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"Light green up": Indocyanine Green Fluorescence Imaging–guided Robotic Bilateral Inguinal Lymphadenectomy by the Hypogastric Subcutaneous Approach for Penile Cancer

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Article info

Abstract

Background: Inguinal lymphadenectomy is of great significance in the management of penile cancer, which aims to mitigate the progression of lymph node metastasis. It is important to improve the efficiency of lymph node dissection and reduce surgical complications.

Objective: To detail a novel technique for robotic bilateral inguinal lymphadenectomy through the hypogastric subcutaneous approach by indocyanine green (ICG) fluorescence imaging, which promotes the identification and dissection of inguinal lymph nodes with considerable safety.

Design, setting, and participants: Ten eligible penile cancer patients who underwent ICG fluorescence imaging–guided robotic bilateral inguinal lymphadenectomy were prospectively enrolled (ICG group). Sixteen patients who underwent the surgery without ICG were retrospectively set as the control (non-ICG) group. Follow-up records for at least 12 mo were required.

Surgical procedure: Inguinal lymphadenectomy was performed by the hypogastric subcutaneous approach. The ICG solution was subcutaneously injected into the prepuce at the beginning of surgery, and ICG fluorescence imaging–guided robotic-assisted bilateral inguinal lymphadenectomy was conducted.

Measurements: Clinical outcomes were collected. The primary study outcome measurement was the number of dissected inguinal lymph nodes.

Results and limitations: The numbers of inguinal overall, superficial, and deep lymph nodes retrieved were all higher in the ICG than in the non-ICG group ($p < 0.05$). No patients had severe perioperative complications. No difference was found in the overall complication rate and 12-mo survival between two groups ($p > 0.05$).

Conclusions: ICG fluorescence imaging–guided robotic inguinal lymphadenectomy via the hypogastric subcutaneous approach is feasible and safe for patients with

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penile cancer, which is beneficial for dissecting more inguinal lymph nodes with few surgical complications.

Patient summary: We developed a promising indocyanine green fluorescence imaging–guided technique to perform robotic bilateral inguinal lymphadenectomy on patients with penile cancer, which conduces to remove more inguinal lymph nodes with limited complications.

1. Introduction

The incidence of penile cancer varies significantly in different regions of the world, which is much common in areas with a high prevalence of human papillomavirus incidence or low socioeconomic status [1]. Inguinal lymph node metastasis as the first step in the development of lymphatic metastases should be detected early and treated timely in patients with penile cancer [2]. Regional lymphatic metastasis in groins occurs early and spreads to the pelvic lymph nodes in even distant organs, which follows the route of anatomical drainage in the development of lymphatic metastases in penile cancer [3]. Up to 30% of cases turn out to be micrometastatic in clinically node-negative (cN0) patients [4]. In cN0 patients with pT1 tumors of intermediate and high risk as well as T2-T4 tumors, bilateral inguinal lymphadenectomy is a preferred choice [5]. It was found that early inguinal lymphadenectomy might reduce recurrence rate and have superiority in long-term patient survival in cN0 patients [6,7]. Usually pelvic nodal disease will not occur without ipsilateral inguinal lymph node metastasis [8]. Therefore, it is of vital significance that inguinal lymphatic metastasis should be detected and treated timely among penile cancer patients.

Management of lymph nodes including either preventive or curative inguinal lymph node dissection is decisive for tumor control and patient survival. There is no denying that surgical complications after inguinal lymph node dissection were dissatisfactory, which may deteriorate patients' quality of life and aggravate their medical economic burden. Both open and laparoscopic inguinal lymphadenectomy are classical surgeries that can be recommended to selected patients. However, surgeons and patients increasingly prefer laparoscopic inguinal lymphadenectomy for its lower incidence of postoperative complications and faster recovery [9]. In recent years, development of the robotic-assisted technology has greatly promoted the minimally invasive procedure despite a possible economic burden [10]. On the contrary, both leg and hypogastric subcutaneous approaches have been proved to be effective and safe in the surgical management of inguinal lymphadenectomy [11].

