The Dutch Breast Implant Registry: Registration of Breast Implant–Associated Anaplastic Large Cell Lymphoma—A Proof of Concept

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PATIENT SAFETY

Background: The Dutch Breast Implant Registry (DBIR) was established in April of 2015 and currently contains information on 38,000 implants in 18,000 women. As a clinical registry, it evaluates the quality of breast implant surgery, including adverse events such as breast implant–associated (BIA) anaplastic large cell lymphoma (ALCL). To examine the efficacy of the DBIR, the capture rate of BIA-ALCL was compared to the registration of BIA-ALCL in the Dutch Nationwide Network and Registry of Histo- and Cytopathology (PALGA) as a gold standard, in combination with matching these databases to obtain complementary information.
Methods: All BIA-ALCL patients diagnosed and registered in The Netherlands in 2016 and 2017 were identified separately in the PALGA and DBIR databases. In addition, both databases were matched using indirect key identifiers. Pathologic information from the PALGA and clinical and device characteristics from the DBIR were obtained for all patients.
Results: Matching of both databases gave a capture rate of BIA-ALCL in the DBIR of 100 percent ($n = 6$) in 2016 and 70 percent ($n = 7$) in 2017. In total, 17 patients were identified in the PALGA, of which 14 patients were also identified in the DBIR; three patients were not registered; and 10 patients were registered false-positive. Of all confirmed patients, symptoms, staging results, treatment, and implant information were registered.
Conclusions: Currently, the DBIR contains 2 full registration years and captures most of the BIA-ALCL patients despite overestimation. Therefore, pathology confirmation remains essential. By matching these databases, complementary clinical and implant information could be retrieved, establishing the DBIR as an essential postmarketing surveillance system for health risk assessments. (*Plast. Reconstr. Surg.* 143: 1298, 2019.)

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Breast implants are class III (high-risk) medical devices that are among the most applied medical devices in plastic surgery.[1–3] Recently, we could determine that, in The Netherlands, 3.3 percent of all women between ages 20 and 70 years carry breast implants.[4] Instigated by the ongoing

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discussion on possible health risks in women with breast implants, national and international stakeholders have called for the need for nationally covering breast implant registries.[3–11] The recently proven significantly elevated risk for breast implant–associated (BIA) anaplastic large cell lymphoma (ALCL) has underpinned the timeliness of these registries.[4,12,13] BIA-ALCL is a rare variant of T-cell non-Hodgkin lymphoma, occurring in the periprosthetic fluid or capsule of women with breast implants, with a calculated absolute risk of 1:35,000 at the age of 50 years to 1:7000 at the age of 75 years.[4] Many aspects of this disease remain unresolved, of which identification of specific patient groups and implant associations that infer a higher risk may be the greatest challenges.

For meaningful studies in such a rare disease, a big-data approach is essential. In this light, use of breast implant registries with an almost complete regional or national coverage is an essential tool in evaluating breast implant–related serious adverse events. Currently, only the breast implant registries in Sweden (Swedish Breast Implant Registry, since 2014), Australia (Australian Breast Device Registry, since 2015), and The Netherlands (Dutch Breast Implant Registry, since 2015) seem to be eligible sources for big data.[11,14,15]

The Dutch Breast Implant Registry (DBIR) is a national, prospective, opt-out registry, with mandatory registration of all breast implant surgery performed in The Netherlands.[14,16,17] Since the start of the DBIR in April of 2015, approximately 18,000 patients and 38,000 breast implants have been registered until December of 2017. In contrast, the Dutch Nationwide Network and Registry of Histo- and Cytopathology (PALGA) was established in 1971 as a comprehensive registration of all national pathology reports, containing coded histocytologic and cytopathologic information from all pathology laboratories in The Netherlands, providing nationwide coverage since 1990.[18]

We investigated the efficacy of the DBIR by measuring the capture rate of BIA-ALCL patients in the DBIR compared to the PALGA as a gold standard, providing an objective quality assessment of the national breast implant registration program. Second, we aimed to determine the compatibility of both databases in merging data, as a support for future research.

