Case Study

The Impact of SPY Angiography on Intraoperative Decision Making and Outcomes for Post-Mastectomy Reconstruction

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Abstract

Objective: While the use of intraoperative laser angiography (SPY) is increasing in mastectomy patients, its impact in the operating room to change the type of reconstruction performed has not been well described. The purpose of this study is to investigate whether SPY angiography influences post-mastectomy reconstruction decisions and outcomes.

Materials and Methods: A retrospective analysis of mastectomy patients with reconstruction at a single institution was performed from 2015–2017. All patients underwent intraoperative SPY after mastectomy but prior to reconstruction. SPY results were defined as 'good', 'questionable', 'bad', or 'had skin excised'. Complications within 60 days of surgery were compared between those whose SPY results did not change the type of reconstruction done versus those who did. Preoperative and intraoperative variables were entered into multivariable logistic regression models if significant at the univariate level. A p-value <0.05 was considered significant.

Results: 267 mastectomies were identified, 42 underwent a change in the type of planned reconstruction due to intraoperative SPY results. Of the 42 breasts that underwent a change in reconstruction, 6 had a 'good' SPY result, 10 'questionable', 25 'bad', and 2 'had areas excised' (p<0.01). After multivariable analysis, predictors of skin necrosis included patients with 'questionable' SPY results (p<0.01,OR:8.1,95%CI:2.06 – 32.2) and smokers (p<0.01,OR:5.7,95%CI:1.5 – 21.2). Predictors of any complication included a change in reconstruction (p<0.05,OR:4.5,95%CI:1.4–14.9) and 'questionable' SPY result (p<0.01,OR:4.4,95%CI:1.6–14.9).

Conclusion: SPY angiography results strongly influence intraoperative surgical decisions regarding the type of reconstruction performed. Patients most at risk for flap necrosis and complication post-mastectomy are those with questionable SPY results.

Background

In recent years, intraoperative laser (SPY) angiography has been shown to be effective in identifying areas of ischemic tissue and predicting skin or nipple areolar necrosis during mastectomies [1–5]. One of the most significant complications following a skin or nipple sparing mastectomy with reconstruction is flap necrosis [6,7]. Consequently, SPY angiography has been found to be a useful adjunct to clinical assessment in identifying and potentially preventing complications such as skin necrosis [2].

While studies have demonstrated the ability of SPY angiography to predict mastectomy flap necrosis, none have investigated the impact of SPY angiography on intraoperative decision making, such as changing the type of reconstruction performed. In order to identify the independent predictive value of SPY angiography for postoperative complications, prior studies have not allowed SPY results to impact intraoperative reconstruction decisions [1]. Other studies have described the usefulness of SPY in identifying areas of flap ischemia intraoperatively so that compromised skin could be excised, resulting in decreased complication rates compared to those who did not use SPY [4]. To date, there are no studies describing whether SPY angiography affects surgical decision making regarding the type of breast reconstruction performed. Nor are there studies evaluating whether SPY angiography results can predict other complications, such as seroma or infection. These complications can result from skin necrosis, but independent predictive values have not been evaluated.

Our study aims to describe the impact of SPY angiography on intraoperative decision making regarding type of breast reconstruction. Additionally, we aim to investigate the utility of SPY in predicting other postoperative complications.

Materials and Methods

Patients

After receiving institutional review board approval, a retrospective analysis was performed of a single institution breast care center from 2015–2017. Adult female patients age 18 or older who underwent Nipple Sparing Mastectomy (NSM) or Skin Sparing Mastectomy (SSM), with or without sentinel lymph node biopsy (SLNB) and/or Axillary Lymph Node Dissection (ALND) were identified. The study included patients with a diagnosis of breast cancer and patients undergoing prophylactic surgery. All mastectomies were performed by

one of three breast surgical oncologists at our institution. All patients underwent immediate reconstruction with Tissue Expander (TE) or fixed volume implant during the same procedure by one of three plastic surgeons, and all had intraoperative indocyanine green (ICG, standard dose of 2.5mg/ml with 4ml) SPY angiography using the SPY Elite System to evaluate skin perfusion prior to reconstruction.

Variables

Preoperative patient variables including age, smoking status (defined as current smoker at the time of surgery), diabetes, obesity (BMI $>/= 30 kg/m^2$), breast weight, and exposures (history of chest wall radiation or chemotherapy) along with intraoperative variables including type of surgery (NSM vs SSM) and ALND were compared. SPY results were defined as described by the plastic surgeon in their operative report as 'good,' 'questionable,' 'bad 'or' areas excised.' Documentation of planned reconstruction was noted in the preoperative clinic note and the performed reconstruction was identified in the final operative report. A change in intraoperative reconstruction was either placement of an expander rather than implant, minimal expansion of an expander, or no reconstruction at all. Complications assessed included necrosis (full or partial flap or Nipple-Areola Complex (NAC) necrosis, dehiscence, or those requiring reoperation), infection (abscess, cellulitis or sepsis), seroma (requiring aspiration or surgical intervention), or explantation of implant within 60 days of surgery. These outcomes were compared between those who had SPY results that changed the type of reconstruction performed and those who did not.

