

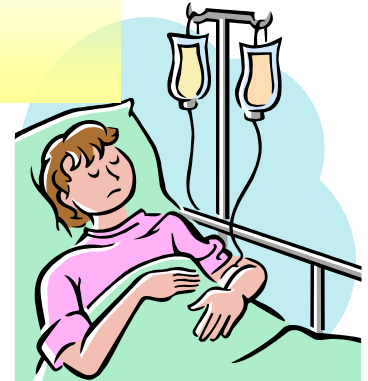


Clinical Outcome of Reconstruction With Tissue Expanders for Patients With Breast Cancer and Mastectomy

Mitsui Memorial Hospital

Department of Breast and Endocrine surgery

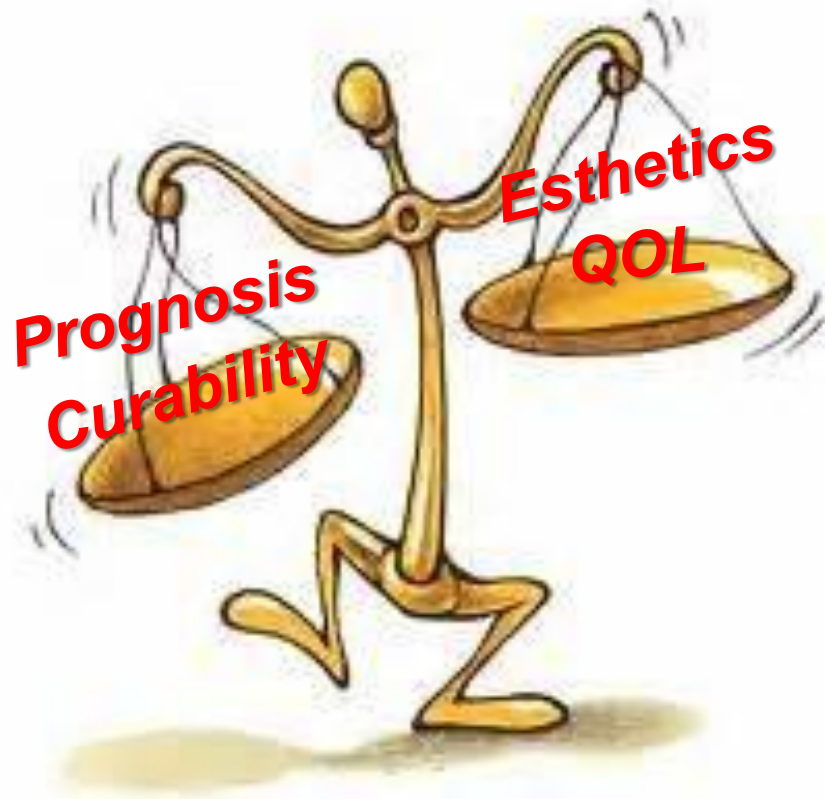
Daisuke Ota



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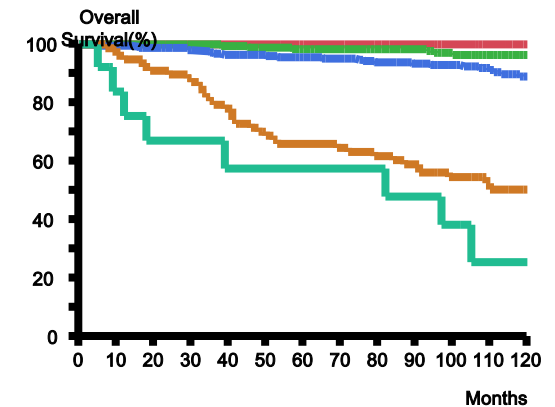
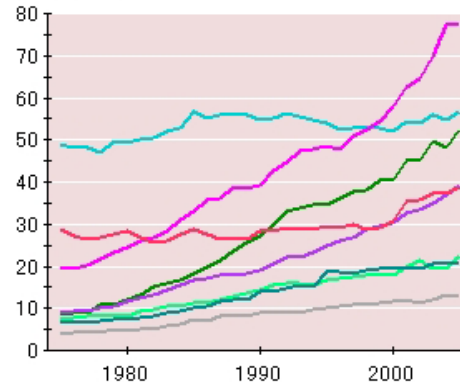
The authors report no conflicts of interest.

The incidence of breast cancer is increasing in Japan. Improved prognosis is expected due to advances in screening and adjuvant therapy.



Improvement in postoperative QOL is a very important issue for breast cancer patients.

Do reconstructions with tissue expanders (TEs) and permanent implants (PIs) affect the prognosis or local recurrence rate?



Did the infection rate increase?

Patients & Methods-1

- ***Of patients who had undergone mastectomies for primary unilateral breast cancer in our hospital between 2000 and 2009, 197 patients who had immediate reconstruction with TEs (TE group) and 540 patients who had mastectomy (MT group) were included.***
- ***An antibiotic was administered pre-operatively based on guidelines for patients undergoing any surgical procedure.***
- ***A J-VAC[®] drain was inserted into the regional axilla. When the drainage was < 50 mL/day, the drainage tube was removed.***

Infection

Infection !!

**Erythema, high fever, pain,
or tenderness**



Types of TEs

Koken Co., Ltd.

2000~2006



Allergan, Inc.

2006~present



Patient characteristics

TE(197)

MT(540)

Number of patients

197

540

Median age (years)

46(27-79)

58(39-88)

p<0.0001

Axillary lymph node

SLN or No treatment
Dissection

*94 (47.7%)
103 (52.3%)

**153 (28.3%)
387 (71.7%)

p<0.0001

Median
follow-up period

93.0 months

93.5 months

p=0.8066

DM and/or HD

Yes
No

3 (1.5%)
194 (98.5%)

25 (4.6%)
515 (95.4%)

p=0.0509

*No treatment = 6 cases

**No treatment = 3 cases

TE(197)

MT(540)

Chemotherapy

Yes	86 (43.7%)	227 (42.0%)	p=0.6942
No	111 (56.3%)	313 (58.0%)	

Endocrine therapy

Yes	131 (66.5%)	344 (63.7%)	p=0.4832
No	66 (33.5%)	196 (36.3%)	

PMRT

Yes	3 (1.5%)	26 (4.8%)	p=0.0419
No	194 (98.5%)	514 (95.2%)	

