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IDEAS AND INNOVATIONS

Breast

Impact of FDA Updates on Public Interest in Breast Implant-associated Anaplastic Large Cell Lymphoma

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Summary: In the United States, the Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of drugs, biological products, and medical devices. In that role, FDA releases timely updates with regard to medical devices and their possible adverse effects. However, the impact of such FDA updates on public interest has not been studied. The timing of multiple FDA updates regarding Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) was noted from September 2014 to September 2019. Impact on Public interest related to ALCL was measured using Google Trends and the number of YouTube video uploads. These objective markers were used to compare the public interest during FDA updates versus weeks with no FDA updates. Five major updates were released by FDA regarding BIA-ALCL during the past 5 years. Google Trends demonstrated a significant increase in public interest regarding ALCL during the week of FDA release, with a mean score of 69 ± 20.82 when compared with a mean score of 10.68 ± 4.71 ($P < 0.001$) during weeks with no FDA release. The mean number of YouTube videos uploaded during the period of FDA release was 11.8 ± 9.42, which was significantly higher than the mean of 2.42 ± 1.31 videos ($P < 0.001$) during the period of no FDA updates. FDA updates correlates with temporal increase in public interest. Plastic surgeons should be aware of FDA information releases on BIA-ALCL and anticipate an increased interest in additional information from patients and the public. *(Plast Reconstr Surg Glob Open 2020;8:e3240; doi: 10.1097/GOX.0000000000003240; Published online 24 November 2020.)*

INTRODUCTION

In the United States, the Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of biological products and medical devices. FDA releases timely updates with regard to medical devices and their possible adverse effects. Lately, Breast Implant-associated Anaplastic Large-cell Lymphoma (BIA-ALCL) has generated significant interest, resulting in multiple FDA updates.[1–5]

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As of September 2019, there have been 573 unique cases of BIA-ALCL reported worldwide, with 33 deaths.[6] The number of reported cases has steadily increased since the FDA's first report on BIA-ALCL in 2011.[7–10] BIA-ALCL has been reported in both breast augmentation and post-mastectomy breast reconstruction patients.[7–10] BIA-ALCL is closely related to the use of textured breast implants. Biocell implants by Allergan display a 6-fold greater risk for the development of BIA-ALCL, which has resulted in a worldwide recall of this product at the behest of the FDA.[6]

Although FDA plays a significant regulatory role, the impact of FDA updates on general public interest has not been studied. Using BIA-ALCL as a case in point, we evaluated the impact of FDA updates on public interest.

METHODS

Recent FDA updates regarding BIA-ALCL released were searched online. On September 20, 2019, we used the keyword "Anaplastic Large-Cell Lymphoma" on Google Trends tool (Google.com/trends)[11] to obtain a temporal interest plot from September 2014 to September

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Table 1. FDA Updates Related to BIA-ALCL

Dates	Agenda of FDA Release
March 21, 2017	FDA safety communication updating the current understanding of BIA-ALCL
November 20, 2018	FDA updates to Medical Device Safety Action Plan to enhance post-market safety related to risk of BIA-ALCL
February 6, 2019	BIA-ALCL-Letter to Health Care Providers released by FDA to create awareness among Health Care Providers
March 25–26, 2019	FDA public advisory committee meeting of the General and Plastic Surgery Devices Panel regarding BIA-ALCL
July 24, 2019	FDA release of Medical Devices report and questions & answers on BIA-ALCL, Request to Allergan for voluntary recall of Natrelle BIOCELL Textured Breast Implants

2019. The search interest represents searches for a specific keyword, relative to the total number of searches done on Google over time. The data are normalized and presented on a scale from 0 to 100. Mean Google Trends score was calculated and compared between the weeks with and without FDA updates.

A search was made on September 20, 2019 in YouTube (www.youtube.com) for videos related to BIA-ALCL from January 2017 to August 2019. This timeline was chosen to capture all the FDA updates. The number of relevant videos was recorded in 2-month blocks. More than 1 upload from the same account during each block was counted as 1 video. The mean number of video uploads was calculated and compared between the periods with and without FDA updates.

GraphPad Prism (v 7.00, La Jolla, Calif.; www.graphpad.com) was used for statistical analysis. $P < 0.05$ was considered as statistically significant.

