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ORIGINAL ARTICLE

Clinical application and technical standardization of indocyanine green (ICG) fluorescence imaging in pediatric minimally invasive surgery

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Abstract

Purpose We reported our preliminary experience using ICG fluorescence in pediatric minimally invasive surgery (MIS) with the aim to standardize indications, dose, timing, and modality of administration of ICG according to different organs.

Methods ICG technology was adopted in 46 MIS procedures performed in our unit over the last 18 months: 30 left varicocele repairs; 5 cholecystectomies in obese adolescents; 3 tumor excisions; 3 nephrectomies; 2 partial nephrectomies; 3 lymphoma excisions. ICG solution was injected intravenously in all cases except for varicocelectomy in which it was injected into the testis. The ICG injection was performed intra-operatively in all cases except for cholecystectomy in which it was injected 18 h prior to the procedure.

Results All procedures were completed laparoscopically without conversions or intra-operative complications. No adverse or allergic reactions to ICG were reported.

Conclusion Our preliminary experience showed that ICG fluorescence is a safe, useful, and versatile technique to adopt in pediatric MIS to achieve a better identification of anatomy and an easier surgical dissection or resection in challenging cases. Currently, the main indications are varicocelectomy, difficult cholecystectomy, tumor excision, nephrectomy, and partial nephrectomy. The main limitation is the needing of a special equipment to use ICG technology.

Keywords Indocyanine green · Fluorescence · Technology · Children · Laparoscopy · MIS

Introduction

In recent years, important advancements in minimally invasive surgery (MIS) have been reported, including the use of high definition (HD) and three-dimensional (3D) imaging systems. In the last few years, use of indocyanine green (ICG) fluorescence imaging has changed the intra-operative decision process in MIS [1–4]. As a near-infrared (NIR) imaging agent, ICG can be traced real time in high resolution, is cost effective and is broadly applicable. Moreover, it has FDA and EMEA approval to be used for imaging blood flow and, therefore, it may be used off-label as a lymphatic tracer in clinical trials [5, 6]. In its first clinical applications, ICG was used for evaluation of cardiac output, anatomy of retinal vessels, and liver residual function in cirrhotic livers [7–9]. Later, ICG fluorescence imaging has also been adopted during laparoscopic procedures with the aim to improve visualization of anatomic structures intra-operatively [6]. Fluorescence is produced by a specific fluorophore (indocyanine green, ICG) when excited using near-infrared (NIR) light and it is visualized using specific cameras and optics. After intravenous injection, ICG is rapidly ligated to different carriers, mainly represented by albumin [10]. ICG undergoes no significant extrahepatic or enterohepatic circulation; it is taken up from the plasma almost exclusively by the hepatic parenchymal cells and is entirely secreted by the liver into the bile. For visualization of efferent lymph vessels, ICG is injected in the peritumoral area, reaching the nearest draining lymph node within 15 min [11]. Current applications of ICG lymphography are for sentinel lymph node biopsy and navigation in tumors of different organs including breast, stomach, colon, melanoma [12–15]. ICG

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technology has also been adopted to perform intra-operative angiography to identify the vascular anatomy or to evaluate the perfusion of different organs or tumors [16, 17]. Analyzing the international literature, there are few publications focused on the use of ICG fluorescence imaging in adult laparoscopy, mostly related to the use of ICG to check vascularization of intestinal anastomoses, to identify pathologic nodes in case of tumors or for biliary pathologies [18–21]. However, no paper exists about the use of ICG-enhanced fluorescence in pediatric patients. We reported our preliminary experience using ICG technology in pediatric MIS procedures with the aim to standardize indications, dose, timing, and modality of administration of ICG according to different organs.

