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On the Ethical Issues of Bilateral and Contralateral Risk-Reducing Mastectomy

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Abstract: *The principles of beneficence and patient autonomy can clash in various ways; this is the case of bilateral risk-reducing (BRRM) and contralateral risk-reducing mastectomy (CRRM). Mastectomy, however, is rarely treated as an ethical issue. The literature of BRRM and CRRM is dominated by the topic of risk-assessment. In this chapter, we are going to analyze BRRM and CRRM from a moral point of view. We are going to argue that patients' autonomy and women's self-determination over their own bodies can be considered as an indication of risk-reducing mastectomies.*

Keywords: *risk-reducing mastectomy; prophylactic mastectomy; clinical medical ethics; shared decision making; patient autonomy; informed consent*

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Introduction

In traditional medical ethics, the central values generally supported the patients' medical interests, *sensu stricto*. In the Hippocratic tradition, the relationship between the physician and the patient is hierarchical, and their communication is unidirectional, as the goal is to "fix" the patient's *bodily* ailments from the external perspective of benevolent paternalism. However, this model is superseded - in theory at least. In their seminal work, *Principles of Biomedical Ethics* [1], Beauchamp and Childress argue that the guiding principle of medical ethics should be *the patient's autonomy*. That is, the silent and passive patient of the Hippocratic model should turn into an active participant and agent, a partner in *Shared Decision Making* [2]. Regardless of this theoretical development, it is still often questioned whether patients should freely decide on their therapy and in what cases should one's autonomy subordinate to benevolent paternalism.

The principles of *beneficence* and *patient autonomy* can clash in various ways; this is the case of bilateral risk-reducing (BRRM) and contralateral risk-reducing mastectomy (CRRM). Mastectomy as a therapeutic option, however, is rarely treated as an ethical issue. The literature of BRRM and CRRM is dominated by the topic of risk-assessment and the identification of high-risk patient groups.

This chapter will analyze BRRM and CRRM from a moral point of view, applying Beauchamp and Childress's principles. We are going to argue that *patients' autonomy* and women's self-determination over their own bodies can be considered as an indication of risk-reducing mastectomies. To support this, we examine other medical interventions that result in quasi-irreversible outcomes, such as contraceptive sterilization and the refusal of life-saving and life-sustaining interventions. Finally, we introduce an ethical guideline meant to complete the medical assessment criteria.

The history of prophylactic risk-reducing mastectomy

In medical literature, only a few cases from the 19th century on report surgeries where surgeons had removed “benign breast masses,” and the first prophylactic mastectomy was carried out in 1917 [3]. By the 1970s, almost a thousand prophylactic mastectomies were being done annually in the United States [4]. This rise sparked some professional debate, but this debate was more medical than ethical in nature. Questions arose regarding the aim of BRRM and CRRM (fear management or actual cancer prevention) and the necessary extent of surgeries [3].

The picture has considerably changed over the past 40 years. According to recent statistics, the number of BRRMs and CRRMs tripled between 2002 and 2012, despite that no superior long-term survival has been confirmed as compared to the conservative therapies. Wong et al. examined 496,488 women diagnosed with unilateral invasive breast cancer. 59.6% chose breast-conserving surgery, 33.4% underwent unilateral mastectomy, and CRRM was chosen by 7.0%. All in all, the number of women who opted for CRRM increased from 3.9% in 2002 to 12.7% in 2012 [5].

Women’s interest in risk-reducing mastectomy has globally increased. The media has a remarkable role in this. Celebrities’ effect on BRRM, CRRM, and genetic screening for BRCA1/BRCA2 mutations has already been examined. The most attention was gained by Angelina Jolie’s bilateral risk-reducing mastectomy in May 2013 [6-7]. After the AJ case, the number of BRRMs and the demand for BRCA-testing measurably increased. However, Evans et al. notice that there was no increase in ‘inappropriate referrals.’ [8]

