

## **A Five -Year Retrospective Study of the Demographic Distribution, Clinical Profile and Treatment of Patients with Foreign Body Injections to the Breast Seen By the Division of Plastic Surgery at the Philippine General Hospital**

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**Objectives:** To describe the demographic distribution of patients who had foreign body injections to the breast who were seen by the Division of Plastic Surgery in the past 5 years. To determine the number of cases of patients with foreign body injection to the breast seen by the Division of Plastic Surgery from January 2004-August 2009. To determine the demographic distribution of patients who have had foreign body injections to the breast with regard to age, occupation, and socioeconomic status. To describe the clinical profile of cases. To review the present management procedures for the treatment of foreign body injections to the breast.

**Methods:** This is a retrospective study on patients seen by the Division of Plastic Surgery of the Philippine General Hospital from January 2004 to August 2009 who were seen for complications from foreign body injections to the breast. Cases were identified by querying the electronic patient registry of the Department of Surgery (ISIS). A review of the records was done. The following information was retrieved from each case: age, occupation, socioeconomic status, clinical presentation and treatment done in these patients.

**Results:** Thirty six female patients both private and charity were seen by the Division of Plastic Surgery of the Philippine General Hospital from January 2004 to August 2009. The incidence of foreign body injections to the breast was most common in young females 25-35, who were entertainers (72.2%). Forty four breasts presented with changes that were classified under Type II of the Ueno classification (firm induration with or without pain) seen between 6-15 years from the time of injection (58.3%). Majority of the patients (27 patients, 75%) did not know the volume that was injected. Only 25% of the women had knowledge of the volume injected, 6 patients (16.7%) received injections ranging from 160-300cc, 2 patients (5.6%) received more than 300cc. Twenty four patients were seen and treated as private cases and 12 patients were seen and treated as charity cases. Seventy two breasts were treated mostly with subcutaneous mastectomy with implant or flap reconstruction.

**Conclusion:** Based on the data gathered, most susceptible were young women with occupations wherein an attractive physical appearance would give them an edge or an advantage in their particular career. This is regardless of financial capability. With this, it is important to have a concerted, cooperative effort to stop the practice through

public education that can be directed at this population. This will also be a jumpstart point to make large volume foreign body injections to the breast illegal and less accessible in the Philippines. Knowledge of the clinical profile may guide other surgeons to early detection and appropriate treatment.

**Key words:** siliconoma, subcutaneous mastectomy

The quest for ideal soft tissue replacement or supplement has for decades focused on the female breast. Soft tissue inadequacy (small or ptotic breasts) has led to women seeking both natural and artificial means of breast augmentation. Prior to the development of silicone breast implants, experiments with alloplastic materials were conducted among these were injection of liquid silicone, petrolatum and mineral oil. Liquid silicone which was initially used for industrial purposes gained popularity. However the rampant usage and high volumes being injected soon had subsequent complications. Studies done by Chen<sup>4</sup>, Lai<sup>5</sup>, and Travis<sup>6</sup> have documented disfiguring and debilitating complications from the use of foreign body injections to the breast. In the '60s, its use was criminalized in the United States.<sup>1</sup> This did not stop the use of these products. At present, the complications of foreign body injections to the breast is a growing health care problem in the Philippines and other parts of Asia. In the Philippines, there have not been any measures taken to impose restriction of the use of large volume liquid foreign body injection. Liquid silicone (pure or with additives) can still be purchased in the

open market. What is more alarming is that injection of this liquid form of silicone is unscrupulously being performed anywhere by unskilled, unlicensed and non-medical personnel. Herein lies the problem, there is not enough information dissemination or education to protect future victims.

