

Original article

A prospective study comparing endoscopic subcutaneous mastectomy plus immediate reconstruction with implants and breast conserving surgery for breast cancer

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Background Breast conserving surgery (BCS) has been the standard surgical procedure for the treatment of early breast cancer. Endoscopic subcutaneous mastectomy (ESM) plus immediate reconstruction with implants is an emerging procedure. The objective of this prospective study was to evaluate the clinical outcomes of these two surgical procedures in our clinical setting.

Methods From March 2004 to October 2007, 43 patients with breast cancer underwent ESM plus axillary lymph node dissection and immediate reconstruction with implants, while 54 patients underwent BCS. The clinical and pathological characteristics, surgical safety, and therapeutic effects were compared between the two groups.

Results There were no significant differences in the age, clinical stage, histopathologic type of tumor, operative blood loss, postoperative drainage time, and postoperative complications between the two groups ($P > 0.05$). The postoperative complications were partial necrosis of the nipple and superficial skin flap in the ESM patients, and hydrops in the axilla and residual cavity in the BCS patients. There was no significant difference in the rate of satisfactory postoperative cosmetic outcomes between the ESM (88.4%, 38/43) and BCS (92.6%, 50/54) patients ($P > 0.05$). During follow-up of 6 months to 4 years, all patients treated with ESM were disease-free, but 3 patients who underwent BCS had metastasis or recurrence — one of these patients died of multiple organ metastasis.

Conclusions After considering the wide indications for use, high surgical safety, and favorable cosmetic outcomes, we conclude that ESM plus axillary lymph node dissection and immediate reconstruction with implants — the new surgery of choice for breast cancer — warrants serious consideration as the prospective next standard surgical procedure.

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Breast conserving surgery (BCS), the standard surgical procedure for the treatment of early breast cancer, is not markedly different from modified radical mastectomy in long-term survival rates; the procedures vary, however, in local recurrence rates even after administering diligent postoperative radiotherapy.¹⁻³ Furthermore, a wide local excision will almost always result in a smaller-sized breast.^{4,5} To explore the suitability of a new procedure, we compared the clinical outcomes of endoscopic subcutaneous mastectomy (ESM; plus axillary lymph node dissection and immediate reconstruction with implants) with BCS.

METHODS

Enrollment and grouping of patients

This prospective study enrolled 97 patients with breast cancer between March 2004 and October 2007. All patients were informed of and allowed to select procedures preoperatively, then assigned to the ESM group ($n=43$, treated with ESM plus axillary lymph nodes dissection and immediate reconstruction with implants) or the BCS group ($n=54$, treated with BCS) according to their preference and disease condition.

The inclusion criteria for patients were: female; less than

55 years of age; invasive breast cancer confirmed histopathologically by preoperative core needle biopsy or excision biopsy; tumor not larger than 3 cm on primary examination or after neoadjuvant chemotherapy; absence of deviation or retraction of the nipple; absence of obviously enlarged or fused axillary lymph nodes; absence of distant metastasis found by auxiliary examination; and consent for neoadjuvant chemotherapy with the TE regimen (taxol 175 mg/m², epirubicin 80 mg/m², IV day 1; cycled every 21 days for 1–4 cycles).

In addition, patients in the ESM group were required to have each breast less than 350 ml in volume without obvious mastoptosis; absence of dimple sign or Peau d'orange on the surface of the breast; a distance of more than 0.5 cm between the tumor surface and skin determined

