

Poor adherence to clinical guidelines for women undergoing breast reduction

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ABSTRACT

INTRODUCTION: Indication for breast reduction in a publicly funded or an insurance-funded setting depends on the severity of the subjective symptoms and on the clinical evaluation. The purpose of this study was to evaluate whether Danish surgeons follow a clinical practice recommending a minimum tissue resection weight of 400-500 g per breast.

METHODS: Included in the study were a total of 366 female patients with breast hypertrophy who underwent bilateral breast reduction surgery at three large university hospitals in Denmark in the period from August 2008 to November 2013. The patients' height, weight and standard breast measurement were registered as was the weight of breast tissue resection. The preoperative breast volume was measured using transparent plastic cups designed for this purpose.

RESULTS: Among the 366 female participants, the median age was 40 years, the median BMI was 24 kg/m², and the median breast volume was 1,050 cc on each side. Only 201 (55%) cases met the resection criterion of a minimum of 400 g tissue per breast, and 130 (36%) had 500 g or more resected. We found a highly significant correlation between the amount of resected breast tissue and the preoperative breast volume ($p < 0.001$, $n = 366$).

CONCLUSIONS: Many surgeons did not follow the clinical practice of resecting 400-500 g of breast tissue in women who underwent breast reduction surgery at three large hospitals in Denmark in the 2008-2013 period. Our findings are surprising and beg the question if the guidelines should be revised to reflect the current practice or vice versa.

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Breast reduction surgery is a common and successful surgical treatment for shoulder/neck pain, bra-strap grooving, back pain and headache due to breast hypertrophy [1, 2]. Several studies have also shown improved quality of life and improvement in psychosocial symptoms after breast reduction surgery [3, 4]. To be operated in a publicly financed healthcare system such as those of the Scandinavian countries, patients seeking breast reduction must present with adequate functional problems and not only with cosmetic concerns [5]. To distinguish cases that are based primarily on cosmetic complaints from those based on functional complaints, a

woman requesting breast reduction surgery in Denmark must, as in most other countries, express relevant physical symptoms, preferably be 18 years of age or more, and shall generally have a body mass index (BMI) below 25 kg/m². According to standard clinical practice, the breast volume must be of a size that allows resection of at least 400-500 g on each side. [5-8]. This is based not on a national guideline, but on local clinical practices [7, 8], which are quite similar over the country (exceptions from these demands are occasionally allowed; for instance, if the woman has co-morbidity, short stature, serious gigantomastia, etc.) Furthermore, to some extent the following measurements may also be used for evaluation: sternal notch-to-nipple distance (NND), ptosis (distance from the lower pole of the breast to the sub-mammary fold) and chest circumference. In a previous study [5], we evaluated the feasibility of measuring preoperative breast volume using special plastic cups, and the pre-operative volume was correlated to the decision of offering breast reduction surgery. This previous study was undertaken in recognition of the need for a more objective criterion for the decision to perform breast reduction surgery. In three departments of plastic surgery in Eastern Denmark, we found full agreement that, in general, women with relevant complaints who fulfilled the inclusion criteria were offered reduction surgery if they had a breast volume of 900 cc or more, while women with a breast volume of less than 800 cc were denied surgery [5]. The aim of the present study was to evaluate whether surgeons actually comply with the clinical practice [7, 8] stipulating a minimum tissue resection weight of 400-500 g per breast.

METHODS

Data collection

For the present study, we searched the electronic surgical database for patients registered with the diagnosis *breast hypertrophy* (N62.9) and the procedure code *breast reduction* (KHAD30 and KHAD35) according to coding system of the International Classification of Diseases, 10th Edition (ICD-10). The search was done in November 2013 and included all patients operated between January 2008 and November 2013 at one of the three plastic surgery departments at the Copenhagen University Hospitals (Herlev Hospital, Roskilde Hospital,

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 TABLE 1

Demographic variables among the 366 study women undergoing breast reduction surgery.