Surgeons and researchers are attempting to accelerate the development of the inguinal lymph node dissection technology with joint effort. The indocyanine green (ICG) near-infrared fluorescence imaging technique has successfully been applied in several surgeries, which is conducive to achieving expectant outcomes in identifying tissues [12,13]. It has been demonstrated that in breast, gastric, and uterus surgeries, lymph node dissection combined with the ICG fluorescence imaging technology has the potential to distinguish lymph nodes more accurately and remove lymph node tissue more precisely [14–16]. The ICG fluorescence imaging technology may help surgeons obtain satisfactory results in improving the number of resected lymph nodes during inguinal lymphadenectomy. This technique is hopeful to promote the exact lymph node staging, which makes for a better adjuvant treatment plan and reduces surgical complications [17,18].

In our current study, we described a novel ICG fluorescence imaging–guided technique to perform robotic bilateral inguinal lymphadenectomy in patients with penile cancer. It aims to investigate the safety and efficacy of ICG fluorescence imaging–guided inguinal lymphadenectomy in patients with penile cancer.

2. Patients and methods

2.1. Patients and eligibility

Included patients should have the following criteria: age 18–80 yr at the time of enrollment or admission; diagnosis of penile cancer confirmed by pathological examination; without distant metastasis; with an indication for inguinal lymphadenectomy; no history of inguinal and pelvic lymph node dissection, radiotherapy, or chemotherapy; without contraindication for surgery; no allergy to ICG or iodine; and with the follow-up time of at least 12 mo. This study was reviewed and approved by the Institutional Review Board of The Third Xiangya Hospital of Central South University. Signed informed consent was obtained from all patients.

Penile cancer patients who received robotic-assisted bilateral inguinal lymphadenectomy with the ICG fluorescence imaging technique by one experienced surgeon (ICG group, from January 2020 to December 2020) were prospectively collected. Patients who received the surgery without ICG (non-ICG group, from January 2018 to December 2019) were included retrospectively. Regular examinations and preparation were performed on all patients preoperatively. Patients received inguinal lymphadenectomy after the resection surgery of the penile primary tumor. All patients in two groups received bilateral inguinal lymphadenectomy via a hypogastric subcutaneous approach in our department.