Materials and methods

We started to adopt ICG technology more than 18 months ago in the new integrated operative rooms of our Division of Pediatric Surgery, that are equipped to use this new technology. In fact, a special camera system and a laparoscope equipped with a special filter are required to use this technology so as the product (ICG) that is available in vials (5 mg/ml) to be reconstituted with distillate water before injection. As for laparoscopic equipment, a laparoscopic system (KARL STORZ GmbH and Co. KG, Tuttlingen, Germany) was used in all cases. The imaging is generated by the high-end full high definition camera system (IMAGE1 S, KARL STORZ) connected to a 0° or 30° optic according to the procedure equipped with a specific filter for optimal detection of the NIR fluorescence and standard white light imaging. Two modes can be adopted for NIR visualization, blue and green. The powerful xenon light source (D-LIGHT P SCB, KARL STORZ) provides both visible and NIR excitation light. Switching from standard white light mode to NIR mode (blue or green) is controlled by the surgeon via foot pedal control. Visualization in both standard and NIR light is improved by a system of professional image enhancement (IMAGE1 S system, KARL STORZ GmbH and Co. KG, Tuttlingen, Germany) which offers adjustable imaging modalities that can be selected according to surgeon's preferences. ICG technology was adopted in 46 pediatric patients who underwent MIS procedures for different indications in our unit over the last 18 months. These included 30 laparoscopic left Palomo varicocele repairs with intra-operative fluorescence lymphography; 5 laparoscopic cholecystectomies in obese adolescents; 3 laparoscopic excisions of abdominal masses; 3 laparoscopic excisions of lymphomas; 3 laparoscopic nephrectomies, and 2 laparoscopic partial nephrectomies. Indocyanine green (Verdye, Pulsion Medical Systems, Munich, Germany), diluted with distilled water, was adopted in all the procedures. Once the ICG solution was reconstituted in the operating room, it was injected intravenously in all cases except for patients with varicocele in whom the ICG solution was directly injected into the testis. Details of the timing, dosages, and modality of administration of ICG, varying according to each procedure, are reported below.

Results

All the procedures were successfully accomplished laparoscopically without conversions to open surgery. No adverse or allergic reactions to ICG injection were reported in our experience. However, all the patients and their parents signed pre-operatively a specific informed consent, according to the specific surgical procedure.

ICG fluorescence-guided laparoscopic cholecystectomy

An elective ICG fluorescence-guided laparoscopic 4-trocars cholecystectomy was performed in five adolescents (three boys and two girls). The average patients' age was 15.8 years (range 8–17) and all patients were obese (mean BMI 32.2 ± 3.5 kg/m^2). In all cases, the ICG dye was injected into a peripheral vein 18 h prior to the procedure using a dosage of 0.4 mg/kg. In this way, it was made sure that most of the agent had accumulated in the extrahepatic duct, while absence of fluorescence was typically noticeable in the liver parenchyma. The gallbladder and the biliary anatomy (cystic duct, CD; common hepatic duct, CHD; common biliary duct, CBD) were clearly identified in all cases, especially the CD–CBD junction, irrespectively of the presence of abundant fatty tissue or severe inflammation and adhesions between the gallbladder and surrounding tissues (Fig. 1). In most cases, ICG-enhanced fluorescence imaging allowed to identify extrahepatic biliary anatomy without or with minimal dissection of Calot's triangle. The average operative time was 52 ± 15 min. No intra- or post-operative complications were reported in all cases.

ICG fluorescence-guided laparoscopic Palomo varicocelectomy

An ICG fluorescence-guided laparoscopic left Palomo varicocelectomy associated with intra-operative fluorescence lymphography was performed in 30 boys. The average patients' age was 16.7 years (range 8–18) and the average weight was 65.4 kg (range 35–90). After pneumoperitoneum induction, the posterior peritoneum covering the inner spermatic vessels (ISV) was opened performing a 2-cm T-shaped incision with the monopolar hook, at a distance of about 3–4 cm from the internal inguinal ring. After this step, a

