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Training High-Volume Melanoma Surgeons to Perform a Novel Minimally Invasive Inguinal Lymphadenectomy: Report of a Prospective Multi-Institutional Trial

James W Jakub, MD, FACS¹, Alicia M Terando, MD, FACS², Amod Sarnaik, MD, FACS³, Charlotte E Ariyan, MD, FACS⁴, Mark B Faries, MD, FACS⁵, Sabino Zani Jr, MD⁶, Heather B Neuman, MD, MS, FACS⁷, Nabil Wasif, MD, FACS⁸, Jeffrey M Farma, MD, FACS⁹, Bruce J Averbook, MD, FACS¹⁰, Karl Y Bilimoria, MD, MS, FACS¹¹, Jacob B (Jake) Allred, MS¹², Vera J Suman, PhD¹², Travis E Grotz, MD¹, Benjamin Zendejas, MD¹, Jeffrey D Wayne, MD, FACS¹¹, and Douglas S Tyler, MD, FACS¹³

¹Department of Surgery, Mayo Clinic, Rochester, MN

²Department of Surgery, Ohio State University Medical Center, Columbus, OH

³Department of Surgery, H. Lee Moffitt Cancer Center, Tampa, FL

⁴Department of Surgery, Memorial Sloan Kettering Cancer Center, New York, NY

⁵Department of Surgical Oncology, John Wayne Cancer Institute, Santa Monica, CA

⁶Department of Surgery, Duke University School of Medicine, Durham, NC

⁷Division of General Surgery, University of Wisconsin School of Medicine and Public Health, Madison, WI

⁸Department of Surgery, Mayo Clinic, Phoenix, AZ

⁹Department of Surgery, Fox Chase Cancer Center, Philadelphia, PA

¹⁰Department of Surgery, MetroHealth Medical Center, Cleveland, OH

¹¹Department of Surgery, Northwestern University Feinberg School of Medicine, Chicago, IL

¹²Department of Biomedical Statistics and Informatics, Mayo Clinic, Rochester, MN

¹³Department of Surgery, University of Texas Medical Branch, Galveston, TX

Abstract

Correspondence address: James W. Jakub, M.D., Department of Surgery, Mayo Clinic, 200 First Street SW, Rochester, MN 55905, Phone: 507-284-3629, Fax: 507-284-5196, jakub.james@mayo.edu.

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Background—Minimally invasive inguinal lymphadenectomy (MILND) is a novel procedure with the potential to decrease surgical morbidity compared with the traditional open approach. The current study examined the feasibility of a combined didactic and hands-on training program to prepare high-volume melanoma surgeons to safely and proficiently perform this procedure.

Study Design—A select group of melanoma surgeons with no prior MILND experience were recruited. After completing a structured training program, surgeons enrolled patients with melanoma who required inguinal lymphadenectomy, and performed the procedure in the minimally invasive fashion. A proficiency score comprised of lymph node yield, operative time and blood loss (or adverse events) was assigned for each case. After performing six cases, surgeons meeting a threshold score were considered proficient in the procedure.

Results—Twelve surgeons from ten institutions enrolled 88 patients. The majority of surgeons were deemed proficient within 6 cases (83%). No differences in operative time or lymph node yield were noted over the course of the study. The rate of conversion was higher during an individual surgeon's early experience (18% (9/49), whereas only one procedure was converted in the 39 cases performed after a surgeon had performed 5 cases (late conversion rate, 3%, $p = 0.038$); however, this did not remain significant after controlling for surgeon.

Conclusions—Following a structured training program, experienced melanoma surgeons adopted a novel surgical technique with acceptable operative times, conversions and lymph node yield. Eight-four percent of the surgeons who completed at least 6 MILND procedures were considered proficient based on our predetermined definition.

Keywords

laparoscopic; learning curve; videoscopic; groin dissection; inguinal; endoscopic; lymph node; groin dissection; melanoma; minimally invasive

Introduction

Inguinal lymphadenectomy is associated with significant perioperative morbidity. Minimally invasive inguinal lymph node dissection (MILND) is a novel approach to inguinal lymphadenectomy, which is a trocar based approach to the groin dissection and eliminates the need for large incisions. It also places the incisions remote from the inguinal crease; eliminating one of the largest sources of morbidity from this operation. Retrospective institutional series have reported that the number of lymph nodes pathologically identified following a MILND is equivalent or greater than the conventional open approach, with less short-term morbidity to date(1, 2).