RESULTS

Five major FDA updates related to BIA-ALCL over the past 5 years were included in our study (Table 1). The dates for release were March 21, 2017; November 20, 2018; February 6, 2019; March 25–26, 2019; and July 24, 2019.[1–5] We observed a significant spike in search interest for "Anaplastic Large-Cell Lymphoma" during each of the 5 weeks of FDA updates (Fig. 1). On a scale of 0 to 100, the Google Trends score ranged from 40 to 100 during these 5 weeks. The maximum Google Trends score during the remaining 256 weeks was 30, which was immediately after the week of last FDA release. The mean Google Trends score during the weeks of FDA updates was 69 ± 20.82 versus a mean score of 10.68 ± 4.71 ($P < 0.001$) during the weeks with no FDA updates.

There was a significantly increased number of YouTube video uploads during the period of FDA updates (Fig. 2). The mean number of YouTube video uploads during the period of FDA updates was 11.80 ± 9.42 compared with a

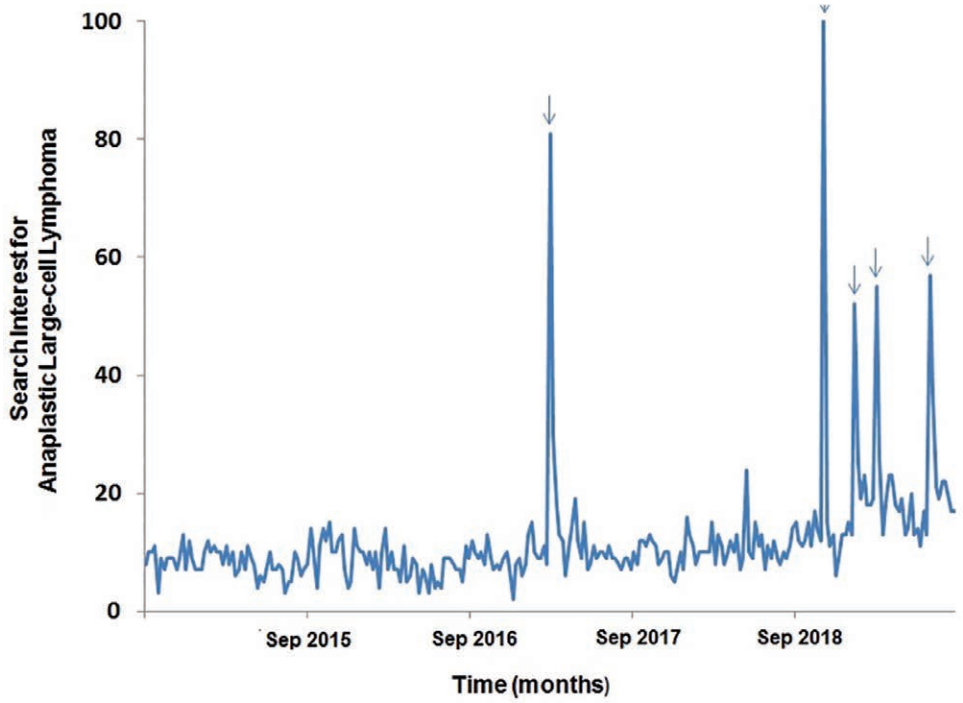

Fig. 1. Temporal trend of Google search interest for "Anaplastic Large-Cell Lymphoma" from September 2014 to September 2019. The arrows indicate the weeks when there were Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) updates from FDA. The search interest on the *y*-axis represents how many searches have been conducted for a particular term, relative to the total number of searches conducted on Google over a period of time. The data are normalized and presented on a scale from 0 to 100. The mean Google Trends score during the weeks of FDA updates was 69 ± 20.82 vs 10.68 ± 4.71 (*P*-value < 0.001) during the weeks with no FDA updates.

