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### IDENTIFYING RISK FACTORS FOR DEVELOPING POST-OPERATIVE COMPLICATIONS AFTER BREAST RECONSTRUCTION SURGERY IN BREAST CANCER PATIENTS

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IDENTIFYING RISK FACTORS FOR DEVELOPING POST-OPERATIVE  
COMPLICATIONS AFTER BREAST RECONSTRUCTION SURGERY IN BREAST  
CANCER PATIENTS

A Scholarly Project Submitted to the Graduate School  
in Partial Fulfillment of the Requirements  
for the Degree of  
Doctor of Nursing Practice

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Pittsburg, Kansas

May 2020

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# IDENTIFYING RISK FACTORS FOR DEVELOPING POST-OPERATIVE COMPLICATIONS AFTER BREAST RECONSTRUCTION SURGERY IN BREAST CANCER PATIENTS

An Abstract of the Scholarly Project by  
Kelsey Akin

The purpose of this project was to identify risk factors for the development of post-operative complications in breast cancer patients after breast reconstruction surgery. The author first identified possible risk factors through a literature review and evaluated a current risk assessment tool being used in current practice. A retrospective chart review was conducted of fifty charts of patients who underwent a mastectomy and breast reconstruction surgery for the treatment of breast cancer. The author compared possible risk factors from the groups of patients who developed complications versus those who did not. The author found two possible relationships between two identified possible risk factors (pre-operative breast size and body mass index) and the loss of reconstruction. The author also found the current risk assessment tool to be a valuable asset in the possible identification of individuals at risk for the development of post-operative complications after breast reconstruction surgery.

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## **CHAPTER I**

### **Introduction**

#### **Description of the Clinical Problem**

Breast cancer is the most common cancer diagnosis for women in both developing and developed countries. It is estimated that approximately 12% of women will develop breast cancer, and approximately 2.9 million women are currently living in the United States with breast cancer (Fraser, Nickel, Fox, Margenthaler, & Olsen, 2016). Surgical treatment options include breast-conserving surgery, such as a lumpectomy, and a mastectomy, which is the total removal of a breast. Studies have shown that although breast-conserving surgery is an appropriate treatment choice for women with early-stage breast cancer, more women are electing to have a mastectomy (Yoon et al., 2018). The rate of women choosing mastectomy for cancer treatment or prophylaxis has been rising for many years (Wilkins et al., 2018). According to Turk and Yilmaz (2018), "mastectomy has a deep and stable negative impact on a woman because, mastectomy as a treatment option, can result in a sense of mutilation and diminished self-worth and may threaten perceptions of femininity" (p. 205). A woman's quality of life can decrease following a mastectomy due to this diminished sense of self-worth and femininity. However, other studies have shown that some of her quality of life may be recovered following a breast reconstruction (Kato et al., 2015). Approximately half of the women



in the United States who undergo a mastectomy will be given the option of a breast reconstruction (Liu, 2017).

Breast reconstruction surgery can greatly improve one's view of themselves, but there are potential complications. Reported complication rates for expander/implant reconstructions range from 18 to 51% and 32 to 43% percent for flap/autologous reconstructions when considering both short-term and long-term complications (Gopie et al., 2011). These post-operative complications can have devastating effects on patients and increase overall healthcare costs. According to Nickel, Fox, Margenthaler, Wallace, Fraser, and Olsen (2016), "Wound complications following breast surgical procedures, including surgical site infections (SSIs) and non-infectious wound complications (NIWCs), result in increased morbidity as well as increased healthcare utilization and costs" (p. 844). These complications include infection, hematomas, necrosis, and implant failure.

Physiological complications not only cause pain and suffering but can lead to psychological distress. It has been found that women who suffered complications following their reconstructions reported higher levels of both depression and anxiety compared to those who did not experience any complications (Gopie et al., 2011). Many women also experience increased body image disturbance and report difficulty with sexual intimacy (Teo et al., 2016).

If breast reconstruction surgery is intended to help women reclaim some of their lost quality of life but carries a significant risk for post-operative complications, it leads to the question of its worth. When the surgery is successful without any adverse events, women have reported a decrease in their anxiety and cancer burden and begin to feel

better about their physical appearance. If the rate of post-operative complications could be reduced, perhaps more breast cancer patients could begin to feel the same relief and improve their quality of life. One way to begin to reduce post-operative complications is by identifying risk factors for these complications in patients. There is limited research identifying possible risk factors in patients that may lead to the development of post-operative complications after breast reconstruction surgery. Further research is needed to identify other potential risk factors. There is also a need for more education on the prevention of post-operative complications in these patients.

### **Target Population**

Breast cancer patients often carry more risk for complications after breast reconstruction surgery compared to patients who elected to have a prophylactic mastectomy due to the burden of disease and adjuvant therapies such as chemotherapy and radiation. For this project, the target population included women who have had a mastectomy for the treatment of breast cancer and those who have had a contralateral prophylactic mastectomy concurrently with their cancer surgery. Patients who have elected to have a prophylactic surgery for positive genetic testing were not included in the target population. According to Boustany, Elmaraghi, Agochukwu, Cloyd, Dugan, and Rinker (2018), "Implant infection following breast reconstruction is not an uncommon event; rates cited in the literature range from 2.5% to 16.5%...Implant infection following breast augmentation is much less common with rates of 1%-2%" (p. 7). Patients with adjuvant radiotherapy are twice as likely to have a wound complication following an immediate breast reconstruction (Olsen, Nickel, & Fox, 2017). The timing of reconstruction and any adverse events can determine the initiation of any adjuvant

therapies. One study showed that breast cancer patients who experienced complications after breast reconstruction surgery typically start chemotherapy or radiation two to three weeks later than patients who do not experience any post-operative complications (Olsen, Nickel, & Fox, 2017).

### **Significance**

Nurses are taught to care for the whole person, not just the disease process. This holistic approach to nursing promotes patient-centered care and produces better patient-reported outcomes. As the nurse is caring for the patient's physiological needs, it is important to address the psychosocial effects of the disease process. According to Mooney, Whisenant, and Sjoberg (2017), "Improving cancer outcomes requires a focus not only on the tumor but also the illness experience and its impact on patients and their families" (para. 2). Nurses must act as advocates for their patient to ensure safe care and a positive experience during their course of treatment. This project embodies this type of nursing as it was focused on decreasing post-operative complications by identifying risk factors to help patients achieve a better quality of life post mastectomy and breast reconstruction surgery. This was to be accomplished by identifying possible risk factors associated with the development of post-operative complications to potentially provide intervention prior to any adverse events. This will allow for better patient outcomes and better patient outcomes create a positive clinical environment for patients and nurses.

