Breast Implant-Associated Anaplastic Large Cell Lymphoma: Solid Data or Fake News?

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■ n 1997, Keech, a medical oncologist, and Creech, a plastic surgeon, [1] reported the first case of breast implant-associated anaplastic large cell lymphoma (ALCL) in a patient presenting with a mass and subsequently cured with chemotherapy. Since then, the number of reported cases worldwide started to accumulate, and in 2011 the United States Food and Drug Administration released a safety communication regarding the potential association between breast implants and ALCL. As of May 2019, the American Society of Plastic Surgery has recognized approximately 282 cases in the United States and 722 cases worldwide [2]. In Israel, the first four known cases of breast implant-associated ALCL are reported in this issue of the Israel *Medical Association Journal (IMAJ)* [3].

Although considered a rare disease, ALCL has started to capture the attention of physicians, patients, regulators, and of course the media. The link between common elective aesthetic and reconstructive surgeries (breast augmentation and reconstruction) and malignancy can cause fear and even panic in patients and surgeons, and it is an extremely viral topic for the media.

However, as clinicians and researchers, it is our duty to gather data and conduct research to promote evidence-based decision making and of course to accurately inform our patients.

On 26 November 2018, the International Consortium of Investigative Journalists

released the "#implantfiles," a 2-year collaboration of more than 250 journalists from 58 media partners in 36 countries. One of the central themes of this report was the inherent limitations of clinical trials in breast implants, demonstrating the need to establish a national device registry in each country for the purpose of tracking outcomes and rare adverse events [4].

Progress can be seen worldwide regarding data gathering. Some countries have already developed voluntary national registries regarding ALCL. The Netherlands has started a mandatory registry that has been operating since 2016 [5]. Within the Netherlands, all cosmetic breast implants (augmentation and reconstruction) incur a €25 surcharge. In addition, insurance providers pay an annual lump-sum payment to the registry, thereby funding the national registry, which is overseen by the Dutch Ministry of Health. While Australia and England have an opt-out model, the United States has an opt-in model that has yet to determine the surgeons to be included [6].

Many questions remain regarding such registries. The determination of funding, as well as the monitoring and protection of the data collected, need to be addressed to allow for transparency.

In Israel, the Israeli Society of Plastic Surgery is to be commended for adding the information regarding ALCL to the consent forms for breast augmentation and breast reconstruction surgeries. It is my opinion that the next step should include the creation of a task force for an Israeli registry of all breast implants, led by the Israeli Society of Plastic Surgery, and composed of representatives from the Israeli Ministry of Health.

The plastic surgery community in Israel, of which I am part, should be doing every-

thing that it can professionally to better understand the implications of the procedures that we perform. In addition, public education for healthcare providers as well as patients, which includes accurate evidence-based information, is extremely important. As such, I appreciate the opportunity given to me by the editors of *IMAJ* to discuss this subject and bring awareness to healthcare providers. It is my hope that this editorial can accelerate the pace of dissemination of data and cooperation among the medical field (medical researchers and plastic surgeons), industry, and patients.

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