Improving Breast Reconstruction Outcomes: An Evidence-Based Analysis

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A mon idole, Djemaa, qui m'a permis d'arriver la ou je suis maintenant, Merci TAV !! Du plus profond du cœur: Gros Merci !

A Najib, Mehdi et Myriam, qui forment la famille la plus merveilleuse au monde,

A Dino, le meilleur neveu au monde,

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ABSTRACT

Background:

As breast reconstruction evolves, plastic surgeons continue to find ways to improve their reconstruction' outcomes. The aim of our study is to demonstrate how plastic surgery research impacts and improves current surgical practices. For instance, we designed three clinical studies which illustrate how research can affect current popular surgical practices, not only during the pre-operative period, but also intra-operative and post-operative periods.

Methods:

In the first study, we performed a meta-analysis to evaluate first the safety and efficacy of Thoracic ParaVertebral Block (TPVB) for breast surgery, and then to compare TPVB to General Anesthesia (GA) with regards to postoperative pain, nausea and vomiting, opioid consumption and length of hospital stay. To do so, an electronic and manual search of English- and Frenchlanguage articles on TPVB in breast surgery (published up to June 2010) was performed. Two levels of screening were used to identify relevant articles. The Mantel-Haenszel method (fixed effect) was used to perform the meta-analysis.

In the second study, we performed a systematic review to evaluate the existing literature, comparing the use of drains or not in reduction mammaplasty. We assessed first, if there is enough evidence to reach a conclusion regarding the routine use of drains after reduction mammaplasty, and then, if there is a need for more randomized control trials. To do so, we searched PubMed, EMBASE, the Cochrane Central Database of Clinical Trials (CENTRAL) on the Cochrane Library and Science Citation Index Expanded for original articles and reviews from January 1980 to June 2009.

Finally, in the third study, we are presenting our clinical experience of using subcutaneous breast tissue expansion prior to reconstruction with Deep Inferior Epigastric Perforator (DIEP) flaps, and we are showing how our new technique eliminates the patch-like appearance of the skin paddle. We developed this technique; surgical technique that was never described or presented before. Over the past 2 years (January 2008 – January 2010), five patients underwent breast reconstruction using this three-stage approach. Retrospective analysis of patients' characteristics, breast history, surgical stay, complications and outcomes were performed.

Results:

Our first study demonstrated that <u>pre-operative</u> TPVB provides effective anesthesia for ambulatory / same-day breast surgery and can result in significant benefits over GA. However further studies are required to determine if these advantages would still persist if an optimal technique for outpatient GA is employed. Adjunctive ultrasonography may contribute to improve the safety of TPVB in breast surgery and requires further investigation.

Our second study, we demonstrated that although placement of <u>intra-operative</u> drains after reduction mammaplasty is common practice, it should not be used routinely in reduction mammaplasty. Further randomized controlled trials are not warranted.

Finally, our third study demonstrated how innovation in plastic surgery research can improve the final, *post-operative* aesthetic outcome. Subcutaneous breast tissue expansion followed by DIEP flap reconstruction can be performed safely, offering patients a completely autologous breast reconstruction with low morbidity, as well as eliminating the classical patch-like appearance of flap reconstructions.

Conclusion:

These three different studies illustrate how plastic surgery research can have an impact on breast reconstruction outcomes. The first two studies demonstrate with a strong level of evidence (meta-analysis and systematic review, respectively) that established pre-operative and post-operative factors can be changed for the benefit of the patient. Finally, we demonstrated how surgical technique innovation can improve the post-operative outcome.

RESUME

Contexte:

Avec l'évolution de la chirurgie reconstructive du sein, les chirurgiens plasticiens continuent de trouver des moyens d'améliorer leurs reconstructions. Le but de notre étude est de démontrer, à travers trois études cliniques, comment la recherche en chirurgie plastique peut améliorer les pratiques chirurgicales courantes, durant les périodes pré-, intra- et postopératoires.

Méthodes:

Lors de notre première étude, nous avons effectué une méta-analyse afin d'évaluer la sécurité d'utilisation et l'efficacité des Blocs Thoraciques Para-Vertébraux (BTPV) pour la chirurgie du sein, en comparaison à l'Anesthésie Générale (AG). Pour cela, nous avons effectué une recherche électronique et manuelle d'articles écrits en anglais et français sur les BTPV en chirurgie du sein (publiés jusqu'en Juin 2010). Deux niveaux de sélection d'articles ont été utilisés. La méthode de Mantel-Haenszel (effets fixes) a été utilisée pour effectuer la méta-analyse.

Lors de notre seconde étude, nous avons effectué une revue systématique afin d'évaluer la littérature existante qui compare l'utilisation de drains ou non lors des réductions mammaires. Pour cela, nous avons cherché Pub Med, EMBASE, le "Cochrane Central Database of Clinical Trials (CENTRAL) on the Cochrane Library" et le "Science Citation Index Expanded" pour les articles et revues de Janvier 1980 à Juin 2009.

Finalement, lors de notre troisième étude, nous présentons notre expérience sur l'utilisation d'expanseurs sous cutanés de seins avant une reconstruction avec un lambeau basé sur la perforante de l'artère inferieure épigastrique profonde (lambeau DIEP). Nous démontrons

comment notre nouvelle technique élimine l'apparence de patch du lambeau DIEP sur le sein. Nous avons développé cette technique; technique chirurgicale qui n'a jamais été décrite ou présentée auparavant. Au courant des deux dernières années (Janvier 2008 – Janvier 2010), cinq patients ont bénéficié de cette approche à trois étapes. Une analyse rétrospective des caractéristiques médicales des patients, de leur pathologie mammaire, de leurs hospitalisations, des complications et de leurs résultats, a été effectuée.

Résultats:

Notre première étude a démontré que les BTPV en *préopératoire* permettent une anesthésie effective pour les cas-de-jour de chirurgie du sein et démontrent des bénéfices supérieurs à l'AG. Cependant, plus d'études sont à faire afin de déterminer si ces avantages perdurent si une technique optimale pour une AG pour patients non-hospitalises est employée. L'échographie pourrait contribuer à améliorer la morbidité possible associée avec les BTPV en chirurgie du sein et devrait être étudiée en profondeur.

Notre seconde étude a démontré que même si le placement routinier de drains en <u>intra-opératoire</u> après réduction mammaire est une pratique très populaire, cela ne devrait pas être utilisé de manière routinière après les réductions mammaires. Plus d'études randomisées contrôlées ne sont pas requises.

Finalement, notre troisième étude a démontré comment l'innovation en recherche en chirurgie plastique peut améliorer le résultat final, *postopératoire*. L'expansion mammaire sous-cutanée suivie par reconstruction avec lambeau DIEP peut être effectuée en toute sécurité et offre aux patients une reconstruction mammaire totalement autologue, avec une faible morbidité, tout en éliminant l'apparence en forme de patch des reconstructions mammaires autologues classiques.

Conclusion:

Ces trois différentes études illustrent bien comment la recherche en chirurgie plastique peut affecter les résultats en reconstruction mammaire. Nos deux premières études démontrent avec un niveau d'évidence très élevé (méta-analyse puis revue systématique) que des pratiques préopératoires et intra-opératoires établies peuvent être modifiées au bénéfice des patients. Finalement, nous avons démontré comment une technique chirurgicale innovatrice peut améliorer les résultats postopératoires.

CONTRIBUTION TO ORIGINAL KNOWLEDGE

- 1. I have demonstrated with a high level of evidence that thoracic paravertebral block is a safe modality for anesthesia in breast surgery and it is a superior anesthetic modality compared to general anesthesia for breast surgery, in terms of postoperative pain scores, narcotics consumption, incidence of post-operative nausea and vomiting as well as length of hospitalization.
- **2.** I have demonstrated with a high level of evidence that routine use of drains in reduction mammaplasty is not warranted.
- **3.** I have demonstrated that further randomized controlled trials comparing the use of drains or not in reduction mammaplasty are not warranted.
- **4.** I demonstrated how our new surgical technique using expansion prior to DIEP flap for breast reconstruction improved the final aesthetic outcome.
- **5.** With these three studies, I illustrated how changes during the preoperative, intraoperative and postoperative period can affect positively breast reconstruction outcomes.

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- Dr. Mehdi Tahiri (Medical student who participated in the data collection of the second manuscript)
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LIST OF ABBREVIATIONS

ANOVA analysis of variance BMI body mass index

CENTRAL cochrane central database of clinical trial

DIEP deep inferior epigastric perforator

GA general anesthesia JP jackson-pratt

MOOSE meta-analysis of observational studies in epidemiology

NAC nipple areolar complex

OR operating room

RCT randomized controlled trial TPVB thoracic paravertebral block

TRAM transverse rectus abdominis myocutaneous

Chapter 1.

Introduction

Most common types of breast reconstructive surgeries

1.1 Reduction Mammaplasty

Reduction mammaplasty is one of the most common surgical procedures performed by plastic surgeons. It is a surgical procedure aimed to treat breast hypertrophy in females and less commonly in males (in the setting of gynecomastia). It involves a reduction of the skin, glandular and adipose tissues. It involves also repositioning the Nipple Areolar Complex (NAC) in a more cranial position (1). The aetiology of breast hypertrophy can vary from idiopathic to developmental such as juvenile virginal hypertrophy (gigantomastia) and obese hyperplasia, to endocrine such as in precocious puberty, lactation, or menopause (due to glandular involution into adipose tissue) (2-14). Patients consulting for breast reduction surgery in plastic surgery clinics usually complain of headaches, shoulder, neck or back pain. Other complaints include posture problems, difficulty in performing sports, dermatitis in the inframmamary fold, psychological disturbances (young girls at school) and finally a heavy anterior chest (15-18).

The goals of the breast reduction surgery are to improve physical and psychological symptoms by reducing breast volume, getting an aesthetically pleasing breast (mature breast with good projection and contour) and to try to preserve enough breast tissue for lactation, sensation and vascularity to the NAC (19-23).

Studies demonstrated that women who benefit from a breast reduction are among the most satisfied patients in the plastic surgeon's practice. Post-operatively, these patients enjoy new activities that were previously unavailable to them. Reduction mammaplasty is certainly one of the surgeries with significant contribution to woman's quality of life (22-26).

