

Lymphatic mapping and sentinel lymph node dissection compared to complete lymphadenectomy in the management of early-stage vulvar cancer: A cost-utility analysis



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HIGHLIGHTS

- Sentinel lymph node biopsy is a potentially cost-effective strategy for the treatment of early-stage vulvar cancer.
- Quality of life differences related to lymphedema impact the cost-utility model of sentinel lymph node biopsy in vulvar cancer.

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ABSTRACT

Objective. Sentinel lymph node biopsy (SLNB) is an acceptable method of evaluating groin lymph nodes in women with vulvar cancer. The purpose of this study is to assess the cost and effectiveness of SLNB compared to universal inguinofemoral lymphadenectomy (LND) for vulvar cancer.

Methods. A modified Markov decision model was generated to compare two surgical approaches for newly diagnosed, early-stage vulvar cancer: (1) radical vulvectomy + LND and (2) radical vulvectomy + SLNB. Published data were used to estimate survival outcomes, probability of positive lymph nodes and lymphedema. Costs of surgery and radiation and lymphedema therapies were estimated from published data. Lymphedema's effect on quality of life (QOL) was extrapolated from other disease sites and assigned a utility score of 0.84. Multiple sensitivity analyses were performed.

Results. SLNB was less costly (\$13,449 versus \$14,261) and more effective (4.16 quality-adjusted life years (QALYs) versus 4.00 QALYs) than LND. The model was sensitive to the impact of lymphedema on QOL. Unless the impact of lymphedema on QOL was minimal (utility score > 0.975) SLNB dominated LND. Variations in the rate of positive SLNB and probability of lymphedema over clinically reasonable ranges did not alter the results.

Conclusions. SLNB is a cost-effective strategy for the treatment of newly diagnosed vulvar cancer, mainly due to the impact of lymphedema on QOL.

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Introduction

Vulvar cancer is the fourth most common gynecologic malignancy in the United States with 4700 patients diagnosed annually [1]. Early-stage vulvar cancer is primarily treated with surgery followed by adjuvant radiation therapy for patients with high-risk features. Surgical treatment for vulvar cancer has evolved from radical vulvectomy with en bloc inguinofemoral lymph node dissection to radical vulvectomy with

separate groin incisions as introduced by Hacker et al. in 1981 [2]. However, even with separate incisions, the surgical treatment of vulvar cancer is associated with significant morbidity related to wound healing and lymphedema [2–4].

Sentinel lymph node biopsy is a promising alternative to full inguinofemoral lymphadenectomy. The safety of SLNB was demonstrated in GROINSS-V where the authors reported a groin recurrence rate of 2.3% in unifocal tumors less than 4 cm [3]. GOG 173 later confirmed these findings and found that SLNB had a negative predictive value of 98% in patients with tumors less than 4 cm and 96.3% in all patients [5]. In addition to its proven safety, SLNB for vulvar cancer is associated with less short and long-term morbidity [3]. Specifically, in GROINSS-V, patients who underwent SLNB only (compared to those treated with

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full LND) had significantly lower rates of groin wound breakdown (11.7% vs. 34%) and lymphedema (1.9% vs. 25.2%) [3]. The authors of GROINSS-V reported no overall difference in quality of life between the two approaches, however the study was not adequately powered to evaluate this [6].

Cost-effectiveness and patient-reported outcomes have become increasingly important indices with regard to cancer care. Vulvar cancer, specifically the evaluation of inguofemoral lymph nodes, provides an arena in which the balance of safety must be weighed against cost and quality of life. The goal of this study was to evaluate the cost-effectiveness of sentinel lymph node biopsy in comparison to full inguofemoral lymphadenectomy in the treatment of early-stage vulvar cancer.

Methods

A modified Markov decision model was designed to inform the surgical decision for patients with apparent early-stage vulvar cancer (Fig. 1). Two surgical management approaches were compared: 1) radical vulvectomy + universal full inguofemoral lymphadenectomy and 2) radical vulvectomy + sentinel lymph node biopsy. Eligibility criteria for the clinical decision conformed to GROINSS-V and GOG 173: squamous cell histology, no clinically suspicious inguofemoral lymph nodes, and tumor size <6 cm [3,5]. Cost was assigned in 2013 US dollars and quality-adjusted life years (QALYs) were used to quantify effectiveness. QALYs were estimated as the product of survival (years) and the health-related quality of life (QOL) utility score.

Key assumptions of the model were: (1) Though undetectable pre-operatively, 5% of patients assigned to SLNB were projected to have grossly positive nodes at the time of surgery, thus requiring conversion to full LND; (2) 50% of both LND and SLNB were bilateral; [3,5] (3) patients with pathologically positive SLN subsequently underwent LND followed by adjuvant radiation therapy; and (4) all patients with lymph node metastasis were treated with post-operative radiation therapy.