	Median (range)	n ^a
Age, yrs	40 (15-80)	366
Height, cm	166 (145-183)	364
Weight, kg	66 (48-86)	364
Body mass index, kg/m ²	24 (17.8-31.8)	364
<i>Breast volume, cc</i>		
Right	1,050 (500-5,500)	362
Left	1,050 (500-3,300)	362
Average	1,050 (500-4,400)	362
<i>Sternal notch-to-nipple distance, cm</i>		
Right	29 (18-48)	366
Left	29 (18-43)	366
Average	29 (18-46)	366
<i>Breast ptosis^b, cm</i>		
Right-sided	7 (1-21)	361
Left-sided	7 (2-20)	361
Average	7 (2-20)	361
<i>Breast tissue resection, g</i>		
Right	459 (100-2,420)	366
Left	460 (100-3,570)	366
Average	463 (100-2,995)	366
Difference in volume in the 2 breasts, cc	50 (0-2,200)	362
Difference in tissue resection in the 2 breasts, g	54 (0-1,150)	366

a) Number of study women for whom the variable in question is known.

b) Ptosis is present if the lower breast pole is below the infra-mammary fold (IMF) and measured in cm from the IMF to the lower breast pole.

and Rigshospitalet, Denmark). A total of 674 patients were identified. Patients were excluded from this study if information about the weight of the resected breast tissue was missing, if surgery was done because of breast cancer or asymmetric breasts, if the patient had a history of previous breast surgery, was of male gender, or had undergone massive weight loss (> 15 BMI points) causing excessive skin since breast operation in that scenario generally was performed on a different indication (breast lift rather than breast reduction).

We recorded the following parameters from electronic and paper-based patient records: age (years), weight (kg), height (cm), BMI (kg/m²), chest circumference (cm), sternal NND distance (cm), the degree of ptosis (cm) measured as the distance from the infra-mammary fold to the lower pole of the breast, weight of resected breast tissue (g) and the preoperative breast volume (cc).

The preoperative breast volume was measured by the surgeon who used transparent plastic cups with eleven different sizes: 200, 275, 350, 500, 650, 850, 950, 1,150, 1,350, 1,600 and 2,000 cc. If the measured volume fell between two cup sizes, the surgeon made a

best estimate (below 750 cc, the estimate was made at 25 cc intervals; above it was made at 50 cc intervals) [5]. The other parameters were measured with a ruler and a weight scale at the preoperative examination.

The decision to operate was made by the examining specialised plastic surgeon. In cases in which the examining surgeon was in training or if the specialised surgeon needed to confer the case, the decision was cleared with a senior colleague or in conference with more colleagues.

The decision was made according to the existing criteria: hypertrophic breasts, relevant functional complaints, normal body weight, a need/possibility to excise more than 400-500 g of tissue per breast; in the later part of the period (2012-2013), a breast volume of 900 cc or more influenced the decision in favour of surgery, provided that the other criteria were met. The weight of the resected breast tissue was found in the patient charts.

This study did not need ethical approval from the local ethical committee.

Statistical analysis

The primary endpoint was to establish whether the surgeons followed clinical practice [7, 8] by resecting a minimum of either 400 or 500 g of breast tissue per breast in patients suffering from breast hypertrophy (both scenarios were tested). Our secondary endpoint was to evaluate if there was a correlation between the demographic variables: patient's age, breast volume, sternal NND, breast ptosis, height, weight, BMI and the weight of the resected breast tissue.

Simple demographic data are presented in frequency tables as medians and ranges. A test to examine if data were normally distributed was performed (the Shapiro-Wilk test); only height and weight followed a normal distribution; all other parameters did not ($p < 0.001$). Side-to-side measures were compared using the non-parametric two-independent samples test, as data were not normally distributed.

The Kruskal-Wallis test was performed to examine a possible difference between the three centres in terms of: 1) meeting the resection criteria and 2) difference in preoperative breast volume and resected breast tissue weight.

We used binary logistic regression analysis to determine if there was an association between resected breast tissue and one or more of the variables mentioned above. In addition, correlation analysis for every possible significant covariate and resected tissue weight was undertaken using SPSS Statistics 20 for Mac to determine Spearman's correlation coefficient.

Trial registration: not relevant.

RESULTS

We identified 674 patients who underwent breast reduction surgery at Herlev Hospital (n = 150), Roskilde Hospital (n = 382) and Rigshospitalet (n = 142) in the period from January 2008 to November 2013. In total, we excluded 308 patients because they were found to have undergone breast reduction due to contralateral breast cancer (symmetrisation/weight reduction), asymmetric breasts, earlier gastric by-pass or male gynaecomastia; and in one case, the weight of the resected breast tissue was missing. Thus, a total of 366 women who underwent bilateral breast reduction surgery due to breast hypertrophy were included in the study.

The median age of the patients was 40 (range: 15-80) years. The median BMI was 24 (range: 17.8-31.8) kg/m². A total of 29 patients had a BMI of 26 kg/m² or above. There was no difference between the right- and left-sided breast volume (p = 0.896) or resection tissue weight between the two sides (p = 0.662). We therefore used the average value of the right and left sides for all bilateral analyses. The median preoperative breast volume was measured to 1,050 cc (range: 500-4,400 cc). A total of five patients had a very low breast volume, below 700 cc, and these patients were among the shortest in the study population. The median weight of breast tissue resection was 463 g (range: 101-2,995 g).

