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What are the ethical and legal considerations when your patient refuses the standard of care?

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Abstract

In medical practice, physicians are sometimes faced with patients who reject the gold-standard treatment for a condition. In this hypothetical clinical scenario, we present the case of a patient who refuses Mohs micrographic surgery for management of infiltrative basal cell carcinoma and instead requests off-label therapy with imiquimod. We discuss the treating dermatologist's options in response to this patient's request and the ethical considerations surrounding the case. We conclude that the physician has the right to refuse to provide treatment that deviates from standard clinical practice but that the physician should counsel the patient on all options, provide thorough informed consent, offer contact information for the patient to pursue a second opinion or a radiation oncology referral, and ensure safe transfer of care should the patient desire treatment with a different provider.

Keywords: standard of care, imiquimod, medical ethics, off-label use, Mohs micrographic surgery, infiltrative basal cell carcinoma

Introduction

The "art of medicine" becomes relevant in dermatologic practice when balancing the desires of the patient with standards of clinical practice. To illustrate this situation and discuss the legal and ethical dilemmas involved, we present the following hypothetical case scenario.

Case Scenario

Dr. Benjamin Cat is a dermatologist seeing a cosmetically-sensitive 65-year-old woman for the first time. The patient, presents with an ulcerative

lesion on her nose. After Dr. Cat expresses his concern and explains the risks and benefits of a shave biopsy, the patient reluctantly agrees to this next step in management. Histopathology confirms the diagnosis of infiltrative basal cell carcinoma (BCC), positive at the deep margins. Dr. Cat reviews this diagnosis with the patient during a follow-up visit and recommends Mohs surgery. The patient adamantly refuses Mohs surgery, as she is terrified of the potential residual scar. Rather, she is only interested in topical treatment with imiquimod, which she heard about from her friend who received this treatment for her BCC. Dr. Cat explains that although imiquimod is an approved treatment for non-facial superficial BCC with a maximum two-centimeter diameter, which may have been her friend's diagnosis, it is neither approved for infiltrative BCC nor for facial lesions. Despite this explanation, the patient refuses treatment with Mohs surgery and insists upon therapy with imiquimod.

Treatment Options

There are several different approaches that the dermatologist can take when considering the treatment of infiltrative BCC for this patient. One option is to do as the patient requests and prescribe treatment with topical imiquimod 5% cream 5-times-a-week for 6-12 weeks with follow-up performed every three weeks. If choosing this first option, the dermatologist would also document that the patient received full informed consent, being sure to include a discussion of the off-label use of the drug, lower cure rate when compared to Mohs surgery, and possibility that the cancer may subsequently spread locally and/or even

metastasize. Alternatively, the dermatologist could refuse to prescribe topical treatment, as it is not a reasonable option given the BCC subtype. Another option is to offer to refer her to another dermatologist/Mohs surgeon for a second opinion or refer her for a radiation therapy consultation.

Discussion

When contemplating the above treatment options, the primary ethical dilemma that is encountered is the conflict between autonomy and beneficence, occurring in the context of a legal climate that pressures physicians to practice defensive medicine. Based on the principle of autonomy, the patient has the right to make her own decision with a full understanding of the information pertinent to her case and without external controlling forces. She must therefore be given proper informed consent, including a discussion of all of her treatment options, including the risks and benefits associated with each option. However, although the patient has the right to make her own decision, the physician is also bound by his or her own code of ethics to provide beneficent care by acting in the best interest of the patient.

Mohs surgery is the treatment of choice for BCCs in cosmetically-sensitive areas owing to its high cure rate and tissue-preserving technique. Radiation is a reasonable alternative for primary treatment of BCCs in patients who are not surgical candidates or who wish to avoid surgical treatment, though there are potential adverse effects including poor long-term cosmetic results. As noted above, topical treatment with imiquimod 5% cream is currently FDA approved for treatment of small non-facial superficial BCCs, but not infiltrative BCCs at any body site. Vismodegib is indicated for metastatic or locally advanced BCCs in patients with recurrence after surgery or in those who are not candidates for surgery or radiation [1]. Mohs surgery is currently the most effective treatment for BCC with a recurrence rate of 1% at 5-year follow-up, whereas the recurrence rate after radiation treatment is 8.7% [1]. There is currently limited data on the efficacy of imiquimod 5% cream for infiltrative BCCs, though one case series reported

a 35% recurrence rate in all cases, with a 40% recurrence rate for infiltrative BCCs [2].