Multiple breast reduction surgical techniques have been described. They are classified depending on the pedicle type involved or the incisions type. Inferior, superior, central, bipedicled, lateral, superomedial vertical and horizontal pedicles have all been described. The inverted T (Wise), the vertical with short horizontal, the vertical-only, the peri-areolar are among the most common incisions used in reduction mammaplasty surgery. The choice of the pedicle type as well as the type of incision is very surgeon dependent (27-39).

One of the common surgical steps seen during a breast reduction surgery is the placement of a drain by the surgeon to prevent a hematoma or seroma in the operated breasts. Drains are used in reduction mammaplasty because they are believed to decrease fluid accumulation and collection into wound and to reduce the dead space between tissues thus, reducing the risks of hematomas and seromas, which may possibly lead to pressure necrosis of the NAC. However, despite these advantages, the use of routine drainage in reduction mammaplasty has always been debated since it is also associated with patient discomfort, pain, increased risk of infection (foreign body) and increases cost and length of hospital stay. Over the past decade, some retrospective and few randomized controlled trials addressed the question of the use of drains or not in reduction

mammaplasty. It appears that the consensus is to not use drains following reduction mammaplasty (40-46)

Reduction mammaplasty is a surgery mostly performed under general anesthesia. It is performed as a same-day surgery; where the patient is discharged home the same as surgery. Post-operatively, the patient is monitored into the recovery room. Pain and nausea are common symptoms that appear post-operatively. Those are usually treated with systemic medication.

With the rapid evolution of plastic surgery towards outpatient and same-day surgery, the focus is increasingly being placed on efficiency and patient recovery. In response to the undesirable side effects of general anesthesia (GA), regional anesthesia has become an attractive alternative. In the past decade, thoracic paravertebral blocks (TPVB) have emerged as an innovative anesthetic technique for breast surgery. Its efficacy has been demonstrated in oncological breast surgery studies. Previous studies comparing TPVB to GA in oncological breast procedures have demonstrated that TPVB can provide adequate surgical anesthesia while decreasing postoperative pain, opioid consumption, narcotic-related side effects (such as nausea and vomiting) and hospital stay (47-58).

1.2 Breast augmentation

Augmentation mammaplasty, also known as breast augmentation, consists of any procedures designed to increase the size of the breast. These procedures are mostly performed under general anesthesia.

In 1895, Czerny was the first one to describe a breast augmentation procedure: he transplanted a lipoma excised from the back into the submammary position to fill in a defect created by the resection of an adenoma (59). Because of a significant resorption of fat, Berson described the use of dermis-fat and dermis-fascia-fat graft for breast augmentation (60).

In 1962, the first silicone implant was use for breast augmentation whereas saline-filled implants were introduced in 1965. In 1976, the American Congress gave to the FDA the authority to control medical devices marketing to the general population. In 1992, with a media triggered campaign against silicone breast implants, associating them with rare and sporadic cases of patients with rheumatologic symptoms, the FDA banned the use of silicone implants in 1992 (61-64). It is only in the past few years that silicone implants are being re-introduced for breast augmentation, after multiple studies demonstrating that silicone was an inert component, not leading to any inflammatory/immunological process (64).

Patients desiring larger breasts, with reasonable expectations and understanding of possible complications are ideal candidates. Patients with an unstable psychiatric state, with unreasonable expectations, who are medically unfit, at high risk for infections and who have other active breast pathologies should not undergo such a procedure (65).

The exact number of women in the United States with breast implants is unknown; however it is approximated at 1-2 million of women, which is slightly more than 1% of the female population in the US. 80 % of these implants are used for cosmetic reasons, while the rest is used for reconstructive purposes (66-68).

There are multiple types of breast implants, different types of incisions, which we are not going to get into too much depth, because it is beyond the scope of our study (69). There are two main types of implants: silicone and saline implants, which come into different shapes (i.e. round vs. anatomical tear-drop, soft vs. textured). The different incisions include the inframmary incisions, the peri-areolar incision, the axillary incision and the transumbilical incision (70-76).

1.3 Post-mastectomy reconstruction

Approximately 10 % of women undergo reconstruction following a mastectomy. Patients seeking a reconstruction tend to be younger (70-78). They are looking to retain their feminity, to feel whole again, more balanced, and to diminish clothing limitations. Reconstruction helps patients to forget about being a cancer victim. (78-82).

Breast reconstruction involves a multidisciplinary team approach: oncologic surgeon, medical oncologist, radiation oncologist, plastic surgeon, pathologist and support groups are all involved in the care of these patients. Communication between the different treating physicians is of prime importance. Plastic surgeons need to be aware of the oncological status of the patient, making sure that the disease is controlled before performing the reconstruction.

When approaching a patient who underwent a mastectomy, three options are offered: to not perform a reconstruction, to perform a reconstruction using alloplastic material such as an expander followed by an implant and finally, to perform an autologous reconstruction, i.e. using the patient's own tissues (83).

1.3.1 Alloplastic reconstruction

Alloplastic reconstruction is the most common mean of reconstruction following a mastectomy. Tissue expansion using an expander, followed by the placement of an implant is the most common technique for alloplastic breast reconstruction. Immediate placement of an implant is rarely done, due to the immediate lack of soft tissue following mastectomy (84).

Alloplastic reconstruction involves the placement of an expander in a subpectoral fashion, using the same incision as the one used for the mastectomy. Two weeks following the insertion of the expander, serial expansions are performed. Patients come weekly at the office, where a certain amount of saline is injected transcutaneously into the expander or through a port-catheter likevalve system. The amount of saline injected at each visit depends on the capacity of the skin to stretch/expand. Usually, saline is injected up to a point when breast skin blanches or the patient complains of pain. Expansion is performed until the desired volume is attained, which depends on the size of the contralateral breast and patient's skin quality. Once the target volume of expansion is attained, the patient is scheduled for removal of the expander and insertion of an implant. Capsulotomies / capsulorraphies are performed if needed, in order to improve the position of the implant on the chest (85-86).

Patients' candidate for alloplastic reconstructions include the ones that are unwilling/unable to tolerate donor site morbidity associated with autologous reconstruction or patients who are unable to tolerate rehabilitation following major autologous reconstructions. Relative contraindications for alloplastic reconstruction include anticipated or previous radiation therapy,

patients with poor healing characteristics (such as patients on corticosteroids, diabetic or transplant patients) (87-88).

The advantages of alloplastic reconstruction include its simplicity, the decreased operative time, the rapid post-operative recovery, the absence of donor site morbidity, the absence of new scar on the breast and finally its suitability for immediate as well as delayed reconstruction. The main disadvantages include the unnatural feel and look of the breast, the difficulty to reproduce a natural, pendulous breast, the significant increase of complications associated with radiation therapy and finally the relatively long process of expansion (89-90).

Complications of these procedures include the formation of a hematoma or a seroma in the pocket that is created to place the expander. The most feared complication is exposure of the expander/implant, which implies that the pocket is contamined, requiring removal of the prosthesis. Other complications include prosthesis deflation, prosthesis leak, capsular contraction, wound infection and wound dehiscence. In his study, Spear (85) demonstrated that the complication rate increased significantly when alloplastic reconstruction is performed in the setting of an irradiated breast. The overall incidence of complications is increased by 50% when radiation therapy is used (85-91).

1.3.2 Autologous reconstruction

Patients not candidate for alloplastic reconstruction but still seeking breast reconstruction following mastectomy, can also be offered an autologous reconstruction. Candidates for

autologous reconstruction are the ones that have had or are going to have radiation therapy, patients with adequate donor site, patients medically fit to undergo a lengthy autologous reconstruction procedure, and patients refusing an alloplastic reconstruction (92).

The advantages associated with autologous reconstruction include a more natural final shape; it is a single stage procedure and tolerates irradiation (in contrast to alloplastic reconstructions). The disadvantages include a lengthier procedure, a technically more complex procedure and donor site morbidity (92). To our perspective, one main aesthetic disadvantage of autologous reconstruction is the patch-like appearance of the transplanted skin paddle in the breast. Up to now, the plastic surgery literature is lacking studies investigating ways of improving this aesthetic outcome.

The most common flaps used in breast reconstruction include the Latissimus Dorsi flap (Lat Dorsi), the Transverse Rectus Abdominis Myocutaneous (TRAM) flap and the Deep Inferior Epigastric Perforator (DIEP) flap (92).

The Lat Dorsi flap is considered a workhorse flap for breast reconstruction. It can be used either as a pedicled flap (most common) or as a free flap. It is rarely used by itself; an implant is usually placed posterior to the Lat Dorsi flap and anterior to the pectoralis major muscle to increase the final volume of the reconstruction. It is used in thin patients (when a TRAM flap is not available), with small to moderate sized breast (93-95). It is a very reliable pedicled flap and patients recover rapidly. The main disadvantages associated with the Lat Dorsi flap reconstruction is the difficult intra-operative positioning (lateral decubitus), because of this, it is

also difficult to perform bilateral reconstructions in a single stage. Finally, the bulk is small, so in contrast to the other flaps, an implant is usually necessary to assure adequate volume of the breast reconstruction (95-98).

For a large majority of plastic surgeons, the TRAM flap is considered the gold-standard when it comes to autologous breast reconstruction. The rectus abdominis muscle receives blood supply from two dominant pedicles: the superior epigastric artery and the inferior epigastric artery. For breast reconstruction, it can be used as a pedicled flap (based on the superior epigastric artery) or as a free flap (based on the inferior epigastric artery) (99-100). The main advantages of the TRAM flap reconstruction include the simultaneous benefit of abdominoplasty (tummy-tuck), the generous amount of tissue available, the reasonable color and texture match and finally the good flexibility with regards to shaping the flap positioning it on the chest wall (99-103). One of the main disadvantages is the donor site morbidity: because the rectus muscle is harvested, patients can suffer from abdominal wall weakness and do have an increased risk of developing abdominal hernias. Because of the abdominal weakness associated with it, bilateral TRAM flap are rarely done due to the significant abdominal weakness associated with the harvesting of both rectus abdominis muscles. Thus, the use of TRAM flap is limited in bilateral reconstruction. In addition, this surgery is associated with a lengthy recovery (4-6 weeks) (104-108).