The clinical practice [7, 8] stipulating that at least 400 g breast tissue has to be removed per breast was met in 201 out of 366 cases (55%), but was not met in the remaining 165 cases (45%). The criterion that at least 500 g breast tissue has to be removed per breast was met in 130 out of the 366 (36%) cases; hence, this criterion was not met in 236 cases (64%). We evaluated if the number of operations and meeting of the weight criterion differed substantially over the years. Variations were found, but none pointed at a distinct pattern (data not shown). Additional clinical data are shown in **Table 1**.

Binary logistic regression analysis using the 400-g-criterion as the dependent variable and age, breast volume, sternal NND, ptosis, height, weight, and BMI as covariates showed that breast volume was the only significant covariate (p < 0.001). Using the 500-g-criterion, we found the breast volume (p < 0.001) and the sternal NND (p = 0.016) to be significant covariates.

We found a strong correlation between breast volume and weight of resected breast tissue (p < 0.001) (**Figure 1**). The correlation between the weight of the resected breast tissue and sternal NND was also statistically significant (p < 0.001) (**Figure 2**).

There was no significant difference in preoperative breast volume (p = 0.122) and the weight of resected breast tissue between the three centres (p = 0.892) (**Figure 3** and **Figure 4**).

DISCUSSION

In the present study, we investigated to which extent clinical practice [7, 8] regarding breast reduction surgery was followed at three large hospitals in Denmark. At present, a national guideline has yet to be prepared, but all Danish departments have a rule of thumb that a minimum of 400 g (some departments) or 500 g (other departments) of breast tissue should be resected in order to justify the need/indication for breast reduction in a public setting. This is in line with most international guidelines [9]. The background for this very specific re-

FIGURE 1

Correlation between breast resection and pre-operative breast volume. Scatter plot demonstrating correlation of pre-operative average breast volume with average resection weight (R² = 0.696).

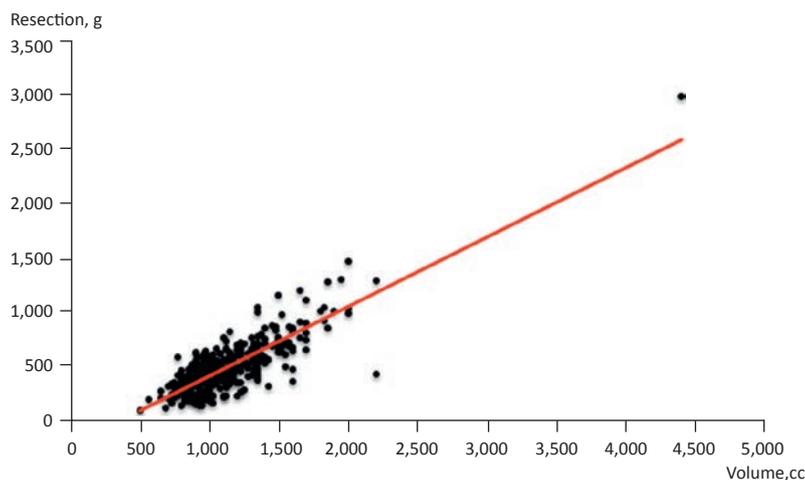


FIGURE 2

Correlation between breast resection and sternal notch-to-nipple distance. Scatter plot demonstrating correlation of pre-operative average sternal notch-to-nipple distance with average resection weight (R² = 0.373).

