].

After PST, surgery is strongly recommended to patients to maximize progression-free survival (PFS) and OS. Before the 1990s, complete mastectomy with axillary block dissection (ABD) was the standard and safest surgical procedure for patients with breast cancer; however, this is the most invasive and complicated option from the patient's perspective. More recent surgical options, including BCS (e.g. quadrantectomy, sectorectomy, or lumpectomy) and sentinel lymph node biopsy (SLNB) for the pathological evaluation of axillary nodes, became accepted alternatives to mastectomy, but it is essential to select patients appropriately [15,17–19]. Performing BCS in unsuitable patients (and sometimes even in carefully selected patients) carries the risk of affecting the surgical margin and leads to R1 or higher stage resections, not only entailing reoperation but also worsening PFS and OS [15].

However, an even more complex problem occurs in daily practice: a small percentage of patients did not give consent to surgery after PST, when they realized the clinical complete remission detected with imaging modalities, or even back out from therapy before the end of the treatment schedule. In the clinical practice of the Oncological Division of the Semmelweis University we treated more than 180 patients in the last 5 years (2008–2013) with PST, and more than 5% of these patients withdrew their consent to therapy at some point during the treatment schedule. Briefly, 3 patients refused to finish the planned chemotherapy and 8 patients did not give consent to the surgical removal of the remnant tumors. Six of these patients died from metastatic disease or were lost to follow-up. This area is difficult to examine, due to ethical reasons, therefore the only chance to characterize this group of patients and to recognize the reasons behind such decisions is to establish clinical register. In the meantime then, the emphasis should be on prevention.

Based on the above, our research group decided to review the available literature on the decision-making process and relevant decision aids pertaining to this patient group, in the hope of reducing the earlier described ratio of decision based therapeutic failures. The questions that need to be asked when determining the

most appropriate treatment include: What is the best option for each individual patient? What are the risks for patients who do not undergo surgery because of refusing the optimal, standard treatment algorithm suggested by international guidelines? What are the available methods to aid the decision-making process for such patients and their treating physicians?

## 2. Methods

Here we focus on the impact of the patients' choice on the strategy adopted for breast cancer. There is extensive research on the factors associated with cancer patients' involvement in decision making. We review the literature concerning opportunities and risks associated with different patient choices and subsequent treatment options in locally advanced breast cancer (LABC), and also examine new approaches after PST. MEDLINE (PubMed, Ovid), Web of Science and SCOPUS databases were searched from the start of the database to the end of 2012. Key terms used were breast cancer, LABC, mastectomy or breast-conserving surgery, PST, decision making, decision aid, decision support, responsibility, patient participation, partnership (i.e. patient–physician relations), multidisciplinary tumor board and their synonyms based on the hypothesis of decision-making process (Fig. 1).

Eligibility criteria were the following: the search was limited to articles collected on participants with breast cancer, having any performance status and being over the age of 18. Included study types were reviews and clinical studies i.e. cross-sectional surveys, observational or prospective cohort studies. Commentaries, short communications and editorials were excluded. Only studies investigating primary, non-metastatic breast cancer patients were included. Studies were excluded if they involved any therapeutic intervention during the decision-aiding process (i.e. psychotherapy or anxiolytic medication) or if the studies involved patients with psychiatric disorders. Studies focusing on religious support (either positive or negative) were also excluded due to possible bias and questionable measurability. Only articles with full text in English were included. Duplicates were eliminated. Articles were screened on the basis of their title and abstract. Eligibility assessment of the titles was performed independently by three authors (T.T, Gy. Sz., and S.K.). Relevant articles were identified after reviewing the entire manuscript according to a consensus reached between the three authors in order to eliminate irrelevant results (i.e. old or disproved data, inappropriate topics) and to take the principles of the PRISMA checklist [20] and the Cochrane criteria [21] into consideration. Article contents were defined as being relevant if the decision-making process was evaluated based on patient or physician characteristics or if in any form, decision-aiding was performed during decision making. Decision could be made during communication with the medical/clinical oncologist, surgeon or with members of a multidisciplinary tumor board. Disagreements between reviewers were resolved by consensus, and were overseen by the leader of the research group (D.M.).

Studies and reviews on PST for LABC and the optimal surgical approach were collected and analyzed separately for the background overview.

## 3. Results

Fig. 1 represented the field in question and the research strategies of the authors, with the main key words applied during

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