

Cost minimization while ensuring safety of reduction mammoplasty

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A prospective randomized study was designed to address the safety of performing reduction mammoplasty without drains. In the same cohort, the postoperative pain requirements, length of stay and complications were recorded in an effort to document the efficacy of performing this surgery in an outpatient setting. All women presenting for reduction mammoplasty at the Royal Victoria Hospital during a one-year period were asked to participate in the study. A total of 75 patients enrolled, and complete data were available at the 28-day follow-up for all women. The overall hematoma rate was 0% with drains and 2.7% without drains. The observed infection rate was 8% with drains and 5% without drains. There is no statistically significant or clinically meaningful difference in complication rates between breasts treated with drains and those treated without drains. In addition, 90% of women can be managed with oral analgesics within 23 h of surgery. Combined, this information suggests a potential cost savings of 57% based on prestudy observations. Careful analysis of the process of care will continue to enable the care of patients to be more efficient without compromising quality or safety.

Key Words: *Complications; Drains; Outpatient surgery; Reduction mammoplasty*

Réduction des coûts et innocuité de la réduction mammaire

RÉSUMÉ : L'innocuité de la réduction mammaire sans pose de drains a fait l'objet d'un essai prospectif avec hasardisation. Des données ont été recueillies, dans une même cohorte, sur la douleur postopératoire, la durée du séjour et les complications afin d'étayer l'efficacité de l'intervention pratiquée en milieu externe. On a demandé à toutes les femmes qui sont allées à l'hôpital Royal Victoria, sur une période de un an, pour subir une réduction mammaire de participer à l'essai. En tout, 75 femmes ont accepté et l'on disposait de données complètes sur toutes les femmes au bout du suivi de 28 jours. Le taux général d'hématome a été de 0 % dans le groupe avec drains et de 2,7 % dans le groupe sans drains. Pour ce qui est du taux d'infections observées, il s'est établi à 8 % dans le groupe avec drains et à 5 % dans le groupe sans drains. On n'a pas enregistré de différences significatives sur les plans statistique ou clinique quant au taux de complications. En outre, les analgésiques par voie orale ont suffi à soulager 90 % des femmes dans les 23 h suivant l'intervention. Ainsi, les données toutes confondues semblent indiquer une réduction possible des coûts de 57 % par rapport aux données accumulées avant l'essai. L'analyse méticuleuse du processus de soins se poursuivra afin d'assurer une prestation encore plus efficiente de services médicaux sans pour autant compromettre la qualité ou l'innocuité.

Reduction mammoplasty has long been performed for the correction of symptoms associated with macromastia and for psychosocial reasons. With rising health care costs, there is increased scrutiny of the relative cost and/or benefit of many therapeutic interventions with the view to determining who or what does and does not get covered by insurance plans. When the present study was first proposed, a data evaluation indicated that during 1992, the Quebec provincial health care plan paid the bill for 7192 reduction mammoplasties.

This resulted in payment of professional surgical and anesthesia fees of \$2,540,130 and \$1,078,800, respectively. At an average duration of 3.3 days of inpatient care, an additional \$12,816,144 in costs was incurred on hospital global budgets. These data result in a total annual cost estimate of over \$16 million, of which 78% relates to hospital costs. In Quebec's present health care system, with the cost of reduction mammoplasty being covered by the provincial health insurance plan, women from all ethnic groups and at all levels

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of income have access to this service. The Quebec government currently insures this procedure for any women who meet the requirement of removal of at least 250 g of tissue per breast. However, the possibility of raising this minimum qualifying weight to 750 g per breast was considered. Based on a survey performed by the Association des spécialistes en chirurgie plastique et esthétique du Québec (personal communication) in which the median weight of resection was 650 g, such a policy would effectively have de-insured this procedure for more than 75% of women who had benefitted from this surgery. There may be alternate ways to realize cost savings to the health care system without directly restricting patient access to this type of care.

In 1992, the majority of reduction mammoplasty procedures undertaken at the Royal Victoria Hospital and elsewhere were performed as inpatient procedures. Over the past decade, inpatient procedures have been used for patients with safety concerns (blood loss and duration of anesthesia), patient comfort (postoperative pain) and nursing care (management of surgical drains, etc). Given that this procedure causes relatively minor trauma, in fact less than herniorrhaphy (a procedure frequently being done as an outpatient procedure), and the low severity and incidence of postoperative complications, the question raised was: could this surgery be performed safely in an outpatient setting? With the exception of some uncontrolled observational studies from the United States, no scientific evidence evaluating this option has been published.