Normative implications of BRRM and CRRM

Distinguishing between appropriate and inappropriate referrals generally creates a normative frame as well. The moral nature of these types of surgeries is basically related to two ethical issues. (1) If yes, by which limitations can medicine do quasi-irreversible harm to patients upon their request? *Autonomy* is the essence of the modern doctor-patient relationship, as well as *informed consent*. However, it is questioned whether detailed medical information – even repeated over several consultations – could be enough as a moral counterweight in case of removing an otherwise cancer-free breast. This is the first question we deal with. (2) Second, we examine those cases in which paternalism in the doctor-patient relationship can be morally justified. We will analyze whether patients’ autonomy and self-determination can be reasonably limited regarding CRRM and BRRM. There is a widely supported moral guideline that states that one’s freedom ends where another one’s begins. In cases in which one does not put another person at risk, limiting the formers’ self-determination could lead to unnecessary paternalism. On the next few

pages, we argue that *benevolent paternalism* that exclusively aims to maximize patients' medical welfare is not justifiable when it comes to CRRM and BRRM requests. Instead of limiting the access to CRRM and BRRM, more emphasis should be put on effective informed consent in the framework of Shared Decision Making (SDM).

Informed consent and risk-reducing mastectomy

Until about the middle of the 20th century, the hierarchical nature of the paternalistic physician-patient relationship limited the information flow between the two parties, wherefore consent to any treatment was usually not sufficiently informed or rooted in real understanding. It comes as no surprise that Katz called the history of physician-patient relationship 'the history of silence' [9]. The normative turning point in the doctor-patient relationship changed the basic ethical standards regarding therapeutic decision making. According to the modern bioethical standards, patients' consent must be informed and the therapy has to be chosen with the patient's active involvement in the decision-making process. Chewing et al. analyzed 119 studies that focused on the attitudes of patients toward being involved in the making of such decisions. They found that 63% (n=75) of the studies concluded that patients want to be involved [10]. However, several meta-analyses emphasize that the desire of patients to be an active member of the decision-making process is not general [11-13]. To assume that all patients would like to have complex and detailed medical information and participate in the decision-making process is inaccurate. However, it does not mean that those patients who refuse to listen to the relevant medical information will benefit all the same from the therapeutic process. Patients who less actively cooperate with their doctors are less satisfied with their medical care [14]. All in all, the comprehensive information of patients and their involvement in the decision making process is essential, but it is just as important to respect their right to refuse to listen to the medical information to abstain from the making of therapeutic decisions. We argue that reference to these facts should be part of the basic information that the physician provides, preferably during the first encounter with the patient. That is, the patient should be aware that while participation in medical decision-making is not obligatory, those who get involved in that way turn out to be more satisfied.

Patient autonomy and breast cancer

Based on the above, it is obvious that providing autonomy in cancer has undeniable benefits, such as greater satisfaction and a better sense of control. The prerequisite of autonomy is that the physician and the patient participate

in the interaction as partners. Emmanuel et al. distinguish between four basic models of the doctor-patient relationship [15]. The traditional and most ancient form is the so-called *paternalistic model*, in which all the relevant therapeutic decisions are made solely by the physician himself. The second type is the *informative model*, in which the doctor informs the patient, but still decides alone. The third model is much closer to the modern medical practice, because in the *interpretive model*, physicians explore their patients' values and inform based on those perceived values. The shared problem with these models is that the patient remains in the shadow of the doctor, therefore has no influence whatsoever on the course of the therapy. This way, autonomy is suppressed. Emmanuel and his colleagues ultimately argue that the optimal relationship between the two parties must be equal in which comprehensive and personalized medical information is provided, and then the doctor and patient make the decisions together. This desirable model is called the *deliberative model* and is in accordance with the modern bioethical standards. In a medical system that applies this model, the right to self-determination and the right to freely influence one's medical care is widely supported. *In summary, regarding breast cancer treatments, it is essential to provide all the patients personalized medical information as well as to provide them the chance to give informed consent to the patient-preferred medical treatment.* As we saw before, cooperation and informed consent improves a range of parameters from satisfaction to the sense of control. There is a number of other reasons for which the paternalistic model just cannot work in breast cancer cases. Each therapeutic decision is influenced by the decision makers' original life situation, value system, goals and fears, etc. The diagnosis of breast cancer is challenging for both the patient and the physician because of this moral/ethical complexity. Patients' attitudes towards the therapies are influenced by the access to health care, the fear of recurrence or occurrence, as well as the effect of a surgical intervention on one's personal appearance (body image) and sexual life [16]. The physician just cannot evaluate these parameters for the individual patient, wherefore all possible efforts must be made to engage patients in decisions about themselves.