Multiple studies have shown that trainees who have not completed surgical training can master advanced technical skills through simulated training, thereby becoming a "pre-trained novice"(3–5). There are fewer studies regarding the manner by which practicing surgeons acquire the skills to perform new procedures. It is common for surgeons to incorporate new surgical techniques and technologies into their practice without any type of formal training. Historically, randomized studies comparing a novel procedure to an established technique have not provided surgeons with formal training in the new procedure or confirmed participating surgeons' technical competency prior to allowing them to enroll

patients into the study. Failure to account for the learning curve inherent in any new procedure, as well as the lack of quality control influences the ability to make a fair comparison between the new and established techniques. One such example is the study by Neumayer et al, which compared open mesh versus laparoscopic mesh inguinal hernia repairs, and reported inferiority of the laparoscopic approach(6). Critics of the study have noted that technical inexperience with the procedure by the participating surgeons, and failure to ensure proper laparoscopic training through credentialing may have jeopardized the validity of the comparison and resulted in an inability to demonstrate superiority of the laparoscopic approach(7). In the prospective COST trial, which studied laparoscopic versus open colectomy, all participating surgeons were required to demonstrate competency prior to enrolling patients(8). This credentialing included submission and favorable review of operative and pathology reports, as well as favorable review of a video recording of one procedure. The COST study group defined a standardized surgical technique up-front, and used random video audits and education to ensure adherence with appropriate operative technique. Although the conversion rate to an open procedure was 21%, these high technical standards were likely the reason that this study ultimately showed that laparoscopic colectomy was not inferior to the open approach for malignant disease(8).

SAFE-MILND (NCT01500304) is a multi-center, phase I/II clinical trial in which established melanoma surgeons were trained in a novel procedure, specifically the minimally invasive technique to perform an inguinal lymphadenectomy. The participating surgeons were all experienced in the conventional open approach, but had never attempted the MILND procedure prior to participating in the structured training program. One of the primary aims of this trial was to determine if this training methodology was feasible and allowed surgeons, newly adopting this procedure, to become proficient. Thus we attempted to determine if what the surgeons learned was able to be translated into clinical practice. Herein, we report the experience and outcomes of this group of surgeons who performed their first MILND following our structured training program.

Methods

A select group of high volume melanoma surgeons practicing in the United States, who perform at least 6 open inguinal lymph node dissections per year, and had no previous MILND experience were identified and invited to participate in a curriculum to learn the innovative MILND procedure. Sixteen surgeons from 12 institutions completed the training program, and 12 surgeons from 10 institutions opened the IRB-approved trial at their institution and prospectively enrolled patients to the trial. All data were submitted to a central repository.

Training

All participating surgeons travelled to Mayo Clinic, Rochester, Minnesota to attend the one day training program. The attendees watched an instructional video, which was created by Mayo Clinic Media Support Services, depicting the procedure in high-quality graphic detail and adhering to effective adult learning principles. The twenty-minute video included a 3-D animated component of the relevant anatomy with key steps of the procedure outlined and

visually depicted, as well as a series of edited operative cases, highlighting the critical aspects of the procedure. The video can be seen at <http://medprofvideos.mayoclinic.org/videos/minimally-invasive-inguinal-lymph-node-dissection-milnd>. Next, all attendees participated in a hands on cadaveric lab in which each participant performed MILND in a controlled environment under instructional supervision; functioning as first assistant for one case and surgeon for one case. Each participant was provided a DVD copy of the educational video allowing them to review the operation in detail as needed.

Enrollment scheme

A two-stage enrollment scheme was utilized. For the first stage, each surgeon performed 5 cases and submitted the associated operative data, nodal yield, and 30-day complications. The procedures were video-recorded, and the videos were sent to a central site. If at most 4 lymph nodes were found on pathologic review in 3 or more of the cases, two or more cases converted to an open procedure or 3 or more cases developed a grade 3+ adverse (excluding seroma or lymphedema), the surgeon would not be allowed to enroll additional cases. Post-operative complications were graded using the National Cancer Institute's (NCI) Common Terminology Criteria for Adverse Events Version (CTCAE v) 4.0. Safety rules and stopping criteria were established. Stopping rules were established including termination of the study if two of the first six surgeons to complete cohort one lost enrollment privileges or 30% or more thereafter. The Mayo Clinic Cancer Center Data Safety Monitoring Board monitored the trial. Institutional Review Board approval was obtained at each participating site and patients signed informed consent to participate.