Local & distant metastases

Yes	32 (16.2%)	114 (21.1%)	p=0.1423
No	165 (83.8%)	426 (78.9%)	

Distant metastasis

Yes	29 (14.7%)	104 (19.3%)	p=0.1562
No	128 (85.3%)	436 (80.7%)	

Clinicopathologic Findings

TE(197)

MT(540)

T factor

Tis-T3

192 (97.5%)

500 (92.6%)

T4

5 (2.5%)

40 (7.4%)

p=0.0146

Hormone receptor

Positive

160 (81.2%)

400 (74.1%)

Negative

30 (15.2%)

140 (25.9%)

Unknown

7 (3.6%)

0

Histologic type

DCIS

31 (15.7%)

39 (7.2%)

IC

166 (84.3%)

501 (92.8%)

p=0.0005

Axillary involvement

Positive

73 (37.1%)

240 (44.4%)

Negative

124 (62.9%)

300 (55.6%)

p=0.0725

Local Recurrence

TE

MT

All patients

Yes	8 (4.1%)	22 (4.1%)	
No	189 (95.9%)	518 (95.9%)	p=0.9936

IC

Yes	8 (4.8%)	22 (4.4%)	
No	158 (95.2%)	479 (95.6%)	p=0.8176

The LR rate in the TE group was not different from the MT group amongst all patients or patients with IC.

Local Recurrence

TE

MT

Axillary LN-negative

Yes	1 (0.8%)	1 (0.3%)	
No	123 (99.2%)	299 (99.7%)	p=0.5178

Axillary LN-positive

Yes	7 (9.6%)	21 (8.8%)	
No	66 (90.4%)	219 (91.2%)	p=0.8259

The LR rate in the TE group was not different from the MT group amongst the patients with or without LN metastases.

Univariate and Multivariate analyses of LR

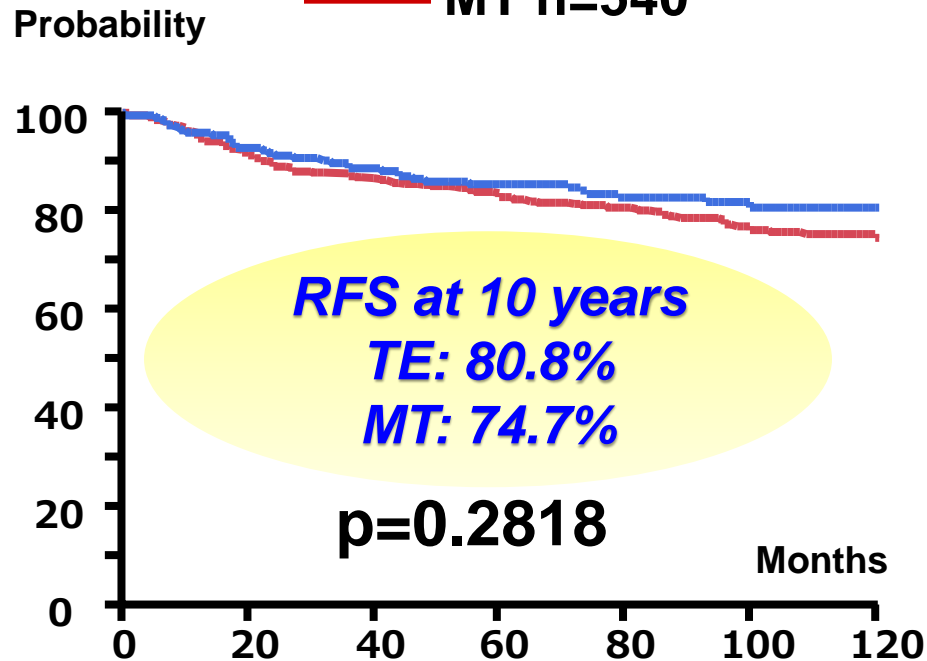
	<u><i>Univariate analysis</i></u>		<u><i>Multivariate analysis</i></u>	
	<i>Odds ratio</i>	<i>p value</i>	<i>Odds ratio</i>	<i>p value</i>
<i>Age < 40 years</i>	5.02	0.0003	3.94	0.0033
<i>T3 or T4</i>	3.61	0.0033	1.96	0.1403
<i>Axillary involvement</i>	20.73	<0.0001	15.19	<0.0001
<i>Lymphatic invasion</i>	5.28	0.0001	1.22	0.7187
<i>HR negative</i>	1.43	0.5142		
<i>Reconstruction with TE</i>	1.00	0.9936		

Reconstruction with TE did not affect the LR rate.

