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NATIONAL BREAST IMPLANT REGISTRY IN ITALY. COMPETENT AUTHORITY PERSPECTIVE TO IMPROVE PATIENTS' SAFETY

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Summary

Background. Despite breast implants have been putting on the market for over 70 years, responsible Competent Authorities on medical devices are requiring the establishment of breast implant registries to improve vigilance and post-market surveillance activities. Although data collected during the pilot phase are not yet representative of breast implant surgery performed in Italy, the authors would share their preliminary results to show the potential that the registry will have in the next future to improve knowledge of the use of breast implants. Moreover, based on the experience gained in more than two years, the authors would describe their perspective on how a national breast implant registry should be structured to effectively monitor implanted patients and the devices' performance over time.

Material and methods. In Italy, the national breast implant registry's pilot phase started on 25th March 2019 and stopped on 31st August 2021. Data related to breast implant surgery were voluntary registered on an IT platform. For each surgery were collected data related to the surgeon, health care facility, patient, procedure and the implanted or removed device. Official breast implant distributors uploaded their respective breast implant catalogs to the IT platform in order to facilitate surgeon data entry. Continuous variables were reported as means with standard deviations (SD) and categorical variables as frequencies and percentages. Implant lifetime was calculated in patients treated for revision surgery as the time between last implantation surgery and time of implant replacement or removal.

Results. In the reference period, 134 surgeons recorded their activities related to 7.734 procedures performed on 4.978 patients. Data analysis returned interesting information that characterized two different population of patients submitted to reconstructive and aesthetic surgery, showing crucial emerging issues. Regarding the implant lifetime, analysis of data showed a critical difference between devices implanted for reconstructive and aesthetic purposes, 6.8 years *versus* 11.2 years, respectively. Although we need an extended period to collect more consistent data, the experience gained through the Italian registry's pilot phase was valuable and led us to share our perspectives and principles that a breast implant registry should follow to be effective and well-structured.

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Conclusions. The pilot phase showed effectiveness in providing high-quality data thanks to the principles that drove its building. The pilot phase granted us further expertise and identified aspects that must be analyzed thoroughly. We rely on the immediate applicability of the registry's mandatory requirement to achieve a complete and effective tool that improves patients' safety and quality of our healthcare system.

Key words: breast implant registry, breast implant, breast surgery, breast device, breast reconstruction, breast augmentation, implant reconstruction

BACKGROUND

Breast implants are the most used devices in breast surgery as they can improve hypo-trophic/hypoplastic glandular tissue volume or restore shape and size to breasts affected by congenital or iatrogenic defects.
Breast augmentation represents about 16% of all aesthetic surgical procedures, with more than 1,600.000 operations worldwide in 2020 [1]. Moreover, prostheses are used in 80% of all breast reconstruction procedures [2-4].
Despite these devices have been putting on the market for over 70 years, responsible Competent Authorities on medical devices require the establishment of breast implant registries, to improve vigilance and post-market surveillance activities.
To date, many registries are recognized worldwide; some of them are collecting high-quality data, while others stopped their activity after the initial enthusiasm. Currently, few registries reach the completeness level needed to ensure the high scientific value of the collected data.
Looking at the breast implant registries that have already gathered experience in this field, thanks to the cooperation of the Italian National Institute of Health, the Italian scientific associations, and the International Collaboration of Breast Registry Activities (ICOBRA), the Italian Ministry of Health has built its national breast implant registry.
Although data collected during the pilot phase are not yet representative of the breast implant surgery performed in Italy, the authors would share their results to show the potential that this registry will have in the next future to improve knowledge of the use of breast implants. Moreover, based on the experience gained in more than two years, the authors would describe their perspective on how a national breast implant registry should be structured to effectively monitor implanted patients and the devices' performance over time.

MATERIAL AND METHODS

The national breast implant registry's pilot phase started on 25th March 2019 and stopped on 31st August 2021.
Data related to breast implant surgery performed in Italy in the reference period were collected on an IT platform. The surgeons had voluntary access to the registry, declaring personal information according to Table I. The patients were enrolled by an OPT-IN method: surgeons only enter data after retrieving the patients' active permission. The system electronically collected data with inbuild validation rules and mandatory fields to facilitate the data entry quality.
For each recorded procedure, the IT platform required information related to the patient, surgery, and implanted or removed device according to Table I. Revision surgeries are referred to all implant revisions performed during the pilot period independently on the time of the primary surgery. For each implanted device were collected serial and batch numbers, ref. code, volume, shape, filling, and surface characteristics according to the ISO 14607 [5]. Official breast implant distributors signed up to the registry and uploaded their respective breast implant catalogs to the IT platform.
Data completeness has been evaluated according to the presence of data for all requested fields.

STATISTICAL METHOD

Continuous variables were reported as means with standard deviations (SD) and categorical variables as frequencies and percentages. Implant lifetime was calculated in patients treated for revision surgery, with both aesthetic and reconstructive purposes, as the time between the last implantation surgery and the time of implant replacement or removal.

