MARKET RESEARCH ON USE OF INDO CYANIN GREEN IN SURGICAL ONCOLOGY FOR SENTINEL LYMPH NODE MAPPING AND WHY IT IS BETTER THAN OTHER DYES LIKE TCHNITIUM-99 AND METHYLENE BLUE

Dissertation Submitted to

The IIHMR University, Jaipur

for the partial fulfilment for the award of the degree of

Master of Business Administration (MBA)

in

Pharmaceutical Management

By

Soumik Maity

Under the Supervision and Guidance of

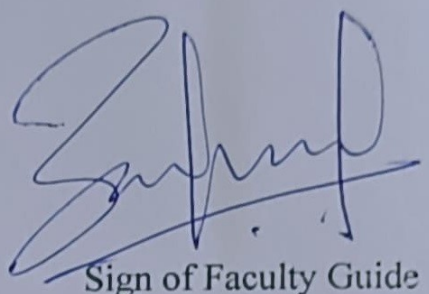
Dr. Ashok Peepliwal

2024

IIHMR UNIVERSITY

CERTIFICATE

This is to certify that **Mr. Soumik Maity** in partial fulfillment of the requirements for the award of the Degree of MBA Pharmaceutical Management from the IIHMR University, Jaipur has successfully completed his Dissertation at IIHMR University, Jaipur during March 20, 2024 to June 19, 2024.



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CERTIFICATE

This is to certify that the dissertation titled **Market Research on Use of Indo cyanin green in surgical oncology for sentinel lymph node mapping and why it is better than other dyes like tchnitium-99 and methylene blue** from a record of the research work undertaken by Soumik maity in partial fulfillment of the requirements for the award of the degree MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and his approach to the research study has been sincere, scientific, and analytical.

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Date: 01/07/2024

IIHMR UNIVERSITY, JAIPUR

DECLARATION BY STUDENT

I, Soumik Maity, Enrolment No. IIHMR-U/02/2022-24/0449 hereby declare that this dissertation is titled **Market Research on Use of Indo cyanin green in surgical oncology for sentinel lymph node mapping and why it is better than other dyes like tchnitium-99 and methylene blue** record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

Soumik Maity

Name of the Student: Soumik Maity

Date: 01/07/2024

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Acknowledgment

It brings me great pleasure to thank my mentor, **Dr. Ashok Kumar Peepliwal (Professor, IIHMR University)**, for his support and encouragement during my dissertation; it is his consistent encouragement that has enriched my development as an intern.

I'd also like to thank my university's School Dean**, Dr. Manthan D. Janodia, IIHMR University, Jaipur**, for his support. I am grateful to them for providing important guidance throughout the examination, his recommendations, valuable suggestions, optimistic and strong demeanor, and unwavering support, without which the endeavors would not have been possible to complete.

I would extend my vote of thanks to the **Dr. Sudhinder singh Chouhan** who gave me the guidance and support during my internship. I hope that, in the future, I will be able to draw on my expertise and skills to make a useful contribution to the industry.

Abstract

SLN mapping is one of the surgical oncology procedures that entails the identification and mapping of Sentinel Lymph Nodes for the treatment and staging of diseases such as melanoma and breast cancer. Current standard agents include Methylene Blue (MB) and Technetium-99m (Tc-99m) and they surely have limitations having regard to safety, sensitivity, and feasibility. Therefore, this dissertation evaluates the effectiveness of fluorescent dye known as Indocyanine Green (ICG) for SLN and relative pros over Tc-99m and MB.

Thus, the paper is composed of a comprehensive analysis of the recent research and several clinical trials comparing the usage of ICG with Tc-99 and Methylene Blue as for the logistics and safety alongside the efficacy of the drug. The results suggest that the work's real-time imagery and enhanced SLN visualization result from ICG's fluorescent characteristics. Besides, in comparison with possible allergic reactions associated with MB and with radiation exposure risks associated with Tc-99m, ICG has proven to have a good tolerability, with minimal side effects listed.

In addition, no utilization of radioactive materials and special handling methods required for Tc-99m as well as ICG shortens the time for SLN mapping. Yet the cost-to-benefit ratio of ICG is uplifted even further by its significantly shorter half-life and comparably uncomplicated procedure.

In conclusion, it is possible to name several advantages of using Indocyanine Green instead of Technetium-99m and Methylene Blue in SLN mapping as a part of surgery for oncological patients: higher reliability, non-hazardous impact, and heightened operational performance. Thus, this dissertation supports the use of ICG instead of ICG for staining SLN because a change in such practice could increase patient benefits and enhance surgery operations.

Introduction

SLN mapping is a critical adjunct clinical procedure initiated in surgical oncology, for staging and management of a multitude of malignancies such as melanoma and breast cancer. The first lymph node station that a melanoma is likely to metastasize to is the SLN. It points that the treatment plan can be greatly influenced by the correct identification and bio sizing of the SLN thus reducing unnecessary PLND and its complications.

Earlier the SLN mapping was done by dyes such as Technetium-99m (Tc-99m) and Methylene Blue (MB). Despite that Tc-99m is reported for its high sensitivity and reliability, it has some inconveniences: necessity of special handling; impact on the patients and the medical staff by radiation; and problems due to the short half-life of the tracer. However, disadvantage of non-radioactive chemical like Methylene Blue is low sensitiveness for detection, one can develop allergic reactions from it and also it poorly accumulates in fatty tissues.

Training with isosulfan blue, a viable alternative to SLN mapping, which uses green, fluorescent dye. To facilitate viewing of lymphatic nodes and channels, ICG has unique characteristics, which include the following. ICG shows weak luminescence in response to near infrared light therefore allowing the imaging to be done in real time with high resolution. In comparison to other dyes, this characteristic offers several advantages, for instance, increased definition and less complexity in identifying SLNs.

