

# THE SAFETY OF POLYPROPYLENE MESH IN NIPPLE-SPARING MASTECTOMY AND IMMEDIATE IMPLANT-BASED BREAST RECONSTRUCTION IN EARLY BREAST CANCER PATIENTS

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*The study aimed to determine the incidence and severity of postoperative complications in early breast cancer (BC) females undergoing immediate breast reconstruction (IBR) with implant and polypropylene mesh (PPM) after nipple-sparing mastectomy (NSM). This study is a retrospective, single-arm and single-institutional trial. The population selected was females with BC treated at Ho Chi Minh City Oncology Hospital from July 01, 2022, to Jan 31, 2024. The inclusion criteria included pathology as carcinoma of breast at preoperative stage as 0, I or II with tumor less than 3cm, and being treated with NSM followed by implant-based IBR with PPM. 28 patients met the inclusion criteria. Of two patients, the former had a late infection, whereas the latter suffered from nipple-areolar necrosis, accounting for 8% of all. Both patients were well managed with medical therapy. We did not find any statistical significance between the postoperative complications and relevant clinical and therapeutic characteristics. PPM enables the cavity to hold the implant, while still maintaining natural breast appearance. This is a safe surgical procedure to perform. PPM may be considered as an alternative for covering the lower anterior aspect of implant, especially in developing countries like Vietnam.*

**Keywords:** Immediate breast reconstruction, nipple-sparing mastectomy, polypropylene mesh.

## I. INTRODUCTION

According to GLOBOCAN 2020, BC had the highest incidence of all cancers in females, representing one-fourths of new cases.<sup>1</sup> In 2022, BC was the most common cancer in Vietnamese women, with 24.563 new cases diagnosed.<sup>2</sup> More than 90% of early BC patients still survive after the 5-year diagnosis duration.<sup>3</sup> Following mastectomy, the breast reconstruction has been an essential step for BC females. However, no breast reconstruction method is currently perceived as standard of care until now.<sup>4</sup>

The advent of skin-sparing mastectomy (SSM) and NSM follows the less-devastating treatment trend for breast reconstruction for BC females. Breast reconstruction based on implant has many benefits such as reducing the surgery duration, preventing another unnecessary scar, and stabilizing the appearance of reconstructed breast.<sup>5-7</sup> The implant is placed under the pectoralis major muscle which covers the upper portion, but its lower anterior aspect may remain uncovered in several cases, due to being constrained by available skin and muscle tissue. This area is the weakest point for implant to be displaced postoperatively, leading to treatment failure. As such, several techniques and materials for covering implant more fully have emerged.<sup>8,9</sup>

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Tissue expander is selected to have a larger pocket to fit the implant, but requires two-stage operation with an interval of several months. Tissue graft option is another technique but also requires another surgical phase. Consequently, the mesh appears to be efficient and safe, providing additional cover, inferior support, larger implant volumes, and improvement of lower pole projection.<sup>8,9</sup> In terms of material, a cellular dermal matrix (ADM) has been considered as the most effective mesh for IBR with implant, but its usage still has been limited due to its high-cost and lesser availability in developing countries.<sup>6,7</sup> Thus far, there have been several evidence indicating the non-inferiority of synthetic mesh with a reasonable cost, as compared to ADM.<sup>10,11,12</sup>

In the clinical practice, implant-based IBR is more popular than two-stage reconstruction with tissue expander, while PPM is more preferred rather than ADM.<sup>13,14</sup> Despite its common use in Vietnam, the safety of PPM in implant-based IBR following NSM has been proven. Therefore, we conducted this study to investigate the safety of PPM use in early BC females undergoing implant-based IBR after NSM.

## II. PATIENTS AND METHODS

### 1. Study population

Breast cancer patients diagnosed and treated at Ho Chi Minh City Oncology Hospital.

The inclusion criteria were the pathology of the tumor is “breast carcinoma” at preoperative stage 0, I or II with the tumor not larger than 3cm, and undergoing post-NSM implant-based IBR with PPM for covering the anterior aspect of implant.

The exclusion criteria were pregnancy, BC recurrence, other primary cancers, history of chest wall radiotherapy regardless of reason, and being treated with neoadjuvant therapy.