Based on the combination of surgical approach (radical vulvectomy + full LND vs. SLNB) and the probability of positive lymph nodes (LN), five clinical cohorts were identified (Fig. 1): (1) aborted SLNB due to grossly positive LN; (2) negative SLNB with no adjuvant therapy; (3) positive SLNB followed by completion LND and adjuvant radiation therapy; (4) LND with positive lymph nodes treated with adjuvant radiation therapy; and (5) LND with negative LN and no adjuvant therapy. Survival estimates, probability of positive LN and other clinical estimates are depicted in Table 1a [3,7–11]. Representative overall survival curves for each cohort were identified in the literature. The model incorporated

Table 1a
Clinical estimates used for the analysis.

Clinical parameter	Value	Range	Reference
<i>Probability of positive lymph nodes</i>			
SLN with grossly negative nodes	31.5%	0–40%	[3]
Full LND	25%	0–25%	[7]
<i>Probability of 5-year OS</i>			
Aborted SLNB due to grossly positive nodes	48%		[10]
SLNB with negative nodes	94%		[3]
SLNB with microscopically positive nodes	53%		[10]
Full LND with negative nodes	78%		[7]
Full LND with positive nodes	53%		[10]
<i>Probability of lymphedema</i>			
Aborted SLNB due to grossly positive nodes	50%	0–50%	[8], Estimate
SLNB with negative nodes	2%		[3]
SLNB with microscopically positive nodes	10%		[8], Estimate
Full LND with negative nodes	40%		[8], Estimate
Full LND with positive nodes	50%		[8], Estimate
Utility of lymphedema	0.84	0.84–1	[14]

5 year overall survival data that was obtained by examination of the respective survival curve for each cohort.

In the model, the probability of lymphedema after SLNB was set at 2% based on data reported in GROINSS-V [3]. The reported range of lymphedema after LND has more variability and was modeled at 40% in the current study based on data reported in GOG 195 [3,4,8,10,12]. In that randomized phase III trial the primary outcome was incidence of lymphedema after LND and therefore unlikely to be biased by under-reporting [8]. Though there is conflicting data on the impact of radiation on lymphedema, we assumed a slightly higher rate in patients who received adjuvant radiation therapy after full LND [10,12,13]. Lymphedema was the primary component of the quality of life assessment and was assigned a utility score of 0.84, where 1 is the equivalent of perfect health and 0 is death. This estimate is based on the preferences of a cohort of 60 cervical cancer patients and healthy volunteers for treatment-related lymphedema, derived using the validated time trade-off method [14]. This estimate is also consistent with the limited QOL literature that has been published regarding cancer-related lymphedema [9].

Medicare reimbursements for 2013 were used for cost estimates (<http://www.cms.gov>). CPT codes and costs for procedures are displayed in Table 1b. For the cohort of patients in whom SLNB was aborted, the cost was estimated to be the same as for SLNB since it is incurred pre-operatively. There are no published reports regarding costs of lymphedema therapy for women with vulvar cancer and for this model estimates were made from breast cancer literature. Of note, the higher cost for the first year is the result of the intensive physical therapy

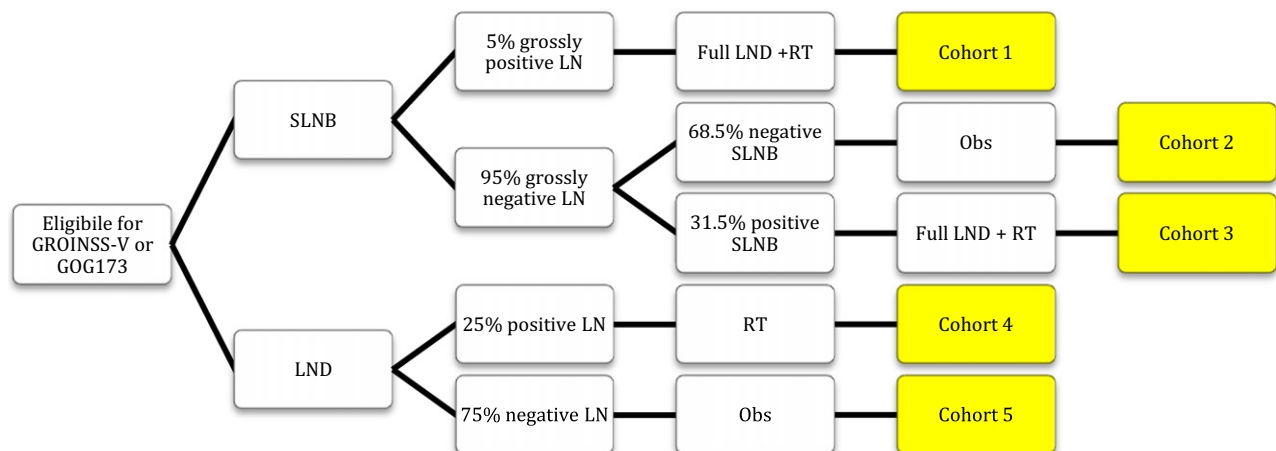


Fig. 1. Diagram of clinical cohorts used for the analysis.

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