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Surgery in Motion

The Role of Intraoperative Indocyanine Green in Robot-assisted Partial Nephrectomy: Results from a Large, Multi-institutional Series

Pietro Diana ^{a,b}, Nicolò Maria Buffi ^{a,b}, Giovanni Lughezzani ^{a,b,*}, Paolo Dell'Oglio ^c, Elio Mazzone ^{c,d}, James Porter ^e, Alex Mottrie ^{c,f}

^a Department of Urology, IRCCS Humanitas Clinical and Research Institute, Rozzano, Italy; ^b Department of Biomedical Sciences, Humanitas University, Pieve Emanuele, Italy; ^c ORSI, Academy, Melle, Belgium; ^d Department of Urology and Division of Experimental Oncology, URI, Urological Research Institute, IRCCS San Raffaele Scientific Institute, Milan, Italy; ^e Department of Urology, Swedish Urology Group, Seattle, WA, USA; ^f Department of Urology, Onze Lieve Vrouw Hospital, Aalst, Belgium

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Abstract

Background: In recent years, novel technologies have been implemented in order to improve the surgical outcomes of robot-assisted partial nephrectomy (RAPN). Intraoperative administration of indocyanine green (ICG) has been proposed to assess kidney perfusion intraoperatively.

Objective: To confirm, on a large scale, the effectiveness of near-infrared fluorescence ICG-guided RAPN in leading the surgeon strategy and to provide hints to the use of this tool.

Design, setting, and participants: The Transatlantic Robotic Nephron-sparing Surgery (TRoNeS) study group collected data from 737 patients subjected to RAPN between 2010 and 2016 at three tertiary care referral centers. Of them, 318 had complete demographic and clinical data, and underwent ICG-guided RAPN for clinically localized kidney cancer.

Surgical procedure: Patients were subjected to RAPN with intraoperative intravenous ICG injection.

Measurements: Optimal surgical outcomes, defined according to both the margin, ischemia, and complication (MIC), and the trifecta score, were assessed.

Results and limitations: A total of 194 (61%) patients were male and 124 (39%) were female. The median patient age was 61 yr and median preoperative tumor size was 30 mm. Median operative time, estimated blood loss, and warm ischemia time were, respectively, 162 min, 100 ml, and 17 min. In total, 228 (71.7%) and 254 (79.9%) individuals, respectively, were selected as optimal surgical patients defined according to MIC and trifecta. The univariate and multivariable logistic regression models showed that tumor complexity nephrometry scores were independent predictors of both trifecta and MIC. The main limitation of this study is the lack of a control group.

Conclusions: We report the largest population of patients who underwent ICG-guided RAPN. Intraprocedural ICG administration represents a useful tool where the vascular anatomy is challenging, and it could be implemented to maximize the adoption of RAPN.

Patient summary: We demonstrated that indocyanine green (ICG) is a reliable tool for guiding the surgeon strategy during robot-assisted partial nephrectomy. ICG may help in procedure tailoring, especially in cases with challenging vascularization or impaired renal function.

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* Corresponding author. Department of Urology, Istituto Clinico Humanitas, Via A. Manzoni 56, Rozzano 20089, Italy. Tel. +393473248136.

E-mail address: giovanni.lughezzani@humanitas.it (G. Lughezzani).

1. Introduction

In the latest years, the trend of treatment for localized kidney masses is going toward a nephron-sparing approach, as it offers acceptable surgical morbidity, equivalent cancer control, and better preservation of renal function and long-term survival compared with radical nephrectomy [1–4]. As a consequence, urologists are progressively facing more and more challenging cases. Novel technologies have been implemented to expand the indications and improve the outcomes of robot-assisted partial nephrectomy (RAPN) [1,5]. Near-infrared fluorescence (NIRF) with indocyanine green (ICG) administration has been proposed to assess kidney perfusion and tumor margins intraoperatively [6,7]. ICG is a green fluorescent dye that can be visualized at NIRF and, thus, functions as an intraoperative tracer [8]. Studies suggest that the use of NIRF-ICG could help the surgeon in a full or selective clamping approach and in the delineation of surgical margins, possibly leading to better preservation of renal function in the short term, compared with a standard whole-clamping RAPN [9–11]. Following intravenous injection, ICG binds rapidly to plasma proteins of renal parenchymal cells, especially lipoproteins. There are no known metabolites, and ICG is rapidly excreted unchanged in the bile about 8 min after injection, depending on liver vascularization and function [8]. The current study is conceived to report on our experience with NIRF-ICG-guided RAPN in the largest ICG-guided RAPN population treated at three referral centers for robotic surgery. The aim of our work is to provide further evidence supporting the effectiveness of NIRF-ICG guidance in leading the surgeon's strategy and indications to the use of this tool.

