EXPERT OPINION

Breast Fillers on the Rise: A Silent Epidemic of Unregulated Aesthetic Trend

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ABSTRACT

The use of breast fillers for aesthetic enhancement is gaining popularity over the past decade, driven by social media influence, accessibility, and the perception of minimal invasiveness. However, unlike approved breast implants, many injectable breast fillers remain unregulated and often administered by unqualified personnel in non-medical settings. This growing trend is accompanied by a striking lack of public awareness regarding its potential complications. Reported complications range from localized inflammatory reactions, granuloma formation, chronic pain, and infection to devastating sequelae such as tissue necrosis, migration of filler material, breast deformity, and systemic embolic phenomena. Breast fillers also cause profound difficulties to routine breast cancer surveillance and diagnosis. These complications often results in substantial physical, psychological and socioeconomic burden to affected individuals. This article highlights the emerging public health concerns surrounding the use of unregulated breast fillers, emphasizing the gap between increasing popularity and insufficient patient education on safety and long-term consequences. Thus, greater regulatory enforcement, improved public awareness, and multidisciplinary collaboration between clinicians, radiologists, and policymakers are urgently needed to curb these unsafe practices, in order to safeguard patient welfare in the era of rapidly expanding aesthetic medicine.

Keywords:
breast filler, breast augmentation, siliconomas, breast cancer, complications

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INTRODUCTION

Breast augmentation is increasingly becoming popular in Malaysia, driven by societal influences that prioritizes certain physical attributes, including breast size and shape, as part of prevailing beauty standards among women. Driven by demands from patients for less invasive and cheaper alternatives to traditional surgical procedures, this aesthetic field has undergone a transformative evolution. This dynamic landscape has fuelled the development and introduction of numerous types of tissue fillers for breast contouring. These tissue filler substances, mostly pose significant, and often severe long-term safety risks.[1,2] This presently widespread, and often unregulated use of breast fillers as breast augmentation alternatives has simultaneously ushered in a silent public health epidemic, particularly in the context of oncological surveillance carried out by screening mammogram. This necessitates immediate academic and regulatory scrutiny to be put in place.

Historical perspective and current trends

Historically, injectable breast augmentation is fraught with examples of many materials initially hailed as outstanding substances, only to be later abandoned due to catastrophic complications. Materials like paraffin, that was used in the early 20th century, were ultimately abandoned because they led to migrating foreign body reactions, fibrosis, and the formation of *paraffinomas*. Similarly, the use of liquid silicone injection and polyacrylamide hydrogel (PAAG), prevalently used in the earlier decades, is now prohibited substance in many countries due to established safety concerns.[2,3,4]

Collagen fillers, which were initially popular due to its natural origin and relatively safe, now also shows significant number of cases of allergic reactions in patients. Another breast filler, the hyaluronic acid (HA) which is a naturally occurring substance in the human

body is currently reported as a good alternative with better biocompatibility and reversibility. HA is approved by the Food and Drug Administration (FDA) United States of America and the European Union Nations as fillers for facial areas, but not for breast augmentation. In this case, a considerably larger volume of filler is required for breast augmentation using HA. Pure HA is commercially available but, due to the high cost, HA products are often compounded with silicone. Due to this mixing, a significant risk of unforeseen complications and permanent tissue damage has been reported with the procedures using HA.[4,5] It is possible that patients may be inadequately informed about the complications prior to the procedure, as both the provider and patients may be unaware of the presence of silicone in the formulation (Figure 1).

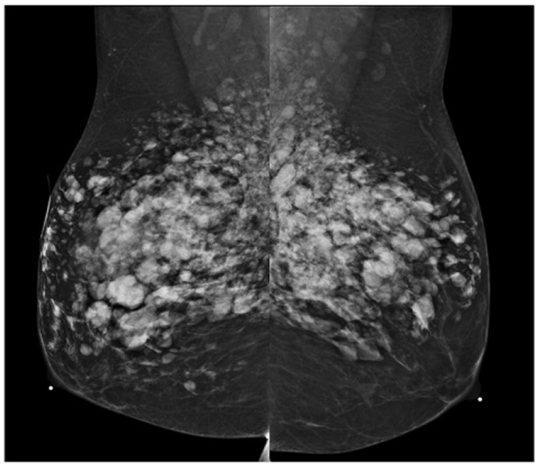

Figure 1: A 50-year-old woman presented for routine screening mammography and was surprised to learn that a supplementary breast MRI was required due to the obscuring effect of previously injected breast fillers. She had undergone the procedure more than a decade earlier and she had been informed at the time that the fillers were not permanent.