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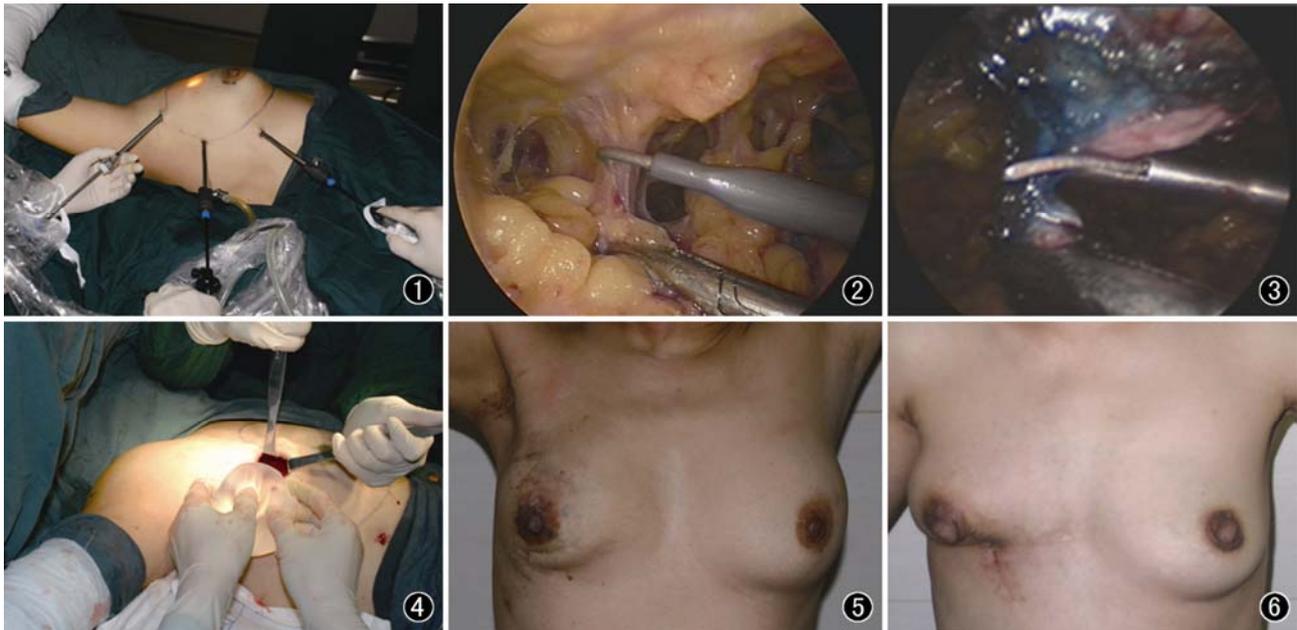


Figure 1. Setting up an operating space for endoscopic subcutaneous mastectomy after lipolysis and liposuction.

Figure 2. Transecting Cooper ligaments between skin and gland with an electric hook under endoscopic monitoring.

Figure 3. Excising the gland superior to the tumor (marked by methylene blue) for intraoperative frozen section analysis.

Figure 4. Implanting a prosthesis into the retropectoral space through the superior incision after axillary lymph node dissection.

Figure 5. Fair cosmetic outcome in a patient from the endoscopic subcutaneous mastectomy group 3 months after surgery.

Figure 6. Poor cosmetic outcome and deformity of the treated breast in a patient from the breast conserving surgery group because of small breast size and large tumor size (3 cm in diameter).

during preoperative ultrasound; intraoperative frozen section analysis (FSA) of the glands inferior to the nipple and superior to the tumor showing no infiltration of cancer; and the possibility of the prosthesis being accepted psychologically. At the same time, patients in the BCS group were required to have had: no multicentric lesions present during preoperative ultrasound and with molybdenum target X-ray; a distance of more than 1 cm between the tumor margin and the areolar margin, and an intraoperative FSA displaying no infiltration of cancer into the incisional margin; no previous radiotherapy on the diseased breast and ipsilateral chest wall; no collagenosis such as systemic lupus erythematosus and scleroderma, or any other contraindications for radiotherapy; and consent for BCS and postoperative radiotherapy.

Operation procedures

ESM group

ESM under general anesthesia with tracheal intubation, the patient was placed in a supine position with the diseased side raised by 15°–30° and the ipsilateral arm abducted to 90° and fixed to the headframe. Incisions of 0.5 cm in length were made at the axillary transverse striation beyond the superolateral margin of the breast (superior incision), the midaxillary line at the nipple level (lateral incision), and the anterior axillary line at the inferolateral margin of the breast (inferior incision). Lipolysis solution (250 ml of sterile purified water, 250 ml of physiological saline, 20 ml of 2% lidocaine, and 1 ml of 0.1% adrenaline mixed as a 521-ml solution) was injected into the subcutaneous and retromammary spaces through the three incisions. The amount of solution injected