### 2. Study design

#### **Study method:**

This is a single-arm retrospective study.

#### **Location:**

Ho Chi Minh City Oncology Hospital.

#### **Time:**

The research was conducted from July 01, 2022 to Jan 31, 2024.

### 3. The variables collected

The dependant variables such as postoperative complications and its severity were collected. The independant ones include age at diagnosis, tumor location, tumor size, the number of tumors, primary tumor pathology, clinical stage, surrogate subtype, skin incision, volume of implant and surgical specimen, implant protrusion length (IPL), duration of surgery, prophylactic antibiotic regimens for washing implant and tissue pocket, and the number of postoperative drains.

### 4. Data processing and analysis

These data were inputted and analyzed using SPSS v.29. Two-tailed Chi-square tests or Fisher's exact tests (if appropriate) were used to compare categorical variables, whereas logistic regression was used to identify independant and/or dependant predictors of postoperative complications. Alpha was set at the standard of 0,05; and the statistical significance was considered as the p value was less than 0,05.

### 5. Ethical considerations

The research was in accordance with the Helsinki Declaration. Our institutional review board approved this study, reference number “671/GCN-HDDDNCYSH-DHYHN”, dated June 04, 2022. study's subjects were explained clearly and comprehensively about the purpose of the study, and they were voluntarily consent to participate in the study.

### III. RESULTS

#### 1. Baseline characteristics

This study consists of 28 patients, who all had cN0. The average age was 40.4 years old (y.o), and the youngest and oldest were 25

and 57 y.o, respectively. The median tumor size was 1,9 cm. Of 28 patients, there was two cases (7%) having both concurrent breast tumors.

**Table 1. Patient's preoperative characteristics**

Characteristics		n (%)	CI 95
Age at diagnosis (N = 28)	≤ 40	16 (57,1)	39,3 – 75,0
	41 – 59	12 (42,9)	25,0 – 60,7
Clinical stage (N = 28)	0	8 (28,6)	10,7 – 46,4
	I	14 (50,0)	32,1 – 67,9
	II	6 (21,4)	7,1 – 35,7
Tumor sidedness (N = 28)	Left	14 (50)	32,1 -67,9
	Right	14 (50)	32,1 -67,9
	Central	4 (14,8)	3,7 – 29,6
Tumor location (N = 27)	Upper outer quadrant	6 (22,2)	7,4 – 40,7
	Upper inner quadrant	4 (14,8)	3,7 – 29,6
	Upper half	8 (29,6)	11,2 – 48,1
	Lower half	1 (3,7)	0,0 – 11,1
	Outer half	4 (14,8)	3,7 – 29,6
The number of tumors (N = 28)	1	26 (92,9)	82,1 -100
	2	2 (7,1)	0,0 – 17,9
Preoperative pathology (N = 28)	Carcinoma in-situ	9 (32,1)	17,9 – 50,0
	Invasive carcinoma	19 (67,9)	50,0 – 82,1
Surrogate subtype (N = 28)	Luminal/HER2-	19 (67,9)	50,0 – 82,1
	Luminal/HER2+	6 (21,4)	7,1 – 39,3
	HER2+	2 (7,1)	0,0 – 17,9
	TNBC	1 (3,6)	0,0 – 10,7

Most tumors were located in the upper half of breast. The tumor pathology as invasive carcinoma accounted for more than two-thirds

of total cases. The luminal/HER2(-) subtype was the most common (about 66%), whereas TNBC was the least common (about 5%).

**Table 2. Patient's surgical and postoperative characteristics**

Characteristics		n (%)	CI 95
Axillary treatment (N = 28)	SLNB	27 (96,4)	89,3 – 100
	Dissection	1 (3,6)	0,0 - 9,8
Skin incision (N = 28)	Periareolar	20 (71,4)	53,6 - 85,7
	Radial	2 (7,1)	0,0 – 17,9
	Inframammary	3 (10,7)	0,0 – 25,0
	Other	3 (10,7)	0,0 – 25,0
Prophylactic intravenous antibiotics (N = 28)	Amapower	9 (32,1)	14,3 -50,0
	Cephazolin	2 (7,2)	0,0 -17,9
	Unasyn	4 (14,3)	3,6 – 28,6
	Zolifast	13 (46,4)	28,6 – 64,3