2. Patients and methods

2.1. Patient population

The Transatlantic Robotic Nephron-sparing Surgery (TRoNeS) study group prospectively collected data from all patients subjected to RAPN for clinically localized kidney cancer between 2010 and 2016 at three high-volume referral centers (Swedish Medical Center, Seattle, WA, USA; Onze-Lieve-Vrouw Hospital, Aalst, Belgium; and Humanitas Clinical and Research Center, Milan, Italy). All patients underwent either preoperative computed tomography (CT) scan or magnetic resonance imaging to define precisely the anatomical characteristics of renal masses. For the goal of this study, only those patients in whom ICG was used were retrospectively included in the analysis. The decision of ICG employment was made based on the surgeon's judgment.

Lesion classification was made by PADUA and RENAL nephrometry scores [12,13]. Intra- and postoperative complications were recorded according to the Clavien-Dindo

classification [14] and functional outcome was assessed through renal functions tests. In addition, we assessed the optimal surgical outcomes defined according to either the margin, ischemia, and complication (MIC) binary system (absence of Clavien-Dindo >2 complications, warm ischemia time [WIT] <20 min, and absence of positive surgical margins) or the trifecta (absence of Clavien-Dindo >2 complications, WIT <25 min, and absence of positive surgical margins) [15,16].

2.2. ICG injection

RAPN was performed using either the da Vinci Si or the Xi surgical system (Intuitive Surgical, Sunnyvale, CA, USA). In each patient, 2–4 ml of a 2.5 mg/mL solution of ICG was injected intravenously (recommended dosage is 0.1–0.5 mg/mL/kg), either before or after arterial clamping [8]. The absence of perfusion to the renal parenchyma surrounding the tumor was confirmed with NIRF Firefly fluorescence imaging. The peak of fluorescence occurred 2 min after the injection.

Table 1 – Patient demographics.

Patients description	
Total number of patients, <i>n</i>	318
Male, <i>n</i> (%)	194 (61.0)
Female, <i>n</i> (%)	124 (39.0)
Patient age, median (IQR)	61 (53.0–69.3)
BMI (kg/m ²), median (IQR)	27 (24.2–31.1)
Age-adjusted CCI, <i>n</i> (%)	
0	19 (6)
1–2	87 (27.4)
≥3	212 (66.6)
Side, <i>n</i> (%)	
Right	156 (49.1)
Left	162 (50.9)
Preoperative tumor size (mm), median (IQR)	30 (21.3–41.0)
Clinical T stage, <i>n</i> (%)	
T1a	229 (72)
T1b	77 (24.2)
T2	12 (3.8)
Solitary kidney, <i>n</i> (%)	15 (4.7)
PADUA score categories, <i>n</i> (%)	
Low	85 (26.7)
Intermediate	126 (39.6)
High	107 (33.6)
RENAL nephrometry score categories, <i>n</i> (%)	
Low	116 (36.5)
Intermediate	165 (51.9)
High	37 (11.6)
Preoperative functional variables	
Creatinine (mg/dl), median (IQR)	1 (0.8–1.1)
eGFR (ml/min/1.73), median (IQR)	76 (62.4–88.9)
CKD stage 1	76 (23.9)
CKD stage 2	178 (56.0)
CKD stage 3a	52 (16.4)
CKD stage 3b	10 (3.1)
CKD stage 4	2 (0.6)

BMI = body mass index; CCI = Charlson Comorbidity Index; CKD = chronic kidney disease; eGFR = estimated glomerular filtration rate; IQR = interquartile range.

