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Utility of indocyanine green (ICG) intra-operative angiography to determine uterine vascular perfusion at the time of radical trachelectomy

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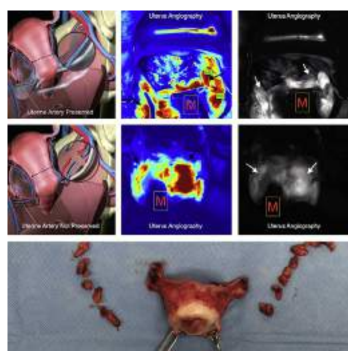
HIGHLIGHTS

- There is no need to preserve the uterine artery during radical trachelectomy
- ICG fluorescence angiography allows assessment of tissue blood flow and perfusion during surgery
- Radical trachelectomy is a safe surgical option for patients presenting with early-stage cervical cancer

GRAPHICAL ABSTRACT



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ABSTRACT

Objectives. The aim of our study was to measure and analyze uterine perfusion utilizing laser angiography with ICG during uterine artery sparing and non-sparing radical trachelectomy.

Methods. Data were collected from all patients diagnosed with early-stage cervical cancer that underwent laser angiography with ICG during open or laparoscopic radical trachelectomy from June 2012 to December 2015. Regression analysis was use to determine the p values and R-squares on fluorescence, surgical time, hospital stay, age and BMI; a p-value < 0.05 was considered statistically significant.

Results. A total of 20 patients met the inclusion criteria and were included in this study. Ten patients underwent uterine artery-sparing surgery, and ten patients underwent uterine artery non-sparing surgery. The most frequent stage for the entire cohort was IA2 (55%), and the most common histologic subtype was squamous cell carcinoma (49%). Lymph-vascular invasion was noted in 30% of the patients. There was no statistical significance difference in the mean ICG fundal fluorescence intensity between the uterine artery-sparing group 162.5 (range, 137–188) and the uterine artery non-sparing group 160.5 (range, 135–186), $p = 0.22$. In both groups, 100% of the patients regained their menstrual function by postoperative week 8. A total of 4 (40%) pregnancies have occurred in the uterine artery-sparing group and 3 (30%) in the non-uterine artery-sparing group.

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Conclusions. Based on our real-time intraoperative angiography observations, there is no need to preserve the uterine artery during radical trachelectomy to maintain uterine viability.

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1. Introduction

Radical trachelectomy is a safe surgical option for patients presenting with early-stage cervical cancer and desiring future fertility. In a recent systematic review that included 485 abdominal radical trachelectomies, the reported pregnancy rate was 16.2%, and relapse and death rates were 3.8% and 2.9%, respectively [1]. Similar outcome data has been reported for laparoscopic trachelectomies by the Asian Gynecologic Cancer Group (AGCG), with a pregnancy rate of 23.9% and a relapse and death rate of 6% and 1.7%; respectively [2].

Although there is extensive literature confirming the safety and feasibility of radical trachelectomy, there are several important issues of discussion about this topic. One of the most frequently debated issues is whether uterine artery preservation should be the norm when performing radical trachelectomy or whether it is safe to transect the uterine vessels. One theoretical concern is that by coagulating the uterine vessels one may predispose the patient to have vascular compromise to the uterus and thus adverse impact the potential for future fertility in such patients [3–5].

In the past, X-ray angiography and Doppler ultrasonography were the only commonly available methods for real-time imaging of organ perfusion/viability and evaluation of blood flow intraoperatively during tissue/flap grafting and transplantation. More recently, other tools have become available to evaluate tissue perfusion. Among these, is indocyanine green (ICG), which is a tri-carbocyanine dye that fluoresces in the near-infrared spectrum when illuminated with 806 nm light. The fluorescent light is then captured using a particular video camera device that enables the ICG to be displayed in the visible light spectrum. Real-time observation of blood flow during surgery is possible using ICG fluorescence imaging. This technology has quickly gained popularity, and its use has expanded to an evaluation of graft vessels [6] in coronary bypass surgery and blood flow evaluation in reconstructed organs such as free flaps [7–9]. The aim of our study was to measure and analyze uterine perfusion utilizing laser angiography with ICG during uterine artery sparing and non-sparing radical trachelectomy. We hope to shed light on this novel tool and its application when performing radical trachelectomy in patients with early-stage cervical cancer.