(about 500–800 ml into each side) was adjusted depending on the size of the breast. Ten minutes after injection of the lipolysis solution, sufficient liposuction was performed in the subcutaneous and retromammary spaces of the breast via the lateral and inferior incisions using a metal aspiration tube with side apertures (a suction tip used for uterine curettage) to remove the adipose tissue around the breast gland, especially the fat inferior to the nipple and superior to the tumor. Then a 5-mm trocar was inserted into each of the incisions and CO₂ was insufflated to establish an operating space (Figure 1). The inflation pressure was maintained at 8 mmHg. After sufficient liposuction, there remained only the Cooper ligaments between the gland and skin, the major ducts between the gland and nipple, and the marginal glands connecting the surrounding fascia around the retromammary space, which were then transected using an electric hook under endoscopic monitoring (Figure 2). The superior incision was then extended to 5 cm along the axillary transverse striation to remove the glands. Furthermore, with the help of the mark for tumor area with methylene blue, the tissues inferior to the nipple and superior to the tumor were taken for intraoperative FSA (Figure 3). After the excision, regional flushing, and thorough hemostasis, the endoscope and trocars were taken out.

Axillary lymph node dissection

Through the extended superior incision, axillary flaps were dissociated; the pectoralis minor was disclosed along the outer edge of the pectoralis major and the coracoclavicular fascia was opened at the outer edge of

the pectoralis minor to expose the axillary vein. The axillary lymph nodes above level II were then dissected.

Prosthesis implantation

From the lateral border to the medial and inferior margin of the pectoralis major, the retropectoral space was fully separated through the superior incision, and the partial attachment of the pectoralis major was cut off when necessary. In light of the volume of the excised gland and contralateral breast size, a suitable prosthesis of 180–260 ml that exactly matched the volume of the excised gland and the contralateral breast was selected and placed into the retropectoral space (Figure 4). A latex drainage tube was placed in the residual cavity near the submammary fold, educed through the inferior incision, and fixed firmly; another tube was placed in the axilla, educed through the lateral incision, and fixed firmly. After the operation, a mild compression dressing was applied for at least 2 weeks to avoid upward displacement of the prosthesis.

BCS group lumpectomy

Under general anesthesia with tracheal intubation, a transverse fusiform incision in the upper inner and upper outer quadrants, or a radiate fusiform incision in the lower quadrants was made, which was at least 1 cm away from the border of the tumor. Skin flaps with thin subcutaneous fat were dissociated to more than 2 cm away from the tumor margin, and the tumor with its surrounding normal tissue of about 1-cm thick was resected radially; tumor incisional margins were marked for FSA. When FSA showed cancer infiltration, the incisional margins were extended by 1 cm. When the margin was found positive after a second examination, a modified radical mastectomy was performed.

Axillary lymph node dissection

A 6-cm incision was made along the axillary transverse striation between the outer edge of the pectoralis major and the anterior edge of the latissimus dorsi, through which the axillary lymph node dissection was performed as in the ESM group. After the surgical procedure, a drainage tube was placed in the axilla, which was subjected to a mild, negative-pressure suction.

Postoperative management

As a preventive measure, antibiotics were administered for 3 to 5 days after the operation. The drainage tubes were removed when they drained less than 10 ml of fluid per day. Postoperative chemotherapy was given in 4 to 6 cycles to all patients (as in neoadjuvant chemotherapy). Radiotherapy of the affected breast was performed routinely in the BCS group and not routinely in the ESM group; radiotherapy of the internal mammary, axillary, and infraclavicular regions was performed in patients when more than four axillary lymph nodes were involved. After radiotherapy, patients with positive results from analysis of the tumor for estrogen receptors or progesterone receptors were managed with endocrine therapy for five years.

Follow-up

After treatment, all patients were followed up in the out-patient department every 3 to 6 months. Patients who did not attend the out-patient department for follow-up were contacted using questionnaires through the mail or over the telephone.

Evaluation criteria for postoperative cosmetic effect

The cosmetic outcome⁶ was evaluated 3 months after the surgical procedure. The items scored were: the appearance of the surgical scar; breast size; breast shape; nipple position; and areolar shape. While scoring these items, the treated breast was compared with the contralateral breast using a 4-point scale: excellent (0), when there was no difference between the breasts; good (1), when there was only a slight difference; fair (2), when a marked difference was present, which could be masked by dress; and poor (3), when the difference was disturbing.

