

Prophylactic Mastectomy on Demand

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This paper presents the case of a breast cancer patient who demanded prophylactic mastectomy after her contralateral breast cancer was treated. Removing the otherwise healthy organ was contraindicated according to both the surgeon and the oncologist, since the patient was neither a BRCA mutation carrier, nor did she have a strong family history with this disease. This situation resulted in the clash of ‘autonomy’ and ‘nil nocere’ bioethical principles. Besides the bioethical aspect, this piece will discuss legal and psychological issues of the case.

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Prophylactic mastectomy; Sword of Damocles syndrome; informed consent; principle of autonomy; principle of nil nocere.

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I. Prophylactic mastectomy

Prophylactic mastectomy (PM) is the removal of one or both breasts to reduce the risk of developing breast cancer. The procedure itself has a long history. In the first century AD the Greek physician Leonides already used a special technique, the 'Escharotomy' to operate breast cancer. Hot poker and incisions were successively used in this method until the breast was fully burnt off. Of course breast cancer surgery has developed a lot since Leonides' first efforts. An important turning-point took place in the late 19th century, when the American William Halsted described the steps of the radical mastectomy and emphasized the importance of aseptic methods and anesthesia. Due to Halsted's contributions, operative mortality rate dropped dramatically, although the survival rates did not prove to increase after the radical mastectomy.

In the 1980s the Halsted dogma on radical mastectomy was questioned step by step, and the surgeons started to turn towards the possibilities for breast conservation (lumpectomy). The latest advances in the evolution of mastectomy are the nipple-preservation techniques [1].

PM is recommended only in particular conditions. The risk assessment takes into consideration several factors. For example the *BRCA1* and *BRCA2* gene mutations might indicate an increased risk for developing breast cancer thus PM is advisable in *BRCA* positive mutation tests. Strong family history is also among the main indications [2]. The medical team also have to consider the impact of the operation on disease free survival and overall survival. In this regard, the field has not had any convincing clinical data yet [3].

As we see, PM is advisable only for a particular risk population. Nevertheless, several studies show an increasing tendency for contralateral PM among women who underwent a surgical treatment for their unilateral breast cancer [4]. For example, Wong et al [5] found that during their study period, the rate of contralateral PM use more than tripled: the proportion of women who received this treatment increased from 3.9% in 2002 to 12.7% in 2012. The number of PM grew despite the fact that no significant improvement in breast cancer-specific survival and overall survival was found for women undergoing this more invasive, radical treatment when it was compared to breast conserving therapy. It seems that several women received a therapy that otherwise did not have any benefit over another less invasive surgical methods. Several reasons account for the increased rate of PM. Media conveys stories about celebrities undergoing mastectomy, strengthening the image of the preventive and life saving effect of this medical option. Heuristics, intuitive lay beliefs also intensify the willingness on more radical procedures. Women try to reduce the uncertainty of the future, and regain the sense of control by demanding PM. They might also manage the so-called future regret, the belief according to which, "I want to do everything I can now, because if I get recurrence, I feel that I did all that I could" [3] (pp. 3210).

This raises several bioethical dilemmas and questions which we would like to discuss and illustrate with a clinical case. First, the case will be presented, after which the bioethical, legal considerations, and guidelines will be outlined. Finally, the psychological background of demanding a PM will be also discussed.

II. The clinical case

The 35 years old female patient discovered the lump in her left breast herself. The mammography and core biopsy confirmed a malignant breast cancer (*neoplasma malignum mamme*). The patient first received neoadjuvant chemotherapy, then the tumour was operated and removed. Later, she also received postoperative radiotherapy. Finally, the treatment resulted in a complete remission.

Four years later the follow-up mammography and core biopsy showed the recurrence of the tumour. This time complete mastectomy was carried out and the axillary lymph nodes were also removed. Her treatment then finished with chemotherapy.