The present study was designed to evaluate patients in the inpatient setting, and to systematically collect data on their surgical time, requirements for pain medication in the postoperative period, nursing needs, complications associated with and without the use of drains and the cost of their care. These measures were chosen as indicators of suitability for outpatient surgery (1). The key hypotheses to be tested were: there is no difference in complication rates (infection and hematoma) between breasts managed with or without a drain; postoperative pain management is such that 95% of patients undergoing reduction mammoplasty could be discharged from hospital within the first 23 h after surgery; and the cost savings realized by performing reduction mammoplasty on an outpatient basis is such that it would reduce the overall cost of mammoplasty procedures to the provincial health care plan by 75%.

PATIENTS AND METHODS

Patients

All patients referred for bilateral reduction mammoplasty to the Plastic Surgery Division of the Royal Victoria Hospital were potentially eligible for entry into the study. There were no exclusion criteria. The study was approved by the Research Ethics Board of the hospital.

Study design

A prospective cohort study with a randomized controlled component was designed. Eligible patients who consented to participate in the study underwent reduction mammoplasty surgery. A computer generated schedule was used to ran-

domly assign a breast (right or left) to be treated with a drain, with the other side having no drain and serving as a control. Patients were blind as to which breast had the drain until the day of its removal, and evaluators remained blind for the duration of the study. All patients entered into the cohort were evaluated before surgery and in the postoperative period at 24 h, seven days, 15 days and 28 days. All patients were managed according to the hospital's standard practice at the time for inpatients.

Treatment

Women were first evaluated in the office by their surgeon and the decision regarding suitability for surgery was determined. Baseline preoperative physical parameters included bra size, patient weight, height and sternal notch to nipple distance. Women were advised to discontinue acetylsalicylic acid (Aspirin; Bayer Inc, Canada) use, and other potential blood thinners, and were provided with written documentation about the potential complications of surgery. Women were admitted to hospital on the day of their surgery after having undergone standard preoperative testing, assessment and teaching. Following general anesthesia, the breasts were infiltrated with a dilute (1:200,000) solution of adrenaline, which was the standard practice. The reduction mammoplasty was then performed using the technique of preference of the surgeon, and the technique (scars, pedicle) was recorded. A standard silicone drain was placed in one breast (randomly assigned as above) and then the dressing was applied. This procedure was performed in such a fashion that neither the patient nor the nurses on the ward were aware of which breast was drained. The drainage volume was documented every 8 h at the end of each nursing shift. On the evening of surgery and the morning of the first postoperative day, the breasts were examined by loosening the upper part of the dressing and checking for the presence of hematoma, as evidenced by increased tension on the breast or compromise of circulation to the nipple areolar complex. Once the drainage volume was less than 30 mL in a 24 h period, the drains and dressings were removed and the patients were discharged home wearing a light gauze dressing and a bra. Patients were instructed to monitor their temperature once daily, and if there was any suggestion of infection, such as increasing pain, fever, redness or discharge from the breast, they were asked to contact their surgeon or the plastic surgery ward. The patients were examined by their surgeon 10 to 12 days postoperatively and assessed for complications, including wound dehiscence, hematoma, fat necrosis, skin or nipple areolar complex necrosis and infection. Routine follow-up continued at three and six weeks, with the documentation of complications.

Pain management

Postoperative pain management followed standard protocols in the recovery room (morphine 2.5 mg intravenously every 10 min to a maximum of 15 mg and droperidol 0.5 mg intravenously every 10 min, as needed, for nausea to a maximum of 1 mg). Once discharged to the inpatient ward, the patient had the

option of requesting parenteral narcotics (pethidine hydrochloride [Demerol, Abbott, Canada] 50 to 75 mg intramuscularly with promethazine hydrochloride [Phenergan, Aventis Pharma, Canada] 25 mg intramuscularly) or, if tolerating oral intake, acetaminophen 325 mg with codeine 30 mg every 3 h.