Statistical analysis

Statistical analysis were performed using SPSS 13.0 (SPSS Inc Chicago, USA). Continuous variables and constituent ratio were expressed as mean \pm standard deviation (mean \pm SD). Comparisons between the two groups were made using a two-tailed Student's *t* test for measurement data and chi-square test for enumeration data. Difference was considered statistically significant when the *P* value was less than 0.05.

RESULTS

Clinical and pathological characteristics of the two groups

There were no differences in patient age, tumor size, tumor staging (according to the AJCC Cancer Staging Atlas, the 6th edition⁷), pathological type of tumor, status of hormone receptors and Her-2, and preoperative chemotherapy cycles between the two groups (*P* >0.05). However, the average distance between the tumor and areola was significantly shorter in the ESM group (2.2 \pm 1.1) than in the BCS group (3.4 \pm 1.3) (*P* <0.01); there were eight patients with sub-areolar lesions in the ESM group (Table).

Operation results

Intraoperative FSA showed no infiltration of cancer into the subcutaneous tissue superior to the tumor in the ESM group and no residual cancer in the incisional margin tissue in the BCS group. There were no significant differences in volumes of blood lost and postoperative-drainage-duration between the two groups (*P* >0.05); however, the duration of surgery was markedly longer in the ESM group than in the BCS group (*P* <0.01). In the ESM group, the total time of lipolysis and liposuction was about 30 minutes (Table).

Postoperative complications

The major complications in the ESM group (with a total

Table. Analysis of clinical and pathological characteristics of breast cancer in the two groups

Parameter	ESM group	BCS group	<i>t</i> or χ^2 value	<i>P</i> value
No. of patients	43	54		
Age (years)	39.7±8.2	42.4±7.9	1.624	0.108
Tumor size (cm)	2.7±0.9	2.6±0.9	0.429	0.669
Distance from the areola (cm)	2.2±1.1	3.4±1.3	5.001	<0.01
Tumor staging			0.687	0.709
I	15	22		
II	22	27		
IIIA	6	5		
Pathological types			0.492	0.569
Infiltrating ductal cancer	38	45		
Other infiltrating cancer	5	9		
Hormone receptor-positive rate	23/43	29/54	0.000	1.000
Her-2 positive rate	16/43	24/54	0.517	0.536
Preoperative chemotherapy cycles	2.1±1.1	1.9±1.1	1.181	0.241
Operation duration (minutes)	168±32	139±37	4.094	<0.01
Intraoperative blood loss (ml)	115±44	102±48	1.409	0.162
Postoperative drainage volume (ml)	150±63	160±69	0.726	0.470
Postoperative drainage duration (days)	6.7±2.1	6.3±2.1	1.070	0.284
Postoperative complications	5/43	6/54	0.006	1.000
Satisfactory postoperative cosmetic outcome	38/43	50/54	0.507	0.504
Follow-up time (months)	16.9±11.2	20.1±11.9	1.332	0.186
Recurrence and metastasis	0/43	3/51	2.613	0.247
Total survival	43/43	50/51	0.852	1.000

incidence of 11.6% (5/43)) were partial necrosis of the nipple in 2 patients, and superficial island necrosis and blistering of the breast skin in 3 patients. These complications healed with little change in breast appearance after incrustation and decrustation. No complete nipple necrosis or subcutaneous hydrops were observed in any patient. In the BCS group, the complications were hydrops in the axilla and residual cavity with a total incidence of 11.1% (6 of 54), which were treated successfully by puncturing and re-draining within 1 month. There was no significant difference in the total incidence of complications between the two groups ($P>0.05$).

Follow-up results

All of the 43 patients in the ESM group and 51 of the patients (94.4%, 51/54) in the BCS group were followed up for 6 months to 4 years. Patients in the ESM group all had a disease-free-survival, while 3 patients in BCS group had distant metastasis or local recurrence. Of these 3 patients, one had multiple bone metastases and liver metastasis 37 months after the operation and died of multiple organ failure 41 months after surgery as a consequence of abandoning treatment; one developed massive ascites and intra-abdominal multiple metastases 15 months after surgery and was stable after chemotherapy and symptomatic treatment; the third patient had local recurrence 28 months after the operation, and survived after modified radical mastectomy, postoperative chemotherapy, and radiotherapy. However, there were no statistically significant differences in total survival, local recurrence, and distant metastasis between the two groups ($P>0.05$).

