Indocyanine Green Angiography For Surgical Treatment of Ischemic Wounds: A Game Changer in Limb Preservation

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Introduction:

• Critical limb ischemia associated with tissue loss is a major global medical problem.

• Estimates of CLI incidence in North America and Europe are 500 to 1000 new cases/million people per year. 1

• Likely to increase due to aging population and the epidemic of diabetes.

• Ischemia causing rest pain and tissue loss is responsible for a 20% mortality rate annually. 2.
• Without revascularization in these patients, wound healing and amputation prevention may not succeed.

• Existing systems such as Rutherford 3. or Fontaine 4. classifications provide clinical descriptions to stratify the severity of limb ischemia.

• Attempts have been made to develop objective criteria for the definition of CLI. 6. 7. in addition to quantifiable threshold measurements of perfusion sufficient to ensure wound healing. 5..
Critical Limb Ischemia

- Before surgical intervention of the diabetic takes place blood flow to the lower extremity should be assessed.
- Transcutaneous tissue oxygenation and thermal mapping have been used to help augment the information provided by standard Doppler arterial waveform and pressure measurements. 8.
- These techniques can provide regional perfusion information lacking with ankle or toe waveforms and pressures, and have been used to predict amputation levels. 9.
- The ankle–brachial index (ABI) while nearly 100% specific for PAD in the non-diabetic patient, can be falsely elevated in diabetic patients due to medial calcinosis of the affected arteries. 10.
Establishing Tissue Perfusion Parameters

- At this time there is no established objective criteria for the application of ICGA in the assessment of tissue and foot perfusion in patients with PAD. 5.
- There is a need for the creation of objective, quantifiable, and reproducible parameters for tissue perfusion.
- Risk stratification is based on three major factors that impact amputation risk and clinical management: Wound, Ischemia, and foot infection (WIfI) 11.
- With these parameters, the surgeon can determine the need for and success of revascular procedures, and in determining levels of amputation/closure as well as wound management.
Indocyanine Green

- Indocyanine green (ICG) is an inert, water soluble, nonradioactive and nontoxic contrast agent, metabolized by the liver, and approved by the USFDA since 1959.
- After intravenous injection, ICG is distributed throughout the intravascular space, where it is rapidly bound to plasma proteins.
- ICG is contraindicated in patients allergic to iodine.
- ICG angiography (ICGA) has the potential to provide regional perfusion information lacking in standard Doppler-derived arterial pressure and waveform measurements. 5.
Advantages of ICGA

• With real time perfusion visualization, clinicians can give patients instant feedback about the diagnosis and treatment of the wound,

• Determine whether there is adequate blood flow, and make informed decisions in regards to the best treatment in each individual case for the best healing outcome.

• Intra-operatively, ICGA imaging can provide objective, quantifiable, and reproducible parameters of perfusion that can aid in determining the level of debridement or amputation in the foot.
Paradigm Shift

- Reduce infection by better sterile techniques and better perfusion.
- Better perfusion by recognizing ischemia

Retrospective:

- Identifying ischemia before infection and necrosis develops.
Other Disciplines for use of ICGA

Fluorescence imagining is commonly used in other medical procedures such as:

- Mastectomy and breast reconstruction
- Colorectal resections and anastamosis
- Head and neck reconstruction
- Facial plastic surgery
- Abdominal wall reconstruction
- Amputations (including replantation)
- Determining the need for hyperbaric oxygen therapy and wound care
Perfusion Assessment Technology

- **LUNA**
  - Fluorescence Imaging
- **PINPOINT**
  - Minimally Invasive Surgery
- **SPY Elite**
  - Open Surgery
History of Perfusion Assessment with Indocyanine Green (ICG)

First used in the 1970’s during retinal angiography

SPY fluorscence technology developed in 1999

SPY introduced to US market for cardiac surgery applications in 2005

SPY used to assess skin perfusion in plastic surgery in 2007

SPY FDA cleared for organ transplant and GI procedures

LUNA developed and introduced into outpatient procedures in 2013
Real Time Florescence Imaging

More than 130 peer-reviewed journal articles demonstrate that the use of SPY Fluorescence positively impacts outcomes and reduces healthcare costs.