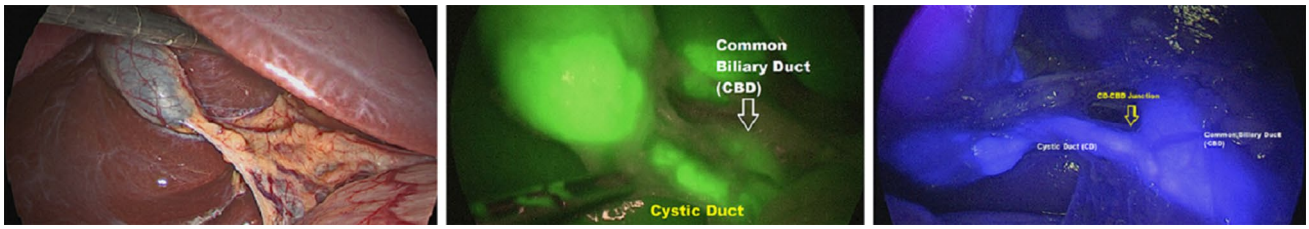

Fig. 1 Identification of the biliary anatomy (cystic duct, CD; common biliary duct, CBD; CD–CBD junction) using ICG-enhanced fluorescence (green and blue mode) during laparoscopic cholecystectomy

vial of ICG was diluted with 8 ml of distilled water and 2 ml of this ICG solution was directly injected into the left testicle using a 23G needle. Using the near-infrared mode, the lymphatic vessels appeared fluorescent (blue or green) and were clearly identified and spared (Fig. 2), then the entire spermatic bundle was clipped and divided according to Palomo's principle. Also using the standard white light mode, the lymphatics were clearly visible because they appeared green colored (Fig. 2). The average operative time was 18 ± 16 min. No intra-operative complications occurred and no patients experienced any testicular pain or damage secondary to the intra-testicular injection, either early or late following surgery. One patient (3.3%) presented post-operatively umbilical port-site infection, treated with oral antibiotics and local therapy (II Clavien). At a maximum follow-up of 18 months, no recurrence or persistence of varicocele was reported and no cases of testicular atrophy or post-operative hydrocele were observed.

ICG fluorescence-guided laparoscopic excision of abdominal masses

ICG-enhanced fluorescence was adopted during laparoscopic removal of abdominal masses (three abdominal lymphomas and three abdominal tumors). The average patients' age was 3.8 years (range 2–8.5) and the average weight was 23.9 kg (range 13.8–35). ICG-enhanced fluorescence imaging was performed after ICG injection into a peripheral vein at a dosage of 0.5 mg/kg and provided a "real-time snapshot" of bowel perfusion. In these cases, ICG fluorescence was very useful to identify the vascular anatomy of the abdominal mass, to define the ideal plane of resection during mesenteric division, to identify the nodes to biopsy or to remove and finally to confirm the adequate perfusion of the bowel prior to anastomosis in patients who underwent bowel resection and re-anastomosis (Fig. 3). For assessment of the bowel perfusion, diluted ICG was injected using two boluses of 3 ml, each at a concentration of 0.2 mg/kg. The first bolus was administered after mesenteric division and facilitated resection by providing relevant informations on well-perfused areas. The second bolus was administered prior to bowel anastomosis to confirm adequate vascularization. The average operative time was 142 ± 11 min. No intra- or postoperative complications were reported in all cases.

ICG fluorescence-guided laparoscopic nephrectomy

ICG-enhanced fluorescence was adopted during laparoscopic nephrectomy in three patients (two boys and one girl). The average patients' age was 5.8 years (range 1–10) and the average weight was 29.7 kg (range 11–37). The nephrectomy was performed to remove a non-functioning kidney secondary to severe hydronephrosis in two cases and reflux nephropathy in one patient. In all cases, the ICG dye was injected into a peripheral vein after dissection of the Gerota's fascia, using a dosage of 0.5 mg/kg. We used ICG-enhanced fluorescence to clarify the vascular anatomy before hilar dissection, above all in patients with severe adhesions