2.2. Surgical procedure

ICG fluorescence imaging–guided bilateral inguinal lymphadenectomy was carried out as follows (a schema of the procedures is displayed in Fig. 1). The da Vinci Si Surgical System, which contains a module for
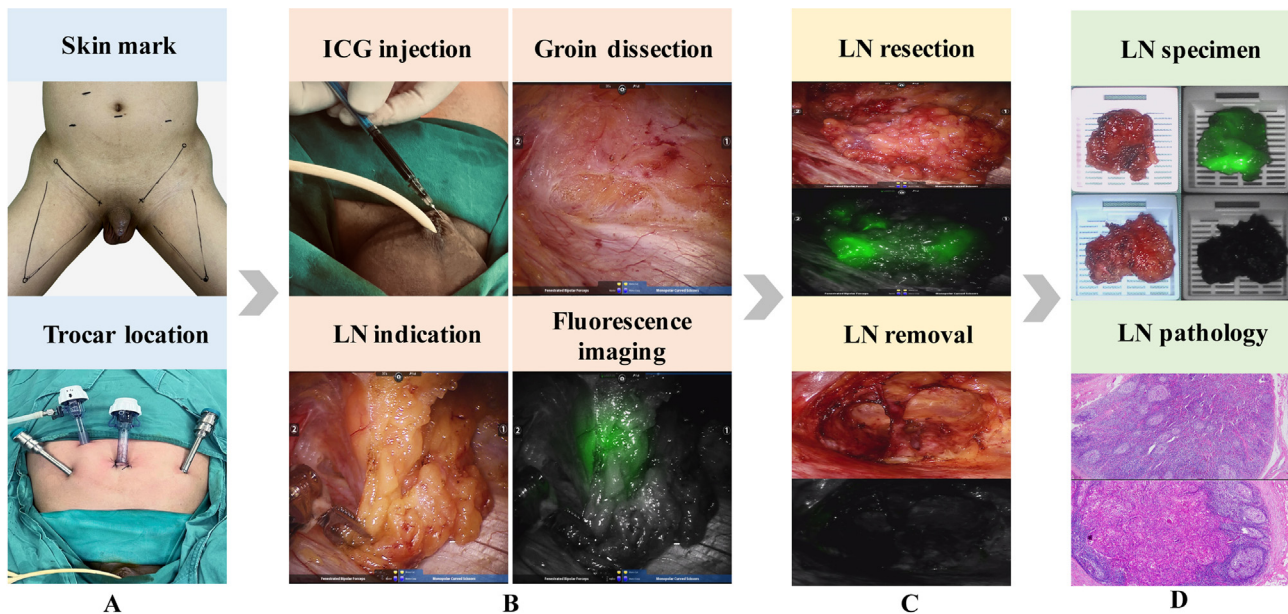
Fig. 1 – A schema of the study procedures of ICG fluorescence imaging–guided bilateral inguinal lymphadenectomy. (A) Skin marks that were labeled in the preoperative preparation and placement of trocars. **(B)** Injection of ICG at the beginning of surgery and identification of lymph nodes (LNs) by ICG fluorescence imaging. **(C)** Intraoperative inguinal superficial and deep lymph node dissection, and preservation of branches of the great saphenous vein. **(D)** Evaluation of specimen in paraffin blocks by ICG fluorescence imaging as well as pathological analysis. ICG = indocyanine green.

fluorescence imaging, was used in the surgery. ICG fluorescence imaging could be obtained after the mode change from a visible light to fluorescence imaging during the surgery.

2.2.1. Position and trocar placement

The patient was placed in the low lithotomy position with lower extremities in padded boot stirrups on the operating table. A catheter was inserted after the skin disinfection. The skin was cut at the lower margin of the umbilicus. Beneath Scarpa's fascia, we started to set up the operative procedure. A total of four trocars were used. The first 12-mm trocar was inserted as a lens hole through the incision after the inguinal region was established by finger dissection. Patient pressure was set at 20 mmHg for creating a working space in a quick manner and was then reduced to 10 mmHg. Metal trocars of arm 1 (right side) and arm 2 (left side) were inserted into the subcutaneous space at the lateral side of the rectus abdominis at the level of 5 mm below the first 12-mm trocar. Another 12-mm trocar was placed as the assistant hole, which combined with the first 12-mm trocar and the metal trocars of arm 1 forming the shape of an equilateral triangle.

2.2.2. ICG injection

ICG 25 mg (Eisai, China) was dissolved into 10 ml sterilized water for injection at a concentration of 2.5 mg/ml. At the beginning of surgery, 2 ml prepared ICG solution was injected subcutaneously at four different points through the prepuce with 0.5 ml for each point. Awaiting time for the fluorescence imaging was usually 10–15 min after the injection of ICG. During the surgery, repeated injections of ICG at new points were conducted or awaiting time was prolonged if inguinal lymph nodes were not well developed.

2.2.3. Identification and dissection of inguinal superficial lymph nodes around the inguinal ligament

Initial dissection was closely along the aponeurosis of the oblique externus abdominis. The inguinal ligament and fascia could be identified by removing the fibrofatty packet. We first detected and dissected inguinal superficial lymph nodes around the inguinal ligament. The range of

inguinal lymphadenectomy was specified as follows: superior to 2 cm above the inguinal ligament, medial to the adductor longus muscle, and lateral to the sartorius muscle. By ICG fluorescence imaging, tissues were developed at different fluorescence intensities, which helped surgeons further distinguish the distribution and location of lymph nodes. Weakly or inconspicuously developed nonlymphatic tissues were preserved as much as possible during the dissection.