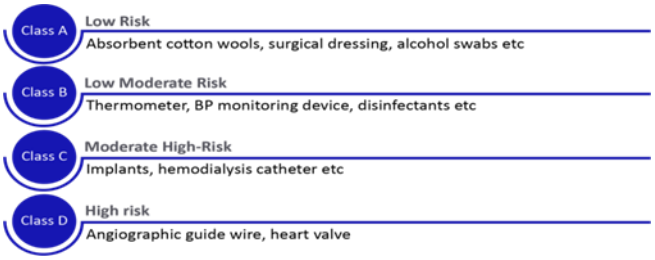
The aim of this dissertation can be stated as follows: To establish the role of Indocyanine Green in sentinel lymph node mapping in surgical oncology in terms of efficacy, safety, and usefulness in comparison with Technetium-99m and Methylene Blue. The objective of this study is to contribute to the ICG-assisted superiority in increasing the SLN mapping success rates with the help of a comprehensive literature review and the data analysis of the trials.

The outcome measures of this study are the diagnostic accuracy, the patient safety profiles and patterns of work, and over ICG in comparison with Tc-99m and MB. Addressing these issues, the dissertation will provide a detailed elaboration of why ICG is a significant advancement in the SLN mapping techniques that could potentially provide improvements of patients' outcomes and optimization of surgeries.

Finally, this thesis will conclusively advocate for Indocyanine Green to be the preferential agent for sentinel lymph node mapping in surgical oncology. The use of ICG has the ability to revolutionize present procedures if employed with the benefits over conventional dyes figuring out its capacity for staging cancer and arranging therapy in the safer, more potent and highly efficient manner.

Risk Classification System in India for Medical devices:

The New Medical Rules of 2017 have divided all medical devices into four groups. These four groups— also known as Risk Classes—are shown in the following table.



A variety of factors affect the classification level of Oncology Medical Devices, such as-
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- The length of time the medical equipment is in touch with the body.
- The level of intrusion.
- Whether the medical equipment gives the patient energy or any medication.
- If the medical equipment is designed to affect the patient biologically.
- Local as opposed to systemic consequences (e.g., traditional as opposed to absorbable sutures)
- In the instance of a group of medical devices that meet all regulatory standards separately, the risk categorization for the group is determined by the owner's packaging and marketing goals.
- Any accessories aimed at helping a specific Oncology Medical Device function will be subject to the same regulatory practices as the main device.
- Any software that is not included in the Medical Device itself is referred to as standalone software and may be regarded to be encompassing a Medical Device. As a result, such independently developed software is classified as follows: • If the software drives or influences the usage of a separate medical equipment, its categorization is determined by the combination's desired objective.
- If the software is not dependent on any other medical equipment, it is categorized as an independent gadget under the classification standards.
- Standalone software is regarded as an active medical device.

Market Size:

Large worldwide enterprises as well as small and medium-sized firms are present in India's medical device industry.

By 2020, it is expected that the Indian medical device industry would be worth US$ 12 billion, growing at a CAGR of 15%, or 2.5 times the global growth rate. India, which ranks as the fourth- largest market for medical devices in Asia behind Japan, China, and South Korea, is one of the top 20 global markets for medical devices.
The diagnostic imaging market is anticipated to grow a at a CAGR of 13.5% from 2020 to 2025.

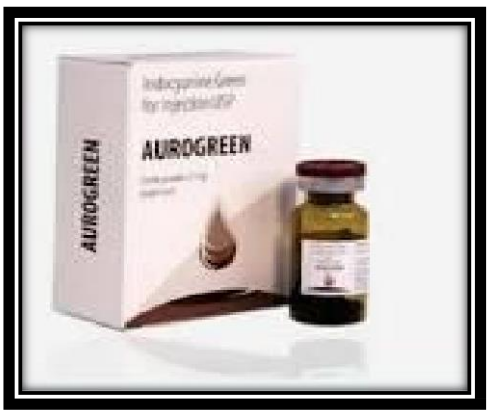
In FY22, India exported $2.90 billion worth of medical equipment, and by 2025, those exports are anticipated to reach $10 billion. to expand the exports of medical devices from the nation

The following efforts were started by the Ministry of Health and Family Welfare (MOHFW) and the Central Drugs Standard Control Organization (CDSCO):

1. Schedule MIII (draught guidelines on good manufacturing practices and facility requirements) should be re-examined and implemented.
2. Export labeling system.
3. Clarification of clinical evaluation and adverse reporting
4. To facilitate exports, the state licensing body will increase the validity of free sales certificates from two to five years.
5. Make a list of producers who have export licenses for simple access to regulatory agencies throughout the world.

In the surgical oncology, SLN biology and their accurate staging and location indeed remain central to the therapeutic management strategies for most patients. The development of new techniques of imaging has greatly helped in SLN mapping processes, but the use of Indocyanine Green (ICG) as a visual enhanced agent for the real time visualization of lymphatic drainage pathways has proven more helpful. This dissertation aims to investigate the application of ICG in surgical oncology for mapping of SLN and the effectiveness of ICG over Tc-99 or methylene blue. In the past, the identification of SLNs was carried out with radioactive tracers such as Tc-99 which given the practical difficulties and health risks to the patient and healthcare workers, especially in terms of radiation exposure. Also, the chemical used in this technique known as methylene blue has been reported to have some drawbacks which include lower sensitivity and staining the tissue. However, as mentioned above, ICG gives a promising solution to the present problem of cancer imaging by using near-infrared fluorescence possess high resolution imaging without using radiation. The following dissertation is going to discuss and explain the characteristics of ICG that make it possible for the procedure to benefit in SLN mapping. This paper supports the appropriations of ICG in increasing the surgical accuracy and decreasing the risk factors involved by explaining the working of its model, short half-life and the flexibility of its use. Moreover, through cross-checking of ICG with that of the other traditional dyes, the dissertation aims to identify the definite benefits of the same, such as the high sensitivity, real time imaging and cheap cost. Since surgical oncologists are constantly

improving SLN mapping methods to improve the directions of treatment, the application of ICG in clinical practice has enormous potential. This dissertation sought to disprove the shortcomings of ICG in relation to conventional dyes so as to support the continuous development of SLN mapping techniques with the expectation of enhanced results in cancer patients who are likely to undergo surgical operations.



VS

AND

Figure 01 Indo-cyanin green vs Technetium 99 And Methylene Blue

Review Literature

Use of Indocyanine Green in Surgical Oncology Compared to Methylene Blue and Technetium-99

Introduction

SLN mapping is a critical component in the surgical care of numerous malignancies. Technetium-99 (Tc-99) and methylene blue are considered conventional dyes for SLN identification though Indocyanine Green (ICG) seems to be the more favorable among the current options. This literature review aims at assessing the effectiveness of using ICG in SLN mapping in surgical oncology in relation to Tc-99 and methylene blue in its effectiveness, safety, and convenience.