PATIENTS AND METHODS

Registries and Timeframe

Anonymized data for this cross-sectional study were obtained using two databases: the DBIR and the PALGA. The DBIR was implemented nationwide in April of 2015, and 2016 was the first full registration year in which "participation in the Dutch Breast Implant Registry" was used as a national quality indicator by the Dutch Health Care Inspectorate. BIA-ALCL cases were selected from two corresponding full registration years in both registries, starting on January 1, 2016, up to and including December 31, 2017.

Case-Finding Strategies

All registered BIA-ALCL cases in The Netherlands were identified using the query "anaplastic large cell lymphoma" and "breast" in the PALGA database as described previously.[4,19] In addition, all cases registered as a revision operation because of BIA-ALCL were selected from the DBIR.

These data were obtained after a centrally approved request by the scientific board of the DBIR, the Dutch Society of Plastic Surgery, and the scientific board of the PALGA. The Medical Research Involving Human Subjects Act does not apply to this study.[18,19]

Matching Patients in the DBIR and the PALGA

After separate data collection from the PALGA and the DBIR, the output of the DBIR was validated using the identified cases in the PALGA database. Interdatabase comparison per identified case was performed manually, using three key variables: date of diagnosis (i.e., date of receipt of pathology samples) in the PALGA versus operation date in the DBIR (with a maximum range of 1 day), age at diagnosis in the PALGA versus age at surgery in the DBIR, and pathology laboratory in the PALGA versus hospital location in the DBIR.

Included Variables

Subsequently, data from the PALGA and the DBIR were merged. From the PALGA, information on the date of diagnosis, age at diagnosis, pathology laboratory, histopathologic and cytopathologic information on diagnosis, and detailed tumor characteristics was obtained. From the DBIR, clinical information at revision surgery was collected, including patient characteristics (i.e., age, American Society of Anesthesiologists classification, smoking, body mass index, and information on previous breast surgery and/or radiotherapy), surgery characteristics (i.e., hospital identification code, date of operation, side of operation, type of intervention, indication for intervention, and operative technique), and device characteristics (i.e., device type, year of implantation, country of implantation, and manufacturer).[20]

RESULTS

Capture Rate of BIA-ALCL

Between January 1, 2016, and December 31, 2017, 13,901 patients and 30,399 breast implants were registered in the DBIR (6336 patients and 12,854 implants in 2016; 7565 patients and 17,745 implants in 2017). Of the 13,901 patients, 4039 patients underwent an unexpected revision operation (2031 in 2016; 2008 in 2017). Registered implants were composed of new implants and revision surgery of breast implants inserted before and after the start of the registry. In the registry, indications for revision surgery are collected and categorized as unexpected or planned, such as the exchange of a tissue expander for an implant or autologous tissue. Of the women with an unexpected breast implant revision in the DBIR, eight patients were reported to have BIA-ALCL in 2016 (0.3 percent) and 16 patients were reported to have BIA-ALCL in 2017 (0.8 percent). Between January 1, 2016, and December 31, 2017, 17 BIA-ALCL cases were identified in the PALGA ($n = 7$ in 2016; $n = 10$ in 2017).

Matching of the patients reported with BIA-ALCL in both databases was performed successfully. All seven patients reported in the PALGA database in 2016 were correctly registered in the DBIR (capture rate, 100 percent). In 2017, seven of 10 patients registered in the PALGA database were correctly registered in the DBIR, whereas three were missing (capture rate, 70 percent; $n = 3$ false-negative cases for the DBIR). In both years, 10 additional patients were registered in the DBIR ($n = 1$ in 2016, and $n = 9$ in 2017). In these patients, BIA-ALCL diagnosis was not histologically or cytologically confirmed and therefore not reported correctly in the PALGA database. These cases were considered false-positive for the DBIR (Fig. 1).