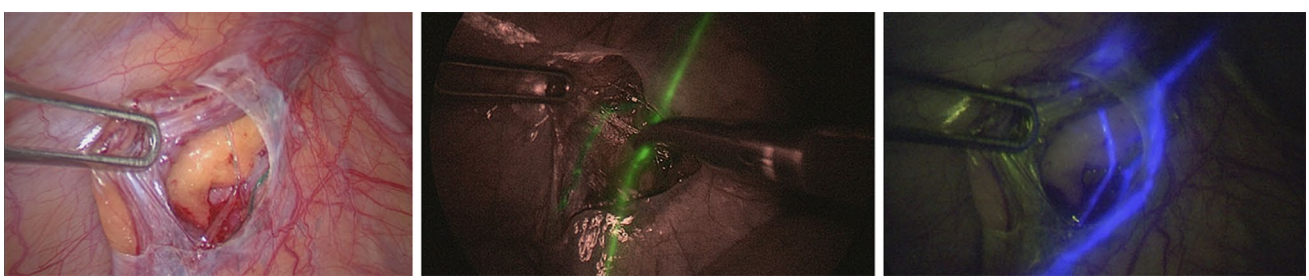

Fig. 2 Following intra-testicular injection of ICG, the lymphatics appeared green colored using the standard white light mode whereas they appeared fluorescent (green or blue) using the near-infrared mode

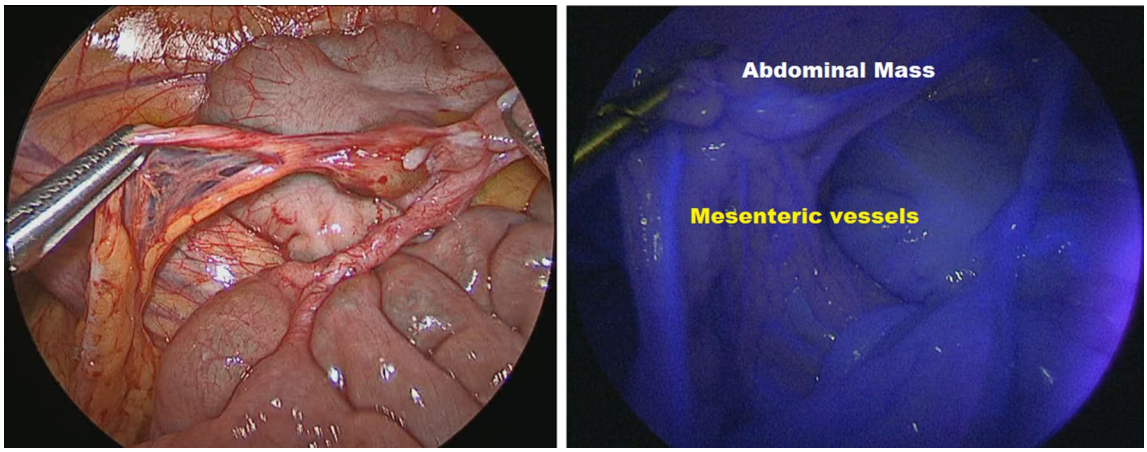

Fig. 3 ICG-enhanced fluorescence allowed identification of anatomy of the abdominal mass and to define its relationship with mesenteric vessels

and fibrosis of the perirenal tissues. The initial pass of the dye was seen as fluorescence of the artery and then the renal vein, followed by the renal parenchyma under NIR imaging (Fig. 4). The average operative time was 68 ± 13 min. No intra- or post-operative complications were reported in all cases.