Relapse-free Survival

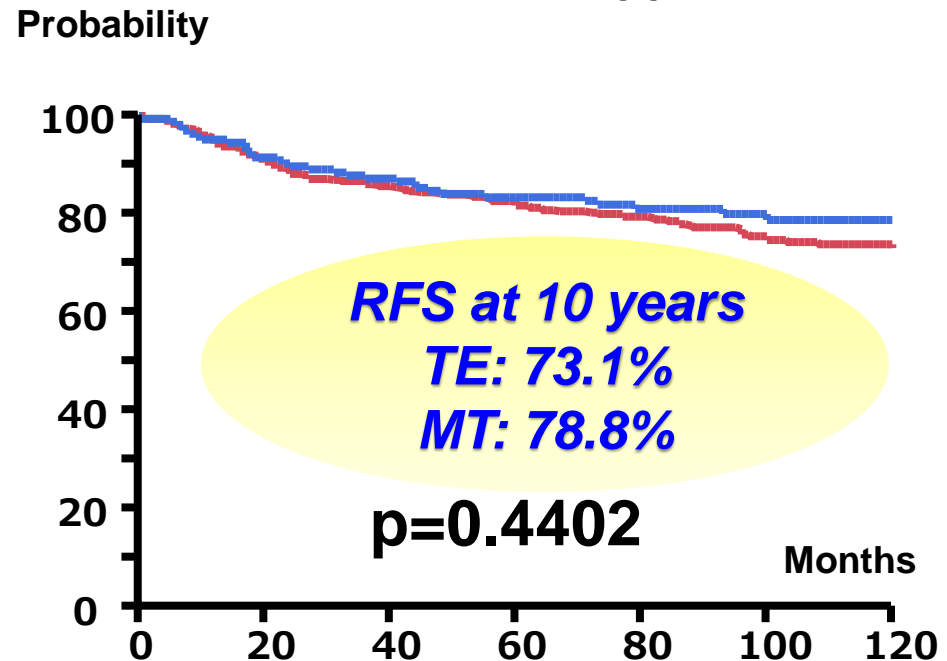
All patients

— TE n=197
— MT n=540



IC

— TE n=166
— MT n=501

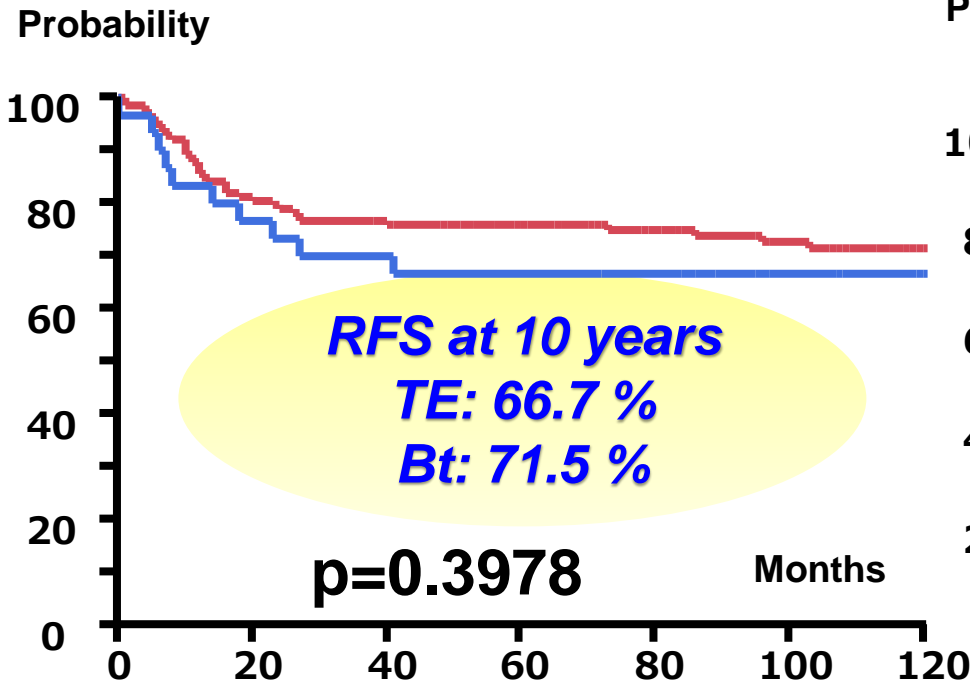


RFS in the TE group was not different from the MT group amongst all patients or patients with IC.

Relapse-free Survival

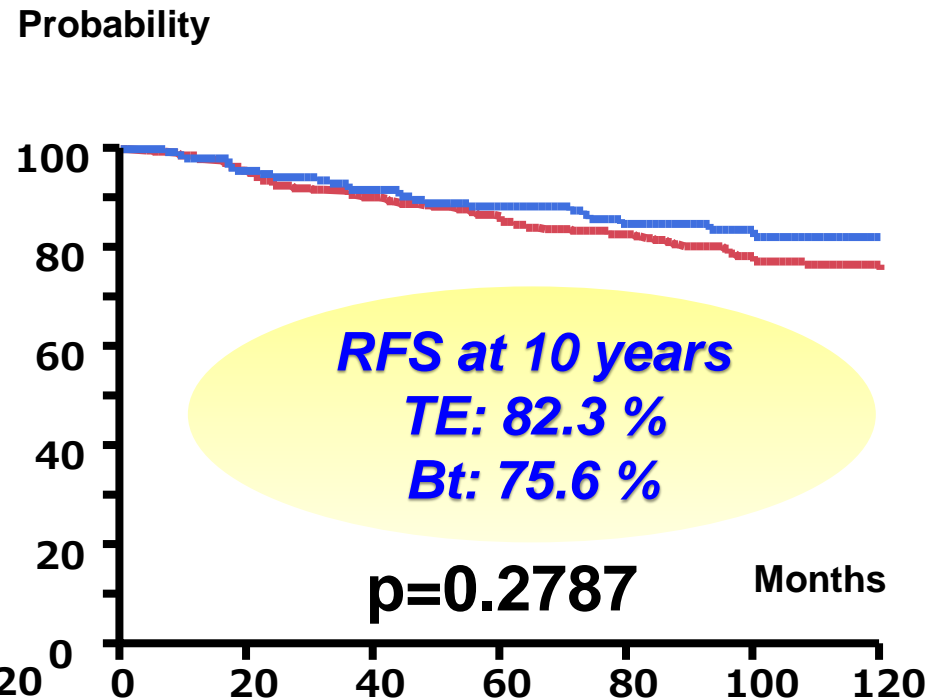
HR-negative

— TE n=30
— MT n=140



HR-positive

— TE n=160
— MT n=400

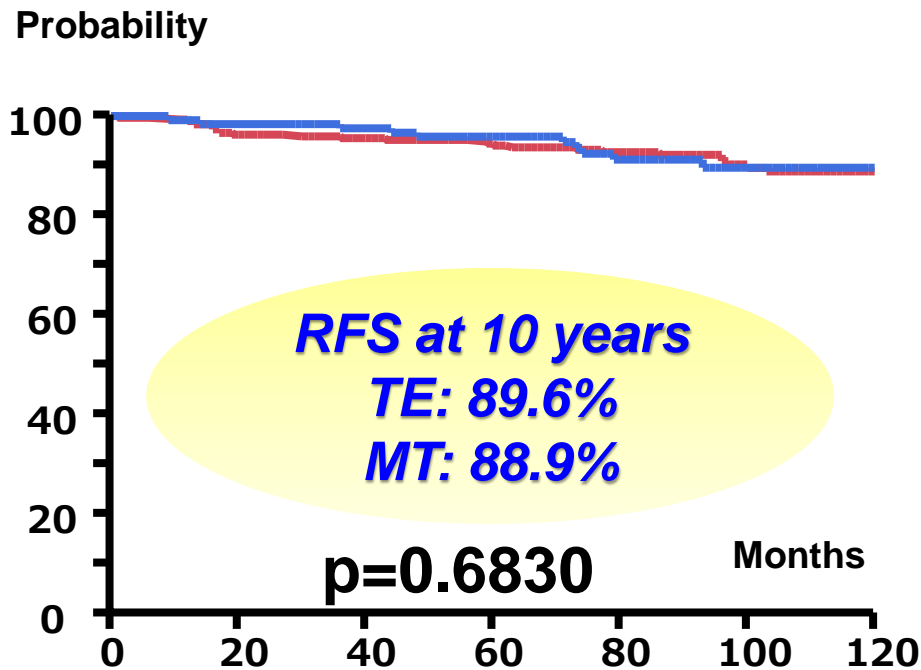


RFS in the TE group was not different from the MT group amongst the patients who were HR-negative or –positive.

