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SILICONE INDUCED GRANULOMA OF BREAST IMPLANT CAPSULE

PLOS One

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1 Works for me dx.doi.org/10.17504/protocols.io.bfn4jmgw

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ABSTRACT

Objective: To evaluate the ability of BMRI to detect silicone gel bleeding in a prospective observational study including consecutive patients referred for a BMRI scan.

Methods: From January 2017 until now, patients referred for BMRI were evaluated in a prospective observational study. Patients who had breast implants were included. BMRI recorded 9 findings according to BI-RADS lexicon and SIGBIC findings, considered equivocal features to detect gel bleeding (GB). Three new original imaging features were added for SIGBIC diagnosis: black drop signal; T2* hypersignal mass; and delayed contrast enhancement, considered as irrevocable signs. The presence of silicones corpuscles was confirmed by percutaneous biopsy or surgical capsulectomy.

The accuracy of BMRI SIGBIC findings to predict GB was determined. We also used univariate analysis for the equivocal features for GB diagnosis. The Backward method was applied for a multivariate Logistic Regression model for the equivocal features.

EXTERNAL LINK

http://medRxiv 2020.01.15.20017350; doi: https://doi.org/10.1101/2020.01.15.20017350

THIS PROTOCOL ACCOMPANIES THE FOLLOWING PUBLICATION

Fleury EF, Rêgo MM, Ramalho LC, Ayres VJ, Seleti RO, Ferreira CA, Roveda Jr D. Silicone-induced granuloma of breast implant capsule (SIGBIC): similarities and differences with anaplastic large cell lymphoma (ALCL) and their differential diagnosis. Breast Cancer (Dove Med Press). 2017;9:133-140 https://doi.org/10.2147/BCTT.S126003

ATTACHMENTS

PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_916491.pdf FR_GRANULOMA.pdf 2020.01.15.20017350v1.full.pdf kaiser2001.pdf gorczyca2001.pdf estatistica.pdf

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PROTOCOL CITATION

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KEYWORDS

Breast implant, granuloma, silicone elastomers, Magnetic Resonance Imaging, Anaplastic Large Cell Lymphoma

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GUIDELINES

We follow the best practice protocols.

MATERIALS

NAME	CATALOG #	VENDOR
1 g Gadodiamide (Omniscan)	orb134342	biorbyt

SAFETY WARNINGS

There is no safety warinings

BEFORE STARTING

Review the state of the art of breast implant breast magnetic resonance imaging features.

1 *OBSERVATION*

Beginning of 2017: we had our first case of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) in IBCC- Instituto Brasileiro de Controle do Câncer (IBCC)
Middle of 2017: we had a suspected case of BIA-ALCL. The case was confirmed as Silicone Induced Granuloma of Breast Implant Capsule. Imaging findings were similar to BIA-ALCL.
Middle of 2017: first published manuscript reviewing the similarities between BIA-ALCL and SIGBIC.
2017: We found three common findings in Breast MRI scans regarding breast implant complications. We described this novelty findings as:

- Black drop signal;
- Mass with hyper signal in T2** weighted sequences;
- Late contrast enhancement.

2017: We observed the patients with these findings had similar clinical complaints.

2 *HYPOTHESIS*

We hypothesized that these novelty findings were related to silicone bleeding/ shedding.
We also found that silicone particles, polydimethylsiloxane (PDMS) were toxic, and develop an immune response in some patients.
We speculated that SIGBIC could be a more indolent manifestation od BIA-ALCL.

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3 *TEST*

We submitted the patients with radiological findings of BIA-ALCL to percutaneous breast biopsy.
All patients had the diagnosis of SIGBIC with silicone corpuscles in breast implant fibrous capsule, despite the integrity of the breast implants. Most of the patients had common clinical complaints.

4 *VALIDATION*

We started a study protocol at IBCC to search SIGBIC in patients submitted to BMRI scans.
Patients with breast implants and SIGBIC diagnosis criteria were submitted to percutaneous breast biopsy/ capsulectomy.

A prospective observational study.
Approved by Plataforma Brasil, with study protocol: CAAE: 77215317.0.0000.0072.
Informed consent obtained from all patients.
Approved by the institutional Ethics Committee.

5 *PUBLICATIONS*

We published many manuscripts regarding SIGBIC where we described new imaging features of breast implant complications and compares our results to that published int literature regarding BIA-ALCL.

6 *MULTICENTRIC VALIDATION*

Validation of the findings in other institutions.

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