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Breast Implant-associated Squamous Cell Carcinoma: Initial Review and Early Recommendations

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Background: The purpose of this study is to identify and describe all published cases of breast implant-associated squamous cell carcinoma (BIA-SCC) to gain a greater understanding of the incidence, presentation, diagnosis, treatment, and prognosis and to support development of recommendations that promote prompt diagnosis and management in clinical practice.
Methods: A scoping review of PubMed and social media sites was performed in August and September 2022 to identify published cases of SCC arising in the breast capsule. No limits were set on search results. Additional data review was begun on deidentified cases reported directly to American Society of Plastic Surgeons.
Results: Twelve articles met inclusion criteria and reported data on 16 total cases. Mean age of patients was 55.56 years (range, 40–81 years). Mean duration from initial implant placement to presentation was 23.56 years (range, 11–40 years). Cases occurred with silicone, saline, textured, and smooth implants. At the time of case publication or reporting, seven patients were alive, five were deceased and/or presumed deceased, and four were unreported.
Conclusions: BIA-SCC seems to be a rare complication of breast implantation that can result in significant morbidity and mortality. Physicians should be aware of the presentation of BIA-SCC to promote prompt diagnosis and treatment. BIA-SCC should be discussed with all patients considering breast implantation as part of the informed-consent process. *(Plast Reconstr Surg Glob Open 2023; 11:e5072; doi: 10.1097/GOX.0000000000005072; Published online 14 June 2023.)*

INTRODUCTION

Placement of breast implants is considered a safe and effective procedure for augmenting and reconstructing breasts. The majority of women with breast implants experience no serious complications; however, there are risks associated with breast implants, including infection, skin flap necrosis, capsular contracture, and implant failure that can occur and result in implant removal.[1] Breast implants have not been linked with an increased risk of primary breast cancer,[2,3] but rare cancers emanating from the breast implant capsule have emerged in the literature. Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is a T-cell lymphoma first reported in 1997 and subsequently confirmed as a rare risk associated with textured breast implants by the US Food and Drug Administration (FDA) in 2011.[4,5] As of September 2022, 1234 cases of BIA-ALCL have been reported through the BIA-ALCL Global Network.[6] Current lifetime risk of BIA-ALCL varies widely (eg, estimates of 1:2,207 to 1:86,029 based upon variable risk with different manufacturer types of textured implants). More recently, cumulative risk over 20 years in breast reconstruction patients implanted with Biocell devices was estimated at 1:354.[7] Although BIA-ALCL has resulted in 59 reported deaths,[6] it is generally considered to be treatable, typically with en bloc capsulectomy and subsequent radiation, chemotherapy, and/or stem cell transplantation as indicated for individual patients.[8]

More recently, cases of breast implant-associated squamous cell carcinoma (BIA-SCC) have come to the attention of the FDA and plastic surgery community, including the American Society of Plastic Surgeons (ASPS). BIA-SCC is a rare, epithelial-based tumor distinct from BIA-ALCL that was first reported in the literature in 1992.[9] Recent

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information reported to the FDA and a subsequent investigation resulted in the agency issuing a safety advisory in September 2022 about the potential risk associated with breast implants.[10] Because of the limited number of cases and associated data, lifetime risk and risk factors for development are unknown, but the cancer appears to be highly aggressive with a poor prognosis. The plastic surgery community should become aware of BIA-SCC and be able to promptly recognize and appropriately manage any cases that develop. Therefore, to educate the plastic surgery community and patients about this potential risk of breast implantation, this article seeks to identify and describe all published cases of BIA-SCC to gain a greater understanding of the incidence, presentation, diagnosis, treatment, and prognosis.

Takeaways

Question: How can physicians better understand BIA-SCC to promote prompt diagnosis and management?

Findings: A scoping review identified 16 published cases of SCC arising in the breast capsule. Review indicates that seroma fluid should be sent for immunohistochemistry markers CD30 and ALK to assess for BIA-ALCL and CK 5/6 and p63 to assess for BIA-SCC; flow cytometry should be analyzed for T-cells and B-cells and also squamous cells and keratin; and patients should undergo a breast ultrasound and MRI with and without contrast at presentation and prior to surgical intervention.

