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Impact of obesity on outcomes in breast reconstruction: A systematic review protocol

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ABSTRACT

Introduction: The worldwide obesity epidemic is creating new challenges for surgeons involved in breast reconstruction. This systematic review aims to summarise the research available in order to determine the surgical and medical complications, the duration of surgery and post-operative hospital stay and the likelihood of reoperation in each of the different techniques of breast reconstruction in women with obesity. To our knowledge, no systematic review is currently available that assesses the impact of obesity on breast reconstruction outcomes.

Methods and analysis: Electronic searches will be conducted on Cochrane, PUBMED and EMBASE, from their inception to 1 June 2016. All cohort studies, case series, randomised controlled trials, and case-control studies on women undergoing breast reconstruction post mastectomy for oncological reasons will be included. Articles must mention at least one of the primary outcomes of interest. Full exclusion and inclusion criteria are described within this protocol. Primary and secondary outcomes are described within this protocol. The search strategy, described within this protocol, aims to identify all articles on "obesity and breast reconstruction."

Discussion: This paper outlines the study protocol for a systematic literature review that will identify and summarise currently available evidence on the effectiveness and complications of breast reconstructive procedures in women with a BMI >30 kg/m^2. This review aims to provide an overview of the evidence in order to create a guide for healthcare professionals involved in the breast reconstruction of obese women.

Dissemination: This review will be published in a peer-reviewed journal and will be presented at various national and international conferences.

Introduction

Obesity is acquiring global epidemic proportions and is imposing a significant public health concern. The most recent data by the World Health Organization, which defines obesity as having a body mass index (BMI) of $\geqslant$30 kg/m^2, states that 13% of the world's adult population is obese [1].

More specifically, obesity is on the rise for women, with 40% of the global female population being overweight and 15% obese [1]. Additionally, breast cancer is on the rise, accounting for approximately 30% of all newly reported cancer cases [2]. Consequently, it is likely that the proportion of women seeking breast reconstruction in the obese population is increasing [3], and it is imperative to evaluate the efficacy and possible complications of the reconstructive techniques currently available.

Studies have shown that obese women, in comparison to those with normal BMI, have an increased risk for perioperative complications in various surgical procedures, including breast reconstruction [4]. Consequently, these patients create unique challenges to healthcare professionals as they have a higher risk of perioperative medical complications, including pulmonary embolism, myocardial infarction, and sepsis [5].

Furthermore, research suggests that this population is more likely to experience complications in both prosthetic and autologous breast reconstruction, with obese women demonstrating complication rates of 25% in comparison to 14% in non-obese individuals [6]. More specifically, research has found a greater occurrence of wound complications in breast reconstruction in obese patients. The same study found that obese patients have a 5.3%

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higher risk of reoperation within 30 days compared with nonobese patients [7].

The risk of failure of prosthetic breast reconstruction in obese patients has been found to be as high as 20–25% [8]. Obesity has been shown to be a positive predictor for skin necrosis and infection, which are the two major complications associated with prosthetic breast reconstruction and which often lead to reoperation [9]. In addition to the increased likelihood of infection and flap necrosis, there is also a positive correlation between obesity and the occurrence of seroma [10,11], with one study finding that a single unit increase in BMI was associated with a 9.23% increase in the odds of seroma [12]. Early prosthesis loss, which is an infrequent but very serious complication of breast reconstruction, has also been correlated to obesity [13].

A higher rate of loss has been correlated between obese patients and tissue expander breast reconstruction [14]. In addition, the pedicled transverse rectus abdominis myocutaneous (TRAM) flap has been reported as having significantly higher rates of flap complications in obese patients [15]. In addition, obesity should be considered a relative contraindication in abdominal donor site autologous reconstruction, according to research [16].

Although it is widely accepted that a raised BMI increases the risk of complications in breast reconstruction, a detailed comparison of the risk associated with each of the numerous reconstructive options available has been elusive [17]. By improving our understanding of the effect of weight on surgical complications and outcomes breast reconstruction healthcare professionals will be able to identify the best strategy for each patient in order to minimise adverse effects.