Any incision cephalad to the apex of the femoral triangle greater than 30 mm was considered a conversion. Excision of the inguinal sentinel lymph node biopsy scar was permitted but had to be performed as the last part of the procedure for specimen extraction purposes only. This was optional and up to the discretion of the individual surgeon. Excising the sentinel lymph node biopsy scar earlier or performing dissection through this scar was considered a conversion and documented as such.

Statistical analysis and study end points

Feasibility—Implementation of the procedure was considered feasible and the training program effective if 80% or more of the surgeons participating in the training program were designated as proficient. It is worth noting that once a surgeon obtained proficiency, it could not be later rescinded.

Learning Curve—Utilizing clinically meaningful endpoints for an inguinal lymphadenectomy a proficiency score was defined a priori to assess the learning curve for each individual surgeon. For each case, a proficiency score was assigned based on the number of lymph nodes pathologically identified (including sentinel lymph nodes, if previously obtained), number of blood transfusions required, and operative time (Table 1). A total score of zero was assigned if the procedure was converted to an open procedure. A maximum of 3 points could be awarded for each case. A plot of the proficiency score versus case number was constructed for each surgeon to create a learning curve. Linear regression modeling was used to determine if there was an inflection point in the slope of the learning

curve for any given surgeon, and if present, where the inflection point was located. To further assess how a particular element within the proficiency score may impact our definition of proficiency, a time series plot of each element was constructed for each MILND a surgeon attempted.

Post hoc, since only one patient required a blood transfusion, the model was revised and scored in three additional manners. In the first alternative scoring scheme, estimated blood loss was used in place of blood transfusions. In the other two alternative scoring schemes, adverse events (excluding seroma, lymph leak, lymphedema, and thromboembolic event +/- wound infections) were included in place of blood transfusions (Table 1).

Proficiency—For surgeons who attempted 6 or more MILNDs, a surgeon was classified as proficient if they performed four consecutive MILNDs that met the following criteria: the mean number of lymph nodes resected and pathologically reported (including sentinel lymph nodes) was at least ten, the inguinal node dissections were completed without conversion to an open procedure or a blood transfusion, and the mean operative time per case was under 240 minutes. Proficiency was not ascribed to surgeons who did not attempt at least 6 MILNDs.

Results

Twelve surgeons from 10 institutions enrolled 88 patients between June 2012 and September 2014. One patient withdrew preoperatively and 87 operations made up the study group with a range of 1–24 MILND cases per participating surgeon. All patients were evaluated at post-op day 30 and/or 90; 83 patients were seen at 30 days, 49 patients at 90 days, and 44 were seen at both time points.

The median operative time was 180 minutes (IQR 136–223). The operative time did not decrease over the study period. Neither the operative time nor the number of lymph nodes pathologically identified was related to surgeon case number (Figure 1), nor was there a relationship between proficiency scores and case number (Figure 2), regardless of the method of calculation.

There were 10 conversions (11.5%) among 7 surgeons. Three surgeons had 2 conversions. Reasons for conversion included more advanced disease than expected (4), intraoperative nerve or venous injury (2), lack of progression/unable to define anatomy (2), bleeding (1) and hypercapnia (1). Nine of the 10 conversions occurred in a surgeon's first 5 cases. The first 5 cases by an individual surgeon made up 49 of the 88 cases. Thus, 9 of these 49 "early" cases (18%) led to a conversion. Conversely, of the 39 cases that were performed after the "early" stage, only 1 (3%) was converted to an open procedure (Figure 3). The one late conversion was secondary to bleeding in a morbidly obese patient. The difference in the rate of conversion for "early" vs. "late" procedures was significant ($p=0.038$); however, after controlling for surgeon there is no evidence that case number has an association with conversion rate. A logistic regression model, stratifying for surgeon, shows no significant relationship between conversion rate and case number (OR=1.18, 95% CI [0.92, 1.51], $p=0.196$). There was no difference in the conversion rates based on the indication for

inguinal lymph node dissection, 12% for SLN positivity vs 9% for clinical nodal disease. The mean BMI was 28.9 (+/- 7.6). None of the patients with a BMI under 25 required conversion. The conversion rate increased with an increasing BMI (0/30 (0%) BMI <25, 6/25 (24%) BMI 25–30, 4/32 (13%) BMI >30, p=0.02, figure 4).