Combining Clinical Information from Two Databases

Combined histocytologic findings and patient, surgery, and implant characteristics of confirmed BIA-ALCL patients are listed in Table 1. The diagnosis of BIA-ALCL was obtained and confirmed after cytologic analysis of periprosthetic seroma, histologic examination of the periprosthetic capsule, or large-needle/incisional biopsy of a BIA-tumor mass. Of the 17 confirmed cases, median age at diagnosis and revision surgery was 56 years (interquartile range, 48 to 59 years; range, 33 to 75 years). Twelve patients presented with a seroma-associated type BIA-ALCL (T1N0M0), and five patients presented with a mass-associated type (T2 to T4), three of which had dissemination outside the breast.[21] Median time from implantation to lymphoma diagnosis was 9 years (interquartile range, 5.5 to 13.5 years; range, 1 to 18 years). In 12 patients, BIA-ALCL was the indication for revision surgery and registration in the DBIR; in two patients, BIA-ALCL was an incidental finding at implant revision. Of five women, the primary indication for breast implants was known ($n = 3$ aesthetic, $n = 2$ reconstructive). Seven patients presented with asymmetry and seroma; in the other patients, the symptoms were not registered. The reported capsular contracture grade varied between grade I and grade IV (according to the Baker classification), and all patients underwent a capsulectomy and removal of the implant. Characteristics of the explanted implants were incomplete in the DBIR data set before September of 2017, as this information has only been registered for explanted devices since its most recent update in September of 2017.

The Accuracy of the DBIR: False-Positive and False-Negative Registrations

As derived from the DBIR and PALGA registration logs, the false-positive registrations in the DBIR ($n = 10$) were entered based on a clinically suspected diagnosis of BIA-ALCL before histocytologic and/or cytopathologic assessment by the local and/or expert pathologist. However, once the negative pathology information became available, the registration was not corrected in the DBIR.

The current registration procedure also explains the missing DBIR registrations ($n = 3$), because novel lymphoma diagnoses were not updated in previously filed registrations at the time of surgery when lymphoma was not clinically suspected or realized. Even though the DBIR is an opt-out registry with mandatory registration for all board-certified plastic surgeons in The Netherlands since January 1, 2016, we cannot exclude that some institutions still fail to reach a complete registration rate. This was not the case for the three missed lymphoma patients, however.

DISCUSSION

In the present study, the adverse event registration of BIA-ALCL in the DBIR was validated using histopathologically confirmed BIA-ALCL cases from the national pathology registration database (i.e., PALGA). This showed the efficacy