ICG fluorescence-guided laparoscopic partial nephrectomy

ICG-enhanced fluorescence was adopted during laparoscopic upper pole partial nephrectomy in two boys. The average patients' age was 2.8 years and the average weight was 15.7 kg. The partial nephrectomy was performed to remove a symptomatic non-functioning upper pole in duplex kidney associated with severe hydronephrosis and obstructive megaureter. In all cases, the ICG dye was injected into a peripheral vein after dissection of the Gerota's fascia, using a dosage of 0.3 mg/kg. We used ICG-enhanced fluorescence to clarify the vascular anatomy of upper pole and to better define the demarcation line between upper and lower pole after division of supplying vessels (Figs. 5, 6). The average operative time was 85.5 ± 9 min. No intra- or post-operative complications were reported in all cases.

Discussion

In recent years, important advancements in minimally invasive surgery (MIS) have been reported, including the use of high definition (HD) and three-dimensional (3D) imaging systems. In the last few years, the use of indocyanine green (ICG) fluorescence imaging has changed the intra-operative decision process in MIS [1–4]. More recently, ICG fluorescence imaging has also been adopted during laparoscopic procedures with the aim to improve visualization of anatomic structures intra-operatively [6]. The ICG dye may be injected intravenously with no reported adverse reactions.

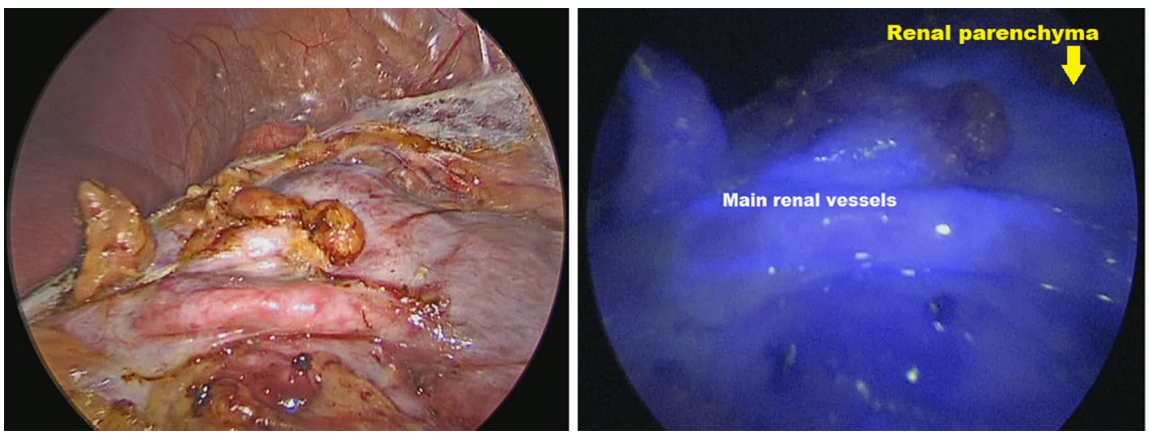

Fig. 4 ICG-enhanced fluorescence allowed an easier identification of main renal vessels during laparoscopic nephrectomy

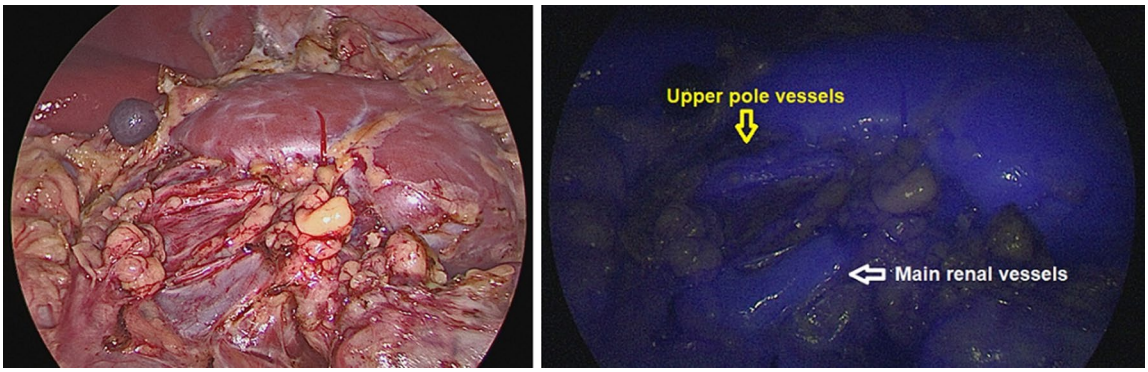

Fig. 5 ICG-enhanced fluorescence allowed an easier identification of the vascular anatomy during upper pole partial nephrectomy