The average duration of surgery as  $167,53 \pm 10,94$  mins, with the shortest and longest was 60 and 300 mins, respectively. The majority (27/28 patients) underwent SLNB, whereas there was one patient treated with the axillary dissection in the beginning of surgery. This patient had a large tumor (5cm), and still decided to have

the axillary dissection instead of SLNB, after the comprehensive consult about the benefit and risk. More than 70% of patients underwent periareolar incision, the radial incision was least chosen. All of patients were prescribed prophylactic antibiotics, most common were beta-lactam and cephalosporin.

**Table 3. Patient's implant characteristics**

Characteristics		n (%)	CI 95
Implant volume (N=28)	< 200 mL	4 (14,3)	3,6 – 28,6
	200-300 mL	17 (60,7)	42,9 – 78,6
	> 300 mL	7 (25,0)	7,2 – 42,9
Implant profile (N=28)	Moderate – High	5 (17,9)	3,6 – 35,7
	High	13 (82,1)	64,3 – 96,4

More than 60% of patients used breast implants with volume as 200-300 mL, whereas more than four-fifths of patients used the high

implant profile, and the rest used the moderate-high one.

Table 4. Patient's other characteristics

Characteristics	Average $\pm$ SD	Medium	Min	Max
Implant volume (mL) (N=28)	278,57 $\pm$ 12,96	287,50	150	350
Surgical specimen volume (mL) (N=28)	240,00 $\pm$ 21,32	250,00	100	400
Clinical tumor size (cm) (N=27)	1,859	1,800	0,7	3

## 2. Postoperative complication characteristics

In the postoperative duration, one patient developed a postoperative infection and another patient experienced skin necrosis at the nipple-areolar region, accounting for 3,6% each. However, both patients had mild-moderate severity, and were well-treated with medical therapy.

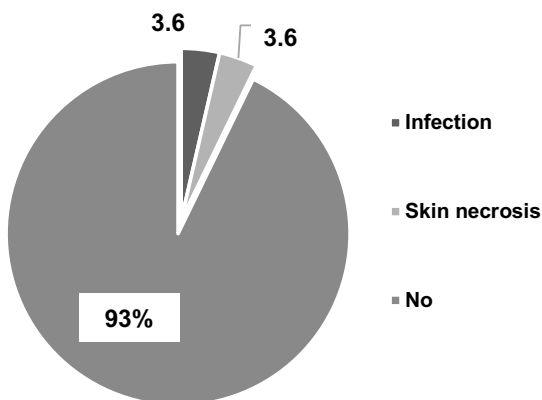


Figure 1. The patients' postoperative complications

As analysing the correlation between the postoperative complications and several relevant clinical and therapeutic characteristics, we did not find any statistically significance (p values > 0,05).

## IV. DISCUSSION

This study consists of 28 patients with cN0, underwent implant-based IBR with PPM following NSM. The majority was less than 40 y.o, compatible with other authors such as Hansson et al, and Blok et al.<sup>10,11</sup> It probably

resulted from that these young females usually have more social relationships and an actively sexual life, leading to their higher aesthetic needs, compared to the elderly. The current IBR trend is to still ensure the oncologic outcomes, as well as the high aesthetic satisfaction of these sensitive BC patients. The operative safety of implant-based IBR and/or mesh following SSM for early BC patients has been reported by some authors, but that following NSM is still scarcely reported, especially in Vietnam.<sup>10,13,14</sup> In this study, we did not select the locally advanced patients, such as cT3 or cN+, due to the significantly high recurrence risk, and probably the poorer aesthetic outcome if the adjuvant RT would be prescribed.

