HTA258

A Hospital-Based Health Technology Assessment of Near-Infrared Fluorescence Using Indocyanine Green for Sentinel Lymph Node Mapping for Breast Cancer and Gynecologic Cancer

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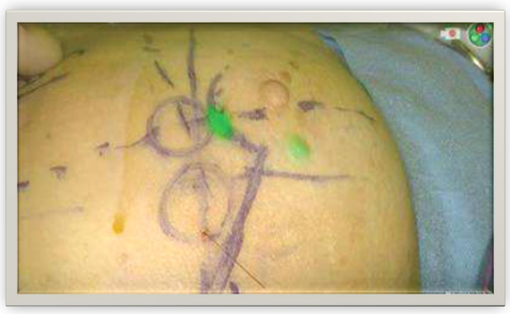
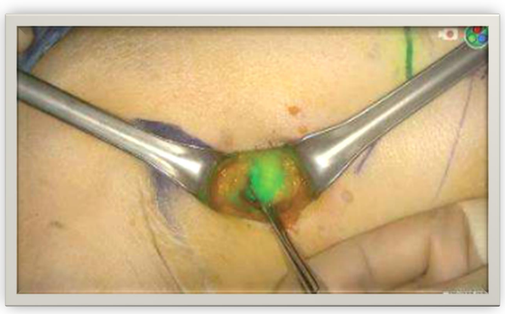
BACKGROUND & OBJECTIVE

- In Italy, the adoption of near-infrared fluorescence-guided surgery using **indocyanine green (ICG)**, is emerging as a viable alternative to Technetium-99 (TC-99), the established gold standard for **sentinel lymph node (SLN)** tracing in breast and gynecologic cancer surgeries.
- ICG has the potential to improve health outcomes, yet the current evidence on its economic value is limited.
- This Hospital-Based Health Technology Assessment (HB-HTA) report provides a multidisciplinary and systematic assessment of using near-infrared fluorescence-guided surgery using ICG as a SLN mapping procedure for early-stage breast cancer and gynecologic cancer as a substitute for TC-99 and Blue Dye (BD) to inform hospital management's decision on adopting this SLN mapping procedure.





METHODS

- The report focuses on the hospital perspective in Italy and follows HB-HTA guidelines, covering the most relevant domains: technological aspects, effectiveness, safety, organizational and economic impact, social, legal, and ethical aspects.
- A systematic review of the existing literature was conducted according to the Cochrane Library for Systematic Reviews. Evidence was extracted according to predefined search strategies, inclusion and exclusion criteria, and was summarized in a reference framework based on the state of art HTA models.
- Results and methodologies were frequently discussed with the advisory board ensuring the reliability of the analysis.
- Qualitative, quantitative, or mixed assessments of the technology were performed according to the type of evidence investigated in the single domain.

KEY REFERENCES

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DISCLOSURE

This HB-HTA was funded by Stryker, which did not participate in the study design and results interpretation.

ACKNOWLEDGEMENTS & CONTACT

Fabio Lodoli, Andrea Marcotto, Luigi Marino (Stryker); Maria Pinelli (Politecnico di Milano). Contact: Luqman Tariq (Luqman.tariq@stryker.com)

RESULTS

The **breast cancer** analysis included 36 records published between 2002 and 2023. Of the 36 studies, 22 were prospective cohort studies, 6 were randomized control studies, and 8 were retrospective cohort studies.

The **gynecologic cancer** analysis included 24 records published between 2014 and 2023. Of the 24 studies, 16 were retrospective cohort studies, and 8 were prospective cohort studies.

	Breast Cancer	Gynecologic Cancer
Total number of studies	36	24
Prospective studies	22	8
Randomized control studies	6	0
Retrospective studies	8	16
No evidence about safety issues or significant reactions to ICG		

In various hospitals, the ICG pathway consistently offers cost savings, ranging from 14% to 18%, compared to the conventional TC-99 pathway in breast and gynecological cases.

- At IFO Hospital, the ICG pathway costs, on average, **17% less** than the conventional TC-99 pathway in breast cases and **14% less** in gynecological cases.
- At Humanitas Hospital, the ICG pathway costs, on average, **16% less** than the conventional TC-99 pathway in gynecological cases.
- In Borgo Trento Hospital, the ICG pathway costs, on average, **18% less** than the conventional TC-99 pathway in breast cases.

DISCUSSION & CONCLUSIONS

- This study provides additional evidence regarding the multidisciplinary impact of the use of ICG in SLN for breast and gynecologic cancer compared to the gold standard.
- Literature regarding the clinical effectiveness of this technology is rich, while studies assessing its organizational and economic impact are lacking.
- Our analysis shows that ICG is a valuable alternative to TC-99 for SLN, not only from a clinical point of view, but also from an organizational and financial perspective.
- These results can be considered highly relevant since the investigation was carried out by a multidisciplinary team merging both clinical and managerial backgrounds.
- Existing studies support the use of ICG as a safe and effective alternative to using TC-99 and BD for SLN mapping for breast cancer and gynecologic cancer patients.
- ICG prehospitalization costs are lower than TC-99 prehospitalization costs due to the avoidance of using the nuclear medicine department for the TC-99 injection.

NEXT STEPS

Further research could involve a broader spectrum of hospitals in the analysis to gain a comprehensive understanding of the technology's potential impact at a national or international level.