### **Purpose**

The purpose of this DNP scholarly project was to investigate the relationship between post-operative complications following breast reconstruction surgery in breast cancer patients and specific variables associated with the development of these

complications. Specific variables were identified through a literature view and the examination of a current risk assessment tool, the Breast Reconstruction Risk Assessment (BRA) score. If additional variables have identified as possible risk factors that are not included in the BRA score, a revised risk assessment tool would have been created. This revised risk assessment tool would have been compared with the BRA score to assess for efficacy. The breast reconstruction surgery is aimed at improving aesthetic appearance and to help regain the quality of life lost following a mastectomy (Kato et al., 2015). Breast surgery is considered a “clean” surgery. Clean surgeries typically only carry a surgical-site infection rate of 1% to 2%, but breast reconstruction surgery often carries a much higher infection rate (Fraser, Nickel, Fox, Margenthaler, & Olsen, 2016). Post-operative complications can cause psychological distress and decrease the quality of life of these patients. Women who experience post-operative complications often experience increased anxiety and depression compared to those who do not experience any complications (Timman et al., 2017). By decreasing post-operative complications through risk factor identification, the researcher hoped to improve the quality of life for these patients by reducing the rates of post-operative infections. In the literature review of this project, different types of post-operative complications were defined. The aim was to investigate how possible variables could be risk factors associated with the development of post-operative complication after breast reconstruction surgery in breast cancer patients. This was accomplished by performing a retrospective chart review to identify specific patient variables and investigate possible correlational relationships. The intention of this project was to increase knowledge and awareness of this problem and provide education for clinicians and patients by providing an educational presentation to

breast cancer specialists in the area. This project also examined how to potentially reduce these complications in the future through screening patients for the risk factors pre-operatively.

### **Theoretical Framework**

This DNP Scholarly Project was based upon Jean Watson's philosophy and theory of transpersonal caring. Watson's theory brings together the science and humanity of nursing. She used the word *nurse* as both a noun and a verb. Watson believed that the nurse should transcend the traditional definition of "nurse" and care for the patient on a professional, emotional, and spiritual level. She asserted that as the nurse grows professional and personally, a deeper level of healing can be achieved (Petiprin, 2016).

According to Petiprin (2016), the major assumptions of this theory are as follows:

- Caring can be effectively demonstrated and practiced only interpersonally.
- Caring consists of carative factors that result in the satisfaction of certain human needs.
- Effective caring promotes health and individual or family growth.
- Caring responses accept the patient as they are now, as well as what he or she may become.
- A caring environment is one that offers the development of potential while allowing the patient to choose the best action for him or herself at a given point in time.
- A science of caring is complementary to the science of curing.
- The practice of caring is central to nursing.

Watson also believed that a nurse's own life experiences and history can help them develop an empathy for others and a passion for caring (Alligood, 2014). These assumptions created by Watson help create a solid foundation on which this project was built. This theory worked well with this topic as it not only explores the physiological suffering of these patients but also the psychological suffering as well. These patients need clinicians who can care for them on multiple levels, not just the physical level.

### **Practice Problems**

The following questions were addressed in this project:

- Is there a correlation between specific patient variables and the development of post-operative complications after breast reconstruction surgery in breast cancer patients? These variables include cardiac history, clotting risk factors, body mass index, post-operative drain use, smoking history, age, type one and type two diabetes mellitus, adjuvant therapies, pre-operative breast size, surgeon experience, hypertension, and immediate versus delayed breast reconstruction.
- Would a revised risk assessment tool be a better prediction than the BRA score of the development of a post-operative complication following breast reconstruction surgery in the pre-operative period?

### **Definition of Key Terms**

***Mastectomy:*** Complete removal of all breast tissue (Fraser et al., 2016).

***Breast reconstruction surgery:*** Surgical reconstruction of the breast (Fraser et al., 2016).

***Immediate breast reconstruction:*** reconstruction carried out at the same time as mastectomy (Yoon et al., 2018).

***Delayed breast reconstruction:*** reconstruction carried out weeks to years after mastectomy (Yoon et al., 2018).

***Surgical site infections (SSI):*** an infection that occurs at the site of surgery (CDC, 2012).

***Non-infectious wound complications (NIWC):*** any complication that occurs without an infectious source (Fraser et al., 2016).

***Early complications:*** Any adverse event which occurs within 30 days of surgery (Sinha et al., 2017).

***Late complications:*** Any adverse event which occurs after 30 days of surgery (Sinha et al., 2017).

***Psychological distress:*** A concept that encompasses the terms of anxiety, depression, and disease distress (Timman et al., 2017).

***Quality of life:*** One's perception of their overall health, satisfaction, and general well-being (Post, 2014).

***Risk factors:*** Something which increases risk (Merriman-Webster Dictionary, 2019).

***Screening:*** A process to evaluate for the potential presence of a problem (World Health Organization, 2019).

### **Logic Model of the Proposed DNP Project**

A logic model was created for this scholarly project to demonstrate the relationships among the inputs, outputs, and outcomes in Figure 1-1. Short-term outcomes of the project include identification of pre-operative risk factors, evaluation of the BRA score, and increased knowledge and awareness of the clinical problem. These short-term outcomes will lead to the medium- and long-term goals. The medium-term outcomes include developing an educational presentation for breast cancer specialists and promoting the need for change in practice. The short- and medium-term outcomes will hopefully lead to the long-term outcomes. The long-term outcomes include better patient reported outcomes and improved quality of life. The long-term outcomes will only be

achieved if post-operative complications can be reduced. This is a significant and ambitious goal.

