Early Results of an Endoscopic Nipple-Sparing Mastectomy for Breast Cancer

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ABSTRACT

Background. Endoscopic mastectomy has been reportedly associated with smaller scars and greater patient satisfaction; however, few reports on this topic have been made. The purpose of this retrospective study was to examine the early results of endoscopic nipple-sparing mastectomy (E-NSM) and to investigate the safety of this procedure.

Methods. Between January 2002 and December 2005, a total of 87 patients with breast cancer but without skin and nipple involvement, including two cases of bilateral breast cancer, underwent E-NSM. In case of bloody nipple discharge and suspicious extension near the nipple as assessed by magnetic resonance imaging, the major ducts within the nipple were cored (nipple coring). In other cases, nipple coring was not performed.

Results. Of the 89 breasts in 87 patients, 42 had tumors of >2 cm and 80 were diagnosed as having invasive carcinoma. Lymph node involvement was observed in 36 procedures. The overall rate of nipple necrosis was 18% (16 of 89). The rate of nipple necrosis among the procedures with nipple coring was statistically higher than that among those without nipple coring (7 of 17, 41%, vs. 9 of 72, 13%) ($P = .01$). Nipple involvement was observed in 2.2% (2 of 89). After a median follow-up period of 52 months, distant metastasis was observed in nine cases; no local recurrences occurred in this series.

Conclusions. E-NSM is an oncologically safe procedure and an acceptable method in selected patients requiring a mastectomy. The higher rate of nipple necrosis may have

been the result of a technical problem, indicating the need for continued improvement in nipple coring procedures.

The removal of the nipple as part of a mastectomy has been routinely performed on the basis of the presumed risk of occult nipple involvement, which reportedly occurs in 5.6% to 58% of cases.^{1–11} However, many patients are dissatisfied with the reconstructed nipple for various reasons, including nipple projection, color matching, shape, size, texture, and position.¹² A nipple-sparing mastectomy (NSM) is a procedure that can be applied as part of a skin-sparing mastectomy, in which the nipple-areola complex (NAC) is preserved for cosmetic reasons.^{9,11,13–19} For patients without skin and nipple involvement, NSM has evolved as an alternative to a mastectomy with a safe oncologic profile and a better cosmetic outcome.^{9,11,13–21}

In the early 1990s, endoscopic surgery of the breast was first applied for the treatment of patients with capsular contracture after breast augmentation.²² Since then, it has been used for aesthetic breast surgery, breast lump excision, and breast surgery for breast cancer.^{23–34} The addition of endoscopy to NSM for patients with breast cancer has been reportedly associated with smaller scars and greater patient satisfaction.^{27–29} However, few reports on endoscopic nipple-sparing mastectomy (E-NSM) have been made, and most of these studies had relatively short follow-up periods and small patient samples.^{27–31} The only report to describe the oncologic safety of E-NSM had a patient sample of 33 women with early-stage breast cancer and a mean follow-up period of 51.2 months (range, 16–86 months).³¹

The purpose of this retrospective study was to examine the early results of E-NSM and to investigate the safety of this procedure.

MATERIALS AND METHODS

Between January 2002 and December 2005, a total of 507 consecutive patients with primary operable breast cancers underwent breast surgery at our institution. Of these patients, 110 (22%) underwent conventional surgery and 397 (78%) underwent endoscopic surgery. Among the 397 patients who underwent endoscopic surgery, 293 (74%) underwent breast-conserving surgery and 104 (26%) received mastectomies. Among the 104 patients who received mastectomies, the NAC was removed in 24 (23%) because of highly suspicious invasion or involvement of the nipple. Finally, 80 patients who underwent primary E-NSM and 7 patients who underwent E-NSM because of involved margins after endoscopic breast-conserving surgery were included in this retrospective study. Two of these patients underwent bilateral E-NSM.

A total of 89 E-NSM procedures in 87 patients (mean patient age, 50 years; range, 28–78 years) were assessed preoperatively by physical examination, mammography, and ultrasound. Magnetic resonance imaging (MRI) was also obtained in all patients to assess nipple involvement and tumor extension. The tumor size, stage of disease, preoperative and adjuvant therapy, axillary nodal status, complications, and recurrence were reviewed.