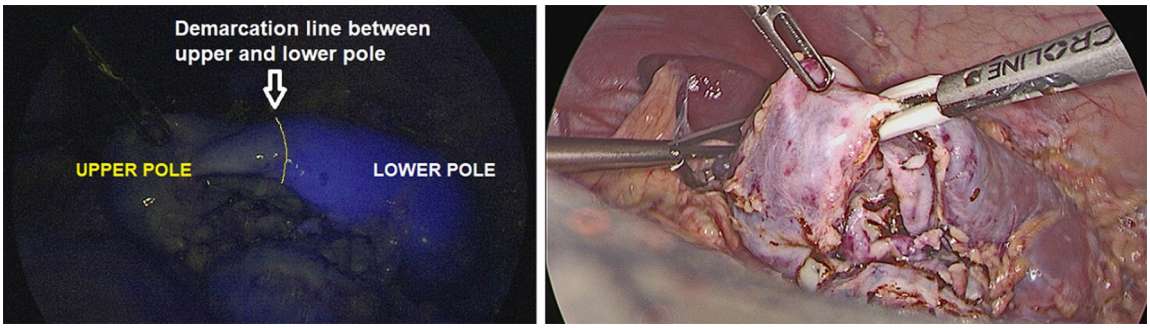

Fig. 6 ICG-enhanced fluorescence showed a clear demarcation line between upper and lower pole during upper pole partial nephrectomy

Fluorescence is produced by exciting the fluorophore ICG with a specific wavelength light (approximately 820 nm) in the near-infrared (NIR) spectrum and it is visualized using specific cameras and optics [3, 17]. Most of the papers published on application of ICG fluorescence in laparoscopic surgery are focused on adult population [17–21]; no data are currently available in the pediatric population.

Since ICG is secreted entirely by the liver into the bile, the visualization of the biliary tree and in particular of the anatomy of Calot's triangle is one of the most common and useful applications [18]. In fact, iatrogenic biliary tract injury, generally due to misinterpretation or poor visualization of biliary tree anatomy, still represents one of the most dangerous complications of cholecystectomy, with an incidence ranging between 0.4 and 1.3%, [22, 23]. So, a careful and precise dissection of the Calot's triangle, possibly combined with an intra-operative cholangiogram, has been demonstrated to reduce the risk of intra-operative injury of biliary ducts [24, 25]. As shown by our experience, ICG fluorescence imaging allowed to perform an intra-operative "virtual cholangiography" and to identify extrahepatic biliary anatomy without or with minimal dissection of Calot's triangle. In our series, ICG sensitivity in the identification of the gallbladder and the biliary anatomy (cystic duct, CD; common hepatic duct, CHD; common biliary duct, CBD), especially the CD–CBD junction, was 100%, irrespectively of the presence of abundant fatty tissue or severe inflammation and adhesions between the gallbladder and surrounding tissues (Fig. 1). Also, the interval time between ICG injection and its secretion into the bile has been matter of debate [24, 25]; in our experience, the ICG dye was injected into a peripheral vein 18 h prior to the procedure using a dosage of 0.4 mg/kg in all cases, with a successful visualization of biliary tree in 100% of cases. Conversely, when ICG was injected just before surgery, we only observed a hyperfluorescence of the liver parenchyma and a scanty visualization of biliary tree.

