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Should immediate breast reconstruction be performed in the setting of radiotherapy? An ethical analysis

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ABSTRACT

Immediate breast reconstruction (IBR) combined with post-mastectomy radiotherapy (PMRT) is associated with an increased risk for complications. Here, we analyse whether IBR combined with PMRT is ethically acceptable. We employ normative analysis following reflective equilibrium and the principles of Beauchamp and Childress: non-maleficence, beneficence, autonomy, and justice. From the perspective of beneficence and non-maleficence, we can choose either IBR or PMRT according to documented risks and complications, delayed autologous breast reconstruction with corresponding benefits but less risk for complications, or even no reconstruction, which for some women, might be equally beneficial. In such a situation, given the level of severity associated with lacking a breast after mastectomy, IBR violates the principles of beneficence and non-maleficence. To deny an IBR in the context of PMRT does not violate the principle of autonomy as it is normally interpreted in the healthcare system, not even when patient-centred care is taken into consideration. Moreover, there is a risk that the decision of the patient will be affected by heuristics, optimism bias, and surgeon bias. IBR in the context of PMRT could be in conflict with the principle of justice, as it could lead to displacement of care for other patient groups. Furthermore, an acceptable level of cost effectiveness should be low, given that living without a breast is a condition of moderate severity. In conclusion, given the current knowledgebase and established ethical norms within the healthcare system, we find strong ethical reasons not to offer IBR when PMRT is expected.

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Introduction

Immediate breast reconstruction (IBR) is an operation performed to increase patient quality of life (QoL). Guidelines on modern breast cancer care, such as the British National Institute for Health and Care Excellence (NICE) guidelines [1] and the Swedish national guidelines [2,3], state that most women who undergo a mastectomy should be offered an IBR. These guidelines are largely consensus-based and influenced by documents, such as the Women's Health and Cancer Rights Act (WHCRA) [4], the New York State (NYS) Breast Cancer Provider Discussion Law [5], and the European Parliament Resolution on breast cancer [6]. The WHCRA [4] was passed to protect financial coverage for women who opt for breast reconstruction following mastectomy, and the NYS Breast Cancer Provider Discussion Law [5] requires surgeons to discuss the availability of breast reconstruction with the patient before mastectomy. The European Parliament Resolution [6] aims to protect the psychological well-being and physical integrity of women by ensuring that 'breast-conserving surgery is available to every woman in every instance where it is medically justified and that, wherever possible, breast reconstruction operations are performed using the patient's own tissue and within the shortest possible time' (§7c). The resolution also gives the patient the rights to 'easily understandable, expert, and appropriate information and advice from the physician before, during, and after treatment' and 'to self-determination based on full information' (§7g)

[6]. Guidelines for IBR are also affected by other policies, such as benchmark quality indicators for breast cancer care. According to the European Society of Breast Cancer Specialists [7], it is a quality indicator that a minimum of 40% of patients receive an IBR at the same time as the mastectomy. This is motivated by the WHCRA and the European Parliament Resolution and that it 'largely reflects patient demand and should be a key consideration in the multidisciplinary management of cancer' [7]. No citation is provided for the statement reflecting patient demand, and it is unclear how a quota of 40% was chosen as a minimum standard and why the frequency of complications and failed reconstructions was not taken into account [7].

IBR in combination with post-mastectomy radiotherapy (PMRT) is associated with an increased risk for complications. In a Swedish study [8] that included 725 patients from four hospitals, estimation of the 5-year failure rate revealed a 10% risk in the non-irradiated group, 28% in the pre-mastectomy radiation group, and 25% in the PMRT group. Moreover, Kearney et al. [9] reported an increased risk of implant removal (26% vs. 8.3%; $p = 0.007$) and expander infection (20% vs. 2.6%; $p = 0.001$) in irradiated as compared with non-irradiated patients. Other long-term complications include capsular contracture, a deformed breast, and pain [10–12]. Additionally, PMRT in combination with IBR significantly decreases patient-reported satisfaction and QoL [8,12,13]. This raises concerns as to whether performance of IBR is ethically acceptable when PMRT is expected. Although the high risk for complications is

well-known in the context of PMRT, IBR is often still offered, as there are guidelines stating that it should be offered to most women undergoing mastectomy.

The aim of this article was to analyse whether IBR in combination with PMRT is ethically acceptable. The analysis was made in relation to a publicly financed welfare-type healthcare system, which is largely driven by need and not by demand or rights. Examples of such healthcare systems include the British National Health System and the Swedish healthcare system.