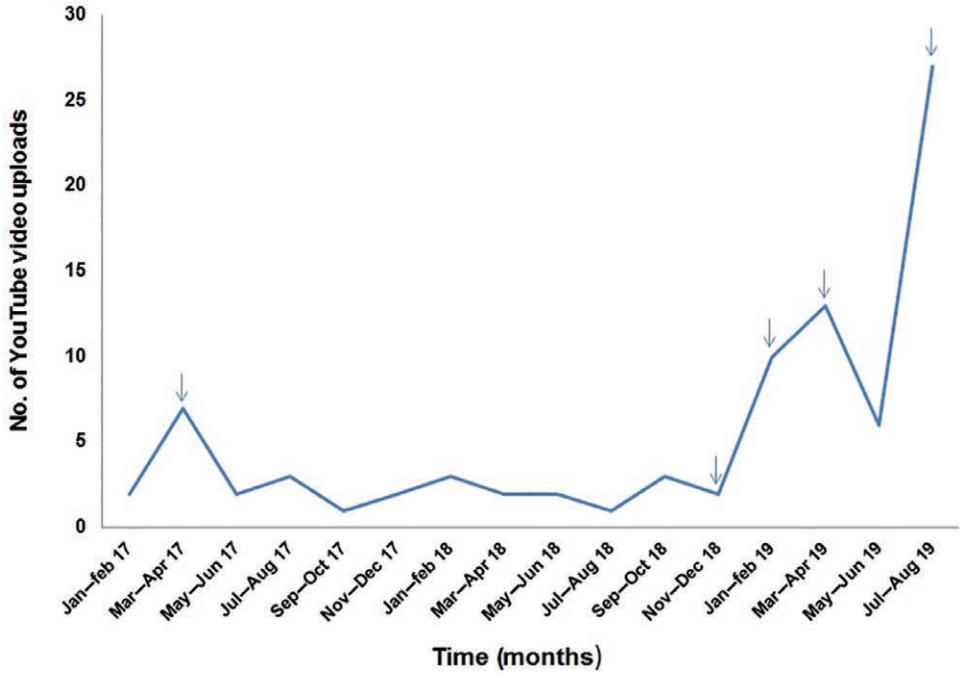

Fig. 2. Temporal trend of the number of videos uploaded on YouTube from January 2017-August 2019. The arrows indicate the weeks when there were Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) updates from FDA. The mean number of YouTube video uploads during the period of FDA updates was 11.80 ± 9.42 vs. 2.42 ± 1.31 ($P < 0.001$) during the period with no FDA updates.

mean of 2.42 ± 1.31 video uploads ($P < 0.001$) during the period with no FDA updates.

DISCUSSION

FDA has played a significant role in regulating the use of breast implants for both reconstructive and cosmetic purposes. In January 1992, FDA issued a voluntary moratorium on silicone-gel–filled breast implants, requesting that manufacturers stop supplying them and surgeons stop implanting them pending further review. In June 1998, FDA approved the use of silicone-gel–filled breast implants for a limited number of augmentations, reconstruction, and revision patients at a limited number of sites based on Allergan's investigation device exemption study. Silicone-gel–filled breast implants were not approved by FDA for breast augmentation for cosmetic indication till November 2006. In January 2011, FDA issued a safety communication on ALCL in women with breast implants. This was followed by multiple updates (which are included in our study), leading to the latest communication causing worldwide voluntary recall of Natrelle BIOCELL textured Allergan breast implants. While the regulatory role of FDA is well established, the effect of such updates on public interest is largely unknown.

Using multiple internet platforms, we objectively demonstrate a significant surge in public interest, which correlates temporally with FDA updates. The increased public interest has several implications for health care providers. Physicians should stay current with FDA updates because the patients may seek detailed information for improved understanding. The transient but significant spike in public interest provides an invaluable opportunity to reach out to general public and prospective patients about the risk factors, symptoms, and danger signs of BIA-ALCL. Perhaps the FDA should consider the dissemination of information in a more timely and audience-inclusive fashion by using these internet portals more effectively. One of the effective ways to achieve this might be to have a stronger online presence of FDA on internet and social media and reaching out to targeted patient groups. A collaborative effort between FDA and plastic surgeons will also result in improved patient engagement. Just simply releasing an update and allowing news sources to follow it might not be the most effective way of disseminating public health safety information.

Our study has limitations. We excluded search engines such as Yahoo/Bing because Google is the most popular search engine and it captures about 70% of the market share. Our findings are limited to BIA-ALCL and FDA updates and the results should not be extrapolated to other FDA updates.

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