Breastfeeding after augmentation mammoplasty: Protocol for a systematic review and meta-analysis

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Abstract

Background: Cosmetic breast augmentation is one of the most common plastic surgery procedures worldwide and uptake in high income countries has increased in the last two decades. Women need information about all associated outcomes of breast augmentation in order to make an informed decision regarding whether to undergo cosmetic breast surgery. We will conduct a systematic review and meta-analysis to assess breastfeeding outcomes among women with and without breast implants.

Methods: A systematic literature search of Medline, Pubmed, CINAHL and Embase databases will be conducted using earliest inclusive dates through December 2013. Article titles and abstracts will be evaluated by two reviewers for potential relevance. Studies that compare breastfeeding outcomes among women with and without breast implants will be reviewed for potential inclusion. The outcomes of interest are: any breastfeeding, and among women who breastfeed, exclusive breastfeeding. No language restrictions will be applied. Methodological quality (using the Newcastle-Ottawa scale) and heterogeneity of studies will be assessed. Data extraction from identified articles will be undertaken by two independent reviewers using a uniform template. Meta-analyses will be performed to determine pooled rate ratios (RR) and 95% confidence intervals (CI).

Discussion: This systematic review will provide information about breastfeeding outcomes that can be incorporated into decision making before undergoing cosmetic breast surgery.

Keywords: breastfeeding; breast implants; mammoplasty; systematic reviews; meta-analysis

Background

Since the introduction of silicone gel and saline breast implants for cosmetic enhancement of breast size in the early 1960's, breast augmentation has become one of the most common plastic surgery procedures worldwide [1]. In 2012, 286,000 women in the U.S. had breast augmentation surgery– an increase of 877% from 1992, when the American Society of Plastic Surgeons began formulating yearly national cosmetic surgical statistics [2]. The majority of women who undergo such surgery do so during their reproductive years [3], despite ambiguity regarding the risks to breastfeeding success associated with breast implants.

Breastfeeding has immediate and longer term nutritional, gastrointestinal, immunological, and neurodevelopmental benefits to the baby, and psychosocial benefits for the mother [4]. WHO recognises that while providing some breast milk to the infant is better than none, exclusive breastfeeding is needed to achieve optimal growth, development, and health for infants [5]. If supplementary formula feeding is initiated, the infant does not receive the full advantages of exclusive breastfeeding, and the breastfeeding mother must also engage in a complicated balancing act between maintaining or increasing the existing supply while ensuring the infant receives adequate nourishment. The potential to compromise lactation as a result of breast augmentation is particularly relevant with regards to cosmetic breast surgery, which is an elective procedure motivated by aesthetic appeal, rather than in reconstructive surgery (such as following mastectomy). Since there is an element of choice, women need information about all associated risks, both short and long term, in order to make an informed decision regarding whether to undergo cosmetic breast surgery.

Review Methods

Objective: to assess breastfeeding outcomes among women with cosmetic breast augmentation (also referred to as breast implants, mammoplasty and mammaplasty) compared to women without breast surgery.

Primary outcomes: to assess 1) the rate of any breastfeeding and 2) among women who breastfeed, the rate of exclusive breast milk feeding

Search strategy for identification of studies and methods of review

To identify relevant published studies, a systematic search of Medline, Pubmed, CINAHL and Embase databases will be conducted using earliest inclusive dates through December 2013. The search strategy will combine terms related to breast surgery with terms related to breastfeeding, using both subject headings and key words when applicable. The "explode" function will be used in each case. Language restrictions will not be applied and every effort will be made to obtain translations; articles unable to be translated will be reported. Searches will be limited to studies of humans and peer-reviewed articles. No effort will be made to identify unpublished studies. Duplicates will be removed.

Eligibility criteria for consideration of inclusion

Study types:

- Randomised controlled trials
- Clinical trials
- Cohort studies
- Cross-sectional studies

Population: Women giving birth

Exposure of interest: Births among women with cosmetic breast augmentation

Comparators: Births among women who have not had breast surgery

Exclusion criteria:

- Augmentation mammoplasty subsequent to treatment for breast cancer, (eg mastectomy, breast reconstruction)
- Studies without a comparison (no surgery) group
- Studies where the comparison group is different types of breast surgery
- Conference abstracts, unpublished studies case reports, letters, and review articles.

Screening of studies

Article titles and abstracts will be evaluated by two reviewers for potential relevance. Where there is disagreement at this stage, the article will remain included until the full text is reviewed prior to a decision being made. Exclusions at this stage will include animal studies, basic science studies, non-pregnant and cancer populations, papers on surgical technique and

studies without a control group. Articles identified through reference lists of included studies and relevant reviews will be considered for inclusion based on their title.

At least two independent reviewers will assess all articles identified in the screening process for potential inclusion, including assessment of methodological quality as outlined below. No effort will be made to contact the listed corresponding author. Consensus between the two authors undertaking review of the study will need to be reached before the article is included. In the case that a consensus is not reached, a third reviewer will be involved as an arbitrator. A flow chart of the study selection procedure will be prepared and a log of rejected studies maintained.