Methods

We conducted a normative analysis focused on reflective equilibrium [14] according to which ethical statements in a system should be largely consistent. Therefore, established principles were applied to the ethical problem according to its specific facts and relative to how these principles are generally interpreted in the health-care system [14]. Additionally, we used the well-established principles of Beauchamp and Childress: non-maleficence, beneficence, autonomy, and justice [15]. In applying these principles to the case of combined IBR and PMRT, we interpreted them consistently with how they are normally interpreted in welfare-based healthcare systems.

Results: analysis

Non-maleficence and beneficence

The principles of non-maleficence and beneficence are closely related, but it is generally accepted that there is a more stringent duty to avoid harming patients as compared with doing what is beneficial for them. This implies a strong duty to not place the patient in a worse condition after intervention than they were in before intervention [15]. Similarly, the degree of acceptable harm is related to the reasonable balance between potential harm and potential benefit(s). This is dependent upon a number of different factors:

- the severity of the condition from which the patient suffers;
- alternative interventions;
- the evidence of harm and benefit(s); and
- conflicts with other patient needs.

Generally, more severe conditions result in greater levels of acceptable harm; however, this also depends on the available alternative interventions. Even for a severe condition, acceptability of harm will be low if there are alternative effective interventions with lower risks of harm. The evidential situation for types of harm and benefits is essential. If there exists sufficient evidence of harm, it is necessary to carefully balance such evidence against even potentially large benefits supported by scarce evidence in order to perform the more stringent duty of avoiding harm.

The severity of outcomes associated with lacking a breast after mastectomy must be considered mild to moderate in relation to other conditions treated in the healthcare system [16]. Utility measurements reveal that a bilateral mastectomy defect [standard gamble (SG): 0.86; and time trade-off (TTO): 0.85] is considered similar to a breast ptosis (SG: 0.90; and TTO: 0.87) [16]. Furthermore, studies show that even women who have had a mastectomy without breast reconstruction adapt quite well in terms of QoL [17,18]. Parker et al. [17] demonstrated similarities in the general patterns of psychosocial adjustment and QoL among women with breast cancer operated on with breast-conserving surgery, mastectomy alone, and mastectomy combined with IBR [17]. Moreover, Harcourt et al. [18] concluded that women who undergo mastectomy with IBR have similar issues involving

altered body image as those reported by women undergoing mastectomy alone at 1-year postoperation. Nevertheless, it is difficult to evaluate the significance of these studies, as they likely included women who opted not to undergo reconstruction, as well as those not medically fit to undergo reconstruction, even if this was not reported. Furthermore, patients tend to come to terms with their choice, as long as they feel involved in the decision-making process [19]. Therefore, randomization of patients into groups receiving reconstruction or not receiving reconstruction would likely not provide a more reliable result.

There are three alternative interventions for a woman who undergoes a mastectomy and requires PMRT:

- IBR and PMRT;
- PMRT and no breast reconstruction; or
- PMRT, followed by a delayed breast reconstruction with autologous tissue (DBR).

Despite a strong norm for IBR in the guidelines, such a norm is only valid when IBR is medically (and we would add ethically) justified. Empirical research and normative discussion present a varied picture of breast reconstruction ranging from radical feminist critiques of this activity reflecting a male gender norm [20], critiques regarding the stereotypical body image underlying such a norm [21], and empirical studies showing that women relate differently to breast reconstruction, which also find that the no-reconstruction alternative can be in line with a positive body image [18,22]. Therefore, none of the alternatives to IBR are necessarily ethically unwarranted.

When supporting their preferred body image, the benefits of a successful breast reconstruction for women are obvious; however, this is dependent on the result, as PMRT after an IBR might result in lower QoL [8,12,13], as well as complications [8,9], suffering, pain, and a deformed breast [10–12]. Such complications alone can decrease patient satisfaction with the reconstruction [23]. Another harm with recurrent complications is further intrusions into the physical integrity of the patient when complications warrant further surgical interventions, which is more often the case than not [8,9]. Arguably, an IBR causes no harm if the reconstruction fails and the patient loses her implant, because she then ends up in a situation similar to that upon having received a simple mastectomy. This suggests that the loss is similar to that associated with a mastectomy, albeit one that was delayed by having the implant for a period of time. In either case, she suffers the loss of a breast. Although this argument is mistaken. During the process of losing an implant, the patient experiences iatrogenic harm and considerable psychosocial suffering. Moreover, she has suffered two losses: first of the breast and then of the implant. Furthermore, evidence suggests a strong tendency in people to suffer more from losing a benefit than from never having acquired said benefit in the first place (i.e. loss aversion) [24]; therefore, such an attitude violates the non-maleficence duty.