Outcome measures

Major hematoma, for the purpose of this study, was defined as excessive tension in the breast leading to compromised nipple areolar complex circulation as judged on the evening of surgery and the morning of the first postoperative day, requiring return to the operating room for hematoma evacuation. Moderate hematoma was defined as excessive bruising going below the inframammary crease, as judged by the first postoperative visit at 10 to 12 days or a hematoma that required percutaneous drainage later in the recovery period and documented at the 28 day follow-up visit. Because an undiagnosed minor hematoma may predispose the patient to infection, the rate of infection was closely monitored.

Infection was documented by clinical examination, wound cultures and response to antibiotics. The surgeon, who was blind with respect to the drained side, assessed the patients for signs of infection. Superficial infection or 'suture spitting' requiring local topical treatment was not considered to be an infection for the purposes of this study.

The timing, type and amount of pain medication received were documented by the nurses while the patients were hospitalized. Following discharge, the women were provided with a medication record and asked to document, when and how many pills were used.

In evaluating costs for any surgical procedure, hospital costs are divided into two general categories, specifically those associated with the procedure and those associated with the postsurgical hospital stay. In the present study, the procedures were the same for both management modes and, therefore, do not require assessment. The difference in cost is a function of the duration of hospital stay. Thus, hospital cost estimates for a 'day of care' were used to compute potential savings. Direct costs accrued by the patient that were associated with obtaining care at home (hired help, relative, friend) could not be considered because all patients were inpatients.

Sample size

Based on a review of the literature, the control rate of hematoma was estimated to be approximately 3% to 4%. To detect a relative risk of 2.5 (a hematoma rate of 8% to 10%) with 70% power and 5% significance, a total of 118 patients with matched observations was required. Patient recruitment was planned over a one-year period.

Data analysis

The relative risk was calculated from the ratio of the incidence of complication in the drained compared with undrained breasts. Chi-square analysis was used to test significance, and a $P < 0.05$ was considered to be significant (2).

TABLE 1
Observed hematoma rates in the breasts of women who underwent reduction mammoplasty

	Breast	
	No drain	Drain
Hematoma	2	0
No hematoma	73	75
Risk	0.027	0

Potential confounding factors such as technique of reduction mammoplasty, patient weight and body mass index (BMI) (kg/m^2), smoking, age, baseline hemoglobin levels, platelet counts, prothombin time and partial thromboplastin time, and surgical data (intraoperative blood loss and volume of adrenaline injected) were not considered because each woman acted as her own control and these factors were controlled for by the study design.

The rate of analgesia exceeding that compatible with outpatient management was defined as the proportion of patients in the cohort that required parenteral narcotic analgesics at a time period of greater than 6 h after return to the inpatient ward. The experience with other surgical outpatients at the Royal Victoria Hospital is that this rate is currently less than 5%.

Cost minimization was defined as the difference in the cost per patient for the two modes: inpatient surgery compared with shortened stay or outpatient surgery and expressed as the percentage of cost savings if all women who could be managed safely as outpatients were so managed.

RESULTS

The mean age of the study subjects was 33.24 years (range 18 to 66 years, $\text{SD} \pm 12.1$), mean height was 1.63 m ($\text{SD} \pm 0.062$), mean weight was 72.6 kg ($\text{SD} \pm 14.02$) and mean BMI was $27.54 \text{ kg}/\text{m}^2$ ($\text{SD} \pm 5.42$). The median preoperative bra band and cup sizes were 38 and D, respectively. Postoperatively, these sizes were 36 and C, respectively. The mean weight of resection per breast was 636 g for the left breast and 645 g for the right breast. Of the 56 patients with complete operative data, the surgical technique used an inferior pedicle in 43 patients, superior pedicle in 12 patients and free nipple graft in one patient. The final scar was anchor-shaped in 43 patients and vertical in 13 patients. The mean duration of anesthesia was 106 min ($\text{SD} \pm 31.3$).

Complications

Event rates for both hematoma and infection were lower than anticipated, and no statistically significant differences between drained and undrained breasts were found (Tables 1,2). Examining the potential predictors of these outcomes shows that there was no effect of size of resection, smoking or BMI greater than $30 \text{ kg}/\text{m}^2$ on infection, but women with infections had a lower hemoglobin concentration ($127.7 \text{ mg}/\text{mL}$) than those without an infection ($134.1 \text{ mg}/\text{mL}$, $P = 0.035$), and women with hematomas were significantly older (40.7 years of age) than those without hematomas (32.8 years of age, $P = 0.017$).