## Methods

This is a retrospective study on patients seen by the Division of Plastic Surgery from January 2004 to August 2009 who consulted and/or were treated for complications from foreign body injections to the breast. Case identification was done by querying the electronic patient registry of the Department of Surgery (ISIS). An anonymized dataset was generated using the following search strategy:

Select all where:

[Admitting diagnosis = “breast siliconoma”  
OR “siliconoma”

OR

Final diagnosis = “siliconoma” OR “breast  
siliconoma” ]

AND

[ consult start date  $\geq$  January 1, 2004

AND

Consult end date  $\leq$  August 31, 2009 ]

Upon verification of the diagnosis, the following information was retrieved from each case from a review of the entries in the registry: age, occupation, socioeconomic status, clinical presentation and treatment done in these patients. A review of the records will likewise be done. All data were collected and tabulated using a data sheet. Data gathered included the age, occupation, socioeconomic status, clinical profile: clinical appearance (Ueno classification<sup>12</sup>, Table 1), interval from time injected to appearance of changes and volume injected.. This study was submitted to and approved by the hospital ethics review board. Only anonymized data were generated from the electronic patient registry and such dataset collated and analyzed in this study. Only authorized personnel from the study

team had access to the review of records. The privacy of patient information was safeguarded and confidentiality rules applied.

**Table 1.** Ueno classification of changes in the breast after injection of foreign material .<sup>12</sup>

| Type    |   |
|---------|---|
| Type I  | Rubber ball- like induration  |
| TypeII  | Firm induration   |
| TypeIII | Firm induration with skin changes and severe or complete of the shape of the breast |

## Results

The demographic and clinical profiles of patients with siliconoma are shown in Table 2. A total of 36 female patients both private and charity were seen by the Division of Plastic Surgery from January 2004 to August 2009. The incidence of foreign body injections to the breast was most common in young females 25-35 age group, 26 patients (72.2%), followed by the 14-24 age group with 6 patients (16.6%) and equal incidences in the 36-50, 51-65 (5.6%) age group. Twenty six (26) patients who had foreign body injections to the breast were entertainers(72.2%), followed by 8 who were housewives (22.2%), and 2 professionals (5.6%).

Most subjects presented with changes that were classified under Type II of the Ueno classification (firm induration with or without pain), 44 breasts (62.5%) followed by 16 breasts with Type I (rubberball-like induration with or without pain) (22.2%) and 10 breasts with Type III (Pain, Firm induration with skin changes and severe or complete distortion of the shape of the breast) (15.93%) . In 2 patients, there were changes in only one breast.

More than half of the women (21 patients) presented with breast changes between 6-15 years from the time of injection (58.3%) followed by 2-5 years (12 patients). Some presented changes as early as 3 months (1 patient) and as late as 16-30 years ( 2 patients).

Majority of the patients (27 patients, 75%) did not know the volume that was injected. Only 25 percent of

**Table 2.** Demographic and clinical profile of patients with siliconoma seen at the Philippine General Hospital from January 2004 to August 2009.

|                       | Frequency | Percentage |
|-----------------------|-----------|------------|
| Age ( in years)       |           |            |
| 14-24                 | 6         | 16.60%     |
| 25-35                 | 26        | 72.20%     |
| 36-50                 | 2         | 5.60%      |
| 51-65                 | 2         | 5.60%      |
| TOTAL                 | 36        | 100%       |
| Occupation            |           |            |
| Professional          | 2         | 5.60%      |
| Housewife             | 8         | 22.20%     |
| Entertainer           | 26        | 72.20%     |
| Breast Changes        |           |            |
| Type I                | 16        | 22.20%     |
| Type II               | 44        | 61.10%     |
| Type III              | 10        | 13.80%     |
| No Signs/Symptoms     | 2         | 2.90%      |
| TOTAL                 | 72        | 100%       |
| Appearance of Changes |           |            |
| 3 mos-1 year          | 1         | 2.70%      |
| 2-5 years             | 12        | 33.30%     |
| 6-15 years            | 21        | 58.30%     |
| 16-30 years           | 2         | 5.60%      |
| TOTAL                 | 36        | 100%       |
| Volume                |           |            |
| 100-150cc             | 1         | 2.70%      |
| 160cc-300cc           | 6         | 16.70%     |
| >300cc                | 2         | 5.60%      |
| Unknown               | 27        | 75%        |
| Socioeconomic Status  |           |            |
| Private               | 24        | 66.70%     |
| Charity               | 12        | 33.30%     |

the women knew how much was injected, 6 patients (16.7%) received injections ranging from 160-300cc, 2 patients (5.6%) received more than 300cc. Twenty four patients were seen and treated as private cases and 12 patients were seen and treated as charity cases.