The partner-like relationship optimally establishes the ground for the patient-centered Shared Decision Making (SDM) process in the oncological care as well, so that evidence- based information can be synchronized with the patient's relative preferences. According to Martinez et al. [15, p. 55], the most important aim of SDM is to support the patient to make a medically sound decision that is at the same time compatible with her value system. The physician has two roles in this process. (1) First, he informs the patient about every relevant detail regarding the treatment options, including their advantages and disadvantages in a comprehensible manner; (2) Second, the physician directly asks for his patients preferences regarding each alternative. It is essential to emphasize that SDM is not complete if the practitioner only lists

the treatment options to his patient expecting the patient to decide on his own. Shared decision making is a dynamic, two-sided process. In the lack of medical knowledge, we must not expect patients to be able to choose between the alternatives. SDM's primarily aims are to maximize patient welfare with the active assistance of the doctors' expertise exploring his patient's preferences towards a treatment's advantages, side effects, short- and long-term consequences.

Personalized medical information is crucial in the era of informed consent. Supporting patients toward an informed and deliberate consent is substantial. It can be facilitated with accessible decision supporting tools, as emphasized in several studies [17]. Waljee et al., in their randomized control study found that decision aids significantly ($p=.024$) improved patients' therapy-related knowledge. Additionally, these tools are suitable to eliminate treatment-decision related conflicts and improve satisfaction rates concerning decision making. *Hence, using such decision supporting tools like online interactive information materials or leaflets should be an integrative part of SDM* [18].

Patient autonomy and informed consent in relation to mastectomy

There are many studies focusing on therapeutic decision making of people who are diagnosed with breast cancer. This paper cannot analyze all the treatment options for breast cancer, thus we restrict our focus on the surgical decisions, or more specifically on the normative concerns of bilateral risk-reducing (BRRM) and contralateral risk-reducing mastectomy (CRRM). However, we also have to talk about an otherwise broadly accepted alternative to mastectomy, the breast conserving surgery (BCS). It is indispensable, because mastectomy and BCS can both be treatment options for many women who are diagnosed with breast cancer. The moral problem comes from this, because the range of potential complications is much wider for mastectomy than for BCS, while their effect on long term survival is not significantly different [15, p. 57]. In the light of these medical facts, it is almost imperative to search for the reasons why an increasing number of breast cancer patients opt for mastectomy of some kind. As long as the effect on long- term survival rates of BCS and mastectomy are in balance, should doctors allow their patients to choose a more invasive and extensive surgery?

The increase in CRRM and BRRM cases is presumably linked to increased access, which is not necessarily accompanied by in-depth understanding. Mastectomy and breast cancer are matters of public discussion/debate much more than they used to be before the millennium. At the same time, the patient population in question is not really aware, or does not actually trust the medical evidence regarding the similar survival rates of the surgical alternatives.

This could be professionally and at the same time morally challenging to the medical team [19].

It is a well-known fact, that a huge proportion of women who are diagnosed with an early stage of breast cancer choose CRRM instead of BCS [20]. *This raises the suspicion that the doctrine of informed consent is violated to different degrees, since it is difficult see why women would choose a more invasive and extensive type of surgery in possession of all available information.* Even if there is reliable medical evidence that contralateral cancer recurrence is rare, many patients wish to undergo mastectomy because of the fear of recurrence [21]. *It seems that even though the patients are generally more conscious and better informed, they do not necessarily favor the medically more supportable options.*