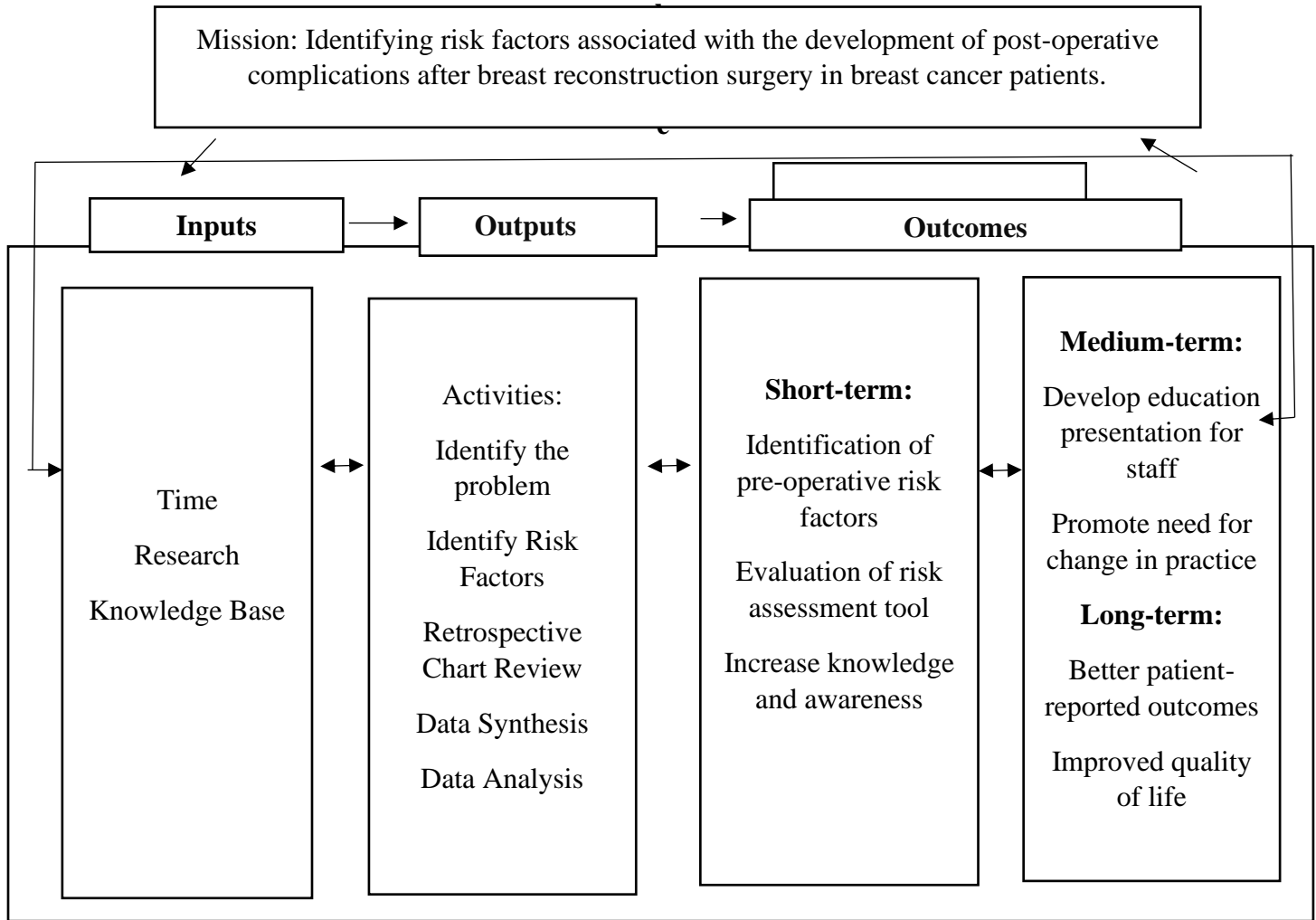


Figure 1-1

### Summary

Breast reconstruction is meant to help patients regain some of their lost quality of life following a mastectomy, but it can carry significant risks. Surgical-site infections and non-infectious wound complications following breast reconstruction surgery can have devastating effects on breast cancer patients that increase psychological distress and physiological pain. These complications can also cause an increase in healthcare use, costs, and patient morbidity. This negatively affects healthcare facilities and patients.



Breast cancer patients already carry the burden of their disease and course of treatment. When post-operative complications occur, this significantly increases their burden and can have significant psychosocial ramifications. The primary aim of this project was to identify the specific factors associated with the development of post-operative complications after breast reconstruction in breast cancer patients. The second aim of this project was to investigate if a screening tool may assist with reducing post-operative complications in breast cancer patients who are undergoing breast reconstruction surgery. Finally, the third aim of the project was to provide education to clinicians on how to reduce these post-operative complications in the target population through screening for the risk factors identified and intervening when appropriate.

## **CHAPTER II**

### **Literature Review**

This literature review will first give a brief overview of the complications that can potentially follow a breast reconstruction surgery. It will also address risk factors that have been identified by the authors as potential indicators for these complications. This literature review will also identify a risk assessment tool in current use.

#### **Description of the Phenomenon & Prevalence**

Breast cancer is the most common cancer for women in the world (“Breast Cancer Burden,” 2018). The American Cancer Society estimated that there would be 266,120 new cases of invasive breast cancer and 66,960 new cases of carcinoma in situ diagnosed in the United States in 2018 (“How Common Is Breast Cancer,” 2018). Many of these women would choose a mastectomy as their treatment of choice; approximately half of them will be given a choice of breast reconstruction surgery (Liu, 2017). According to the American Society of Plastic Surgeons (2018), breast reconstruction is “achieved through several plastic surgery techniques that attempt to restore a breast to near normal shape, appearance and size following mastectomy” (para. 1). This surgery can be immediate or delayed. An immediate breast reconstruction is completed at the same time as a mastectomy. Conversely, a delayed breast reconstruction is performed months or years following a mastectomy (“When Is Breast Reconstruction Done,” 2016). There are

two methods of reconstructions: expander/implant and flap/autologous (“What Is Breast Reconstruction,” 2018). Understanding the different types of breast reconstruction surgeries is important for this literature review as many of these studies reference specific types of surgeries. These types of surgery include the widely popular expander/implant method and autologous flap reconstruction. An expander/implant reconstruction is often a staged approach to the reconstruction. Initially, the surgeon places an expander under the skin where the breast tissue was removed. This allows the skin to stretch slowly to allow a permanent implant to be placed at a later surgery. If there is enough skin after the mastectomy, a surgeon may be able to place a permanent implant rather than an expander. This is a single stage immediate implant breast reconstruction (“Implant reconstruction,” 2019). An autologous flap reconstruction is using tissue from the patient’s body to create the breast form. The most common sites of tissue harvest include the abdomen, back, thighs, and buttocks (“Autologous or flap,” 2019).

Breast reconstruction surgery can greatly improve one’s view of oneself, but there are potential complications. Reported post-operative complication rates for expander/implant reconstructions range from 18% to 51% and the rates from flap/autologous range from 32% to 43% (Gopie et al., 2011). Those numbers are only for the physiological complications. These short-term complications include infection, seromas, hematomas, and wound dehiscence. Some of these short-term complications can become a long-term complication like a permanent loss of sensation (Lagergren, Wickman, & Hansson, 2010). In the long-term, some women require revision surgery after experiencing implant rupture, fat necrosis, or severe infection. It is possible to completely lose one’s reconstructed breast. There are also psychological effects of

having part of your body removed and rebuilt. Risk factors, such as diabetes, body mass index, and smoking status, have been identified for this review. The Breast Reconstruction Risk Assessment (BRA) score is a risk assessment tool, created by a group of institute researchers, being used in current practice to help identify potential predictors of post-operative complications (“Breast reconstruction risk score,” 2019). It is available online and an open-access tool. This risk assessment tool was examined in this literature review. The risk assessment questions for the BRA score are listed in Appendix A.