Statistics

Univariate analyses were performed using chi-square tests, Fisher's exact test, independent sample t-tests, and F-tests in ANOVA for categorical and quantitative variable analysis, respectively. A change in reconstruction was used as the predictor variable with each outcome of interest being the dependent variable tested for significant univariate association. Patient demographics and intraoperative variables were tested for univariate association with our predictor variable to identify possible confounders. These variables were adjusted for in multivariable logistic regression models when the respective univariate p-value was less than 0.1. Covariates in the final multivariable logistic model were considered statistically significant if the p-value was less than 0.05. All statistical analysis was done using SAS version 9.3 (Cary, NC).

Results

Of the 267 mastectomies identified, 42 breasts from 25 patients (15.7%) underwent a change in the type of reconstruction intraoperatively due to SPY results. Of the 42 changes in reconstruction type, 6 breasts had 'good' SPY results, 10 had 'questionable' SPY results, 25 had 'bad' SPY results, and 2 breasts 'had areas excised' (p<0.0001) (Table 1). Of the patients who underwent a change in reconstruction, 39 of 42 breasts (92.8%) had a TE placed instead of implant or a TE placed with lower volume, while 3 breasts (7.1%) did not undergo any reconstruction based on intraoperative assessment.

The patient demographics that were statistically significant on univariate analysis in relation to those who had no change versus those who had a change in reconstruction included smoking (p<0.001), obesity (p<0.01), and breast weight (p<0.0001). Age, diabetes, and history of chemotherapy or chest wall radiation were not statistically significant (Table 2). Patients who did not have a change in reconstruction were more likely to have undergone a SSM versus a NSM (p<0.01) and have a 'good' SPY result (p<0.0001) compared to those who underwent a change in reconstruction (Table 2). There was a statistically significant increase in complications including necrosis (p<0.01), infection (p<0.01), and seroma (p<0.0001) for patients who had a change in reconstruction based on SPY results compared to those who did not (Table 3).

Table 1. SPY results and frequency of intraoperative decision change.

	All Subjects N=267	Good N=165 (61.8)	Questionable N=25 (9.4)	Bad N=25 (9.4)	Areas excised N=52 (19.5)	p-value
	N (%)					
Change in Reconstruction	42 (15.7)	6 (3.6)	10 (40)	25 (100)	1 (1.9)	**<.0001***

A multivariable analysis was performed adjusting for significant co-variates including preoperative factors and intraoperative factors if a variable produced a p<0.1. Predictors of necrosis within 60 days of surgery included those who had a 'questionable' SPY result (p<0.01 OR: 8.1 95% CI 2.1–32.2) and current smoker (p<0.01 OR: 5.7 95% CI 1.5 – 21.2) (Table 4). Predictors of infection included those who underwent a change in reconstruction (p<0.01 OR: 34.6 95% CI 2.7 – 448) and obesity (p<0.001 OR: 79 95% CI 6.1 – 1000) (Table 5).

Predictors of seroma included those who underwent a change in reconstruction (p < 0.05 OR: 4.3 95% CI 1.2–14.7) (Table 6). There were no significant predictors of explantation after multivariable analysis (Table 7). Predictors of one or more complications were significant for patients who had a change in type of reconstruction (p<0.05 OR: 4.5 95% CI 1.4–14.9) and those who had a "questionable" SPY result (p<0.01, OR: 4.4 95% CI 1.6 – 12.1) (Table 8). There were no mortalities within 60 days.

Table 2. Demographic and intraoperative variables for patients with no change in reconstruction compared to change in reconstruction.

	No Change in Reconstruction (N=225)	Change in Reconstruction (N=42)	p-value
Demographics	**N (%) or mean +/- SD**		
Age	45.6 ± 10.7	47.3 ± 12.20	0.36
Smoker	10 (4.4)	9 (21.4)	**<0.001***
Obesity (kg/m²)	44 (19.6)	0 (0)	**<0.01***
Diabetes	11 (4.9)	0 (0)	0.15
Breast weight (gm)	607.0 ± 377.8	403.4 ± 190.8	**<.0001***
History of Chemo	56 (24.9)	9 (21.4)	0.63
History of Radiation	13 (5.8)	2 (4.8)	0.79
Intraoperative variables			
SSM	69 (30.7)	4 (9.5)	**<0.01***
ALND	19 (8.4)	6 (14.3)	0.25
SPY Result			**<.0001***
Good	159 (70.7)	6 (14.3)	
Questionable	15 (6.67)	10 (23.8)	
Bad	0 (0)	25 (59.5)	
Areas Excised	51 (22.7)	1 (2.4)	

Table 3. 60-day outcomes for no change in reconstruction compared to change in reconstruction.

