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Original Article

## Loco-Regional Recurrence after Nipple-Sparing Mastectomy in Breast Cancer Patients

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### Abstract

**Objectives:** There are relatively few studies of locoregional recurrence (LRR) after nipple-sparing mastectomy (NSM) for breast cancer. The aim of the present study was to determine the oncologic safety of nipple-areolar complex (NAC)-sparing mastectomy in breast cancer patients and to determine risk factors for LRR.

**Patients and Methods:** We analyzed 65 NSMs that were performed on 63 patients for both therapeutic and prophylactic indications between January 2007 and June 2017. Patient demographics, operative details, oncologic outcomes, and postoperative complications were recorded. Factors associated with LRR were also analyzed.

**Results:** The mean age of the patients was 43 years (range, 30 to 61 years). Fifty-eight NSMs (89%) were performed for cancer treatment. Skin necrosis was the most common complication (19%), but most cases were successfully managed conservatively. Fifty-one NSMs were included in the oncologic evaluation. Forty of 51 patients (78%) underwent surgery for invasive breast cancer, and the rest had carcinoma in situ. After a mean follow-up period of 70 months (24 to 162 months), four patients (8%) developed LRR, with mostly in the regional lymph nodes. Only one patient developed Paget's disease of the nipple after surgery and required NAC excision. Five-year disease-free survival was 87%. In a subgroup analysis, only tumor size and Ki-67 level showed an association with LRR, but only Ki-67 level was statistically significant (HR 1.07; 95% CI 1.00 to 1.15).

**Conclusion:** NSM is oncologically safe and is technically feasible in selected patients. A low rate of LRR was also observed. Only Ki-67 level showed an association with LRR. Long-term outcomes should be closely monitored.

**Keywords:** Breast cancer, Locoregional recurrence, Nipple-areolar complex-sparing mastectomy, Nipple-sparing mastectomy, Oncologic safety

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## INTRODUCTION

Breast cancer is the most common cancer affecting women worldwide. There were 1.67 million new cases of breast cancer, with more than 500,000 deaths reported in 2012.<sup>1</sup> The incidence has been increasing over the past decade. Surgery is the mainstay of curative treatment for breast cancer, but more conservative surgical techniques have been developed. Breast conserving surgery (BCS) provides the best aesthetic results with oncologic safety, serving as the gold standard in early breast cancer treatment.<sup>2</sup> However, mastectomy may play a role in some situations, such as for multicentric breast cancer, large tumors, post-radiated patients, and for prophylaxis.

Success in reconstruction techniques has led to a change from radical to more conservative approaches. In 1991, Toth described the skin-sparing mastectomy (SSM) technique.<sup>3</sup> This technique has been widely adopted as a preferred reconstruction technique in terms of oncologic safety and cosmesis. The nipple-areolar complex (NAC) is the signature of the breast and has the greatest impact on patients' satisfaction and feelings of mutilation, but oncologic safety is still a major concern.<sup>4</sup> Freeman reported on the NAC-sparing technique in 1962 and named it subcutaneous mastectomy, which was used for benign breast lesions.<sup>5,6</sup> NAC involvement in breast cancer was found to be from 0 to 58% in previous reports.<sup>7</sup> These results vary widely because of the differences in populations, staging, and sampling techniques among the studies.

Based on Sappey's theory, all lymphatic systems drain towards the subareolar plexus and should be removed in an oncologic resection. Wellings et al. proposed the theory that neoplastic breast lesions are generated from the terminal duct lobular unit (TDLU).<sup>8,9</sup> Previous publications identified TDLU in nipple specimens in only about 0 to 9% of cases.<sup>10-14</sup> Most were found near the base of the nipple and not at the tip, suggesting that NAC-sparing mastectomy should be safe if there is no tumor involvement at the base of the nipple. However, no randomized study has compared NAC-sparing mastectomy with standard surgical techniques. Previous reported locoregional recurrence (LRR) rate of 2.4% (range, 0 to 19.1%) was comparable to that seen in breast-conserving surgery (BCS).<sup>15</sup> In these studies, almost all the patients experienced recurrence outside the NAC. Factors related to NAC involvement included tumor size, tumor-nipple distance, lymphovascular invasion, and axillary lymph node involvement. There are no standardized patient selection criteria. The objective of the present study was

to determine the oncologic safety and risk factors of LRR in patients who underwent NAC-sparing mastectomy.