2.2.4. Identification and dissection of inguinal deep lymph nodes

After the removal of inguinal superficial lymph nodes around the inguinal ligament, the fascia lata was dissociated and opened, followed by the exploration of inguinal deep lymph nodes that were medial to the femoral vein and up to the inguinal ligament. By ICG fluorescence imaging, deep lymph nodes could be recognized clearly and excised.

2.2.5. Identification and dissection of inguinal superficial lymph nodes around the blood vessels

Inguinal superficial lymph nodes around the saphenous vein, femoral artery, and femoral vein were sought. When carefully dissecting the saphenous vein, its branches were preserved as much as possible. With the help of ICG fluorescence imaging, small lymph nodes or those at obscure positions could be exposed and drifted away.

2.2.6. Pathological examinations and pelvic lymphadenectomy if necessary

Lymph nodes above the inguinal region were separately withdrawn in three steps. Superficial and deep lymph nodes were placed in different specimen bags as labeled. Inguinal lymphadenectomy on the other side was then conducted through initial four trocars by the same procedures as above. All the specimens were sent to pathologists for frozen pathological examinations as well as further paraffin sectioning. Ipsilateral pelvic lymphadenectomy was recommended if frozen pathological results showed that two or more inguinal lymph nodes were deemed to have metastasis on one side or extracapsular nodal metastasis was confirmed.

Table 1 – Demographic and clinicopathological data of all patients included in the study

	ICG group (n = 10)	Non-ICG group (n = 16)	p value
Age (yr), median (IQR)	59 (51.5–65.8)	57 (49–64)	0.702
BMI (kg/m^2), median (IQR)	23.5 (21.1–25.1)	21.4 (20.3–25.2)	0.595
HPV infection, n (%)	4 (40)	6 (37.5)	1.000
Smoking status, n (%)			0.878
Never smoking, n (%)	2 (20)	5 (31.3)	
Give up smoking for half a year, n (%)	3 (30)	5 (31.3)	
Smoking, n (%)	5 (50)	6 (37.4)	
ASA score, n (%)			0.228
1	5 (50)	9 (56.2)	
2	4 (40)	5 (31.3)	
3	1 (10)	2 (12.5)	
Pathological stage of primary tumor, n (%)			0.422
T1	4 (40)	7 (43.8)	
T2	4 (40)	6 (37.5)	
T3	2 (20)	3 (18.7)	
Clinical stage of nodes, n (%)			0.226
N0	5 (50)	6 (37.5)	
N1	3 (30)	6 (37.5)	
N2	2 (20)	4 (25)	

ASA = American Society of Anesthesiologists; BMI = body mass index; HPV= human papillomavirus; ICG = indocyanine green; IQR = interquartile range.

2.2.7.   Drainage and wound closure

In order to obliterate the subcutaneous dead space, we closed up the subcutaneous tissue by the suture from the inside issues to the skin at three or four points in the groin areas. At the end of surgery, a drainage tube was placed at each groin area and was exited from the inguinal region. Then the port incisions were closed. Pressure by using the elastic compression bandage was applied at the groin areas.

2.3.   Follow-up schedule

All patients received a 12-mo follow-up schedule with at least four visits (including in the 1st, 3rd, 6th, and 12th months after surgery). Management of complications should be based on the guidelines and experience from the medical group.

2.4.   Outcome measures

Baseline characteristics and clinicopathological items were recorded and evaluated. In this study, operative time was defined as the time from successful installation of all four robotic arms to the end of wound suture.

