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Evaluation of the videoscopic inguinal lymphadenectomy in melanoma patients

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ABSTRACT

Introduction: A completion or therapeutic inguinal lymph node dissection is a procedure accompanied with a high rate of postoperative complications. A novel, minimally invasive alternative has been developed; the videoscopic inguinal lymphadenectomy. The aim of this study is to present our first experience with the videoscopic inguinal lymphadenectomy among melanoma patients with inguinal metastases.

Methods: Melanoma patients with a histologically confirmed inguinal metastases who underwent a videoscopic inguinal lymphadenectomy between November 2015 and January 2018 were included. Outcome measures were operation time, nodal yield, and postoperative complications. Furthermore, lymphedema measurements were performed both subjectively and objectively.

Results: A total of 20 patients (3 males and 17 females) underwent a videoscopic inguinal lymphadenectomy. In 75% of patients the procedure was combined with an open iliac lymphadenectomy. Median operation time of the videoscopic procedure was 110 min (range, 79–165). There were no perioperative complications or conversions. In 12 patients (60%) there was ≥1 postoperative complication. The most frequent complications were seroma and wound infection. All complications were treated conservatively without the need for a surgical re-intervention. The median nodal yield of the videoscopic procedure was 9 (range, 1–19). Lymphedema was present in nine patients (45%) after three months of follow-up.

Conclusion: Our initial results show that the videoscopic inguinal lymphadenectomy is an attractive alternative to the conventional open technique. The number of complications is comparable with the complication rate reported for the conventional open procedure, but they are less severe and there is no need for a surgical re-intervention.

Introduction

In the last decade, a completion or therapeutic lymph node dissection (CLND or TLND) has been standard of care for melanoma patients with a positive sentinel lymph node biopsy (SLNB) or a clinically positive nodal metastasis.

An open inguinal lymph node dissection is accompanied by high complication rates up to 70% [1–9]. The postoperative complications are mostly related to the large inguinal incision required for adequate exposure, and include wound infection, dehiscence, necrosis, seroma, and early lymphedema [7]. On the long-term, chronic lymphedema can occur, accompanied by complications such as enlarged extremities, mobility problems, and an increased risk of recurring infections of the swollen extremity [10]. These complications can result in a significant limitation of everyday activities and quality of life of patients. This has led to the search for a procedure with lower rates of postoperative complications and morbidity.

A novel minimally invasive alternative to the conventional open technique has been developed, the videoscopic inguinal lymphadenectomy (VIL). This procedure was first reported in melanoma patients by Delman et al., 2010 [11]. The procedure has already been performed in some centers in melanoma patients with promising results including a lower complication rate and comparable oncologic outcome [12–14]. However, there are just a few small series

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presenting their initial experience with VIL. Furthermore, the presence of lymphedema following VIL has never been well assessed objectively. Therefore, the aim of this study is to present our experience with VIL among melanoma patients with regional inguinal metastases including objective measurements of lymphedema.

Methods

Study population and design

A prospective study was conducted at the University Medical Center Groningen (UMCG), a tertiary referral center and one of the nine melanoma centers in the Netherlands. Melanoma patients who underwent a VIL for inguinal lymph node metastases (either micrometastases or macrometastases) between November 2015 and January 2018 were included.

If eligible for VIL, patients received oral and written information about the procedure. Furthermore, the novelty of this procedure was discussed. When patients declined a videoscopic procedure, they received the conventional therapy, i.e. an open lymph node dissection. The surgical procedure was either an inguinal lymph node dissection or a combined inguinal-iliac lymph node dissection. If a combined inguinal-iliac procedure was performed, patients first underwent a videoscopic inguinal approach, followed by an open iliac lymph node dissection via a separate skin incision. For the first procedure, a patient with a positive SLN biopsy was selected. Following this procedure, also patients with macrometastases were included for the VIL.