## PATIENTS AND METHODS

All patients who underwent NSM for therapeutic or prophylactic indications in the Breast and Endocrinology Unit at our institution between January 2007 and June 2017 were included. All patients underwent standard preoperative evaluations, including clinical examination, digital mammography, and breast ultrasonography. Magnetic resonance imaging is not routinely performed at our institution. NSM were performed if the primary tumor located outside of the areola, with the absence of nipple retraction or bloody nipple discharge, and absence of microcalcification in the retroareolar region. Some patients with multicentric/multifocal lesions that were distant from the areola also underwent NSM. Patients with preoperative chemotherapy or radiotherapy were excluded from the study. Patients with inflammatory breast cancer and Paget's disease were not candidates for NSM. The study was approved by the Research Ethics Committee of our institute. A flowchart of patient selection is shown in Figure 1.

The operative technique has been described in a previous study.<sup>16</sup> Different types of skin incisions have also been previously reported.<sup>17</sup> We preferred the superolateral radial incision to provide good exposure and a low rate of ischemic complications. The glandular tissue and all ducts were cored out, and subareolar base tissue was sent for pathological examination in all patients (Figures 2 to 4).

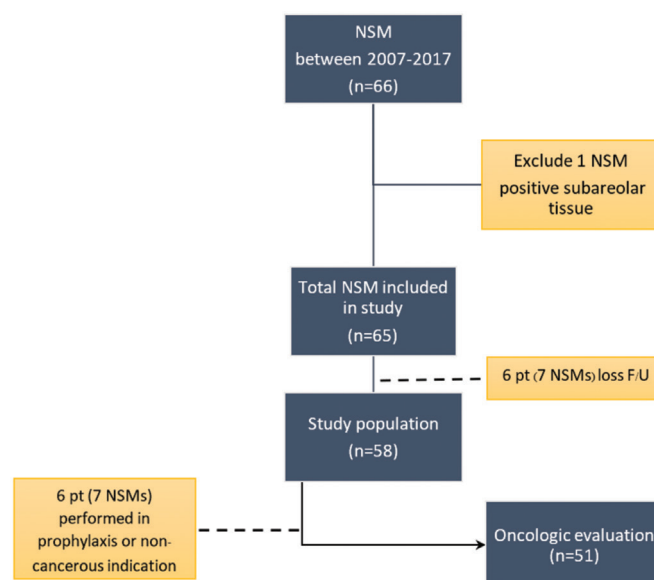


Figure 1 Patient selection flowchart

The NAC was excised if the base tissue was involved by cancer. Immediate reconstruction was performed in all patients with implants, autologous flaps, or both.

The decision for adjuvant treatment was discussed in a multidisciplinary breast cancer care team. All patients were followed up within 1 month after the operation, then every 3 months for the following 2 years, and every 6 months for 5 years thereafter. Only patients with a follow-up duration of > 24 months were included in the oncological analysis.

All demographic data, tumor characteristics, complications, and oncological outcomes were presented using descriptive statistics. Means, standard deviations (SD), medians, and ranges were used for continuous

variables, while frequencies and percentages were used for the categorical variables. The primary outcome was LRR. Unpaired T-test, ranksum test and Fisher's exact test, as appropriate, were used to identify the association between the primary outcome and any risk factor. Cox's proportional hazard regression model was used to identify independent risk factors for LRR. All statistical analyses were performed using STATA version 14.0.



**Figure 2** Coring out of glandular tissue from the nipple: subareolar base tissue is identified.



**Figure 3** Subareolar base tissue is cored out and sent for frozen section.



**Figure 4** All subareolar base tissue has been removed.

## RESULTS

Sixty-four women underwent 66 NSMs between January 2007 and June 2017. The subareolar margin was positive for malignant cells in one patient (2%); therefore, this patient was excluded from the study. The mean age of the patients was 43 years (range, 30 to 61 years). Fifty-eight patients (89%) underwent NSM under therapeutic indication (95% were invasive or carcinoma in situ and 5% were phyllodes tumors). Three patients with phyllodes tumors and four NSMs performed for benign diseases were excluded from the oncologic analysis. Patient characteristics are shown in [Table 1](#).