### **Purpose**

The purpose of this literature review was to identify risk factors associated with the development of post-operative complications following breast reconstruction. Identifying a risk assessment tool in current use was also a purpose of this literature review.

The research search questions for this literature review are as follows:

1. What are the post-operative complications and their prevalence following breast reconstruction surgery?
2. What are the common risk factors for developing these complications?
3. What risk assessment tools are currently used in clinical practice?

### **Post-Operative Complications**

Immediate complications following breast reconstruction are considered to happen within the first year of surgery and the most common of these are infection, seroma, wound dehiscence, and hematoma. An early short-term complication is defined as any adverse event that occurs within thirty days of surgery. A late short-term

complication is defined as any adverse event which occurs after thirty days of surgery (Sinha et al., 2017). A retrospective study done in Denmark of 189 women who had an immediate reconstruction without radiation therapy found the risk for a complication in the first year postoperatively to be 52.4% (Hvilsom et al, 2011). Of the 189 women, 19% had an infection, 11.1% had a hematoma, and 12.2% had a seroma within the first year of their surgery (Hvilsom et al, 2011). A retrospective chart study of 4,439 women who had immediate reconstructive surgery in the United States were found to have an overall complication rate of 15.9% (Kim et al, 2015). The researchers continue to break these cases into specific subcategories of complication prevalence rates which were as follows: infection (4.0%), seroma (3.4%), and wound dehiscence (6.1%) (Kim et al, 2015). Another retrospective chart review study was performed in the United States of 312 women who underwent a breast reconstruction, either immediate or delayed, without or without radiation therapy, with a result of an infection rate of 3.2% (Leyngold et al., 2012). The authors indicate that they gave a vastly different definition of “infection” than their predecessors with much narrow parameters which resulted in a much lower infection rate.

Two studies compared the complication rates of patients who underwent a mastectomy without reconstruction and with reconstruction, either implant or autologous. One study used a retrospective cohort design to study 180,085 cases from a database from seven-year span (Olsen et al, 2016). This study compared surgical site infections over 180 days in four categories of women: mastectomy without reconstruction, mastectomy with immediate implant reconstruction, mastectomy with immediate flap reconstruction, and mastectomy with immediate implant and flap reconstruction. The

overall infection rate for the cases after 180 days was 8.1%. After 180 days, the infection rate for women who had a mastectomy with reconstruction was 5%. Women who had an implant reconstruction, flap reconstruction, and implant/flap combination reconstruction had infection rates of 10.3%, 10.7%, and 10.3%, respectively (Olsen et al., 2016). The authors concluded that women who have an immediate reconstruction are twice as likely to get a surgical site infection (Olsen et al, 2016). The second study was conducted by using an insurance company's database and 14,894 cases from a ten-year period were studied. This study concluded that in the first two years post-operatively, women without a reconstruction had a 2.3% rate of "wound complications" in comparison to 4.4% and 9.5% of women with implant reconstructions and autologous reconstructions, respectively (Jagsi et al, 2017). In the first two years following surgery, it was found the infection rate was 12.7% in women who had a mastectomy without reconstruction. In the same time period, the infection rate for women who had an autologous implant after mastectomy was 20.7%. For women who had an implant reconstruction after mastectomy, the infection rate was 20.5% after two years (Jagsi et al., 2017).

The most significant and devastating long-term complication is the removal, replacement, or loss of reconstruction. This complication requires a reoperation, which can lead to more acute complications and anxiety. This typically occurs years following the initial operation, but it can also occur within the first two years. Jagsi et al. (2017) examined implant removal and fat necrosis in women who underwent mastectomies with and without reconstruction. This study concluded within the first two years post-operatively implant removal occurred in 24.7% of women who had an implant reconstruction. It also concluded fat necrosis occurred in 15.7% of flap reconstruction

cases (Jagsi et al, 2017). These complications would have resulted in reoperation and loss of their reconstructions. A retrospective study from Denmark examined 145 cases of immediate reconstruction for late complications (Stralman, Mollerup, Kristoffersen, & Elberg, 2008). It was found that approximately 27% of women required a reoperation for implant rupture, fat necrosis, capsular contracture, implant displacement, or another indication for revision surgery. It was also concluded that women with implant reconstruction were more likely to have a late complication than women with flap/autologous reconstructions (Stralman, Mollerup, Kristoffersen, & Elberg, 2008).

There were two pieces of literature reviewed that studied how radiation therapy post-operatively affected complication rates long-term. One study reviewed the chart of 151 women who had two-stage expander/implant reconstruction surgery and radiation therapy post-operatively. At the seven-year follow up, it was found that 17.1% of the cases required implant replacement and 13.3% required implant removal (Ho et al, 2011). The indications for the replacements and removal included implant extrusion, shift, leak, and rupture (Ho et al, 2011). The other study was a retrospective study conducted in Salt Lake City, Utah of 157 cases of women who underwent a mastectomy with a two-stage expander/implant reconstruction and post-operative radiation therapy. The mean follow-up time for long-term complications was 44 months for these cases (Anker et al, 2015). The result was 22% of the patients required implant removal, which the authors noted was in accordance with previous studies (Anker et al, 2015). Radiation therapy post-operatively has been shown to increase the risk of implant explanation and removal long-term.

Breast reconstruction surgery cannot only produce physiological complications, but psychological ones as well. One study sent questionnaires to 71 women who were scheduled for a reconstruction and their pre-operative and post-operative anxiety and depression was measured using the Hospital Anxiety and Depression Scale (Gopie et al, 2011). It was found that women who suffered complications following their reconstructions reported higher levels of both depression and anxiety than their counterparts that did not have complications (Gopie et al, 2011).