Limitations of patient autonomy

If BCS is chosen by the patient, then the *nil nocere* (do no harm) principle also prevails, as the goal is achieved by a less invasive method. This is the optimal case. But let us imagine a bit more complicated scenario. It is conceivable that weighing the pros and cons of each treatment option, the surgeon would prefer BCS, but the patient holds on to mastectomy. If the doctor decides to suppress his patient's wish, it is a breach of autonomy. Women diagnosed with breast cancer, after having received comprehensive medical information, can still choose a treatment option that is medically not the "best," one that the surgeon cannot identify with. *The progress of medicine cannot be measured solely by focusing on the decreasing mortality rates and longevity, because nowadays we need to complete the former approach with the patient's evaluation of each treatment's outcome, risks, etc* [19, p. 5]. The origo of all breast cancer treatments is the patient herself, whose right to self-determination and autonomy must be protected. In the above thought experiment, the imaginary surgeon would impose unnecessary paternalism. It is a moral obligation of a physician who respects patients' autonomy to inform them about all the relevant details in a comprehensive and objective manner. Regarding CRM and BRRM, the additional disadvantages must be shared as well. All in all, only the patient herself is entitled to evaluate whether to accept the higher chance of sepsis, infections, pain or even rare mortality [22].

Everyone could harm themselves

In the field of medicine, limitation of patient autonomy is accepted only under certain circumstances. These circumstances are well defined and special. Cases of public health emergency, life-threatening emergency situations, incompetent (minor, mentally ill, etc.) patients are often cited cases regarding the limitation of informed consent [23]. These are situations when the actual risk overrules the relatively abstract concept of autonomy. There exist controversial

treatment options that are seemingly clearly harmful or too risky from the medical point of view. In case of disputable patient requests, doctors tend to back out, in order to save patients from “irrational decisions.” Nevertheless, it is questionable whether a request that is illogical or irrational from the physician’s point of view, grants the right to the physician to curb patient autonomy. *Suppressing an otherwise competent patient’s request on the grounds that it is not compatible with the physician’s value system would lead to unjustifiable paternalism, even if the physician-preferred treatment option would promote the wellbeing of the patient. Accepting or rejecting a treatment decision of a patient should not solely depend on its’ rationality, but rather on the patient’s capacity and informed consent.* Julien Savulescu argues:

When doctors or others disagree with people’s values or probability estimates, they should reason with them and engage them in normative dialogue. But if the patient is competent, the best reason for not respecting their choices is not the choice is imprudent or irrational, but on the basis of justice considerations and the fair allocation of medical resources, or on the basis of harm to others. The importance of freedom to construct our own conception of the good life, and to act on it, requires that doctors respect irrational choices, and, where resources allow, facilitate the originality and diversity of human existence. [24, p. 34-35]

Examples to voluntary self-harm

In support of BRRM and CRRM it is worth considering two commonly supported medical therapies that result in physical harm upon the voluntary request of a competent individual. This is to show that risk-reducing mastectomy rises less serious ethical dilemmas than usually thought. That is, it often happens in the field of medicine that the two basic ethical principles namely “nil nocere” and patient autonomy clash and it does not often lead to unresolvable conflicts.

In the major part of the world, contraceptive sterilization of men and women became the most widely used method for couples in the reproductive age [25]. Sterilization as a permanent method for family planning is, however, still the subject of bioethical debates, since it is a quasi-irreversible contraceptive alternative. The ethical issue from the medical point of view stems from the conflict of the basic bioethical principles referred to above. The moral dilemma has been solved with different legal solutions in different countries, but nowadays the number of states that strictly restrict the use of this highly effective intervention is decreasing. This appears to be a clear sign that the world tends to opt for patient autonomy in this respect. According to the International Federation of Gynecology and Obstetrics (FIGO) comprehensive and understandable medical information is the only moral

counterweight that is needed. Any further limitation, such as the consideration of parity, age, waiting time, etc. would unreasonably restrict patient autonomy [26].

