Laparoscopic inguinal lymph node dissection in carcinoma of the vulva: experience and intermediate results at one institution

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Objective: The goal of the study was to assess the feasibility of Laparoscopic Minimally Invasive Inguinal Lymph Node Dissection (L-MILND) for carcinoma of the vulva where sentinel lymph node biopsy could not be done. Laparoscopic Minimally Invasive Inguinal Lymph Node Dissection (L-MILND) is a procedure developed to decrease morbidity associated with inguinal lymphadenectomy while maintaining acceptable oncological outcomes. Initial experience and feasibility of this technique at the authors' institution is reported.

Setting: Dr George Mukhari Academic Hospital/Sefako Makgatho Health Sciences University.

Patients: Sixteen L-MILND performed in nine patients with T1b squamous cell carcinoma of the vulva from May 2016 to April 2020. This is a retrospective analysis of the preoperative, intraoperative and postoperative characteristics.

Results: The median age was 40 years (37–71 years). L-MILND’s median duration and the radical wide local excision was 223 ± 40 minutes (180 to 300 minutes). There were no intraoperative complications. The mean drain output per patient of both inguinal areas was 315 ml (50–990 ml). On average, drains were removed on day 6 (range 3–10 days). The mean number of nodes harvested was 5 (range 0–32 nodes). One patient had 1 positive node out of 32 harvested. The postoperative complications included: lymphoedema (1 groin, 6.25%), seroma (6 groins, 37.5%) and lymphorrhea (4 groins, 25.0%). Overall follow-up has been 3–50 (mean 28.3 months) months, and all patients were alive with no disease.

Conclusion: The significant advantage of L-MILND appears to be the low rate of inguinal wound complications that may be associated with open procedures. This nevertheless comes at the expense of long operative times and seroma formation. This procedure is feasible and safe, though there is a need for large prospective studies with extended follow-up.

Keywords: carcinoma of vulva, laparoscopic minimally invasive inguinal lymph node dissection

Introduction

Vulval carcinoma is uncommon, accounting for 2% to 5% of gynaecological cancers, with squamous cell carcinoma as the most common histological type.1 It has been surgically staged since 1988 and the staging system was updated in 2009 by the International Federation of Gynecology and Obstetrics (FIGO). The stage will depend on the size of the lesion, amount of lymph node metastasis, extracapsular spread of the metastasis, involvement of adjacent structure and distant metastasis.2 The status of inguinal lymph nodes is an important prognostic factor that determines survival in patients with carcinoma of the vulva. Most patients will have early stage disease, for which the standard treatment is wide local excision and inguinofemoral lymph node dissection.3 This procedure is associated, in 85% of patients, with surgical morbidity such as wound breakdown, cellulitis, lymphocele, lymphoedema and infection.4 But only 25–35% of early stage vulva cancers have lymph node metastasis.5–7 There are different techniques with variable outcomes in the literature seeking to reduce groin morbidity after inguinofemoral nodal dissection, including sparing of the saphenous vein,8 Sartorius muscle transposition9 and preservation of fascia lata.7 Furthermore, to try to reduce groin surgical morbidity, a sentinel lymph node procedure was adopted for vulvar carcinoma and found to be feasible for cancer of the vulva.10 The GROINSS V I study demonstrated the SLN algorithm to be safe in vulval cancer, but only for patients with well-differentiated, small unifocal lesions of <4 cm,10 excluding patients with operable early stage disease larger than 4 cm and/or poorly differentiated multifocal disease. The development of laparoscopic inguinofemoral lymph node dissection was first described by Bishoff to breach this gap. He described a technique of endoscopic inguinofemoral node dissection in two cadavers and one live patient.11 This novel technique was found to be associated with low groin morbidity (wound breakdown and cellulitis) in patients with penile cancer, melanoma and recently vulval carcinoma, compared with the standard open technique.12–14 All the above authors use what is called a LEG approach, for which the stepwise approach was described by Master and colleagues in 2009.15

We report our experience and results of the first series of L-MILND performed by our group in South Africa between May 2016 and April 2020. This is a feasibility study that provides a retrospective analysis of the preoperative, intraoperative and postoperative data.