In a very active patient, wishing to preserve abdominal muscle integrity, the DIEP flap is a good alternative to the TRAM flap (109). The DIEP flap is a free flap based on the deep inferior epigastric artery. In contrast to the TRAM flap, the rectus abdominis muscle is not harvested. Perforators are dissected carefully by splitting the muscle in the direction of its fibers, to finally

expose the inferior epigastric pedicle. It is used to reconstruct small to moderate breast. Because of this flap is based on perforators, pre-operative angiography demonstrating the presence of perforators is usually done prior to proceed with surgery. The main advantages of this procedure are the absence of muscle harvest and thus less abdominal morbidity and a faster recovery. However, it is a more technically demanding surgery, requiring a significant learning curve and it is associated with the usual complications associated with microsurgery, including thrombosis and flap loss (110).

Complications associated with the TRAM and DIEP flap can be divided into recipient site complications and donor site complications. Recipient site complications include partial or total flap necrosis, wound problems (including dehiscence and infection), fat necrosis (more common in DIEP flap than in TRAM flap), hematoma and seroma formation. Donor site complications include hematoma and seroma formation, abdominal weakness with an increased risk of hernia (in the TRAM population), umbilical malposition, umbilical necrosis, wound problems (including dehiscence and infection) and abdominal wall hypoesthesia. Because of the long operative time associated with these procedures, the risk of deep vein thrombosis is also increased, as well as all risks associated with prolonged anesthesia and intubation. Finally, these autologous reconstructions are also associated with aesthetic limitations such as asymmetries, irregularities and also the patch-like appearance of the skin paddle on the breast (109, 111).

1.4 Rationale for the current study

As breast reconstruction evolves, plastic surgeons continue to find ways to improve their reconstruction' outcomes. The main goals are to decrease morbidity and improve the functional, aesthetic and psychological benefits of their surgery. The aim of our study is to demonstrate how plastic surgery research impacts and improves current surgical practices. For instance, we designed three clinical studies which illustrate how research can help to optimize current popular surgical practices.

We conducted these three studies in order to have a comprehensive approach to research in the field of surgery and to dedicate one study for each operative period: pre-, intra- and post-operative periods. We wanted to demonstrate that research should involve all aspects of the surgical care of the patient. Complete surgical care of the patient involves not only a successful operation, but a well-rounded care, including optimization of the pre-operative and post-operative care. Furthermore, a comprehensive approach does not limit itself to a successful functional outcome, but also a pleasing aesthetic outcome.

Chapter 2.

General Anesthesia vs. Thoracic Paravertebral Block for Breast

Surgery: a Meta-Analysis

Tahiri Y, Tran D, Bouteaud J, Xu L, Lalonde D, Luc M, Nikolis A.

2.1 ABSTRACT

Background:

Thoracic paravertebral block (TPVB) offers an attractive alternative to general anesthesia (GA) for ambulatory breast surgery. The aim of this meta-analysis was firstly to evaluate the safety and efficacy of TPVB for breast surgery, and secondly to compare TPVB to GA with regard to postoperative pain, nausea and vomiting, opioid consumption and length of hospital stay.

Methods:

An electronic and manual search of English- and French- language articles on TPVB in breast surgery (published from January 1980 to June 2010) yielded 41 citations. Two levels of screening identified 11 relevant studies. The Mantel-Haenszel method (fixed effect) was used to perform the meta-analysis.

Results:

Eleven studies were retained for analysis. When TPVB was used instead of GA, pain scores were significantly decreased at 1 and 6 hours postoperatively (mean difference of 2.48 [95%CI: 2.20-

2.75] and 1.71 [95%CI: 1.64-1.78], respectively). Furthermore, postoperative analgesic consumption was significantly lower in patients who received TPVB compared to GA (RR 0.23, [95%CI: 0.15-0.37]). Thoracic paravertebral block was also associated with significantly less postoperative nausea and vomiting (RR 0.27 [95%CI: 0.12-0.61]). Increased patient satisfaction and a shorter hospital stay also favoured TPVB compared to GA.

Conclusions:

Thoracic paravertebral block provides effective anesthesia for ambulatory breast surgery and can result in significant benefits over GA. However further studies are required to determine if these advantages would still be present if an optimal technique for outpatient GA is employed.

Adjunctive ultrasonography may contribute to improve the safety of TPVB in breast surgery and requires further investigation.

Key words:

Breast Surgery, General Anesthesia, Thoracic Paravertebral Block

2.2 INTRODUCTION

With the rapid evolution of plastic surgery towards outpatient and same-day surgery, the focus is increasingly being placed on efficiency and patient recovery. In response to the undesirable side effects of general anesthesia (GA), regional anesthesia has become an attractive alternative. In the past decade, thoracic paravertebral blocks (TPVB) have emerged as an innovative anesthetic technique for breast surgery (47-58).

Previous studies comparing TPVB to GA in oncological breast procedures have demonstrated that TPVB can provide adequate surgical anesthesia while decreasing postoperative pain, opioid consumption, narcotic-related side effects (such as nausea and vomiting) and hospital stay (112-123). The complication rate, less than 2.6% in most studies (113, 116, 121-130), includes hypotension, pneumothorax as well as epidural spread of local anesthetic agents. Despite the low incidence of adverse events and numerous benefits, the use of TPVB remains limited in breast surgery. Furthermore, compared to oncological procedures, its application seems even less frequent in plastic surgery. To date, only two studies have investigated the use of TPVB in breast plastic surgery. Both trials reported favourable results in breast augmentation as well as aesthetic and reconstructive surgery (114, 121)

Is there enough evidence to support the use of TPVB as an alternative to GA? This meta-analysis aims to compare TPVB and GA for breast surgery.

2.3 METHODS

Data Sources

We searched the Medline, PubMed and EMBASE databases as well as the Cochrane library and Current Contents and Science citation for original articles published from January 1980 to June 2010. Our Keywords included *paravertebral block* and *breast*. We limited our search to studies published in English or French. The bibliographies of all selected articles were manually checked for relevant references.

Study Selection

Two researchers (YT, JB) independently selected the articles for review.

Articles were included if they met the following criteria:

- Population: human adults (18 years and over) who underwent breast surgery.
- Intervention: TPVB alone or compared with GA
- Outcomes:
 - o Efficacy (additional anaesthetic / sedation needed and conversion to GA)
 - o Intra- and postoperative complications
 - Length of hospital stay
 - o Postoperative pain
 - o Postoperative narcotic use
 - o Postoperative nausea/ vomiting

Study selection was performed through two levels of screening.

In the first level, abstracts were reviewed for the following exclusion criteria:

- Studies combining both GA and TPVB
- Letters, comments, and editorials
- Languages other than French and English
- Publication of abstracts only
- Animal or cadaveric studies and physiologic or anatomic studies

In the second level, all articles filtered through the first level were read in their entirety and further triaged according to the above inclusion and exclusion criteria.

Only studies that successfully passed both levels of screening were included in our analysis.

Data Extraction

Data extraction was performed according to the guidelines outlined by the Meta-analysis Of Observational Studies in Epidemiology (MOOSE) statement (131). Two researchers with training in biostatistics and epidemiology (YT, JB) independently reviewed selected studies using standardized forms and collected data about lead author, publication year, study design, patient demographics, inclusion/ exclusion criteria, type of surgery, method of anesthesia, length of hospital stay, postoperative pain, postoperative nausea/ vomiting, postoperative analgesic use, and intra- or postoperative complications. Any difference with regards to findings was resolved through discussion.

Data Synthesis and Analysis

A meta-analysis was performed if two or more randomized controlled trials (RCTs) reported data for comparable outcomes. The Mantel-Haenszel fixed effect method was used to synthesize

pooled estimates from the results of individual studies (132). For dichotomous outcomes, relative risks were calculated using a fixed effects model with a 95 % confidence interval. All calculations were performed using Review Manager (RevMan [Computer program]. Version 5.0. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2008). The rest of the data was reported in a narrative manner.

2.4 RESULTS

1. Study Selection

Eleven studies were retained for analysis. There were four case series (112-115) and two retrospective studies (116, 117) describing the use of TPVB in breast surgery as well as five randomized controlled trials (118-122) comparing TPVB to GA (Figure 1 and Table 1). One reference (123) could not be retrieved despite multiple attempts to contact the authors, the journal, and other international libraries. Studies comparing GA to GA combined with TPVB were excluded for the purpose of this review (124-127).

2. Efficacy and Safety

Efficacy

Ten studies (112-117, 119-122) reported the rate of additional local anesthetic and/or sedation use intraoperatively. Most studies reported a rate ranging from 10 to 13% (Table 2). Additional anesthetic and/or sedation were more frequently used in women undergoing axillary dissection (115, 119, 122). The rate of conversion to GA (due to TPVB failure) ranged from 0 to 15.8%

with most studies reporting 0% conversion (112-122). Najarian et al (117), who reported the highest rate of conversion (15.8%), observed a significant difference in the rate of TPVB failure according to the anesthesiologist's experience. In this study, 79% of the failed TPVB had been performed by operators who had done fewer than 15 blocks (117). Coveney et al (116) also reported an increased success rate with the anesthesiologist who had previously performed the largest number of TPVBs.

Safety

The rate of complication in patients undergoing TPVB was reported in all 11 studies and ranged from 0 to 12%. Nine out of 11 studies reported a complication rate inferior to 2.6% (112-122). The most common adverse event was hypotension/ bradycardia (n = 12) followed by epidural spread (n = 5) and pneumothorax (n = 2). All patients recovered within 24 hours of surgery and no long-term sequelae occurred.

3. Patient Experience

Postoperative pain

All five RCTs (118-122) reported pain scores for patients in TPVB and GA groups. Pain scores were measured using either a verbal or visual analogue scale and systematically found to be (significantly) lower with TPVB compared to GA at the various time points. Terheggen et al (120) recorded postoperative pain at 15, 30, 60, 90, and 120 minutes and reported lower scores in the TPVB group. Statistical significance was reached for all time points (P<0.01) except at 120 minutes, where almost all patients were pain free. Klein et al (121) also reported significantly

lower pain scores in the TPVB group immediately after surgery (at 30 and 60 minutes) (P<0.001). At 1, 3, 6 and 24 hours, subjects in the TPVB group still demonstrated lower pain scores than those in the GA group (all P \leq 0.04) (118-121). Similar results were observed between 2 and 12 hours after surgery by Pusch et al (122). In one study, a statistically significant difference was present even five days after surgery (119).

At one hour after surgery, a meta-analysis of pain scores showed a mean difference across the two groups of 2.48 [95%CI: 2.20-2.75] and clearly favoured TPVB over GA (Figure 2). Another meta-analysis of pain scores at six hours after surgery showed a mean difference across the groups of 1.71 [95%CI: 1.64-1.78] and also favoured TPVB over GA (118-122).