Outcome	No Change in Reconstruction (N=225)	Change in Reconstruction (N=42)	p-value
Demographics	**N (%)**		
Necrosis	15 (6.7)	9 (21.4)	**<0.01***
Infection	6 (2.7)	5 (11.9)	**<0.01***
Seroma	29 (12.9)	17 (40.5)	**<.0001***
Explantation	3 (1.3)	3 (7.1)	0.052

Table 4. Multivariable logistic regression model predicting necrosis within 60 days of surgery.

Variable	OR (95% CI)	p-value
Change in Reconstruction	3.1 (0.67 – 14.4)	0.15
Questionable SPY	8.1 (2.1 – 32.2)	**<0.01***
Bad SPY	1.2 (0.15 – 9.5)	0.86
Areas Excised SPY	3.4 (0.97 – 11.8)	0.06
Smoker	5.7 (1.5 – 21.2)	**<0.01***
Obesity	2.04 (0.54 – 7.7)	0.30
SSM	0.44 (0.11 – 1.7)	0.24
Breast weight (grams)	1.001 (1.000 – 1.002)**	0.19

Table 5. Multivariable logistic regression model predicting infection within 60 days of surgery.

Variable	OR (95% CI)	p-value
Change in reconstruction	34.6 (2.7 – 448)	**<0.01***
Questionable SPY	1.6 (0.19 – 13.5)	0.66
Bad SPY	0.21 (0.01 – 3.3)	0.26
Areas Excised SPY	0.82 (0.12 – 5.7)	0.84
Smoker	0.80 (0.08 – 8.2)	0.84
Obesity	79 (6.1 – 1000)	**<0.0001***
SSM	1.3 (0.20 – 8.9)	5
Breast weight (gm)	0.99 (0.99 – 1.0)	0.09

Table 6. Multivariable logistic regression model predicting seroma within 60 days of surgery.

Variable	OR (95% CI)	p-value
Change in reconstruction	4.3 (1.2 – 14.7)	**<0.05***
Questionable SPY	1.5 (0.45 – 4.7)	0.53
Bad SPY	1.2 (0.28 – 5.4)	0.79
Areas Excised SPY	0.92 (0.36 – 2.4)	0.87
Smoker	1.1 (0.35 – 3.4)	0.85
Obesity	0.91 (0.30 – 2.7)	0.86
SSM	2.3 (0.89 – 5.7)	0.09
Breast weight (grams)	1.001 (0.99 – 1.001)**	0.70

Table 7. Multivariable logistic regression model predicting explantation within 60 days of surgery

Variable	OR (95% CI)	p-value
Questionable SPY	7.4 (0.37 – 146.2)	0.19
Areas Excised SPY	0.94 (0.06 – 15.7)	0.97
SSM	1.5 (0.09 – 24.5)	0.79
Breast weight (gm)	1.0 (0.991 – 1.003)**	0.83

Table 8. Multivariable logistic regression model predicting any complication within 60 days of surgery.

Variable	OR (95% CI)	p-value
Change in reconstruction	4.5 (1.4 – 14.9)	**<0.05***
Questionable SPY	4.4 (1.6 - 12.1)	**<0.01***
Bad SPY	0.82 (0.19 – 3.5)	0.79
Areas Excised SPY	1.2 (0.56 – 2.7)	0.61
Smoker	1.3 (0.44 – 3.7)	0.66
Obesity	2.1 (0.87 – 4.9)	0.10
SSM	1.7 (0.74 – 3.7)	0.22
Breast weight (gm)	1.000 (0.999 – 1.001)**	0.87

* = significant, p < 0.05

** = 3 decimal places needed to accurately show OR and CI

OR = odds ratio

CI = confidence interval

SSM – skin sparing mastectomy, ALND - axillary lymph node dissection

Discussion

To date, this has been the first study describing how SPY angiography impacts intraoperative decision making with respect to reconstruction after mastectomy. In this study, nearly 20% of patients underwent excision of compromised tissue and 16% had a change in reconstruction due to findings on SPY angiography (Table 1). Our study also found that SPY results strongly affected the plastic surgeon's intraoperative decision making, where 100% of 'bad' SPY results resulted in a change in type of reconstruction and 40% in the 'questionable' SPY group (Table 1). Furthermore, a change in reconstruction type was predictive of infection, seroma, and any complication, while established risk factors such as smoking and obesity increased risk of necrosis and infection. Interestingly, 'questionable' SPY results were an independent risk factor for postoperative necrosis and other complications while 'bad' results were not.