A total of 72 breasts were treated (Table 3). Sixteen breasts were classified as Type I, 14 of which did not undergo intervention and two were aspirated. Forty-five (45) breasts were classified as Type II, 42 of which underwent subcutaneous mastectomy with implant reconstruction, 40 of which was done by the division

and two done by another physician, 2 did not undergo intervention since the patient was lost to follow-up and one breast was managed with a mastectomy and expander. Eleven (11) were classified as Type III, 2 of which were managed with a subcutaneous mastectomy with bilateral latissimus dorsi flap reconstruction. Four breasts were managed with a subcutaneous mastectomy with bilateral transverse rectus abdominis myocutaneous (TRAM) flap reconstruction. One breast (unilateral involvement) was managed with a subcutaneous mastectomy with unilateral latissimus dorsi flap reconstruction. Two breasts were managed with a mastectomy and split-thickness skin grafting. Two breasts were managed with a subcutaneous mastectomy and implant reconstruction.

**Table 3.** Classification and management of patients with siliconoma seen at the Philippine General Hospital from from January 2004 to August 2009.

| UENO CLASSIFICATION <sup>12</sup> | # of breasts | INTERVENTION  |
|-----------------------------------|--------------|---|
|                                   | 36 pts       |   |
|                                   | 72 breasts   |   |
| I                                 | 16           | 14 No intervention<br>2 Aspiration  |
| II                                | 45           | 2 No intervention (lost to ff-up)<br>40 Subq mastectomy with implant reconstruction<br>2 Subq mastectomy with implant reconstruction (not done by authors)-consult<br>1 Mastectomy with expander (CA)     |
| III                               | 11           | 2 Subq mastectomy with bilateral Lat dorsi<br>4 Subq mastectomy with bilateral TRAM<br>2 Mastectomy STSG;<br>1 Subq mastectomy with unilateral Lat dorsi<br>2 Subq mastectomy with implant reconstruction |

**Discussion**

Through the years, there has been a paradigm shift in the popularity of the use of foreign body injections to

the breast. Those patients who were once enthusiasts of what was deemed a safe and simple alternative in breast augmentation have since then undergone major surgical procedures to manage the concomitant deforming complications.

Based on the data gathered, the most vulnerable target population to these injections were women 20-35 years of age. At this age, most women are concerned about how to improve their physical appearances due to the growing peer pressure brought about by society and the media. Although there were others at extremes of age, these patients were just as self-conscious of their appearance as the other patients. Patients, with occupations where an attractive physical appearance is an advantage, were also more susceptible to undergoing these procedures. Although the second subset of patients were housewives, and a minority being professionals, these patients still sought aesthetic enhancement.

Socioeconomic status did not have a significant effect on the incidence of foreign body to the breasts. However, an important observation is that anyone, regardless of financial capability, seeking physical improvement would still be most likely to choose a less costly procedure with minimal down-time. For the patients who had injections beyond 150cc (large volume), complications were more severe and breast changes were more apparent. Treatment for most patients who were classified as type II and type III were subjected to major surgical operations such as subcutaneous mastectomy with breast reconstruction.

## Conclusion

The epidemiologic data gathered may be used in the prevention of future foreign body injections to the breast by having a specific description or demographic picture of the population who would be at risk of subjecting themselves to this procedure. Based on the results, the most susceptible population were young

women with occupations wherein an attractive physical appearance would give them an edge or an advantage in their particular career. This is regardless of financial capability.

With this, it is important to have a concerted, cooperative effort to stop the practice through public education that can be directed at this population. This will also be a jumpstart point to make large volume foreign body injections to the breast illegal and less accessible in the Philippines. Knowledge of the clinical presentation may guide other surgeons to early detection and appropriate treatment.

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## **Early Discharge After Mastectomy: A Safe Alternative to the Standard Duration of Postoperative Hospital Confinement**

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**Objective:** To determine if early discharge after mastectomy is a safe alternative to the standard duration of postoperative hospital confinement.

**Methods:** This is a review of breast cancer patients who were discharged early after mastectomy consulting at the breast specialty clinic at Cebu Velez General Hospital and the breast center at the Vicente Sotto Memorial Medical Center from May 2007-May 2010. The following variables were recorded: date of surgery, date of discharge, presence of surgical site morbidities such as infection, dehiscence, necrosis and significant pain, date of 1st drain removal, date of 2nd drain removal, presence of seroma, application of elastic bandage.