Relapse-free Survival

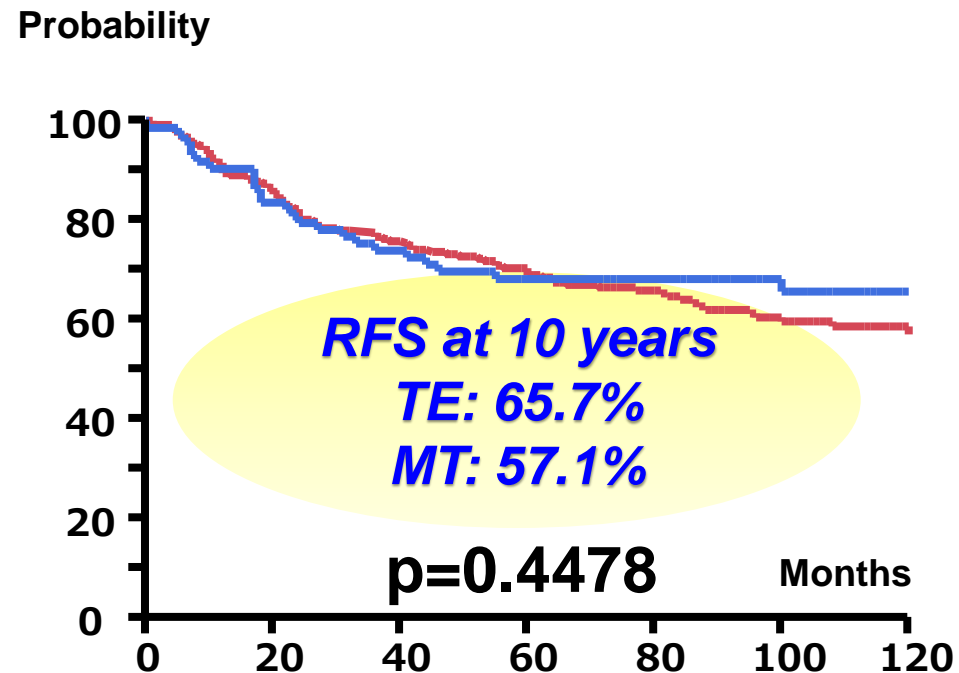
Node-negative

— TE n=124
— MT n=300



Node-positive

— TE n=73
— MT n=240

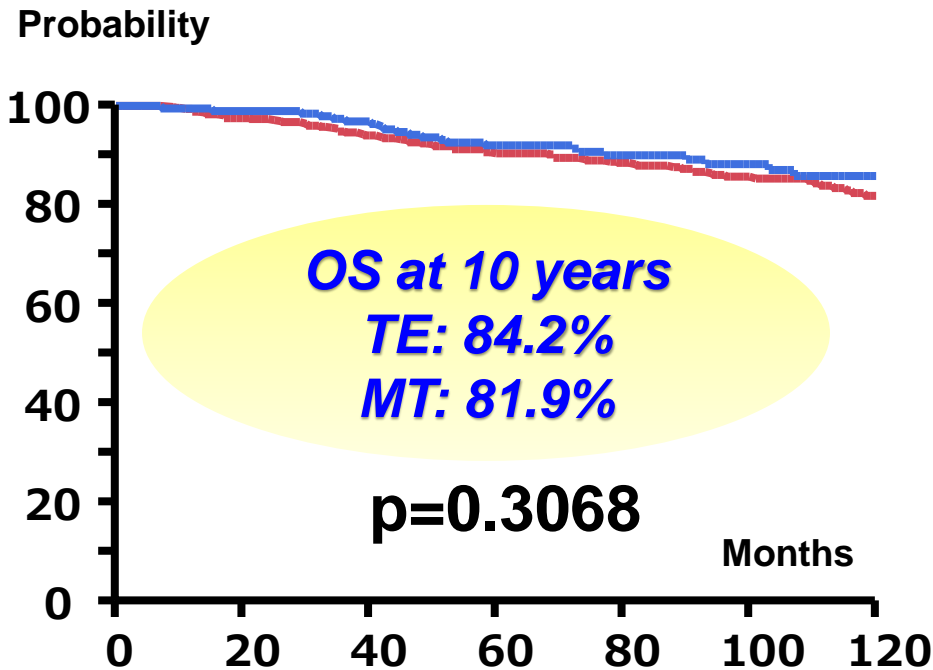


RFS in the TE group was not different from the MT group amongst the patients with or without LN metastases.