Meaning: BIA-SCC's presentation is similar to BIA-ALCL; surgeons should consider both possibilities when treating a patient with late onset seroma.

METHODS

Two reviewers (S.B.G., C.A.S.) performed a scoping review of PubMed in August and September 2022. Search terms included "breast implant squamous cell carcinoma," "breast implant capsule," "breast implant," "capsule," and "squamous cell carcinoma." No limits were set during the search, and all articles were considered for inclusion. Articles meeting inclusion criteria were those reporting cases of SCC arising in the breast capsule. Three articles reporting cases of primary SCC of the breast or SCC arising in relation to silicone injections to the breast, gluteal implants, or a subcutaneous bullet were excluded. The bibliographies of relevant articles were then hand searched to identify other published cases, which were then cross-checked with the initial search results and inclusion criteria. In addition to PubMed, social media sites dedicated to the topic of BIA-SCC were searched for potential cases.

Two reviewers (SBG, CAS) reviewed the included articles and extracted data on each case into a spreadsheet. Data elements included publication information, including year, primary author location, and journal; patient age at diagnosis and presenting symptoms; patient prior implant history and indication; pathologic and radiologic findings; surgical diagnostic and treatment procedures; treatment; and patient outcomes.

RESULTS

Of the articles retrieved through the literature search, 12 met inclusion criteria and reported data on 16 total cases of BIA-SCC[9,11–22] (Table 1). In addition, data from seven deidentified cases were reported directly to ASPS from Society members[23] after ASPS issued a follow-up BIA-SCC safety advisory.[26] Data from these seven cases are described separately below, but not included in this analysis.

Mean age of patients was 55.56 years (range, 40–81 years). Breast implant placement was performed for aesthetic and reconstructive purposes over a four-decade period. Cases occurred with silicone, saline, textured, and smooth implants. Mean duration from initial implant placement to presentation was 23.56 years (range, 11–40 years). Patients typically presented with unilateral breast enlargement/swelling (seroma), fluid collection, pain, erythema, and capsular contracture (Baker Grade IV). Extracapsular spread was identified in approximately 69% of cases at presentation. At the time of case publication or reporting, seven patients were alive; four were deceased; and five were lost to follow-up, unreported, and/or presumed deceased. Mean follow-up for the reported survivors was 20 months (1–96). To provide some perspective, using only the cases reported in the literature and summarized in this report, the 6-month mortality rate can be calculated to be 41.6%.

From the published cases of BIA-SCC, pathology seems to be composed of sheets of squamous cells lining the capsule in nests and bundles[9,11–22]. Although BIA-SCC does not seem to spread to breast tissue, it can exhibit highly invasive properties, including spread to adjacent local tissues, such as muscle and bone, and in some cases metastasize to distant sites including lymph nodes, lung, and liver.[14,16,18,19] Tissue markers seem to be positive for cytokeratin 5/6[11,13,15,18] and p63 expression[13,15,18] in the cases where histology was tested. Flow cytometry usually shows either squamous cells[9,11–22] or keratin.[11,13,14,16,19,21] Preoperative imaging, usually CT scans or ultrasound, tend to show fluid and inflammation, often underdiagnosing the full extent of the disease. The mass or tumor is often mistaken for inflammation. At surgery, gross findings include a thick, almost mucous-like fluid.[9,11–22] A mass is often found on the capsule, typically on the posterior side (hence, not clinically found preoperatively on examination).[9,11,14,15,17,19] Fifty percent of the reviewed cases demonstrated this tumor placement. Capsules tend to be thick and often calcified, with tan-appearing areas of epithelial cells.

Cases were often initially mistaken as recurrent or new breast cancer, but no evidence of primary breast cancer was found, and all tumor tissue was found to be negative for estrogen receptor, progesterone receptor, and human epidermal growth factor receptor expression (ER-/PR-/HER2-).