2.5.   Statistical analysis

Statistic Package for Social Science (SPSS) software version 24.0 was used for data analysis. Median and interquartile range were indicated for continuous variables, and frequency (N, %) was reported for categorical variables. Categorical variables were compared using the chi-square test, and continuous variables were analyzed by the Student t test. All tests were two sided, and $p < 0.05$ was considered to be statistically significant.

3. Results

ICG fluorescence was not well developed during surgery in two patients who were excluded. Therefore, ten eligible patients were finally included in the ICG group, and 16 patients were included in the non-ICG group. There was no significant difference in the demographic characteristics between the two groups, which are displayed in Table 1 ($p > 0.05$). No death or major complication occurred during surgery, and no patient in the ICG group needed pelvic lymphadenectomy. We found that ICG fluorescence imaging contributed to better identification of lymph nodes during surgery (Fig. 2).

The results of surgical and pathological characteristics are shown in Table 2. The numbers of retrieved bilateral inguinal overall, superficial, and deep lymph nodes were higher in the ICG group than in the non-ICG group ($p < 0.05$). In the ICG group, two patients suffered from postoperative complications, including wound infection (one patient, grade I) and lymphorrhea (one patient, grade I). In the non-ICG group, four patients experienced postoperative complications, including wound infection (one patient, grade I), lymphorrhea (two patients, one grade I and one grade II), and lymphocele (one patient, grade III). Percutaneous drainage was performed on the patient with a lymphocele. There was no significant difference between two groups with regard to postoperative complications ($p > 0.05$). All patients who developed postoperative complications eventually recovered well (Table 3). All patients survived during the follow-up period, except for one patient who had no history of cardiovascular disease but died of acute myocardial infarction. No postoperative tumor recurrence or metastasis occurred in the dead man.

4. Discussion

Timely and standardized treatment is crucial for penile cancer patients, which can greatly improve the survival and quality of life. If metastatic inguinal lymph nodes can be found and treated in time, metastasis of pelvic lymph nodes or more distant regions is likely to be blocked effectively [19]. Moreover, it was demonstrated that inguinal lymph node dissection was conducive to overall survival in penile cancer patients, with more removed lymph nodes indicating better survival [20,21].