Studies have shown that Immediate Breast Reconstruction (IBR) has increased complication rates compared to delayed reconstruction with flap necrosis being reported as the most common complication [8–10]. Flap necrosis rates after IBR have been noted to range anywhere from 3.8% up to 42% [8,9,11]. However, morbidity rates for IBR have decreased over time even with nipple sparing technique [12]. This improvement is likely multifactorial and has been largely attributed to increased surgeon experience and technique modification. Our study found a necrosis complication rate of 8.9% for all patients undergoing mastectomy with reconstruction, which is consistent with prior studies [8,9,11]. While preoperative risk factors for complications have been well studied, the intraoperative evaluation for necrosis with SPY angiography is the next potential area of intervention to reduce morbidity [13].

Our study found that 15.7% of breasts with planned IBR ultimately underwent a change in reconstruction intraoperatively based on SPY results either by undergoing TE placement rather than implant, TE with less volume, or no reconstruction at all. While patients who had a change in reconstruction were at increased risk of a complication on univariate analysis, our study also shows that patients who are smokers or had a 'questionable' SPY result are at greater risk for necrosis on multivariate analysis (Table 4). Smoking has been established as a known independent risk factor for skin and flap necrosis [7,10,13]. This was seen within our patient population as well and stresses the importance of SPY for these smokers who undergo IBR. Those patients with a 'questionable' SPY were more likely to have necrosis compared to those with a 'good' result, while those with a 'bad' or 'had areas excised' result were not. This is likely because excision of skin for a 'questionable' spy was not performed. This confirms the utility of SPY intraoperatively in identifying ischemic areas that can be excised in order to reduce postoperative complications and suggests that a more aggressive approach for 'questionable' areas should be taken. After multivariable analysis, patients with SPY results that were not clearly identified as "under-perfused/bad" or "well-perfused/good" were at the greatest risk for necrosis complications.

The objective methods by which SPY can be reported have varied in the literature, with studies investigating anatomic blood flow patterns and the quantitative measurements of perfusion including intensity of fluorescence (also known as absolute perfusion or relative perfusion.) [3,5,14] These studies were limited by small sample size, and because SPY angiography is an "instantaneous index of perfusion" it can be impacted by variations in blood pressure or possibly during the operation [1,3,4,5,14]. In addition, because images are black and white with shades of gray defining areas of perfusion, SPY angiography may be subject to user interpretation and operator experience.[6] Overall, most studies have made a consensus that SPY should be used in conjunction with clinical assessment to assess perfusion [3–6,14]. Our study confirms SPY is helpful in assessing flap perfusion but there continues to be a need for standardization of perfusion measurements. While 100% of patients with a 'bad' SPY result underwent a downgrade in reconstruction, only 40% of those with a 'questionable' SPY result had a change, suggesting that surgeons should be more vigilant in downgrading reconstruction options, delaying reconstruction for patients, or excising areas of skin that are compromised with a questionable SPY result. This is further supported by the finding that intraoperative change in reconstruction was not an independent risk factor for necrosis (Table 4).

Obesity is another known risk factor for postoperative complications [10]. In this study, obesity and a change in reconstruction were independent risk factors for infection. Those who underwent a change in reconstruction were at higher risk for infection as well as seroma formation (Table 4, Table 5). The increased risk of infection in those who underwent a change in reconstruction may have been related to ischemia or necrosis while the increased risk for seroma formation may have been due to placement of a TE with minimal expansion instead of placement of an implant.

SPY angiography continues to be an important adjunct in assessing tissue perfusion and can guide intraoperative decision making including excision of ischemic tissue and change in reconstruction options. While changing reconstruction may result in increased seroma formation, it may reduce other complications when there is indeterminate or 'questionable' SPY imaging result. There are multiple limitations to our study. The single institution and retrospective nature of our study are limitations as well as the small sample size. As with many other studies, the subjective nature of a SPY result interpretation by the surgeon continues to be present. Since SPY was introduced at our institution in 2014, operator experience may have affected our study as other studies have demonstrated that there is a learning curve for surgeons [6]. In addition, long term and oncologic outcomes were not assessed. Further prospective studies using a standardized measurement to assess tissue perfusion with SPY angiography are needed.

Conclusions

SPY angiography can influence intraoperative decision making for reconstruction, and whether direct to implant reconstruction is possible or expanders are necessary. The patients who were at greatest risk for flap necrosis or other complications in this study were those with 'questionable' SPY results as interpreted by the surgeon. Further studies are needed using a SPY angiography standardized perfusion measurement to identify patients who are at risk for post-mastectomy complications.

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