TABLE 2
Observed infection rates in the breasts of women who underwent reduction mammoplasty

	Breast	
	No drain	Drain
Infection	4	6
No infection	71	69
Risk	0.053	0.08

Risk ratio 0.67; 95% CI, 0.196 to 2.267

Minor complications occurred in 12 breasts of eight women (eight of 75 or 10.7%) and included discharge on the dressing from minor wound dehiscence treated with local wound care (n=5), course of antibiotics prescribed by the physician without evidence of infection (n=3), minor hematoma (n=2), drug reaction (n=1) and minor dehiscence requiring re-suturing of wound under local anesthesia at the bedside (n=1).

Pain management

Of the 74 patients with pain data, 33 (45%) were taking oral pain medications with adequate control on the day of surgery. Another 33 (45%) patients were taking oral pain medications with adequate control on the first postoperative day. The final eight patients (10%) requested continued intramuscular pain medications beyond the first postoperative day.

Cost per length of hospital stay

The average observed length of hospital stay for the study was 1.77 days (Table 3). If a new policy based on the observed rate of analgesia requirements with reduced hospital stay was introduced, then there would be, in these 74 patients, a reduction from 131 days to 68.5 days, making a difference of 62.5 days or 52.3%. Therefore, there would be a reduction of 0.84 days per patient. At a rate of \$600/day of hospitalization, this would result in savings of \$507/patient. This amount shows a potential 57.4% saving from the prestudy audit and a 33% saving from the costs observed in the study.

DISCUSSION

The first hypothesis of our study was that the absence of a drain would make no difference in the rates of infection and hematoma. Our original study was designed to test for the presence of a 2.5-fold increase in the risk of complications without a drain. Our actual observed rate was much lower than this, and, although we did not see any statistical difference between the two groups, the risk of a beta error was present. Our study had inadequate power to assess the statistical significance of the observed difference. To assess the statistical significance of the observed differences (power 0.70 and alpha of 0.05) in hematoma rates (2.7% compared with 0%) we would have required a sample size of approximately 300 women, with one breast per woman randomly assigned to receive a drain. To assess the statistical significance of the observed differences in infection rates (5% compared

TABLE 3
Costs per case, based on professional fees collected and hospital estimate of daily cost

	Estimated costs at time of study design	Observed costs during the study	Projected costs based on study findings
Professional fee	\$353.20	\$353.20	\$353.20
Anesthesia fee	\$150.00	\$150.00	\$150.00
Hospital stay and cost estimates (\$600/day)	3.3 days: \$1980.00	1.77 days: \$1062.00	0.92 days: \$555.00
Total	\$2483.20	\$1565.20	\$1058.20*

*This represents a 33% saving from the study cohort and a 57.4% saving from the prestudy audit

with 8%) would have required a sample size of approximately 500 women, with one breast per woman randomly assigned to receive a drain. Thus, we conclude that a much larger sample size is required to test for statistical significance. However, in looking for clinical significance, it appears that, although the presence of a drain may decrease the risk for one complication, hematoma, it may simultaneously increase the risk for another complication, infection. In this study, we did not employ routine perioperative antibiotics.

Other studies in the literature that have addressed the role of postoperative drains have failed to randomly assign patients, or more importantly, to randomly assign breasts such that it was possible to control for other systemic confounders. The majority of these studies have been uncontrolled, retrospective case reviews (Table 4).

Our second hypothesis to be tested was that postoperative pain management is such that 95% of patients undergoing reduction mammoplasty could be discharged from hospital within the first 23 h after surgery. Our data indicated that by using a standard protocol, 90% of patients could be managed by oral pain medications within 23 h of surgery. Of these patients one-half were managed by oral pain medication on the day of surgery, and the other half were managed on the first postoperative day. We suggest that with a more aggressive approach to oral narcotic pain management, this percentage could most likely be increased beyond 95%. We were unable to find any published records specifically addressing postoperative analgesia requirements for women having undergone reduction mammoplasty. Our own data suggest that pain requirements should not be a limiting factor when considering performing this surgery as an outpatient procedure.

