Diagnostic Green

White Paper

Economic Health Technology Assessment (HTA) Approach on Surgical Endoscopy Procedures using Indocyanine Green (ICG)

July 2020

Summary of a number of key findings published in Surgical Endoscopy, April 2020

Could fluorescence-guided surgery be an efficient and sustainable option? A SICE (Italian Society of Endoscopic Surgery) health technology assessment summary.

Vettoretto, N; Foglia, E; Ferrario, L; Gerardi, C; Molteni, B; Nocco, U; Lettieri, E; Molfino, S; Baiocchi, G.L; Elmore, U; Rosati, R; Currò, G; Cassinotti, E; Boni, L; Cirocchi, R; Marano, A, Petz, W.L; Arezzo, A; Bonino, M.A; Davini, F; Biondi, A; Anania A; Agresta, A; Silecchia, G.

https://link.springer.com/article/10.1007/s00464-020-07542-3

A paper published in Surgical Endoscopy, April 2020, undertook a Health Technology Assessment (HTA) approach to investigate the economic, social, ethical and organizational implications related to the adoption of ICG based fluorescence surgery.

This white paper summarizes some of the key findings in the paper.

With the support of a multidisciplinary team, qualitative and quantitative data were collected, by means of literature evidence, validated questionnaires and self-reported interviews. Research included a systematic search of literature. This present paper, under the patronage of Italian Society of Endoscopic Surgery, based on an HTA approach, supports "the use of fluorescence-guided vision in minimally invasive surgery, ….as an efficient and economically sustainable technology".

"the use of fluorescence-guided vision in minimally invasive surgery, ….as an efficient and economically sustainable technology"

Recently image-guided by indocyanine green (ICG) fluorescence has been introduced in minimally invasive clinical practice. The fluorescence approach is detected thanks to special cameras that are sensitive to the near-infrared (NIR) spectrum. ICG absorbs NIR light at wavelengths of 800 to 810 nm. This fluorophore emits fluorescence at 830 nm when bound to tissue proteins if excited, with specific wavelength light in the NIR spectrum (w820 nm).

85% of those interviewed believe ICG Fluorescence Based Surgery will become standard in the near future.

Fifty-six surgeons working in both teaching and community, public and private hospitals (covering 75% of the Italian regions), answered a questionnaire. 66.1% of the responders already used fluorescence during their everyday practice. 63.3% of the surgeons consider ICG fluorescence-guided surgery as an improvement of their practice, while 62.5% think that this technology can help in surgical education. When asked about the potential growth of ICG, 85% of those interviewed believe that it has the potential to become a standard vision technology, in the near future.

Efficacy, safety and organizational results: evidence from literature review

Procedure	***Papers evaluated***	***Results reported***
Hepatic surgery	1337 screened papers, six papers included, one RCT, four case–control study, one observational	The use of ICG in liver surgery *may be useful to reduce bile leakage (improve perioperative outcome and hospital stay*), to identify additional injuries in association with conventional techniques and to guide the surgeon in obtaining adequate margins during liver resection with consequent lower risk of recurrence and better long-term survival.
Cholecystectomy and biliary tree	697 screened paper, four papers included, one RCT, two prospective, one retrospective	The use of ICG in gallbladder and biliary surgery can be considered *a safe and sustainable technique*. Fluorescence guided surgery can help in identifying extra hepatic biliary structures faster and more frequently when compared to white light. It can also help in the *recognition of anatomical variants, reducing the risk of bile duct lesions.* It could reduce the misinterpretation of normal anatomy and any anatomical variants without interrupting the workflow. Finally, technological innovation can be useful during the learning curve phases, especially for young surgeons.
Colorectal surgery	667 screened papers, 11 papers included, one RCT, 10 comparative studies prospective or retrospective.	In colorectal surgery, two different groups were analyzed, one for the study of vascularization. There is a significant difference in the subgroup of rectal resections, in which the *ICG significantly reduced the number of leakages (anastomotic re-do surgery by 17%).*

Patient Pathway Average Costs

Depicting the average comparative economic evaluation of patients' pathway, it reported economic benefits of 12.82% on average per patient (or €1,025) for those using ICG.

	Cost per patient No ICG	***Cost per patient using ICG***	***Difference***
Surgery, technology, + other costs	€4,795	€4,831	+€36
Medical cost	€3,201	€2,139	-€1,062
Average total cost	***€7,996***	***€6,970***	***-€1,025***

Cost Effectiveness analysis

Cost Effectiveness Value (CEV) was defined and revealed the dominant nature of the innovative ICG technology (*note: the lower the CEV, the preferable the technology*), indicating that by using ICG, the average cost saving per procedure was €2,664 due to the reduced occurrence of re-do anastomosis.

Vascularization	***No ICG***	***ICG Use***
Efficacy (% of surgery without re-do anastomosis)	85.91%	96.9%
CEV	***€10,565***	***€7,901***

Length of Stay in Hospital

Where ICG is used for vascularization evaluation in surgeries, there was a 42.86% reduction in the "length of stay" in hospital for patients.

42.86% reduction in length of hospital stay

Qualitative impacts: evidence from the professionals' perceptions

A qualitative questionnaire was administered to 17 surgeons to evaluate their perceptions on ICG use, focusing on the following dimensions: organizational, equity, ethical, social, and legal. ICG could be the preferable solution from an effectiveness point of view (average value: 0.54 vs 2.14, p-value = 0.000). Fluorescence would thus be favorable on patients' reported outcomes, *on the detection rate, on image quality, on the visualization of vascularization, on the precision of the surgical technique, on the separation/discrimination between healthy and not healthy tissues*. The use of ICG is perceived as improving the precision of the surgical technique, the identification of the blood vessels, allowing for a better image quality compared with standard white light.

ICG results in favorable patient outcomes

Full reference

Source: Could fluorescence-guided surgery be an efficient and sustainable option? A SICE (Italian Society of Endoscopic Surgery) health technology assessment summary

Vettoretto, N; Foglia, E; Ferrario, L; Gerardi, C; Molteni, B; Nocco, U; Lettieri, E; Molfino, S; Baiocchi, G.L; Elmore, U; Rosati, R; Currò, G; Cassinotti, E; Boni, L; Cirocchi, R; Marano, A, Petz, W.L; Arezzo, A; Bonino, M.A; Davini, F; Biondi, A; Anania A; Agresta, A; Silecchia, G.

Surgical Endoscopy, April, 2020

https://link.springer.com/article/10.1007/s00464-020-07542-3