Postoperative use of analgesics

Ten studies (112-117, 119-122) reported the number of patients who received postoperative analgesics (NSAIDs and/or opioids) but only three studies recorded the dose received. Despite large variations observed across the different studies (Table 3), consumption of postoperative analgesics was less frequent in patient who had received TPVB compared to GA. A meta-analysis confirmed these findings and showed a relative risk of 0.23 [95%CI: 0.15-0.37] in favour of TPVB (Figure 3). Three studies (120-122) specifically recorded the use of opioids (separate from other analgesics): again breakthrough consumption was less common in the TPVB group.

In addition to a lower frequency of use, the dose of narcotics was also decreased with TPVB compared to GA. Patients receiving GA required three times more supplemental narcotics in the Post Anesthesia Care Unit (121). Dabbagh et al (118) reported 24-hour postoperative morphine doses of 1.5 + 2.1 and to 4.15 + 1.5 mg in the TPVB and GA groups, respectively (P<0.001).

This echoes the findings of another study were total doses of narcotic were 6.2 and 10.1 units for the TPVB and GA groups, respectively (P<0.05) (117).

Postoperative Nausea and Vomiting (PONV)

Five studies compared the incidence of PONV between TPVB and GA. The rate of PONV in subjects receiving TPVB (0-23.5%) was systematically lower than that of patients undergoing GA (6.7-40%). A meta-analysis of the three RCTs reporting this outcome revealed a relative risk of 0.27 [95%CI: 0.12-0.61] in favour of TPVB (Figure 4).

Length of Hospital Stay (LOS)

Three studies recorded the LOS (116, 118, 119). In a retrospective comparative study, TPVB resulted in a significantly shorter hospital stay (P<0.0001): 28.2% of patients from the TPVB group were discharged on the day of surgery compared to 11% in the GA group (116). Two RCTs also reported a statistically decreased LOS with TPVB (1.9 \pm 0.6 days vs. 3.05 \pm 0.7 days and 1 vs. 2 days; both P<0.01) (118-119).

Patient Satisfaction

In three different studies, 93.3% (112), 100% (113) and 96.7% (119) of patients reported a high level of satisfaction with paravertebral blocks. Only one RCT compared patient satisfaction between TPVB and GA. On a 3-point scale (with 3 being "very satisfied"), patient satisfaction with GA and TPVB were rated 2.3 and 2.8, respectively. This difference was statistically significant and favoured TPVB (P=0.008).

2.5 DISCUSSION

The results of this review and meta-analysis demonstrate with a high level of evidence that, combined with sedation, TPVB provides effective surgical anesthesia for patients undergoing oncological breast procedures and breast augmentation.

Thoracic paravertebral blocks may also offer significant advantages over GA in terms of postoperative pain, opioid consumption, PONV, LOS and patient satisfaction (112-123). In addition to decreased pain in the immediate period, TPVB also seems to provide analgesia that exceeds the duration of action of the local anesthetic agent. For instance, Klein et al (121) demonstrated a beneficial effect lasting up to 72 hours. We speculate that the dissection of the pectoralis major muscle is associated with significant sensitization of pain receptors and thus may benefit from the pre-emptive analgesia provided by TPVB. After breast surgery, the incidence of PONV can be as high as 84% in patients undergoing GA (133). With TPVB, PONV is most likely reduced due to better analgesia and decreased opioid consumption. Another important benefit of TPVB stems from the shortened LOS (134). In the current climate of health care provision, increasing emphasis is being placed on ambulatory surgery and cost efficiency. When TPVB was compared to GA, Wetz et al (112) and Coveney et al (116) both demonstrated significant cost savings (up to 22%) with the former. The lower costs were attributed to a reduced need for postoperative monitoring and nursing staff (114, 135).

The findings of our review and meta-analysis seem to echo those of Shnabel et al's recent article (136). In the latter, the authors also concluded that, compared to GA, TPVB resulted in lower (worst) postoperative scores as well as a decreased incidence of PONV. However Shnabel et al

(136) included studies that compared GA to GA combined with TPVB whereas we focused exclusively on the comparison between TPVB and GA. Furthermore, according to our search criteria, we did not limit ourselves to RCTs and also considered data stemming from case series and retrospective reports (112-117). Although we did not include subjects from these studies in our meta-analysis, we incorporated them in the narrative portion of our review article (Table 1). This allowed us to extract data from an additional 722 patients thus strengthening our conclusions.

Despite the many reported benefits of TPVB over GA, caution should be exercised when interpreting these results in order to avoid premature conclusions. For instance, careful scrutiny of the available literature reveals that, in all but 2 studies (121-122), PONV prophylaxis, a mainstay in modern ambulatory anesthesiology, was not provided to patients undergoing GA. In fact, most authors used nitrous oxide, a gas known for its pro-emetic properties (Table 1). Furthermore, for maintenance of GA, 57.1 % of studies employed halothane or isoflurane instead of the shorter-lasting sevoflurane, desflurane or propofol. This could have contributed to the longer hospital stay after GA. Furthermore LOS is a notoriously difficult outcome to record objectively. In non randomized trials, the primary selection of patients undergoing GA or TPVB may have constituted a bias in itself. In RCTs, based on the patient's level of consciousness, the nursing staff in the Post Anesthesia Care Unit could have easily identified patients belonging to each group (GA or TPVB) thus potentially favouring one group over the other for discharge. Finally, multimodal analysesia was not provided to patients undergoing GA. Arguably, the use of agents such as gabapentin (137) or pregabalin (138) could have improved pain control and decreased postoperative narcotic consumption. Thus, further well designed RCTs are required to

compare TPVB and GA. For the latter, PONV prophylaxis, short acting anesthetic agents and multimodal analgesia should be systematically implemented.

Although rare, complications can occur with TPVB. The most notable ones include pleural puncture and epidural spread of local anesthetic agents. While the latter requires only transient supportive therapy with fluids and vasopressors, the presence of a pneumothorax may necessitate overnight admission with or without tube thoracostomy. This can be particularly problematic if breast surgery is carried out in a private clinic or outpatient surgical center. As expected, the rate of complications increases with elevated body mass indices (139). Various strategies have been advocated to decrease the occurrence of adverse events. The use of a nerve stimulator may improve the accuracy of the block, thus minimizing the risk of pleural puncture (119). As with other regional blocks, a learning curve exists for the performance of safe and successful TPVBs. In their study, Najarian et al (117) observed that 79% of failed TPVBs were performed by anesthesiologists who had done fewer than 15 blocks. Coveney et al (116) reported an increased success rate with the operator who had performed the largest number of blocks. To improve its safety profile and its dissemination, Cooter et al (114) suggested that TPVB should only be performed in patients with body mass indices lower than 25, using a single-site injection technique. Furthermore, because of the risk of bilateral pneumothoraces, bilateral TPVBs should be reserved for operators experienced in the technique. Recently, the introduction of adjunctive ultrasonography in the practice of regional anesthesia has resulted in improved success, efficiency and safety of brachial plexus, femoral and sciatic nerve block (140). By allowing the operator to visualize the needle, nerve, surrounding structures and spread of local anesthetic agents, ultrasound guidance could also increase the safety profile of TPVB by minimizing the

risk of pleural puncture, vascular puncture and epidural injection (141). Furthermore it could facilitate the performance of bilateral TPVBs and contribute to implement TPVB in smaller centers, where operators may lack extensive experience with the traditional techniques (loss of resistance, neurostimulation). However further studies are required to validate the use of ultrasonography for TPVB in breast surgery.

In conclusion, TPVB provides effective anesthesia for ambulatory breast surgery and constitutes a viable alternative to GA for aesthetic and reconstructive breast surgery. The available literature suggests that it offers important advantages over GA in terms of postoperative analgesia, postoperative nausea/vomiting, opioid consumption and length of hospital stay. However further studies are required to determine if these benefits would still be present if an optimal technique for outpatient GA is employed (PONV prophylaxis, short acting anesthetic agent, multimodal analgesia). Finally, adjunctive ultrasonography may contribute to improve the safety profile of TPVB in breast surgery and requires further investigation.

We just demonstrated with a high level of evidence that an optimization of the pre-operative care using TPVB can improve patient's post-operative outcome, with an improved overall recovery. In the next study, we are going to demonstrate how through a systematic review, we can change certain intra-operative routines in order to decrease morbidity and improve patient physical and psychological outcome.

Chapter 3.

Routine Drainage in Reduction Mammaplasty:

an Evidence-Based Analysis

Tahiri Y, Bouteaud J, Tahiri M, Lessard L, Williams HB, Nikolis A.

3.1 ABSTRACT

Background: Despite previous retrospective studies and recent well designed randomized controlled trials demonstrating that routine drainage after reduction mammaplasty was not necessary; the use of closed suction drainage is still the standard of care for many plastic surgeons. Our goal was to evaluate the existing literature, comparing the use of drains or not in reduction mammaplasty, through a systematic review. We assessed first, if there is enough evidence to reach a conclusion regarding the use of drain, and then, if there is a need for more randomized control trials.

Methods: We searched PubMed, EMBASE, the Cochrane Central Database of Clinical Trials (CENTRAL) on the Cochrane Library and Science Citation Index Expanded for original articles and reviews from 1980 to June 2009. Our Keywords included "reduction mammaplasty" or "breast reduction" and "drain" or "drainage".

Results: Seven studies comparing the use of drain or not in reduction mammaplasty were reviewed. There was minimal evidence of publication bias and statistical study heterogeneity.

There was no difference that was statistically significant in the complication rates between

patients treated with drains and those treated without drains; however patients were more

comfortable without the use of drains.

Conclusions: Routine drainage should not be used routinely in reduction mammaplasty. Further

randomized controlled trials are not warranted.

Key Words: reduction mammaplasty, drainage, routine

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3.2 INTRODUCTION

A systematic review is a scientific, structured review that is designed according to clear and strict scientific methods and guidelines. A complete review of the existing literature is conducted and any possible sources of bias are minimized. An important role of a Systematic Review is to clarify and summarize the existing body of literature on a topic and help avoid duplication of prior studies, particularly randomized controlled trials, in order to avoid unnecessary, unethical treatment of patients and resource wasting (142). According to the Oxford Center for Evidence-Based Medicine's Level of Evidence, systematic reviews of randomized controlled trials have higher level of evidence than randomized controlled trials and other studies (143). Systematic reviews are more frequently cited in scientific papers than any other studies, including randomized controlled studies and that for many years following publication (144).