### **Risk Factors for Complications**

Identifying risk factors for infections and other complications is important for reducing future complications and identifying at risk populations. Multiple studies have identified these risk factors and some studies are dedicated solely to identifying risk factors or creating tools for risk scoring. One such study was able to identify multiple risk factors during the tissue expansion phase of a tissue/implant reconstruction. These risk factors include diabetes, large expander size (>400 mL), repeated expander insertion, pre-operative chemotherapy, and nipple-sparing mastectomies (Kato et al., 2013). Leyngold et al. (2012) identified diabetes and immediate reconstruction as risk factors that may contribute to infections in implant reconstructions. A study by Jonczyk et al. (2019) found non-diabetics reduce their odds of having post-operative infections by 41% and complications by 40%. It was also found diabetics on oral therapy have 25% fewer complications than those on insulin therapy. Smoking has been associated with many short-term complications, such as infection and skin necrosis (Thorarinsson et al., 2017). A study of the effects of smoking on scar healing after mammoplasty reduction found smokers have a post-operative complication incidence rate of 40% compared to non-



smokers (Deliaert et al., 2012). Breast size, as measured by grams post-mastectomy, has shown to be a significant risk factor for post-operative complications, specifically greater than 600 g (Negenborn et al., 2018). According to Voineskos et al. (2015), “large pre-operative breast size, a cup size of D or larger, may be associated with an increased risk of complication and an increased risk of reconstructive failure.” An elevated BMI has been shown to drastically increase the risk for infection. According to Boustany et al. (2018), “a one unit increase in BMI was associated with a 6.3% increase in the odds of an implant infection” (p. 10). Huo et al. (2016) found obese patients had higher rates of infectious and wound complications with TE/implant-based reconstruction than non-obese patients. According to Chang et al. (2017), “high BMI is associated with microvascular dysfunction and may contribute to reduced perfusion in the mastectomy skin flap, leading to further complications” (para. 14). Voineskos et al. (2015) stated that patients aged 65 years and older have an increased risk for pre-operative complications. A study by Boustany et al. found there was a significant correlational relationship to be found between the use of drains postoperative and infection. Another study found the odds of infection increased 76.2% with each additional week a post-operative drain is in place (Chen et al., 2016). Radiation therapy post-operatively has been shown to increase long-term complications in implant reconstructions (Anker et al, 2015). Voineskos et al. (2015) found radiation therapy, regardless of its timing, can lead to post-operative complications and reconstruction failure.

### **Risk Assessment Tool**

The Breast Reconstruction Risk Assessment (BRA) score is a risk calculator for potential outcomes in breast reconstruction surgery (Khavanin et al., 2014). It was

developed using the National Surgical Quality Improvement program. The BRA score uses patient variables to assess the risk of post-operative complications in breast reconstruction surgery (Kim et al., 2015). The variables used to calculate risk include height, age, weight, cardiac history, smoking history, bleeding risks, and any adjuvant therapies (“Breast Reconstruction Risk Score,” 2019). In one external validation study, “the BRA Score tissue expander/implant reconstruction models performed with generally good calibration, discrimination, and accuracy” (Khavanin et al., 2017, para. 4). One limitation identified with the BRA score is lack of specific variables which have been identified as increasing the risk of post-operative complications. These variables include surgeon experience, mastectomy type, and timing of reconstruction (Kim et al., 2015). This has been identified as a gap in literature. These patient variables need to be examined for a possible correlational relationship to the development of post-operative complications. If a correlational relationship exists, the variables should be added to a risk assessment tool for a more comprehensive screening.

## **Summary**

Breast cancer patients who have had a mastectomy and breast reconstruction surgery have suffered enough devastating news, physiological pain, and psychological trauma without having to endure a complication after breast reconstruction. The purpose of this literature review was to identify and examine these complications and the risk factors for these complications. The risk assessment tool currently being used in practice was also identified and examined.

## **CHAPTER III**

### **Methodology**

#### **Project Design**

This Doctor of Nursing Practice (DNP) Scholarly Project used a research design approach using a retrospective chart review. This scholarly project used a quantitative and correlational design method. This approach is driven by answering a clinical question. According to Moran, Burson, and Conrad (2017), research correlational projects can “be used to assess behaviors of healthcare professionals, patients, communities, and systems or to provide baseline data that can be used to drive practice improvements” (p. 352). A retrospective chart review design was chosen because it is efficient and uses patient-centered data. This approach allowed the researcher to review past medical charts of patients to determine if there is a correlational relationship between the selected variables and the development of post-operative complications. This helped answer the research questions being proposed by this project. The research questions answered in this project were:

- Is there a correlation between specific patient variables and the development of post-operative complications after breast reconstruction surgery in breast cancer patients?
  - These patient variables include:

- Body mass index
  - Post-operative drain use
  - Pre-operative breast size
  - Smoking history
  - Age
  - Type 1 and Type 2 Diabetes mellitus
  - Adjuvant therapies, including chemotherapy and radiation
  - Years of surgeon experience
  - Hypertension
  - Cardiac History
  - Clotting risk factors
  - Immediate versus delayed breast reconstruction
- Would a revised risk assessment tool be a better prediction than the BRA score of the development of a post-operative complication following breast reconstruction surgery in the pre-operative period?

### **Sample/Target Population**

The target population for this project was breast cancer patients who have breast reconstruction surgery after mastectomy. This population could be found in a surgeon's office and a medical facility that provides these surgical procedures. This project used a retrospective chart review study design. The medical charts of the sample were chosen and reviewed based on the inclusion criteria. A sample size of fifty patient charts was utilized for this study.

### ***Inclusion/Exclusion Criteria***

The inclusion criteria for this project includes women, aged 18 years or older, with a confirmatory diagnosis of cancer of the breast. The patients must have had a mastectomy and breast reconstruction surgery, either immediate or delayed. The timing of breast reconstruction surgery, immediate versus delayed, will be noted in the patient chart. Women who have had a prophylactic surgery for a positive genetic screening and/or family history of breast cancer were excluded from this project. A woman who has had a prophylactic contralateral mastectomy may be included if a mastectomy of the cancer affected breast is being performed concurrently.

### ***Institutional Review Board***

Permission to perform this study was obtained from the Institutional Review Board (IRB) from School of Nursing at Pittsburg State University, Pittsburg State University, and the medical facility where the study occurred. The necessary paperwork was turned into the IRBs for review prior to initiating the study. An exemption for research involving human studies and informed consent waiver was also submitted.

### ***Instruments***

This DNP scholarly project uses hypotheses to drive the project. These hypotheses helped the researcher to identify if any correlational relationships exist between the variables and the development of any post-operative complications. Many possible risk factors were identified by the literature review as variables for this study. These variables being measured include cardiac history, clotting risk factors, body mass index, hypertension, smoking history, age, diabetes mellitus, adjuvant therapies, and pre-operative breast size. The researcher has also identified additional variables of interest to

be studied through examining the Breast Reconstruction Risk Assessment (BRA) score. The variables used to calculate risk in the BRA score include pre-operative height, age, weight, cardiac history, smoking history, bleeding risks, and any adjuvant therapies (“Breast Reconstruction Risk Score,” 2019). However, there were additional variables identified as a gap in literature and were evaluated as possible risk factors. These include surgeon experience, post-operative drain use, and immediate versus delayed breast reconstruction.