The main advantage of NSM is to achieve the best aesthetic outcome, due to the larger implant volume probably applied as the result of the maximal flat skin preservation. As compared to SSM, NSM facilitates the breast appearance more natural-looking, and skin sensation preservation related to the nipple-areolar complex, which plays a vital role to augment these patients' quality of life (QoL).<sup>15</sup> There are, however, some concerns as to NSM that the skin flat or nipple-areolar anaemia may lead to the postoperative skin necrosis. As known, a careful dissection and respecting the anatomical structure are highly required to ensure an effective blood supply for the nipple-areola after surgery. Despite being careful in the operation, this study still had a patient suffering

a partial nipple necrosis with the mild-moderate grade severity, then well-treated with medical therapy. There are several possible risks for this case, such as the large breast specimen volume (350mL), periareolar incision, central tumor just beneath the skin surface, which may negatively affect the nipple-areolar blood supply, perceived as the origin of problem. There was no case with any other complication in the first postoperative month, but we found a patient with the late incision infection with an interval of 3 months postoperatively. This patient was still effectively treated by medical therapy, including antibiotics and anti-inflammatory drugs, in the duration of several weeks.

As turning to IBR with implant after NSM, the lower anterior aspect of implant may remain uncovered in many cases, due to being constrained by available skin and muscle tissue. This uncovered area is the site for the breast implant to displace postoperatively, leading to the treatment failure.<sup>8,9</sup> Despite a larger pocket induced by tissue expander to fit the breast implant, it still requires two-stage operation with an interval of several months, but still having the risk of failure. That is why all the patients in this study performed IBR, rather than two-stage breast reconstruction, with the utility of an adjunct to cover implant fully. Tissue graft was not used in this study since it requires a longer surgical duration, with another unnecessary incision for females who are looking forward to the best aesthetic outcome. Moreover, all of the patients in this study were used mesh along with implant, which provides additional cover and support inferiorly, enabling faster surrounding tissue expansion, larger implant volumes, as well as enhancement of lower pole projection.<sup>8,9</sup>

Meshes supporting breast implant such as ADM and the synthetic mesh, are

comprehensively investigated in many studies.<sup>16</sup> The efficiency and safety of ADM has been demonstrated in several trials, but its high cost is still a great hurdle in the developing countries. This is why this study included only patients using PPM for implant-based IBR after NSM, due to its reasonable price and high availability in Vietnam. According to this study, PPM is highly safe, with more than 90% of cases without any postoperative complications. It suggests that PPM may be an alternative for covering the lower anterior aspect of implant, especially in developing countries where ADM appears not to be an available option to opt in the daily clinical practice.

Among two complicated patients, their severity was just mild-moderate grade, and all of them were well-treated with medical therapy. The patient suffering a partial nipple necrosis was discussed in detail above. While the other patient had a late incision infection in a duration of 3 months postoperatively, accounted for just 3,5% of total cases. This complication's ratio highly varies among several different studies, ranging from 0% to 20%, possibly resulting from multiple factors affecting the outcome, such as prophylactic antibiotics, the sterility quality of the operating room, the antibiotic resistance status in each medical center...<sup>10,11,17</sup> After a timely diagnosis in the follow-up duration, she was well treated with antibiotics and anti-inflammatory drugs in several weeks. Furthermore, several authors reported many different complications with different ratios, such as seroma, postoperative bleeding, skin necrosis, and even implant loss...<sup>10-12,17</sup> In general, the reason for this wide variation is still unknown till now, possibly due to a large number of factors affecting the outcome, which are highly challenging to effectively control in those clinical trials.

In the postoperative duration, most of patients experienced a temporarily unfamiliar feeling with the reconstructed breast, but they felt highly satisfied with the breast appearance as asked postoperatively. Despite that, the more reliable outcomes such as aesthetic and QoL outcomes need to be investigated in the future, to comprehensively reflect the patient's postoperative life. Furthermore, we did not find any statistically significance ( $p$  value > 0,05) as analyzing the correlation between the postoperative complications and several relevant clinical and therapeutic characteristics, such as age at diagnosis, clinical stage, operative procedure, prophylactic antibiotic regimen... This is possibly due to the limitation in the population size of this study, leading to statistically insignificant results.

## V. CONCLUSION

In conclusion, covering the lower anterior aspect of implant with meshes enables to expand the pocket for possibly fit a larger breast implant, while still maintaining the natural breast appearance after IBR. The implant-based IBR with PPM after NSM in early BC females has not yet shown any major surgical complications, and several larger studies are needed for further confirmation. Compared to ADM, PPM may be highly considered as an alternative for covering the lower anterior aspect of implant, especially in developing countries including Vietnam.

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