RESULTS

Between the 25th March 2019 and the 31st August 2021, 134 surgeons recorded their activities: 102 of them (76.1%) were plastic surgeons, 31 (23%) were breast surgeons, and 1 (0.74%) was a thoracic surgeon. Surgeries were performed in 63 (50%) HCFs funded by the national public health care system, in 50 (39.7%) private HCFs, and in 13 (10.3%) facilities supported by a mixed remuneration.

Table I. Data collected by the IT platform.

Surgeon's data
Name and surname
License for surgical practice
Healthcare facility
Name
Address
Phone and e-mail
Patient's data
Gender
Age
Smoke
Ipertension
Diabetes
Coagulation disorder
Food/drugs allergy
Autoimmune disorder
Breast cancer history
BRCA1 BRCA2 mutations
Chemotherapy
Radiotherapy
Surgical procedure's data
Date of the surgery
Side of surgery (right, left or bilateral)
Surgery purpose (aesthetic or reconstructive)
Timing of surgery (primary or revision)
Diagnosis
Surgical procedure details
Incision site
Previous tissue expander
Axillary dissection
Capsulectomy
Simultaneous flap harvesting
Simultaneous fat graft transplantation
Simultaneous implantation of other medical devices
Date of previous breast prosthesis implantation
"Good Practice" Procedures
Surgical pocket treatment
Gloves change
Breast implant treatment before implantation
Drains

Table II. Data collected by the Italian National Registry of Breast Implant up to 31st of August 2021.

Health care facilities	126
Surgeons	134
Surgery	5.003
Patients	4.978
Surgical procedures	7.734
Implanted breast prostheses	7.456
Explanted breast prostheses	1.966
Breast implants uploaded by Italian distributors	85.951

The registry collected 7,734 procedures performed on 4.978 patients (Tab. II).
Procedures had reconstructive purposes in 61.5% of the cases and aesthetic in 38.5%.

Breast implant surgery for reconstructive purposes

The mean age of patients submitted to primary implantation was 51.1 years, and 54.8 years for those treated for revision surgery. Clinical history was negative in 13.8% of the patients. Table III shows the patients' clinical history. Procedures were unilateral in 55.8% of the cases.
In 80.9% of primary procedures, a breast implant was placed following a breast cancer diagnosis; in 13.5% after prophylactic mastectomies; in 5.6% of the cases to treat congenital breast deformities. The device was implanted immediately in 70.2% and 84.4% of the cases after therapeutic mastectomies and prophylactic, respectively; while as a second stage procedure, after tissue expander positioning in 29.8% and 15.6% for therapeutic mastectomies and prophylactic, respectively (Tab IV).
A breast implant was placed after a nipple-sparing mastectomy (NSM) for oncological purposes in 64.2% and after a prophylactic treatment in 86.6% of the cases (Tab. V). Flap harvesting and/or fat transplantation were performed simultaneously with the device implantation in 1.178 (31.8%) procedures. Flap harvesting was the most common combined procedure performed: 28.2% of the cases after a therapeutic mastectomy, 26.9% after a prophylactic mastectomy, and 15.9% after congenital breast deformities (Tab. VI).
Biological or synthetic meshes to support implants were used in 20.9% of the cases.
Capsular contracture (33.3%) and implant rupture (17.2%) were the most common reason for implant replacement or removal. Revision surgery not directly linked to device complications was performed in 21.6% of the cases (Fig. 1). The previous scar was used as surgical access in 88.6% of the cases.
Surgeons used antibiotics and/or antiseptic solutions to irrigate implant pockets and prostheses in 87.4% and 95.5% of the procedures, respectively. Gloves change was performed in 88.0% of the procedures before implant replacement. Surgical drains were used in 97.4% of the procedures.
The mean lifetime of the implant used for reconstructive purposes was 6.8 years.

Breast implant surgery for aesthetic purposes

The mean age of patients undergoing primary and revision surgeries was 36.4 and 47.9 years, respectively.

Table III. Reconstructive patient's characteristics.