Our third hypothesis was that the cost savings realized by performing reduction mammoplasty on an outpatient basis is such that it would reduce the overall cost to the provincial health care plan by 75%. Our data indicated that the percentage of savings depended on what point one took as the initial reference point. Compared with our initial projection at the time of grant submission and study design, the average length of hospital stay for women undergoing reduction mammoplasty was 3.3 days. The projected savings could, thus, be as

TABLE 4
Complication rates for reduction mammoplasty, as reported in the literature

Reference	Patients (n)	Study design	Infection	Hematoma
7	380	Retrospective, all breasts had drains and antibiotics	0%	0.3%
8	36	No drains	5.6% infected hematomas	5.6%
9	235	Retrospective, drains, no antibiotics	3%	Not reported
10	200	Nonrandomized, one-half of patients had drains	No difference in complication rates between women with or without drains	No difference in complication rates between women with or without drains
11	300	No drains, retrospective	Not reported	1.17% requiring intervention
6	171	Outpatient, retrospective, no drains	8.19%	3.5%
Present study	75	Inpatient, prospective, randomly assigned to have drains, no antibiotics	5%–8%	0%–2.7%

high as 57%. It is interesting to note that during our study, the actual length of stay was 1.77 days. This improvement may be a reflection of the Hawthorne effect (3) or may be a sign of other forces within the health care system. Schnur et al (4) have looked at the charges for reduction mammoplasty and documented potential savings of 32% based on changing from a 3.1 day inpatient stay to care in an ambulatory setting.

Outpatient surgery

Since completing our study, Buenaventura et al (5) have published a retrospective review of complications in the outpatient setting. The report did not specify the details of patient management with respect to the use of drains, prophylactic antibiotics or postoperative analgesia. Of the 338 patients reviewed, 286 (84.6%) were managed as outpatients, defined as discharged home on the day of surgery, and 52 were managed as inpatients (15.4%). Major complications were defined as complications requiring re-operation, re-admission or visit to the emergency room, and one such complication was identified in the total study population (rate of 0.2%). Minor complications were considered to be those handled in the office setting with wound care, oral antibiotics, or a minor procedure such as needle aspiration or incision and drainage. A total of 73 patients (21.6%) suffered minor complications.

In addition, Economides and Sifakis (6) reported on their retrospective review of 171 women who had breast reduction surgery performed as outpatients in an ambulatory care setting and without the use of drains between 1986 and 1995. A chart review of these cases revealed a 12.28% rate of acute complications. This included excessive bleeding in 3.5% of patients, localized infection in 8.19% and partial or complete nipple areolar loss in 2.33%.

Financial savings

We believe that our estimates of cost savings are very conservative and that if patients received improved preoperative teaching and there was a change in attitude toward using stronger oral analgesics, then the majority of patients could be safely managed on an outpatient basis. In addition, teaching patients about the care of surgical drains would likewise, not require them to be hospitalized solely for nursing man-

agement of drains. Other centres have reported on short hospital stay (less than 23 h) (6,7) but have not specifically assessed the safety or cost savings of such an approach. Buenaventura et al (5) estimated average charges at a surgical centre outpatient facility to be US\$4,500, at a hospital with a one-day stay to be US\$6,000 and at another hospital to be US\$7,000. They concluded that outpatient surgery can save between US\$1,500 and US\$2,500. These funds reflect current customary charges, not the actual cost. The former is not always a very accurate proxy for the latter. In our study, the financial impact of a change in policy is based on customary professional fees reimbursed in Quebec. The hospital's estimate of the true cost of a one-day stay in the hospital, as derived from its global budget, is used as a proxy for actual cost. Our findings suggest that a change from an inpatient setting to an outpatient setting would result in a 57% saving from our original estimate or a 33% saving from our observed costs.

CONCLUSIONS

Our study and previous reports in the literature support that performing reduction mammoplasty in the outpatient setting as opposed to the inpatient setting results in similar complication rates and significant cost savings. Complications, as reported in the literature, indicate significant variations from one practice setting to another. It is likely that future studies focusing on an analysis of these variations would enable us to establish some 'best practice' recommendations to bring all complication rates down to a minimum. Likewise, a careful analysis of the steps in the process of care would most likely enable further cost savings as unnecessary steps are eliminated. The authors have each incorporated changes into their practices as a result of this close look at their experiences. The authors perform reduction mammoplasty on an outpatient basis and discharge patients on the day of surgery; only those patients with cause (persistent nausea and vomiting) are admitted to hospital. Two authors have discontinued the use of drains, while one author continues to use drains for the first 18 to 24 h and has added a single intraoperative dose of antibiotics to the perioperative regimen.

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