The postoperative complications and types of ischemia are shown in [Table 2](#). Skin ischemia was the most common complication observed in our study. Nipple ischemia occurred in 12 patients (19%). Three developed full-thickness necrosis, but only two required surgical debridement. Only one patient had nipple loss requiring total NAC excision. Partial skin flap ischemia occurred in 13 NSMs (20%) and was successfully managed conservatively. Infection and seroma were also rather common, but most resolved with conservative treatment.



**Table 1** Baseline characteristics of 65 nipple-sparing mastectomies (NSM)

Characteristics	Summary
<b>Age (years) : median (range)</b>	43.66 (30 - 61)
<b>BMI (kg/m<sup>2</sup>): median (range)</b>	23.3 (15.4 - 43.8)
<b>Family history of breast cancer: n (%)</b>	13 (20)
<b>Co-morbidity: n (%)</b>	
None	55 (85)
Diabetes mellitus	4 (6)
Hypertension	3 (5)
Others	3 (5)
<b>Preoperative diagnosis: n (%)</b>	
Cancer	54 (83)
Non-cancer	11 (17)
<b>Indication for surgery: n (%)</b>	
Therapeutic	58 (89)
Prophylaxis	7 (11)

**Table 2** Postoperative complications in 65 nipple-sparing mastectomies

Complications	Number (%)
<b>Seroma</b>	18 (28)
<b>Infection</b>	12 (19)
<b>Fat necrosis</b>	5 (8)
<b>Wound dehiscence</b>	1 (2)
<b>Skin flap ischemia</b>	13 (20)
<b>Nipple ischemia</b>	
Partial	9 (14)
Full thickness	3 (5)

We performed an oncologic evaluation of 51 NSMs in patients with breast cancer. Forty (78%) patients had invasive cancer, and the remainder had carcinoma in situ. Ten NSMs (20%) had multifocal cancers. Half of the patients were classified as T2 and T3 according to the 8<sup>th</sup> edition of the American Joint Committee on Cancer (AJCC) staging. The median tumor size was 2.4 cm (range, 0.1 to 7.7 cm). The median tumor-nipple distance was 3.3 cm (range, 0.9 to 7.8 cm). Seventeen patients (33%) had axillary lymph node metastasis. Eight of 51 patients received postoperative radiotherapy. Half of the patients with invasive cancer had the luminal subtype (hormonal receptor-positive breast cancer).

After a mean follow-up period of 70 months (range, 24 to 162 months), 4 patients (8%) developed LRR. One patient underwent NSM and sentinel lymph node biopsy for ductal carcinoma in situ. She developed Paget's disease of the nipple 31 months after surgery and required NAC excision. Another patient had hormone-positive / HER-2 negative breast cancer staged pT2N1M0. She had cutaneous recurrence at the ipsilateral breast after 47 months and underwent wide excision. The 2 remaining patients had triple-negative invasive breast cancer subtype. One of these was staged pT2N0M0. She had recurrence in the ipsilateral axillary lymph nodes 15 months after surgery without lesions in the NAC. Axillary lymph node dissection and postoperative radiotherapy was performed. The last patient was staged pT2N1M0. She had local recurrence in the ipsilateral breast and internal mammary lymph nodes after 15 months. She was treated with systemic chemotherapy followed by mastectomy, excision of the internal mammary lymph nodes, and postoperative radiotherapy. The patient developed distant metastasis 42 months later. Two patients developed distant metastasis without locoregional disease (one had lung and another liver metastasis), leading to an overall recurrence rate of 12%.

The median time-to-recurrence was 23 months. Five-year disease-free survival was 87%. In our study, LRR in triple-negative breast cancer (TNBC) subtype was 29% compared with 5% in other subtypes. We evaluated factors associated with LRR (Table 3). Only Ki-67 level showed an association with LRR (HR 1.07; 95% CI 1.00 to 1.15) at the 5% level.