	Primary	Revision	Total
	N = 2868	N = 823	N = 3691
Gender, N (%):			
Female	2862 (99.8%)	820 (99,6%)	3682 (99.8%)
Male	6 (0.2%)	3 (0,36%)	9 (0.2%)
Age, mean (SD)	51.1 (11.0)	54,8 (10,1)	52.0 (10.9)
Smoke, N (%):			
No	2645 (92.2%)	727 (88,3%)	3372 (91.4%)
Yes	223 (7.8%)	96 (11,7%)	319 (8.6%)
Ipertension, N (%):			
No	2650 (92.4%)	734 (89,2%)	3384 (91.7%)
Yes	218 (7.6%)	89 (10,8%)	307 (8.3%)
Diabetes, N (%):			
No	2822 (98.4%)	807 (98,1%)	3629 (98.3%)
Yes	46 (1.6%)	16 (1,9%)	62 (1.7%)
Coagulation disorder, N (%):			
No	2828 (98.6%)	815 (99,0%)	3643 (98.7%)
Yes	40 (1.4%)	8 (1,0%)	48 (1.3%)
Food/drugs allergy, N (%):			
No	2663 (92.9%)	746 (90,6%)	3409 (92.4%)
Yes	205 (7.1%)	77 (9,4%)	282 (7.6%)
Autoimmune disorder, N (%):			
No	2785 (97.1%)	793 (96,4%)	3578 (96.9%)
Yes	83 (2.9%)	30 (3,6%)	113 (3.1%)
Breast cancer history, N (%):			
No	2472 (86.2%)	754 (91,6%)	3226 (87.4%)
Yes	396 (13.8%)	69 (8,4%)	465 (12.6%)
BRCA1 - BRCA2 mutations, N (%):			
No	2595 (90.5%)	766 (93,1%)	3361 (91.1%)
Yes	273 (9.5%)	57 (6,9%)	330 (8.9%)
Chemotherapy, N (%):			
No	2099 (73.2%)	509 (61,8%)	2608 (70,7%)
Yes	769 (26.8%)	314 (38,2%)	1083 (29,3%)
Radiotherapy, N (%):			
No	2412 (84.1%)	617 (75.0%)	3029 (82,1%)
Yes	456 (15.9%)	206 (25,0%)	662 (17.9%)

Table IV. Tissue expander use in primary procedures of reconstructive patients.

	Tissue Expander		Total
	No	Yes	
Breast cancer	2103 (70.2%)	893 (29.8%)	2996
Cancer risk reduction	421 (84.4%)	78 (15.6%)	499
Breast deformities	207 (99.5%)	1 (0.5%)	208
Trauma	1 (100.0%)	0 (0.0%)	1
Total	**2.624**	**972**	**3704**

Clinical history was negative in 78.3% of the patients. Table VII shows patients' clinical history. Surgery was bilateral in 97.3% of procedures. The indications for breast implant surgery were breast hypoplasia/hypotrophy in 77.1%, and breast ptosis in 22.9%. The implant was placed under the pectoralis major muscle in 72.3% of the procedures, in a retromammary location in 22.6%, and in a subfascial plane in 5.0%. Table VIII

Table V. Primary implantation according to diagnosis in reconstructive patients.

Diagnosis	Surgical procedure performed	N	%
Breast cancer	Immediate implantation after NSM	1923	64.2%
	Immediate implantation after SSM	519	17.3%
	Immediate implantation after segmental mastectomy	5	0.2%
	Immediate implantation after radical mastectomy	68	2.3%
	Delayed implantation	481	16.1%
		2996	
Cancer risk reduction	Immediate implantation after NSM	432	86.6%
	Immediate implantation after SSM	55	11.0%
	Immediate implantation after radical mastectomy	12	2.4%
		499	
Breast deformities	Sub-glandular implantation	72	34.6%
	Sub-fascial implantation	11	5.3%
	Sub-pectoral implantation	51	24.5%
	Dual plane implantation	74	35.6%
		208	
Trauma	Sub-pectoral implantation	1	100%
		1	

Table VI. Primary implantation and simultaneous adjunctive procedures in reconstructive patients.

	Implant only	Implant + local flap	Implant + fat graft transplantation	Implant + combined local flap and fat graft transplantation	Total
	N	N	N	N	
Breast cancer	2014 (67.2%)	844 (28.2%)	81 (2.7%)	57 (1.9%)	2996
Cancer risk reduction	352 (70.5%)	134 (26.9%)	9 (1.8%)	4 (0.8%)	499
Breast deformities	159 (76.4%)	33 (15.9%)	12 (5.8%)	4 (1.9%)	208
Trauma	1 (100.0%)	-	-	-	1
Total	**2.526**	**1.011**	**102**	**65**	**3.704**

shows implant location according to diagnosis. Simultaneous fat grafting was performed in 6.6, 3.9, and 3.7% when the implant was placed in the retromammary, retrofascial and retromuscular locations, respectively. The inframammary fold was the preferred surgical access in 53.3% of procedures (Fig. 2). Figure 3 shows the surgical access used according to the implant plane.

The most frequent indication of revision surgery was not related to the device (36.0% of the cases); pericapsular contracture and implant rupture were diagnosed in 32.1%and 22.9%, respectively (Fig. 4). In 5.5% of the procedures, the prosthesis was removed, and flap harvesting and fat grafting were performed in 28% and 4%, respectively. Antibiotics and/or antiseptic solutions to irrigate implant pocket and implant were used respectively in 84.7% and 95.0% of procedures. Glove change before handling implants was performed in 99.5% of the procedures. Drains were used in 77.3% of the procedures to reduce the risk of hematoma.