Overall Survival

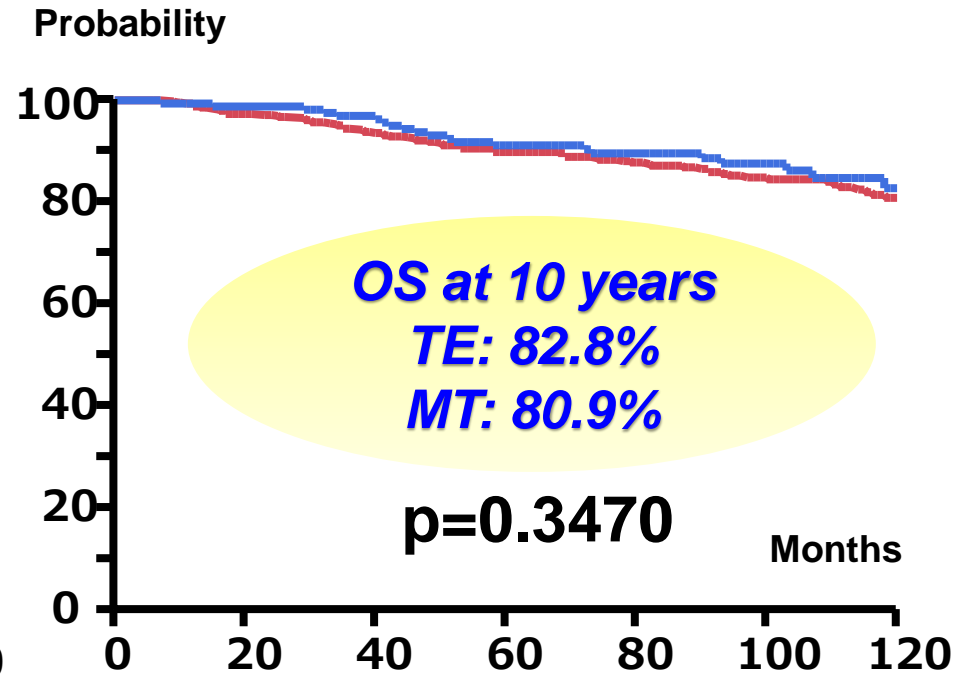
All patients

— TE n=197
— MT n=540



IC

— TE n=166
— MT n=501

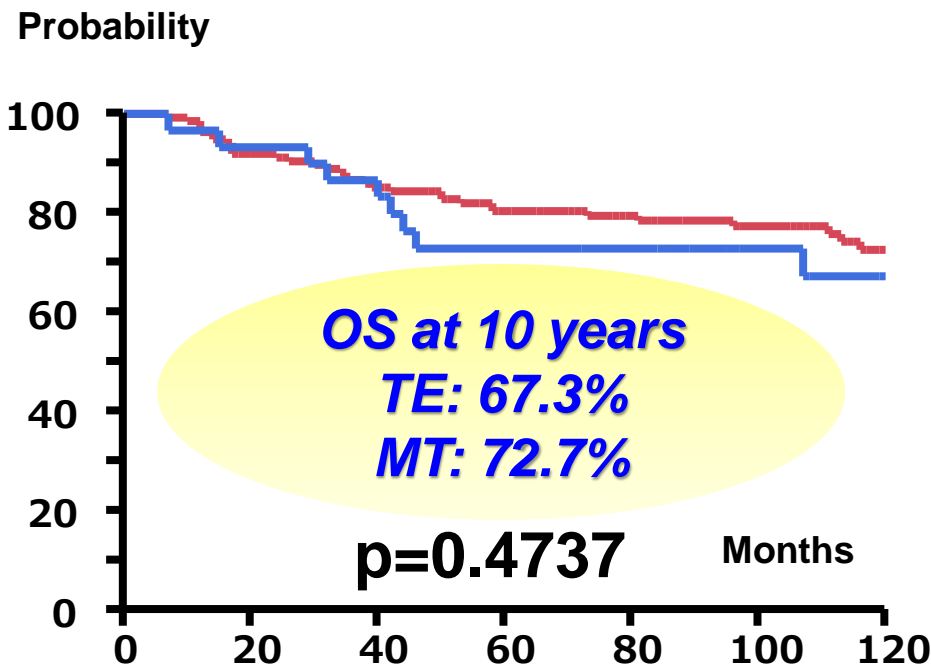


OS in the TE group was not different from the MT group amongst all patients or IC patients.

