The case for a national breast implant registry in Canada

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Summary

The House of Commons Standing Committee on Health proposed in 2022 to start a national registry for breast implants. Why, and what requirements are needed, will be outlined. Breast implant products are not always in compliance with international norms and standards, and several scandals have occurred because of industry fraud. To trace which patients have defective breast implants, a good registry is an absolute must. Furthermore, some diseases, such as lymphomas, autoimmune diseases, and so-called breast implant illness, are believed to be associated with breast implants. An accurate estimation of how often these diseases occur in patients with breast implants is lacking. A registry in which not only surgical data but also patient-reported outcome measurements are recorded will result in a better understanding of patient outcomes and device performance. The registry should not be a voluntary ("opt-in") registry but a mandatory ("opt-out") registry, in which only the patient (and not the surgeon) has the choice whether to participate.

It is estimated that 3%–4% of women in Western countries have silicone breast implants. Of these, 70% are placed for cosmetic reasons, whereas about 30% are placed for reconstruction after mastectomy. Several surgical or local adverse effects may occur. In addition, severe diseases have been associated with breast implants.

In February 2022, Luc Thériault, vice-chair of the House of Commons Standing Committee on Health, proposed to start a national registry for breast implants. Why such a registry is a must will be outlined.

Scandals

Breast implant products are not always in compliance with international norms and standards. In Europe, scandals concerning breast implants occurred in 2010 (Poly Implant Prothèse [PIP])[1] and in 2015 (Silimed).[2]

Poly Implant Prothèse was a fraudulent French company that manufactured breast implants. Reports of potential problems (e.g., premature rupture) of PIP implants started soon after their introduction as medical devices at the end of the last century. In 2010, these implants were banned after inspection of the manufacturer by the French government, which concluded that the company used unapproved fillers (i.e., nonmedical industrial silicone gel).

Silimed is based in Brazil and is the largest manufacturer of breast implants in Latin America. In 2015, German and Dutch health authorities found evidence that the surfaces of their textured implants and their polyurethane-covered implants were contaminated with man-made mineral fibres, which are potentially carcinogenic to humans.

In a Dutch market surveillance study in 2015, it was shown that the technical files of 10 out of 10 manufacturers marketing silicone breast implants in the Netherlands were not in order.[3] In 2018, the International Consortium of Investigative Journalists released the "Implant files," revealing many shortcomings in breast implant clinical trials.[4] The consortium concluded that health authorities around the globe failed to protect patients from poorly

tested implants. In 2020, the BellaGel breast implant scandal occurred in Korea.[5] The manufacturer of these implants deliberately replaced approved constituents with unapproved materials that were potentially toxic for humans. Finally, as of May 30, 2023, Ideal Implant Incorporated has stopped all operations, raising concerns regarding warranty claims and replacement options.[6]

When potential safety hazards occur, it should be made possible to warn patients regarding the potentially unsafe nature of their implant. However, without a good registry, recalls — as performed in the automotive industry — are impossible.

Three types of severe diseases that are associated with breast implants

In 1997, a specific breast implant–associated malignant disease, anaplastic large cell lymphoma (ALCL), was first reported. In 2011, the US Food and Drug Administration (FDA) issued a warning but stated that it could not identify a definite association between breast implants and ALCL. Because most of the patients with ALCL had textured implants, the FDA and Health Canada requested in 2019 that Allergan recall its textured implants. In 2023, the FDA and Health Canada issued a safety communication that other lymphomas as well as breast implant associated–squamous cell carcinoma may occur in patients with silicone breast implants. Although an accurate estimation of how often these malignant tumours occur in patients with silicone breast implants does not exist, ALCL researchers calculate the risk to be 1 in 2832 women.[7]

Various autoimmune diseases are also reported to occur more frequently among patients with silicone breast implants. Again, the estimated risk is difficult to quantify, and a long-standing debate occurred about whether silicone breast implants were really a risk factor for the development of these autoimmune diseases. In 2018, however, a large study from Israel convincingly showed that autoimmune diseases occurred more often among patients with silicone breast implants than women without breast implants.[8] Patients with silicone breast implants appear to have a 45% higher risk of developing autoimmune diseases (e.g., sarcoidosis, systemic sclerosis, and multiple sclerosis). As with malignancies, most diseases occur more than 10 years after implantation.[7]