The mean lifetime of the implant used for aesthetic purposes was 11.2 years

Characteristics of the implanted devices according to ISO 14607

Surface

The implant had a textured surface in 60.7% of the cases, 24.5% were in polyurethane, and 14.8% were smooth. The devices used for reconstructive purposes had a microtextured surface in 64.1% of the cases, polyurethane in 29.4%, smooth in 4.9%, and macrotextured in 1.6%. Implants used for aesthetic procedures were microtextured in 37.2% of the cases, smooth in 31.2%, polyurethane in 16.3%, and macrotextured in 15.3% of the cases (Tab. IX).

Shape. In 74.2% of procedures, the implants were anatomically shaped, and 25.8% were round. In reconstructive procedures, implants were anatomical in 92.0% and round in 8.0%; in aesthetic surgery, the device was round in 44.7% and anatomical in 55.3% of procedures.

Filling. Implants were silicone-filled in 99.5% of the cases.

Volume

Implants were medium-sized (300-550 cc) in 59.2% of the cases, small-sized (< 300 cc) in 35.6%, and large-sized (555-800 cc) in 5.2%. The device's mean volume used for reconstructive purposes was 367 cc, while for aesthetic purposes was 312 cc.

Data completeness

The completeness level for each requested data ranged from 95.2 to 100%. A lower level of completeness has been observed for those non-mandatory fields (24.5-57.7%) only admitted for the removed implants' information.

DISCUSSION

Breast implants faced serious safety and conformities problems in the last ten years. Poly Implant Prostheses (PIP) and Silimed devices were found against the essential requirements of breast implant safeness established by the European Regulation [6]. Moreover, the recent discussions on the etiopathogenesis of the Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) [7] added further concerns on the safety of these devices.

To date, although considered safe to be placed on the market, like any implantable device, breast implants need to be strictly monitored over time.

Table VII. Clinical history of aesthetic patients.

	Primary	Revision	Total
	N = 840	**N = 447**	**N = 1287**
Gender, N (%):			
Female	839 (99.9%)	444 (99.3%)	1283 (99.7%)
Male	1 (0.12%)	3 (0.7%)	4 (0.3%)
Age, mean (SD)	36.4 (9.54)	47.9 (11.0)	40.4 (11.5)
Smoke, N (%):			
No	736 (87.6%)	399 (89.3%)	1135 (88.2%)
Yes	104 (12.4%)	48 (10.7%)	152 (11.8%)
Ipertension, N (%):			
No	834 (99.3%)	430 (96.2%)	1264 (98.2%)
Yes	6 (0.7%)	17 (3.8%)	23 (1.79%)
Diabetes, N (%):			
No	839 (99.9%)	446 (99.8%)	1285 (99.8%)
Yes	1 (0.12%)	1 (0.2%)	2 (0.2%)
Coagulation disorder, N (%):			
No	828 (98.6%)	436 (97.5%)	1264 (98.2%)
Yes	12 (1.43%)	11 (2.5%)	23 (1.8%)
Food/drugs allergy, N (%):			
No	802 (95.5%)	428 (95.7%)	1230 (95.6%)
Yes	38 (4.52%)	19 (4.3%)	57 (4.4%)
Autoimmune disorder, N (%):			
No	834 (99.3%)	430 (96.2%)	1264 (98.2%)
Yes	6 (0.7%)	17 (3.8%)	23 (1.8%)
Breast cancer history, N (%):			
No	825 (98.2%)	440 (98.4%)	1265 (98.3%)
Yes	15 (1.8%)	7 (1.6%)	22 (1.7%)
BRCA1 BRCA2 mutations, N (%):			
No	840 (100%)	447 (100%)	1287 (100%)
Yes	0	0	0
Chemotherapy, N (%):			
No	840 (100%)	447 (100%)	1287 (100%)
Yes	0	0	0
Radiotherapy, N (%):			
No	840 (100%)	447 (100%)	1287 (100%)
Yes	0	0	0

Table VIII. Primary procedures by diagnosis in aesthetic patients.

Diagnosis	Implant location	N	%
Hypoplasia/hypotrophy breast	Dual plane	707	44.5%
	Sub-fascial	83	5.2%
	Sub-glandular	349	21.9%
	Sub-pectoral	452	28.4%
		1591	
Ptotic breast	Dual plane	157	33.2%
	Sub-fascial	21	4.5%
	Sub-glandular	118	24.9%
	Sub-pectoral	177	37.4%
		473	

The critical role of device implant registries has been widely recognized from a public health perspective [8-10] since they represent the most effective tools for monitoring implanted patients. Indeed, registries allow for evaluating the long-term results of the implanted devices in terms of effectiveness and performance and identifying the implanted patients, if necessary. Registries might provide an early warning system for identifying risks, shortening the time before health hazards can be widely perceived. They should be tools for collecting data to correlate long-term results of this type of surgery with details of the surgical procedure and patients' clinical history. Registries can improve the quality of medical and surgical treatments, as device failure can be rapidly detected and potentially dangerous implants averted [11]. Such registries can also provide data to test epidemiological and biomedical hypotheses and avoid useless and costly surgical procedures for national health services [12].