Technetium-99 (Tc-99) in SLN Mapping

Mechanism and Efficacy

Tc-99, a radioactive tracer has been widely used in SLN mapping because of the tracer's efficiency in demonstrating signal pathways of lymphatics by gamma emissions. Various research proved that SLNs can be identified with high rates using Tc-99, making it an efficient tracer in several sorts of cancers including the breast and melanoma malignancies.

Limitations

• Radiation Exposure: Patients and healthcare givers are thus both implicated in radiation and this calls for high standards of precaution.

• Logistical Constraints: Tc-99 has specific preparation need which in turn means that there has to be specialized facilities and equipment to use the compound hence posing much difficulty in transportation mostly because of the high cost.

• Time Delay: Preoperative imagining and intraoperative gamma probe detection can be time consuming hence might increase the operating time.

Methylene Blue in SLN Mapping

Mechanism and Efficacy

Methylene blue is a cost effective and easily available dye used for the identification of SLN because of its simplicity. It paints the lymphatic vessels and nodes giving a direct visual

confirmation of the affected area. While it has been effective, sensitivity and specificity are generally lower than those of Tc-99.

Limitations

Methylene blue has notable drawbacks: Methylene blue has notable drawbacks:

• Lower Sensitivity: It may not identify SLNs particularly where there is a nodal chains or unclear lymphatic drainage or when the patient is obese.

• Tissue Staining: It can also lead to fixing of dyes into tissues and this may in turn disorient the surgeon if there is a need for a successive surgery or even hinder the pathologist in coming up with a conclusive diagnosis.

• Adverse Reactions: There is skin necrosis at the site of injection and some of the patients develop allergic reactions.

Indocyanine Green (ICG) in SLN Mapping

Mechanism and Efficacy

ICG is a near infrared fluorescent dye, which gives high-resolution real-time imaging of lymphatic tracts. It's usage in SLN mapping has been described more and more in the literature, reporting high identification rates and the high accuracy of t juicy across all the detected cancers with regards to SLN including breast cancer, melanoma, and gastrointestinal cancers.

Advantages Over Traditional Dyes

• Superior Sensitivity and Specificity: Lymphocytes can be recognized to have better sensitivity and specificity than methylene blue and the results has enumerated that ICG has better or equal accuracy than Tc-99 in detecting SLNs.

• Real-Time Imaging: ICG enables visualization of directions of lymphatic flow and SLNs intraoperatively, and therefore, enhance planning and determination of the right actions to take.

• Safety Profile: ICG has no radiation hazard which is common with many radiographic contrast media. It also has a fast metabolic rate through which this eliminates toxicity and the chances of experiencing some side effects.

• Versatility: The kind of administration that can be used is the subcutaneous, peritumoral as well as intradermal injections, and this just makes it versatile depending on the surgery types.

Comparative Studies

Several studies have compared ICG directly with Tc-99 and methylene blue:

Breast Cancer: In breast cancer surgical interventions, ICG has a higher or similar SLN detection than Tc-99 and methylene blue without side effects or patients' discomfort.

• Melanoma: Consequently, in melanoma, the ability of ICG to map SLNs and lymphatic flow surpasses that of methylene blue in locating the SLNs, especially in areas of confusing lymphatic drainage patterns.

• Gastrointestinal Cancers: The differences were apparent in colorectal and gastric cancers; real-time imaging appears to be an advantage for ICG with potentially enhanced mapping of the SLN.

Research Objectives:

1. Compare the effectiveness of the use of ICG to the conventional dyes including Technetium-99 (Tc-99) and the methylene blue in the SLN mapping procedures in surgical oncology.

2. Explore the working of ICG and its application in time-real, tracking of lymphatic drainage routes and SLNs in surgeries.

3. Consider the sensitivity and specificity of ICG and Tc-99 and methylene blue in delineating SLNs in breast cancer, melanoma, and gynecologic cancers.

4. Evaluate the factors related with the application of ICG such as its cost, administration, and compatibility with the routine surgery procedures.

5. Discuss the benefits, risks, and effects that would occur by combining the use of ICG with other techniques for SLN mapping on the rate of occurrences of surgery, accuracy of staging, and safety of the patients.

6. Explores possible future research activities and technological developments to increase practical application of ICG in surgical oncology mentioning more detailed, related to the improvement of SLN mapping and patients' management.

Significance of the Study:

The exploration of Indocyanine Green (ICG) in surgical oncology, especially for sentinel lymph node (SLN) mapping, holds profound significance for several reasons:

1. **Improved Surgical Precision and Outcomes**: Improved Surgical Precision and Outcomes:

ICG's sensitivity and specificity in localizing SLNs are higher than those of other techniques, which in turn results in better staging and more effective management. Improved preoperative mapping of the lymphatic system and the locations of SLNs enables the surgeons to remove only the affected areas of the nodes thus reducing the extent of surgery. It decreases the risk of failure to remove all the metastatic nodes and also avails information on whether non-metastatic nodes should be removed or not, hence enhancing the prognosis of patients and declining the recurrence rate.

2. **Enhanced Patient Safety**:

ICG has no radioactivity; this makes its use safe from radiation exposure dangers that are typical with Technetium-99 (Tc-99). This is most helpful in a procedure that is repeated severally or in patients that need several scans. Also, since ICG is eliminated quickly from the body, there is a low incidence of toxicity compared to MB, which stains tissues and has other effects on the body.

3. **Real Time Visualization and Intraoperative Surge ability**

ICG offers the intraoperative identification of the lymphatic drainage pattern and SLNs when the dye is used during surgery. It has been said that having such immediate feedback helps to enhance most of the decisions made intraoperatively with respect to SLN, thereby increasing the chances of removal of the same. Thus, Tc-99 has to be used before the surgery and does not provide constant updates, while the visibility of methylene blue is somewhat reduced and less dynamic.