Before undergoing E-NSMs, the patients were thoroughly informed of the possible risks and advantages related to the preservation of the NAC and the use of an endoscopic technique. Our institutional review board required neither the patients' approval nor the patients' informed consent for a review of their medical records to be made.

Indications for E-NSM

The indications for a mastectomy were multifocal or multicentric breast carcinoma, unicentric carcinoma not suitable for breast-conserving surgery, extensive intraductal neoplasia involving more than one quadrant, and residual tumor after endoscopic breast-conserving surgery. The contraindications for E-NSM were skin involvement, Paget disease, and suspicious NAC involvement of a centrally located tumor as assessed by physical examination, and highly suspicious skin or NAC involvement as assessed by MRI evaluation.

Indications for Nipple Coring

In case of bloody nipple discharge without evidence of nipple involvement and suspicious intraductal extension near the nipple as assessed by MRI, the major ducts within the nipple were cored at the time of the operation (nipple coring). In other cases, nipple coring was not performed.

Surgical Procedure

Preoperative markings were made on the skin over the area of the resection and over the site of the skin incision. The level of the nipple was also marked in the midline of the body with the patient in a sitting position (Fig. 1). After induction of general anesthesia, the patient was placed in the flat supine position with the arm abducted to 90°. The breast, chest wall, and arm were prepared and draped in the usual sterile fashion. Video monitors were set on both sides of the patient. E-NSM was performed according a previously described approach.^{30,34} Figure 2 shows the tools used for this surgery.

Sentinel Lymph Node (SLN) Biopsy

When performing the SLN biopsy, it was carried out by the blue dye and radioisotope method. A 3-cm-long skin incision was made along the skin crease of the axilla. Dissection of the subcutaneous tissue was carefully carried out, down to the lateral border of the pectoralis major muscle. Visiport Plus (Covidien, Mansfield, MA) was inserted via the incision, and the stained lymph node was found by following the blue lymphatic channels through the intact axillary fascia under endoscopic guidance. After incision of the axillary fascia with a crescent-shaped knife blade at the distal end of the Visiport Plus, the SLN was held with straight grasping forceps and removed under direct vision. SLN biopsy was also carried out with gamma probe guidance. If the patient was found to have a positive SLN, a complete axillary node dissection was performed after extension of the incision by up to 5 cm.

FIG. 1 Preoperative markings. The area of the resection (outlined by dots), the site of the skin incision (continuous line at axilla and periareolar region), and the level of the nipple with the patient in a sitting position (X) are marked

FIG. 2 Endoscopic surgical instruments. **a** Visiport Plus. **b** Ultra Retractor. **c** Endopath Xcel Bladeless Trocar. **d** PowerStar bipolar scissors

Dissection of Reverse Side of Breast

The dissection of the fascia off the anterior surfaces of the pectoralis major muscle was carried out as far as possible under direct vision. Then an Ultra Retractor (Johnson & Johnson, New Brunswick, NJ) with an inserted 5-mm, 30° endoscope (Olympus, Tokyo, Japan) was placed into the space, and the dissection of the pectoralis fascia was continued endoscopically by pushing the Ultra Retractor along the muscle fibers or cutting the fascia with PowerStar bipolar scissors (Johnson & Johnson) with the Ultra Retractor pulled up to create a sufficient working space (Fig. 3a–c). Arterial perforators were coagulated with a PowerStar bipolar scissors or electrocautery as needed. This process was repeated distally and proximally until the breast tissue along with the pectoral fascia was dissected off the major pectoral muscle up to the clavicle superiorly, up to the inframammary fold inferiorly, and to the sternum medially.

On the lateral side, the breast was dissected from the serratus fascia and anterior border of the latissimus dorsi with PowerStar bipolar scissors under endoscopic vision (Fig. 3d).