Data collected during the pilot phase does not yet represent breast implant surgery performed in Italy,

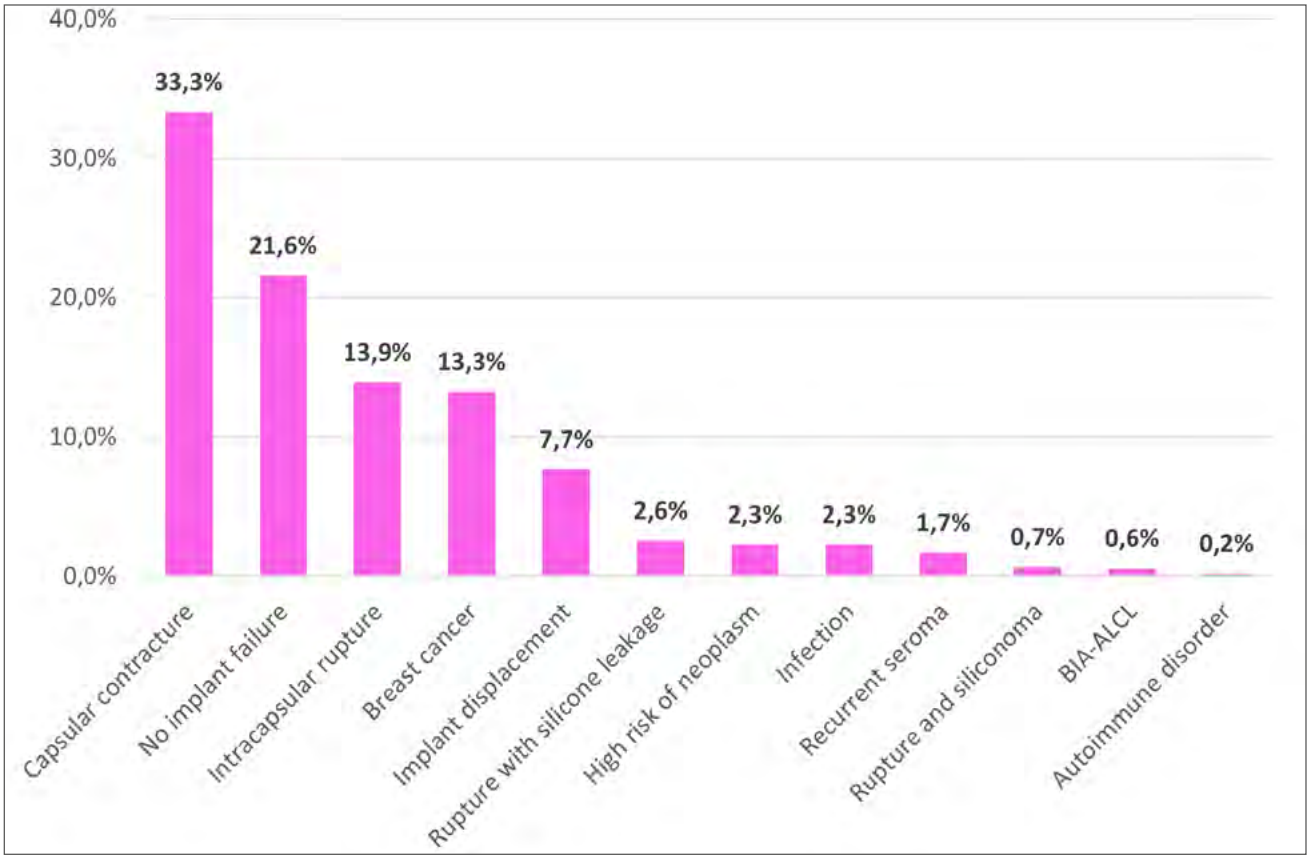

Figure 1. Indications to revision surgery in reconstructive procedures.

