Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.JournalofSurgicalResearch.com

A prospective randomized double-blinded controlled trial evaluating indocyanine green fluorescence angiography on reducing wound complications in complex abdominal wall reconstruction

Blair A. Wormer, MD,[a] Ciara R. Huntington, MD,[a] Samuel W. Ross, MD, MPH,[a] Paul D. Colavita, MD,[a] Amy E. Lincourt, PhD,[a] Tanushree Prasad, MA,[a] Ronald F. Sing, DO,[a] Stanley B. Getz, MD,[b] Igor Belyansky, MD,[c] B. Todd Heniford, MD,[a] and Vedra A. Augenstein, MD[a,]*

[a] *Division of Gastrointestinal and Minimally Invasive Surgery, Department of Surgery, Carolinas Medical Center, Charlotte, North Carolina*

[b] *Division of Plastic Surgery, Department of Surgery, Carolinas Medical Center, Charlotte, North Carolina*

[c] *Department of Surgery, Anne Arundel Medical Center, Annapolis, Maryland*

ARTICLE INFO

Article history:
Received 5 December 2015
Received in revised form
10 January 2016
Accepted 20 January 2016
Available online 30 January 2016

Keywords:
Randomized trial
Abdominal wall reconstruction
Panniculectomy
Indocyanine green angiography
ICG
Wound complication

ABSTRACT

Background: The purpose of this prospective, randomized, double-blinded controlled trial was to investigate the utility of indocyanine green fluorescence angiography (ICG-FA) in reducing wound complications in complex abdominal wall reconstruction.

Materials and methods: All consented patients underwent ICG-FA with SPY Elite after hernia repair and before flap closure. They were randomized into the control group, in which the surgical team was blinded to ICG-FA images and performed surgery as they normally would, or the experimental group, in which the surgery team viewed the images and could modify tissue flaps according to their findings. Patient variables and wound complications were compared with standard statistical methods.

Results: Among 95 patients, $n = 49$ control *versus* $n = 46$ experimental, preoperative characteristics were similar including age (58.3 *versus* 56.7 y; $P = 0.4$), body mass index (34.9 *versus* 33.6 kg/m^2; $P = 0.8$), tobacco use (8.2% *versus* 8.7%; $P = 0.9$), diabetes (30.6% *versus* 37.0%; $P = 0.5$), and previous hernia repair (71.4% *versus* 60.9%; $P = 0.3$). Operative characteristics were also similar, including rate of panniculectomy (69.4% *versus* 58.7%; $P = 0.3$) and component separation (73.5% *versus* 69.6%; $P = 0.6$). The experimental group more often had advancement flaps modified (37% *versus* 4.1%, $P < 0.0001$). There was no difference between groups in rates of skin necrosis (6.1% *versus* 2.2%; $P = 0.3$), fat necrosis (10.2% *versus* 13.0%, $P = 0.7$), reoperation (14.3% *versus* 26.1%, $P = 0.7$), wound infection (10.2% *versus* 21.7%; $P = 0.12$), or overall wound-related complications (32.7% *versus* 37.0%, $P = 0.7$).

Presentation: 2016 Academic Surgical Congress, Abstract#: ASC20161435.

* *Corresponding author*. Division of Gastrointestinal and Minimally Invasive Surgery, Department of General Surgery, Carolinas Medical Center, 1025 Morehead Medical Drive, Suite #300, Charlotte, NC 28203. Tel.: +(704) 355 3168; fax: +(704) 355 5619.
E-mail address: vedra.augenstein@carolinashealthcare.org (V.A. Augenstein).

0022-4804/$ – see front matter
http://dx.doi.org/10.1016/j.jss.2016.01.029

Skin/subcutaneous hypoperfusion on ICG-FA was associated with higher rates of wound infection (28% *versus* 9.4%, $P < 0.02$), but flap modification after viewing images did not prevent wound-related complications (15.6% *versus* 12.5%, $P = 0.99$).

Conclusions: This is the first randomized, double-blinded, controlled trial to evaluate ICG-FA in abdominal wall reconstruction. Although ICG-FA guidance and intraoperative modification of flaps did not prevent wound-related complications or reoperation, it did identify at risk patients.