Initial treatment typically involved explantation and partial or total capsulectomy,[9,11–14,16–22] but complete capsulectomy was frequently reportedly difficult because

Table 1. Summary of Published BIA-SCC Case Characteristics

Characteristics	Characteristics	Case Reference Citation
Patients, N	16	
Mean age, y (range)	55.56 y (40–81 y)	[9, 11–22]
Decade of first implant placement, n (%)		
1970s	3	[9, 15 (Case 2), 16]
1980s	4	[11, 13, 14, 19 (Case 2)]
1990s	5	[12, 15 (Case 1), 17, 21 (Cases 1 & 2)]
2000s	3	[18, 19 (Case 1), 22]
Unreported	1	[20]
Indication, n		
Aesthetic	11	[9, 11, 13, 14, 15 (Case 1), 16, 17, 19 (Case 1), 20, 21 (Cases 1 & 2)]
Reconstructive	5	[12, 15 (Case 2), 18, 19, 22]
Implant texture, n		
Smooth	3	[14, 19 (Case 1), 20]
Textured	3	[15 (Case 1), 18, 21 (Case 1)]
Unreported	10	[9, 11, 12 13, 15 (Case 2), 16, 17, 19 (Case 2), 21 (Case 2), 22]
Implant fill, n		
Silicone*	9	[9, 11, 12, 14, 15 (Case 2), 16, 17, 18, 19 (Case 2)]
Saline	6	[15 (Case 1), 19 (Case 1), 20, 21 (Cases 1 & 2), 22]
Unreported	1	[13]
Mean duration of implant exposure, y (range)	23.2 y (range, 11–40 y)	[9, 11–18, 20–22]
Unreported		[19]
Presentation, n		
Breast enlargement/swelling	15	[9, 12–22]
Fluid collection	15	[9, 11–15 (Case 1), 16–22]
Pain	13	[9, 11, 14–21]
Erythema	9	[13–15 (Case 1), 16, 19 (Cases 1 & 2),21 (Cases 1 & 2), 22]
Capsular contracture (Baker IV)	8	[9, 11, 15 (Case 1), 17, 19 (Cases 1 & 2), 20, 21 (Case 2)]
Extracapsular involvement	11	[9, 14, 15 (Cases 1 & 2), 16, 17, 18, 19 (Cases 1 & 2), 20, 21 (Case 2)]
Treatment reported, n		
Implant removal	16	[9, 11–22]
Capsulectomy	14	[9, 11–14, 16–22]
Mastectomy	7	[9, 13–15 (Cases 1 & 2), 16, 20]
Subsequent surgery†	6	[9, 11, 14, 16, 17, 19 (Case 1)]
Chemotherapy	7	[15 (Cases 1 & 2), 18, 19 (Cases 1 & 2), 20, 22]
Radiation therapy	7	[15 (Cases 1 & 2), 16–18, 19 (Case 2), 20]
Outcome, n		
Alive	7	[9, 11, 13, 16, 18, 20, 21 (Case 1)]
Deceased	4	[15 (Case 2), 17, 19 (Cases 1 & 2)]
Presumed deceased	1	[15 (Case 1)]
Lost to follow-up/not reported	4	[12, 14, 21 (Case 2), 22]

*Includes Hyer Schulte.
†Includes radical mastectomy and chest wall reconstruction, capsulectomy and cyst removal, re-excision of residual chest wall mass.

of adherence to the chest wall. These cases were often aborted leaving the posterior capsule on the chest wall with plans to return for a second surgery.[9,11,14,16,17,19] Secondary treatments included mastectomy with lymph node sampling (either sentinel or palpable)[9,13–16,20] and additional chest wall resection.[14,16–18] Tumors tended to show aggressive growth and spread between these surgeries. Patients who had aggressive first-stage surgery seemed to have a better prognosis and outcome. Neoadjuvant and postoperative chemotherapy has been used with limited to no success.[15,18–20,22] Radiation therapy was used on a limited basis and mostly for palliative purposes.[15–20]

After the September 2022 safety advisories issued by the FDA and ASPS, ASPS was made aware of 17 additional cases of BIA-SCC from Society members. ASPS has received preliminary data on seven of those cases in private communications, as shown in Table 2, and deidentified data has been requested on the remaining ones. To avoid confusion with the analysis of the cases available in the published literature, a chart summarizing these additional cases is presented below.