In our previous study, we found that laparoscopic inguinal lymphadenectomy via the hypogastric subcutaneous approach was effective and safe for patients with penile
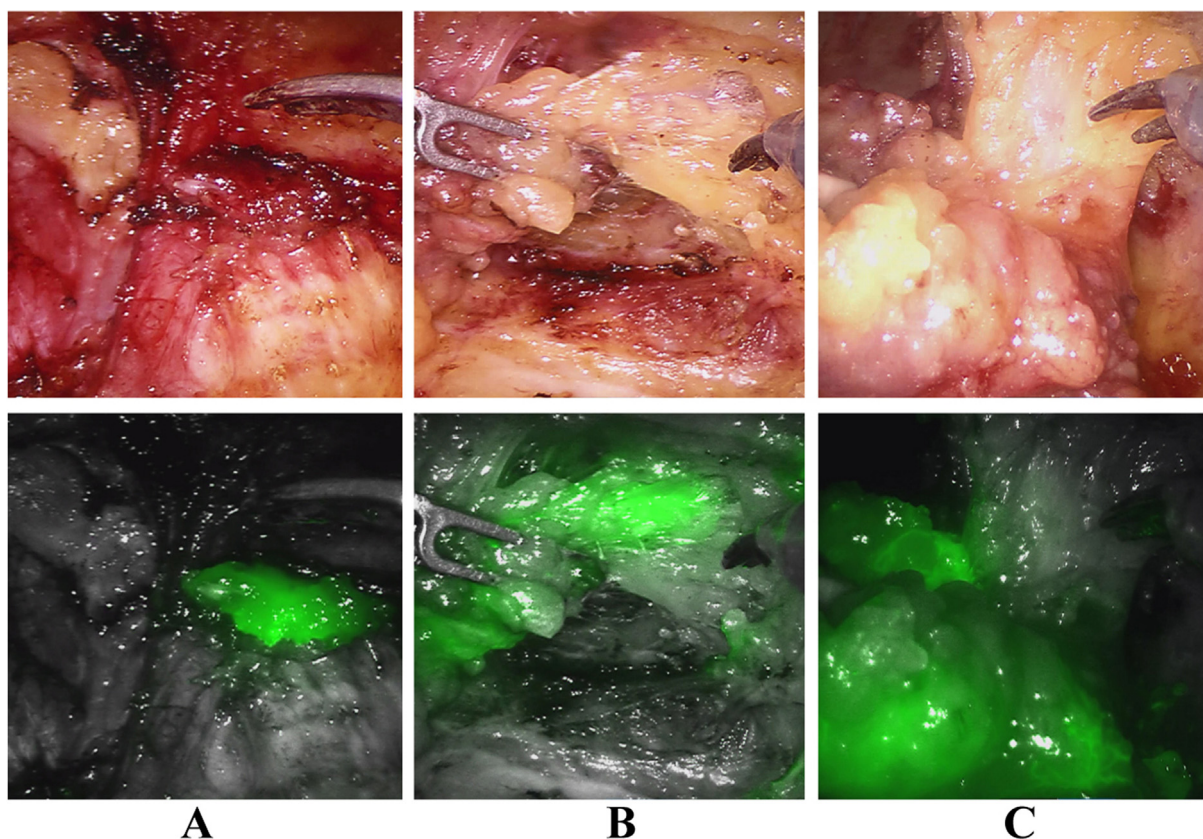
Fig. 2 – ICG fluorescence imaging–guided inguinal lymph node dissection. Exact location of inguinal (A) superficial and (B) deep lymph nodes. (C) Accurate assessment of the extent of tissue resection. ICG = indocyanine green.

Table 2 – Surgical and pathological characteristics of all patients included in the study

	ICG group (n = 10)	Non-ICG group (n = 16)	p value
Operative time (min), median (IQR)	99.5 (89.8–105.5)	105.5 (95.75–113)	0.454
Operative blood loss (ml), median (IQR)	70 (52.5–113.8)	87.5 (52.5–108.8)	0.756
Amount of drain (ml), median (IQR)	100 (80–287.5)	110 (87.5–212.5)	0.946
Duration of drain (d), median (IQR)	6 (4.8–7.8)	7 (4–7.5)	0.756
Postoperative hospital stay (d), median (IQR)	5.5 (4–6.5)	6 (3.8–7.3)	0.667
Number of dissected bilateral lymph nodes, median (IQR)			
Deep lymph nodes	3 (2–3)	1.5 (1–2)	0.024
Superficial lymph nodes	26.5 (24.5–29.5)	22 (18–25)	0.004
Total lymph nodes	29.5 (27.3–32)	25 (19–26)	0.001
Pathological stage of lymph nodes, n (%)			0.668
N0	8 (80)	11 (68.8)	
N1	2 (20)	5 (31.2)	
Deep lymph node metastasis, n (%)	0	0	1.000

ICG = indocyanine green; IQR = interquartile range.

cancer. This procedure has its advantages in shortening the operative time, optimizing the skin incision, and prettifying the aesthetic appearance. If necessary, pelvic lymphadenectomy can be performed intraoperatively through the original abdominal trocar, which can shorten the surgical time and reduce the number of wounds [11]. Several researchers have been studying inguinal lymphadenectomy via the hypogastric subcutaneous approach, and it was indicated that this surgery could be recommended as for its feasibility and safety [22,23].

