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Legal Aspects of Bilateral Mastectomies for Patients With or Without Mutated Genes

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Since Angelina Jolie broke the news of her bilateral mastectomy and oophorectomy, most breast surgeons have regularly been facing the question of this type of surgery whatever the age of the patient.[1] Familial breast cancers have received a lot of media coverage. They are often aggressive with bad prognosis, and the discovery of predisposing genes, such as mutated *BRCA1* and *BRCA2,* has opened a window of hope. For the first time it was possible to prevent cancer by the identification of the gene and removal of the targeted organ.[2]

Surgery and the identification of constitutional genomic alterations have been merged for the benefits of our patients. However, several difficulties appeared quickly in the management of the patients according to their presentation with cancer or before the cancer diagnosis. Bilateral mastectomy could be discussed when the patient is tested positive for *BRCA* mutation. However, when the patient had cancer in a high-risk family, until recently, the results of the tests took very long to obtain, and this prevented the medical team from offering the best choice to the patient. This is not the case anymore, and the results can now be obtained in a few weeks for a reasonable price. On the other hand, aside from the *BRCA* mutations, new predisposition genes have been discovered, including high-penetrance *p53*, and *PALB2*, and other genes called VUS (variants of unknown significance) in which the risk is unknown or very low.[3] Therefore, delivering comprehensive information is increasingly becoming critical for clinicians.

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To go back to the title of the paper, I will describe three situations in which legal aspects were involved, and allow to open a discussion. The first one is the story of a patient who tested positive for *BRCA1* and was offered a bilateral prophylactic mastectomy with immediate reconstruction and bilateral oophorectomy. Several members of her family had died of breast cancer and she was initially very happy to undergo surgery. A couple of years later, she told me at the clinic, "Thank you, Doctor, for saving me from dying, but I am not a woman anymore." Early menopause, loss of libido, difficult sexual relationship, depression, and a future divorce had made her life very difficult. The patient had had several sessions of counseling with the geneticist, cancer surgeon, plastic surgeon, her gynecologist, and a psychologist before surgery. Despite all the medical advice and the fact that all the medical management was uneventful, she remains actually severely depressed and she will probably lose her job soon.

The second one describes a patient who was initially treated for breast cancer with breast-conserving therapy followed by chemotherapy, radiation therapy, but not hormonal therapy, because she had triple-negative breast cancer. She was a heavy smoker. Her younger sister developed breast cancer some years later. They both were tested for the mutation and were positive for *BRCA1*. She was advised to undergo prophylactic surgery, but she delayed the decision for 8 years for personal reasons. Finally, she decided to be operated on and asked for a bilateral deep inferior epigastric perforators (DIEP). After the surgery, she had a bilateral DIEP necrosis, with several months of healing with vacuum assisted closure (VAC) therapy and secondary healing. Finally, her breasts were reconstructed with several lipofillings over a 3-year period. Like the first patient, she was severely depressed and lost her job.

The third story is the story of a 35-year-old woman who was diagnosed with triple-negative

breast cancer. She received neoadjuvant chemotherapy, followed by a lumpectomy with an oncoplasty and a contralateral symmetrization during the same operative time. There was a complete pathologic response. During the neoadjuvant treatment, the medical oncologist had asked for the presence of the mutation. The result, however, was delivered to the surgeon a month after the surgery and was positive for *BRCA1*.

Any surgeon involved in breast cancer management and reconstruction has similar stories to tell. How can we protect ourselves from legal issues arising from the cases similar to the first two cases?

The legal aspects of this new field of prophylactic surgery, i.e., removing an organ to prevent the occurrence of cancer, varies according to the countries. In France, for instance, surgery constitutes "voluntary assault and battery," but, since it is performed to prevent life-threatening conditions, it is not subject to legal action. Moreover, in the United States, when a patient decides to be operated on, if he or she signs the informed consent form, normally no lawsuit is filed against the surgeon. The legal aspects vary from one country to another.

As doctors, we must remain aware that our patients are in a permanent state of stress, first of all, because they have cancer. In addition, they have a predisposing mutation, and everything is again increased when a postoperative complication occurs. Complications after the surgery are always disastrous in breast cancer patients, but it is even worse when they occur after the hope given by the idea of prevention.

This is our responsibility as surgeons to avoid and limit the side effects of our treatments by providing the most comprehensive information possible. However, when a patient in the USA requires, due to the presence of an identified mutation, a bilateral prophylactic mastectomy for a T1N0 breast cancer, we can be surprised. Actually, about 50% of American women ask for this type of surgery. The data referring to a 30%–40% complication rate seems unable to prevent the patients from this obviously unnecessary surgery. However, American scholarly journals, as well as media, sponsored by famous surgeons, keep presenting data in favor of this type of surgery, supported by the female advocacy organizations.

If we want to avoid needless surgery in treatment of our patients and limit the consequent lawsuits, bilateral surgery must be exclusively reserved to the carriers of the mutated genes (except patients with severely dystrophic breasts).

The multidisciplinary approach (involving a geneticist, cancer surgeon, plastic surgeon, gynecologist, and a psychologist or psychiatrist) is mandatory to give the patient a more objective and comprehensive preoperative information.

The constant postoperative depression is increased by bilateral surgery, and the patients must be correctly informed about it before and after surgery. Although a good cosmetic result would limit these side effects, it is not sufficient to prevent the personal problems induced by the surgery, which will be most certainly complicated over the postoperative course. In addition, it is important to protect ourselves from patients' or their families' aggressiveness when deciding this complex surgery. Documentation of all the given information, orally and written, is necessary and can help demonstrate the objectivity and honesty of the medical team facing a patient who had put a great hope in the preventive surgery to remove the fear of cancer death but actually has to deal with the usual postoperative problems. There are few chances are that artificial intelligence will be able to solve that kind of questions in the near future.

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