### **Procedure**

A systematic review of the literature has been performed to identify possible risk factors associated with the development of post-operative complications. The appropriate paperwork was submitted to the IRBs of the university and participating facility. Upon approval from the IRBs, the researcher began identifying the participants for the study based on the inclusion criteria through a chart review. The researcher gave the inclusion criteria to the IT department at the medical facility and a database of medical charts was created. Two hundred twenty-four charts were identified between January 1, 2016 and December 31, 2017. The researcher then reviewed each chart to check for any exclusion criteria. Eighty-four charts were identified to fit the project’s criteria. Fifty charts were randomly chosen from this pool of identified charts using randomizing software. A form was made by the researcher that included each variable based on the variables identified from literature and the BRA score in addition to hypertension, surgeon experience, and timing of breast reconstruction (immediate versus delayed). Appendix A has a list of the assessment questions from the BRA score. Appendix B has the assessment questions for the additional variables not found in the BRA score. The form was filled out by the

researcher for each chart reviewed. Each chart was assigned a BRA score and a score from the revised assessment tool. These scores were compared for efficacy. The data collected in the forms were entered by the researcher in the IBM SPSS Statistics software program. The researcher then analyzed the data for any statistical differences in the groups who did and did not develop a post-operative complication for each variable. A report was completed by the researcher. The findings of this study and the risk assessment tool will be present to a group of breast specialists in southwest Missouri at a future date.

### **Treatment of Data**

The data was treated in a secure manner. Data was kept on a secure flash drive that only the researcher has access. The data will be kept securely at the School of Nursing for three years and then will be destroyed. The participants in the study, chosen by the researcher using the inclusion criteria, will be kept anonymous. Any identifying information about the charts being reviewed was kept out of the data to ensure anonymity and data security. Once the data has been collected, it was coded and entered appropriately. Each variable was analyzed for a possible correlation to post-operative complications. The data was analyzed using two sample t-tests in IBM SPSS.

### **Outcomes**

The primary outcome of this study was to identify risk factors in addition to the BRA score in patients that can lead to the development of post-operative complications after breast reconstruction surgery. The secondary outcome of this study was to determine if these patient variables are significant enough for a revision of the BRA score to help reduce post-operative complications.

## **Evaluation and Sustainability**

To evaluate the primary outcome of this study, each individual patient variable identified was analyzed for a possible correlational relationship for the development of post-operative complication. For the secondary outcome, the researcher analyzed the variables that were identified in a gap of literature (hypertension, immediate versus delayed breast reconstruction surgery, and surgeon experience) are considered risk factors. Based on the findings, the researcher plans to present the findings to a group of breast cancer specialists in southwest Missouri for educational purposes. The education provided will help providers to screen patients for risk factors pre-operatively to prevent post-operative complications. By decreasing post-operative complications, it will help increase the quality of life in these patients.



## **CHAPTER IV**

### **Evaluation Results**

#### **Introduction**

This DNP Scholarly Project had three main objectives. The first objective was to identify the specific factors associated with the development of post-operative complications after breast reconstruction in breast cancer patients. The second was to investigate if a screening tool may assist with reducing post-operative complications in breast cancer patients who are undergoing breast reconstruction surgery. Finally, the third was to educate clinicians on how to reduce these post-operative complications in the target population through screening for the risk factors identified and intervening when appropriate. There were also two research questions that the researched had hoped to answer during this project. These questions include:

- Is there a correlation between specific patient variables and the development of post-operative complications after breast reconstruction surgery in breast cancer patients?
  - These patient variables include:
    - Body mass index
    - Post-operative drain use
    - Pre-operative breast size

- Smoking history
  - Age
  - Type 1 and Type 2 Diabetes mellitus
  - Adjuvant therapies, including chemotherapy and radiation
  - Years of surgeon experience
  - Hypertension
  - Cardiac History
  - Clotting risk factors
  - Immediate versus delayed breast reconstruction
- Would a revised risk assessment tool be a better prediction than the BRA score of the development of a post-operative complication following breast reconstruction surgery in the pre-operative period?

### **Description of the Sample**

After receiving approval from Pittsburg State University and the medical facility, data collection began from the fifty cases randomly selected from the larger pool of medical charts created by the IT department at medical facility in Joplin, MO. The data collection process took approximately three weeks. The sample consisted of fifty female patients who had previously underwent a mastectomy and breast reconstruction surgery at the medical facility between January 1, 2016 and December 31, 2017. The ages of the participants range from 26 to 77 years old, with a mean age of 54.8 years. There was not any other demographic information collected on the participants.

## **Description of Key Variables**

There are multiple quasi-independent variables that were evaluated during this research project. The quasi-independent variables evaluated were as follows: body mass index, pre-operative breast size, smoking history, age, comorbidities, adjuvant therapies, cardiac history, clotting risk factors, and timing of breast reconstruction (immediate versus delayed). Many of these variables are a part of the BRA score and have already been established as risk factors for post-operative complications. Pre-operative breast size, body mass index, and timing of breast reconstruction were quasi-independent variables identified as possible risk factors not associated with the BRA Score. The researcher also identified post-operative drain use, surgeon experience, and type of diabetes mellitus as variables to be evaluated; however, these variables were not able to be evaluated due to lack of data. The date of the removal of post-operative drains was not recorded in the identified charts, making it impossible for the researcher to record how many days the drains were in use. There was only one reconstructive plastic surgeon performing breast reconstructions at the facility being studied, which made it impossible for the researcher to compare surgeon experience as a possible risk factor. Finally, there were not enough patients identified as diabetic to accurately predict if the type of diabetes mellitus may play a part in the development of post-operative complications in the patient population.

There were also multiple dependent variables being evaluated in this project. The first was the development of complications, whether within in 30 days of surgery (early) or after the first 30 days (late). Three of the fifty cases (6%) developed an early complication and twenty-one of the fifty cases (42%) developed a late complication. Of

the early complications, one was infection (2%), one was a hematoma (2%), and one was classified as “other” (2%). Of the late complication, the breakdown was as follows: six cases of infection (12%), one case of seroma (2%), one case of hematoma (2%), one case of wound dehiscence (2%), eleven cases capsular contracture (22%), and one case classified as “other” (2%). The infection rate of the studied population does correlate with previous studies that were reviewed. The study by Gopie et al. (2011) reported complication rates for expander/implant reconstructions range from 18 to 51%. The other two dependent variables studied included the need for a re-surgery and loss of reconstruction based on the development of complications. Twenty-two of the fifty cases (44%) required a re-surgery and eight of the fifty cases (16%) had a loss of reconstruction for any length of time. This number is higher than the data from a study that was reviewed by the researcher. It was found that approximately 27% of women required a reoperation for implant rupture, fat necrosis, capsular contracture, implant displacement, or another indication for revision surgery (Stralman, Mollerup, Kristoffersen, & Elberg, 2008). The higher number could possibly be contributed to the low sample size of this project.