Value = Quality/Cost
Intra-Operative Fluorescent System

- SPY (intra-operative) Fluorescent Imaging System utilizes a laser light source and distance sensor.
- The laser operates at a power density of 40 mW/cm², far below the hazard threshold of 200 mW/cm².
- ICG is taken up by almost exclusively by the hepatic parenchymal cells, and secreted entirely into the bile.
- Critical in the ESRD patient as it is not cleared via the renal system.
- The dye is non-toxic, and has a low incidence of adverse reactions (4 out of 240,000 doses).
Indocyanine Green

- Developed by Kodak in the 1950's
- Widely used in medical applications since the 1970's:
  - Retinal angiography
  - Liver function and cardiac output tests
- Strong record of safe clinical use
- Excreted hepatically – not contraindicated in patients with compromised renal function
- 3-5 minute half-life
- Only contraindication – should be used with caution in patients that have a history of sensitivity to iodides
Quantification
Fluorescence Imaging

- Fluorescence intensity can be viewed in:
- Grey scale with a greater white indicative of higher intensity.
- Heat map mode where red indicates higher intensity, and blue, lower intensity.
Case Presentation 1.

Heat Map

Grey Scale
Case Presentation 2.
Case Presentation 3.
Case Presentation 3.
Case Presentation 4.
Chronic Osteomyelitis
Enhancing intra-operative visualization of blood flow and tissue perfusion in real time
Predict where it's going to work
Presentation 5.
Case Presentation 6.

- 74 y.o female DM, CAD, HTN, arthritis, CKD, PAD, chronic osteomyelitis, hx critical lower limb ischemia s/p right pop-plantar arch bi pass 2014.
- Ischemic leg pain, bilateral feet. Right foot improved since surgery, but left has become progressively worse.
- LLE angiogram 7/15 reveals inline flow via left peroneal artery, SFA/pop patent with mild disease.
11/12/15 LLE B.K. popliteal to medial plantar bypass with reversed ipsilateral thigh GSV and angiogram.

Findings: Excellent ipsilateral thigh GSV from bulb to knee, 3 mm diameter.

Occluded P.T.A at malleolar level, occluded lateral plantar artery, small caliber -1.5 mm medial plantar artery
Vascular Intervention

- Reversed vein graft from BK popliteal artery to medial plantar artery with excellent graft dependent plantar signal.
- Excellent completion arteriogram.
- Toe wounds and heel ulcer edges now bleeding after incisions for bi pass closed. (no wound bleeding prior to bi pass).
Pre-Op Assessment-Gangrene
Game Changer- ICGA Intra-Op
Foot Preservation
Case Presentation 7.
Case Presentation 8.
Case Presentation 9.

- 82 year old female
- DM
- PVD
- CKD Renal Dialysis
- 1-week post op Fem-Pop Bypass
- Chronic ulcerations with osteomyelitis
Case Presentation 9.
Pre Op ICGA
Intra-operative blood flow
Post Op ICGA
Immediate Post op ICGA
Case Presentation 10.

69 y.o male hx of CAD, DM, PVD 6-months post debridement, acellular dermal matrix, and NPWT
Application STSG
2 Weeks Post STSG
Case Presentation 11.
Game Changer

- Analogy to a football game
- When the defense is blitzing and stunting
- The offensive line and backfield coaches need to alter their game plan.
- Adaptation to changing circumstances, in order to win.
- Limb preservation is a “win-win”.
What is Your Game Plan?
Conclusions

We need to be open to explore and be committed to adopt proven newer technologies and best practices.

Scott Spear, MD
Conclusions

- Utilizing Spy technology, intra-operative fluorescence angiography provides a minimally invasive tool to help determine tissue viability and perfusion to the extremities.
- The ICGA can be useful as a surgical planning option for the surgeon and informative tool for the patient.
- The SPY technology can help predict which tissues are viable (flaps), vs. those at risk lacking adequate perfusion.
- This can help determine at which level an amputation can be performed, and how well the closure site(s) will heal.
References


References


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