Overall Survival

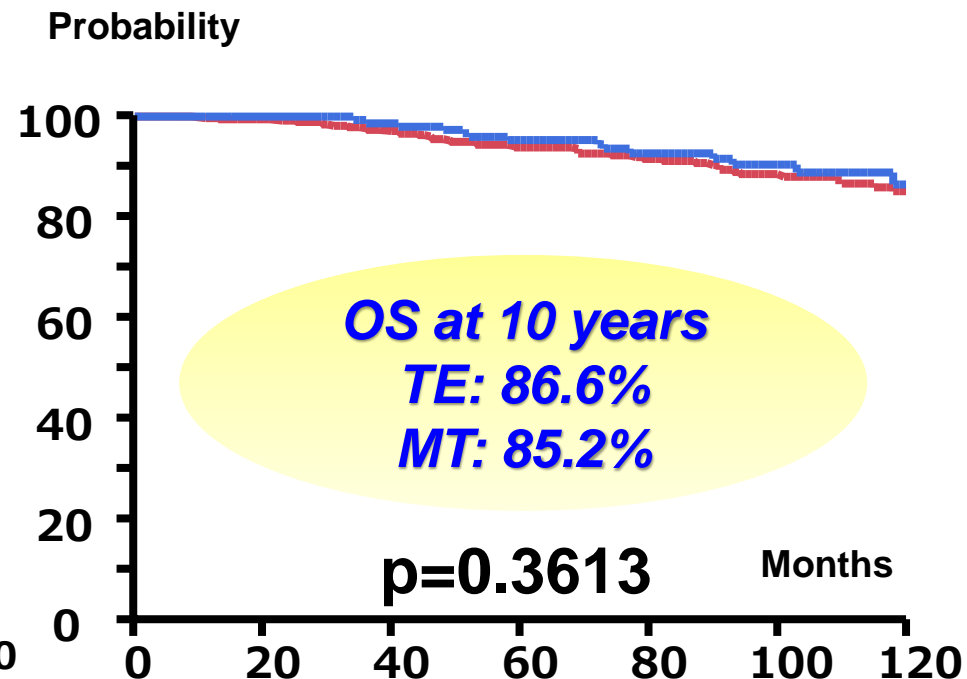
HR-negative

— TE n=30
— MT n=140



HR-positive

— TE n=160
— MT n=400

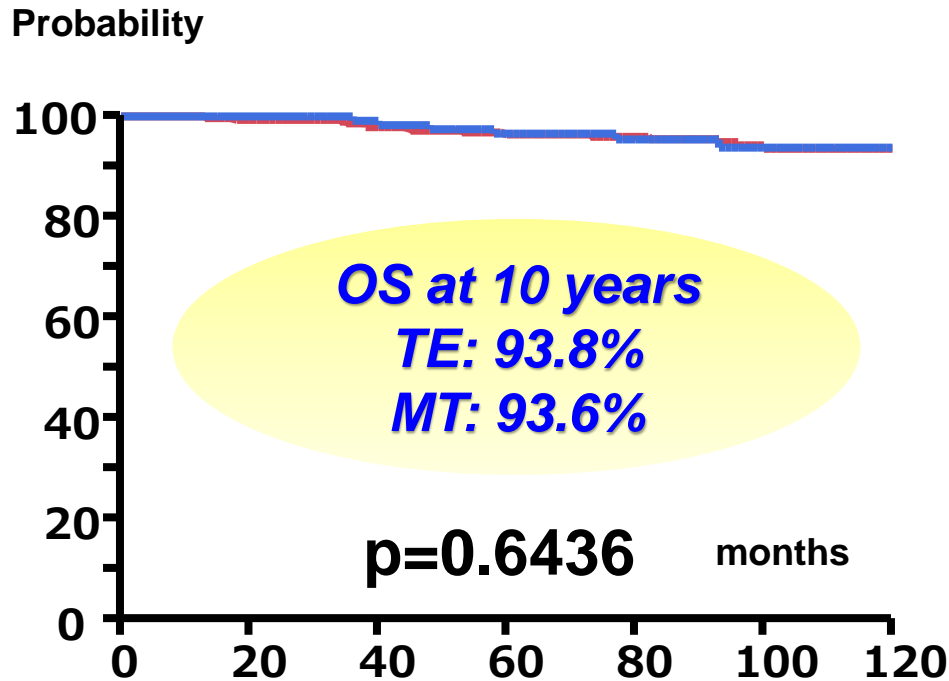


OS in the TE group was not different from the MT group amongst the patients who were HR-negative or -positive.

Overall Survival

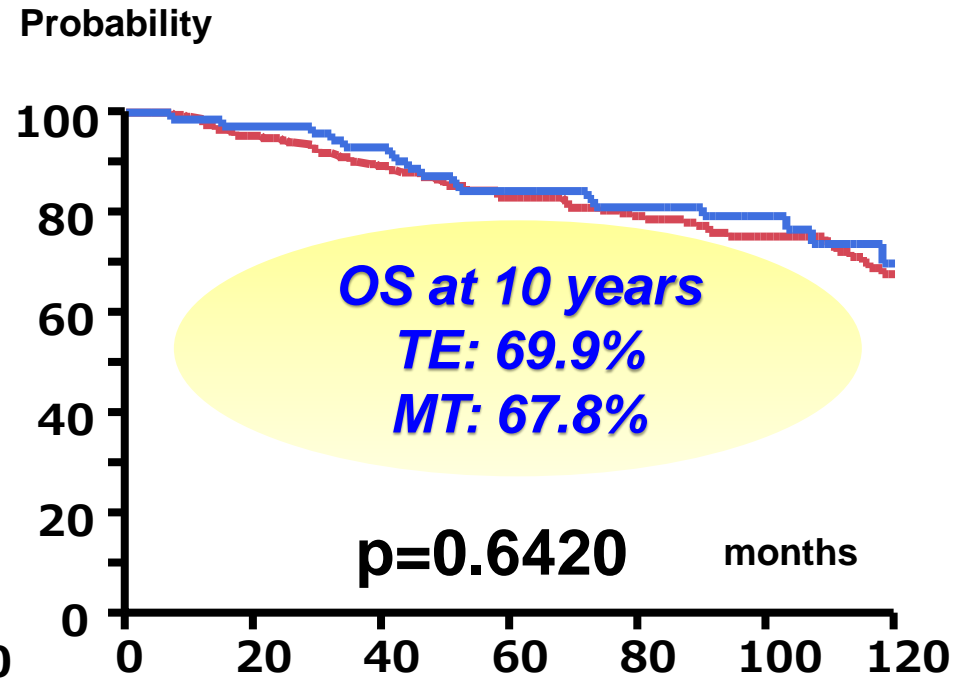
Node-negative

— TE n=124
— MT n=300



Node-positive

— TE n=73
— MT n=240



OS in the TE group was not different from the MT group amongst the patients with or without LN metastasis.

Univariate and Multivariate Analyses of RFS

	<i>Univariate analysis</i>		<i>Multivariate analysis</i>	
	<i>Risk ratio</i>	<i>p value</i>	<i>Risk ratio</i>	<i>p value</i>
<i>Age <40 years</i>	<i>2.26</i>	<i>0.0005</i>	<i>1.87</i>	<i>0.0064</i>
<i>T3 or T4</i>	<i>3.50</i>	<i><0.0001</i>	<i>2.28</i>	<i><0.0001</i>
<i>Axillary involvement</i>	<i>5.97</i>	<i><0.0001</i>	<i>5.76</i>	<i><0.0001</i>
<i>HR-negative</i>	<i>1.63</i>	<i>0.0046</i>	<i>2.58</i>	<i><0.0001</i>
<i>Reconstruction with TE</i>	<i>1.35</i>	<i>0.1251</i>		

Reconstruction with TE did not affect prognosis.

Incidence of Infection

Infection	TE	MT	p value
Yes	26 (13.2%)	22 (4.1%)	
No	171 (86.8%)	518 (95.9%)	<i>p<0.0001</i>

The incidence of infection was 13.2% and 4.1% in the TE and MT groups, respectively. The incidence of infection in the TE group was significantly higher than in the MT group ($p < 0.0001$).