Therefore, given the rising prevalence of obesity among breast reconstruction patients, this review seeks to analyse and summarise the current literature to provide a better understanding of the risks related to breast reconstruction among women with obesity. The findings from such a review aim to provide a guide for the treatment of such women. Here we report our protocol for the systematic review.

Objective

To perform a comprehensive systematic review of the current literature in order to assess the peri-operative outcomes in obese women who have undergone breast reconstruction.

The outcome measures of interest are:

1. Surgical morbidity.
2. Medical complications.
3. Length of postoperative hospital stay.
4. Reoperation.
5. Patient satisfaction.

Methodology

This systematic review will be conducted in line with the recommendations outlined in the Cochrane Handbook for Systematic Reviews of Interventions version 5.1.0 [18]. It will be reported according to the Preferred Reporting Items for Systematic Reviews and meta-Analyses (PRISMA) statement [19].

Criteria for selecting studies

The following inclusion criteria were selected to address the research question stated.

Types of studies/material

Studies to be included are cohort studies, case series, randomised controlled trials, and case-control studies. Included articles must mention at least one of the primary outcomes of interest. Articles to be excluded are unpublished trials and reports, studies that fail to provide an indication for the procedure, case reports, duplicate studies, cost-effectiveness studies, and studies that do not provide the original data such systematic reviews, meta-analyses, editorials, discussions, commentaries and letters.

Types of participants

Female patients with a BMI >30 kg/m^2 undergoing immediate or delayed breast reconstruction following a mastectomy for the treatment of breast cancer. Transgender cases will not be included.

Types of interventions

This review will consider the following surgical interventions: prosthetic implants, including tissue expander and acellular dermal matrix use, and autologous fat grafting, including pedicled, free and muscle sparing TRAM flaps, latissimus dorsi myocutaneous (LDM) flaps, deep inferior epigastric perforators (DIEP) flaps, and superficial inferior epigastric artery (SIEA) flap. The surgeries included should have been performed solely for the purpose of reconstruction following oncological surgery. Traumatic breast defects (such as amputations, trauma or burns), as well as cosmetic procedures, will be excluded.

Types of comparator

Studies with a comparator will not be excluded from this review. There are no restrictions on the type of comparator and could include overweight women as well as women with normal BMI.

Outcomes

There are five distinct outcomes of interest:
Primary outcomes:

1. Surgical morbidity: in terms of intra- and postoperative complications, including local wound infection or disruption, palpable nodules, fat necrosis, seroma and prosthesis/flap failure.
2. Medical complications: including deep vein thrombosis, pulmonary embolism, acute renal failure, myocardial infarction and sepsis. The validated Clavien–Dindo classification will be used for grading of postoperative complications.
3. Length of postoperative hospital stay.
4. Reoperation: number of sessions required to achieve a satisfactory outcome.
5. Patient satisfaction.

Secondary outcomes:

1. To determine optimal methods of breast reconstruction.
2. To help refine patient selection for each procedure.

Search methodology for identification of studies

Electronic searches

The following electronic databases will be screened from their inception to 1 June 2016: Cochrane, PUBMED and EMBASE.

Search terms and keywords

The databases will be searched using the following keywords: obesity, morbid obesity, Body Mass Index, BMI, weight, quetelet index, breast reconstruction, prosthetic breast implant, breast

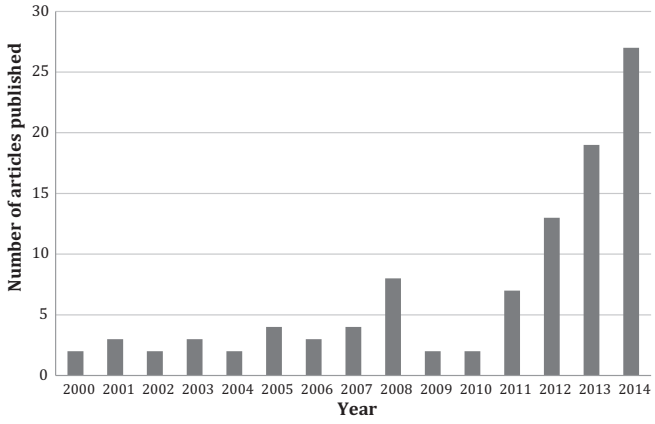

Fig. 1. Number of articles published per year and indexed by Pubmed under the search term "breast reconstruction and obesity."