## **Analyses of Project Questions**

### ***Research Question #1***

The first research question of this scholarly project was to determine if there was a possible correlational relationship among the variables. The correlational relationship between the quasi-independent variables in the BRA Score has already been previously established by the research used to create the tool. These variables are height, age, weight, cardiac history, smoking history, bleeding risks, and any adjuvant therapies

(“Breast Reconstruction Risk Score,” 2019). The data collected by this researcher did echo the same correlational relationships between those variables identified in the BRA score and the development of post-operative complications in the target population. There were three quasi-independent variables identified and evaluated by the researcher as possible risk factors for the development of post-operative complications in breast cancer patients undergoing breast reconstruction surgery. The researcher used a two-sample t-test to determine if there was significant difference between the groups of patients who did develop post-operative complications and the group of patients who did not develop any complications. These include pre-operative breast size, body mass index, and timing of reconstruction. These are not included in the BRA score questionnaire.

**Pre-operative breast size.** A two-sample t-test was used to compare the average pre-operative breast size of patients who did develop post-operative complications and those who did not. According to the data collected, patients who developed early and late complications had a higher average pre-operative breast size than those who did not develop a complication. The average pre-operative breast size for patient who did not develop an early complication was 611 grams versus the 800-gram average for those did develop an early complication. However, according to the data analysis, there was not a significant difference in the weights for those who developed an early complication ( $M=800$  g,  $SD=350$  g) and those who did not ( $M=611$  g,  $SD=240$  g);  $t(48)=-1.248$ ,  $p=0.205$ . For late complications, the average pre-operative breast size for those who did not develop a complication was 570 grams versus 701 grams for those who did develop complications. There was not a significant difference in the weights for those who developed a late complication ( $M=701.6$  g,  $SD=255.5$  g) and those who did not ( $M=$

570.5 g, SD= 227.7 g);  $t(48)=-1.909$ ,  $p = 0.602$ . Patients who required a re-surgery for their complication also had a higher pre-operative breast size than those who did not. The average pre-operative breast size for those who required a re-surgery was 703 grams versus 564 grams for those who did not require a re-surgery. There was not a significant difference in the weights for those who required a re-surgery (M= 703.8 g, SD=249.6 g) and those who did not (M= 564.1 g, SD= 229.2 g);  $t(47)=-2.058$ ,  $p = 0.45$ . There is significant difference in the weights for those who lost their reconstructed breast for any length of time (M= 887.5 g, SD=287.5 g) and those who did not (M= 575.7 g, SD= 205.7 g) conditions;  $t(47)=-3.683$ ,  $p = 0.001$ .

**Body Mass Index.** There was no difference in average body mass indexes (BMI) in patients who did and did not develop an early complication. There was not significant difference in the for the BMIs in those who developed an early complication (M= 30.3, SD=6.6) and those who did not (M= 30.9, SD= 7.9);  $t(48)=.139$ ,  $p = 0.890$ . There was a slight difference in the averages in the development of a late complication. However, there was not a significant difference in the BMI scores for those who developed a late complication (M= 31.7, SD=9.1) and those who did not (M= 30.1, SD= 6.8) conditions;  $t(48)=-0.730$ ,  $p = 0.469$ . There was a slight difference in the average BMI of those who required a re-surgery and those who did not, but there was not a significant difference in the BMI scores for those who required a re-surgery (M= 31.5, SD=8.9) and those who did not (M= 30.2, SD= 6.9);  $t(48)=-0.551$ ,  $p = 0.584$ . There was a significant difference in the BMI scores for those who lost their reconstructed breast for any length of time (M=39.4, SD=8.9) and those who did not (M= 29.1, SD= 6.5) conditions;  $t(48)=-3.873$ ,  $p < 0.000$ .

**Immediate versus Delayed Reconstruction.** Of the fifty cases, five patients had a delayed reconstruction (10%) and forty-five patients had an immediate reconstruction (90%). According to the two-sample t-tests, there was not a significant difference found between the development of a complication, requiring a re-surgery, or loss of the reconstructed breast and the timing of the breast reconstruction surgery. For the purpose of this study, a score of “1” was given to those patients with an immediate reconstruction and a score of “2” was given to those with a delayed reconstruction. There was not a significant difference in the scores for those who developed an early complication (M= 1.0, SD=0.0) and those who did not (M= 1.1, SD= 0.31);  $t(48)=.592$ ,  $p = 0.556$ . There was not a significant difference in the scores for those who developed a late complication (M= 1.04, SD=0.35) and those who did not (M= 1.14, SD= 0.22);  $t(48)=1.041$ ,  $p = 0.303$ . There was not significant difference in the scores for those who required a re-surgery (M= 1.05, SD=0.21) and those who did not (M= 1.14, SD= 0.36);  $t(48)=1.131$ ,  $p = 0.264$ . There was not a significant difference in the scores for those who lost their reconstructed breast for any length of time (M= 1.12, SD=0.35) and those who did not (M= 1.09, SD= 0.29);  $t(48)=-0.252$ ,  $p = 0.802$ .

### ***Research Question #2***

The second research question of this project was to determine if a revised risk assessment tool would be a better a predictor of the development of post-operative complications in the patient population studied. Although two significant differences were found between BMI and pre-operative breast size and the loss of the reconstructed breast for any length of time, the researcher did not feel as though the research was adequate to warrant creating a revised risk assessment tool. The researcher feels more

research would need to be done before it could be determined if a revised risk assessment tool would be a better predictor. However, the researcher did find the BRA score is an excellent predictor of long-term post-operative complications. Patients who had a late complication, required a re-surgery, or lost their reconstructed breast had significantly higher one-year BRA scores than those who did not.

### **Summary**

The purpose of this study was to identify possible risk factors for the development of complications in breast cancer patients having breast reconstruction surgery. The other purpose of this study was to determine if the current risk assessment tool used in practice, the BRA Score, should be revised to include new risk factors to be a better predictor of the development of post-operative complications. The researcher found BMI and pre-operative breast size could have a potential impact on the development of a post-operative complication. However, the researcher did not feel that these findings were significant enough to revise the current risk assessment tool.



## **CHAPTER V**

### **Discussion**

#### **Introduction**

The overall purpose of this project was to better predict the development of post-operative complications in breast cancer patients undergoing breast reconstruction surgery. Possible risk factors were evaluated for significant differences for developing complications. The research did show a possible relationship between body mass index and pre-operative breast size and the loss of the reconstructed breast, but there was not enough to evidence to validate a decision to add these variables to a revised risk assessment tool.

#### **Relationship of Outcomes to Research**

To answer the first question of the research project, the researcher used the literature review to identify a risk assessment tool in current practice (the BRA score) and any possible variables that could be risk factors. The researcher did find a possible relationship between increased BMI and pre-operative breast size and the development of post-operative complications in the cases studied. The researcher did not find a probable any significant differences between the timing of reconstruction as theorized. The researcher also found she was unable to find adequate data to study if surgeon

experience, post-operative drain use, and type of diabetes mellitus could be identified as a possible risk factor.