Patient satisfaction has always been high following reduction mammaplasty. The functional, aesthetic and psychological aspects of patient care are addressed with well documented benefits in the literature (145, 146). The safety, the reliability and the aesthetic results of reduction keep improving over the years, particularly with the advances in surgical techniques.

The use of drains for wound drainage has been a longstanding practice in medicine. A significant proportion of surgeons use drains nowdays. Established routines are difficult to modify unless a need rises. Drains are used in reduction mammaplasty because they are believed to decrease fluid accumulation and collection into wound and to reduce the dead space between tissues thus, reducing the risks of hematomas and seromas.

However, despite these advantages, the use of routine drainage in reduction mammaplasty has always been debated since it is also associated with patient discomfort, pain, increased risk of infection (foreign body) and increases cost and length of hospital stay (147-149).

In 1998, an informal survey at the Breast Symposium meeting in Atlanta revealed that 80% of plastic surgeons were using drains routinely in breast reduction surgery (150). Since, some retrospective and few randomized controlled trials addressed the question of the use of drains or not in reduction mammaplasty. It appears that the consensus is to not use drains following reduction mammaplasty (150-156).

However, despite these levels of evidence, many plastic surgeons are still using drains routinely after reduction mammaplasty. In 2007, a survey of 140 consultant plastic surgeons in the UK and Ireland revealed that 79% always used drains, 11% often did and 10% either never or occasionally used drains (157).

We decided to conduct a systematic review in order 1) to evaluate the existing literature, comparing the use of drains or not in reduction mammaplasty, 2) to assess if there is enough evidence to reach a conclusion regarding the use of drains, and finally 3) to assess the need for more randomized control trials.

3.3 METHODS

Data Sources

We searched PubMed, EMBASE, the Cochrane Central Database of Clinical Trials (CENTRAL) on the Cochrane Library and Science Citation Index Expanded for original articles and reviews from 1980 to June 2009. Our Keywords included "reduction mammaplasty" or "breast reduction" and "drain" or "drainage". We limited our search to studies involving the use of drains in adult patients undergoing breast reduction. We further searched reference lists of identified original articles and reviews for other relevant articles. We did not include abstracts, book chapters, conference proceedings or correspondences.

Study Selection

Two investigators, with training in clinical epidemiology, independently selected the articles for review. The selection process was done in 2 steps: titles and abstracts, and then full text articles. We selected cohort studies or randomized controlled trials that clearly indicated whether drains were used and for how long as well as postoperative complication rates and type.

Data Extraction and Quality Assessment

Two investigators independently reviewed selected studies using standardized forms to collect data about study design, patient demographics, inclusion and exclusions criteria used in the study, surgical technique, infiltration performed, use of antibiotics (pre, intra, and postoperatively), type of drain used, cue for drain removal, quantity of tissue removed, complication rate and type, length of hospital stay and pain assessment.

No study was excluded based on quality.

MetaAnalysis and Further Statistical Analysis

Studies were assessed for meta-analysis.

3.4 RESULTS

Through our electronic and reference search we identified 30 citations. Figure 5 summarized the results of these searches and of the selection process. We identified 7 studies matching our selection criteria including 3 retrospective, 1 prospective cohort and 4 randomized control trials. All studies had adequate follow-up (over one month).

The questioning of routine drainage in reduction mammaplasty started in the late nineties, when Matarasso et al.(151) and Arrowsmith et al. (152) both published retrospective studies comparing cohorts of 50 patients who underwent reduction mammaplasty without the use of drain to previously published data. In the first study, the complication rate in a cohort of patient who did not have drains postoperatively was found to compare favorably with previously published series. In the second study, the complication rates were similar (152). In both studies, the difference in complication rates failed to reach statistical significance but it nonetheless indicated that reduction mammaplasty without drainage could be safe and probably did not lead to an increase in complication rates. It should be noted that both studies were comparing cohorts of

patients on whom no drain was used to previously published series which do not always state whether drains were used.

In a later retrospective study, Scott et al. compared an earlier cohort in which drains were used post-operatively to a latter cohort in which drains were used in only 7% of the patients. While the complication rate was lower in the later cohort, the association with the lower rate of drain use cannot be fully assessed since various changes to the approach to surgical care were made as indicated by the authors (153). In 2003, Vandeweyer carried out a prospective study comparing 35 patients who underwent reduction mammaplasty without drains to previously published series. The complication rate was found to be lower than in published series using drains performed around the same period of time and using the same surgical technique (154). To further test the hypothesis that routine drainage is not required in reduction mammaplasty, three prospective randomized controlled trials have since been conducted.

The first prospective randomized trial was conducted by Wrye et al. between 1999 and 2000 and included 49 subjects. Patients served as their own control and were randomized to having a drain in either the right or left breast inserted. Post operative comfort level was also assessed. No significant different in the number or type of complication was observed between the drain and the un-drained breast treated (p=1.00). However, 89 % of the patient reported that the un-drained breast was clearly more comfortable in the postoperative period (150). While this study was well designed, the small sample size and the lack of patients having had a large breast reduction (mass of tissue removed > 1100g per breast) raise the question of generalization. These issues were addressed in the study conducted by Collis et al. a few years later. The exact same methodology

(same study design and same surgical technique) was used but 150 patients were recruited and more than 25% had a reduction of greater than 1000g per breast. The results were similar to the ones observed in the previous study even for large breast reduction and it added to the body of evidence that routine drainage in reduction mammaplasty was safe and even beneficial for the patient (p=1) (155).

In 2009, Corion et al. published another randomized controlled trial. 107 patients were randomized to receive bilateral postoperative drainage or no drainage at all and the rate of complication was compared in between the two groups. The patients who underwent bilateral drainage were found to have a higher rate of complication than the patients on which no drain was used. However, this did not reach statistical significance. Postoperative discomfort was also higher in the drain group but no difference was observed in postoperative pain and in satisfaction (p=0.092) (156).

When the studies were evaluated in view of performing a meta-analysis, it appeared that 4 out of 7 studies compared study patients to previously published data and risk difference could not be calculated. In the remaining three studies, the way the outcome was defined, assessed and reported varied. For example, in 2 out of the 3 randomized control studies, the outcome was assessed for each breast rather than for the patient as a whole. Therefore, while meta-analysis usually produces higher level of evidence, it appeared unnecessary and even inappropriate in this context.

3.5 DISCUSSION

The functional, aesthetic and psychological benefits of reduction mammaplasty are well documented in the literature. Advances in surgical techniques in performing breast reduction clearly improved the final outcome of this procedure (22-26).

With the advent of silicone drains, the use of closed suction drains became common practice in surgery. It is believed to decrease fluid accumulation and collection into a wound and to reduce the dead space between tissues, thus, reducing the risks of hematomas, seromas and other complications. However, their benefits have not been always accepted. Varley et al. demonstrated that these drains effectively reduces the risk of hematomas only if they are in situ (158) and also reported, using ultrasound studies, that hematomas can occur up to 10 days post-operatively, meaning using drains only for the early few post-operative days may be useless (159). So in order to reduce the risk of hematomas, drains should be used for at least 10 days; consequently, increasing the risk of infection. Watson et al (149) demonstrated that bacteria have been cultured from drain tips as early as 2 days postoperatively.

With the more widespread use of vaso-constrictive infiltration of the breast tissue and the subsequent peri-operative vasoconstriction, several studies reported that blood loss was reduced significantly without noticing any rebound hemorrhage. So the need for drains required reevaluation (160-162).

Routine drainage in reduction mammaplasty is still common practice. In 1998, an informal survey at the Breast Symposium meeting in Atlanta revealed that 80% of plastic surgeons were using drains routinely in reduction mammaplasty (150).

Since 1998 and the retrospective study designed by Matarasso et al. (151), the question of using routine drainage after reduction mammaplasty has been challenged. Matarasso et al. (151), Arrowsmith et al. (152) as well as Scott et al. (153) and Vandeweyer et al. (154) all reported, in retrospect, that routine drainage was not necessary in reduction mammaplasty. The main argument is a similar complication rate in patients with and without drains after breast reduction. However, because of the nature of their study design (retrospective), more studies, and particularly randomized controlled trials, were needed to investigate the value of routine drainage after breast reduction.

Following these retrospective studies, letters to the editors (163-168) were written and few prospective, randomized studies (150, 155, 156) were designed to further support the present evidence that routine drainage in breast reduction is not required.

All of these studies demonstrated that the difference in complication rates between groups using drains post-operatively and groups who do not, was not statistically significant. The incidence of hematomas, seromas, infections and partial/total nipple necrosis was similar.

In addition to this evidence, multiple arguments against the use of drains exist: an increase in patient discomfort, an increase in patient anxiety at time of drain care and drain removal, an increase in hospital stay, an increase in costs (of drain and drain care) (152) and an increase in both nursing requirement and exposure to patient's blood. An increase in wound infection

through bacterial migration along the drain tract has also been reported (147-149). If the drains are brought through a separate stab wound, an additional scar is avoided if no drain is used.

Regarding, the effect of size of reduction on the need of post-operative drainage, Collis et al. (155) clearly reported that large reductions (>1000g) are not associated with a higher number of complications post-operatively. In the different studies presented in this systematic review, different surgical techniques for reduction mammaplasty have been used, and it is also clear that this difference in technique does not affect the incidence of complications post-operatively. High-risk patients (heavy smokers, diabetics and other at high risk for wound healing problems), have not been studied specifically. We believe that in such cases, it is at the discretion of the surgeon to use drains or not.

In many surgical subspecialties such as General Surgery, Otolaryngology and Orthopedics, the routine use of drain is controversial; however in many cases, it seems that the trend is to limit the use of routine drainage (169-177). There are and will always be individual cases when drainage is necessary; however we conclude that in the majority of cases, routine drainage after reduction mammaplasty should not be used. Given the body of evidence we believe that additional randomized controlled trials are not warranted. Routine drainage will constitute an unnecessary treatment as well as a waste of resource.

So far, through high level of evidence studies, we demonstrated that the modification of certain surgical habits during the pre-operative and intra-operative period can have a significant impact on patient's outcome and improvement of their care.