2. Materials and methods

The study was conducted after Institutional Review Board approval was obtained. Data were collected from all patients diagnosed with early-stage cervical cancer that underwent laser angiography with ICG during open or laparoscopic radical trachelectomy from June 2012 to December 2015. Patients were considered ideal candidates for radical trachelectomy if they met any of the following criteria: strong desire to preserve fertility, a histologic diagnosis of invasive squamous, adenocarcinoma or adenosquamous cervical cancer, a tumor size <2 cm, stage IA1 with LVSI, IA2 or IB1, a preoperative imaging with pelvic MRI or PET/CT that ruled out metastatic disease, and age < 40 with no prior infertility diagnosis. When the surgical margin was grossly positive or close (<5 mm) during frozen section analysis for invasive cancer, the patient underwent resection of additional tissue. If this was not possible, then immediate conversion to radical hysterectomy was elected.

Data extracted included a patient's age at diagnosis, race, body mass index, pregnancy history, preoperative imaging. Findings in the preoperative pelvic examination, operative times, estimated blood loss, preservation of uterine arteries, use of cerclage, blood transfusions, the length of hospital stay, duration of follow-up, and incidence of intraoperative complications were recorded. Pathologic data included tumor histologic subtype and grade, residual tumor, surgical margin, parametrial compromise, presence or absence of lymph-vascular space invasion, the number of lymph nodes removed and nodal status.

The surgical approach was based on a preoperative discussion with the patient regarding the risks and benefits of the different surgical procedures. Uterine preservation vs. no preservation was based on vascular anatomy during the case as well as surgeon preference. The surgical technique for open and laparoscopic radical trachelectomy, have been previously published [10–12]. The uterine artery and vein, as well as the vessels of the infundibulum-pelvic ligament, were carefully dissected; patients underwent laser angiography with ICG utilizing the SPY Elite Imaging System (Novadaq Technologies Inc. British Columbia, Canada) for open radical trachelectomy and the PINPOINT Endoscopic Fluorescence Imaging (Novadaq Technologies Inc. British Columbia, Canada) for the laparoscopic radical trachelectomy.

The SPY system uses an intensity scale from 1 to 256 that objectively quantifies the light emitted from the tissue. This scale was used to compare the intensity of light (perfusion) emanated from the uterus and adnexa during uterine artery sparing and non-sparing surgical technique. To obtain an objective comparison of the intensity (perfusion) of the uterus, the average of intensity values in the uterine fundus and adnexa was calculated for the uterine artery sparing technique. This average was then compared with the intensity value standards for the uterine artery non-sparing technique. Similarly, qualitative observations were obtained utilizing the Pinpoint system. We measured the uterine perfusion at baseline, then 1–3 min after the ICG IV injection and recorded the ultimate level of perfusion in the uterus and surrounding tissues with and without color-segmental analysis during uterine artery sparing and non-sparing technique. Statistical analyses were performed using SAS 9.3 for Windows g(Copyright © 2002–2010 by SAS Institute Inc., Cary, NC). Regression analysis was use to determine the p values and R-squares on fluorescence, surgical time, hospital stay time, age and BMI; a p-value < 0.05 was considered statistically significant.

3. Results

A total of 20 patients met the inclusion criteria and were included in this study. Ten patients underwent uterine artery-sparing surgery, and ten patients underwent uterine artery non-sparing surgery. There were no statistical differences in age, BMI, tumor histology, or stage between the sparing and non-sparing groups. The median age for the uterine artery-sparing surgery group was 28 years (range, 21–35). The median body mass index was 25.8 kg/m^2 (range, 19.5–32) in this group. The median age for the uterine artery-non-sparing surgery group was 30.6 years (range, 21–40). The median body mass index was 24.75 kg/m^2 (range, 18.5–31) in this group.

The most frequent stage for the entire cohort was IA2 (55%), and the most common histologic subtype was squamous cell carcinoma (49%). Lymph-vascular invasion was noted in 30% of the patients. Overall, 13 (60%) patients underwent an open radical trachelectomy, and seven patients (40%) underwent MIS (laparoscopic) trachelectomy. Patients undergoing a uterine artery-sparing approach had significantly longer surgical times than patients undergoing a non-sparing approach (260 min (range, 150–370) vs. 240 min (range, 180–300); respectively, ($p = 0.048$). Patients undergoing non-sparing surgery had significantly lower median blood loss than patients undergoing uterine-artery sparing surgery (65 mL (range, 50–80) vs. 150 mL (range, 100–200); respectively ($p = 0.0002$)) (Table 1).