Create a Skin Flap

A periareolar semicircular incision (less than half of the circumference) was made to create a thin skin flap. Skin hooks were used for retraction to minimize trauma to the skin flaps during dissection. After the skin flaps were raised in the subdermal plane for 2 cm from the incision under direct vision, multiple parallel tunnels were created at intervals of 2 cm at a fixed depth of the subdermal tissue with the Endopath Xcel Bladeless Trocar (Johnson &

Johnson) with an inserted 10-mm, 0° endoscope (Olympus), and the septa between the tunnels were cut with PowerStar bipolar scissors under direct vision (Fig. 4). Mamma Retractor/Right Guide (Four Medics, Tokyo, Japan) was used to provide illumination and gentle traction on the skin flaps for exposure. When the dissection of the skin flaps reached the standard boundaries of the breast, the previously dissected reverse side of the breast was exposed by cutting the subcutaneous tissue toward the chest wall in all directions. The excised breast tissue was pulled out through the periareolar incision or the axillary incision.

Nipple Coring

In cases where nipple coring was indicated, an additional radial incision was made over the areola to remove the tissue within the nipple and the small amount of skin at the tip of the nipple (Fig. 5). In cases where nipple coring was not indicated, a frozen-section biopsy on the base of the nipple was performed. If analysis of this biopsy sample revealed tumor involvement, the nipple was removed.

Skin Closure

The base of the nipple and the major pectoral muscle were sutured at the level of the marking made earlier on the midline of the body. After placement of two closed-suction drains, the incision was closed (Fig. 6).

Final Pathological Assessment of Nipple

During the final pathological assessment, if malignant cells in the cored duct (in cases with nipple coring) or at the

FIG. 3 **a** A retractor is inserted from the skin incision in the axilla. **b** The dissection of the pectoralis fascia is carried out distally and proximally. **c, d** View of the endoscopic monitor

FIG. 4 **a** Skin flap is made by the Endopath Xcel Bladeless Trocar. **b** Multiple parallel tunnels are created at intervals of 2 cm at a fixed depth of the subdermal tissue

FIG. 5 Skin incision with nipple coring

FIG. 6 Appearance of the breast after endoscopic nipple-sparing mastectomy

margin beneath the nipple (in cases without nipple coring) were identified, the nipple was removed, leaving the areola, during a second scheduled surgery.

Statistical Analysis

We divided nipple necrosis into partial necrosis and total necrosis. Partial necrosis was judged as necrosis accounting for less than a third of the total skin area of the nipple.¹⁵ The statistical analysis was performed by Fisher's exact test. For all the analyses, a *P* value of < .05 was considered statistically significant.

RESULTS

E-NSM procedures were performed in 62 breasts (70%) with unicentric carcinoma with or without an extensive intraductal component, in 15 breasts (17%) with multifocal or multicentric tumors, in 6 breasts (6.7%) with highly suspicious residual tumor after breast conservation therapy, and in 6 breasts (6.7%) at the patients' request. Table 1 shows the clinicopathological features of these E-NSM cases. Of the 89 breasts in 87 patients, 42 breasts (47%) had tumors of > 2 cm, 37 (42%) had tumors classified as stage 0/I, 50 (56%) had tumors classified as stage IIA/IIB, and 2 (2.2%) had tumors classified as stage IIIA. Median tumor size in invasive carcinoma was 2.1 cm (range, .1 to 5.6). Histology revealed ductal carcinoma-in-situ in 9 E-NSM specimens (10%) and invasive carcinoma in 80 E-NSM specimens (90%). An axillary dissection was performed in 54 procedures (61%), and lymph node involvement was observed in 36 (40%) of 89 procedures. Lymphovascular invasion (LVI) was observed in 43 breasts (48%). Systemic chemotherapy was performed for 56 (64%) of the 87 patients, and radiotherapy was administered to 27 (30%) of the 89 breasts.