Materials and method

A retrospective study at Dr George Mukhari Academic Hospital/ Sefako Makgatho Health Sciences University is presented. After approval by the institutional research ethics review committee, a retrospective review of records of patients who underwent L-MILND for vulval carcinoma was carried out. Patient identifiers were anonymised for analysis. A total of 9 patients who had 16 L-MILND procedures were identified. Seven patients had bilateral laparoscopic inguinal node dissections, one patient...
underwent laparoscopic inguinal node dissection on the left side only, and one patient had only a right-sided laparoscopic inguinal lymphadenectomy. The following parameters were analysed: operative time, blood loss, intraoperative complications, drain output, day of drain removal, number of lymph nodes harvested, the histological status of the lymph nodes, and recurrence on follow-up. Consent for participation in the study was given.

Data management was performed using Microsoft Excel, 2018 (Microsoft Corp, Redmond, WA, USA). Data analysis was performed using the Stata 14.2 (StataCorp LLP, College Station, TX, USA) software package. Descriptive methods involved the expression of frequencies and percentages; continuous variables were expressed as means with standard deviations with ranges.

Surgical procedure
Patients were counselled and signed consent for the procedure. The procedure was done under general anaesthesia and was performed as described earlier.15 We used the LEG approach. The patient was placed in a supine position with the legs externally rotated and abducted. The room setup and patient position are shown in Figure 1. The patient was cleaned and draped. We made a 10 mm incision 2 cm caudal to the femoral triangle’s apex, extending the incision to below Scarpa’s fascia. We then developed a working space with scissors and finger blunt dissection. A 5 cm working space was developed in this fashion. A 10 mm port was then inserted into the incision, and carbon dioxide (CO2) gas insufflated to pressure of 10 mmHg; two additional 5 mm ports were inserted under vision about 5 cm lateral and medial to the vision port (Figure 2). The working space was extended by dissection.

Figure 1: Room setting, with laparoscopy stack placed at the patient’s head, with patient’s thighs abducted and internally rotated to access femoral triangle.

Figure 2: (A) 10 mm vision port placed 2 mm caudal to the apex of the femoral triangle with telescope inserted. (B) Second trocar (5 mm) inserted under vision 5 cm medial to the vision port. (C) All THREE ports inserted and working space developed further cranially.

Figure 3: Undermining the skin flap below the Scarpa fascia and cranial extension of the working space.
with a LigaSure (Medtronic, Minneapolis, MN, USA) instrument up to 2 cm cranial to the inguinal ligament, the lateral border of Sartorius and the adductor muscle (Figure 3). The superficial lymph node basin is dissected from the floor of the femoral triangle (Figure 4), sparing the saphenous vein (Figure 5). The nodes are then delivered, the incision closed and suction drain left in situ (Figure 6).

**Results**

Table 1 gives patients’ background characteristics. A total of 9 patients underwent L-MILND from May 2016 to April 2020, and among these 16 groins were dissected using L-MILND. The median age of the patients was 40 years (range, 37–71 years). Mean BMI was 30 (range, 21.3–42.1). Seven patients were HIV-positive and 2 had no comorbid diseases. All our patients had radical wide local excision (WLE) and 2 had only unilateral L-MILND. Table 2 gives perioperative and pathological characteristics of the patients. Eight patients had no lymph node metastasis (pT1bN0M0), whereas one patient had 1 metastatic lymph node (pT1bN1aM0). The mean duration of surgery was 223 ± 40 minutes (180 to 300 minutes). We determined the duration of surgery from induction of anaesthesia to the extubation of the patient because it was the consistently recorded time in the records. Average drain output was 314.9 ± 359.9 ml. On average the drain was removed on day 6 (3–10 days). Two patients experienced vulva wound breakdown and stayed in the hospital for 28 and 30 days respectively. The other 7 patients stayed in the hospital on average for 4 (range 3–10) days. The median number of lymph nodes harvested was 5 (range 0–32 nodes). Table 3 shows lymph node harvest per groin.

There was no groin-related wound breakdown, skin necrosis or cellulitis reported. Only lymphoedema, lymphorrhoea and seroma complications were noted. The per groin postoperative complications were lymphoedema (1 groin, 6.25%), seroma (6 groins, 37.5%) and lymphorrhoea (4 groins, 25.0%).