One year later, the patient demanded contralateral PM for reducing the risk of developing cancer in the other breast. Neither the oncologists nor the surgeon found this treatment advisable in her case for several reasons. First of all, the patient's *BRCA* tests proved to be negative, thus she was not a *BRCA* mutation carrier. Furthermore, she did not have a strong family history with similar diseases. The surgeon also informed the patient that the operation could cause unnecessary complications and harm with no likely benefit. He further argued against the procedure by emphasizing that it would remove a completely healthy organ which is also part of her femininity. Consequently, although the patient insisted on her request, the surgeon denied it.

Next, the patient was offered psychological and psychiatric consultation, which she accepted. It resulted that the patient was suffering from extreme distress (the psychological aspects of the case will be detailed later). A bioethical specialist was also involved in the case and in the end, considering the patient's psychological state, a different surgeon carried out the PM.

III. Ethical and legal aspects of the case

Like any other medical treatment, PM implicates moral issues. Bioethical principles provide useful guides in the medical practice to resolve such ethical dilemmas [6]. In the case of risk-reducing mastectomy there are usually two conflicting bioethical principles: the principle of beneficence and the principle of autonomy. The principle of beneficence means that the health care provider should assure the

benefit of the patient. This includes both preventing harm and protecting the patient. Within the medical context, the principle of autonomy means that patients are rational agents who are involved in making informed and voluntary decisions [6]. This also implies that only those agents who can understand and choose between the offered therapeutic options can be considered autonomous. In the case of the impaired or those lacking cognitive or volitional capacities, autonomous action is reduced or impossible [7].

The two bioethical principles typically clash when more medical options are plausible for treating breast cancer, such as a radical risk-reducing mastectomy or a conserving surgery. The patient may choose the more invasive mastectomy over the conserving surgery. Nevertheless, the surgeon's aim is to achieve the same outcome with a less harmful conserving surgery which can also reduce the risk of complications.

In our case, a different kind of bioethical dilemma can be identified: the opposition of the patient's autonomy and the *nil nocere* (do not harm) principles. *Nil nocere* or non-maleficence requires the health practitioner to not cause any form of intentional harm either through acts of commission or omission [6]. The complexity of the situation stems from the fact that the patient demanded the removal of an otherwise healthy organ. The surgeon argued against the PM and most of his arguments reflected on the principle of *nil nocere*. From the medical perspective, the surgeon's standpoint was decent and correct. Nevertheless, he also had to suppress an otherwise competent patient's request, and violate her autonomy. Angelos et al. [3, p. 3210] highlighted the essence of the dilemma:

A central controversy is the following: Are we seeing the appropriate extension of respect for patient autonomy in going along with all requests for CPM? Or has the pendulum swung too far such that physicians no longer have input on what will benefit patients? Patient choice is critical in breast cancer surgery. **contralateral prophylactic mastectomy*

Eventually, the surgeon's decision resulted in the so-called benevolent paternalism. The roots of the paternalistic attitude can be found in the Hippocratic Oath, the ethical code which implicitly ruled worldwide medical practice for centuries. The dominant principle in the

oath is the principle of the previously-discussed beneficence. The overemphasis of this principle and the subordination of the other assumptions to it, leads to medical paternalism. The paternalistic attitude implies that every medical act is morally correct if it serves the patient's well-being. It is also based on the presumption that the patients do not want to know their own personal good, and they would automatically consent the physician's option as being the best [8].

The possible legal guidelines for similar problems should be outlined at this point. The "Act CLIV of 1997 on Health" [9] of the Hungarian law includes two relevant sections: "The Right to Self-determination Section 15. §" and "The Right to Deny Care Section 131. §". The former assures the patient's autonomy in some cases:

- (1) The patient shall have a right of self-determination, which may only be restricted in the cases and in the ways defined by law.
- (2) Within the framework of exercising the right of self-determination, the patient is free to decide whether he wishes to use health care services, and which procedures to consent to or to refuse in the course of using such services...