## DISCUSSION

We evaluated the oncological safety and factors associated with LRR after NSM at our institute. In the past, NSM was only performed in a prophylactic setting because of the lack of strong supporting evidence for the safety of this technique in breast cancer. To date, only large prospective studies have shown recurrence rates comparable to that of BCS.<sup>15,18</sup>

There is currently no standard NSM, with differences in the surgical techniques used, criteria for patient selection, and adjunctive post-surgery treatment across studies. One large study by Petit et al. reported 934 NSM with 16 Gy of intraoperative radiotherapy (ELIOT). This study showed 3.6% and 4.0% incidences of invasive and non-invasive local recurrences in the breast, respectively.

**Table 3** Locoregional recurrence (LRR) in 51 NSMs performed for cancerous lesions

Variable	LRR (N=4)	No LRR (N=47)	p-value	Unadjusted HR (95% CI)	Adjusted HR (95% CI)	p-value
<b>Age (years): mean <math>\pm</math> SD</b>	41.3 $\pm$ 2.2	44.0 $\pm$ 8.0	0.498			
<b>BMI (kg/m<sup>2</sup>): mean <math>\pm</math> SD</b>	22.3 $\pm$ 1.4	23.7 $\pm$ 5.6	0.614			
<b>Family history of breast cancer: n (%)</b>			0.564			
Yes	0	10 (23)				
No	4 (100)	33 (77)				
<b>Breast density: n (%)</b>			0.403			
Scatter dense	0	5 (12)				
Heterogeneous dense	4 (100)	22 (52)				
Extremely dense	0	15 (36)				
<b>Tumor size (cm): median (IQR)</b>	2.9 (2.5, 4.3)	2.1 (1.5, 2.8)	0.079	2.23 (1.03, 4.78)	1.50 (0.63, 3.58)	0.353
<b>Tumor-Nipple distance (cm): median (IQR)</b>	2.87 (2.30, 5.16)	2.75 (2.32, 4.60)	0.826			
<b>Multifocal lesion: n (%)</b>			0.999			
Yes	1 (25)	9 (19)				
No	3 (75)	36 (77)				
Unknown	0	2 (4)				
<b>T-stage: n (%)</b>			0.577			
In situ	1 (25)	10 (21)				
1	0	14 (30)				
2	3 (75)	22 (47)				
3	0	1 (2)				
<b>Number of lymph node involvement: median (IQR)</b>	0.5 (0, 1)	0 (0, 1)	0.705			
<b>N-stage: n (%)</b>			0.259			
0	2 (50)	32 (68)				
1	2 (50)	9 (19)				
2	0	6 (13)				
<b>Stage: n (%)</b>			0.249			
In situ	1 (25)	10 (22)				
1A	0	9 (20)				
1B	1 (25)	1 (2)				
2A	1 (25)	14 (30)				
2B	1 (25)	5 (11)				
3A	0	7 (15)				
<b>Tumor grading: n (%)</b>			0.699			
1	0	3 (6)				
2	3 (75)	21 (47)				
3	1 (25)	21 (47)				
<b>Hormone receptors: n (%)</b>			0.310			
Positive	2 (50)	34 (26)				
Negative	2 (50)	12 (74)				
<b>HER-2: n (%)</b>			0.999			
Negative	3 (75)	25 (56)				
Equivocal	0	5 (11)				
Positive	1 (25)	15 (33)				
<b>Subtypes: n (%)</b>			0.176			
Luminal	2 (50)	34 (74)				
HER-2	0	7 (15)				
Triple negative	2 (50)	5 (11)				
<b>Ki-67: median (IQR)</b>	65 (45, 80)	30 (15, 50)	0.034	1.07 (1.01, 1.15)	1.07 (1.00, 1.15)	0.050
<b>Lymphovascular invasion: n (%)</b>			0.530			
Yes	1 (25)	7 (16)				
No	3 (75)	37 (84)				
<b>Radiotherapy: n (%)</b>			0.999			
Yes	0	8 (17)				
No	4 (100)	39 (83)				

SD: standard deviation; IQR: interquartile range; BMI: body-mass index; LRR (locoregional recurrence)

Only 11 patients (1.2%) had recurrence at the NAC after a 50-month median follow-up time. A 5-year cumulative incidence of breast-related events in invasive cancer patients was 14.7% and overall survival was 95.5%.<sup>18</sup>

In the present study, after a mean follow-up time of 70 months, 2 of 40 patients with invasive cancer (5%) had in-breast recurrence. Only one patient (2%) with non-invasive (in situ) cancer who underwent NSM developed Paget's disease of the nipple after 31 months. Our 5-year local recurrence rate for both invasive and non-invasive cancer was 10% and the overall 5-year survival was 97.5%. This result was not substantially different from those of previous studies, even though intraoperative radiotherapy was not used in the present study. Eight patients (22%) received postoperative radiotherapy, but the local recurrence rates were not different between patients who had and those who did not have radiotherapy.