Ten groins had no complications recorded; for further details, see Table 4. All patients had squamous cell carcinoma; we spared the great saphenous vein in all patients, blood loss associated with the laparoscopic inguinal lymphadenectomy was negligible and there were no intraoperative complications. Four (44.5%) patients required adjuvant treatment for close resection margins on the vulva, and 5 (55.5%) did not require any adjuvant treatment. Median follow-up was 38 months (range 3–50 months) and all patients were alive without any evidence of disease recurrence.

**Discussion**

We address the feasibility and complication profile of nine patients who had L-MILND and simple vulvectomy for carcinoma of the vulva at our institution. Though a small series, we found that the procedure to remove the nodes appears safe and feasible with no significant intraoperative complication. The significant advantage of the minimally invasive procedure is that it appears to reduce wound-related complication length of stay in the hospital after the surgery. Having said this, however, some complications did arise specific to the inguinal areas, but they were relatively mild, and none of these complications resulted in an additional stay in hospital.

Our results showed a mean operating time of 223 minutes (range 180–300) for the L-MILND and simple vulvectomy. In comparative studies, a significantly longer operative time was recorded with minimally invasive approach as compared with open techniques. Zhang and colleagues in their study comparing 48 patients who underwent L-MILND (21 patients) and standard inguinal lymphadenectomy (27 patients) in patients with vulval carcinoma, reported mean operative times were 109 ± 29.5 minutes and 45.3 ± 5.1 minutes, respectively (p < 0.001). Tobias-Machado et al. performed standard inguinal lymphadenectomy in 1 limb and L-MILND in the contralateral limb in 10 patients with penile cancer. They found operative time to be significantly longer in the L-MILND compared with the standard open procedure (126 vs. 92 minutes). Additionally, Abbot et al. in melanoma patients found operative time in L-MILND to be longer than in an open procedure (245 vs. 138 minutes). A systematic review by Liu and colleagues reported a total of 9 studies containing 249 L-MILND procedures in 138 patients;
Table 1: Patients’ background characteristics

| Patient # | Age, years | BMI (kg/m²) | Clinical characteristics | Type of surgery |
|-----------|------------|-------------|--------------------------|-----------------|
| V1        | 51         | 31.2        | HIV+, CD4:454, On FDC, 3 cm polypoid lesion involving labia minora, grade 2 squamous cell carcinoma | Radical WLE+unilateral L-MILND+open GND |
| V2        | 39         | 21.3        | HIV+, CD4:660, On FDC, 4 cm ulcerative lesion involving clitoris and labia majora, grade 2 squamous cell carcinoma, high-grade VIN | Radical WLE+bilateral L-MILND |
| V3        | 55         | 42.1        | HIV+, 5 cm flat lesion, diagnosis: squamous cell carcinoma, high-grade VIN | Radical WLE+bilateral L-MILND |
| V4        | 38         | 28.1        | HIV+, CD4:403, On FDC, lesion 4 cm on the left labia minora, diagnosis: grade 3 squamous cell carcinoma | Radical WLE+bilateral L-MILND |
| V5        | 55         | 24.2        | HIV+, CD4:585, On FDC, lesion 3 cm polypoid around the clitoris, diagnosis: grade 3 squamous cell carcinoma, HGSIL | Radical WLE+bilateral L-MILND |
| V6        | 37         | 25.7        | HIV+, CD4:214, 2 cm ulcerative lesion on the left labia majora, squamous cell carcinoma | Radical WLE+bilateral L-MILND |
| V7        | 40         | 30.5        | HIV+, CD4:231, On FDC, diagnosis: grade 2 squamous cell carcinoma, VIN3 | Radical WLE+bilateral L-MILND |
| V8        | 39         | 40.2        | HIV+, CD4:373, On FDC, 4 cm labia minora, lateral 4 cm from midline, grade 2 squamous cell carcinoma, VIN3 | Radical WLE+bilateral L-MILND |
| V9        | 71         | 29.0        | No comorbid disease, 4 cm ulcerative lesion left labia majora, diagnosis: grade 2 squamous cell carcinoma | Radical WLE+unilateral L-MILND |
| Mean 47   | Mean 30.25 |             |                          |                 |
| Median 40 | Median 29.0|             |                          |                 |

BMI: body mass index, HIV: human immunodeficiency virus, FDC: fixed dose combination, VIN: vulval intraepithelial neoplasia, HGSIL: high-grade squamous intraepithelial lesion, WLE: wide local excision, GND: groin nodal dissection, L-MILND: laparoscopic minimally invasive inguinal lymph node dissection.