Univariate and Multivariate Analyses of Infection

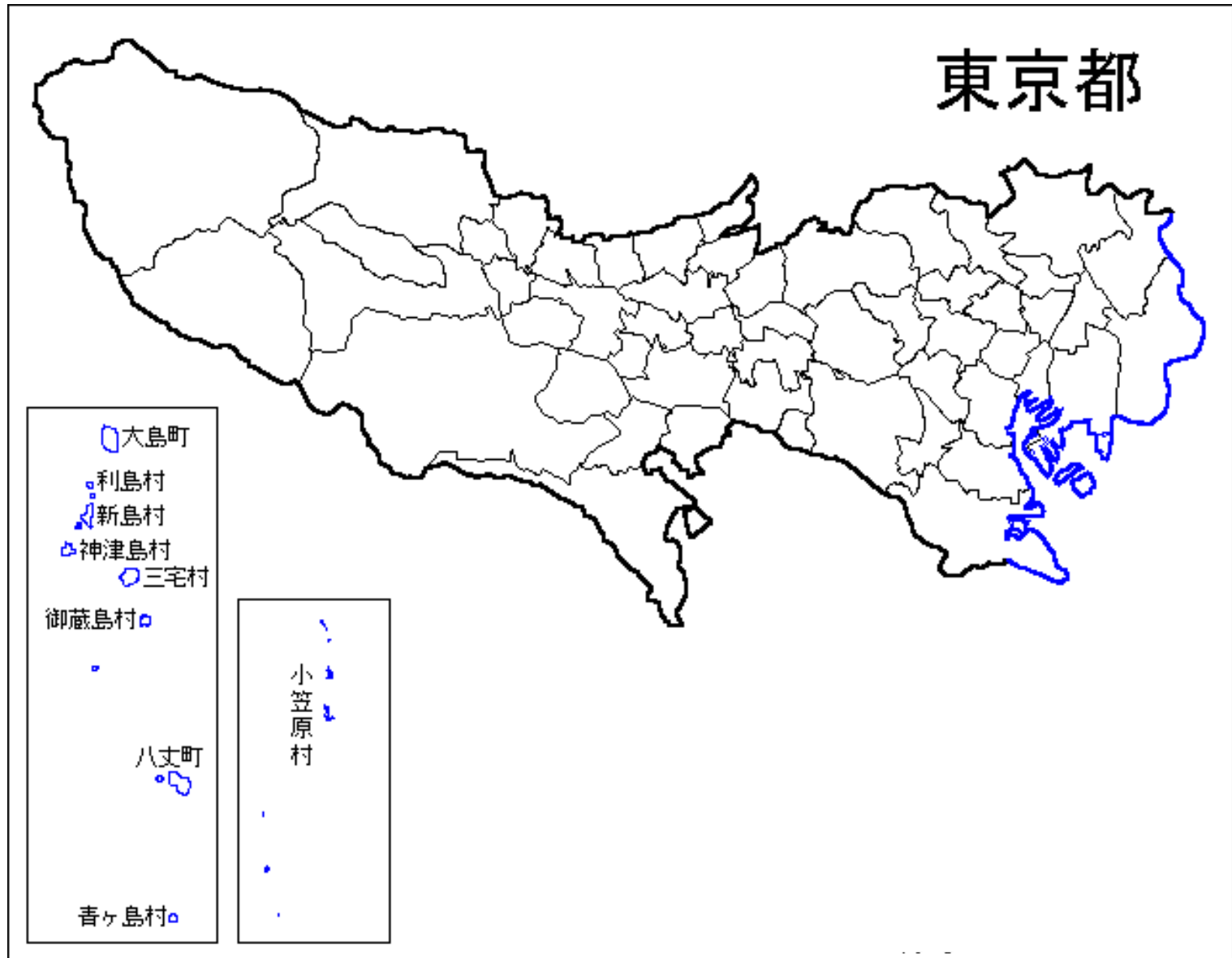
	<u><i>Univariate analysis</i></u>		<u><i>Multivariate analysis</i></u>	
	<i>Odds ratio</i>	<i>p value</i>	<i>Odds ratio</i>	<i>p value</i>
<i>Axillary clearance</i>	1.99	0.0455	2.61	0.0081
<i>BMI ≥ 25 kg/m²</i>	3.56	<0.0001	4.98	<0.0001
<i>Chemotherapy</i>	1.65	0.0921		
<i>Reconstruction with TE</i>	3.58	<0.0001	5.90	<0.0001

Multivariate analysis of infection indicated that axillary clearance, BMI ≥25 kg/m² and reconstruction with TE were independent risk factors for infection.