Baseline demographic information, including patient's age, gender, medical history, and primary melanoma characteristics were obtained from digital files stored in the electronic database of the hospital. Data collection was conducted according to the declaration of Helsinki ethical principles for medical research involving human subjects [15].

Outcome measures

Data concerning the VIL, including operation time, estimated blood loss, need for conversion to open procedure, and nodal yield were registered. The operation time was defined as the time in minutes of the videoscopic procedure, the time required for the open iliac lymph node dissection was not taken into account. The postoperative complications were graded according to the Clavien-Dindo complication classification [16]. The admission time was defined as the time in days between surgery and discharge form clinic.

Lymphedema

Lymphedema measures were performed at baseline and at three months postoperatively. Lymphedema was assessed subjectively and objectively by means of pre- and postoperative limb measurements and the Lymph–ICF–LL questionnaire. The total score of the Lymph–ICF–LL questionnaire ranged from 0 to 100. The scores were interpreted as follows: a score between 0 and 4 indicated no problem, a score between 5 and 24 indicated a small problem, a score between 25 and 49 indicated a moderate problem, a score between 50 and 95 indicated a severe problem and a score between 96 and 100 indicated a very severe problem [17]. Circumferential leg measurements were performed on both legs at 10 cm intervals from the lower border of the calcaneus to the groin. Additionally, the volume of both legs was determined by a water displacement technique [18]. Each leg was immersed in a water-filled cylinder to a marked level, followed by measuring the volume of displacement [18]. Lymphedema was defined as an interlimb volume difference of 6.5% between the relevant limb and the opposite limb [3]. The lymphedema was classified into four categories according to Baas et al.: normal (volume difference 0–6.5%), slight edema (volume difference 6.5–20%), moderate edema (volume difference 20–40%), and severe edema (volume difference >40%) [1,3].

Surgical procedure

The VIL was performed as described previously [19,20]. Patients were positioned on a split-leg table with the operative leg externally rotated. The boundaries of the femoral triangle were marked and a three-incision technique was used. Dissection was performed superficial to Scarpa's fascia until the borders of the femoral triangle, followed by mobilization of the lymph node packet. For the dissection, a laparoscopic sealing device was used. The specimen was placed in a removal bag and removed through the first incision site. A drain was left behind, and wounds were closed.

Postoperatively, patients were allowed to ambulate immediately except for the patients who underwent a concomitant iliac lymph node dissection. Patients record daily drain outputs until the drain was removed (output < 50 ml per 24 h).

Statistical analyses

SPSS Statistics version 22 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY:IBM Corp.) was used for statistical analysis. Baseline characteristics were described as mean with standard deviation (SD) or median with interquartile range (IQR) for continuous variables and as count (n) with percentage (%) for categorical variables. To compare baseline and follow-up lymphedema measures, Wilcoxon signed rank was used.

Ethical approval

The Medical Ethical Committee granted dispensation according to the Dutch law regarding patient based medical research obligation (METc registration no. 2015279). The study was approved by the institutional review board of the UMCG.

Results

Patient characteristics

A total of 20 patients (3 males and 17 females) were treated with VIL between November 2015 and January 2018. The baseline clinical and pathological patient characteristics are summarized in Table 1. The median age at lymph node dissection was 59 years (range, 31–76). Median overall Breslow thickness of the primary melanoma was 1.9 mm (range, 0.8–9.0). Superficial spreading melanoma was the most common histological subtype (55%), followed by nodular melanoma (20%).

Lymph node dissection

The majority of patients (75%) underwent a VIL combined with an open iliac lymph node dissection. Five patients (25%) underwent a VIL alone. Indications were macrometastases in 11 patients (55%) and micrometastases in 9 patients (45%). The median operation time of the videoscopic procedure was 110 min (range, 79–165). The median number of lymph nodes pathologically identified following VIL was 9 (range, 1–19) (Table 2).

Overall, one or more wound complications occurred in 12 patients (60%). The most frequent complication was seroma (44%), followed by wound infection (38%). The wound infections were

Table 1
Clinical and pathological characteristics (n = 20).