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Table 1
Patient characteristics and outcomes.

	Uterine artery sparing surgery (N = 10)		Non uterine artery sparing surgery (N = 10)		p value
Median BMI	25.8 kg/m^2 (19.5–32)		24.75 kg/m^2 (18.5–31)		$p = 0.20$
Mean hospital stay time	35.5 h (23–48)		27 h (24–30)		$p = 0.42$
Median age	28.4 years (21–35)		30.6 years (21–40)		$p = 0.10$
Median duration of surgery	260 min (150–370)		240 min (180–300)		$p = 0.048$
Median estimated blood loss	150 mL (100 − 200)		65 mL (50–80)		$p = 0.00020$
Blood transfusions	0		0		
Lymph vascular invasion	1 (10%)		2 (20%)		
Regain of menstrual function	10 (100%)		10 (100%)		
ICG fundal fluorescence (intensity laparotomy)	162.5 (range 137–188)		160.5 (range 135–86)		$p = 0.22$
Number of nodes removed	25.2 (range 16–32)		27.5 (range 19–36)		$p = 0.07$
Tumor histology	Squamous	6 (60%)	Squamous	5 (50%)	
	Adenocarcinoma	4 (40%)	Adenocarcinom	3 (30%)	
	Mixed	0 (0%)	Mixed	2 (20%)	
Tumor stage	IA1 + LVSI	2 (20%)	IA1 + LVSI	2 (20%)	
	IA2	5 (50%)	IA2	5 (50%)	
	IB1	3 (30%)	IB1	3 (30%)	

After administration of 2 mL of 2.5 mg/mL of ICG flushed by 9 mL of intravenous sterile saline IV push, ICG angiography readings were obtained. The uterus reached maximal intensity levels of 225 (on a scale of 1 to 256). Following the radical trachelectomy, there was no statistical significance difference in the mean ICG fundal fluorescence intensity in the uterine artery-sparing group 162.5 (range, 137–188) and the uterine artery non-sparing group 160.5 (range, 135–186), $p = 0.22$ (Fig. 1). Intra-operative laser angiography laparoscopically