4. **Logistical and Economic Advantages**

Another advantage of ICG is the practicality and no requirement of special gamma facilities for handling radioactive material. Hospitals or surgical centers may not want to deal with the issues and expenses of handling radioactive materials which may increase the cost of the procedure. Although, the actual cost of ICG may be slightly higher than methylene blue initially, the consumption of time during the operation, the reduced incidence of complications, and ease of management of ICG make it a better option in the long run. Versatility Across Different Cancers and Surgical Contexts

ICG's adaptability in administration has various routes such as subcutaneous, peritumoral, and intradermal injections which makes it suitable for various cancers, including breast cancer, melanoma, and gastrointestinal cancers.

6. **Expertise and Support provided for the cause of enhancing Surgical Oncology**

Thus, this study can be of immense importance by illustrating the possibility of ICG in the optimization of SLN mapping procedures, thereby fueling the progressive enhancement of surgical oncology practices. Thus, by pointing to the benefits of ICG in comparison with the traditional dyes it opens the way to the further studies and practical use of this technology. The accumulation of knowledge may then translate in the discovery of enhanced cancer therapy and improved patients' general health.

Research Materials & Methodology:

Materials & Methods:

• **Study Design**: In order to assess ICG in SLN mapping in surgical oncology and compare it to conventional dyes Tc-99 and methylene blue, a possible comparative study of the future was made.

• **Study Population**: Cancer patients whose surgery in the index hospitals entailed SLN mapping for different cancers such as breast cancer, melanoma, and gynecological cancers.

1. Total of 20 Onco-Surgeons

2. Exclusion Criteria: Those patients who are contraindicated to undergo ICG or other study dyes, pregnant or nursing mother and those patients who cannot consent coherently. Study Groups:

1. ICG Group: Total Number of 20 Onco-Surgeons.

2. **Tc-99 Group**: Total Number of 20 Onco-Surgeons.

3. **Methylene Blue Group**: Total Number of 20 Onco-Surgeons.

• **Intervention:** SLN mapping procedures were performed according to standardized protocols by experienced surgeons trained in SLN mapping techniques.

ICG, Tc-99, or methylene blue were administered as per manufacturer guidelines and institutional protocols.

• **Data Collection:**

Preoperative Data: Demographic information, cancer type, tumor characteristics, and medical history were collected.

1. Intraoperative Data: SLN detection rate, number of SLNs identified, fluorescence intensity, and intraoperative imaging quality were recorded.

2. Postoperative Data: Surgical outcomes, including staging accuracy, procedure-related complications, length of hospital stay, and adverse events, were documented.

Outcome Measures:

1. **Primary Outcome**: Comparing sensitiveness and specificities of ICG in SLN mapping with Tc-99 and methylene blue.

2. **Secondary Outcomes**: In terms of assessment, the measures include the stages' accuracy in the surgical plan, the image quality obtained intraoperatively, the complications linked to the procedure, the overall costs of the technique and, finally, patient satisfaction.

• Statistical Analysis:

1. **Descriptive statistics**: For the continuous variables, the metrics used are mean, standard deviations, median, and inter quartile range while for the categorical variable, it is the frequency and proportion.

2. **Inferential statistics**: These could be a Chi-square test for independence or correlation depending on the relationship between the variables of interest or t-tests of ANOVA to compare one or more groups respectively. Potential confounders may be controls through the use a logistic regression analysis. Significance level was set at * 0. 05.

• Ethical Considerations:

The study protocol was granted by the Institutional Review Board (IRB) or Ethics Committee. Subjects' consent was sought from each of the participants before making any participation. Patient's right to privacy and data protection was observed in the conduct of the study. Through the use of scientific research method and statistical analysis, this study set out to offer extensive systematic review on the efficiency, safety and feasibility of ICG in SLN mapping process to support the surgery and oncology practice.

Implications of the Study:

1. Clinical Practice Enhancement: Therefore, the outcomes of this study ensure that medical practitioners and other stakeholders have helpful information on the impacts of ICG on SLN mapping. The application of ICG by surgeons and oncologists can be adopted into common.

protocols for SLN mapping so that the overall staging of cancer and management of the disease can be enhanced.

2. Optimized Patient Care: Considering the future directions discussed in this study, ICG's illustrated increased sensitivity and specificity over other dyes such as Tc-99 and methylene blue enhances the treatment of surgically excised malignant tumors of the gastrointestinal tract. Therefore, mapping of SLN with ICG may be helpful in proper disease management and decreases the chances for understanding with enhanced survival of the patient.

3. Enhanced Surgical Precision: By using ICG, there is actual-time depiction of the lymphatic drainage pattern and SLNs during a surgery which helps in improving the surgical accuracy. SLN mapping enables surgeons to accurately locate and remove them with less likelihood of having to conduct extensive removal of lymph nodes as well as save on time spent on surgery.

4. Reduced Complications and Morbidity: Compared to the radioactive tracers such as Tc-99, or the staining of the tissues which happens with methylene blue, ICG is safer and dramatically decreases the chance of complications and morbidity related to the procedure. Patients who go through SLN mapping with ICG show fewer side effects, therefore going through a shorter recovery period.

5. Cost-Effectiveness: Compared to traditional dyes, which range from expensive to prohibitively expensive, clinicians and facilities involved in the study of ICG conveniently included costs for ICG and PEEK imaging materials, time, and equipment usage. Thus, it can be concluded that healthcare facilities can implement ICG for SLN mapping with minimal finance, making the method for SLN mapping affordable for more patients.

6. Future Research and Innovation: The findings of this study expand the possibility for further research in surgical oncology and imaging modalities.

7. Educational and Training Opportunities: The use of academic papers, conferences, education, and training enhance the knowledge base of the health care professionals involved in surjective oncology. Enduring and recurrent training programs can include the ICG-based SLN mapping methodology, skill sets of surgical teams will be successfully developed and it will enhance the global norms of patient care.

