

Evaluation of Indocyanine Green for Sentinel Lymph Node Biopsy in Breast Cancer: Two Arm Open Label Parallel Design Non-inferiority Randomised Control Trial

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Introduction

- Sentinel lymph node biopsy (SLNB) is gold standard for staging axilla in clinically node negative early breast cancer(1).
- Radiocolloid and blue dye are standard agents for SLNB in breast cancer.
- Blue dye has low identification and high false negative rate.
- Limited centres offer nuclear medicine services and there are logistic barriers associated with use of radioisotopes in resource limited countries(2).
- We compared indocyanine green (ICG) with radiocolloid & methylene blue (MB) dye combination for SLNB.

Aim

- To compare Sentinel lymph node identification proportions of radiocolloid-blue dye [Group A] with Indocyanine Green [Group B]

Methodology

- **Study Design:** Two-arm open label parallel design non inferiority randomised controlled trial.
- **Study Duration:** August 2022 to May 2024.
- **Sample size:** 70 (35 in each arm)
- **Inclusion:** Upfront operable node negative early breast cancer (Tis,T1,T2-N0).
- **Statistical Analysis:** Chi-square/Fisher exact test. p value < 0.05 represents statistical significance.

Results

- The clinico-demographic and tumour characteristics were similar in both the groups.
- **The overall SLN identification:** 98.57%, (69 out of 70 patients).
- **The SLN identification rate:** Group A- 100% (35/35 patients); Group B- 97.14% (34/35 patients).
- **The median number of SLNs identified:** Group A - 3(1-11); Group B- 3(0-9) nodes.
- **The median time taken to perform SLNB:** Group A - 12(6-33) minutes; Group B - 12(8-28.5) minutes.

Table1: Clinico-demographic characteristics

Variables	Group A: Tc99m + MB (N=35)	Group B: ICG (N=35)	p value
Age (years) [Mean(SD)]	56.02(10.94)	53.82(10.25)	0.388
Body mass index (kg/m ²) [Mean(SD)]	24.75(4.85)	26.76(4.90)	0.088
Menstrual status(%) Pre menopausal Post menopausal	11(31.43%) 24(68.57%)	13(38.23%) 21(61.76%)	0.505
Mean tumour size(cm) [Mean(SD)]	2.94(1.03)	3.4(0.98)	0.055
T stage(%): Tis(pagets) Tis(dcis) T1 T2	0(0) 6(17.14%) 4(11.43%) 25(71.43%)	1(2.86%) 6(17.14%) 3(8.57%) 25(71.43%)	0.999
Molecular subtype(%): Luminal-A Luminal-B Her2 enriched Basal subtype	14(42.42%) 9(27.27%) 7(21.21%) 3(9.09%)	10(32.26%) 10(32.36%) 8(25.81%) 3(9.68%)	0.868

Table2: Sentinel node identification

Variables	Group A: Tc99m + MB (N=35)	Group B: ICG (N=35)	p value
SLN identification rate (%)	100%	97.14%	0.999
Median number of nodes identified	3(1-12)	3(0-9)	0.871
SLN positivity(%)	8(22.86%)	10(28.57%)	0.584
Median time taken for SLNB (minutes)	12(6-33)	12(8-28.5)	0.755

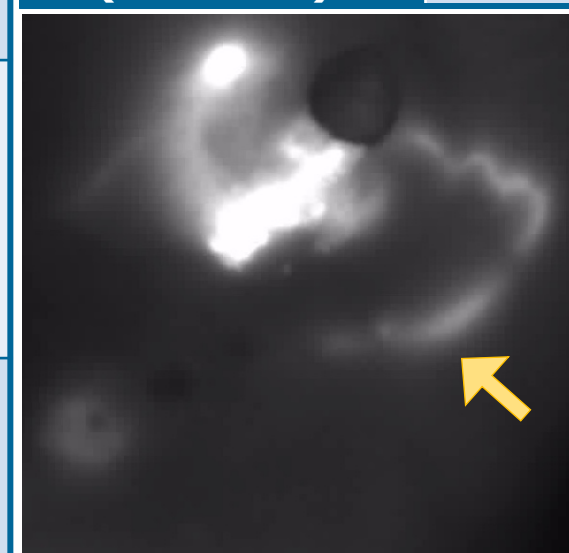


Figure1: Fluorescent lymphatics



Figure2: Fluorescent lymph node

Conclusion

- ICG is **non-inferior** to radioisotope & MB combination for detection of SLNB with comparable time required to perform the procedure.
- It also overcomes barriers associated with use of radioisotope & blue dye method in resource limited settings.

References

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2. Ahmed M, Purushotham AD, Douek M (2014) Novel techniques for sentinel lymph node biopsy in breast cancer: a systematic review. Lancet Oncol 15:e351-e362