For women who prefer a reconstructed breast but are unsuitable for an IBR, DBR with autologous tissue is an available alternative. Such a reconstruction can be performed with potentially less long-term risks and complications and better QoL than an implant-based reconstruction combined with PMRT [25]. However, in some ways, autologous breast reconstruction and an IBR with an implant are not equivalent, as autologous reconstruction is a more extensive intervention, and there are patients for whom such surgery is inappropriate for medical reasons. Therefore, from the perspective of avoiding intrusive interventions, autologous breast reconstruction might not appear to be a better choice. Still, if it is a planned intervention, the patient has been given the

opportunity to assess and consent to whether the expected gain is worth the physical intrusion. When handling acute complications with further surgical interventions, patients' might not have much choice than to accept the intrusion (potentially affecting their experience for the worse).

Cancer patients are often mentally and/or physically fragile, which makes it even more questionable to subject them to an IBR and PMRT and expose them to risks for complications and lower QoL. The general patterns of psychosocial adjustment and QoL, which are similar among women with breast cancer operated on with mastectomy alone, and mastectomy and IBR [17,18], indicate that a period without a breast might not be harmful to the patient, and that delayed reconstructive techniques are safer [25]. This suggests that a delayed reconstruction has to be considered a viable alternative in the context of PMRT.

In situations where IBR and PMRT are required, these are potentially conflicting needs based on the associated risks and complications, where both might not be satisfactorily met. This raises the issue of whether any of these needs take precedence over the other. If PMRT is indicated, the need for the PMRT is generally greater than the need for an IBR. PMRT is needed to reduce the risk of breast cancer relapse with resulting morbidity, whereas an IBR is a requirement related to maintaining QoL. Potentially, an IBR might influence the patient to refuse PMRT in order to avoid complications, thereby interfering with the greater need for a PMRT.

From the perspective of beneficence and non-maleficence and in the setting of radiotherapy, the choice will be between an IBR and its documented risks and complications or a DBR and its corresponding benefits but less risk for complications (or even no reconstruction, which for some women, might be equally beneficial). In such a situation and based on the moderate severity associated with lacking a breast after a mastectomy, IBR violates the principles of beneficence and non-maleficence.

Autonomy

Respect for patient autonomy in needs-based welfare-type healthcare systems is generally interpreted in terms of informed consent to treatment and some degree of choice. It does not, however, imply that healthcare should be demand-driven based on patient preferences. Traditionally, professionals assess whether there is a healthcare need and offer care accordingly, after which the patient provides informed consent to the care. Whether healthcare is indicated is dependent upon evidence of patient benefit and whether there is a reasonable balance between risks and benefits. In some cases, different alternative interventions might be warranted, at which time the patient can be offered a choice [15]. The introduction of patient-centred care [23,26] emphasizes a stronger role for the patient in shared decision-making, where patient and professional dialogue encourages arrival at a relevant description of patient need and a jointly acceptable intervention for that need. However, restrictions in what is offered to the patient are reasonable, even in this paradigm [27]. Relative to IBR in a setting of patient-centred care, this implies that the healthcare system is under no obligation to offer the intervention based on the respect for autonomy, even if the patient wants it. If the level of risk and complication relative to the benefits are unreasonable, the patient can still be denied access.

A basic prerequisite for autonomy is that the patient understands the risks and benefits associated with an intervention. Studies on the framing of information and how patients relate to risk information show that understanding and making a decision