Characteristics	
Gender	
Male	3 (15.0%)
Female	17 (85.0%)
Age, years[a]	59.0 (31–76)
BMI, kg/m^2	25.8 (18.0–41.3)
Diabetes Mellitus	
Yes	1 (5.0%)
No	19 (95.0%)
Smoking	
Yes	4 (20.0%)
No	16 (80.0%)
Histologic typing	
Superficial spreading	11 (55.0%)
Nodular	4 (20.0%)
Other	2 (10.0%)
Unknown primary	2 (10.0%)
Unknown	1 (5.0%)
Breslow thickness, mm	1.9 (0.8–9.0)
T stage	
Tis	1 (5.0%)
T1 (<1.00 mm)	1 (5.0%)
T2 (1.01–2.00 mm)	8 (40.0%)
T3 (2.01–4.00 mm)	5 (25.0%)
T4 (>4.00 mm)	3 (20.0%)
Unknown primary	2 (10.0%)
Ulceration	
Yes	3 (15.0%)
No	13 (65.0%)
Unknown primary	2 (10.0%)
Unknown	2 (10.0%)

Data are presented as n (%) or median (range)
Abbreviations: BMI, Body Mass Index.
[a] Age at lymph node dissection.

Table 2
Indication and outcome of the videoscopic lymph node dissection.

Variable	Result
Operation	
Videoscopic inguinal lymphadenectomy	5 (25.0%)
Additional open iliac lymphadenectomy	15 (75.0%)
Indication[a]	
Micrometastases	9 (45.0%)
Macrometastases	11 (55.0%)
Operation time videoscopic procedure, minutes	110.0 (79.0–165.0)
Lymph node count	9.0 (1–19)
Largest diameter positive lymph node, mm	35 (5.0–60.0)
Postoperative radiotherapy	
Yes	7 (35.0%)
No	13 (65.0%)
≥1wound complication[b]	
Yes	12 (60.0%)
No	8 (40.0%)
Type of complication	
Wound infection	6 (37.5%)
Wound dehiscence	1 (6.3%)
Seroma	7 (43.8%)
Hematoma	2 (12.5%)
Necrosis	0 (0.0%)
Complication grade[c]	
Grade I	5 (31.3%)
Grade II	6 (37.7%)
Grade IIIa	5 (31.3%)
IIIb	0 (0.0%)
Grade IV	0 (0.0%)
Admission time, days	
Videoscopic inguinal lymphadenectomy	4.0 (2.0–5.0)
Additional open iliac lymphadenectomy	4.0 (2.0–6.0)

Data are presented as n (%) or median (range).
[a] Micrometastasis is defined as tumor load in the sentinel lymph node biopsy; macrometastases is defined as a palpable inguinal lymph node.
[b] Within 30 days following surgery.
[c] According to the Clavien-Dindo complication classification.

treated with oral or intravenous antibiotics. The majority of complications were grade I or II complications (69%). There were six (31%) grade IIIa complications, including drainage of seroma by needle aspiration. There were no surgical re-interventions. Median hospital admission time following VIL was 4.0 days (range 2–5).

Lymphedema

Subjective and objective assessment of lymphedema measures at baseline and three months postoperatively are presented in Table 3. The Lymph–ICF–LL score increased significantly between baseline (median 0) and three months postoperatively (median 19.5) ($p < 0.001$). At three months postoperatively, most patients (40%) experienced a small problem with lymphedema according to the Lymph–ICF–LL questionnaire.

The median circumferential difference between both legs increased from zero at baseline to 12 cm at three months postoperatively ($p < 0.001$). A volume difference of 100 mL (range -200 – 750) was seen between both legs at baseline compared to a volume difference of 675 mL (range -600 – 2400) at three months postoperatively ($p = 0.013$). According to the lymphedema classification, eight patients (40.0%) had slight edema and one patient had moderate edema (4.8%) at three months postoperatively. None of the patients had severe edema.