In our current study, we applied the ICG fluorescence imaging technology to inguinal lymph node dissection by robotic system for the treatment of selected penile cancer patients, which aimed to optimize the operation and improve the efficacy along with surgical safety. First, ICG have been proved to be safe in human body, which has also been used widely for fluorescence imaging in several surgeries [24,25]. In this study, the results showed that the use of ICG for inguinal lymph node dissection in penile cancer patients is safe. No patient had ICG-related adverse reac-

Table 3 – Comparison of complications between the two groups in the study

	ICG group (n = 10)	Non-ICG group (n = 16)	p value
Follow-up time (mo), median (IQR)	18.5 (15.3–21.8)	28.5 (25.8–38.5)	[a]
Classification, n (%)			1.000
None	8 (80)	12 (75)	
Wound infection	1 (10)	1 (6.25)	
Lymphorrhea	1 (10)	2 (12.5)	
Lymphocele	0	1 (6.25)	
Clavien-Dindo classification, n (%)			1.000
None	8 (80)	12 (75)	
I	1 (10)	2 (12.5)	
II	1 (10)	1 (6.25)	
III	0	1 (6.25)	

ICG = indocyanine green; IQR = interquartile range.
[a] Comparison was not needed.

tions. Furthermore, it has been reported by other researchers that surgeons could remove the tumor in a precise manner by accurately identifying the tumor tissue and normal tissue under the guidance of ICG fluorescence imaging, which contributed to the achievement of the goal of total removal of tumor [26].

ICG fluorescence imaging–guided inguinal lymphadenectomy was feasible and effective in penile cancer patients through our own designed method of ICG injection as well as imaging system and equipment. We administered ICG subcutaneously at the beginning of surgery rather than applying an intravenous injection on the day prior to surgery. Inguinal lymph nodes could usually be well developed. If not, repeated or multiple injections with the total dose allowed would achieve a satisfactory effect. The convenience of the surgical procedure was improved and systemic effects were minimized by a subcutaneous injection.

The results also showed that the number of overall dissected nodes, including inguinal deep and superficial lymph nodes, was increased significantly by using ICG fluorescence imaging. It was often difficult for surgeons to accurately identify inguinal deep lymph nodes as these were located in an obscure region and were closely related to surrounding tissues. Dissection of deep lymph nodes was sometimes limited for avoidance of excessive resection and extensive damage. However, deep lymph nodes could be distinguished precisely and separated from surrounding tissues accurately by ICG fluorescence imaging. Therefore, ICG fluorescence imaging might significantly increase the efficacy of inguinal lymph node dissection and be useful for more accurate staging in penile cancer patients.

What is more, we found that the number of dissected lymph nodes was increased without a growing trend in postoperative complications in ICG fluorescence imaging–guided inguinal lymphadenectomy. Now, fast track surgery was drawing more and more attention, which contributed to shorten the length of hospital stay and ameliorate the economic burden [27]. In addition, long time was required for observation, monitoring, nursing, or treatment if patients suffered from complications such as lymphorrhea. However, the cooperative model with community hospitals not only enabled these patients to receive effective treatment, but also improved the efficiency of bed utilization in large hospitals with a high patient volume.

Our study found that the application of ICG fluorescence imaging is safe and effective in inguinal lymphadenectomy, which could be recommended for more selected penile cancer patients with a widespread use in more institutions, but there still exist some problems to be further discussed. The limited number of patients and duration of follow-up may lead to little association between the difference in the number of lymph nodes and cancer outcome. High-quality researches with a large sample are significant for further study on the evaluation of the safety and efficiency of ICG fluorescence imaging–guided inguinal lymphadenectomy in patients with penile cancer. In addition, a longer follow-up time for patients is needed for more a comprehensive assessment of ICG fluorescence imaging.

5. Conclusions

ICG fluorescence imaging–guided robotic bilateral inguinal lymphadenectomy is safe and effective for patients with penile cancer. This technique may promote the number of both superficial and deep inguinal lymph node dissections with few postoperative complications. ICG fluorescence imaging–guided robotic inguinal lymphadenectomy is an alternative and promising surgical choice for patients with penile cancer.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.euros.2022.08.020.

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