2.3. Statistical analyses

Demographic and perioperative data were analyzed using descriptive statistics. Multivariable logistic regression models adjusted by age, gender, and surgical approach (transperitoneal vs retroperitoneal) were fitted to test the predictors of surgical outcomes. In addition, descriptive data of both the ICG-guided and the standard RAPN populations are listed in Supplementary Tables 1 and 2; a multivariate logistic regression model adjusted for age, gender, and surgical approach was performed to analyze the role of ICG in the whole population (Supplementary Tables 3 and 4). For all statistical analyses, two-sided $p < 0.05$ was considered statistically significant. All analyses were performed using IBM SPSS version 23 (SPSS Inc., Chicago, IL, USA).

3. Results

Descriptive characteristics of the study cohort are listed in Table 1. Among 737 patients subjected to RAPN within the study period, 536 had complete demographic, perioperative, and pathological information. Of them, 318 (59.3%) underwent NIRF-ICG-guided RAPN and were included in the analysis. A total of 194 (61%) patients were male and 124 (39%) were female. The median (interquartile range [IQR]) patient age was 61 (53–69.3) yr, median (IQR) BMI was 27 (24.2–31.1), and median (IQR) preoperative tumor size was 30 (21.3–41.0) mm. Right tumors were observed in 156 (49.1%) patients. According to the PADUA score, 85 (26.7%), 126 (39.6%), and 107 (33.6%) patients had low, intermediate, and high-risk of overall complications, respectively. Similarly, when stratifying tumor complexity according to the RENAL nephrometry score, 116 (36.5%) individuals had a low-complexity tumor, as compared with 165 (51.9%) and 37 (11.6%) patients with intermediate- and high-complexity tumors, respectively.

Intra- and postoperative variables are shown in Table 2. Overall, a transperitoneal and a retroperitoneal approach were performed in 172 (54.1%) and 146 (45.9%) patients, respectively (Table 2). In total, 232 (73%) and 86 (27%) cases harbored, respectively, one and more than one renal artery. The median (IQR) operative time was 162 (135–200) min and median (IQR) estimated blood loss was 100 (70–200) ml. The median (IQR) WIT was 17 (14–20) min. Only three (0.9%) patients required conversion to open surgery. Malignant tumors were observed in 156 (72%) and positive surgical margins in 11 (3.5%) individuals. The overall complication rate was 11.3% ($n = 36$), but only 13 (4.1%) of these patients experienced a high-grade complication according to the Clavien-Dindo classification; a list of high-grade complications and subsequent intervention is provided in Table 3. Finally, optimal surgical outcomes defined according to the MIC and trifecta scores were achieved in 228 (71.7%) and 254 (79.9%) individuals, respectively.

Functional outcomes are shown in Tables 1 and 2. The median (IQR) preoperative creatinine and estimated

glomerular filtration rate (eGFR) were 1 (0.8–1.1) and 76 (62.4–88.9), respectively. The median (IQR) postoperative creatinine and eGFR were 1.0 (0.9–1.3) and 65 (54.0–79.1), respectively. The mean percentage of change between pre- and postoperative eGFR was –8.0%.

Success rates according to the MIC and trifecta scores stratified in terms of tumor complexity by both PADUA and RENAL nephrometry scores are shown in Table 4.

Table 2 – Intra- and postoperative variables.

<i>Intraoperative variables</i>	
Approach, n (%)	
Transperitoneal	172 (54.1)
Retroperitoneal	146 (45.9)
Number of arteries, n (%)	
1	232 (73)
2	86 (24.5)
3–4	8 (2.5)
Operative time (min), median (IQR)	162 (135–200)
EBL (cc), median (IQR)	100 (70–200)
Selective clamping, n (%)	54 (17)
Warm ischemia time (min), median (IQR)	17 (14–20)
Conversion to radical nephrectomy, n (%)	3 (0.9)
<i>Postoperative variables</i>	
Length of stay, median (IQR)	1 (1–2)
Postoperative tumor size (mm), median (IQR)	30 (21.5–41.0)
Pathology results, n (%)	
Malignant	244 (76.7)
Benign	74 (23.3)
Number of complications, n (%)	36 (11.3)
Clavien-Dindo 1	9 (2.8)
Clavien-Dindo 2	14 (4.4)
Clavien-Dindo 3a	2 (0.6)
Clavien-Dindo 3b	11 (3.5)
Margins	
Negative (%)	307 (96.5)
Positive (%)	11 (3.5)
MIC score achievement, n (%)	
Yes	228 (71.7)
Trifecta achievement, n (%)	
Yes	254 (79.9)
<i>Postoperative functional variables</i>	
Creatinine (mg/dl), median (IQR)	1.0 (0.9–1.3)
eGFR (ml/min/1.73), median (IQR)	65.0 (54.0–79.1)
CKD stage 1	72 (22.6)
CKD stage 2	156 (49.1)
CKD stage 3a	70 (22.0)
CKD stage 3b	18 (5.7)
CKD stage 4	2 (0.6)