Introduction

Starting in the late 1990s, indocyanine green fluorescence angiography (ICG-FA) has become a major adjunct to reconstructive surgery in evaluating microcirculation and tissue viability.[1,2] Although used in numerous fields of surgery, it has garnered a strong foothold in soft-tissue surgery[3,4] where it has been successful in predicting wound complications in breast reconstruction by determining flap viability and need for intraoperative modification of potential sites of skin necrosis.[5,6] Due to the promising results from this technology in preventing soft-tissue complications, there has been expansion of applying ICG-FA to complex ventral hernia repair (VHR) and abdominal wall reconstruction (AWR).[7–10]

With over 54% of Americans having abdominal obesity,[11] AWR has become increasingly challenging, often being performed in conjunction with concomitant panniculectomy and/or component separation techniques (CSTs) for abdominal wall closure.[12–16] In addition to the increased surgical and postoperative risks of obesity, the addition of advanced techniques, especially concomitant panniculectomy has been shown to increase rates of wound infection, incidence of reoperation, and overall wound complications 5-fold.[12,17,18] CST, popularized by Ramirez *et al.*[19] in 1990, may additionally compound morbidity in AWR with wound complications such as skin necrosis in up to 57% of patients.[20,21] Underscoring the significance in reducing the burden of postoperative complications after complex AWR is the fact that more than $3.2 billion is spent annually on VHR in the United States[22] and that individual wound complications cost an average of more than $47,000 each.[23] Knowing this, any technique or adjunct to surgery that can reduce the rate of wound complications in complex VHR will have profound effects on patients, health care providers, and the financial burden of the entire health care system.

AWR appears to be an obvious candidate for intervention with ICG-FA due to the frequent need to undermine large subcutaneous skin advancement flaps, potential for sacrificing perforating vessels during CST, and high risk of wound complications described previously. A few retrospective case series that evaluate ICG-FA in AWR have demonstrated promising results for identifying skin and subcutaneous hypoperfusion as potential sites of wound complications.[7,9,10] The largest series to date, performed by our group as a preliminary analysis of this technology and a pilot for the present study, demonstrated in a blinded study a sensitivity of 100% and specificity of 90.9% for predicting wound complications using ICG-FA in AWR.[8] These results were encouraging but required a higher level of evidence with prospective investigation of ICG-FA's predictive value and therapeutic effect on preventing wound complications.

Herein, the authors report the results of a prospective, randomized, double-blinded, controlled trial using ICG-FA to reduce postoperative wound complications in AWR. In this study, all patients underwent ICG-FA to evaluate for abdominal wall hypoperfusion and were randomized into a control group, where the surgeon could not view the images and performed the surgery as usual, or into an experimental group. In the experimental group, the surgeon and the surgical team could view the images and perform intraoperative modifications at the surgeon's discretion and also as dictated by the ICG-FA. Our objective was to evaluate both the diagnostic accuracy of ICG-FA in predicting wound complication and the therapeutic effect of surgeon intervention on intraoperative ICG-FA findings. The authors hypothesized that ICG-FA would predict potential wound complications based on sites of hypoperfusion and that the experimental group would have decreased postoperative wound complications resulting from subsequent flap modification of poorly perfused areas seen on ICG-FA imaging.

Materials and methods

Patient population

The authors performed a two-center prospective, randomized control trial on elective AWR patients who presented to Carolinas Hernia Center at Carolinas Medical Center, Charlotte, North Carolina and Anne Arundel Medical Center, Annapolis, Maryland. Consecutive patients who met inclusion/exclusion criteria (Table 1) were enrolled from October 2012 to February 2015. Both sites are specialized hernia centers, which receive local, state, national and international referrals, and have a high percentage of complex, multiply recurrent incisional hernias in high-risk patients. AWR with concomitant CST and panniculectomy are frequently required, and AWR was conducted with one of four hernia surgeons in conjunction with a single plastic and reconstructive surgeon at each site when panniculectomy was performed.

Study design

Before initial enrollment, institutional review board approved the study for patient accrual at each participating center (Carolinas Medical Center IRB#: 10-11-06A, Anne Arundel Medical Center IRB#: 53-11-47) and registered at clinicaltrials.gov (NCT#01886963; NCT Title: A Randomized, Prospective,