Finally, patients with silicone breast implants often have symptoms suggestive of an abnormal functioning autonomous nervous system (so-called breast implant illness; Figure 1). Symptoms include severe fatigue, widespread pain in muscles and joints, severe dry eyes and dry mouth, feverish feelings, and cognitive impairment, among others. The symptoms generally occur 7–10 years after placement of silicone breast implants. In about 80% of patients, these symptoms ameliorate or disappear after explantation.[8] Again, the estimated risk is difficult to quantify, and there is still debate about whether breast implant illness really exists. Recently, it was shown that purified immunoglobulin G (IgG) antibodies from patients with breast implant illness dysregulate inflammatory cytokines in activated human peripheral blood mononuclear cells and that symptoms of breast implant illness occur after intracerebroventricular injection of these IgGs into mice.[9] In addition, application of the Bradford Hill criteria for causality suggests that breast implants do cause breast implant illness.[7]

Why a national breast implant registry is needed

When the PIP implants were recalled in the Netherlands, there was voluntary registration of patients with silicone breast implants ("opt-in" registration).[10] This meant that only 10%–20% of women with PIP implants could be traced. Not only is a mandatory registry required for recalls, but with the registry it is also possible to calculate how often local or systemic complications develop after placement of silicone breast implants. Thus, patient-reported outcome measurements must be implemented in the registry. As no randomized clinical trials were performed to show the possible safety of silicone breast implants, we currently have only postmarketing surveillance to monitor their safety. Manufacturers must conduct these studies, and plastic surgeons must report events to the manufacturers. Unfortunately, there are no criteria for these reports. They are infrequently made, are not peer reviewed, and are not open to the public. Because there are several signals that breast implants may not (always) be safe, it is prudent to start with a registry as soon as possible. As discussed, this should not be a voluntary ("opt-in") registry but a mandatory ("opt-out") registry in which only the patient (and not the surgeon) has the choice whether to participate.

Requirements for a registry

It is important that Canadian authorities be able to detect health risks of breast implants at an early stage; thus, a legal basis for a mandatory breast implant registry in all provinces and territories should be created. In the Canadian registry, data collection should be adopted from the International Collaboration of Breast Registry Activities data set, including patient reported outcomes at 1, 2, 5, 10, 15, and 20 years after implantation.[11,12] The Canadian Institute for Health Information (CIHI) would be an appropriate administrator of the registry. The CIHI has extensive experience with data collection, including for the Canadian Joint Replacement Registry. Surgeons who place implants should be responsible for the data collection.

Compliance with the mandatory registry could be an issue. In the Netherlands, all hospitals and private clinics have the legal responsibility for registrations. In addition, compliance with the registry is a requirement for renewing licences (e.g., the licence to work as a plastic surgeon) in