Research relies significantly on innovation. Researchers aim constantly to discover new medical and surgical treatment modalities, new diagnostic tools that will improve current treatment trends and current care.

When performing their surgeries, reconstructive breast surgeons address not only the functional aspect and psychological aspect of patient's care but also and importantly, the final aesthetic outcome of their reconstruction. In our next and last chapter, we are showing how, using a new surgical technique, we can improve the final post-operative aesthetic outcome.

Chapter 4.

Subcutaneous Pre-Expansion of Mastectomy Flaps Prior to Breast Reconstruction with DIEP flaps -- Eliminating the Patch-Like Appearance and Improving Aesthetic Outcomes

Schwarz K and Tahiri Y.

4.1 ABSTRACT

Introduction: Free tissue transfer and tissue expansion are important tools in the reconstructive surgeon's armamentarium, yet are not often used in conjunction. While tissue transfer has its advantages, the patch-like appearance of the skin paddle on the breast can be unappealing.

Objective: To present our clinical experience of using subcutaneous breast tissue expansion prior to reconstruction with Deep Inferior Epigastric Perforator (DIEP) flaps, and to show how this technique eliminates the patch-like appearance of the skin paddle.

Methods: Five patients underwent breast reconstruction using a three-stage approach. During the first stage, tissue expanders were placed in the subcutaneous plane beneath the mastectomy flaps. Following complete tissue expansion, the second stage involved removal of the tissue expanders and reconstruction of the breasts by burying de-epithelialized DIEP flaps beneath the preexpanded skin flaps. Revisions and nipple reconstructions were carried out in the third stage.

Retrospective analysis of patients' characteristics, breast history, surgical stay, complications and

outcomes were performed.

Results: The patients were on average 49 years of age, with an average BMI of 26.3. One patient

underwent bilateral breast reconstruction while the rest had unilateral reconstructions. Two

patients had minor complications. There were no DIEP failure or take-back.

Conclusion: Subcutaneous breast tissue expansion followed by DIEP flap reconstruction can be

performed safely, offering patients a completely autologous breast reconstruction with low

morbidity, as well as eliminating the classical patch-like appearance of flap reconstructions.

Key words: Breast reconstructiom; DIEP flap; Pre-Expansion; Aesthetic Outcome

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4.2 INTRODUCTION

The Deep Inferior Epigastric Perforator (DIEP) flap was initially described in 1989 by Koshima and Soeda (178) for reconstruction of floor-of-mouth and groin defects. Its use in breast reconstruction was pioneered by Allen and Treece in 1994 (179). Since then, it has become a popular option for breast reconstruction due to its reliable blood supply, low donor site morbidity, and its flexibility in shaping the breast (180-181).

As with any free or pedicled flap for breast reconstruction, one of the disadvantages is the patchlike appearance of the skin paddle on the reconstructed breast (182).

In addition to autologous tissue transfer, tissue expansion is an excellent tool present in the armamentarium of the reconstructive breast surgeon. Since its first description in 1982 (183), tissue expansion for breast reconstruction remains a simple and reliable technique when used in the appropriate settings (184).

As breast reconstruction evolves, plastic surgeons continue to find ways in which to improve the appearance of reconstructions while keeping donor site morbidity to a minimum. In an effort to improve aesthetic outcomes of autologous reconstructions, we now use a staged approach which combines the advantages of tissue expansion with that of reconstruction with DIEP flaps. This technique eliminates the patch-like appearance of the skin paddle typically seen with autologous reconstructions.

4.3 METHODS

Study Period and Study Population

Five patients had breast reconstruction using a three-staged approach from August 2008 to February 2010.

Non-smokers patients with donor sites appropriate for DIEP flap reconstruction (185) and with no history of radiation therapy were considered candidates for this staged procedure.

Our Three-stage Procedure

In the first stage, patients underwent delayed reconstruction by placing tissue expanders in a **subcutaneous** plane. The expanders were inserted via previous mastectomy scars. Anatomic tissue expanders were chosen based on base diameter, height of the breast, the amount of abdominal tissue available, the contralateral breast volume, and patients' desired volume. Expansion was started two weeks post-operatively and repeated on a weekly basis, until the adequate volume was reached. As early as one month later, patients underwent the second stage procedure. The expanders were removed and ipsilateral DIEP flaps were harvested, with the internal mammary system used as recipient vessels in all cases. The DIEP flaps were then deepithelialized and buried under the native mastectomy flaps, leaving behind only a 1cm wide, temporary skin paddle for monitoring purposes (skin paddle that is excised in the office under local anaesthesia 3-4 weeks later). Radial capsulotomies were performed prior to in-setting in order to improve re-draping of the mastectomy flaps over the DIEP flaps. Breast incisions were closed in layers over 7mm Jackson-Pratt (JP) drains (Cardinal Health, McGaw Park, IL).

As early as three months later, the third stage was performed. This included revision of reconstruction, NAC reconstruction using modified star flaps, lipo-infiltration if needed, and contralateral symmetry procedures. Tatooing of the NAC was planned for three months following the third stage.

4.4 RESULTS

Five patients benefited from this delayed three-stage expander to DIEP flap breast reconstruction procedure from August 2008 to February 2010. One patient underwent bilateral breast reconstruction whereas the rest had unilateral reconstruction.

Patients' ages ranged from 38 to 64 years old, with an average of 49 years. Their BMI ranged from 22.7 to 33.7, with an average of 26.3. One patient, a heavy smoker who stopped 4 weeks before the first stage, resumed smoking one and a half packs a day several weeks later.

Anatomic expanders ranging from 550cc to 650cc were used. Intra-operative expansion ranged from 50cc to 100cc. Weekly expansion volumes ranged from 50cc to 100cc. Final expansion volumes ranged from 475cc to 650cc, with an average of 532cc. Average time of expansion was 37 days. There were no DIEP flap losses. One patient who underwent bilateral reconstruction developed unilateral fat necrosis, which was treated by excision and subsequently corrected by lipo-infiltration. The patient who resumed smoking despite our recommendations developed a breast seroma which was aspirated via ultrasound in the early expansion period. The same patient also experienced a1x3cm area necrosis of the distal, central abdominal donor site, which was treated conservatively.

Table 5 presents patients' medical and surgical characteristics.

Three cases are shown: two unilateral reconstructions and one bilateral breast reconstruction (Figure 6, 7 and 8).

4.5 DISCUSSION

Breast reconstruction consists of re-creating a complex three-dimensional structure with boundaries that are often difficult to define, where shape, texture, and color are of prime importance. In an effort to improve the patch-like appearance of autologous reconstructions, Spear and Davison described the different aesthetic subunits of the breast (186).

While major improvements continue to be made in both implant-based and autologous reconstruction, they are rarely used in conjunction (187). Recently, Kajikawa et al. reported the combined use of Transverse Rectus Abdominis Myocutaneous flap and tissue expansion for breast reconstruction (182).

Tissue expansion continues to be the most common procedure for breast reconstruction after mastectomy (188-193). This is partly due to a shorter OR time, no donor site morbidity, and a faster recovery compared to autologous breast reconstruction (194). Despite this, patients continue to benefit from autologous breast reconstruction, which provides a more natural-looking breast that lasts a lifetime (195-199). However, as seen with all flaps, one of the disadvantages of autologous reconstruction is the patch-like appearance of the skin paddle on the breast.

In this series, we present a technique that eliminates this problem, leaving only the patient's native breast skin overlying a completely autologous reconstruction.

The important considerations for this technique include patient selection and careful intra- and post-operative expansion.

Given that we perform subcutaneous expansion, patients who have had radiotherapy or smokers should be excluded, given the blood supply issues (199). Increased complication rates in these patients are well documented in the literature (199). In our series, one patient, who relapsed into smoking post-operatively, developed a seroma in the breast during early expansion and a small area of tissue necrosis at the donor site. It is important to select motivated, compliant patients.

We also performed this technique only in delayed reconstructions, being careful to avoid placing a subcutaneous expander in immediate reconstructions, where blood supply to the mastectomy flaps can be precarious. However, we do not believe that this technique is contraindicated in immediate reconstruction.

Although immediate reconstruction offers many advantages (200, 201), the risk of requiring radiation therapy post-operatively cannot be fully predicted pre-operatively, and that may alter the "sequencing of breast reconstruction". This limitation can be overcome by using the "delayed-immediate breast reconstruction approach" presented by Kronowitz (202).

The downside to our technique is that it requires an additional step, making it a three-stage reconstruction, as opposed to the traditional, two-stage approach. However, given the subcutaneous placement of the expander, patients recovered quickly and with little pain.

Expansion lasted on average 37 days and the second stage can be safely performed one month later.

We believe that this additional procedure allows for a significantly improved breast appearance, eliminating the patch-like skin paddle - a signature of traditional autologous reconstruction. It can be performed safely if patients are carefully selected and the appropriate intra- and post-operative principles outlined in this article are followed.

Chapter 5.

Conclusion

Medical research is a vast domain, which extends from basic science research to clinical research and further practical applications. Basic science research helps us understand biological mechanisms, which can then be applied in clinical research. The goal is then to improve our understanding of diseases and to improve our conception of new diagnostic tests, medical and surgical treatments. For instance, new medications, new diagnostic tools and innovative surgical techniques are all the results of dedicated research. The end point of this research is to finally improve patients' care, by improving our diagnostic tools, our medical and surgical treatments and our prevention strategies.

Reconstructive breast surgery is a growing domain. An increasing proportion of women are diagnosed with breast cancer in North America and an increasing proportion of those seek breast reconstruction. With the information available on the Internet, women are more informed and, understandably, have high expectations.

Breast reconstruction consists of re-creating a complex three-dimensional structure with boundaries that are often difficult to define, where shape, texture, and color are of prime importance. As breast reconstruction evolves, plastic surgeons continue to find ways to improve their final outcomes. These outcomes can vary from an improved functional to an improved aesthetic final result.

These three studies illustrate how plastic surgery research can improve final reconstructive outcomes. The reason we decided to conduct three studies is to adopt a comprehensive approach and to dedicate one study for each operative period: pre-, intra- and post-operative periods. We wanted to demonstrate that research should involve all aspects of the medical and surgical care of the patient. Complete surgical care of the patient involves not only a successful operation, but a well-rounded care, including optimization of the pre-operative and post-operative care. Furthermore, complete care does not limit itself to a successful functional outcome, but also a pleasing aesthetic outcome.