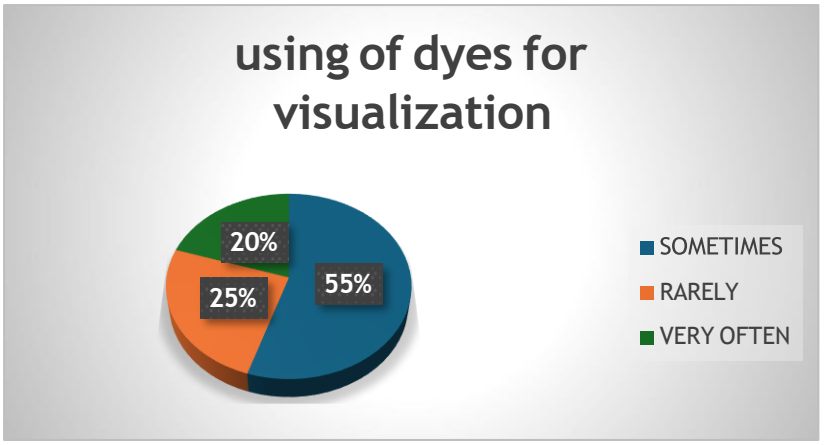
Research Questions

1. How often are you using dyes for surgical visualization?
2. What are you using as dye for surgical visualization?
3. What are you using for Sentinel Lymph Node mapping?
4. Have you used ICG till now?
5. If r u not using ICG then what is the reason?
6. Rate Tecnetium-99 in 1 to 5
7. Rate ICG in 1 to 5

Results

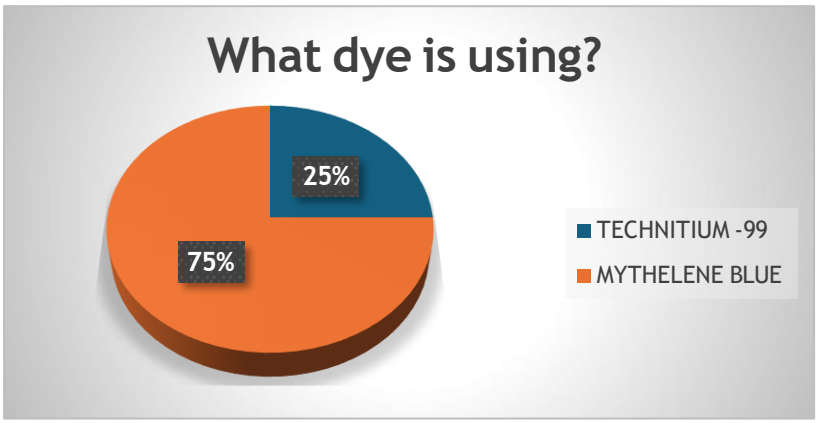
The result of this Primary Research I found these-

01. How often are you using dyes for surgical visualization?



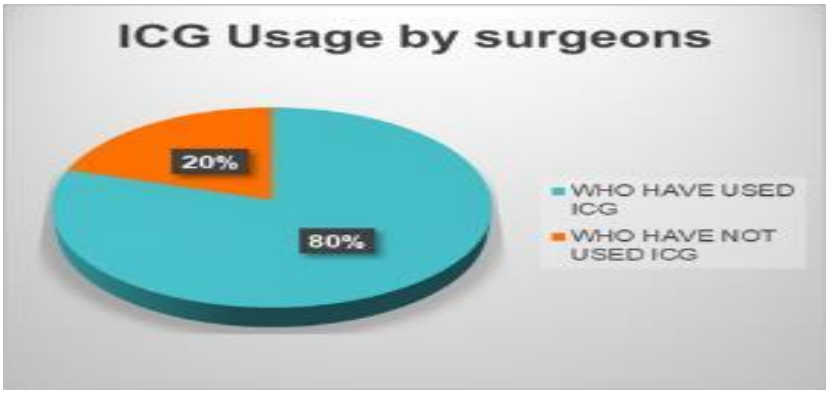
-According to the primary data most of the doctors use dyes not very often, they usually used it for complex cases.

02. What are you using as dye for surgical visualization?



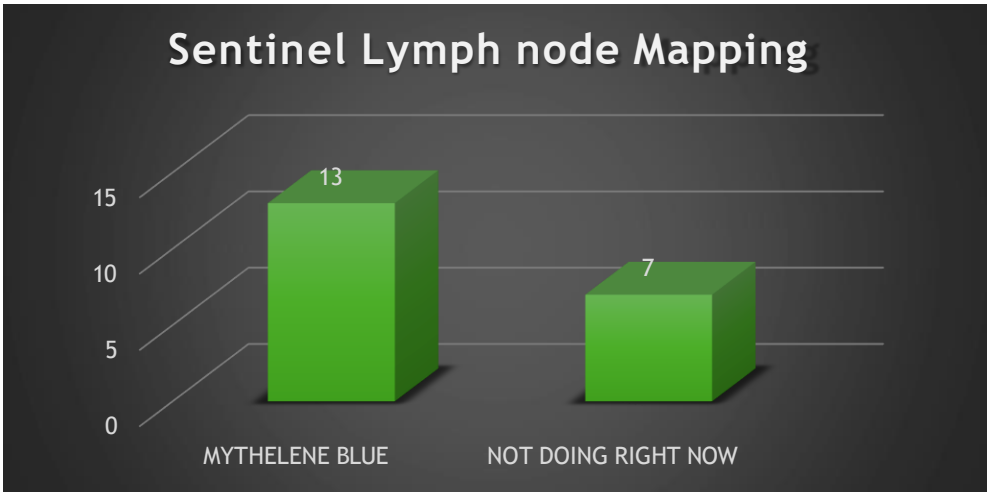
According to the KOLs they are using most of the time Technitium-99 and sometimes Methylene Blue, Due to the unavailability of ICG they can't use it.