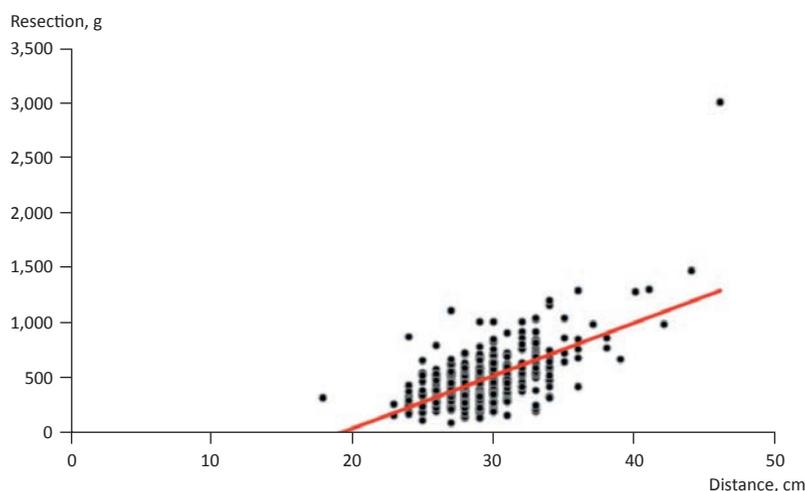


FIGURE 3

Centre-specific percentage of criterion met. Proportion of patients for whom the criterion for surgical intervention was met (i.e. a minimum tissue resection weight of 400-500 g per breast) by centre. For 400-g- and 500-g-criteria we found no difference between the three centres; $p = 0.406$ and $p = 0.142$, respectively.

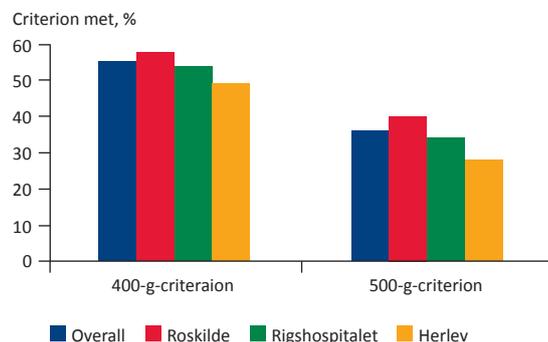
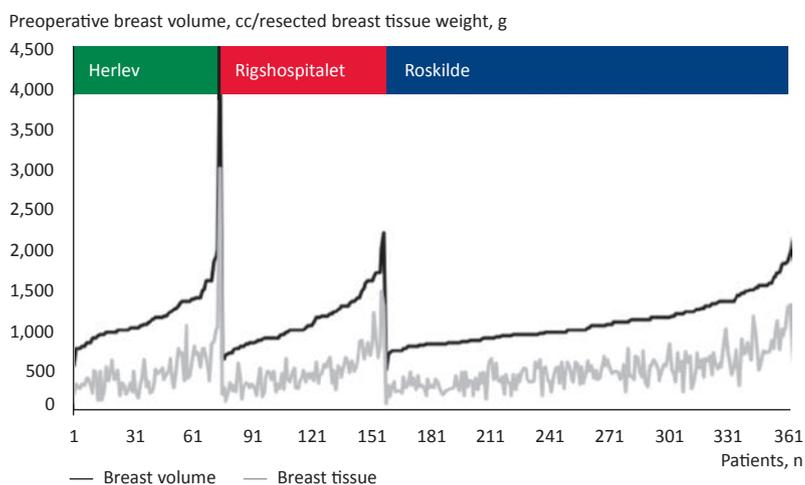


FIGURE 4

Centre-specific distribution of preoperative breast volume and resected breast tissue. The average preoperative breast volume and average weight of resected breast tissue for the three centres. We found no significant difference in average preoperative breast volume or average resection weight between the centres, ($p = 0.122$) and ($p = 0.892$) respectively.



quirement remains somewhat obscure, but it presumably originates from the insurance-funded sector where an objective criterion for reimbursement has been demanded [9]. The main finding of the present study including 366 women who were operated between 2008 and 2013 was that the resection weight criterion was met only in 36-55% of cases, depending on whether the 500 g or the 400 g criterion was used. The amount of resected tissue was significantly associated with the preoperative breast volume. However, breast density is not always 1 kg/l. A recent study showed that breast volume calculated from magnetic resonance imaging corresponds well with the subsequent mastectomy specimen weight; however, in dense breasts with pronounced fibroglandular tissue, the breast volume would be overestimated when based on weight information. A math-

ematical model including breast density was developed [10].

We found a few patients with preoperative breast volumes below 700 cc ($n = 5$, range: 500-688 cc). All these women were of short stature or had a preoperative BMI of 26 kg/m² or higher ($n = 29$, range: 26.0-31.8). These patients should not generally have been approved for breast reduction. We can therefore conclude that also the general admittance criteria were not always met.

The three hospitals that participated in this study did not vary significantly with regard to their surgical practice, and we therefore believe that the Danish practice is reflected in this study.