might be difficult [28]. People generally view interventions as riskier for others than for themselves, suggesting an optimism bias [29,30]. Therefore, several factors might influence the ability of a patient to make an autonomous decision in this situation, as she might minimize the risks and complications associated with IBR and PMRT. Patients facing such a situation are often those newly diagnosed with cancer, which puts them in a vulnerable position [31]. This is not unique for this patient group but needs to be factored into such analyses associated with having to make a life-saving decision. Another complicating factor is that the doctor communicating the risk information might be biased and deemphasize areas of uncertainty [28]. For IBR, the surgeon might feel pressured to achieve a quality indicator suggesting that a minimum of 40% of patients should receive an IBR at the time of mastectomy [7]. Because only quotas of IBRs performed are measured and not the frequency of failed reconstructions and re-operations, surgeons might be prone to subject individual patients to risks in order to achieve better statistics for the hospital. This suggests that the personal preference of a surgeon might influence the information delivered. For example, a breast surgeon might recommend an IBR, as he/she specializes in implant-based reconstruction, whereas a plastic surgeon might be prone to opt for a delayed autologous reconstruction, as he/she finds this type of surgery more challenging to perform. Nevertheless, the communication process influences both patient choice and the psychological adjustment of the cancer patient [32,33]. Professionals need to be careful not to motivate a decision to opt for surgery by referring to false patient autonomy: 'I'm merely doing what the patient wants!'. In summary, it is uncertain whether a patient is capable of making a fully autonomous decision when it comes to IBR and PMRT.

Considering professional autonomy, it is reasonable to consider whether there is strong resistance in the profession to offer an intervention associated with a high level of risks and complications. This is also necessary based on the possibility of moral stress associated with acting against professional convictions [34]. In a healthcare system that emphasizes equal access to care, individual professional autonomy might be problematic. However, if there is a general resistance within the profession, it does not jeopardize *equal* access to the same extent, since all patients will then be exposed to this general resistance.

In conclusion, to deny an IBR in the context of PMRT does not violate the principle of autonomy, even when accounting for a move toward patient-centred care. Moreover, there is invariably a risk that the decision will be affected by heuristics, optimism bias, and surgeon bias, which are problematic from an autonomy perspective. Furthermore, professional autonomy needs to be considered in the decision for IBR and PMRT; therefore, the principle of autonomy does not support performing IBR and PMRT. Moreover, because considerations of beneficence and non-maleficence recommend against offering IBR and PMRT, considerations of autonomy do not provide a sufficiently strong counterargument.

Justice

The principle of justice covers both equality and distributive justice. Equality deals with the extent to which interventions are equally accessible to different patient groups, independent of irrelevant aspects, such as gender, ethnicity, socioeconomics, and age. Distributive justice considers how scarce resources should be fairly distributed [15].

In the case of equality, it is often argued that equal cases should be treated equally. Therefore, the fact that other breast

cancer patients have access to IBR warrants IBR in combination with PMRT. This argument is not necessarily sound, because unequal treatment based on relevant differences is acceptable. Because IBR is associated with different outcomes, risks, and complications depending on receipt of PMRT, patients can be treated differently without violating concerns regarding equality. On the other hand, if IBR combined with PMRT is offered despite the risks and complications, this would warrant denial of an intervention in other situations, and access could pose an equality problem for other patient groups.

In regard to distributive justice, many healthcare jurisdictions might allow considerations of severity, effectiveness, and cost-effectiveness to be taken into account, implying that more severe conditions warrant higher resource expenditures as long as the treatment is cost effective [35–37]. Lacking a breast after a mastectomy is a condition of mild to moderate severity, implying that cost-effectiveness needs to be high. For example, in England, there is a general cost-effectiveness threshold of 20,000 GBP/quality adjusted life-years (QALYs) to 30,000 GBP/QALYs [38]. In Sweden, decision-making concerning pharmaceutical use reflects a threshold of 100,000 €/QALYs for the most severe conditions and a falling threshold for less severe conditions [39]. We found only one analysis of the cost effectiveness of IBR combined with PMRT as compared with DBR with autologous tissue and no reconstruction [40]. Given that this study was performed in the United States healthcare system and did not employ ordinary QALYs but rather breast-QALYs, it is difficult to translate the findings into other healthcare contexts. The study shows that IBR is more cost effective than DBR relative to no reconstruction due to the greater cost of DBR, even when DBR has a greater QoL gain than IBR; however, we cannot determine whether any of the interventions are cost effective enough, given the mild to moderate severity of the condition. Moreover, if we have reason to abstain from IBR according to the principles of beneficence and non-maleficence, this cannot be countered by the presence of a greater cost-effectiveness ratio. Additionally, possible displacement of care for other patient groups needs to be considered. Access to surgical facilities and staff is often a rationed resource, and acute complications requiring surgical interventions specifically risk displacing other patients, including those with higher medical priority.

In conclusion, IBR in the context of PMRT might conflict with the principle of justice, as it could lead to displacement of care for other patient groups. The acceptable cost effectiveness should be high, given that living without a breast is a condition of mild to moderate severity.