Seventeen E-NSM procedures in 17 cases (19%) involved nipple coring, whereas the remaining 72 E-NSM procedures in 70 cases (81%) involved surgeries that preserved the major ducts within the nipple. The reasons for nipple coring were bloody nipple discharge in 6 patients (35%) and suspicious extensions near the nipple (as observed by MRI) in 11 patients (65%). In the 17 cases with nipple coring, the final histology revealed nipple involvement in 2 (12%), whereas the remaining 15 cases (88%) were negative for malignancies. The two cases of nipple involvement had undergone nipple coring on the basis of the presence of suspicious extensions near the nipple as observed by MRI. One had a 2.6-cm-size invasive tumor with severe LVI, and six involved lymph nodes. The nipple was found to be intact as assessed by physical examination; however, Paget cells were observed in the

TABLE 1 Characteristics of 89 patients

Characteristic	Value
Average age (y)	50
Tumor size, <i>n</i> (%)	
Tis/T1	47 (53)
T2	40 (45)
T3	2 (2.2)
TNM stage, <i>n</i> (%)	
0/I	37 (42)
IIA/IIB	50 (56)
IIIA	2 (2.2)
Histology, <i>n</i> (%)	
Ductal carcinoma-in-situ	9 (10)
Microinvasive carcinoma	4 (4.5)
Invasive ductal carcinoma	68 (76)
Invasive lobular carcinoma	3 (3.4)
Other ^a	5 (5.6)
Axillary dissection, <i>n</i> (%)	54 (61)
Lymph node status, <i>n</i> (%)	
Negative	53 (60)
<3 positive nodes	23 (26)
≥4 positive nodes	13 (15)
Chemotherapy, <i>n</i> (%)	56 (64)
Radiotherapy, <i>n</i> (%)	27 (30)

TNM tumor, node, metastasis system

^a Diagnosis include apocrine carcinoma, medullary carcinoma, and mucinous carcinoma

skin of the cored specimen, with no evidence of intraductal extension. The final pathology of the nipple base was negative for malignancy. The other patient had a 4.5-cm-size invasive tumor with severe LVI and one involved lymph node. An invasive tumor with intraductal extension was observed in the cored specimen and the final pathology of the nipple base was positive for malignancy. In the 72 E-NSM procedures that were performed without nipple coring, the pathologic assessments of the frozen and final sections were all negative for malignancies. The final histology of the peripheral margins was negative in all cases.

Table 2 shows the complications that were experienced and the recurrence of E-NSM. The overall complication rate was 22% (20 of 89); these complications included infection in 1 procedure (1.1%), skin flap necrosis in 3 procedures (3.4%), and nipple necrosis in 16 procedures (18%), of which partial necrosis was observed in 7 procedures (7.9%) and total necrosis was observed in 9 procedures (10%). The overall rates of nipple necrosis, the rates of partial necrosis, and the rates of total necrosis were 41% (7 of 17), 18% (3 of 17), and 24% (4 of 17), respectively, among the E-NSM procedures with nipple coring and 13% (9 of 72), 5.6% (4 of 72), and 6.9% (5 of

72), respectively, among those without nipple coring. The overall rate of nipple necrosis among the E-NSM procedures with nipple coring was statistically higher than that among those without nipple coring ($P = .01$).

During the median follow-up period of 52 months (range, 16–80 months), distant metastasis was observed in nine cases (10%), of which only one had a suspicious subcutaneous mass in the axillary tail accompanied by multiple lung and bone metastases 13 months after the initial operation. The original tumor in this case was an invasive ductal carcinoma measuring 2.5 cm in size with five lymph node involvements and severe LVI. No local or NAC recurrences occurred in this series.

DISCUSSION

Many studies have reported the risk of NAC involvement on the basis of histological analyses of mastectomy specimens and have concluded that a central tumor location, tumor size, nodal positivity, LVI, and multicentricity or multifocality were associated with NAC involvement.^{1–11} The indications for NSM are clinically decided in consideration of these risk factors.