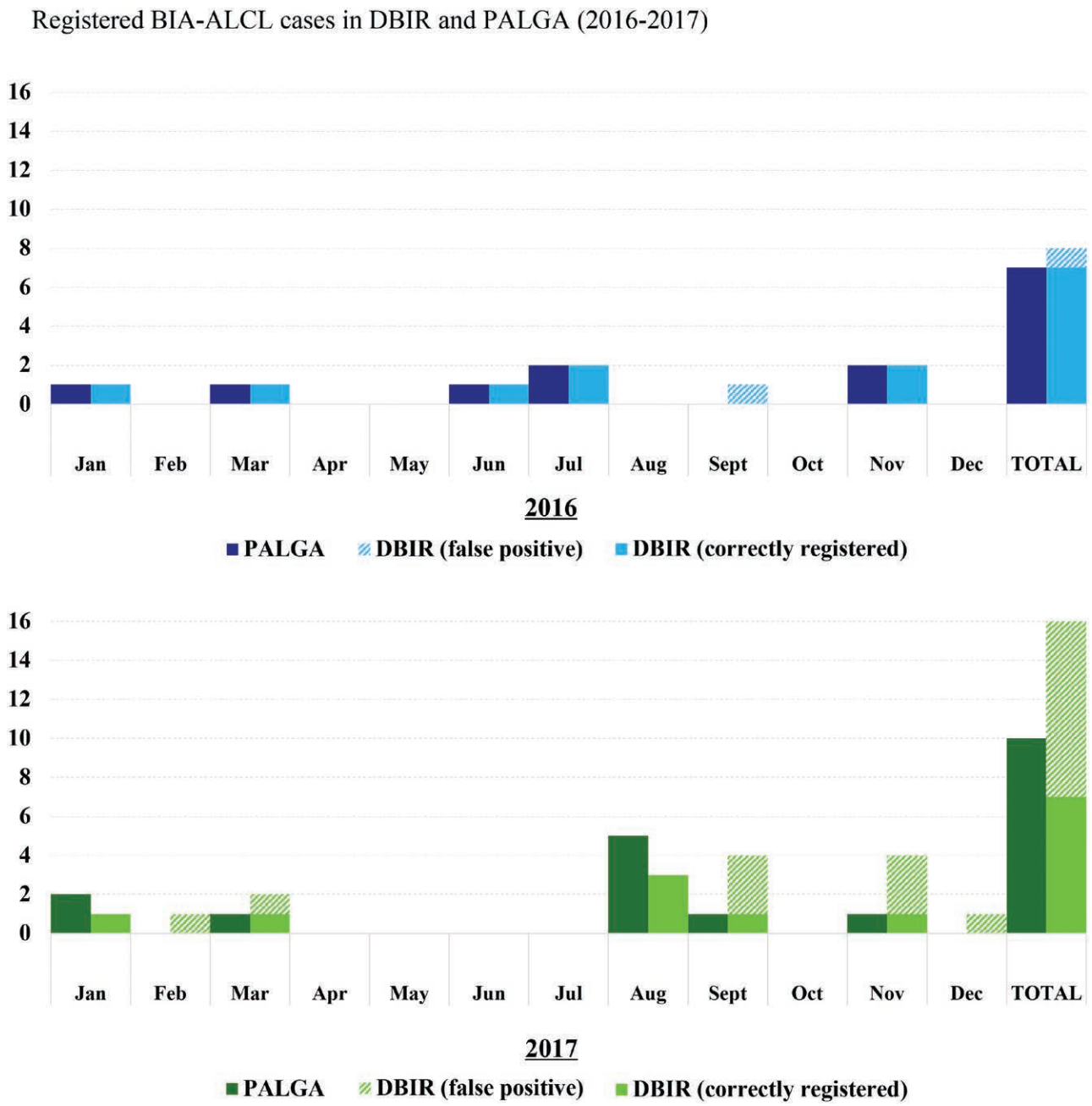

Fig. 1. Registered BIA-ALCL cases per year in the DBIR and the PALGA databases (2016 to 2017). The number of registered BIA-ALCL cases per month in 2016 and 2017 in the PALGA database (*dark green* and *dark blue*), and the corresponding registrations in the DBIR (*light green* and *light blue*). Registered cases in the DBIR without a histopathologic confirmation in the PALGA database were labeled false-positive (*hatched*).

of registration of BIA-ALCL in the DBIR to be 100 percent in 2016 and 70 percent in 2017, with a total of 10 patients reported as false-positive, underpinning the importance of histopathologic or cytopathologic confirmation. Furthermore, both databases could be matched, resulting in a larger data set with relevant variables for BIA-ALCL without the need for manual extraction of information from medical records. Data points included implant characteristics, surgery characteristics, and histopathologic information.[4,12,13,22–24]

Quality Control Strategies for Breast Implants in the DBIR Design

The DBIR has three purposes, all aiming to improve health care quality and patient safety. Besides the evaluation of health care provided, it contains data for recall purposes and determines

Table 1. Complementary Character of the DBIR and the PALGA Database with Histopathologic, Clinical, and Breast Implant Information per Case (2016–2017)