No surgeons were required to stop enrollment based of the predefined criteria. Only surgeons who performed at least six MILND procedures on protocol were evaluated for proficiency. Seven of the 12 surgeons, having met the threshold of performing 6 cases, were assessed by the criteria outlined in the protocol. Of these 7 surgeons, 6 (83%) attained the label as proficient at some point. One surgeon performed 6 MILND procedures and had a conversion in the 1st and 5th case. Thus, this surgeon did not have 4 consecutive cases without conversion and was therefore not designated as proficient.

Discussion

Our study demonstrates that this type of structured training program is feasible and high volume melanoma surgeons adopted a novel surgical technique with acceptable operative time, conversions and lymph nodal yields. Eighty-four percent of the surgeons who completed at least 6 MILND were considered proficient based on our predetermined definition.

Neither the lymph node count nor operative time was related to surgeon case number. Though conversions to open were more common during the early phase of the trial, we found no evidence of a classically described learning curve, based on the metrics analyzed and MILND proficiency scores created. There are a number of possible reasons that we did not identify a learning curve in this prospective multi-institutional trial. **1.** The surgical experience for each participant is too small and the learning curve has not been reached. Essentially every procedure has a learning curve (procedural, institutional and individual) and a surgeon's outcomes would be expected to improve with experience. Data on the learning curve of other complex laparoscopic operations have yielded learning curves of up to 250 procedures(9). The improved conversion rate from 18% to 3% in the early vs late procedures appeared to suggest this was already happening. The late conversion was secondary to a hemorrhagic event while 6 of the early conversions were secondary to more advanced disease than expected or lack of progression. These earlier conversions could more likely reflect a matter of judgement in patient selection which improves with experience. After stratifying for surgeon, for each additional case a surgeon performed there was an 18% increase in the odds of completing the procedure without conversion; however, this increased odds ratio was not significant. **2.** The model we developed to calculate a learning curve is not appropriate. Our MILND proficiency score used to determine a learning curve was probably too punitive, placing too large an emphasis on conversion as a negative. In the COST trial there was a 21% conversion rate because the focus was on assuring adequate technique(8). The success of the procedure was defined by oncologic outcomes, not the operative time or if it could be completed laparoscopically. In our current trial it was also stressed to all investigators that the focus always needs to remain on the care of the patient and not worrying about operative time or considering conversion a failure, but that the best interests of the patient need to trump all other considerations. **3.** The training program was

successful in mitigating a learning curve. The selection process of participants and required training prior to enrollment assured surgeons were proficient early in the procedural process. The adequacy of the lymph node count for the 12 participating surgeons certainly supports the fact that an adequate lymphadenectomy was being performed from the very first case, as the average number of lymph nodes examined on the first cases exceeds the benchmarks described in the literature for an open inguinal lymphadenectomy(10–12). Other studies have shown that structured training can allow for a significantly improved learning curve. In one example a pioneer hospital had a long learning curve for hyperthermic intraperitoneal chemotherapy with high blood loss, long operative time, high complications and inadequate debulking; however, following rigorous training a new institution adopting the procedure was able to have outcomes similar to the pioneers institutions most recent 100 procedures, and significantly improved compared with the pioneer institutions first 100 cases (13). A procedural learning curve can be clearly seen with the implementation of sentinel lymph node biopsy. The rate of failed lymphatic mapping was 35% when a pioneer surgeon introduced sentinel lymph node biopsy; (14); however, with refinements in the technique, surgeons trained today rarely experience failure to identify the sentinel lymph node. We believe all three of these explanations contributed to our lack of defining a learning curve. It is impossible to know which factor above was most contributory, but the number of cases being too few to define one cannot be overlooked, as only 7 of the surgeons performed 6 or more cases.

Minimally invasive lymph node dissection is a novel approach to inguinal lymph node staging and treatment, (1, 15–17). A model that describes the stages of innovation in surgery is IDEAL: Innovation, Development, Exploration, Assessment, Long-term study. The next step for MILND on that continuum would be a randomized controlled trial (RCT); Attempts have been made to mount such a trial. After modifying the MILND technique to be appropriate for melanoma Keith Delman began a single institution RCT comparing MILND to the open procedure, unfortunately it failed to accrue, recently closed and the findings will be submitted for publication in the coming months (personal communication). The impetus for our study was to establish a group of high volume melanoma surgeons proficient in MILND and this was intended as a lead in trial, to perform a RCT. However, this group of surgeons, and importantly patients, no longer feel there is equipoise between these two approaches and as such are not comfortable enrolling in a RCT.