To answer the second question of the research project, the researcher sought to see if the BRA score should be revised to create a more comprehensive risk assessment tool to be a better predictor of the development of post-operative complications in the sample population. Although the researcher did find a possible causation relationship between two variables and the development of post-operative complications, the researcher does not feel as if the data collected is significant enough to revise the BRA score. The data collected did show the BRA score was a good predictor of the development in late complications in the sample population.

### **Observations**

The research in this project was interesting to the researcher as it brought to light how many complications are occurring in a local population. However, it was disappointing to not find as many significant differences as hoped or to find it necessary to create a revised risk assessment tool. Although, it was interesting to see how effective the BRA score could be if used in common practice.

### **Evaluation of Theoretical Framework**

This DNP Scholarly Project was based upon Jean Watson's philosophy and theory of transpersonal caring. Watson believed that the nurse should transcend the traditional definition of "nurse" and care for the patient on a professional, emotional, and spiritual level. She asserted that as the nurse grows professional and personally, a deeper level of healing can be achieved (Petiprin, 2016). This project tried to embody this theory in a few ways. First, the researcher used this project to grow professionally to be

able to better care for this patient population. This is a significant part of the theory. The motivation behind this project for the researcher was to create a better experience for breast cancer patients wanting breast reconstruction surgery through reducing post-operative complications. Although this was not the result of the project, the motivation embodied the theory in a desire to care for patients on more than just the physical level.

### **Evaluation of Logic Model**

A logic model was created at the beginning of this project to assess short-, medium-, and long-term outcomes. Short-term outcomes of the project included identification of pre-operative risk factors, evaluation of the BRA score, and increased knowledge and awareness of the clinical problem. These short-term outcomes were accomplished throughout the project. The logic model stated the short-term outcomes would lead to the medium- and long-term goals. The medium-term outcome was to develop an educational presentation for breast cancer specialists and to promote the need for change in practice. This has yet to be completed due to schedule constraints. The long-term outcome was to promote better patient outcomes and improve quality of life. The data collected in this project is not adequate to meet this long-term outcome, but perhaps it will be a stepping board to more research that can accomplish this goal.

### **Limitations**

There were multiple limitations to this project. The first is there was inadequate data about some of the variables that were identified as possible risk factors, including surgeon experience and post-operative drain use. There was only one reconstructive plastic surgeon who performed all the breast reconstruction surgeries studied, which meant surgeon experience could not be studied. Another limitation was the surgeon only

performed expander/implant reconstructions, so other types of reconstruction could not be studied. If these limitations did not exist, the outcome of the research could have been significantly different.

### **Implications for Future Research**

Although the research did not produce the outcome expected or desired by the researcher, it could be used for future studies. This study may produce significantly different results in a larger population with multiple surgeons and types of reconstruction. A study in a different facility could also produce data about post-operative drain use, which was unable to be studied in this sample population. If a larger study were able to find correlational relationships between the possible risk factors identified, perhaps the risk assessment tool would be revised to be comprehensive.

### **Implications for Practice**

The researcher did evaluate the effectiveness of the BRA score, which was found to be a good predictor of the development of late complications in the sample population. The researcher has not seen the BRA score utilized in current practice in the local area, but it would be a great tool to implement in the pre-operative process. Identifying patients at risk for developing post-operative complications could potentially spark changes in protocol that would reduce those post-operative complications.

### **Conclusion**

The purpose of this DNP scholarly project was to investigate the relationship between post-operative complications following breast reconstruction surgery in breast cancer patients and specific variables associated with the development of these complications. An additional purpose was to investigate if a revised risk assessment tool

would be a better predictor of the development of post-operative complications in the target population. Ultimately, the research did find possible significant differences between BMI and pre-operative breast size in the development of post-operative complications, but the researcher did not feel the outcome of the research was adequate to revise the current risk assessment tool. The researcher did find the BRA score (the current risk assessment tool) is a good predictor of the development of post-operative complications after breast reconstruction and should be incorporated into the pre-operative process in common practice. In the future, it is hoped more research will be conducted to identify risk factors and reduce post-operative complications in the target population.

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## **APPENDIX**

## Appendix A

### The Breast Reconstruction Risk Assessment (BRA) Score Questions

1. Age \_\_\_\_\_
2. Height \_\_\_\_\_ (inches)
3. Weight \_\_\_\_\_ (pounds)
4. Smoking status:
  - a. Never
  - b. Not within 1 year
  - c. Not within 30 days
  - d. Currently
5. History of
  - a. Vitamin K Deficiency
  - b. Thrombocytopenia
  - c. Hemophilia
  - d. Other Clotting disorder
6. Is the patient taking any of the following medications?
  - a. Coumadin, NSAIDs, or other anti-coagulants
  - b. If yes, can the patient stop it before surgery?
  - c. Chronic Aspirin therapy
  - d. Blood pressure medication
7. History of:
  - a. Balloon angioplasty
  - b. Stent placement
  - c. CABG

- d. Valve replacement
  - e. Pacemaker/defibrillation placement
  - f. Other major cardiac surgery
8. History of:
- a. Diabetes Mellitus
  - b. Coronary artery disease or peripheral vascular disease
  - c. Hypertension
  - d. Dyspnea
9. Pre-operative chemotherapy: Yes or No
10. Pre-operative radiation: Yes or No
11. Post-operative radiation: Yes or No
12. American Society of Anesthesiologists (ASA) physical score classification: \_\_\_\_\_

## Appendix B

### Additional Variable Questions

1. Body Mass Index: \_\_\_\_\_
2. Immediate or Delayed Reconstruction
3. Surgeon \_\_\_\_\_
4. Pre-operative breast size: \_\_\_\_\_ g
5. If diabetic, type 1 or type 2?
6. Number of days of post-operative drain use: \_\_\_\_\_
7. Did the patient have a post-operative complication within 30 days of surgery?
  - a. Yes
  - b. No
8. If yes to number 7, which complication?
  - a. Infection
  - b. Hematoma
  - c. Seroma
  - d. Necrosis
  - e. Wound Dehiscence
9. Did the patient have a post-operative complication 31 days or greater after surgery?
  - a. Yes
  - b. No
10. If yes to number 9, which complication?
  - a. Infection
  - b. Hematoma



- c. Seroma
- d. Necrosis
- e. Wound dehiscence
- f. Capsular contracture
- g. other

11. Did the patient require a re-surgery?

- a. Yes
- b. No

12. Did the patient lose their reconstructed breast for any length of time?

- a. Yes
- b. No