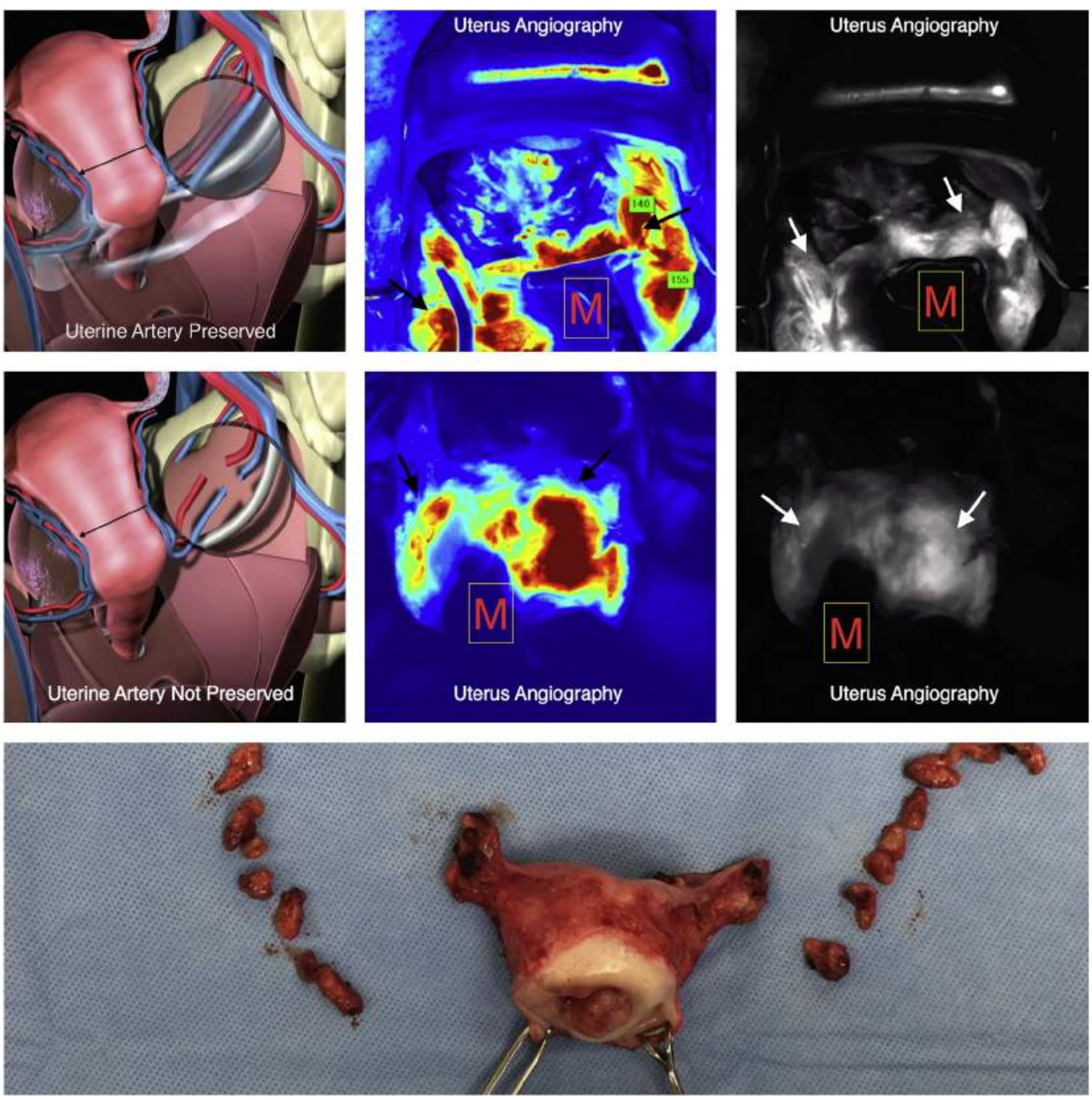

Fig. 1. ICG fluorescence angiography, M - manipulator.

demonstrated similar fundal perfusion with color segmental analysis between patients who underwent uterine artery sparing surgery vs. uterine artery non-sparing surgery (Video 1). The entire uterus including the cervical stump was evaluated during real time fluorescence angiography. On the video, it appears to be an area in the lower uterine segment - cervical stump with less perfusion under color segmental analysis, however, this finding was not confirmed when the tissue was evaluated under fluorescence or SPY mode. No cervical stenosis was observed in the cohort.

There were two intra-operative complications, one incidental cystotomy, recognized and repaired in two layers with 3–0 Vicryl suture, and one genitofemoral nerve injury. Neither of these patients experienced long-term sequela. Post-operatively, two patients (10%) had urinary tract infection, and one patient had a wound-skin infection, both treated accordingly with antibiotics.

In both groups, 100% of the patients regained their regular menstrual function by postoperative week 8. Excluding the one patient that underwent a hysterectomy due to a positive frozen section margin and the six patients that were lost to follow-up; the median follow-up time for all patients was 22 months [range 1–32]. A total of 4 (40%) pregnancies have occurred in the uterine artery-sparing group, and two resulted in a first-trimester loss, and 2 in pre-term deliveries (34–37 weeks). In the non-uterine artery-sparing group, there were three pregnancies (30%). One resulted in a first-trimester loss, one in a preterm delivery at 37 weeks, and one in a term pregnancy.

4. Discussion

Our study showed that ICG fluorescence angiography provides real-time evaluation of uterine perfusion after radical trachelectomy in patients with early-stage cervical cancer. Compared with conventional intraoperative X-ray angiography, ICG laser angiography has the advantages of minimal to no uptake by peripheral tissues, rapid elimination from the circulation (half-life, 2–3 min), a potential for repeated uses, no need for surgeon or operative staff shielding, and comparatively high safety with few side effects.

The uterus has three primary sources of blood supply (ovarian, uterine, and vaginal vessels). Uterine blood flow is a significant factor in uterine viability, but the number of blood vessels required to maintain viability is uncertain, variable and debatable. Utilizing female cynomolgus macaques and ICG fluorescence imaging, Kisu et al. cut the uterus from the vaginal canal to mimic a trachelectomy or uterine transplantation surgery in which uterine perfusion was maintained only with uterine and ovarian vessels (uterine artery-sparing) technique. The investigators found that uterine vessels may be responsible for uterine blood flow, and even one uterine vessel may be sufficient to maintain uterine viability in cynomolgus macaque. [13].