The previous study by Petit et al. reported that LRR after NSM was related to the tumor size, number of positive lymph nodes, histological subtype, and the biological features of the disease (e.g., HER-2/neu, Ki-67, nuclear grading, and vascular invasion). Our study also seemed to show an association between LRR and the Ki-67 level (HR 1.07; 95% CI 1.00 to 1.15). A positive HER-2 status is associated with increased LRR, and is used as a contraindication for NSM in some institutions. The present study, however, could not demonstrate an association between HER-2 status and LRR, nor any association between LRR and other biological factors. Although LRR was more common in the triple-negative subtype (see Table 3), this was not statistically significant. Tumor size has also been used to select patients for NSM in the literature. Although LRR was more common in larger tumors, but again, the difference was not statistically significant in the present study.

Major complications after NSM include NAC and skin flap ischemia. The nipple necrosis rate from previous reports was 5.9% (range, 0 to 37.5%).<sup>15,17</sup> Our study showed 3 patients (5%) with full-thickness necrosis of the NAC and a 1.5% rate of NAC removal, which is consistent with the results of previous studies. Although the rates of partial NAC and skin flap ischemia were quite high (14% and 20%, respectively), in most cases the involved area was tiny, and all were successfully managed conservatively.

## CONCLUSION

In summary, the present study demonstrated the feasibility and oncological safety of performing NSM in selected patients, with a low risk of NAC removal and low LRR rate after a mean follow-up of 70 months. Only Ki-67 level seemed to show an association with LRR. Further study is needed to confirm the oncologic safety and to standardize techniques of NSM, as well as to highlight NSM as a standard option for breast reconstruction in breast cancer patients.

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## CONFLICT OF INTEREST

No authors have any potential conflict of interest to disclose or none of the authors disclose any potential conflict of interest. We did not receive any specific grant for this research from any funding agency in the public, commercial, or not-for-profit sectors.

## DATA SHARING STATEMENT

The protocol is registered in the Thai Clinical Trials Registry (TCTR) which is in a primary registry of the World Health Organization (WHO) registry network (UIN TCTR20200106004).

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## บทคัดย่อ การกลับเป็นซ้ำเฉพาะที่ในผู้ป่วยมะเร็งเต้านมภายหลังการผ่าตัดเต้านมออกทั้งหมดแบบสงวนหัวนม และลานหัวนม

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**ความเป็นมา:** แม้ว่าในปัจจุบันการผ่าตัดแบบสงวนเต้านมจะได้รับการยอมรับอย่างแพร่หลายและเป็นการรักษาหลักในการรักษาผู้ป่วยมะเร็งเต้านมระยะเริ่มต้น แต่อย่างไรก็ตามการผ่าตัดเต้านมออกทั้งหมดยังคงมีบทบาทสำคัญในผู้ป่วยที่มีเนื้อมะเร็งหลายตำแหน่งภายในเต้านม และในการผ่าตัดเพื่อป้องกันการเกิดมะเร็งเต้านม จากผลการศึกษาที่ผ่านมาพบว่าการกลับเป็นซ้ำเฉพาะที่ภายหลังการผ่าตัดเต้านมออกทั้งหมดแบบสงวนหัวนมไม่แตกต่างจากการผ่าตัดแบบสงวนเต้านม แต่จนถึงปัจจุบันยังคงไม่มีเกณฑ์มาตรฐานในการคัดเลือกผู้ป่วยที่เหมาะสมเพื่อเข้ารับการผ่าตัดดังกล่าว