Data extraction

Data extraction from identified articles will be undertaken by two independent reviewers using a uniform template. Discrepancies will be resolved by discussion, and where applicable, arbitration by a third reviewer. Where available, the following information will be extracted:

Study characteristics: Authors, year of publication, study design, location, time period of included pregnancies, data sources and outcome measures

Population characteristics: Number of participants, number of pregnancies, age, parity

Breast augmentation characteristics: type of implant, surgical approach

Breastfeeding outcomes: attempted breastfeeding, duration of breastfeeding, exclusive and non-exclusive (supplementation with formula) breastfeeding

Assessment of methodological quality

We consider it unlikely that there will be any randomised studies eligible for inclusion. If there are, the risk of bias in randomised studies will be assessed using the Cochrane Collaboration's tool for assessing risk of bias [6]. This tool provides a model to evaluate the risk of bias across a number of domains; how a study selects participants, measures performance, blinds participants and investigators, explores attrition and reports findings. Each domain for each study will be allocated a ranking of "low", "unclear" or "high" risk of bias, in accordance with the Cochrane Collaboration's approach by two separate reviewers. Where there is a discrepancy between the two reviewers, a third reviewer will be used as an arbitrator.

For non-randomised studies, the risk of bias will be assessed using the Newcastle–Ottawa scale (NOS) for assessing the quality of non-randomised studies in meta-analyses [7]. The NOS will be adapted to meet the specific needs of this systematic review (Table 1). Using the NOS, studies will be awarded a maximum of nine points on items related to the selection of the study groups, the comparability of the groups and the ascertainment of the outcomes of interest. This will be undertaken by at least two separate reviewers. Where there is disagreement, a third reviewer will be used as an arbitrator.

Data analysis and presentation

A table with descriptive information for each study will be produced. Assuming data can be pooled, they will be analysed using reported rate ratios (RR) or odds ratios (OR) and 95% confidence intervals (CI), either adjusted for confounders or crude measures if confounding is not assessed. If these measures are not reported, they will be calculated based on summarized data using a spreadsheet package. Based on the synthesis of these measures, a summary rate ratio and 95% CI will be calculated using both fixed-effects and random effects modelling. Additionally, heterogeneity of the included studies will be assessed using the heterogeneity statistic (I-squared). Significant heterogeneity will be explored by categorisation of the study design, the time period within which pregnancies occur and population characteristics (ethnicity, age range, parity). No subgroup analyses are planned.

In general, the strength of evidence will be assessed with respect to the study designs, methodological quality of the individual studies, consistency of the results across studies and strength of any associations. Consistency of effect will also be important both as demonstrated visually in forest plots and as quantified by the I^2 statistic.

Discussion

The proposed systematic review is of importance in the context of increasing rates of cosmetic breast augmentation worldwide. Meta-analyses of observational studies present challenges because of inherent biases within different study designs [8]. Nevertheless they help understanding and quantify variation in results between studies [9]. This systematic review could provide information about breastfeeding outcomes that can be incorporated into decision making before undergoing cosmetic breast surgery.

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Table 1: Adapted Newcastle–Ottawa scale (NOS) [7] for Breastfeeding after augmentation mammoplasty: systematic review and meta-analysis

Criteria	**Star allocated** (Maximum 9 stars)*
Selection	
*1) **Representativeness of the exposed cohort***	
a) truly representative of the average breast augmentation population	1
b) somewhat representative of the average breast augmentation population	1
c) selected group of users eg clinic patients, nurses, volunteers	
d) no description of the derivation of the cohort	
2**) Selection of the non exposed cohort**	
a) drawn from the same community as the exposed cohort	1
b) drawn from a different source	
c) no description of the derivation of the non exposed cohort	
3) **Ascertainment of exposure – breast augmentations**	
a) secure record (eg surgical records)	1
b) structured interview	1
c) written self report	
d) no description	
4) **Demonstration that outcome of interest was not present at start of study**	
a) yes	1
b) no	
c) N/A	
Comparability	
1) **Comparability of cohorts on the basis of the design or analysis**	
a) study controls for the maternal age	1
b) study also controls for parity, gestational age at birth and type of delivery	1
Outcome	
1) **Assessment of outcome**	
a) independent assessment	1
b) record linkage	1
c) self report	
d) no description	
2) **Was follow-up long enough for outcomes to occur**	
a) yes - – one month minimum	1
b) no	
3**) Adequacy of follow up of cohorts**	
a) complete follow up - all subjects accounted for	1
b) subjects lost to follow up unlikely to introduce bias - small number lost - ≤10 % follow up, or description provided of those lost	1
c) follow up rate >10% and no description of those lost	
d) no statement	

* A study can be awarded a maximum of one star for each numbered item within the selection and outcome categories. A maximum of two stars can be given for comparability