Several studies on NSM have shown that the rate of nipple involvement (malignancy in the nipple or in the base of the nipple) detected in the frozen section or final resected section ranges from 5.4% to 24%.^{14–17,19–21,31} In the current study, all the patients underwent an MRI examination in addition to a physical examination and mammography, and nipple involvement was observed in only 2.2% (2 of 89) of the E-NSM procedures, even though many cases in the study had a high risk of nipple involvement, LVI (43 of 89, 48%), lymph node involvement (36 of 89, 40%), large primary tumor size (> 2 cm, 42 of 89, 47%), and multifocal or multicentric tumors (15 of 89, 17%) were regarded as risk factors for nipple involvement. Moreover, centrally located tumors have been regarded as a contraindication of NSM in previous reports, whereas centrally located tumors were considered to be suitable for E-NSM in our study, except in

cases with suspicious NAC involvement as assessed by physical examination and MRI.^{1–3,6–11} The two NACs with nipple involvement accounted for 18% (2 of 11) of the breasts with suspicious extensions near the nipple as viewed by MRI. The other NACs without suspicious involvement on MRI examination (85 of 87, 98%) all tested negative for malignancy in the final histology examination. Wijayanayagam et al. also performed preoperative assessments by MRI and reported occult nipple involvement in two patients (2 of 64, 3%).³⁵ The low rate of nipple involvement in these studies shows the usefulness of MRI for selecting candidates for NSM. Moreover, the current results also suggested that nipple coring may not have been necessary in 88% (15 of 17) of the cases that underwent this procedure; if nipple coring had not been performed in these patients, this would have reduced the frequency of nipple necrosis complications.

Regarding NSM, a number of studies have demonstrated its oncologic safety; however, this procedure is still controversial.^{9,11,13–21} Benediktsson and Perbeck reported that the frequency of local recurrence was 8.5% (4 of 47) among patients who received radiotherapy and 28.4% (48 of 169) among nonirradiated patients with a mean follow-up period of 156 months.¹⁹ They suggested that the high local recurrence rate among the nonirradiated patients was a result of inadequate surgery. In contrast, many studies have reported that the local recurrence rate after NSM, including recurrence of disease in the nipple, ranges from 1% to 5.9%, with mean follow-up periods ranging from 13 to 66 months.^{9,11,13–18,20,21} Recurrence of disease in the nipple has been reported in a few studies. Gerber et al., Kissin and Kark, Caruso et al., and Psaila et al. each reported one case of disease recurrence in the nipple in their studies with median follow-up periods of 59, 50, 66, and 18 months, respectively; these collective findings suggest a recurrence rate of disease in the nipple of 5%.^{9,13,14,18} However, a number of the studies on NSM were uncontrolled retrospective studies from single institutions with modest patient numbers and/or relatively short

TABLE 2 Complications and recurrence of endoscopic nipple-sparing mastectomy

Characteristic	Nipple coring ($n = 17$), n (%)	Without nipple coring ($n = 72$), n (%)	Total ($n = 89$), n (%)	P
Complication	7 (41)	13 (18)	20 (22)	.05
Infection	0	1 (1.4)	1 (1.1)	NS
Skin necrosis	0	3 (4.2)	3 (3.4)	NS
Nipple necrosis	7 (41)	9 (13)	16 (18)	.01
Partial necrosis	3 (18)	4 (5.6)	7 (7.9)	
Complete necrosis	4 (24)	5 (6.9)	9 (10)	
Recurrence				
Local recurrence	0	0	0	
Distant metastasis	2 (11)	7 (9.7)	9 (10)	NS

NS not significant

follow-up periods.^{9,11,13–21} Therefore, further investigation is needed.

The technical advantages of E-NSM over NSM without endoscopic assistance were that the dissection of the reverse side of the breast was performed endoscopically. In the E-NSM procedure, a smaller skin incision with acceptable curability can be obtained. Among the reports on E-NSM, Ito et al. evaluated 33 patients with early-stage breast cancer and reported no local recurrences in a study with a mean follow-up period of 51.2 months.³¹ The current study included patients with T2 or T3 tumors (47%) and axillary lymph node involvement (40%). However, there was no local recurrence within a median follow-up period of 52 months. Radiotherapy (27 of 89, 30%) may reduce the local recurrence of relatively advanced-stage breast cancer.