Postoperative cosmetic evaluation showed (Figures 5 and 6) that in the ESM group, the outcome achieved was excellent in 9 patients (20.9%), good in 16 patients

(37.2%), fair in 13 (30.2%) and poor in 5 (11.6%), with a total satisfactory rate (excellent + good + fair) of 88.4% (38/43). Among the 5 patients with poor cosmetic outcome, 2 patients had serious asymmetry because of the upper reconstructed breast and the ptotic untreated one and 3 because of a smaller reconstructed breast and a bigger untreated one. The reconstructed breast was slightly higher than the contralateral breast during the initial stage after surgery in the ESM group, which resulted in discontentment with the cosmetic outcome. However, three months later, the cosmetic effect improved because the reconstructed breast shifted downwards and molded and had subcutaneous fat deposition. In the BCS group, the total satisfactory rate was 92.6% (50/54); the 4 patients with a poor cosmetic result had marked asymmetry because of the excess removal of glands and skin. There was no significant difference in the rate of satisfactory cosmetic outcome between the two groups ($\chi^2=0.507$, $P=0.504$).

DISCUSSION

ESM can reduce the use of breast radiotherapy treatment for breast cancer

The evolution of breast cancer treatment from radical mastectomy to modified radical mastectomy to BCS illustrates the continual need for improvement of surgical concepts and techniques in breast surgery — all in pursuit of “cure of breast cancer concomitant with maximal conservation of tissue” amongst both doctors and patients. BCS includes lumpectomy plus axillary lymph node dissection with postoperative breast radiotherapy for all cancer stages to avoid recurrence, the reported local recurrence rate in the literature was 26.4% without breast radiotherapy.⁸ In our study, patients in the BCS group underwent outpatient radiotherapy once a day for more than one month. This prolonged the total therapy time and

resulted in complications such as skin damage, breast edema, radiation pneumonitis,⁹ and, in addition, increased pain and financial burden for patients.¹⁰ In contrast, patients treated with ESM could avoid postoperative breast radiotherapy because of the total removal of the glands and, thus, did not suffer from radiation-based complications, postoperative local recurrence, and breast stump carcinoma. In this study, there were no significant differences between the two groups in prognostic factors such as tumor staging, hormone receptor status, and Her-2 status. Three patients in the BCS group developed recurrence and metastasis postoperatively in spite of the regular radiotherapy, while all patients in the ESM group survived disease-free; however, the differences between the two groups were not statistically significant, probably because of the small number of patients studied.

Wider indications for ESM plus axillary lymph node dissection and immediate breast reconstruction compared with BCS

Patients with a tumor of more than 3 cm in diameter, less than 2 cm away from the areola, or with multicentric lesions should be excluded from BCS.⁴ However, ESM has no severe limitations imposed by tumor size and position as long as the skin and main duct are not affected by the cancer. In addition, ESM is also suitable for the multicentric lesion, which is one of the key factors causing postoperative recurrence after BCS.^{11,12}

Central breast cancer is considered a contraindication for BCS and modified mastectomy with conservation of the nipple/areola complex.¹³ The literature suggests that the chances of malignant nipple/areola involvement may have been overestimated.¹⁴ In the ESM group that included 8 patients with central breast cancer, the distance between the tumor and areola was much shorter than that in the BCS group; no cancer infiltration of the subcutaneous tissue over the tumor was found using intraoperative FSA, and no cancer recurrence or metastasis were observed during the follow-up period. Therefore, central breast cancer without the involvement of the nipple/areola and skin (observed during preoperative examination) can be managed with ESM. The indications for selecting ESM plus axillary lymph node dissection and immediate breast reconstruction are, therefore, wider than BCS.