**Results:** Of the 60 patients: 43 (71.7%) were from CVGH Breast Specialty Clinic and 17 (28.3%) from VSMMC Breast Clinic. There were 9 patients (15%) who developed surgical site morbidities, namely: infection-3 (5.0%), minimal partial wound dehiscence- 4 (6.7%), superficial skin necrosis-2 (3.3%). No patient complained of significant pain on follow-up. The first drain was removed within a mean of 6 days. The second drain was removed a mean of 7 days. Fifteen patients (25%) developed seroma. There was no readmission due to morbidities.

**Conclusion:** Early discharge after mastectomy is a safe alternative to the standard duration of postoperative hospital confinement.

**Key words:** mastectomy, postoperative pain

After mastectomy for breast cancer, there are three things that need to be monitored: adequate pain relief, sign of surgical site infection and rubber bulb drainage.

While postoperative pain may be readily controlled, international studies have shown that the standard hospital stay after mastectomy is about a week<sup>1,2</sup> until the rubber bulb drains with catheters positioned under the skin flaps are removed. This practice obliges the patient to remain within the unfamiliar hospital environment and this further translates into more financial burden related to hospital stay. If the patient can only be safely sent home earlier, she will not only recuperate faster within a home environment, but also incur less expense.

The general objective was to determine if early discharge after mastectomy is a safe (no major morbidity necessitating patient readmission) alternative to the standard duration of postoperative hospital confinement.

The specific objectives were: 1) to determine if any surgical site morbidity (such as pain, infection, dehiscence, necrosis and others) can be promptly detected and treated after early discharge, and 2) to determine if the rubber bulb drainage can be adequately managed after early discharge.

### **Methods**

All patients consulting at the Breast Specialty Clinic at Cebu Velez General Hospital (CVGH) and at the Breast Center at the Vicente Sotto Memorial Medical Center (VSMMC) who needed to undergo mastectomy for breast cancer was briefed preoperatively as to the early discharge protocol which allowed patients to be discharged within 3 days after surgery with drains in situ and manage the drain at home based on information

printed on a locally developed pamphlet used as a guide for recording various events such as surgical site morbidities and rubber bulb drainage. Early discharge means that patients are discharged within 3 days after breast surgery. All patients were started on coxibs per orem on the first postoperative day and continued for 3 to 4 days. Upon discharge, they were instructed to take the analgesic when necessary for significant pain (pain score of 4/10 or higher).

The contents of each rubber bulb drain were regularly evacuated and the drainage were recorded regularly and the total amount for 24 hours summed up. The patient or the designated caregiver was briefed on how to handle the drainage. The patient was then discharged early, meaning within 3 days post mastectomy, and requested to follow-up on an outpatient basis at 2-3 day intervals. Each drain was removed when the drainage was 30ml or less per drain. A 4- or 6-inch (whichever was available) elastic bandage over a small towel was applied to the upper torso across the operative site whenever the first day drainage was more than 200 ml from any of the drains or whenever the patient still had more than 30 ml drainage during the removal of the last drain.

The following variables were recorded: date of surgery, date of discharge, presence of surgical site morbidities such as infection, dehiscence, necrosis and significant pain, date of first drain removal, date of second drain removal, presence of seroma a week after the last drain removal, application of elastic bandage.

All these data were tabulated and analyzed.

**Results**

There were a total of 60 patients: 43 (71.7%) from CVGH Breast Specialty Clinic and 17 (28.3%) from VSMMC Breast Clinic. Table 1 shows that among 60 patients, there were 9 patients (15%) who developed surgical site morbidities, namely: infection-3 (5.0%), minimal partial wound dehiscence- 4 (6.7%), superficial skin necrosis-2 (3.3%). All the surgical site infections and partial wound dehiscence responded well to local wound care. No patient complained of significant pain on follow-up.

The first drain was removed within 1-12 days with a mean of 6 days. The second drain was removed within

3-21 days with a mean of 7 days. Fifteen patients (25%) developed seroma after a week from last drain removal. The amount of seroma drained ranged from 20ml to 250ml with a mean of 76ml. Twenty four patients (40%) had elastic bandage applied.