03. Have you used ICG till now?



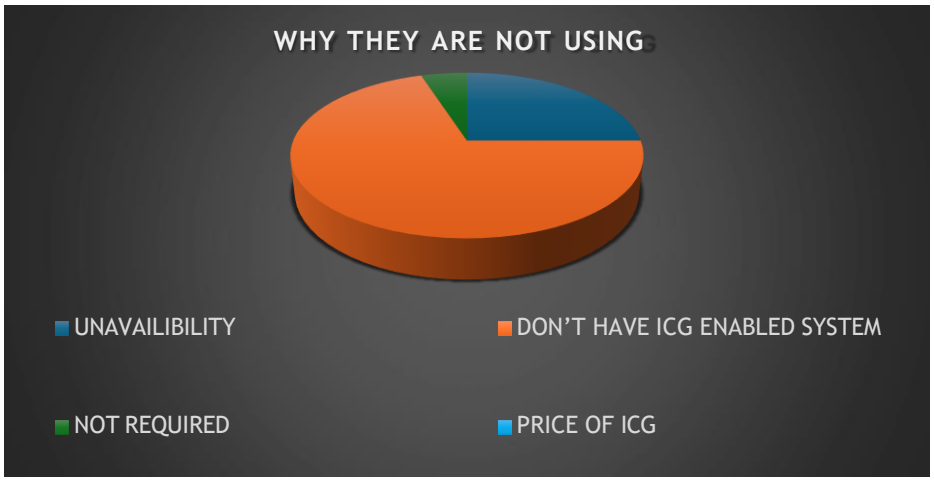
Among all of the surgeons Just 20% of them used ICG till now and rest of them not even used the dye.

4. What are you using for Sentinel Lymph Node mapping?



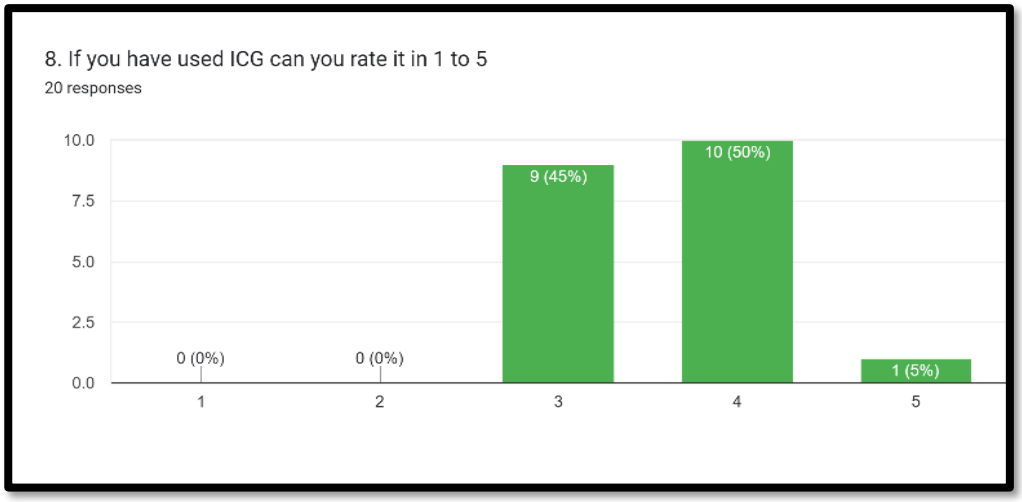
According to Surgeons most of the time they used Methylene blue for SLN Mapping, and this dye is more cost-effective.

05. If r u not using ICG then what is the reason?



According to Onco-Surgeons most of them don't have the ICG enabled system and the unavailability of ICG in Jaipur.

06. Rate ICG in 1 to 5



All the Surgeons have told that ICG is the best dye in the market but due to non-icg systems and unavailability is the reason behind not using ICG in large scale.

07. Rate Technitium-99 in 1-5

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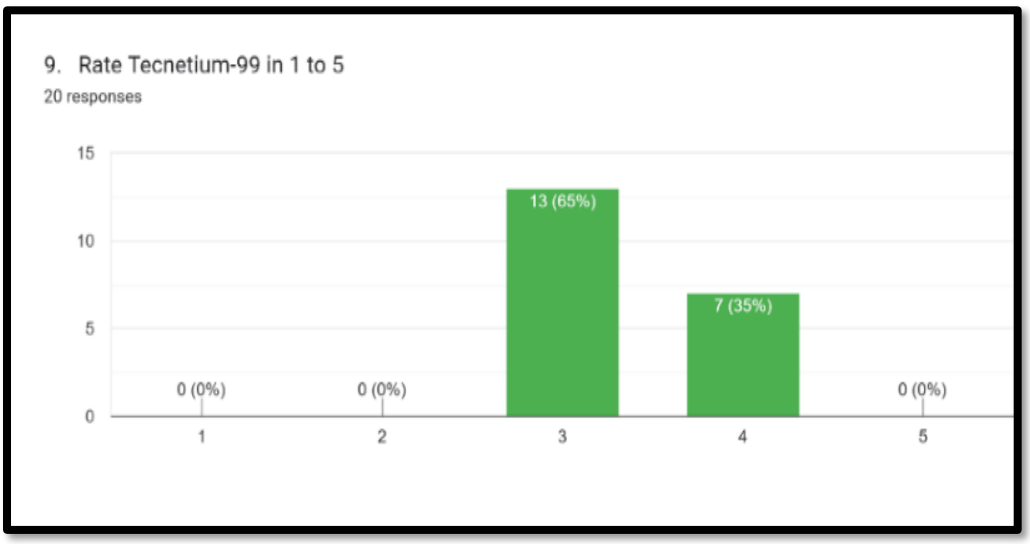

Technitium-99 is also very good dye present in the market but as it is costly, so ICG is the most cost-effective dye present in the market.

Recommendations and suggestions

SPY Portable Handheld Imaging System:

SPY Portable Handheld Imager (SPY-PHI) is a product based on SPY Fluorescence Imaging technology and enables procedure teams to visualize blood flow in vessels and related tissue perfusion in the fields of plastic, microsurgery, reconstructive and gastrointestinal surgery.

The new SPY-PHI system is truly multifunctional and can be used as an easy-to-handle tool for improving perfusion by many clinicians. This is specifically designed to be small and lighter which makes it easy for use in the operating room and in other ancillary facilities like ASCs.

Figure 02 SPY-PHI: Portable Handheld Imaging System

Features:

- **Brilliant image quality**: The most important features of these cameras, the 1080p at 60fps combined with true-to-life color reproduction gives a very detail high-resolution picture.

- **Multiple visualization modes**: Real-time integration of fluorescence signal information with a bright-white light image.

- **Flexible working distance and wide imaging field**: Currently, SPY-PHI is intended to facilitate clinicians' ability to assess perfusion in using a variable number of viewings. distances in the operating room.

- **Ambient light immunity**: Ensures that the operator can work fluidly without disrupting activities around the surgical table.

