

## Evaluation of indocyanine green (ICG) and handheld fluorescence imager in the management of early-stage gynecological cancer.

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**Background:** Current management in most early-stage cancers is complete lymphadenectomy for staging. Since surgery is the mainstay of treatment tailoring extent of surgery is vital. Only 15–20% of early-stage gynecologic cancers have lymph node metastases yet complete lymphadenectomy is recommended. Sentinel lymph (SLN) node evaluation is a bridge to avoid morbidity due to lymphadenectomy. Fluorescence imaging utilizing near-infrared (NIR) spectrum (700–900 nm) is a valuable tool for mapping lymphatics and lymph nodes and fluorescence imaging is available on robotic and laparoscopic platforms. However, open surgery is the preferred approach for most early-stage gynecological cancers except endometrial malignancy. This research plans to assess hand-held fluorescence imager using ICG dye for feasibility, ergonomics, accuracy and applicability in all gynecologic cancers. Indocyanine green (ICG) is a valuable agent for NIR lymphatic mapping and is used routinely for sentinel node mapping of breast, skin and gastrointestinal carcinomas with superior safety profile. **Methods:** This exploratory study plans to recruit 30–50 women with early stage endometrial, cervical, ovarian, and vulvar malignancies for intraoperative evaluation of sentinel nodes using ICG and hand held fluorescence imager with SPY-PHI camera and pinpoint video processor (Stryker). Eligibility criteria include women aged 18 years and older, biopsy proven cases of endometrial, cervical & vulvar cancers. For women with suspected ovarian malignancy, sentinel node mapping will be done after laparotomy but SLN biopsy will be done once frozen section report is available. Indications for SLN biopsy are those with uterine confined malignancy (aggressive and non-aggressive endometrial histotypes), stage I cervical cancer with tumor size less than 4 cm, unifocal vulvar tumors less than 4 cm with negative groin nodes and women with stage I and II ovarian cancers and suspicious ovarian masses planned for hysterectomy and or salpingo-oophorectomy. 25 women of early-stage cancers have been enrolled. Fluorescence is detected by tracing fluorescent lymphatics to sentinel node prior to opening retroperitoneal spaces or incising skin in cases of vulvar cancer. Data is being captured and final analysis awaited. The distribution of cancer types till date are endometrial cancer n=12, cervical cancer n= 6, vulvar cancer n=1 and ovarian masses n=6. Sentinel lymph nodes were mapped in 23 out of 25 cases intra-operatively. Clinical trial information: CTRI/2023/03/051086. Research Sponsor: Indian Council of Medical Research; 9618.