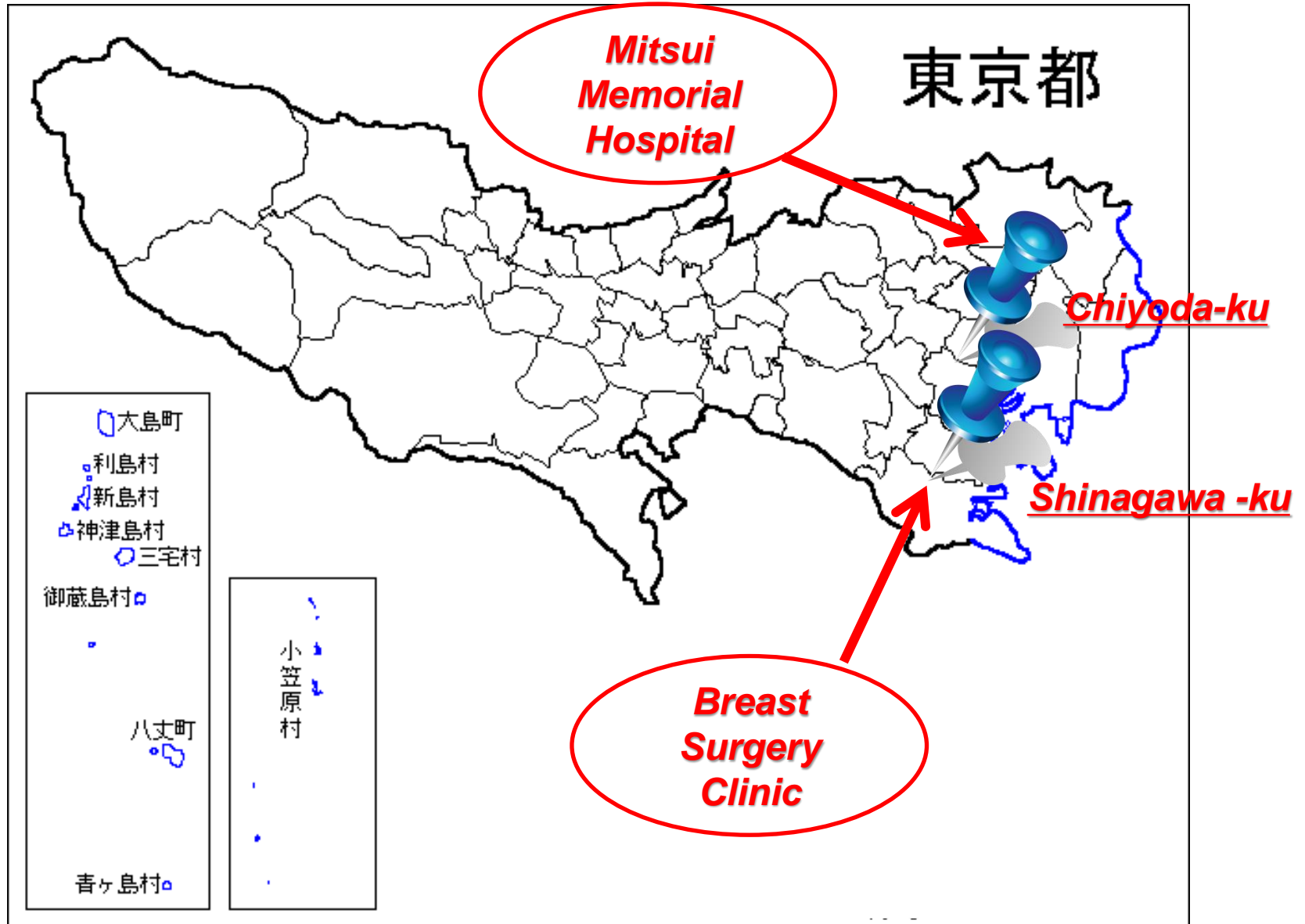
Summary-1

- ***Compared with the MT group, immediate reconstruction with TEs did not reduce the RFS and OS. Univariate analysis of LR and RFS revealed that reconstruction with TEs was not a risk factor.***
- ***The incidence of infection in the TE group was significantly higher than in the MT group ($P < .0001$).***
- ***Multivariate analysis indicated that axillary clearance, a BMI ≥ 25 kg/m², and reconstruction with TEs were independent risk factors for infection.***

Map of Tokyo



Map of Tokyo



Breast Surgery Clinic



Dr. Yoshiko Iwahira





**Identification of complications in
mastectomy with immediate
reconstruction using TEs and PIs**



What complications of reconstruction developed, such as removal of TEs or PIs?

What were the causes for the complications?

Yes ! We evaluated the complications.



Patients & Methods

A retrospective review was performed involving 233 patients (239 reconstructions) undergoing post-mastectomy breast reconstruction between 1997 and 2009.

Patient characteristics

- **Number of patients** 233
- **Reconstructions** 239
- **Simultaneous bilateral reconstructions** 3% (6/233 patients)
- **Median age** 46 years (range, 27-79 years)
- **Axillary lymph node resection**
 - Yes 55% (131/239 reconstructions)
 - No 45% (108/239 reconstructions)
- **BMI**
 - ≥25 (kg/m²) 9% (20/233 patients)
 - <25 (kg/m²) 91% (213/233 patients)
- **Chemotherapy**
 - Yes 42% (97/233 patients)
 - No 58% (136/233 patients)
- **Radiotherapy**
 - Yes 1% (3/239 reconstructions)
 - No 99% (237/239 reconstructions)

Patient characteristics

- **Invasive cancer**
 - Yes 84% (201/239 reconstructions)
 - No 16% (38/239 reconstructions)
- **T factor**
 - T4 3% (8/239 reconstructions)
 - T0-3 97% (231/239 reconstructions)
- **Nodal involvement**
 - Yes 34% (81/239 reconstructions)
 - No 66% (158/239 reconstructions)
- **Hormone-responsive**
 - Yes 81% (195/239 reconstructions)
 - No 14% (33/239 reconstructions)
 - Unknown 5% (5/239 reconstructions)
- **Diabetes mellitus** 1% (2/233 patients)
- **Recurrence**
 - Local recurrence 3% (7/239 reconstructions)
 - Local and distant metastases 14% (32/233 patients)

239 reconstructions with TEs

Removal of TEs or PIs
15.5%(37/239)

Re-reconstruction
7.6%(18/239)

- TE infections 16.7% (3/18)
- PI infections 11.1% (2/18)
- TE deflation 16.7% (3/18)
- PI deflation 11.1% (2/18)
- Mismatched PI 22.2% (4/18)
- Wound complication 16.7% (3/18)
- Dislocated TE 5.5% (1/18)

Failed Reconstruction
7.9%(19/239)

- **TE infections** 57.8% (11/19)
- PI infections 15.8% (3/19)
- TE deflation 15.8% (3/19)
- Local recurrence 5.3% (1/19)
- Severe post-operative pain 5.3% (1/19)

Completion of Reconstruction
92.1 %(220/239)

Correlation between TE Infections and Failed Reconstruction

	TE Infections		
	Yes	No	p value
<u>Completion of reconstruction</u>	13 (54%)	207 (96%)	
<u>Failed reconstruction</u>	11 (46%)	8 (4%)	<i>p<0.0001</i>

The reconstruction completion rate among patients without TE infections was significantly higher than in patients with TE infections.

Risk Factors for TE Infections

	TE with infection	TE without infection	p value
<u>Lymph node metastasis</u>			
Yes (n=81)	12 (50%)	69 (32%)	p=0.0788
No (n=158)	12 (50%)	146 (68%)	
<u>Lymph node resection</u>			
Yes (n=131)	16 (67%)	115 (54%)	p=0.2186
No (n=108)	8 (33%)	100 (46%)	
<u>Chemotherapy</u>			
Yes (n=94)	9 (45%)	85 (40%)	p=0.6332
No (n=141)	11 (55%)	130 (60%)	
<u>BMI</u>			
≥25 kg/m ² (n=20)	6 (25%)	14 (7%)	<u>p=0.0019</u>
<25 kg/m ² (n=219)	18 (75%)	201 (93%)	
<u>Seroma aspiration</u>			
Yes (n=40)	16 (67%)	24 (11%)	<u>p<0.0001</u>
No (n=199)	8 (33%)	191 (89%)	

Multivariate Analysis for TE Infections

Factors	Multivariate analysis		
	OR	95% CI	p value
BMI ≥ 25 kg/m²	3.47	0.93-12.13	0.0625
Seroma aspiration	28.75	5.71-40.03	<0.0001

Seroma aspiration was a significant independent risk factor for TE infection.

Summary-2

- **15.5% of the reconstructions (37 reconstructions) required removal of TEs or Pls.**
- **7.9% of the patients (19 patients) declined re-reconstruction. The most frequent reason was infection of TEs.**
- **The reconstruction completion rate among patients without TE infections was significantly higher than in patients with TE infections.**
- **Seroma aspiration was a significant independent predictive factor for TE infections.**

Conclusion

- ***Immediate reconstruction with TEs did not affect local recurrence or prognosis.***
- ***To improve the reconstruction completion rate, it is important to prevent TE infections, and inhibition of seroma formation is needed.***



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ORIGINAL ARTICLE

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Tsunehiro Nishi

Breast Cancer

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Mitsui Memorial Hospital We are the Breast Cancer Team !!



Mitsui Memorial Hospital