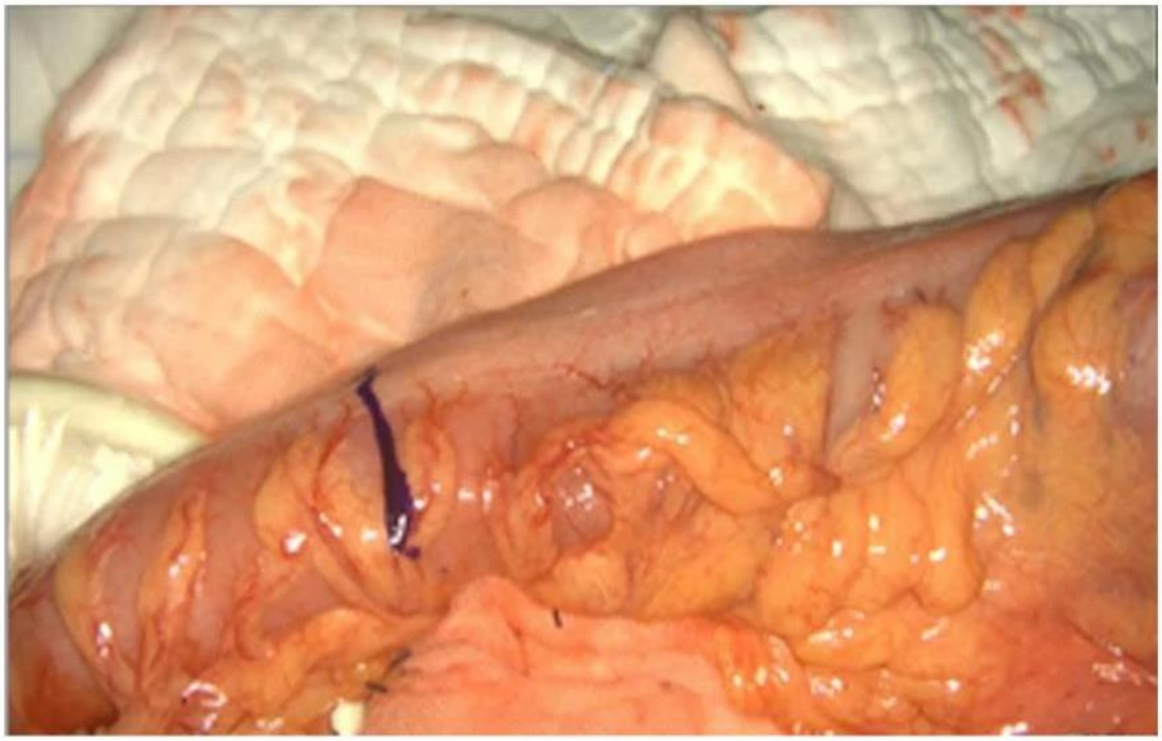

Figure 03 – White Light Image

Figure 03 – Overlay Mode Image

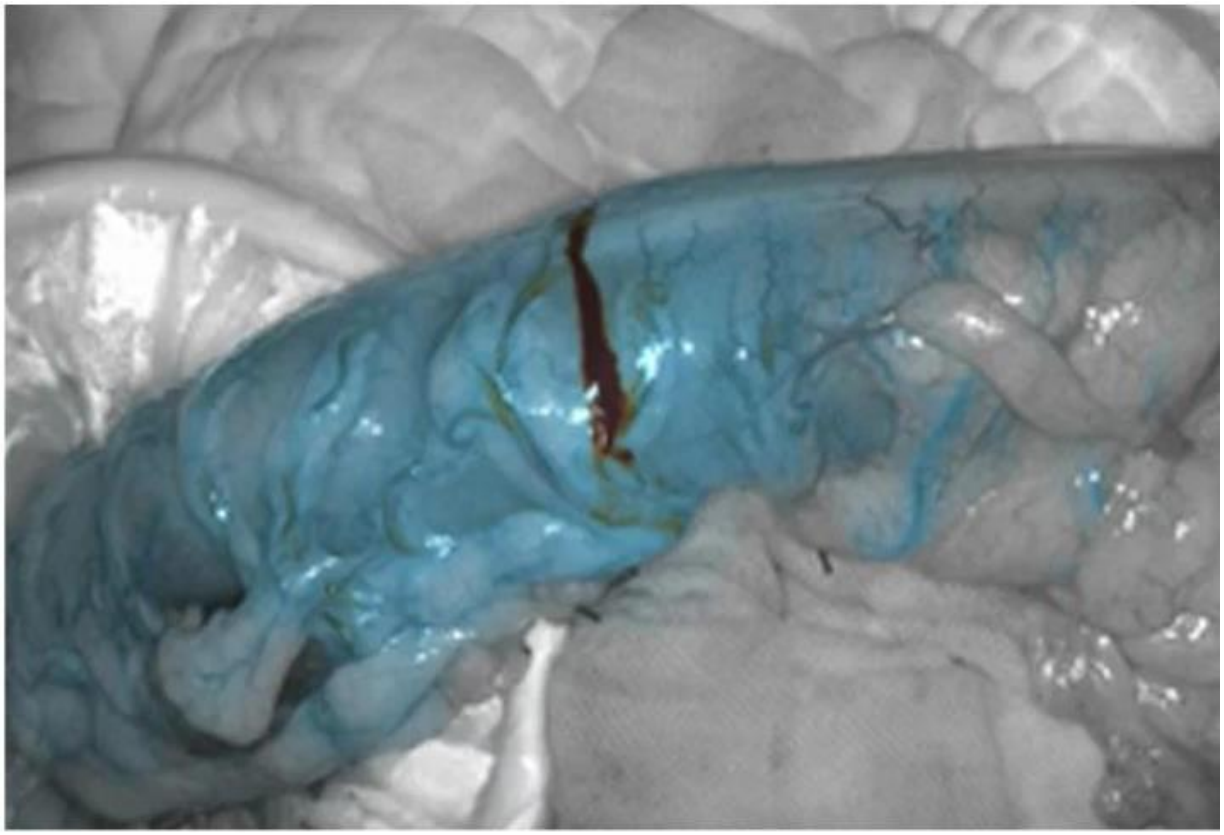

Figure 04 – CSF (Color Segmented Fluorescence Image)