Table 2: Perioperative and pathological characteristics

| Patient # | Duration of surgery, min | Average drain output, ml | Drain removal (postoperative day) | Final histology | Lymph node yield, N | Histopathology of lymph nodes | Follow-up (months) |
|-----------|--------------------------|--------------------------|----------------------------------|-----------------|---------------------|-----------------------------|-------------------|
| V1        | 240                      | 138                      | 6                                | 2.5 cm lesion, 0.5 cm stromal invasion, VIN3, 17 mm margins | 0       | Negative          | 50                |
| V2        | 240                      | 418                      | 10                               | 3.5 cm ulcerative tumour, 5.5 mm margins            | 17      | Negative          | 49                |
| V3        | 300                      | 50                       | 8                                | 9 cm polypoid tumour, 5.5 mm stromal invasion, VIN3, completely excised | 3       | Negative          | 48                |
| V4        | 180                      | 63                       | 4                                | 2.5 cm ulcer/2.2 mm margins/6.6 mm infiltration/no LVSI, VIN3 | 4       | Negative          | 45                |
| V5        | 240                      | 842                      | 4                                | Multifocal lesions (3.5 cm and 2 cm) 5.5 mm closest margins/VIN3 | 32      | Positive (1)     | 38                |
| V6        | 180                      | 990                      | 7                                | 2 cm lesion with fibrosis, completely excised        | 7       | Negative          | 9                 |
| V7        | 210                      | 75                       | 3                                | Basaloid, 9 mm lesion, 5 mm depth, 1 mm closest margins, VIN3 | 4       | Negative          | 8                 |
| V8        | 240                      | 125                      | 4                                | 3.5 cm ulcerated fungating lesion, 7 mm depth of invasion, 5 mm closest margin, VIN3 | 11      | Negative          | 4                 |
| V9        | 180                      | 133                      | 6                                | 3.5 cm punched-out lesion/3 mm closest margin       | 5       | Negative          | 3                 |
| Mean: 223 +/- 40 | Median: 133 Range 50–990 | Mean: 5.8/+−2.3     | Mean: 9.2/+−9.9                | Mean: 28.2/+−21.4 |
| (Median = 240 (180–300) | Mean: 314.9/+−3598     | Median: 6 (3–10)             | Median = 5 (0–32)              | Median = 38 (3–50) |
the operative time among these studies ranged between 62 and 110 minutes.\textsuperscript{18}

In our study, the operative time included time to administer the anaesthetic, positioning of the patient, time for the L-MILND, and time to complete the simple vulvectomy. This contributed to longer operative time in our study.

The mean drain output in our study was 314 ml (50 to 990 ml), and the drain was removed at mean on day 6 (3–10 days). The drain appears to have been removed at between 6 and 9.8 days across the reports in the systematic review of L-MILND by Liu and colleagues,\textsuperscript{18} although Zhang \textit{et al.} reported longer post-operative drainage duration with L-MILND vs. open technique, 16 days vs. 8 days respectively.\textsuperscript{16} L-MILND shows longer post-operative lymph drainage. The mean lymph node yield in our study was 5 (0–32) per groin, but of note was that there was no harvest from two groins, 1 node from 1 groin and 2 nodes from 2 groins, so that of 16 L-MILND performed in our study, 5 groins had only 0–2 nodes. There have not been any groin recurrences after follow-up of 3 to 50 months, though follow-up was too short to reach any conclusions on oncological outcomes.