In the first study, using a meta-analysis, we evaluated the safety and efficacy of TPVB for breast surgery, and compared TPVB to GA with regards to postoperative pain, nausea and vomiting, opioid consumption and length of hospital stay. With the highest level of evidence, we demonstrated that *pre-operative* TPVB provides effective anesthesia for ambulatory / same-day breast surgery and can result in significant benefits over GA, in terms of improved pain control, decreased consumption of opioids, decreased occurrence of nausea and vomiting and reduced hospital stay. However, we believe that further studies are required to determine if these advantages would still persist if an optimal technique for outpatient GA is employed. Adjunctive ultrasonography may contribute to improve the safety of TPVB in breast surgery anesthesia and requires further investigation.

In the second study, we performed a systematic review to evaluate the existing literature, comparing the use of drains or not in reduction mammaplasty. We assessed first, if there is enough evidence to reach a conclusion regarding the routine use of drains after reduction

mammaplasty, and then, if there is a need for more randomized control trials. We demonstrated with a high level of evidence (systematic review) that although the routine placement of *intra-operative* drains after reduction mammaplasty is common practice, it should not be used routinely in reduction mammaplasty. It does not increase the risk of hematoma or seroma formation, but increases patient discomfort and potentially increases the risk of post-operative infections. In addition, given the body of evidence we believe that additional randomized controlled trials are not warranted. Routine drainage constitutes an unnecessary treatment as well as a waste of resource for the health care system.

Finally, in the third study, we are presenting our clinical experience of using subcutaneous breast tissue expansion prior to reconstruction with Deep Inferior Epigastric Perforator (DIEP) flaps, and we illustrated how our new technique eliminates the patch-like appearance of the skin paddle. We developed this three-stage procedure; surgical technique that was never described or presented before. Through this study, we demonstrated how innovation in plastic surgery research can improve the final, *post-operative* aesthetic outcome. Subcutaneous breast tissue expansion followed by DIEP flap reconstruction can be performed safely, offering patients a completely autologous breast reconstruction with low morbidity, as well as eliminating the classical patch-like appearance of flap reconstructions.

These three studies demonstrate how plastic surgery research can help us improve and optimize the surgical treatment of patients seeking breast reconstruction. The pre-, intra- and post-operative periods were being addressed, to improve breast reconstruction final outcomes and to improve our overall care of our breast cancer patients' population.

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TABLES

Table 1. Summary of included studies

Authors (year)	Type of Study	N (GA/ TPVB)	Type of Surgery (GA/ TPVB)	Anestheti c Agent for GA	PONV Prophyla xis for GA (agent)	Intraopera tive Sedation for TPVB	Technique for TPVB
Weltz et al. (1995)	CS	0/ 15	Wide excision with axillary dissection (0/7) Modified radical mastectomy (0/5) Simple mastectomy (0/4)	NA	NA	Propofol/ fentanyl	ML injection at T1-T8 No description of endpoint for needle advancement 4 mL bupivacaine 0.5 % with epinephrine 2.5 µg/ mL per level
Greengra ss et al. (1996)	CS	0/ 25	Wide excision with axillary dissection (0/4) Modified radical mastectomy and axillary dissection (0/13) Simple mastectomy (0/3) Lumpectomy with axillary dissection (0/5)	NA	NA	Propofol/ fentanyl	ML injection at T1-T7 Needle advanced 1.5-2 cm over TP 3-4 mL bupivacaine 0.5 % with epinephrine 2.5 μg/ mL per level
Coveney et al. (1998)	R	100/ 156	Wide local excision with axillary dissection (28/48) Modified radical mastectomy (56/75) Simple mastectomy (5/18) Axillary dissection only (1/10) Wide local excision (7/3) Bilateral procedure (3/2)	Isoflurane / nitrous oxide	N	Propofol/ fentanyl	ML injection at T1-T7 Needle advanced 1.5-2 cm over TP 3-4 mL bupivacaine 0.5 % with epinephrine 2.5 µg/ mL per level
Pusch et al. (1999)	RCT	42/44	Mastectomy with axillary dissection (5/4) Lumpectomy with axillary dissection (10/11) Simple mastectomy (4/5) Lumpectomy (22/23) Axillary dissection (1/1)	Propofol	Y (propofol	Propofol	SL injection at T4 LOR 0.3 mL/ kg bupivacaine 0.5 %
Klein et al. (2000)	RCT	30/29	Implant insertion (12/2) Implant replacement (16/22) Implant removal (1/4) Nipple reconstruction (1/1) Bilateral reconstruction (13/18)	Isoflurane / nitrous oxide	Y (ondanset ron)	Propofol/ fentanyl	ML injection at T1-T7 Needle advanced 1 cm over TP 4 mL bupivacaine 0.5 % with epinephrine 2.5 µg/ mL per level

Terhegge n et al. (2002)	RCT	15/ 15	Radiograph wired localized breast biopsy (9/10) Lumpectomy, quadrantectomy +/- SLN procedure (6/5)	Propofol/ nitrous oxide	N	Propofol	TPVB catheter at T3-4 LOR 15-20 mL bupivacaine 0.5 % with epinephrine 5 µg/ mL
Naja et al. (2003)	RCT	30/30	Modified radical mastectomy (9/8) Simple mastectomy (3/2) Partial mastectomy (18/20)	Isoflurane / nirous oxide	N	Propofol	ML injection at T1-T5 Neurostimulation 3-3.5 mL of lidocaine 1.33 % - bupivacaine 0.17 % - epinephrine 2.5 μg/ mL – fentanyl 50 μg – clonidine 300 μg per level
Najarian et al. (2003)	R	152/ 128	Mastectomy (61/77) Lumpectomy (65/46) Axilla (2/2) Axillary lymph node dissection (32/37) SLN biopsy (17/15) Axillary lymph node dissection with SLN biopsy (59/48)	NR	NR	Propofol or midazolam	ML injection at T1-T6 Needle advanced 1-1.5 cm past TP 5 mL ropivacaine 0.5 % with epinephrine 2.5 μg/ mL per level
Dabbagh et al. (2007)	RCT	30/30	NR	Halothan e/ nitrous oxide	N	Midazolam / fentanyl	SL injection at T4 LOR 15 mL lidocaine 2 %
Cooter et al. (2007)	CS	0/ 100	Breast augmentation (0/100)	NA	NA	Propofol/ fentanyl	SL injection at T4 LOR 15 mL ropivacaine 0.75 % + 5 mL NS
Kumar et al. (2009)	CS	0/46	Modified radical mastectomy (0/20) Simple mastectomy (0/12) Mastectomy with axillary lymph node dissection (0/8) Wide excision with or without axillary dissection (0/6)	NA	NA	Propofol/ fentanyl	SL injection at T4 LOR 0.4 mL/ kg bupivacaine 0.5 %

CS = case series; GA = general anesthesia; LOR = loss of resistance; ML = multiple level; N = no; NA = not applicable; NR = not reported; PONV = post-operative nausea and vomiting; R = retrospective study; RCT = randomized controlled trial; SL = single level; SLN = sentinel lymph node; TP = transverse process; TPVB = thoracic paravertebral block; Y = yes.

 $\label{thm:complex} \textbf{Table 2. Block failures and complications in patients undergoing breast surgery under GA or TPVB$

Authors		local anesthesia tion required	Conversion to GA required	Complication rate and type				
	GA	TPVB % (n/N)	% (n/N)	GA % (n/N)	TPVB %(n/N)			
Weltz et al.	NA	12.5% (2/16)	0%	NA	0%			
Greengrass et al.	NA	12.0% (3/25)	8.0% (2/25)	NA	0%			
Cooter et al.	NA	13.0% (13/100)	0%	NA	12.00% (12/100): - Pre-convulsion (1) - Hypotension/ bradycardia (10) - Epidural spread (1)			
Kumar et al.	NA	6.5% (3/46)	6.5% (3/46)	NA	2.20% (1/46): - sensory block of 2 dermatomes on the opposite side (1)			
Coveney et al.	NR	5.8% (9/156)	9.0% (14/156)	0%	2.61% (4/156): - Epidural involvement (2) - Epinephrine absorption (1) - Pneumothorax (managed without tube thoracostomy) (1)			
Najarian et al.	1.60%	25.7% (39/152)	15.8% (24/152)	0%	1.80% (3/164): - Hypotension (2) - Pneumothorax (managed with tube thoracostomy) (1)			
Pusch et al.	NR	6.8% (3/44)	0%	0%	2.27% (1/44): - Epidural spread with Horner's syndrome (1)			
Terheggen et al.	NR	0%	3.3% (1/30 because of epidural spread)	0%	6.67% (2/30): - Epidural spread (1) - Pleural puncture without pneumothorax (1)			
Naja et al.	NR	3.3% (1/30)	0%	0%	0%			
Dabbagh et al.	NR	NR	NR	0%	0%			
Klein et al.	NR	10.0% (3/30)	3.3% (1/30)	0%	0%			

GA = general anesthesia; NA = not applicable; NR = not reported; TPVB = thoracic paravertebral block.

 $Table \ 3. \ Incidence \ of postoperative \ nausea \ and \ vomiting \ and \ analgesic \ consumption \ in patients \ receiving \ GA \ and \ TPVB$

Authors		PONV * % (n/N)		Postoperative analgesic consumption % (n/N)				
	GA	TPVB	P	GA	TPVB	P		
Weltz et al.	NA	20.0% (3/15)	NA	NA	40.0% (6/15)	NA		
Greengrass et al.	NA	23.5% (4/17)	NA	NA	52.9% (9/17)	NA		
Cooter et al.	NA	10.0% (10/100)	NA	NA	6.0 % (6/100)	NA		
Kumar et al.	NA	19% (9/46)	NA	NA	26.1% (12/46)	NA		
Coveney et al.	40.0% (40/100)	15.4% (24/156)	<0.0001	97.8% (87/89)	25.0% (28/112)	NR		
Najarian et al.	24.0% (24/100)	16.0% (20/125)	0.101	93.0% (93/100)	81.0% (101/125)	<0.01		
Pusch et al.	28.6% (12/42)	9.1% (4/44)	<0.05	52.4% (22/42)	4.5% (2/44)	<0.05		
Terheggen et al.	6.7% (1/15)	0%	0.325	26.7% (4/15)	0%	0.032		
Naja et al.	33.3% (10/30)	6.7% (2/30)	<0.05	100% (30/30)	16.7% (5/30)	<0.01		
Dabbagh et al.	NR	NR	NA	NR	NR	NA		
Klein et al.	NR	NR	NA	56.7% (17/30)	26.7% (8/30)	NR		

GA = general anesthesia; NA = not applicable; NR = not reported; NS = not statistically significant; PONV = postoperative nausea and vomiting; TPVB = thoracic paravertebral block.