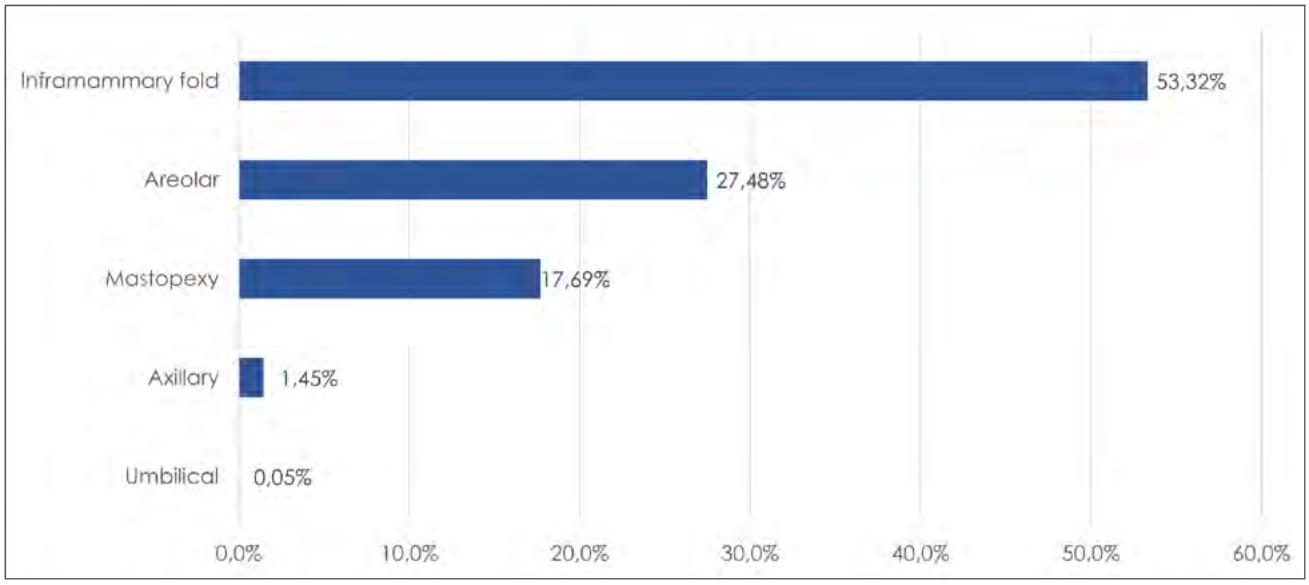

Figure 2. Surgical access for device implantation.

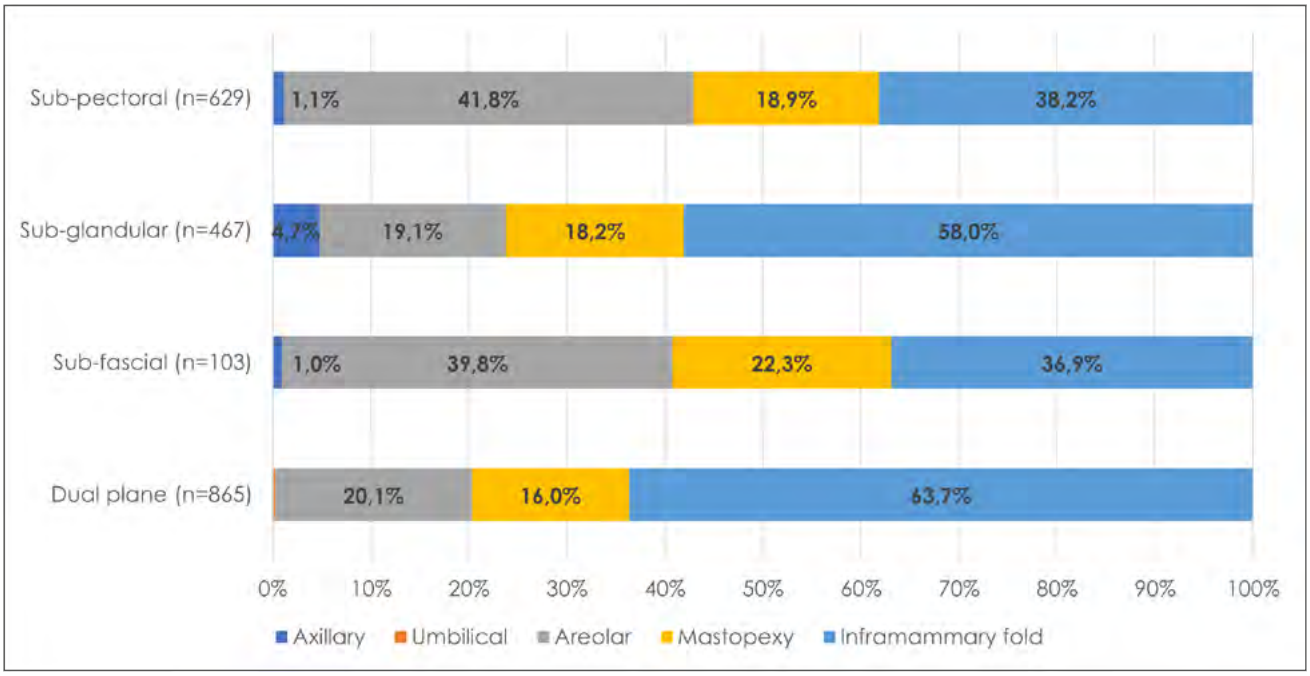

Figure 3. Surgical access according to implant plane.

as the surgeon's goodwill affects it and still causes a low registry coverage. Moreover, due to the registry's short lifetime, we are still unable to evaluate the devices' performance. However, according to the "minimum data set" internationally required, our data can be easily compared with those collected by other active registries worldwide. They show the potential to improve knowledge in the breast implant field. In addition, our results show crucial emerging issues such as the mean implant lifetime that must be analyzed over time. Indeed, although we are still unable to evaluate the devices' performance, we noted a critical lifetime difference between implants placed for reconstructive purposes and aesthetic ones: 6.8 years *versus* 11.2 years, respectively.