Leaving tissue around the NAC creates a risk of recurrence of disease in the nipple.^{9,13,14,18} However, the complete removal of these tissues may affect the vascularization of the nipple, increasing the probability of necrosis.³⁶ The surgical approach to removing tissue from around the NAC differs from surgeon to surgeon. Several studies have described the use of nipple coring, whereas others left the duct within the nipple.^{9,14–21,35,37,38} In the study of Benediktsson and Perbeck, they left a 5-mm thick plate of gland tissue with a diameter of 2 cm beneath the nipple.¹⁹ Petit et al. added irradiation to the retained breast tissue in the NAC area.^{17,20}

In the present study, the overall rate of nipple necrosis was 18% (16 of 89), which was within the previously reported range of 0% to 20%.^{9,11,14–21,35,37,38} In addition, the rate of nipple necrosis among the E-NSM procedures without nipple coring was similar to that of previous studies (1.7% to 15% for overall, 1.7% to 10% for partial, and 0% to 7.9% for total necrosis).^{9,14,16,17,19,20,38} However, the overall rate of nipple necrosis among the E-NSM procedures with nipple coring was statistically higher than that of the E-NSM procedures without nipple coring (7 of 17, 41%, vs. 9 of 72, 13%) ($P = .01$). Among the E-NSM procedures with nipple coring, the respective rates of partial necrosis and total necrosis were 18% (3 of 17) and 24% (4 of 17); these rates were higher than previously reported rates for patients that have undergone nipple coring: 0% (0 of 82) and 0% (0 of 82) reported by Stoller et al., 6.8% (13 of 192) and 4.6% (9 of 192) reported by Sacchini et al., 6.3% (3 of 48) and 0% reported by Crowe et al., and 16% (10 of 64) and 4.7% (3 of 64) reported by Wijayanayagam et al.^{15,21,35,37} These previous reports described several techniques that can be used to minimize nipple necrosis: using gentle traction of the skin flaps, leaving approximately 2 mm of tissue at the tip of the nipple, using scissors rather than electrocautery to avoid thermal damage to the NAC, and making a radial or lateral skin incision

rather than a medially located incision.^{15,21,35,37} In the current study, we used a radial incision to the areola in addition to the periareolar incision and removed a small amount of skin at the tip of the nipple and the ductal tissue inside the nipple. The higher rate of nipple necrosis in our study may have been a result of this technique. Careful attention to the treatment of the nipple and the incision site is necessary to minimize complications.

Our study had several limitations: first, evidence obtained from retrospective studies, like ours, is statistically weak. A randomized trial comparing E-NSM with the conventional method should be offered to a subset of patients who have indications for both techniques. Second, the follow-up period was relatively short, and additional careful follow-up is needed to ascertain the long-term results of this procedure. Third, immediate reconstruction was rarely performed during the study period. Our breast reconstructions with mammary prosthesis under endoscopic assistance were usually performed 3 to 5 years after the initial operation.³⁰ Therefore, the reconstructive outcome was not evaluated. The cosmetic results of this study will be assessed over time. Fourth, our nipple necrosis rate was not lower than that reported in previous literature in cases where immediate reconstruction was performed. The rate might have increased because of the immediate reconstruction. At the beginning of the study, only two of the four surgeons had experience in E-NSM, which might have accounted for the higher necrosis rate. However, the candidates for nipple coring could reduce in number according to the current results, and the nipple necrosis rate of E-NSM performed by surgeons with a large experience should be evaluated further in the future.

In conclusion, the overall rate of nipple necrosis, the rate of partial necrosis, and the rate of total necrosis were 41%, 18%, and 24%, respectively, among the E-NSM procedures with nipple coring and 13%, 5.6%, and 6.9%, respectively, among the E-NSM procedures without nipple coring. The lower rate of pathologically positive nipples (2 of 89, 2.2%) indicates the usefulness of MRI for selecting candidates for NSM. No local recurrences were observed in this study, which shows the safety of this procedure. According to our data, E-NSM is an acceptable method for selected patients requiring a mastectomy.

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