Female symptomatic breast hypertrophy is defined as a syndrome of large breast causing persistent muscle strain such as neck/shoulder/back pain, headache, brassiere-strap grooving and often chronic rash in the inframammary fold [1, 2]. In addition, women suffering from symptomatic breast hypertrophy report physical limitations regarding exercise and activities, as well as a gradual change in posture with a trend towards kyphosis. Furthermore, several studies have shown improved quality of life and improvement in psychological and psychosocial symptoms after breast reduction [3, 4]. Kerrigan et al reported that 87.6% of females with breast hypertrophy have at least two out of seven breast-related physical symptoms that occur all or most of the time compared with 2% of females with a normal breast size (C cup or smaller) [11]. Breast reduction surgery in women with breast hypertrophy has also been found to improve quality of life, which includes increased sociability, emotional stability, self-esteem and decreased anxiety and depressive symptoms [12, 13].

In the present study, we found that in 45-64% of cases, the plastic surgeons in three large hospitals in Denmark removed less than the 400-500 g of breast tissue stipulated by clinical practice [7, 8]. There is evidence to support that females with similar preoperative breast hypertrophy-related symptoms have similar post-operative symptom relief after breast reduction, regardless of their resection weight [14]. Another study comparing females who were covered by insurance (the criterion of 500 g of breast tissue removal was met) with a control group who was not (criterion of 500 g breast tissue removal was not met) reported no difference in preoperative symptoms and post-operative improvement in quality of life [11]. In addition, several studies have found a strong correlation between breast resection weight and the risk of complications such as delayed wound healing, wound dehiscence, nipple/areola necrosis, haematoma, seroma, fat necrosis, hypertrophic scarring and infection [1, 15-17]. The preoperative breast volume probably confounds this correlation:

the larger the breast, the more is resected, as demonstrated in the present study. Concerning BMI, studies show no difference in post-operative complications and rates in females with a BMI above 25 compared with females with a BMI below 25 [1, 15-17].

The ideal breast shape has changed throughout history, going from the Victorian monobosom to the small and flat, and to nowadays big and often with an artificially rounded appearance [18]. It seems that “the normal breast has become larger” during the last decade. Implants used for breast augmentation have increased [19], and this may actually explain why we observed a lower than required resection of hypertrophic breast tissue in the present study. One study shows “that plastic surgeons and patients seeking breast augmentation may have drastically different perceptions of what constitutes an attractive, natural and ideal breast shape” [20]. By applying his/her own sense of aesthetics to the final outcome, the surgeon’s opinion may be a confounding variable on the amount of resected breast tissue. On the other hand, the patients’ perception of what constitutes an ideal breast shape may as well influence the surgeon who seeks to satisfy the patient’s perceived need.

CONCLUSIONS

This study concludes that surgeons of three large Danish university hospitals do not always remove a minimum of 400 g of breast tissue on each side in females with breast hypertrophy. We should either change our practice to abide by the clinical practice or create new, realistic guidelines. Evidence supports that females with symptomatic breast hypertrophy experience symptom relief after breast reduction surgery regardless of their resection weight [14], which is probably because the lifting included in a normal breast reduction surgery shortens the “downhill-vector” predominant both in breast ptosis and hypertrophy. This results in less direct weight load in the bra, and thereby on the patient’s neck and shoulders. However, we speculate that recurrence of the ptosis and thus the weight symptoms will occur more readily and earlier in small reductions than in big reductions if other parameters remain unchanged. In any case, we believe that the criteria for breast reduction should be defined by individual symptomatology taking multiple parameters into consideration rather than by reference to breast size alone.

The present study has several strength and limitations. Among the limitations is the study’s retrospective design which could give rise to bias in data recording, selection and analysis. Besides, confounding variables may go unrecognised because of inadequate knowledge of how they interrelate with the outcome of interest. Several surgeons in the three participating hospitals performed the clinical preoperative breast measurements

and often did not operate on the patient themselves. Inter-observer variability could be present. However, there is no reason to believe that such variability be systematically skewed among the study participants. Among the strengths of the study are the relatively large number of participants, the rather even distribution among hospitals and the thorough documentation of data. Since the resection weight was recorded without knowledge of this study, no trend to influence the outcome was present. There is good reason to assume that this study is representative of the breast reduction practice in Denmark.

We would like our clinical practice to match reality and vice versa. In a restrictive setting, arguments could be presented for new and stricter guidelines. However, in the authors’ opinion, a considerable number of patients who seek surgery are refused already [5], and – compared with other publicly funded procedures – the current practice [7, 8] does comply fairly well with the practice among similar procedures (operation for gynaecomastia, skin reduction procedures after massive weight loss, etc.) Instead, we suggest that a new and more appropriate national guideline be prepared.

Such guidelines should take into account other criteria than weight, e.g. health-related quality of life, and they should perhaps also use more sophisticated biomechanical measurements, taking the predominant “downhill-vector” forces in breast ptosis and hypertrophy into consideration. Further research is needed to clarify these issues.

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