In review of the data from these additional patients, several observations can be made. First, patient demographics, initial procedure indication, and type of implant in the reported cases do not seem to be substantively different than those reported in the literature data set. Pathology results for each of the cases reported to ASPS are also similar. Importantly, the rate of extracapsular

spread at the time of initial surgery and the fact that most of it is grossly visible also seems to be consistent with cases described in the literature. Finally, and regrettably, the rate of six-month mortality appears to rise with the addition of these cases. Plastic surgeons are advised to be vigilant in monitoring and treating patients, and the society will be proactive in the search for data on these cases as they are brought forward.

DISCUSSION

Based upon review of known pathologies, BIA-SCC seems to be a disease process that originates from the breast implant capsule and has unique features such as sheets of squamous cells varying from normal cells to dysplasia to metaplasia and, ultimately, squamous cell carcinoma. In the cases reviewed in this report, most of the primary tumors seem to be on the posterior capsule, making it difficult to assess clinically until seen, often for the first time, intraoperatively. Specimens were positive for immunohistochemistry markers CK 5/6 and p63, and seroma fluid appeared thicker than normal due to its keratin and squamous cell content.

Table 2. Summary of Additional Cases Reported Directly to ASPS

Case	Presentation and Treatment Overview	Status
1	(S/P augmentation) Patient presented with unilateral swelling, MRI revealed enhancing capsule. Total capsulectomy and explantation performed. Radiation therapy postop. Patient presented at 10 months postoperatively with lung metastasis requiring resection.	Patient deceased at 1 year post initial surgery and 2 months post lung resection.
2	(S/P reconstruction) Patient presented with metastatic disease at initial presentation. No surgery performed.	Patient deceased 2 months following presentation.
3	(S/P augmentation) Patient presented with unilateral swelling and seroma. Surgery attempt at explantation and total capsulectomy unable to be completed due to posterior capsule attachment to chest wall.	Currently receiving chemotherapy.
4	(S/P augmentation) Patient presented with unilateral swelling and seroma. Total capsulectomy unable to be completed due to invasion of chest wall. Patient refused all further treatments including surgery and chemotherapy.	Condition of the patient is unknown at the time of publication.
5	(S/P reconstruction) Patient presented with unilateral swelling and seroma. Underwent explantation and capsulectomy. Four years postoperatively presented with lung and brain metastases.	Patient currently in hospice care.
6	(S/P augmentation) Currently active case. Patient presented with unilateral swelling and seroma, cytology and flow cytometry showed squamous cells and keratin.	Patient awaiting surgery at the time of publication of this article.
7	(S/P) augmentation) Patient presented with unilateral swelling and seroma. Cytology and flow cytometry revealed squamous cells, surgical explantation and total capsulectomy completed successfully.	Pathology with only squamous metaplasia.

Given the limited amount of data available, the etiology of this tumor can only be hypothesized. It is clearly not normal to have epithelial cells within primary breast tissue or even on breast implant capsules. Possible sources of these epithelial cells include skin brought into the wound during the primary surgery, portions of breast skin left inside the wound during the initial surgery, or ductal epithelial cells which enter the breast tissue when ducts are cut during initial surgery. Another possibility is that similar to Marjolin's ulcer transformation. The chronic inflammation often seen with an implant may be the etiology of such a transformation, as this is similar to that often seen in chronic wound changes.[24] The ductal epithelium as a source may make the most sense, given that ductal epithelium is likely the etiology of primary squamous cell carcinomas of the breast tissue.