From the data analysis, it emerges that preoperative chemotherapy and radiotherapy negatively influence the lifetime of the implant. Appropriately, the average

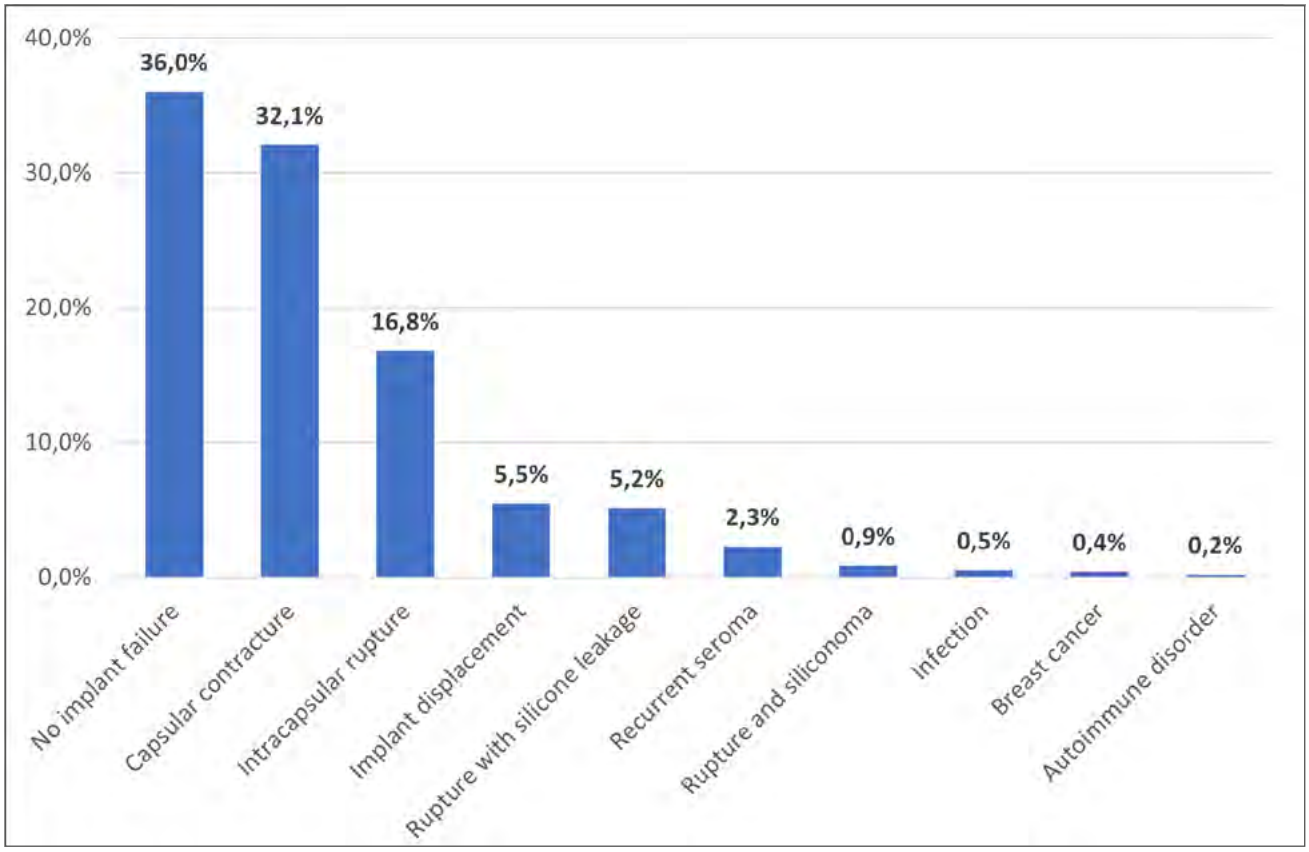

Figure 4. Indications to revision surgery in aesthetic procedures.

implant lifetime is 6.2, 5.4, and 5.1 years in case of previous chemotherapy, previous radiotherapy, and previous combined chemo and radiotherapy, respectively. These findings underly the necessity to pair different oncological scenarios to appropriate reconstructive indications. Type of cancer, treatment, age, and patient's clinical status should be evaluated to select the best reconstructive option. Moreover, a patient treated with previous adjuvant therapies should be fully aware that opting for an implant-based reconstruction might take her back to surgery for implant replacement or removal a few years later. This consideration is still more important for younger patients that could be exposed to multiple surgical procedures of implant surgery in their life. Therefore, as breast implants cannot be considered lifetime devices, it is essential to know which variables can influence their lifetime to guide the surgeon and the healthcare system to the correct choices that preserve patients' health. Although we would need an extended period to collect more consistent data, the experience gained through the Italian registry's pilot phase was valuable. Nevertheless, we like to share perspectives and principles that a breast implant registry should follow to be effective and well-structured.