MILND is a technique to perform a procedure and a RCT has not been the benchmark for most other minimally invasive techniques, that respect the same anatomic landmarks, used to perform the open operation and have been adopted into clinical oncologic surgical practice, such as robotic surgery for prostate cancer, robotic surgery for gynecologic cancer, laparoscopic pancreatic surgery, thoracoscopic lung surgery, minimally invasive esophagectomies, laparoscopic nephrectomy and laparoscopic liver resection. The exception of having a RCT for a new oncologic surgical technique that purely modifies the access used to complete the same operation is laparoscopic surgery for colon and most recently rectal cancers(8, 18). Melanoma is a cutaneous disease that can be unforgiving in terms of local-regional relapse and concern for trocar site metastasis may be more of concern than other malignancies. Oncologic outcomes need to be continually monitored and reported and it is appropriate to remain cautious as only one such study has been published to date (2).

Despite this, another attempt at a RCT is unlikely to be attempted in the United States to address this procedure compared to a conventional open approach.

We have demonstrated that in a structured training program, surgeons who already perform high volume open inguinal lymphadenectomies can rapidly attain proficiency and adopt this new technique safely. As new techniques are continually developed dissemination of the procedure and safe incorporation into one's practice remains a challenge. The type of training we have utilized in this study is intended to eliminate the steep portion of the learning curve in direct patient care, allowing one to learn in environments outside of the surgeon's first case. A structured training curriculum or documentation of proficiency for surgeons participating in a research study of a novel technique can potentially eliminate a learning curve and should be strongly considered for surgical trials. Many institutions and societies are now offering hands on courses with this intent and the Society of Surgical Oncology's offering a MILND pre-course workshop at their 2015 annual meeting would be such an example. We have also uploaded and made publically available our full 40 minute educational video of this procedure in order to improve dissemination of this new technique; however, we believe the cadaveric workshop was critical to the success of this procedure being successfully adopted. Our study findings do not address the feasibility and safety of surgeons adopting MILND into their practice who do not participate in a structured training program or have performed few open inguinal lymphadenectomies.

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A

B

C

Figure 1.

(A) Operative time and conversions based on case number. (B) Lymph node count and conversions based on case number. (C) Mean lymph node count and operative time based on case number. Number of surgeons who performed each case number also shown.

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Figure 2.

Learning curve showing minimally invasive lymph node dissection proficiency score based on case number. For each case, a proficiency score was assigned based on the number of lymph nodes pathologically identified (including sentinel lymph nodes, if previously obtained), number of blood transfusions required, and operative time. A total score of zero was assigned if the procedure was converted to an open procedure. Complication #1 adverse events (excluding seroma, lymph leak, lymphedema, and thromboembolic event, wound infections) were included in place of blood transfusions. Complication #2 same as #1 except wound infections were excluded. Number of surgeons who performed each case number also shown.

Figure 3.
Conversion rate based on surgeon case number.

Figure 4.
Converted procedures vs case number and BMI.

Table 1**Minimally Invasive Lymph Node Dissection Proficiency Scoring System**

Element	Score
EBL/blood transfusions	
No. of lymph nodes pathologically identified	
10+	1.0
7–9	0.50
5–7	0.25
4	0
Operative time, min	
179	1.0
180–210	0.75
211–239	0.50
240–269	0.25
> 270	0
EBL replaced blood transfusion, U	
0	1.0
1	0.50
2	0
Complications	
No. of lymph nodes pathologically identified	
10+	1.0
7–9	0.50
5–7	0.25
4	0
Operative time, min	
179	1.0
180–210	0.75
211–239	0.50
240–269	0.25
> 270	0
Complications, not EBL	
No AE	1
Grade I AE	0.75
Grade II AE	0.5
Grade III AE	0

Minimally Invasive Lymph Node Dissection Proficiency Score was calculated based on the number of lymph nodes pathologically identified (including sentinel lymph nodes, if previously obtained), number of blood transfusions required, and operative time. A total score of zero was assigned if the procedure was converted to an open procedure. Complication #1 adverse events (excluding seroma, lymph leak, lymphedema, and thromboembolic event, wound infections) were included in place of blood transfusions. Complication #2 same as number 1 except wound infections were excluded.

EBL, estimated blood loss; AE, adverse events.

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