Feasibility and surgical safety of ESM plus axillary lymph node dissection and immediate breast reconstruction

The use of endoscopic techniques for subcutaneous excision of breast tumors is well established.¹⁵⁻¹⁷ ESM was performed through small incisions made in hidden sites after sufficient lipolysis and liposuction, axillary lymph node dissection, and finally prosthesis implantation through the axillary incision. In our study, the duration of surgery in the ESM group was longer (an average duration of 168 minutes) than that of the BCS group, where an incision was made directly on the tumor surface and excision was performed under direct vision.

Lipolysis and liposuction are time-consuming, and the longer duration of surgery might also be partly due to the unskilled technique of the surgeon in the ESM group.

To avoid residual cancer after ESM, the case-inclusion criteria have to be strictly enforced and FSA of the tissue inferior to the nipple and superior to the tumor must be meticulously performed intraoperatively. In the ESM group in our study, no recurrence or metastasis occurred during follow-up, indicating that proper endoscopic techniques were employed and our case-selection criteria were adequate.

The postoperative complications in our ESM group were partial necrosis of nipple and superficial necrosis of the breast skin, which were caused by insufficient blood supply to the nipple. Nipple blood supply comprises two parts: the vascular network from the surrounding skin and subcutis; and the perforating vessels from the mammary gland. After a subcutaneous mastectomy, the nipple depends for its blood supply only on the vascular network from the surrounding skin and subcutis.¹⁸ In the ESM group, 2 patients suffered from partial nipple necrosis and 3 from superficial skin necrosis — all healed with little change of appearance within a month. These complications were avoided by refinement of the surgical skills required for the procedure; therefore, no nipple necrosis was found among the remaining 38 patients in the ESM group. To avoid subcutaneous vascular network injury, we suggest that the tip of the suction nozzle not face the skin during liposuction. In addition, we also suggest that a small amount of the gland be spared beneath the nipple and areola to prevent ischemia and aversion. The postoperative complication in the BCS group was subcutaneous hydrops, which was caused by impaired lymphatic drainage and lymph leakage.¹⁹ Subcutaneous hydrops did not occur with ESM because the entire breast tissue, the source of lymph, was resected.

Postoperative cosmetic effect of ESM plus axillary lymph node dissection and immediate breast reconstruction for breast cancer

One of the aims of BCS and ESM is to retain the original breast contour (for cosmetic reasons) after surgery.²⁰⁻²² After a wide local excision in a large breast, the postoperative contour is usually satisfactory; but this can be a challenge with small-sized breasts because it is difficult to maintain symmetry with the contralateral breasts.⁴ Among the 54 patients in the BCS group of this study, 4 patients with small breasts had poor cosmetic results because of asymmetry. With ESM, subcutaneous mastectomy can be performed through 3 incisions hidden beyond the breast margins, which will conserve skin, while the prosthesis can be inserted through the axillary incision to reconstruct the original breast contour, all resulting in acceptable postoperative cosmetic results. This is ideal for medium- and small-sized breasts where maintaining bisymmetry is a challenge. For large-sized or drooping breasts, endoscopic surgery is difficult and

time-consuming to perform. Moreover, the reconstructed breast usually lacks natural ptosis and will be smaller than the untreated breast because the prosthesis can only be inserted into the retropectoral space, which has a limited interstitial volume. Breast reconstruction is, therefore, not suitable for patients with large or drooping breasts, where better cosmetic results can be achieved by autologous tissue flap transfer.²³

In our study, even though the difference in rates of satisfactory cosmetic outcomes between the ESM and BCS groups was not statistically significant, the cosmetic effect was worse in the ESM group (88.4%; BCS group, 92.6%). The possible reasons for this are prosthesis deviation due to technical factors, uneven symmetry because of ptotic or larger contralateral normal breast, and unrealistic expectations of cosmetic outcome after surgery in some patients who underwent ESM. To achieve optimal aesthetic results, we recommend that BCS be used in patients with large breasts and ESM plus axillary lymph node dissection and breast reconstruction with implants be used in patients with small, non-droopy breasts.

After considering the wide indications for use, high surgical safety factor, and favorable cosmetic outcome, we believe that ESM plus axillary lymph node dissection and immediate reconstruction with implants — the new choice in surgery for breast cancer — warrants serious consideration as the prospective next standard surgical procedure.

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