Contrary to the primate data mentioned above, our study suggests that the ovarian vessels may be the primary source of vascularization to maintain uterine viability in humans. In our study, during open radical trachelectomies, the SPY camera was used to track ICG into the uterine fundus pre- and post-trachelectomy with both uterine artery-sparing and non-sparing techniques and to quantify the intensity of the light emitted. There was no statistical significance difference in the mean ICG fundal fluorescence intensity readings of uterine perfusion regardless of uterine artery preservation (Fig. 1). These were also confirmed by the PINPOINT endoscopic fluorescence imaging system utilizing three modes (fluorescence, SPY fluorescence and SPY CSF (Color Segmented Fluorescence)), demonstrating that ovarian vessels alone sufficiently perfused the uterus regardless of uterine artery preservation.

To date, two manuscripts have addressed previously uterine perfusion after radical trachelectomy. The first report, from Tang et al. [14], including 26 patients (the uterine arteries were preserved in 16 and ligated in 10 of them) who underwent computed tomography angiography (CTA), demonstrated 87.2% rate of unilateral or bilateral uterine artery oclusión when these vessels were spared. More recently, Makino et al. [15] using dynamic contrast-enhanced (DCE) magnetic resonance (MR) imaging, showed no differences in uterine enhancement rate in ten patients underwent uterine sparing abdominal radical trachelectomy, with serial measurements done preoperatively, 1 and three months after radical abdominal trachelectomy.

Almost 20 years ago, Smith et al. [10] in their first description of the technique, emphasized the need to preserve the uterine artery when doing an abdominal radical trachelectomy; in fact, some authors have tried to maintain or even, re-anastomose the uterine vessels in order to “preserve” the uterine blood supply [16,17]. In 2005, Ungar et al. [18], published the largest series on radical abdominal trachelectomy at that time, including 33 patients, and all of them underwent uterine artery ligation at its origin. All the patients, but two, resumed their menses. The literature is heterogeneous regarding whether ligate or not uterine artery; some authors use to ligate the uterine artery in all of their patients [19–22]; other authors always preserved the uterine arteries [23–26] and another group published papers on ligation/no ligation at a variable proportion [27–29]. Interestingly, Nishio's et al. [23], where all the patients spared their uterine arteries, the amenorrhea rate reached 8%. The largest available systematic literature review, including almost 500 patients undergoing radical abdominal trachelectomy [1], showed a re-assuming menses rate of 97.8% (428/438), regardless uterine artery preservation or not.

Return of menstrual function after radical trachelectomy sparing or non-sparing the uterine arteries is a surrogate marker not only for tissue viability (adequate uterine perfusion) but also of proper physiological function of the uterus. Furthermore, in this small series, there were no differences in pregnancy rates between the uterine-artery sparing and non-sparing cohorts, although the follow-up time may be short to draw conclusive evidence of equivalency definitively.

To our knowledge, our study represents the first evaluation of ICG fluorescence angiography in patients undergoing radical trachelectomy to evaluate uterine perfusion. Based on our real-time intraoperative angiography observations, there is no need to preserve the uterine artery during radical trachelectomy to maintain uterine viability.

There are, however, several limitations to this study. The most significant limitation is the retrospective nature and small sample size of the study, as well as the implications inherent in such a design. It can also be argued that the gold standard for the objective measure of blood flow intra-operatively, such as in tissue grafts or vascular anastomosis, is Doppler ultrasonography, including calculation of flow velocity and indices such as the pulsatility index [PI] and resistance index [RI]. ICG laser angiography currently lacks the software to acquire such objective measurements. However, most of these actual measurements by Doppler ultrasonography are usually performed in large and straight arteries and veins, making the evaluation of blood flow in the genital system using such systems particularly challenging. Finally, 6 patients (30%) of the cohort were loss to follow-up, which may be considered significant.

In summary, ICG fluorescence angiography allows the surgeon to assess the quality of blood flow clinically in vessels, and related tissue perfusion including identification of anatomical vascular variants in real time, demonstrating that there is no need to preserve the uterine artery during radical trachelectomy to maintain uterine viability.

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.ygyno.2016.08.239.

Conflict of interest statement

None of the authors have a conflict of interest for this work.

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