Discussion

This study analyses whether IBR combined with PMRT is ethically warranted in a welfare- and needs-based healthcare system. One of the key issues is the definition of what constitutes an acceptable complication rate. Currently, IBR combined with PMRT results in higher complication rates [8–12] and lower QoL [17,18,25] relative to IBR without radiotherapy. In the present study, we argue that this complication rate is too high given that IBR is an operation performed to increase the patient's quality of life, not to save the patient's life, and that there are alternative interventions, such as delayed autologous reconstruction, that invariably offer better long-term results in the context of PMRT. Nevertheless, further research is needed to define acceptable complication rates in the context of breast reconstruction, especially from a patient perspective.

Medical guidelines should be evidence-based and continuously under revision. IBR and PMRT confer an increased risk for reconstructive failure [8,9], capsular contracture, a deformed breast, and pain [10–12], as well as a lower QoL [8,12,13], as compared with the absence of radiotherapy. Given the nature of the intervention and the mild to moderate severity associated with living with one breast, it is necessary to ensure that performing IBR and PMRT does not cause the patient harm. In light of this, it is the responsibility of surgeons to critically evaluate current guidelines and not merely implement them. Additional studies are needed to explore the long-term effects of different alternatives in order to increase the evidence-based nature of the guidelines.

Additionally, it is the responsibility of the surgeon to consider the best interests of the patient. This requires an awareness of factors potentially influencing the information provided to patients and, subsequently, their informed decision. Therefore, it is necessary for surgeons to scrutinize their practices and minimize the effect of factors, such as non-evidence-based quality indicators, surgical preferences, and power struggles between professionals. The informed consent provided by a patient is not an excuse to perform an intervention known to have an unfavourable balance between benefit and harm. If the patient consents to a procedure with such an unfavourable balance, it should be considered that the patient might be inadequately informed about the intervention and its consequences.

It is often argued that women have the right to a new breast; however, welfare-based healthcare systems are not generally rights driven but rather needs driven. Therefore, patients do not have a legal right to a breast. Nevertheless, even if we would grant that women have a moral right to have breasts, it does not follow that this right has to be provided through IBR rather than some other means. Further, if women did have such a moral right, it's reasonable to assume that it wouldn't be a fundamental, inalienable right. Presumably, it can be outweighed at times by other moral considerations; for instance, the rights claims that other people have, the resources available to respect a particular right, etc. Statements concerning 'rights' are inferred from documents, such as the WHCRA [4], the NYS Breast Cancer Provider Discussion Law [5], and the European Parliament Resolution on breast cancer [6]. However, if we scrutinize these documents, none go so far as to imply that the patient has the right to an IBR or should be subjected to interventions with high rates of complications and failed reconstructions. The WHCRA [4] states that breast reconstruction is part of basic breast cancer care that should be covered by medical insurance in the United States; however, this does not imply that it has to be an IBR nor that it is compulsory to have a breast reconstruction. The NYS Breast Cancer Provider Discussion Law [5] requires that surgeons discuss the availability of breast reconstructions with patients before mastectomy, and the European Parliament Resolution [6] states that the patient has the right to 'easily understandable, expert, and appropriate information and advice from the physician' and 'to self-determination based on full information' (§7g). The right to full information and self-determination does not imply the right to an intervention that leads to complications and lower QoL, but rather information on why it is not offered and what alternatives exist. In fact, the aim of the resolution to protect the psychological well-being and physical integrity of women can be seen as a reason not to offer IBR in the context of PMRT. The statement that a breast reconstruction should be offered 'within the shortest possible time' (§7c) does not imply that an IBR needs to be offered. Medical factors and safety still have to be considered, and in the case of PMRT, it can be argued that an IBR is not

the best alternative when a delayed autologous reconstruction is sufficient as soon as medically advisable. In summary, the laws and regulations do not state that an IBR needs to be offered in cases where it might lead to complications and lower QoL but rather argues the right of the patients to be informed on what alternatives are the safest and why. It is unreasonable that laws passed to protect the rights of women and quality indicators created to increase quality of care are interpreted in ways implying the opposite effect for individual patients.

In conclusion, according to the current knowledgebase and based on established ethical norms within the healthcare system, we find strong ethical reasons to not offer IBR when PMRT is expected.

Disclosure statement

No potential conflict of interest was reported by the authors.

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