CKD = chronic kidney disease; EBL = estimated blood loss; eGFR = estimated glomerular filtration rate; IQR = interquartile range; MIC = margin, ischemia, and complication.

Table 3 – High-grade complications and subsequent interventions.

Complication (Clavien-Dindo >2)	Intervention
3 Pseudoaneurysm	Embolization
1 AV fistula	
1 Kidney bleeding	
1 Torn left gastroepiploic artery	Emergency surgery
1 Intra-abdominal bleeding	
2 Pneumothorax	Chest tube placement
4 Urinary extravasation from collecting system	Stent placement
AV = arteriovenous.	

Table 4 – Preoperative risk scores and success rate.

	Success rate	
	MIC achievement	Trifecta achievement
Padua score risk stratification		
Low risk	73/85 (85.9%)	77/85 (90.6%)
Intermediate risk	93/126 (73.8%)	102/126 (80.9%)
High risk	62/107 (57.9%)	75/107 (70.1%)
Renal nephrometry score risk stratification		
Low risk	101/116 (87.1%)	103/116 (88.8%)
Intermediate risk	113/165 (68.5%)	128/165 (77.6%)
High risk	14/37 (37.8%)	23/37 (62.2%)
MIC = margin, ischemia, and complication.		

In both univariate and multivariable logistic regression models, both PADUA and RENAL nephrometry scores were independent predictors of trifecta. Similar results were found using MIC as the outcome of the analysis. Results are shown in [Tables 5 and 6](#).

Finally, we performed a comparison between the patients subjected to ICG-guided versus standard RAPN. Demographic and operative data are reported in Supplementary Tables 1 and 2. Both univariate and multivariate logistic regression models for both MIC and trifecta are shown in Supplementary Tables 3 and 4. Considering PADUA and RENAL, the use of ICG resulted in an independent predictor of the achievement of trifecta (1.886 [1.109–3.209], $p = 0.0019$ and 1.965 [1.160–3.361], $p = 0.012$, respectively). This independency of ICG was not found in the prediction of MIC.

4. Discussion

To our knowledge, our multi-institutional prospective study reports the largest population of ICG-guided RAPN. ICG injection results in a feasible and safe tool that can be used intraoperatively to provide enhanced insight into kidney

vascularization for the urologist. It represents a guide in those particular cases where kidney perfusion is tricky and the surgeon requires confirmation about which strategy is best to adopt to carry out a safe procedure for the patient.

NIRF-ICG has been used and implemented by urologists in various kinds of surgeries [17,18], and it is well known that, in the setting of RAPN, it can be useful to ensure complete ischemia of the kidney, identifying the arterial blood supply to the tumor, allowing a selective clamping approach [9,19,20]. Furthermore, hypofluorescence of renal tumors, in comparison with normal renal parenchyma after ICG usage, might allow for better differentiation of margins and more precise dissection of the tumor [21]. However, the role of NIRF-ICG in surgical practice has not been defined precisely, and apparently, no clear advantages have been reported in the literature regarding intra- or postoperative complication rates or incidence of positive margins at histology. Although some studies show an advantage from a functional point of view, as reported by Vecchia et al [11], its benefit is still under debate. In our population, we did not find a clear advantage from a functional point of view; as seen in [Tables 1 and 2](#), upstaging to a higher chronic kidney disease (CKD) stage was relatively uncommon, and more importantly, no upstaging to a CKD stage 4 or 5 was recorded. As a consequence, the impact of ICG use on functional outcomes may be considered negligible.