When considering the above treatments for BCC, Mohs surgery is the most effective option and is indicated in this patient's case. The physician is thus ethically motivated by the principle of beneficence to provide the patient with Mohs surgery. The physician should elucidate the root cause of the patient's anxiety over cosmetic outcomes and counsel and educate the patient on outcomes after Mohs surgery using pre- and postoperative photographs of prior patients when appropriate.

The administration of imiquimod 5% cream in this case would be an off-label use. Off-label use of medications is common practice in dermatology and does not, by itself, qualify as either medical malpractice or physician negligence. However, a physician may be found negligent if harm was done to the patient after the physician deviated from the standard of care by prescribing an off-label medication [3]. Although informed consent is not legally necessary when prescribing medications off-label, it may be advisable in certain cases [3]. There is limited evidence at this time demonstrating the efficacy of imiquimod 5% cream for treating infiltrative BCCs [2], and its use is currently only recommended as monotherapy for superficial BCCs [4]. Thus, the dermatologist in this case might be at risk for legal ramifications if he/she prescribes imiquimod for this patient, especially if the treatment is not efficacious and her BCC subsequently recurs, enlarges, or metastasizes.

Recommended Approach

The legally safest option would be to refuse to prescribe topical therapy and offer referrals to another dermatologist/Mohs surgeon for a second opinion or refer her for a radiation therapy consultation. The dermatologist should provide the patient with extensive counseling on the risks and benefits of each treatment and ask the patient to sign an informed consent expressing her understanding of her treatment options and her choice to refuse Mohs surgery. Although the patient may not get the treatment she wants, she is given the option to thoroughly discuss her diagnosis and

management with another doctor and to explore alternative therapeutic options.

When a physician is faced with a patient refusing the standard of care, the physician can draft a document stating the patient's disease and the treatments that are within the standard of care. Should the patient refuse these treatment options, the patient, physician, and a witness should sign this document including initialing next to each treatment option that the patient has refused. This form should be retained in the patient's medical record. If the patient refuses to sign the document, the refusal should be witnessed by someone in the office and noted in the medical record. It would be wise at this time to inform the malpractice carrier that this patient may make a claim against the physician. Should the patient report the refusal of care to the state medical board, the physician should contact a lawyer.

Additionally, if the patient does not choose definitive treatment with Mohs surgery, the current physician should offer the patient a second opinion from a similarly qualified dermatologist as well as a consultation for radiation therapy. Should the patient agree to one or both options, the physician should give the patient contact information for the appropriate alternative practitioners. The referring doctor should contact these other providers to inform them of the background information of the case. If the patient chooses a treatment offered by a different physician, the current provider should document that the patient has transferred her care elsewhere.

Potential adverse consequences of each option

Although prescribing imiquimod after obtaining informed consent is the option that most respects

the patient's autonomy, it puts the provider at risk by deviating from standard clinical practice. This option may be viable if there is a very thorough discussion during the informed consent, if the patient agrees to re-biopsy later on, and if the patient would consider treatment with Mohs surgery if the cancer does not respond to topical therapy. Refusing to prescribe topical treatment may be harmful to the therapeutic alliance and puts the patient at risk of obtaining no treatment. However, it is within the physician's rights to refuse to provide treatment that does not follow standard of care. Providing referrals to other physicians is also an acceptable response, but referring the patient to others runs the risk of "kicking the can down the road." The current treating physician cannot be certain of whether the patient would pursue further care and does not know what treatment the subsequent provider would recommend.

Conclusion

Although the patient has the right to reject the gold-standard treatment for her condition, the physician, too, has the right to refuse to provide treatment that deviates from standard clinical practice. The physician should counsel the patient on all of her treatment options, obtain thorough informed consent for whatever option is chosen, offer contact information for a second opinion or referral to a radiation oncologist if the patient wishes, and ensure a safe transfer of care should the patient choose to continue care with a different provider.

Potential conflicts of interest

The authors declare no conflicts of interests.

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