Type of data to be collected

Data for each surgical procedure should be limited to the essential information requested to assess breast implant surgery outcomes accurately. Moreover, the registry should collect a "minimum data set" [13] to be comparable with other registries established for the same device. All clinical information, and data regarding the procedure's details, that can affect short or long-term results of this kind of surgery should be collected. Manufacturer, surface characteristics, filling, and shape of the implanted device must be recorded to monitor patients implanted with a specific device and allow breast prostheses performance and traceability.
In the case of implantable device registries, the current European Regulation establishes that personal data must be provided to recall a patient in case of an adverse event [14]. Consequently, the Italian breast implant registry fixed the data set to be collected under this Regulation.

Mandatory to be filled in

Breast implant registries are recognized as essential tools to improve implanted patients' health safety. Consequently, their feeding should not be left to the

surgeons' goodwill, and patients should be mandatorily registered. The OPT-OUT method, i.e., all patients are included unless they do not actively opt-out, results in higher inclusion rates than the OPT-IN option [15]. However, patients should be made aware of the necessity to include their breast surgery data in the registry and assured that all the security measures (according to EU General Data Protection Regulation) are satisfied.

To date, breast implant surgeries' coverage of the existing registries worldwide is heterogeneous. It is affected by different cultures and national regulations. The Dutch Breast Implant Registry (DBIR), which catches 97% of the health care institutions eligible for breast implant surgery, has achieved the highest coverage rates; in the Netherlands, only board-certified plastic surgeons can perform breast implant surgery [16]. The Australian Breast Device Registry (ABDR) captures around 80% of device surgeries [17] and about 88% of the eligible surgeons [18]. In 2017, the total level of coverage of the Swedish Breast Implant registry (BRIMP) was approximately 65% [19]; in 2020, the registry reports the activities of 85% of the plastic surgeons in private practice and the registration of 65% of all implants sold in Sweden, according to the reliable industry sales data [20]. The Breast and Cosmetic Implant Registry (BCIR) of England and Scotland has a case ascertainment of approximately 55% [21].

According to the 2019 American Society of Plastic Surgeons (ASPS) Procedural Statistical Report [22], over 400,000 breast implant procedures are performed annually in the USA, but only 17,015 cases were entered between 2018 and 2020 [23].

We strongly believe that all the information requested for each surgical procedure should be provided by the surgeons mandatorily. The registry collects only essential data to assess this type of surgical procedure. Therefore, all the information requested by the IT platform should be provided. The results of our study show the highest level of completeness achieved when the surgeon has been obliged to provide data to finalize the registration. Collection of data only voluntarily has a lower completeness rate.

Managed and supported by an independent Institution

Registries shall contribute to the independent evaluation of devices' long-term safety and performance[6]. The Italian breast implant registry is funded and supported by the Ministry of Health, the Competent Authority on medical devices, constantly working to protect health care safety through vigilance and post-market surveillance activities.

Linked with the manufacturer catalogues

Registry data access should be guaranteed to the manufacturers of breast implants to guarantee high-quality data regarding the characteristics of implanted or removed breast devices. They should upload all data related to every device addressed to be implanted, such as serial number, batch number, and reference code. All the information about the surface, filling, and shape linked to the device's reference code according to European International Organization for Standardization (ISO) 14607 should be uploaded to the registry to facilitate traceability and epidemiological and research studies. Moreover, it could reduce surgeons' data entry as by providing just the serial device number, the IT system can automatically identify and self-populate the additional device's details. A further data entry improvement could be reached using a barcode scanner to minimize potential errors during the serial number data entry.

CONCLUSIONS

Breast implant registries are essential for monitoring patients' health and long-term device safety, performance, and traceability. European Regulators are encouraging the establishment of such registries. Due to the short time since its establishment and the low coverage of breast implant surgery in our country, the Italian national registry cannot still return representative data or guarantee patient and device traceability. However, the pilot phase showed effectiveness in providing high-quality data thanks to the principles that drove its building. The pilot phase granted us further expertise and identified aspects that must be analyzed thoroughly. We rely on the immediate applicability of the registry mandatory requirement to achieve a complete and effective tool that improves patients' safety and the quality of the health care provided.

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None.

Conflict of interest statement

We, hereby certify, that to the best of our knowledge no financial support or benefits have been received by author or any co-author, by any member of our immediate family or any individual or entity with whom or with which we have a significant relationship from any commercial source which is related directly or indirectly to the scientific work which is reported on in the article. None of the authors has a financial interest in any of the products, devices, or drugs mentioned in this manuscript.

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Authors' contributions

Antonella Campanale: A, D, DT, W
Marco Ventimiglia: D, DT, S
Daniela Minella: W
Letizia Sampaolo: DT
Achille Iachino: A
Lucia Lispi: DT

Abbreviations

A: conceived and designed the analysis
D: collected the data
DT: contributed data or analysis tool
S: performed the analysis
W: wrote the paper
O: other contribution (specify contribution in more detail)

Ethical consideration

The research was conducted ethically, with all study procedures being performed in accordance with the requirements of the World Medical Association's Declaration of Helsinki.
Written informed consent was obtained from each participant/patient for study participation.

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