Two remarks should be stressed here. Firstly, the section refers to the situations in which the patient's autonomy can be limited: public health emergency, life-threatening emergency situations, or the cases of incompetent patients (minors, mentally impaired, unconscious etc.) are the most typical examples. Second, the section warrants the patients' self-determination only for accepting or refusing a treatment, while not providing a similar right to demand a treatment. This is in line with the "The Right to Deny Care Section 131. §":

- (3) A physician may refuse to provide care for a patient only following an examination, if in the course of the examination he determines that a) the patient's health status does not require medical care, b) the treatment requested by the referring physician or the patient is not justified professionally.

In summary, the law seems to represent only a partial patient autonomy in cases when the treatment is already recommended. The final choice is entirely in the physicians' hands when the patient himself

or herself initiates the treatment. So it is still a question of how the patient autonomy can be assured in this situation.

Although the right to self-determination is considered the cornerstone of the patient-centred care, the legal framework also emphasises the rights of the health care provider. Altogether, the Hungarian patient right system follows the global trend, thus a comprehensive medical information grants autonomy in practice. However, the Hungarian patient right system that links Hungary to all the other countries that facilitate the partner-like doctor-patient relationship with the declaration of the right to self determination has only been valid since 1997. Consequently, it still takes time more to abolish the potentially-harmful practice of paternalism and change the mindset of both doctors and lay people to routinely involve patients in the decision-making process.

IV. The shared decision making, the waiting time, and the Manchester guideline

The most important pragmatic manifestation of patient autonomy is the Shared Decision Making. Shared Decision Making is “an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences” [10] (p. 1361). In general, Shared Decision Making can be a three-step-process. During the step of the *choice discussion*, the patient’s awareness of the existing alternatives is raised. During the *option discussion*, the patients receive more detailed information on treatment options. Finally, the *decision discussion* includes the consideration and debate of the preferences as well as the final choice [10]. This strategy also helps maximize the patient’s autonomy in breast cancer decisions by synchronizing the patients’ own values with the physicians’ expertise which is based on up-to-date medical science [11]. In an optimal situation, the patient, in the end, gives an informed consent.

The use of the so-called “cooling off” period might also promote informed consent. As patients are usually overwhelmed or shocked by the different alternatives, it can be effective to postpone the final decision. Thus bad and premature decisions, born under the emotionally-overloaded situation, can be prevented.

The *Manchester Guidelines for Contralateral Risk-Reducing Mastectomy* is a 5-step recommendation developed by a multidisciplinary team especially for cases where women request PM [12]. The guideline integrates the aforementioned autonomy promoting the strategies of Shared Decision Making and waiting period. The importance of guideline should be stressed here, as the clinical team dealing with our case study managed the ethically-challenging case in a similar way. Step 1 is observing the history which includes the clarification of the major reason for the PM request. Our clinical team repeated this phase several times. The surgeon and two oncologists explored the patient's priorities and discussed with her the different alternatives. During step 2, the risk of developing contralateral breast cancer is assessed. As we mentioned, the patient was not assigned to the risk population according to the risk analysis. Step 3 represents the cooling off period, although this phase can be introduced at any time of the process. It is important to note here that the guideline does not give any specific recommendation regarding the length of the cooling off period. In our case, consultations with various specialists automatically provided repeated waiting periods for the patient. It took approximately 5 months until the patient was finally operated. During step 4, a multidisciplinary team, including a breast care nurse, a pathologist, a breast surgeon, and a radiologist should assess and discuss the case. The presence of a psychologist or psychiatrist is not mandatory but additional psychology exploration can also be necessary in some cases. Our case was reported and discussed within an onco-team only comprised of physicians (oncologists, radiologist, surgeon). Later, when the communication with the patient reached a blockage, a psychologist, a psychiatrist and a bioethical specialist were also involved in the case. During the waiting period, the patient visited 6 times the psychiatrist who was specialized in oncological cases. During step 5, the specialist first summarizes the positive and negative aspects, the possible outcomes and side effects, followed by the patient who signs the informed consent form.

V. A psychological assessment protocol for women requesting prophylactic mastectomy

Since psychological consultation and exploration with our patient led to a better understanding of her values, priorities, and motivation, it would be useful to present a psychological assessment protocol which can be used in similar situations. The patient's psychological status will be also described in this section, giving an example on the motivations which result in the wish to undergo PM.