**วัตถุประสงค์:** เพื่อศึกษาถึงความปลอดภัย และอัตราการกลับเป็นซ้ำเฉพาะที่ภายหลังการผ่าตัดเต้านมออกทั้งหมดแบบสงวนหัวนม

**วิธีการศึกษา:** ผู้วิจัยได้ทำการวิเคราะห์ข้อมูลจากจำนวนครั้งของการผ่าตัดเต้านมออกทั้งหมดแบบสงวนหัวนมทั้งหมด 65 ครั้ง ในผู้ป่วยมะเร็งเต้านม 63 ราย ที่เข้ารับการผ่าตัดเพื่อรักษามะเร็งเต้านม และผู้ที่เข้ารับการผ่าตัดเพื่อป้องกันการเกิดมะเร็งเต้านมตั้งแต่เดือนมกราคม พ.ศ. 2550 ถึงเดือนมิถุนายน พ.ศ. 2560 โดยทำการเก็บรวบรวมข้อมูลพื้นฐานของผู้ป่วย ข้อมูลการผ่าตัด ผลการรักษา และภาวะแทรกซ้อนจากการผ่าตัด เพื่อวิเคราะห์หาความสัมพันธ์กับการกลับเป็นซ้ำเฉพาะที่

**ผลการศึกษา:** ในกลุ่มผู้ป่วยที่ศึกษาพบมีค่าเฉลี่ยของอายุที่ 43 ปี (30-61 ปี) แบ่งเป็นการผ่าตัดเพื่อรักษามะเร็งเต้านม 58 ครั้ง คิดเป็นร้อยละ 89 ของการผ่าตัดทั้งหมด ภาวะแทรกซ้อนที่พบได้บ่อยที่สุด ได้แก่ การเกิดเนื้อตายบริเวณแผลผ่าตัดพบได้ร้อยละ 19 แต่ทุกรายมีอาการที่ดีขึ้นภายหลังการรักษาแบบประคับประคองโดยไม่ต้องผ่าตัด จากการผ่าตัดทั้งสิ้น 65 ครั้ง มีการผ่าตัด 51 ครั้งที่เข้าเกณฑ์การคัดเลือกเพื่อนำมาวิเคราะห์ผลการรักษา โดยแบ่งเป็นผู้ป่วย 40 ราย (ร้อยละ 78) ที่เข้ารับการผ่าตัดเพื่อรักษามะเร็งเต้านมชนิดลุกลาม และอีก 11 รายที่ทำการผ่าตัดในมะเร็งเต้านมชนิดยังไม่ลุกลาม ภายหลังการตรวจติดตามการรักษาระยะเวลาเฉลี่ย 70 เดือน (24-162 เดือน) พบมีการกลับเป็นซ้ำเฉพาะที่ในผู้ป่วย 4 ราย คิดเป็นร้อยละ 7.8 โดยพบมีการกลับเป็นซ้ำมากที่สุดบริเวณต่อมน้ำเหลืองใกล้เคียง พบผู้ป่วยเพียง 1 รายที่มีโรคมะเร็งชนิดไม่ลุกลามบริเวณหัวนม และได้รับการผ่าตัดเพื่อนำหัวนม และลานหัวนมออกในเวลาต่อมา จากการศึกษาพบมีอัตราการรอดชีวิตแบบปลอดโรคที่ 5 ปีร้อยละ 87 เมื่อทำการวิเคราะห์กลุ่มย่อยเพิ่มเติมพบว่ามีความสามารถในการแบ่งตัวของเซลล์มะเร็ง (Ki-67) เท่านั้นที่มีความสัมพันธ์กับการกลับเป็นซ้ำเฉพาะที่ (HR 1.07; 95% CI 1.00 to 1.15)

**สรุปผลการศึกษา:** การผ่าตัดเต้านมออกทั้งหมดแบบสงวนหัวนมมีความปลอดภัยเมื่อทำการคัดเลือกผู้ป่วยอย่างเหมาะสม โดยพบมีการกลับเป็นซ้ำเฉพาะที่ต่ำ จากการศึกษาพบเพียงค่าความสามารถในการแบ่งตัวของเซลล์มะเร็งเท่านั้นที่สัมพันธ์กับการกลับเป็นซ้ำเฉพาะที่ อย่างไรก็ตามยังคงต้องการข้อมูลการศึกษาในระยะยาวเพิ่มเติม