BIA-SCC's clinical presentation is very similar to BIA-ALCL, and surgeons should now consider the possibility of BIA-ALCL and BIA-SCC when treating a patient with late onset seroma. To correctly diagnose this entity, plastic surgeons should immediately modify their treatment protocol in three important ways. First, seroma fluid should be sent not only for immunohistochemistry markers CD30 and ALK to assess for BIA-ALCL, but also for CK 5/6 and p63 to assess for BIA-SCC. Second, flow cytometry on specimens should not only be analyzed for T-cells and B-cells, but also squamous cells and keratin. Finally, and most significantly, patients should undergo a breast ultrasound and magnetic resonance imaging (MRI) with and without contrast at the time of presentation and prior to surgical intervention. While the rationale for this recommendation is based upon a limited number of cases, the seemingly aggressive nature of this disease process, especially between procedures, suggests that thorough preoperative imaging will allow for the most appropriately planned, single-stage surgery with the greatest chance of a survival and positive outcomes. In addition, both MRI and PET-CT seem to be much more sensitive than CT scans and ultrasound in assessing these patients and the extent of their disease.

Specifically, within this patient cohort, a very high number (69%) presented with either gross or histologic extracapsular spread at the time of initial surgery, often necessitating a second stage surgery. Perhaps, because CT scans seem to have underread the extent of the disease in the studied cases, an early MRI might change the surgical plan to include a more extensive resection or even chest wall resection as part of the initial surgery. The apparent lack of response of this tumor to both chemotherapy (neoadjuvant or postoperative) and radiation therapy also suggests that a more extensive surgical resection will yield better outcomes.

With regard to future direction of research, diagnosis and care, the apparent consistent gradient transition within all of the pathology specimens from squamous metaplasia to carcinoma may present an early clue to detection and prevention. There are only minimal data available; so although only a hypothesis, it may be that

squamous metaplasia is actually a precursor to an eventual squamous cell carcinoma. Several surgeons have reported to the authors the incidental finding of squamous metaplasia on routine capsulectomies performed. Additionally, it has recently been suggested that in addition to BIA-SCC, capsular epithelialization as a benign phenomenon might also represent a precursor to squamous cell carcinoma.[25] Pathologists consider the finding of squamous metaplasia as benign; however, the future monitoring of these cases might eventually provide a clue as to earlier detection and treatment of BIA-SCC.

Although not a new disease process, given its apparent origin within the breast implant capsule, BIA-SCC is an entity that the plastic surgical community must proactively monitor with the same level of vigilance as BIA-ALCL. In view of broad specialty-wide awareness of BIA-ALCL, ASPS published a simple, comparative chart to support surgeon's knowledge of how to diagnose and treat BIA-ALCL versus BIA-SCC.[26] The currently documented number of BIA-SCC cases is very small, and the inclination to describe this a "rare" tumor is correct; however, both future research and retrospective data review to find potential cases are necessary. In the short time since ASPS released its safety advisory, multiple surgeons have reached out to report past cases that they now realize were BIA-SCC. The PSF's PROFILE Registry was expanded in early 2023 to serve as the central database to capture data related to BIA-ALCL cases as well as BIA-SCC and other implant-associated cancers. The National Breast Implant Registry can also serve as a real time mechanism to monitor breast implant safety as it continues to fulfill its promise to collect real-world data and detect safety signals.

CONCLUSIONS

BIA-SCC seems to be a rare but aggressive complication of breast implantation that can result in significant morbidity and mortality. The plastic surgery community should be aware of the presentation of BIA-SCC to promote prompt diagnosis and treatment in such cases. BIA-SCC should be discussed with all patients considering breast implantation as part of the informed-consent process.

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DISCLOSURE

Dr. Glasberg is a consultant and expert witness consultant at Allergan; consultant at 3M/KCI Corp.; Gerson Lerman Group; Guidepoint Global; and Scar Guard and Shareholder at Red Rock Holdings. The other authors have no financial interests to declare in relation to the content of this article.

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