	PALGA	DBIR		
Case	Pathologic Report	Patient*	Surgery	Breast Implant (Explanted)*
1	Periprosthetic seroma, CD30+, ALK1− ALCL Mass-associated type TNM: T4N0M0	ASA classification: 2 Smoking: N/A BMI: N/A Previous RTx: N/A	Primary indication for breast implants: N/A Side and intervention: Left, explantation only Indication for revision: ALCL Additional findings: No Device rupture: No Silicone extravasation: No Capsular contracture: Grade II, capsulectomy	Type: Permanent breast implant Texture, coating, fill: N/A Manufacturer: N/A Year of implantation: N/A Country of implantation: The Netherlands
2	Periprosthetic seroma, CD30+, ALK1− ALCL Seroma-associated type TNM: T1N0M0	ASA classification: 2 Smoking: N/A BMI: N/A Previous RTx: N/A	Primary indication for breast implants: N/A Side and intervention: Left, explantation only Indication for revision: ALCL Additional findings: No Device rupture: No Silicone extravasation: No Capsular contracture: Grade IV, capsulectomy	Type: Permanent breast implant Texture, coating, fill: N/A Manufacturer: N/A Year of implantation: N/A Country of implantation: Abroad (country unknown)
3	Periprosthetic seroma, CD30+, ALK1− ALCL Mass-associated type TNM: T3N0M0	ASA classification: 2 Smoking: N/A BMI: N/A Previous RTx: N/A	Primary indication for breast implants: N/A Side and intervention: Left, replacement with new implant Indication for revision: Seroma and asymmetry Additional findings: ALCL Device rupture: No Silicone extravasation: No Capsular contracture: Grade I, capsulectomy	Type: Permanent breast implant Texture, coating, fill: N/A Manufacturer: Allergan Year of implantation: 2013 Country of implantation: The Netherlands NB: New implanted breast implant: Allergan, textured
4	Periprosthetic seroma, CD30+, ALK1− ALCL Seroma-associated type TNM: T1N0M0	ASA classification: 2 Smoking: N/A BMI: N/A Previous RTx: No	Primary indication for breast implants: Aesthetic Side and intervention: Right, explantation only Indication for revision: Seroma/hematoma Additional findings: ALCL Device rupture: No Silicone extravasation: No Capsular contracture: Grade I, capsulectomy	Type: Permanent breast implant Texture, coating, fill: N/A Manufacturer: Allergan Year of implantation: 2016 Country of implantation: The Netherlands
5	Periprosthetic seroma, CD30+, ALK1− ALCL Seroma-associated type TNM: T1N0M0	ASA classification: 2 Smoking: N/A BMI: N/A Previous RTx: N/A	Primary indication for breast implants: N/A Side and intervention: Bilateral, explantation only Indication for revision: ALCL Additional findings: Asymmetric device rupture: No Silicone extravasation: No Capsular contracture: Grade I, capsulectomy	Type: Permanent breast implant Texture, coating, fill: N/A Manufacturer: Laboratoires Sebbin Year of implantation: 2012 Country of implantation: Belgium
6	Periprosthetic seroma, CD30+, ALK1− ALCL Mass-associated type TNM: T4N1M0	ASA classification: 2 Smoking: N/A BMI: N/A Previous RTx: N/A	Primary indication for breast implants: N/A Side and intervention: Left, explantation only Indication for revision: ALCL Additional findings: No Device rupture: No Silicone extravasation: No Capsular contracture: Grade II, capsulectomy	Type: Permanent breast implant Texture, coating, fill: N/A Manufacturer: Allergan Year of implantation: 2009 Country of implantation: The Netherlands
7	Periprosthetic seroma and capsule, CD30+, ALK1− ALCL Mass-associated type TNM: T3N2M1	ASA classification: 3 Smoking: N/A BMI: N/A Previous RTx: N/A	Primary indication for breast implants: N/A Side and intervention: Bilateral, explantation only Indication for revision: ALCL Additional findings: Seroma, asymmetry, breast pain Device rupture: Yes Silicone extravasation: Yes, intracapsular Capsular contracture: Grade IV, capsulectomy	Type: Permanent breast implant Texture, coating, fill: N/A Manufacturer: Allergan Year of implantation: 2001 Country of implantation: The Netherlands

(*Continued*)