An innovative indication of ICG-enhanced fluorescence using in pediatric age is probably to perform an intra-operative lymphography during laparoscopic Palomo varicocelectomy. Following intra-testicular injection of ICG solution, lymphatics appear fluorescent and it is extremely easy to spare them, before section of the spermatic bundle; also, using standard light vision, lymphatics appear green colored and are easy to identify and spare (Fig. 2). Before introduction of ICG-enhanced fluorescence technology, we already standardized the technique of injection of the vital dye, isosulfan blue, that we routinely used to perform

lymphatic-sparing Palomo varicocelectomy [26]. Our operative technique included a tandem intra-dartoic/intra-testicular injection of isosulfan blue that allowed us to visualize the peri-funicular lymphatics in 100% of cases and completely avoid the risk of post-operative hydrocele [26]. We did not report in our experience any adverse reactions to vital dye or any testicular damages such as atrophy, inflammation or pain [26]. After introduction of ICG technology, we started to adopt indocyanine green (ICG) instead of isosulfan blue and we standardized the technique of injection that was performed directly into the body of the left testicle using a 23G needle [27]. This injection technique proved to be safe with no damages referred to the testicle and highly effective with a 100% visualization rate of the lymphatics, as we recently published [27]. Based upon these results, ICG-enhanced fluorescence has become our preferred method to perform routinely lymphatic sparing Palomo varicocelectomy since ICG also allowed us to overcome some disadvantages of isosulfan blue such as the formation of a blue slick on the scrotum in the site of injection and the blue coloration of urines [27].

Another interesting clinical application of ICG fluorescence is during laparoscopic removal of tumors. In our experience, ICG technology was very useful to perform a safe dissection of neoplastic masses or lymphomas because fluorescence allowed a more precise identification of the resection margins as well as the vascular anatomy of the mass and its vascular relationships with mesenteric vessels or other main vessels. A further application of ICG fluorescence is for intra-operative evaluation of the perfusion of bowel before or after anastomosis during tumor excisions requiring bowel resection and re-anastomosis [19, 28, 29].

Regarding nephrectomy and partial nephrectomy, ICG-guided fluorescence was useful to ease the vascular dissection in challenging or unclear anatomic situations [30–34] and to delineate the demarcation line between upper and lower pole during upper pole partial nephrectomy [35].

ICG fluorescence application in pediatric patients showed several advantages in our experience: the ICG dye was very cheap, easily available, and the procedure was not time consuming since it required only a pre- or intra-operative ICG injection; and fluorescent images of the interested organs were obtained in real time at any point during surgery. Only for elective laparoscopic cholecystectomy, ICG injection was performed 18 h prior to the procedure. Furthermore, the procedure was very safe. No exposure to radiation was required and the dosages commonly administered in our clinical practice (0.1–0.5 mg/kg) were much lower than the toxicity level. The modality of administration was intravenous injection in all cases except for varicocele repair in which the ICG was directly injected into the testis. In our series, no allergy or other adverse systemic reactions to ICG were reported; neither any testicular pain nor damage secondary to the intra-testicular was reported ICG injection, either early or late following surgery. The only contraindication for clinical use of ICG is in patients who have a history of allergy to iodides since it contains sodium iodide.

In conclusion, our preliminary experience showed that ICG fluorescence imaging is a very useful and versatile technique that we can adopt in pediatric MIS to obtain a better visualization of anatomic structures and to ease the surgical dissection or resection in challenging cases. Currently, the main indications for using ICG fluorescence in pediatric MIS are varicocelectomy, difficult cholecystectomy, tumor excision, nephrectomy, and partial nephrectomy but further indications and applications will be surely discovered in the near future. The ICG fluorescence is easy to perform and safe, without adverse effects for the patient. The main limitation is the needing of a special equipment to use ICG technology.

Compliance with ethical standard

Conflict of interest The authors declare that they have no conflict of interest or financial ties to disclose.

Ethical approval All procedures performed in this study involving human participants were in accordance with Federico II University research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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