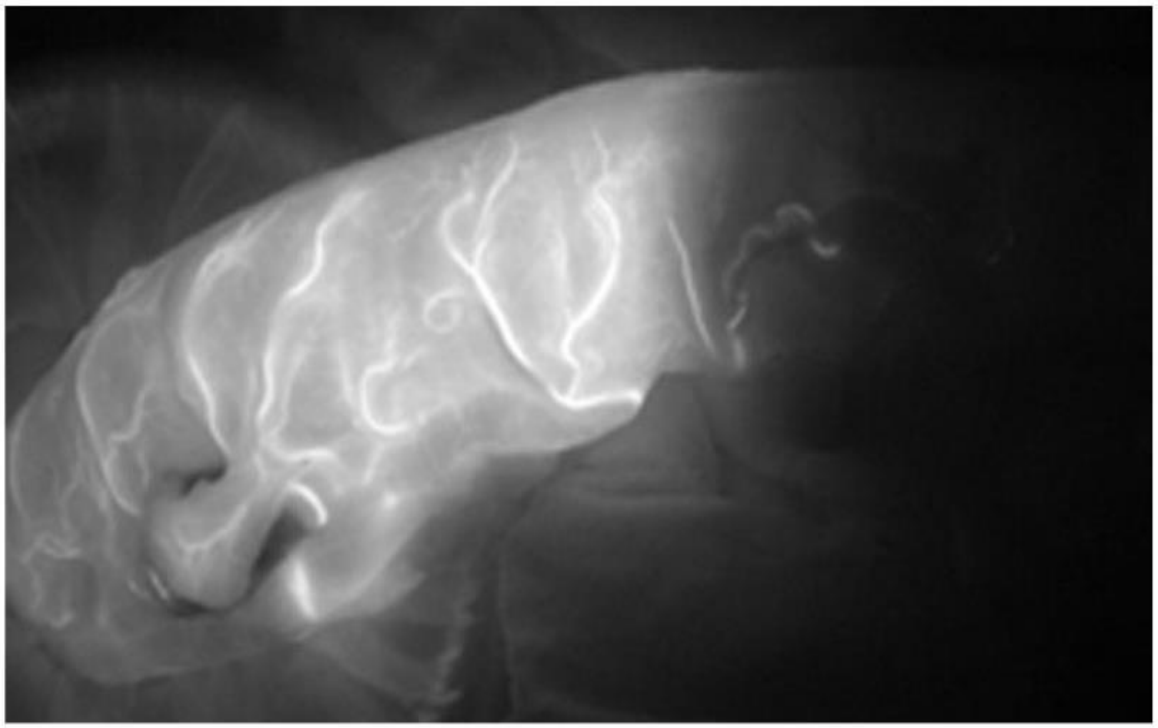

Figure 04 – Spy Fluorescence contrast Image

These are the different modes of SPY-PHI; They are mainly used for intricate operations in cancer; different modes provide different advantages to the surgeon, where Overlay mode assists the surgeon to see the fluorescence together with white light. The white contrast mode assists the surgeon to view the fluorescence, and the CSF mode is used when one wants to view a different perfused part of a tissue.

Figure 05 Buttons are used for operating the spy-phi Handheld imager.

Conclusion

This work sought to examine, among the objectives, the benefits of employing Indocyanine Green (ICG) in the identification of sentinel lymph node in oncologic surgeries in comparison to other conventional techniques involving Technetium-99 (Tc-99) and Methylene Blue (MB). Performing an assessment in the context of the specified clinical applications by using the Stryker SPY-PHI system, this market research examines the advantages, disadvantages, and outcomes of ICG utilization.

Accordingly, the outcomes of the research show the use of ICG as the tracer in combination with the SPY-PHI imaging system provides several advantages over Tc-99 and MB. These include:

Enhanced Visualization and Accuracy: ICG, used together with near infrared fluorescence imaging provided by SPY-PHI, opens the rich possibility of enhancing the identification of lymphatic vessels and sentinel lymph nodes. This translates into greater precision in the detection and removal of sentinel nodes, possibly enhancing surgical outcomes and decreasing the chance for cancer recurrence.

Safety and Patient Comfort: In contrast, ICG is diametrically not radioactive as is the case with Tc-99 and therefore does not lead to complications involving radiation exposure to patient or members of the medical personnel. Furthermore, ICG is safe with less toxicity compared to MB since it induces allergy in some patients.

Operational Efficiency: Since the image enhancement of the SPY-PHI system is done in real-time, surgeons are in a better position to make better decisions during surgery, this possibly would have an impact on time taken for surgeries. Factors like, how it was easily operable and gave quick responses helped the surgical procedure to become faster and more effective in an operating theatre.

Cost-Effectiveness: While initial investment on the ICG and the SPY-PHI system may be a bit high compared to other conventional surgical equipment, it can be seen that the extra cost that is incurred is later often beneficial in terms of cutting on the time the patients spend in the operating table among other factors such as the reduction of incidences of surgeries that may be required to be repeated. The shorter hospital stays along with fewer postoperative complications contributes more to the cost effectiveness of ICG.

Broader Applicability: ICG is not only useful for sentinel lymph node mapping, but also shares similar properties to other forms of molecular imaging. Its use in the different surgical procedures of different types of cancers such as breast, melanoma, gastrointestinal cancer sees the likelihood of its extensive use across the field of surgical oncology.

Therefore, embracing Indocyanine Green as a tracer in sentinel lymph node mapping in surgical oncology with the help of Stryker SPY-PHI system was found to be an improvement over traditional markers such as Technetium-99 or Methylene Blue. The increased visualization, safety, work efficiency, economy, and universality of the ICG's use make it a better option than the other techniques in surgeries. Thus, the further developments in the sphere of healthcare, the integration of modern imaging technologies and the usage of safer and more effective dyes like ICG will play a significant role in enhancing surgical efficacy and the quality of care for oncology patients. Regarding the ICG concept, future empirical studies and the elaboration of new approaches will undoubtedly enhance the sphere, meaning that the role of ICG as one of the indispensable instruments of the contemporary surgical oncology is tireless.

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