Table 1. ***Continued***

	PALGA	DBIR		
Case	**Pathologic Report**	**Patient***	**Surgery**	**Breast Implant (Explanted)***
8	Periprosthetic seroma, CD30$^+$, ALK1$^-$ ALCL Seroma-associated type TNM: T1N0M0	Missing in DBIR		
9	Periprosthetic seroma, CD30$^+$, ALK1$^-$ ALCL Seroma-associated type TNM: T1N0M0	ASA classification: 1 Smoking: N/A BMI: 29 kg/m^2 Previous RTx: No	Primary indication for breast implants: N/A Side and intervention: Left, explantation only Indication for revision: ALCL Additional findings: No Device rupture: N/A Silicone extravasation: N/A Capsular contracture: Grade II, capsulectomy	Type: N/A Texture, coating, fill: N/A Manufacturer: Allergan Year of implantation: 2007 Country of implantation: N/A
10	Periprosthetic seroma, CD30$^+$, ALK1$^-$ ALCL Seroma-associated type TNM: T1N0M0	ASA classification: 1 Smoking: N/A BMI: N/A Previous RTx: No	Primary indication for breast implants: Aesthetic Side and intervention: Left, explantation only Indication for revision: ALCL Additional findings: No Device rupture: No Silicone extravasation: No Capsular contracture: Grade IV, capsulectomy	Type: Permanent breast implant Texture, coating, fill: Textured, silicone Manufacturer: Allergan Year of implantation: 2008 Country of implantation: N/A
11	Periprosthetic seroma and capsule, CD30$^+$, ALK1$^-$ ALCL Mass-associated type TNM: T2N0M1	ASA classification: 3 Smoking: N/A BMI: 23 kg/m^2 Previous RTx: No	Primary indication for breast implants: Aesthetic Side and intervention: Bilateral, explantation only Indication for revision: ALCL and asymmetry Additional findings: No Device rupture: No Silicone extravasation: No Capsular contracture: Grade IV, capsulectomy	Type: Permanent breast implant Texture, coating, fill: N/A Manufacturer: N/A Year of implantation: 1999 Country of implantation: N/A
12	Periprosthetic seroma, CD30$^+$, ALK1$^-$ ALCL Seroma-associated type TNM: T1N0M0	Missing in DBIR		
13	Periprosthetic seroma and capsule, CD30$^+$, ALK1$^-$ ALCL Seroma-associated type TNM: T1N0M0	Missing in DBIR		
14	Periprosthetic seroma and capsule, CD30$^+$, ALK1$^-$ ALCL Seroma-associated type TNM: T1N0M0	ASA classification: 1 Smoking: N/A BMI: N/A Previous RTx: N/A	Primary indication for breast implants: N/A Side and intervention: Bilateral, explantation only Indication for revision: ALCL Additional findings: No Device rupture: No Silicone extravasation: No Capsular contracture: Grade N/A, capsulectomy	Type: Permanent breast implant Texture, coating, fill: N/A Manufacturer: Allergan Year of implantation: 2004 Country of implantation: N/A
15	Periprosthetic seroma and capsule, CD30$^+$, ALK1$^-$ ALCL Seroma-associated type TNM: T1N0M0	ASA classification: N/A Smoking: N/A BMI: N/A Previous RTx: No	Primary indication for breast implants: N/A Side and intervention: Bilateral, explantation only Indication for revision: ALCL Additional findings: No Device rupture: No Silicone extravasation: No Capsular contracture: Grade I, capsulectomy	Type: Permanent breast implant Texture, coating, fill: N/A Manufacturer: CUI Year of implantation: 2003 Country of implantation: N/A

(*Continued*)

Table 1. *Continued*

Case	PALGA	DBIR		
	Pathologic Report	**Patient***	**Surgery**	**Breast Implant (Explanted)***
16	Periprosthetic seroma and capsule, $CD30^+$, $ALK1^-$ ALCL Seroma-associated type TNM: T1N0M0	ASA classification: 1 Smoking: No BMI: 32 kg/m^2 Previous RTx: No	Primary indication for breast implants: Reconstructive Side and intervention: Bilateral, explantation only Indication for revision: ALCL and seroma Additional findings: No Device rupture: No Silicone extravasation: No Capsular contracture: N/A, capsulectomy	Type: Permanent breast implant Texture, coating, fill: Textured, silicone Manufacturer: Allergan Year of implantation: 2008 Country of implantation: The Netherlands
17	Periprosthetic seroma and capsule, $CD30^+$, $ALK1^-$ ALCL Seroma-associated type TNM: T1N0M0	ASA classification: 1 Smoking: No BMI: 26 kg/m^2 Previous RTx: No	Primary indication for breast implants: Reconstructive Side and intervention: Left, replacement Indication for revision: ALCL, seroma, and asymmetry Additional findings: No Device rupture: No Silicone extravasation: No Capsular contracture: Grade N/A, capsulectomy	Type: Permanent breast implant Texture, coating, fill: Textured, silicone Manufacturer: Allergan Year of implantation: 2009 Country of implantation: The Netherlands NB: New implanted breast implants: Allergan, smooth, silicone

ASA, American Society of Anesthesiologists; N/A, not available; TNM, tumor, node, metastasis; BMI, body mass index, RTx, radiotherapy; NB, nota bene (note well).
*Variables registered since September of 2017: BMI; smoking; and from the explanted devices' texture, coating, and fill.

the performance of all registered devices.[14] Because the quality and completeness of registered information depends on the accuracy of the registry and its users, control mechanisms are recommended.[25] To achieve maximal capture rates and improve data completeness, the DBIR uses an opt-out structure, and is "Registration in the Dutch Breast Implant Registry," a mandatory quality indicator for the Dutch National Health Care Inspectorate since January of 2016. A structure of mandatory input in all registration fields guarantees data completeness.