Clinical complications

The common clinical complications reported due to these breast fillers include infection, hematoma and seroma formation, induration and pain.[6] Extensive migration and displacement of the materials can cause serious medical complications such as pulmonary embolism and stroke.[7,8,9] Furthermore, this foreign material can trigger a chronic inflammatory response in the surrounding breast tissue. This intense inflammatory response and foreign body reaction may then result in granuloma formation, tissue necrosis, and breast asymmetry, and finally posing a significant source of morbidity for the affected patients.[5,7] Recent studies report that PAAG injections are associated with high rates of complication which include induration or nodules (60%), pain (27.4%), migration (13.3%), infection (5.2%), and calcification (3.7%). The above complications often manifest months or even years after the procedure has been done, with some cases being reported up to 20 years later.[1,3]

Perhaps the most critical and often overlooked danger of unregulated injectable augmentation is the profound challenge it poses to routine breast cancer surveillance and diagnosis.[8,10] The presence of these synthetic materials and the subsequent inflammatory and foreign body reaction fundamentally alter the radiological appearance of the breast, creating a diagnostic quagmire for radiologists. Worryingly, breast cancer in augmented breasts is notoriously difficult to detect, as the injected materials often obscure lesions on conventional screening modalities like mammography and sonography.[11,12] Sometimes, the use of unidentified injection substances, often by unverified operators, can present with radiological findings that mimic suspicious breast microcalcifications. These unidentified materials may often appear as asymmetric, rounded amorphous densities with scattered dystrophic calcifications, making it difficult for radiologists to differentiate post-augmentation changes from true malignancy. In many cases radiologists need to use additional and more advanced multimodality imaging such as Magnetic Resonance Imaging (MRI) and Contrast-Enhanced Spectral Mammography (CESM) which are more expensive and less widely available to resolve this issue. [10,12,13] (Figure 2).

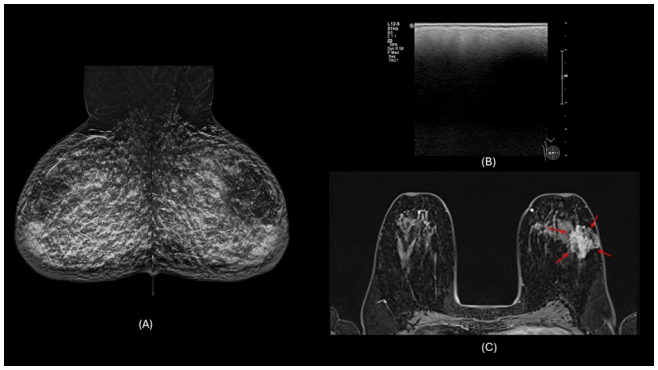

Figure 2: A 64-year-old woman, who had experienced persistent "lumpy breasts" following a prior breast augmentation procedure, presented late after noticing a significant increase in lump size. Mammography (A) and ultrasound (B) failed to reveal any suspicious lesion. Subsequent MRI (C) identified a suspicious mass in the left breast (arrows). The lesion was biopsied, and histopathology confirmed invasive carcinoma.

It is important to also note here that not all patients experience positive psychological outcomes following breast fillers procedures. This is so particularly in those patients who have experienced complications, as these patients have reported a lower level of satisfaction and self-esteem. Unfortunately, in the majority of the above cases, the risks were not adequately explained to patients prior to the procedure. Many women who experience such adverse events following unregulated breast augmentation often choose not to come forward or seek justice due to a complex interplay of emotional, social, cultural and systemic barriers. Many of them fear of being judged for their choices of going for breast augmentation. Among Muslim women, this cosmetic procedure is often regarded as religiously impermissible[14], leading many patients to seek to undergo such procedures in private centres and demand strict confidentiality. Consequently, the affected individuals hesitate to report complications due to fear of potential repercussions, while many others remain unaware of their rights or the legal avenues available to them.

Despite all the above concerns, contemporary unregulated injectable breast fillers continue to enter the market as the demand grows. The surge of such breast fillers represents a serious and growing public health crisis. The harmful effects of unregulated breast fillers are not merely cosmetic but they encompass various forms of complications, which includes the necessity for more complicated surgical intervention in certain cases. And most importantly, the profound challenge to oncological surveillance that delays or obscures the diagnosis of life-threatening breast cancer.

In our experience at our centres, we are seeing more and more cases each year, and especially in younger patients involved in these procedures. In previous years, women in 40s and above usually undergo this procedure. But now, patients as young as in their late twenties already opt for this type of breast augmentation. The psychological impact of the adverse event is also worrying with many women suffering in silence and these unlicensed practitioners seldom face any kind of accountability. While the global academic evidence unequivocally highlights the long-term dangers of these injectable materials, there is a notable lack of scientific data from Malaysia. This gap highlights the urgent need for more comprehensive research in Malaysia and a regulatory paradigm shift to address safety concerns and thus protect patients.

Regulatory landscape and Recommendations

Guidelines by the Ministry of Health Malaysia (MOH) pertaining to aesthetic procedures have been introduced but lack of specific regulation addressing the use of fillers is one of the main concerns.[15] Reports of unlicensed practitioners offering breast filler injections also raise the issue of lack in enforcement and monitoring system of the existing regulations. To address these challenges, there is a need for collaboration between MOH, healthcare professionals, academicians, researchers and industry stakeholders. Regulatory authorities must implement stricter controls on the use of these materials and the procedures. An informed comprehensive counselling should be mandated to patients before the procedure and must be done by adequately trained providers. A standardised, long-term follow-up guidelines including psychological assessment should be formulated for all patients with a history of injection augmentation mammoplasty. Public awareness campaigns must be launched to educate prospective female patients of the grave, long-term consequences of these procedures and to counteract the often, unrealistic portrayals of these procedures in the media and advertising. Only through such concerted efforts across regulatory, medical, and public health sectors can this silent epidemic of unregulated aesthetic trends of unregulated breast fillers be addressed in order to protect patients from what are often devastating and avoidable long-term health consequences.

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