Comparison of the Indocyanine Green Fluorescence and Blue Dye Methods in Detection of Sentinel Lymph Nodes in Early-Stage Breast Cancer

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Background

- Sentinel lymph node (SLN) biopsy using indocyanine green (ICG) fluorescence method is a technique that utilizes the fluorescing property of ICG reagent that is used in the dye method.
- This florescence technique leads to the first SLN as a real time image from outside the body, and enables orderly and sequential dissection along the lymphatic flow.
- ICG fluorescence detection was superior to the blue dye in terms of the number of SLNs identified and detection rate in early stage breast cancer.
- No statistical analyses has clearly demonstrated the superiority of the ICG fluorescence method over the dye method following a standard procedure.

Objectives

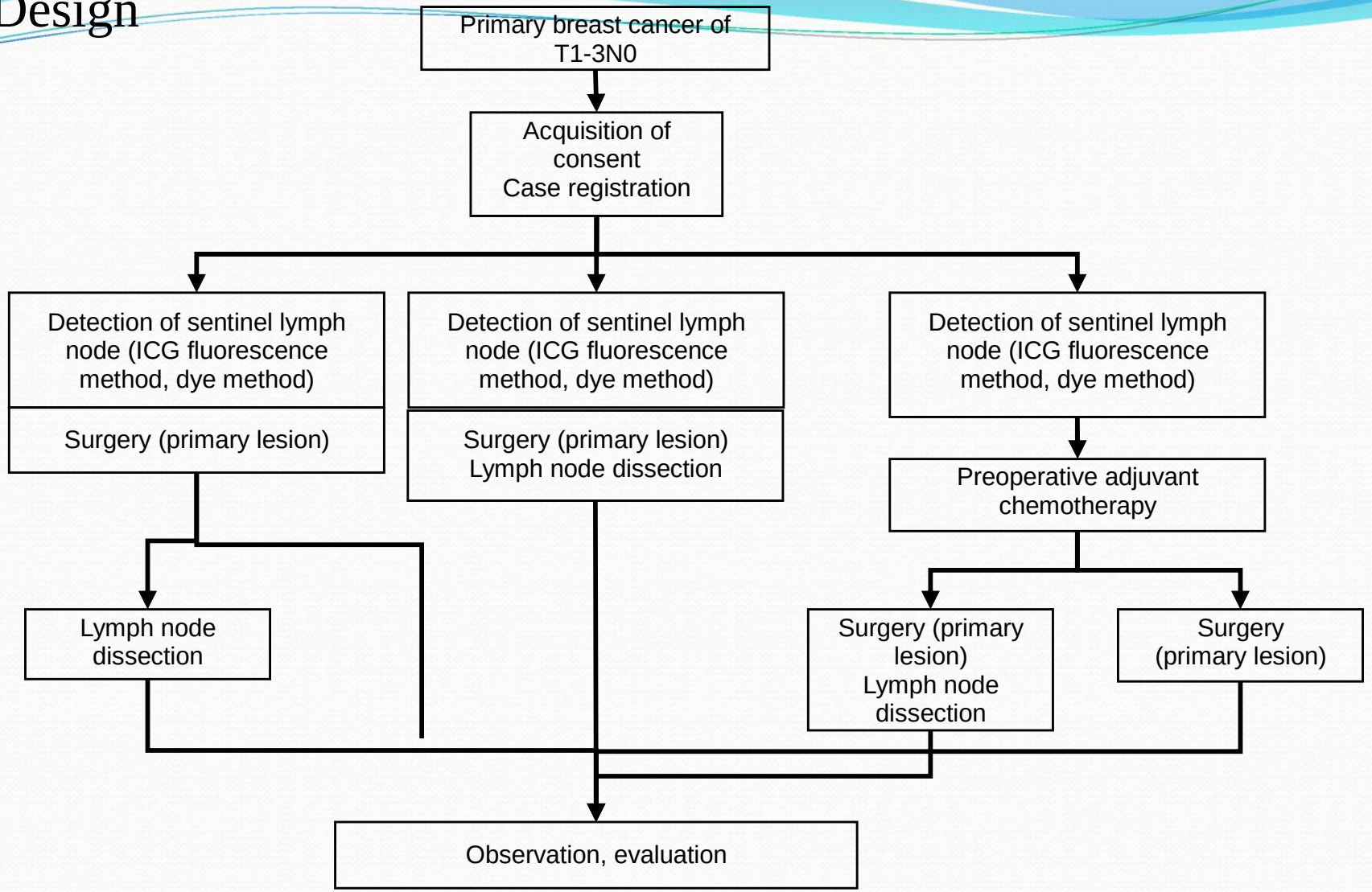
- Primary Objective:

Compare the number of lymph nodes identified by the ICG fluorescence or the blue dye method

- Secondary Objectives:

1. Identification rate, metastasis rate of SLN
2. Metastasis rate according to the order of SLN
3. Identification rate by age and BMI
4. Items of adverse reactions and the prevalence

Study Design



Patients and tumor characteristics (n=99)

Characteristics		Values	Characteristics		Values
Age	Mean (range)	60 (29-75)	**PR**	Negative	24 (24%)
Pathology	Invasive	92 (93%)		Positive	73 (73%)
	Noninvasive	7 (7%)		Unknown	2 (2%)
Tumor size	Tis	4 (4%)	**HER2**	Negative	37 (37%)
	T1a	4 (4%)		1+	32 (32%)
	T1b	15 (15%)		2+	15 (15%)
	T1c	39 (39%)		3+	12 (12 %)
	T2	34 (34%)		Unknown	3 (3%)
	T3	1 (1%)			
	Tx	2 (2%)	**BMI (kg/m^2)**	<18.5	11 (11%)
Grade	1	36 (36%)		≥18.5, <22	39 (39%)
	2	37 (37%)		≥22, <25	32 (32%)
	3	23 (23%)		≥25, <30	13 (13%)
	Unknown	3 (3%)		≥30	4 (4%)
ER	Negative	17 (17%)			
	Positive	81 (81%)			
	Unknown	1 (1%)			

Comparison of SLN detection between the ICG fluorescence method and the dye method

	Results	*p*
Difference in number of nodes identified		
Differences (ICG fluorescence – blue dye)	1.0 (rage, 0-6)	<0.001
Detection rate		
ICG fluorescence	99% (98/99)	<0.001
Dye	78% (77/99)	

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Classification of SLN in terms of fluorescence and dye

	% patients (n=99)	% SLNs identified (n=340)
Flu+dye+	78 (77/99)	36 (121/340)
Flu+dye-	69 (68/99)	47 (160/340)
Flu-dye+	0 (0/99)	0 (0/340)
Flue-dye-	35 (35/99)	17 (59/340)

Flu ; fluorescence

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SLN detection rate according to age and BMI using the ICG fluorescence method and the dye method

	ICG (%)	*p*	Dye (%)	*p*
Age				
<50	100 (30/30)	1.00	87 (26/30)	0.03
≥50, <60	100 (19/19)		95 (18/19)	
≥60, <70	97 (34/35)		69 (24/35)	
≥70	100 (15/15)		60 (9/15)	
BMI				
<18.5	100 (11/11)	0.61	100 (11/11)	0.20
≥18.5, <22	100 (39/39)		79 (31/39)	
≥22, <25	97 (31/32)		75 (24/32)	
≥25, <30	100 (13/13)		62 (8/13)	
≥30	100 (4/4)		75 (3/4)	

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SLN and non-SLN involvement in terms of the order of SLN removal

Characteristics	% Patients
Patients with positive SLNs	20 (20/99)
Positive SLN identified by	
ICG	100 (20/20)
Dye	70 (14/20)
1st SLN positive alone	60 (12/20)
Completion of ALND	67 (8/12)
Non SLN negative	100 (8/8)
Non SLN positive	0 (0/8)
1st SLN and 2nd or further positive	40 (8/20)
Completion of ALND	100 (8/8)
Non SLN negative	50 (4/8)
Non SLN positive	50 (4/8)

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Conclusions

- ICG fluorescence method leads to a high rate of SLN detection
- The detection rate of SLN is stable irrelevant to age and BMI .
- The first SLN identified by fluorescence imaging represents the exact axillary status.
- The patients with the isolated involvement in the first SLN can be spared subsequent completion of ALND.