The protocol addresses the issues below during the psychological consultation [13] (pp. 712). Many of them were discussed with the patient:

- The impact of family history and risk understanding
- Motivating factors and the process of decision making
- Sexuality and body image
- Interaction with partner, close family members and their reaction to potential surgical procedure
- Past psychiatric history and current mental health
- Impact of family history and bereavements on mental health
- Expectations of surgery and discussion of potential post-operative complications

The patient's major motivation for undergoing the risk-reducing mastectomy was managing her extreme fear of developing contralateral breast cancer. She explained that she had recently discovered a lump in her breast. Although it was proved to be benign and harmless, it intensified her anxiety and fear. She wanted to do everything to avoid the shock she underwent when her first malignant tumour was diagnosed. This is known as the Sword of Damocles syndrome, the extreme fear of cancer reoccurrence or development [14]. It is in line with several findings according to which reducing future risk [15], or reducing the anxiety of developing cancer [16] were among the women's main reasons to request PM. Regarding her sexuality and body image, the patient stated that she was ready to accept further changes on her body, it was irrelevant to her, although this was one of the surgeon's main arguments. The patient had strong family ties who supported her demand for the PM. Either her mother or her husband were also present during the medical consultations. The patient did not

have any psychiatric history, and her mental status (appearance, cognitive functions, thought process, level of consciousness) seemed normal, except for her mood and emotional state. Regarding the latter, the patient was very anxious and frustrated, and reported suicidal thoughts. Her frustration came from the feeling that she had been treated as a child who could not make a decision about her own body. Based on these symptoms, she was diagnosed with “adjustment disorder, unspecified” (ICD-10 Code: F 4320). There was no aspect in the patient’s family history (including bereavement) which would have influenced her mental status. Finally, the patient had clear and realistic expectations of the surgery and the potential post-operative complications. Many patients’ decision is driven by their misconceptions and heuristics about mastectomy [3]. Kimberly Van Zee, surgical oncologist wrote [17] (p. 1722) that “there is a huge misconception out there. Many women think that removing their other breast will cure them of the disease they already have, but there is no survival advantage.”

This was not the case with our patient. She was aware of the possible complications, the long and painful recovery period and the worst scenario: the cancer can come back in another form with or without the mastectomy.

In summary, the patient considered the PM as a means of coping with her anxiety caused by an uncertain future and the possibility of developing another cancer. After realizing this, the medical team was flexible enough to revise their first decision.

After the surgery, the patient had follow-up visits at the psycho-oncology ambulance. She was satisfied with her decision, and her anxiety and distress were dramatically reduced, while her current quality of life was significantly improved. Her psychotherapy had a new focus: return to work. gradually, she changed her stressful job for a less exhausting one.

VI. Discussion and conclusion

We presented a case in which a female patient requested a PM. At the beginning, her request was denied on the basis of several medical assumptions causing a clash between the bioethical principle of *nil nocere* and autonomy. Finally, the patient’s autonomy overwrote *nil nocere* and

the patient was satisfied with the decision. Nevertheless, the case still raises questions and issues.

First of all, can psychological factors, such as the patient's Sword of Damokles syndrome, weigh more than medical concerns which deem the relative benefit of the treatment too low compared to its possible complications. In our case, the answer was yes. Nevertheless, future protocols of PM should give more focus on psychological assessment too.

Another conclusion of this case stands in the difficulty of actually carrying out the Shared Decision Making. Although the patient's priorities and values were obvious at the beginning, it was hard to establish their agreement with the medical concerns.

The final issue raised by the case is the patient's long-term satisfaction with her decision, i.e. could a patient psychologically profit from a relatively ineffective, and inadvisable surgical treatment? And if yes, could favourable psychological outcomes compensate for the possible medical complications? According to empirical evidence, the majority of the women who had PM were highly satisfied with their decisions [18-19]. Furthermore, they also reported reduced emotional concern about developing breast cancer [19].

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