Discussion

In this prospective study, the outcome of the VIL was assessed in melanoma patients with inguinal metastases. The number of complications is comparable with the complication rate reported for the conventional open procedure [6]. However, the severity of the complications seems less, with a majority Grade I or II complications. Furthermore, all complications were treated conservatively without the need for a surgical re-intervention. Our initial experience shows that the VIL might be an attractive alternative to the conventional open inguinal lymphadenectomy.

A CLND has been standard of care following a positive SLN biopsy in melanoma patients. Following the results of the second Multicenter Selective Lymphadenectomy Trial (MSLT-II), which showed no survival benefit for an immediate CLND in melanoma patients with a positive SLN biopsy, the CLND might be abandoned [21]. It is unclear how this will affect future guidelines worldwide. However, there remains an indication for a TLND in patients with macroscopic disease. Despite several modifications to the conventional open procedure, including relocating skin incisions, thicker skin flaps, preservation of the saphenous vein, and sartorius muscle transposition, complication rates have not substantially decreased [22–25]. In literature, complication rates up to 70% have been described for the open inguinal lymphadenectomy [1–7]. The VIL has been developed to improve the postoperative outcome, and is described in patients with penile and vulvar cancer, and melanoma. The complication rate of the VIL in previous studies is comparable with our study and the open procedure (Table 4). However, these studies presented their initial experience with VIL, whilst the conventional open inguinal lymphadenectomy has been performed for several years. Probably, the number of complications will decrease after reaching the learning curve for the VIL, as also illustrated by Delman et al., who published a complication rate of 40% in their initiation series, decreasing to 18% with growing experience in the following year [11,13]. Furthermore, less severe complications have been seen following the VIL [13,26]. The three-port approach eliminates the large inguinal incision, a major cause

Table 3
Lymphedema measures at baseline and three months postoperatively.

Variable	Baseline	3 months	p-value
Lymph–ICF–LL score	0 (0–61)	19.5 (2–68)	<0.001
Classification Lymph–ICF–LL			<0.001
No problem (0–4)	15 (75.0%)	2 (10.0%)	
Small problem (5–24)	4 (20.0%)	8 (40.0%)	
Moderate problem (25–49)	0 (0.0%)	5 (25.0%)	
Severe problem (50–95)	1 (5.0%)	3 (15.0%)	
Very severe problem (96–100)	0 (0.0%)	0 (0.0%)	
Unknown	0 (0.0%)	2 (10.0%)	
Stemmer's test affected leg			0.317
Negative	16 (84.2%)	13 (76.5%)	
Positive	3 (1580%)	4 (23.5%)	
Pitting test affected leg			0.317
Negative	16 (84.2%)	14 (82.4%)	
Positive	3 (15.8%)	3 (17.6%)	
Circumferential difference between both limbs (cm)	0.0 (-11 – 22)	12.0 (-8 – 35)	0.006
Volume difference between both limbs (ml)	100 (-200 – 750)	675 (-600 – 2400)	0.013
Lymphedema classification*			0.004
Normal	19 (95.0%)	8 (40.0%)	
Slight edema	1 (5.0%)	8 (40.0%)	
Moderate edema	0 (0.0%)	1 (5.0%)	
Severe edema	0 (0.0%)	0 (0.0%)	
Missing	0 (0.0%)	3 (15.0%)	

Data are presented as n (%) or median (range).
[a] Classified according to Baas et al. (ref).

Table 4
Outcome parameters of VIL from several reported series in the literature.