Our lymph node yield is variable. There are variable reports on how the number of lymph nodes harvested affects the oncological outcome. In one, it was reported that a lymph node count of less than 9 was related to groin recurrence,\textsuperscript{19} although Diehl \textit{et al.} noted that dissection of more than 6 lymph nodes in each groin does not improve groin recurrences in patients with vulvar cancer,\textsuperscript{20} whilst a study by Stehman \textit{et al.} found that lymph node count in stage 1 vulvar carcinoma was not associated with groin recurrence rate.\textsuperscript{21} Besides surgeon proficiency, lymph node count depends on patient characteristics and pathologist expertise. Patient characteristics include anatomy, age, body mass index, immune status and exposure to toxins, which affect lymph node yield. Variability among pathologists on how nodes are retrieved from fibrofatty tissue and interobserver and intraobserver variability at microscopy on how lymph nodes are examined among pathologists both may affect lymph node yield.\textsuperscript{22} These factors make the lymph node count an unreliable measure of surgery quality.

The L-MILND certainly is feasible, but it does appear to increase the time needed for the entire surgery significantly. In our hands, there was variable outcome in the number of nodes removed from each groin, and on two occasions no nodes were harvested from a groin region. Although this is the case and of concern to us, the literature does not conclude or specify the minimum number of lymph nodes recommended to predict or exclude the likelihood of inguinal recurrences and, to date, in our series there have not been any recurrences after a median follow-up of 38 months.

We had no major groin wound-related morbidity in our cohort. The L-MILND does not interfere with completing the simple vulvectomy and only two patients that had a protracted stay in hospital and recovery, which was due to a breakdown of the vulvar incisions. We had lymphoedema, lymphorrhea and seroma occurring in 6.25%, 25.0% and 37.5% of groins, respectively. Zhang and colleagues in their study found wound complications to be significantly rare with a minimally invasive approach compared with a standard open approach (4.8% vs. 55.6%), and there was no significant difference in the incidence of lymphocele and lymphoedema in their study.\textsuperscript{16} Furthermore, patients who underwent a minimally invasive approach experienced higher body image scores and cosmetic scores.\textsuperscript{16} In a systematic literature review of 10 series (236 minimally invasive inguinal node dissection) that included 168 patients, wound-

| Complication                        | Postoperative complications per groin | Postoperative complications per patient |
|-------------------------------------|---------------------------------------|----------------------------------------|
| Groin wound necrosis, cellulitis or breakdown | 0 (0%)                               | 0 (0%)                                 |
| Lymphoedema                         | 1 (6.25%)                             | 1 (11.11%)                             |
| Lymphorrhea                         | 4 (25.0%)                             | 2 (22.22%)                             |
| Seroma                              | 6 (37.5%)                             | 4 (44.44%)                             |
| No complications of groin dissection | 10 (62.5%)                            | 4 (44.44%)                             |
| > 1 complication of groin dissection | 4 (25.0%)                             | 2 (22.22%)                             |

Figure 6: Closure and suction drain inserted.
related complications ranged between 0% and 13.3%; lymphatic/seroma-related complications ranged between 4% and 38%.23 Jain et al. reported seroma, lymphoedema, lymphorrhoea and cellullitis of 27.3%, 27.3%, 4.5% and 9.1% of groins, respectively. No major inguinal wound-related complications were reported in the study.24

The significant advantage of MILND is the reduction in inguinal incision wound complications, especially wound breakdown, which may increase the hospital stay and rate of readmission for wound care. Seroma formation is a frequent complication of L-MILND. Risk factors for the development of seroma in L-MILND are ipsilateral lymphoedema, use of large suction bulbs, number of metastatic lymph nodes, increased BMI, age and drain output 24 hours before removal. There is no reliable method to reduce this complication.25

Conclusion

Bearing in mind the limitations (retrospective nature, single institution, single surgeon and selection bias) of our study, L-MILND is a safe and feasible operative technique in patients with vulval carcinoma but the inguinal nodal harvest is not consistently predictable. Our result shows that there is a low groin wound-related morbidity, especially with a view to groin skin breakdown, cellullitis, lymphoedema, seroma formation or lymphorrhoea, with satisfactory oncological outcomes. More studies must take place, especially multicentre randomised or well-designed observational studies. Nevertheless, the available studies, including ours, shows that it is a safe, feasible, although time-consuming procedure.

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