^{*} If no information is provided for the rate of postoperative nausea and vomiting, the latter is estimated by the number of patients requiring antiemetics postoperatively.

Table 4. Study Summary

Study	Country	Years study was conducted	Design	Comparative	# of patients	Drain use	Mean age	Technique	Infiltration	Mass of tissue	tal	Com	plication Type :	and rate	Satisfaction of the patient
Mattarasso et al.	USA	Not given (published in 1998)	Retrospective case series	Historical data	50	No drain	28	42 superior pedicle (pitanguy) 7 inferior pedicle 1 amputative technique with nipple graft	epinephrine	953 g	Not given	Partial Nipple loss Hematoma Fat necrosis Wound disruption	2% 2% 4% 4%	0.05 0.01	
Arrowsmith et al.	UK	1994-1997	Retrospective Case series	Historical data	50	No Drain	32	Inferior dermoglandula r pedicle	glandular infiltration of adrenaline, in conjunction with either lignocaine or marcaine	750g	3 days	Hematoma Minor Wound Dehiscence Infection		0% 2% 2%	
					Cohort 1	- Drains	•				ort 1 - rains		C1	C2	
		1992-1994		Comparing an	113	drains (Jackson -Pratt)	40	Inferior (wise	Marcaine 0.25% with	883g	27h (over night stay)	Hematoma Dehiscence Reoperatio Nipple	12 (10.6%) 5 (4.8 %) 5 (4.4 %) 3 (2.7%)	10 (9.8 %) 4 (3.9 %) 3 (29 %) 3(2 %)	
Scott et al.	USA	(drains) 1999-2001 (no drains)	Retrospective	earlier to a later patient cohort	Cohort 2	No drain		pattern) Inferior (wise pattern)	1/100,00 solution of epinephrine	Cohort drain	2 - No	epidermoly sis	25 (22 %)	20 (19.6 %)	
					103	no drain			фиерине	622g	5h (day surgery)	Nipple necrosis Cellulitis Nipple graft	1 (0.8 %) 1 (0.8 %)	0 (0 %) 0(0 %)	
Vandeweyer	Belgium	2001	Prospective	Comparing to previously published series	35	No drain	36.6	Vertical reduction (Lejour)	No infiltration	579.8 g	1 day	Hematomas Partial nipple necrosis	2 4	1.8 % 1.2 %	
				Patients served				-				_	Drained	Undrained	• 89 % reported that
Wrye et al.	USA	1999-2000	Randomized – intra-patient	as their own controls (drained breast compared to undrained breast)	49	One side has drains (n 10 flat Blake or Jackson Pratt)/ other side no drain	33	Inferior pedicle (except for one patient who underwent amputation and free mipple grafting)	No epinephrine use	675g	l day	Partial nipple loss Wound breakdown Fat necrosis Hematoma TOTAL	1 (2%) 2 (4%) 2 (4%) 1 (2%) 6(12%)	0 (0%) 3 (6%) 1 (2%) 1 (2%) 5 (10%)	the undrained breast was more comfortable • 19 % reported little to no difference • No difference in long term satisfaction
Collis et al.	UK	Not indiquated (published in 2005)	Randomized – intra-patient	Patients served as their own controls (drained breast compared to undrained breast)	150	Bellovac	37	141 patients – inferior pedicle 9 patients	Not indicated	799g (25% of patie nts >100 og per breas t)		Hematoma Minor wound healing Major wound healing Fat necrosis Abscess drainage Minor infection Seroma aspiration	Drained 3 12 3 4 1	Undrained 4 12 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
					Cohort 1 -	Drains				Cohort I	1-		Drained	Undrained	
					55	55 36				1110 g		Hematoma Oedema	6 1	4 2	Discomfort was
Corion et al.	Netherla nds	2003-2005	Randomized – inter-patient	Drained group is compared to the undrained group	Cohort 2 – No drain		Cranio-medial pedicle	No epinephrine use	Cohort 2 drain	 Infection 		8 5 2	3 0	rated as high in the drained group. But difference in postoperative pain	
				-	52	52 No drains 35			1085 g		Nipple loss TOTAL	22	12	postoperative pain and in satisfaction	

Table 5. Patients' medical and surgical characteristics

Case	Age (years)	ВМІ	Risk Factors	Indication	Procedure	Length of expansion	Volume of expansion	Recipient site Complications	Donor site Complications
				Right modified radical mastectomy	R expansion then				
1	38	26.9	None	(MRM)	DIEP flap	39 days	500cc	None	None
2	64	23.8	Smoker	Left MRM	L expansion then DIEP flap	52 days	475cc	Seroma (30 cc aspirated)	Midline skin edge necrosis
3	44	22.7	None	Left MRM	L expansion then DIEP flap	30 days	550cc	None	None
4	55	33.7	Obese	Left MRM	L expansion then DIEP flap	35 days	650cc	None	None
5	44	24.2	None	Bilateral MRM	Bilateral expansion then DIEP flap	28 days	Both: 510cc	Unilateral Fat necrosis (excised)	None

FIGURES

Figure 1. Study Selection Process

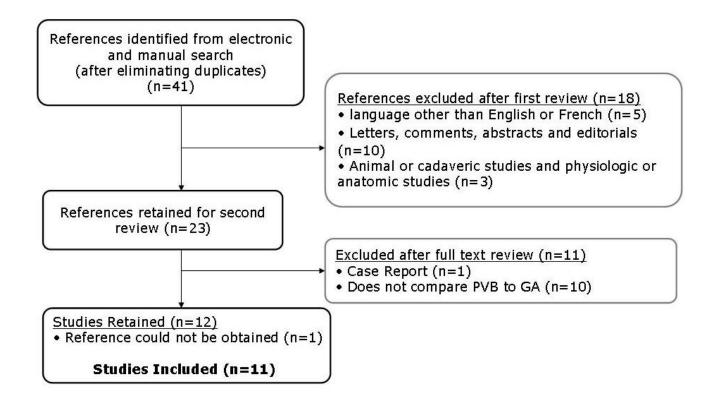


Figure 2. Meta-analysis of pain scores difference observed at 1 hour after surgery between patients who received TPVB and patients who received GA

	PVB			GA				Mean Difference	Mean Difference		
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI	IV, Fixed, 95	5% CI	
Dabbagh	4.3	1.29	30	2.1	1.04	30	21.9%	2.20 [1.61, 2.79]			
Klein	4	3	30	0.6	2	29	4.6%	3.40 [2.10, 4.70]			
Pusch	0	0	0	0	0	0		Not estimable			
Terheggen	3.5	0.5	15	1	0.4	15	73.5%	2.50 [2.18, 2.82]			
Total (95% CI) 75				74	100.0% 2.48 [2.20, 2.75]			♦			
Heterogeneity: Chi ² = 2.80, df = 2 (P = 0.25); I^2 = 29%											
Test for overall effect: Z = 17.47 (P < 0.00001) Favours GA Favours PVB									vours PVB		

Figure 3. Meta-analysis of the risk of analgesics use after surgery in patients who received TPVB versus GA

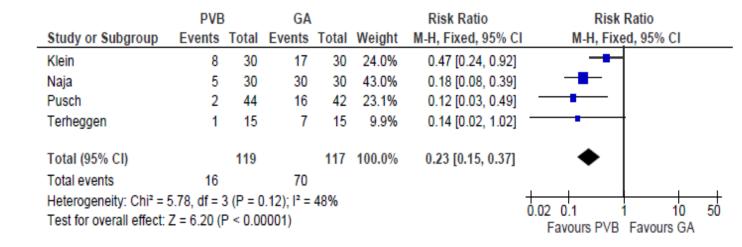


Figure 4. Meta-analysis of the risk of nausea/vomiting after surgery in patients who received TPVB versus GA

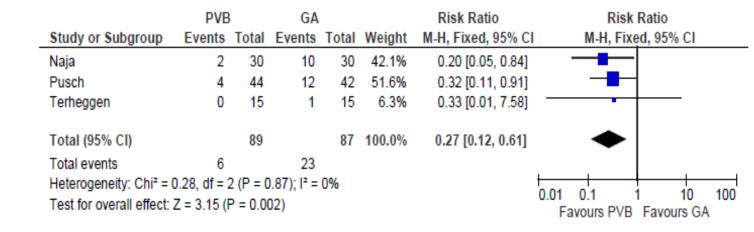


Figure 5. Summary of literature search and study selection

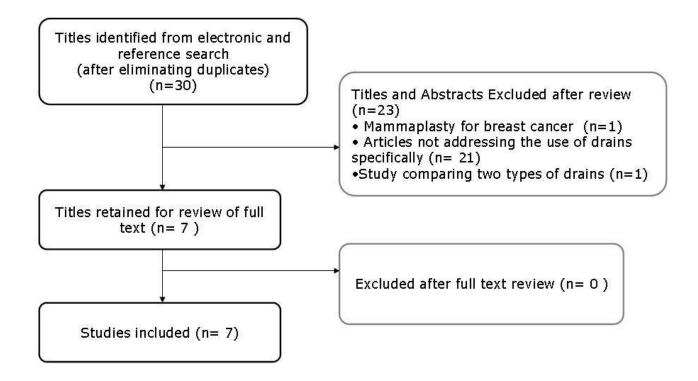


Figure 6.

38 year old female post right modified radical mastectomy: (left to right) 1) Two weeks post-operative appearance following expander insertion; 2) Appearance following ipsilateral DIEP flap; 3) Appearance following nipple reconstruction on the affected side and mastopexy on the contralateral side



Figure 7.

55 year old female post left modified radical mastectomy: (left to right) 1) Pre-operative appearance; 2) Appearance during expansion; 3) Appearance following ipsilateral DIEP flap and Nipple Areolar Complex reconstruction on the affected side and breast reduction on the contralateral side



44 year old female: (left to right) 1) Appearance prior to bilateral modified radical mastectomy; 2) Appearance following bilateral breast reconstruction using DIEP flaps; 3) Appearance following bilateral Nipple Areolar Complex reconstruction

Figure 8.