In our experience, NIRF-ICG is used in those cases in which the surgeon is in doubt about organ vascularization and reperfusion. The selective clamping setting is for sure the clearest indication for the use of NIRF-ICG, but as we show also in cases of complete organ ischemia, the implementation in the visualization and definition of the organ supply can be necessary in some exceptional cases. Further extension of the indications for an organ-sparing surgery even in case of a large mass is the tendency in renal surgery [5], but this can be challenging. Larger tumors tend to have more complex and accessory vascularization that cannot always be predicted or clearly

Table 5 – Univariate and multivariate logistic regression models for predicting trifecta achievement.

Variable	Univariate		Multivariate (according to PADUA score)		Multivariate (according to RENAL score)	
	OR (95% CI)	p value	OR (95% CI)	p value	OR (95% CI)	p value
Gender						
Male vs female	0.924 (0.525–1.626)	0.784	0.907 (0.506–1.624)	0.742	0.909 (0.507–1.631)	0.750
Age						
	1.004 (0.983–1.027)	0.696	1.011 (0.978–1.046)	0.504	1.004 (0.971–1.038)	0.804
Age-adjusted CCI categories						
CCI 1–2 vs 0	1.391 (0.365–5.302)	0.629	1.398 (0.398–5.761)	0.643	1.761 (0.417–7.435)	0.415
CCI ≥ 3 vs 0	1.365 (0.380–4.899)	0.633	1.236 (0.255–5.988)	0.793	1.919 (0.380–9.702)	0.432
Surgical approach						
Retroperitoneal vs transperitoneal	0.970 (0.559–1.683)	0.914	0.968 (0.548–1.710)	0.910	0.943 (0.531–1.672)	0.840
Selective clamping (no vs yes)	1.498 (0.757–2.963)	0.246	1.395 (0.688–2.827)	0.356	1.499 (0.736–3.053)	0.265
PADUA score categories						
Intermediate vs low	2.625 (0.965–5.315)	0.017	2.319 (0.984–5.461)	0.06		
High vs low	4.107 (1.777–9.488)	<0.001	4.353 (1.866–10.150)	0.001		
RENAL score categories						
Intermediate vs low	2.290 (1.157–4.535)	0.060			2.375 (1.192–4.733)	0.014
High vs low	4.823 (2.001–11.626)	0.001			5.425 (2.166–13.586)	<0.001

CCI = Charlson Comorbidity Index; CI = confidence interval; OR = odds ratio.

Table 6 – Univariate and multivariate logistic regression models for predicting MIC achievement.

Variable	Univariate		Multivariate (according to PADUA score)		Multivariate (according to RENAL score)	
	OR (95% CI)	p value	OR (95% CI)	p value	OR (95% CI)	p value
Gender						
Male vs female	0.432 (0.251–0.741)	0.002	0.400 (0.227–0.704)	0.001	0.387 (0.217–0.691)	0.001
Age	0.991 (0.973–1.011)	0.382	0.998 (0.968–1.029)	0.905	0.988 (0.957–1.020)	0.444
Age-adjusted CCI categories						
CCI 1–2 vs 0	1.400 (0.459–4.266)	0.554	1.727 (0.510–5.845)	0.380	2.664 (0.732–9.690)	0.137
CCI ≥3 vs 0	1.012 (0.348–2.937)	0.983	1.305 (0.323–5.277)	0.709	2.835 (0.644–12.486)	0.168
Surgical approach						
Retroperitoneal vs transperitoneal	1.182 (0.725–1.926)	0.503	1.201 (0.713–2.022)	0.491	1.178 (0.687–2.021)	0.551
Selective clamping (no vs yes)	1.202 (0.637–2.267)	0.570	1.231 (0.624–2.427)	0.549	1.309 (0.645–2.657)	0.456
PADUA score categories						
Intermediate vs low	3.099 (1.644–5.841)	<0.001	2.120 (1.006–4.468)	0.048		
High vs low	11.062 (4.692–26.079)	<0.001	4.593 (2.184–9.659)	<0.001		
RENAL score categories						
Intermediate vs low	2.159 (1.042–4.472)	0.038			3.348 (1.748–6.410)	<0.001
High vs low	4.415 (2.147–9.081)	<0.001			13.012 (5.158–32.825)	<0.001