There was no readmission due to a morbidity. Readmission due to significant morbidities not remediable on outpatient care i.e. serious infection, full wound dehiscence.

**Table 1.** Surgical site morbidities recorded with patients discharged early after mastectomy for breast cancer.

| Morbidity                        | Number of Patients<br>n = 9 | Percentage (%) |
|----------------------------------|-----------------------------|----------------|
| Infection                        | 3                           | 5              |
| Minimal partial wound dehiscence | 4                           | 6.7            |
| Superficial flap necrosis        | 2                           | 3.3            |
| Pain                             | 0                           | 0              |
| Total                            | 9                           | 15             |

**Discussion**

In the Philippines, reduction of costs of health care is a very important component in caring for our patients. To reduce the costs of health care in the US, patients undergoing mastectomy are discharged routinely 24 hours after surgery.<sup>3</sup> This financially motivated concept was first introduced in 1998 by Dr. Gordon Wishart.<sup>4</sup> Though controversial at that time, it has gained acceptance in the field of breast cancer surgery over the years.

In this study, women were educated in terms of detection of infection, pain control and drain care at home and were discharged 1-3 days after surgery. This is possible with careful attention to perioperative care and instruction to patients and relatives.<sup>5</sup> It also requires extra input from the breast center nurses to gain patient’s confidence to manage the drain at home. Sending the patient home with drains in situ is practiced in several institutions. It seems feasible, and no increase in either seroma formation or infections has been reported; moreover, it is well tolerated by the patients.<sup>6</sup>

In an unpublished study done at VSMMC, 26.7% of post mastectomy patients developed seroma after a standard hospital stay.<sup>7</sup> This is comparable to the seroma formation in patients discharged early which was 25%.

In 2004, statistics at the Breast Center at VSMMC showed a morbidity rate (namely, SSI, seroma formation, and superficial flap necrosis) of 16%. This was before early discharge was implemented in the said institution. In this review, patients sent home early had a comparable morbidity rate of 15%. Prolonged drainage, however, probably increases the risk for infection, and some patients prefer to stay in the hospital for as long as the drain is in place.<sup>8</sup> A reasonable way to handle most patients with drainage after breast surgery would be to keep the drain in place for the first 24 hours and then discharge the patient after removing the drain. If a large quantity of fluid has been collected during the first 24 hours, the patient could be sent home with the drain in situ.<sup>8</sup>

In this series, no patient complained of significant pain on follow-up. Previous works have shown that all women discharged early also had reduced incidence of wound pain and they required less analgesia.<sup>1,3</sup>

In a study done by Bonnema, et al. overall patient satisfaction, hospital bed-days saved and low complication rates showed the efficacy of this early discharge policy. However, they recommended that greater attention should be paid to allaying patient anxiety during the first day at home, especially in older patients.<sup>9</sup>

The morbidity rate and our results are consistent with the literature.<sup>1,3,10</sup> A review done by Edwards, et al. confirms that complication rates are not increased by reduced hospital stay. It clearly demonstrates that attention to the details of perioperative care and outpatient evaluation, thorough patient and family instruction regarding wound and drain care, admission on the day of surgery, and discharge with drainage catheters in place result in significantly decreased hospital stay and total charges without increased morbidity.<sup>10</sup>

Early discharge after mastectomy benefits the patient by reducing risk of hospital acquired infection, recovery in a more acceptable home environment and financial savings.<sup>6</sup> It also benefits the facility

by reducing hospital stay with better utilization and availability of inpatient beds.<sup>6</sup> The number of days patients had their drains *in situ* at home can be equated to the number of bed-days in hospital theoretically saved.<sup>2</sup> Previous work has found keeping patients in hospital until their drains are removed takes an average of 7 days.<sup>1,2</sup> Therefore, our review showed no increase in the length of time for drain removal if monitoring is carried out at home.

However, the psychological aspect was not assessed in this group of patients. We recommend that additional questionnaires be given to detect depressive and other psychological illnesses. This was merely a descriptive study and a randomized controlled clinical trial is ideal to show a significant decrease in morbidity and financial cost in mastectomy patients who are discharged early.

## Conclusion

Early discharge after mastectomy is a safe alternative to the standard postoperative confinement.

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