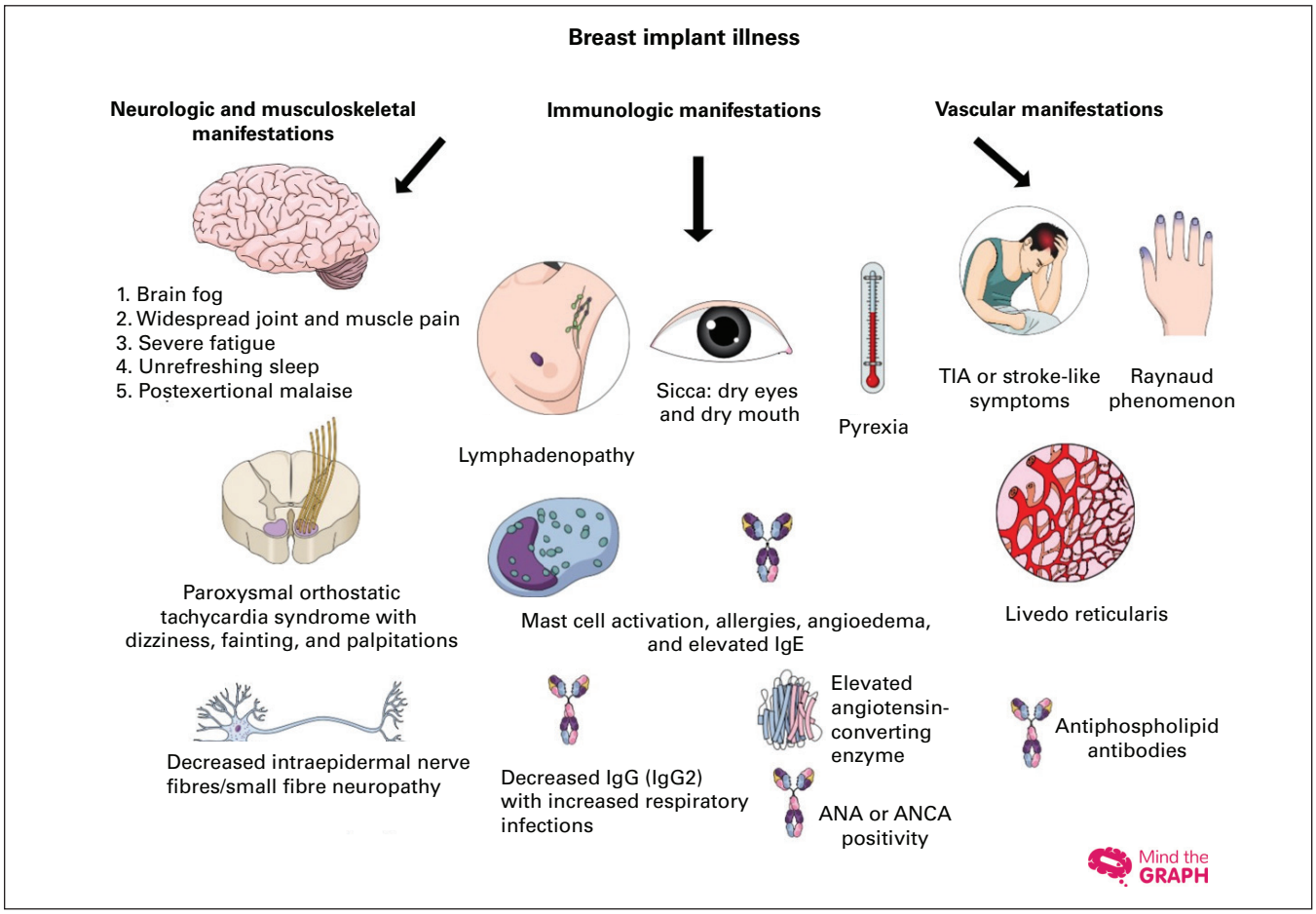

Fig. 1. Clinical features of breast implant illness,[7] which presents with neurologic and musculoskeletal, immunologic, and/or vascular manifestations. Note: ANA = antinuclear antibodies; ANCA = anti-neutrophil cytoplasmic antibodies; IgG2 = immunoglobulin G2; IgE = immunoglobulin E; TIA = transient ischemic attack. Pictograms from mindthegraph.com.

the Netherlands. In Germany, surgeons who fail to confirm the registration in the registry lose the right to charge for the entire procedure.[13] In the case of a self-financed surgery, the patient would be informed that they could reclaim the entire sum they were charged.

Privacy should be guaranteed by registering patient data anonymously with up-to-date encryption. In addition to the CIHI coordinating the registry, an independent administrative centre would be needed to ensure an optimal level of data privacy.[13] Data access and processing would need to be strictly regulated. Access to data is primarily allowed in the event of an implant-related problem as part of the track-and-trace mechanism. To facilitate the registry, manufacturers should be asked to develop barcodes on the implant packing so that, with a barcode scanning module, data can be entered without mistakes.

The funding of the registry is another factor of importance. The developmental phase of the registry should be financed by Health Canada, and a long-term funding system should be developed. In the Netherlands, patients pay an extra Can$40 for their surgery; patients with breast reconstruction are reimbursed by their health insurance.

Conclusion

Breast implants are high-risk medical devices. Long-term, sound, epidemiologic data are lacking, despite the fact that breast implants have been on the market for more than 60 years. Recalls, which have occurred in the past and may be needed in the future, are not successful if there is no good registry of patients and their breast implants. An urgent need exists to start a national registry for breast implants in Canada. Once implemented, the registry should be used by all surgeons who place implants. It could be used for possible future recalls and would provide us with better information about diseases that are associated with or caused by breast implants.

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Competing interests: Jan Willem Cohen Tervaert has appeared as an expert witness in court for patients with adverse effects due to biomaterials and is a member of the European Commission Expert Panel on Medical Devices. Dr. Cohen Tervaert reports receiving grants from the Dutch Kidney Foundation and the Arthritis Society, advisory

board honoraria from Mallinckrodt and Otsuka, and speaker honoraria from Pfizer, Medexus, and Otsuka. From 2017 to 2022, he was chair of the data safety monitoring board for the InflaRx: IFX-1 study. He is a member of the ME/CFS (myalgic encephalomyelitis/chronic fatigue syndrome) Research Program Committee (The Netherlands Organisation for Health Research and Development).

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