Besides quality control of submitted data, external validation of the registrations is at least as essential. Although no gold standard is known, several methods have been described, such as comparisons with locally held data, comparisons with other registries, or monitoring by dedicated personnel.[26–28] In the DBIR, all registered implants used for implantation surgery have been compared with a selection of sales data from breast implant vendors in The Netherlands, resulting in an estimated capture rate of 75 percent in its first registration year (data not shown). However, validation of the capture rate of implants that are removed during revision surgery is more difficult, as validation tools with complete, reliable coverage for these operations are unavailable. Therefore, it was valuable to use the PALGA database, which has nationwide coverage, as an external validation tool for this particular group.

Complementarity of Databases

Matching pathologic data from the PALGA database with clinical and implant data from the DBIR proved the complementarity of both databases. Eventually, this could serve as a basic system, substituting for the manual collection of case-based information and minimizing the burden of double registration. Because the DBIR is a clinical audit, additional information such as body mass index, a history of smoking or previous radiotherapy of the breast, previous and subsequent implant operations, and additional findings at revision surgery is automatically asked for. Extensive information on other clinical history and (oncologic) follow-up, however, is not (yet) registered and needs to be extracted from medical records when necessary.

Optimizing the Quality of BIA-ALCL Diagnoses in the DBIR

This study has allowed us to identify various aspects of DBIR registration that will help to

improve the quality of the database in the next registry update. Most importantly, 10 patients with a false-positive registration for BIA-ALCL were found and in three registered patients, the BIA-ALCL listings were missing and were considered false-negative. All misclassifications were caused by registrations based on clinical data at the time of surgery without manual correction after pathology reports were received. First, this underpins the importance of including cases with pathologically confirmed diagnoses in institutional and international/national databases in general. For the DBIR in particular, we plan to include two registration fields for diagnosis: "BIA-ALCL pathologically confirmed" and "suspicion of BIA-ALCL, not pathologically confirmed." All patients without a definite diagnosis will be automatically tagged and the reporting physician will receive an alert to update the registration based on a final pathologic diagnosis within 1 month after surgery. This procedure is currently being tested. To avoid false-negative registrations, all BIA-ALCL patients registered in the PALGA database will be matched to the DBIR periodically.

Limitations

A limitation is the fact that a minimum period of 3 years is indicated for a properly functioning clinical audit with reliable data.[14] With 2 full registration years, the DBIR is still relatively young, and data completeness needs to improve. Increasing compliance, data validation, and awareness among plastic surgeons is continuously needed to ensure high-quality and completely registered data in the future.

Future Perspectives

The results from this study imply that breast implant registries can be used as an objective, national medical device evaluation system, without financial disclosures, to function as postmarketing surveillance systems, once the collected data have been validated.[29] Longitudinal long-term data collections in regular medical device postapproval studies often do not have a sufficient sample size to detect rare diseases such as BIA-ALCL, do not follow participants for a sufficient length of time, and are not equipped to identify influencing factors for the development or prevention of BIA-ALCL. Although matching the DBIR to the PALGA was executed manually for this study, a real-time patient-based matching process is ideally desired. For that, however, solid data validity and more advanced information and communication technology structures are required. A trusted third party may assist in this, but proven reliable search queries and key variables are essential when realizing an automatic matching process. Eventually, the concept of such a combined data set, either manually or automatically, might even be implemented internationally. However, different privacy laws could become an obstacle, requiring attention beforehand.

CONCLUSIONS

This study supports the potential of breast implant registries to identify serious adverse events, using BIA-ALCL as an example. Despite its short existence and still growing compliance, the DBIR proved to be effective as a registration system for BIA-ALCL. It showed a 100 percent match in its first registration year, and a 70 percent match in its second full registration year, as validated by the PALGA, albeit at the cost of false-positive registrations, emphasizing the importance of histopathologic confirmation of the diagnosis. By matching databases with patient-related, tissue-related, and implant-related information, reliable complementary data could be retrieved. In the future, a mature DBIR could provide complementary data that can be used for surveillance, monitoring, and to further study severe adverse events such as BIA-ALCL.

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