autologous tissue flap, breast free flap, transverse rectus abdominis myocutaneous flap, pedicled TRAM flap, free muscle-sparing TRAM flap, latissimus dorsi myocutaneous flap, deep inferior epigastric perforators flap, superficial inferior epigastric artery flap, breast tissue expander. The language will be restricted to English and the search format will be tailored to the appropriate syntax of each database.

Identification and selection of articles

The article selection process will be a two-stage process completed by two independent reviewers. The citation, title and abstracts of studies identified through the electronic search will be tabulated into Microsoft Excel and duplicates will be removed. First, the titles and abstracts will be scanned for relevance. The full manuscript of articles that have passed through this selection stage will then be assessed for eligibility. If the two independent reviewers disagree on inclusion or exclusion of a title/abstract/paper, a third reviewer will be consulted to achieve consensus. The inclusion and exclusion criteria used to select the studies for this review are listed in Table 1. Once the inclusion list is finalised, data extraction will take place.

Data extraction and management

Data extraction will be conducted by two independent reviewers with discrepancies resolved by discussion between the two reviewers. Data will be extracted to pre-established extraction forms, formatted in a Microsoft Excel database, where relevant data for each study will be collated.

The following data will be extracted.

- Reference (lead author, year of publication, country)
- Type of study
- LoE (Oxford Centre for Evidence-based Medicine)
- Reconstructive technique
- Number of patients
- Mean or median BMI of participants
- Mean or median age of participants
- Previous breast surgery
- Number of previous breast reconstruction surgery
- Time interval between previous breast surgery and reconstructive surgery
- Duration of surgery
- Length of postoperative hospital stay
- Follow-up duration
- Loss to follow-up expressed as a percentage
- Surgical and medical complications as outlined above

Data synthesis and statistical analysis

The outcomes of interest, as defined above, will be tabulated and shown in descriptive or numeric form as appropriate and summarised

Dissemination

The review can be regarded as a valuable working document for healthcare professionals who need to be aware of the outcomes of breast reconstruction when caring for obese women. It will be published in a peer-reviewed journal in the English language and will be presented at various national and international surgical conferences.

Conclusion

This systematic review aims to summarise available evidence in order to evaluate the effectiveness, complications and outcomes of the various breast reconstruction techniques in women with a BMI greater than 30 kg/m^2. It will explore if, and how, previous breast surgery affects the outcome of breast reconstruction. It will also explore if, and how, obesity impacts length of surgery and hospital stay and whether it increases the likelihood of reoperation. Overall

Table 1
Inclusion and exclusion criteria for study selection.

Inclusion criteria
Cohort studies, case series, randomised controlled trials, and case–control studies
Prospective and retrospective studies
Patients who underwent breast reconstruction following a mastectomy for the treatment of breast cancer
Female patients of any age
Patients that underwent prosthetic implant (saline or silicone) or autologous tissue flap (TRAM flap, pedicled TRAM flap, free muscle-sparing TRAM flap, LDM flap, DIEP flap, SIEA flap) breast reconstruction
At least one primary outcome reported
Exclusion criteria
Unpublished trials and reports, case reports, duplicate studies, cost-effectiveness studies, and studies that do not provide the original data such systematic reviews, meta-analyses, editorials, discussions, commentaries and letters
Non–English language studies
Studies conducted on cadavers or animals
Studies conducted on male or transgender patients
Studies with no data on complications
Studies that used combined techniques
Studies that do not indicate a reason for the procedure
Patients who underwent breast reconstruction for aesthetic purposes or for traumatic breast defects
Studies that did not specify the number of patients

the review should be useful in guiding healthcare practitioners to the select the most appropriate form of surgery for obese women seeking breast reconstruction. (Fig. 1)

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.isjp.2016.10.001.

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