Another remarkable example of the same dilemma is the right to refuse medical care, even if it is life-saving or life-sustaining. Similarly to contraceptive sterilization, the ways and means of how one can practice the right of refusal depends on the legal environment of the given country. In general, in spite of the genuine moral difficulty, patients' therapeutic freedom overrules the medically beneficial decisions, therefore people have the ultimate right to accept or not a medical treatment. Of course, moral counterweights are needed here as well. Informed consent is a universally supported tool as the minimum ethical standard, and additionally several different are in use, such as waiting time [27].

Through these examples we tried to show that medicine does allow patients to choose treatment options that are irrational or at least controversial at first sight. However, such ethically loaded practices necessitate transparent guidelines and protocols. Below we give a brief description of a guideline related to such issues, which we find an ideal blend of medical and ethical considerations.

Guideline to risk-reducing mastectomy

The literature of BRRM and CRRM are mainly limited to the risk-assessment and almost no moral or ethical issues are discussed. Another frustrating gap is that most of the studies focus on the higher-risk group patients. Consequently, the therapeutic preferences of lower-risk patient are barely discussed. The *Manchester guidelines for contralateral risk-reducing mastectomy* however is a rare exception [28]. The discussion of CRRM is interweaved by all the necessary ethical standards, and accordingly the preoperative stage of contralateral mastectomy is under the influence of SDM. In practice, it seems quite easy; the patient and her physician consult multiple times before she finally gives her consent to the chosen treatment. The Manchester guidelines suggests a five-step evaluation of each patient who request CRRM. It starts with *history taking*. Open-ended questions are emphasized, hence doctors can understand the motives underlying patient decisions. The second step aims to *calculate the risk of contralateral breast cancer*. As a result, patients are classified to one of four risk-groups. The third stage of the evaluation process recommends a well-known ethical counterweight, namely waiting time. *The cooling off period* aims to reduce the number of bad decisions that may stem from the emotionally vulnerable period after the emotional vulnerability in the period after being informed of the diagnosis. Reviewing the literature of post-mastectomy regret, it is proven that 90% of women who chose risk-reducing

mastectomy are satisfied with their decision for a longer term [29-30]. However, we argue that if medically agreeable, it is worth considering a shorter or longer waiting time before performing any type of risk-reducing mastectomy, as well as multiple doctor-patient consultations. The fourth step of the Manchester guidelines is the assessment of each CRRM request in a *multi-disciplinary (MDT) setting*. The team includes “breast cancer nurse, breast surgeon, oncologist, radiologist, pathologist and where possible, an oncoplastic-reconstructive surgeon familiar with the various reconstructive options including free TRAM/DIEP.” [28, p. 4] Psychological support is a part of the MDT as well. The team estimates the risk of the contralateral breast cancer, assesses the chance of survival, outcomes and side-effects of each treatment option. Since the comprehensible and personalized medical information is essential to facilitate SDM, the MDT could enhance the application theory to practice. Finally, before the patient makes her informed consent the physician summarizes all the possible outcomes, side effects and long term consequences of each treatment option. It is only after this that the patient can sign the informed consent form.

Conclusion

Choosing the appropriate treatment option for breast cancer could be challenging for both patient and physician. Modern bioethical standards require that patients be involved in the process of decision making. Accordingly, the ultimate authorization to start or stop a medical treatment must be based on a comprehensive information process. However it poses a dilemma, how to reconcile patient autonomy with the principle of doing no harm. Solving the theoretical dilemma and implementing it to practice is challenging, but the shared-decision-making model appears to be a promising tool in this respect. Regarding CRRM and BRRM the *Manchester guidelines for contralateral risk-reducing mastectomy* provides a great example of how to complete the solely medical assessment of the patient who requests mastectomy for risk-reductive reasons with ethical considerations. The Manchester guidelines encourages the use of simple and comprehensible language, personalized medical information tailored to the given patient, and if it is medically agreeable the insertion of some waiting time. The latter, we argue is not necessarily a disproportionate limitation of patient autonomy. It is clear that the patient information and informed consent of women who request risk-reduction mastectomy raises complex ethical issues. We propose, that most of these issues can be satisfactorily resolved in the framework shared decision making.

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