

A Prospective Comparative Study of Sentinel Lymph Node Biopsy with Indo-Cyanine Green (ICG) Florescence Technique versus Dual Dye (Radio-colloid & Blue Dye) Technique for Early Breast Cancer - Going Beyond the Horizon

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### INTRODUCTION:

- Axillary staging is an important component of the surgical procedure performed in patients with breast
- Sentinel lymph node (SLN) mapping is regarded as standard of care in staging of the axilla in breast cancer patients with clinically negative axillary lymph
- Dual dve technique with radio-colloid and blue dve is the gold standard for identification of SLNB.3
- Limitations with dual dye has limited its penetration to
- > Optical imaging using the near-infrared (NIR) fluorescence lymphatic tracer indocvanine green (ICG) has been put forward as an alternative for, or an addition to, conventional SLN mapping. 4

### PROBLEM STATEMENT IN INDIA

- > Increasing Number of breast cancer in young patients (<40 years)
- > Increasing awareness regarding breast cancer screening allowing detection of early breast cancer.
- ➤ Roughly around less than 20-25 centres have facility for nuclear medicine department in entire India

### MATERIALS & METHODS:

- Investigator Initiated Trial
- Study Design: Prospective Observational Study
- Duration : August 2017 August 2018
- No Of Patients: 60
- ➤ IRB Approved
- > SLNB procedure was done using technetium-99m radio colloid (R), methylene blue dye (MB), and ICG.
- All SLNs that were removed during surgery were labeled as hot, blue or/and fluorescent and sent for pathological examination.
- The detection rate of SLNs and positive SLNs, and the number of SLNs of ICG, MB+ R, ICG + MB, ICG + R were compared.
- Modified Delphi consensus developed quality indicators for
- SLNB questionnaire was also used to assess the quality of SLNB. Injection safety of ICG and MB was evaluated.

### NEED FOR THIS STUDY

To look for a Safe, Easy & Economically feasible alternative to gold standard combination of radio-colloid & blue dye for detecting SLNB in Early Breast Cancer











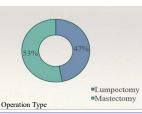






# RESULTS:



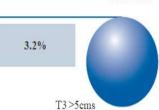


21.8%

74.9%

T1 <2cms

T2 2-5cms

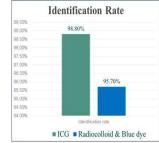


# IDENTIFICATION RATES

Sentinel Lymph Node was identified in all 60 cases (Identification rate = 100%)

Total Sentinel lymph nodes removed = 164 The mean number of sentinel lymph nodes

removed was 2.6 (Range 2-5)



#### Pathologic evaluation protocol > 90% 60 (100) Pathologic reporting by AJCC guidelines > 90% 60 (100) Protocol for injection of radiocolloid > 90% 60 (100) Proper identification of SLN > 90% 60 (100) SLNB performance in eligible patients > 80% 14/14 (100) SLNB concurrent with lumpectomy/mastectomy > 80% 32/32 (100)

> 75%

< 5%

25%\_34%

60%-70%

### POSITIVE NODES

- Number of nationts with positive nodes= 21/60 (35%)
- > Number of positive nodes =28/164

Completion ALND for positive SLNB

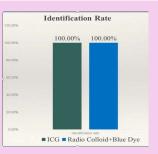
SLNB performance in ineligible patients

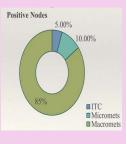
Axillary node positivity rate

Number of nodes removed

Axillary recurrence rate at 5 years

	ICG	RADIOCOLLOID & BLUE DYE
Sensitivity	100% (CI 83.16% to 100.00%)	100% (CI 83.16% to 100.00%)
Positive Predictive Value	100%	100%
Accuracy	100%	100%





14/21 ( 66.6)

21/60 (35.0)

60/60 (100)

Need follow up

0/0

### COMPLICATIONS

odified Delphi Consensus Statement: Sentinel lymph node biopsy quality indicator results

None of the patients had any local or systemic reaction with ICG

3 patients with blue dye had tattooing & staining of skin





# DISCUSSION:

- 1.Multiple studies & systematic review have demonstrated a detection rate of 90-100% with ICG alone which is equal to or more than the standard dual dye
- 2. The false negative rate has been reported to be between 3-12%. 6
- 3. The average no of SLNB detected by ICG was more than that by dual dye or individual dve in comparison.
- 3. Because of the ethical issues surrounding doing of axillary clearance post SLNB there is lack of evidence for demonstrating false negative rates, which we have tried to overcome By using modified Delphi consensus quality indicators of SLNB
- 4. Studies related to examining the efficacy of new agent in comparison with the standard technique leads to bias which is due to mutual sensitization of agents which has to be kept in mind.

# ADVANTAGES OF ICG

- Lymphatic channel visualized
- Site of Skin incision
- Easy to prepare
- Easy to handle
- Easy to use
- No skin necrosis. tattooing, ulceration
- ✓ No Nuclear medicine
- ✓ No technician
- ✓ Solution prepared by doctors
- ✓ Intraoperative injection
- ✓ Not Radioactive
- ✓ Alone 95-98%
- ✓ No special licensing or storage procedure

# CONCLUSION:

- > ICG is safe & as effective as the dual dye for SLNB.
- > In addition, as a near-infrared dye, it has the advantages of real-time visualization, lower cost, and wider availability, since no radioactive material needs to be handled
- > A combination of blue dye and ICG is useful dual approach when radioisotope is unavailable
- > The higher SLN retrieval number for ICG compared with conventional methods in theearly breast cancer setting indicate that ICG may be an optimal tracer for SLNB after NAC
- It can be a boon for developing countries & second tier centers of developed country where there is limited access to nuclear medicine department facility & the cost involved in its establishment

NO CONFLICTS OF INTEREST & DISCLOSURES NONE

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