Article	Number of procedures	Number of lymph nodes	Conversion	Complication
Delman KA et al., 2010	5	Median 10 (range 4–13)	0 (0.0%)	40%
Delman KA et al., 2011	45	Median 11 (range 4–24)	2 (4.4%)	18%
Master VA et al., 2012	41	Median 11 (range 3–24)	0 (0.0%)	41%
Martin BM et al., 2013	40	Mean 12.6 (range 3–24)	0 (0.0%)	48%
Abbott AM et al., 2013	13	Median 11 (IQR 9–15)	1 (7.7%)	54%
Sommariva A et al., 2016	24	Median 9.5 (IQR 8–14.5)	4 (16.7%)	58%
Jakub JW et al., 2017	87	Median 12 (IQR 8–14)	11 (12.6%)	71%
Postlewait LM et al., 2017	137	Mean 11.2 (SD 4.6)	6 (4.4%)	N/A

Abbreviations: IQR, Inter Quartile Range, N/A, Not Available.

of wound complications such as necrosis, infection, and dehiscence. The present analysis demonstrated no necrosis, and the most frequent complications were seroma and a superficial wound infection. All complications were treated conservatively and there was no need for a surgical re-intervention, an important advantage of the VIL.

The lymph node count is an important surrogate marker for the quality of the lymph node dissection. According to literature, the recommended number of harvested lymph nodes for the inguinal lymphadenectomy in melanoma patients varies from 5 to 10 [27–31]. Another parameter for surgical quality control is the minimal number of lymph nodes resected in 80% or 90% of cases, as reported by Spillane (90% ≥ 8) and Rossi (90% ≥ 6) for the open inguinal lymphadenectomy [31,32]. In our study, the median lymph node count was 9 (not including the SLNB), which is within the recommended lymph node count. The number of lymph nodes harvested in 80% of cases was ≥6. The relatively low number of harvest lymph nodes in this study is probably due to the fact that quite a few patients had undergone previous lymph node surgery. A learning curve might be another explanation, as also shown by the higher lymph node count in our historical data of the open procedure (median 10, range 0–26) [6]. One may argue that less extensive resection led to less complications. However, in our experience, resection after previous procedures usually leads to a greater wound surface. Furthermore, the number of harvested lymph nodes is a multifactorial value, which depends not only on the surgical procedure, but also on the pathological analysis, and the patient's anatomy. There was no dedicated pathologist assigned to our study. The resected specimen was assessed by different analysts and pathologists with a variation in how the nodes were retrieved from the fibrofatty tissue.

To our knowledge, this is the first study objectively assessing lymphedema following the VIL. Only a subjective assessment of lymphedema has been described, with lymphedema in 11% of patients [33]. In our study, the volume of both legs was determined using a water displacement technique. In eight patients (38.1%) there was slight lymphedema and in one patient (4.8%) moderate edema. No severe lymphedema was seen. The percentage of patients with lymphedema following the V-IFL in our study is comparable to the percentages reported for the open inguinal lymphadenectomy (20%–64% depending on the definition for lymphedema used) [1,3,34]. However, most are long term data instead of three months postoperatively as in our study. The preservation of intact dermal lymphatic's and the reduction of severe wound complication, especially wound infections, might contribute to a decreased long-term incidence of lymphedema in patients following the VIL.

Not only the inguinal lymphadenectomy can be performed minimally invasive, but also the iliacal lymphadenectomy [35–37]. As we have historically performed the iliacal lymphadenectomy by open surgery, we thought it unwise to change this procedure at the same time as starting the VIL. Combining two learning curves may

lead to inferior outcome. We are currently planning to change the open iliacal procedure to a minimally invasive technique.

There are several limitations to this study that need to be addressed. First of all, the number of patients and duration of follow-up is limited. Further research is necessary to assess the long term (oncological) outcome of the VIL. Second, for the first procedure, we selected a patient with a positive SLN biopsy (selection bias). Following this procedure, also patients with a macrometastases were included for the VIL. The largest diameter of positive lymph node resected was 6.0 cm.

Conclusion

Our initial results show that the VIL might be an attractive alternative to the conventional open technique. The number of complications seems comparable with the complication rate reported for the conventional open procedure, but there was no need for a surgical re-intervention. Furthermore, no severe lymphedema was seen. The nodal yield is adequate.

Conflict of interest statement

The authors have no conflict of interest to declare.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejso.2019.04.018.

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