CCI = Charlson Comorbidity Index; CI = confidence interval; MIC = margin, ischemia, and complication; OR = odds ratio.

identified by imaging techniques; the intraoperative use of ICG can enhance the insight in this setting. The use of ICG also finds indication in these complex cases, such as horseshoe, solitary, or pelvic kidney, where the definition of organ supply is challenging and the use of this additional tool can confirm or change the urologist's intraoperative strategy. In the reperfusion setting, the new concept of the role of ICG in checking the residual parenchyma blood supply after renorrhaphy is not to be underestimated, specifically in CKD patients in whom renal function is already impaired and suturing itself can lead to ischemia, thus resulting in a healthy parenchymal loss and worsening or induction of a CKD [22,23].

Other potential uses of ICG in a setting of RAPN have been explored in the latest years. As proposed by Simone et al [24], preoperative superselective transarterial delivery of a lipiodol-ICG mixture to the endophytic renal mass can be performed; they described the use of this procedure in a small series of patients to trace the endophytic tumor. The results provided the opportunity to avoid the use of intraoperative ultrasound (US) or an alternative to US if it is not available, while allowing quick tumor identification and complete control of tumor margins during RAPN dissection.

ICG can also be used in addition to other technological tools that are becoming important in the preoperative surgical strategy such as three-dimensional (3D) reconstructions, and as proposed by Bertolo et al [5], implementation of robotic surgery may allow expansion of the indications of partial nephrectomy [25]. The complementary use of NIRF-ICG and preoperative 3D reconstruction models could help push the limits of RAPN even further. Of course, the advantages in using the combination of these technologies should be proved and a cost-effective analysis should be performed.

The main intrinsic limitation of NIRF-ICG is the “one shot” opportunity it gives the surgeon to check the blood supply since, once injected, the molecule remains in the

circulation. A handful of allergic reactions to ICG have been described and, even though extremely rare, should not be understated as the vulnerable population remains unknown [26]. The main strengths of our work focus on the multi-institutional nature of the study involving three high-volume centers, surgeons highly experienced in performing RAPN, and large population of patients. Our study is not devoid of limitations. First, no comparison with a control group is provided. However, ICG has been used depending on the surgeon's intraoperative judgment from case to case. Therefore, a simple comparison with a group of patients undergoing RAPN without ICG will have a strong selection bias. Second, our data were derived from highly experienced surgeons with high annual caseload. Therefore, generalizability of our findings may be limited to centers with similar caseload and experience. Despite the aforementioned limitation of the lack of an unbiased comparative group, we performed a logistic regression analysis (Supplementary Tables 3 and 4) adding the use of ICG as a potential predictor of surgical outcome in the overall population of 536 patients with available information on the ICG use. Interestingly, ICG use was an independent predictor of trifecta achievement. Conversely, ICG use did not emerge as an independent predictor if we consider the surgical success according to MIC. This discrepancy is expected as the WIT was slightly higher in the ICG population (as can be seen from the Supplementary tables), and thus, it is more common not to reach the MIC in this population.

A prospective randomized controlled study is warranted to define the real advantages of this technique in decreasing the risk of intra- and postoperative complications and the risk of a functional impairment.

5. Conclusions

To the best of our knowledge, the current series represents the largest population of patients who underwent ICG-guided RAPN. Intraprocedural ICG administration repre-

sents a reliable method to provide enhanced insight into kidney vascularization and could represent a useful tool in those cases where vascular anatomy is challenging. According to our experience, ICG is an easy-to-use tool that can safely be implemented in the urologists' armamentarium to maximize the adoption and outcomes of RAPN.

Author contributions: Giovanni Lughezzani had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Diana, Buffi, Lughezzani.

Acquisition of data: Lughezzani, Dell'Oglio and Porter.

Analysis and interpretation of data: Diana, Buffi, Lughezzani.

Drafting of the manuscript: Diana, Buffi, Lughezzani.

Critical revision of the manuscript for important intellectual content: Mazzone, Dell'Oglio.

Statistical analysis: Diana, Lughezzani.

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Appendix A. Supplementary data

The Surgery in Motion video accompanying this article can be found in the online version at doi: <https://doi.org/10.1016/j.eururo.2020.05.040> and via www.europeanurology.com.

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