Implementing a Cervical Sentinel Lymph Node Biopsy Program: Quality Improvement in Gynaecologic Oncology

Maria C. Cusimano, MD;[1,2] Rachel Walker, MSc;[2] Marcus Q. Bernardini, MD;[1,2] Geneviève Bouchard-Fortier, MD;[1,2] Stephane Laframboise, MD;[1,2] Taymaa May, MD;[1,2] Joan Murphy, MD;[1,2] Barry Rosen, MD;[1,2] Al Covens, MD;[1,3] Blaise Clarke, MD;[4] Patricia Shaw, MD;[4] Marjan Rouzbahman, MD;[4] Ravi Mohan, MD;[5] Sarah E. Ferguson, MD[1,2]

[1]Department of Obstetrics and Gynaecology, University of Toronto, Toronto, ON

[2]Division of Gynaecologic Oncology, Princess Margaret Cancer Centre, Toronto, ON

[3]Division of Gynaecologic Oncology, Odette Cancer Centre, Toronto, ON

[4]Department of Pathology, University Health Network, Toronto, ON

[5]Department of Radiology, University Health Network, Toronto, ON

Abstract

Objective: Sentinel lymph node (SLN) biopsy is becoming a reasonable alternative to pelvic lymphadenectomy in early-stage cervical cancer. It is therefore imperative that centres without prior experience are able to successfully implement the procedure. The objectives of the current study were to (1) describe the process of implementing an SLN biopsy program with a novel peer mentorship component and (2) assess post-program quality improvement metrics, including SLN detection rate (DR) and diagnostic parameters.

Methods: An institutional SLN biopsy protocol was developed collaboratively by gynaecologic oncology, nuclear medicine, and pathology departments at University Health Network, Toronto, Ontario. All decisions were based on the best evidence available. Newly diagnosed, early-stage cervical cancer patients undergoing primary surgery were then recruited prospectively for SLN biopsy with combined technique, followed by pelvic lymphadenectomy to evaluate key quality indicators, including SLN DR, sensitivity, and negative predictive value. Surgeons with previous SLN biopsy experience mentored surgeons unfamiliar with the technique. Interim analyses and multidisciplinary rounds were regularly carried out to identify failures of technique or protocol.

Results: Thirty-nine patients (median age 42) were enrolled in the study between August 2010 and February 2014. The median number of SLNs and total pelvic lymph nodes removed per patient were 3 and 19, respectively. SLN DRs were 92% per patient (36/39), 88.5% per hemipelvis (69/78), and 85% bilaterally (33/39). SLN biopsy correctly identified seven of eight hemipelvises with nodal metastases, yielding a sensitivity of 88% (95% CI 0.47 to 1.00) and a false negative rate of 12% (95% CI 0 to 0.53). Surgeons undergoing peer mentorship (n = 3) performed as effectively (DR 100%) as surgeons (n = 2) with prior experience (DR 85%).

Conclusions: This study provides a model upon which other centres can adopt and validate cervical SLN biopsy. High SLN DRs and accurate identification of lymph node metastases can be achieved by focusing on multidisciplinary collaboration, knowledge translation with creation of evidence-based protocols, peer mentorship, and ongoing quality control.

Key Words: Cervical cancer, sentinel lymph node biopsy, peer mentorship, quality improvement

Corresponding Author: Dr. Sarah E. Ferguson, Division of Gynaecologic Oncology, Princess Margaret Cancer Centre, Toronto, ON. sarah.ferguson@uhn.ca

Competing interests: None declared.

Received on November 15, 2016

Accepted on February 15, 2017

Résumé

Objectif : La biopsie des ganglions sentinelles (GS) devient une solution de rechange à la lymphadénectomie pelvienne de plus en plus acceptable dans les cas de cancer du col utérin de stade précoce. Par conséquent, il est essentiel que les centres n'ayant jamais pratiqué cette intervention soient capable de l'exécuter avec succès. La présente étude avait pour buts de : 1) décrire le processus de mise en œuvre d'un programme de biopsie des GS comportant une approche novatrice de mentorat par les pairs; et 2) évaluer les indicateurs d'amélioration de la qualité après la mise en œuvre du programme, y compris le taux de détection (TD) des GS et les paramètres diagnostiques.

Méthodologie : Un protocole institutionnel de biopsie des GS a été développé grâce à une collaboration entre les services de gynéco-oncologie, de médecine nucléaire et de pathologie. Toutes les décisions ont été prises selon les meilleures données probantes disponibles. Des patientes ayant subi une intervention chirurgicale primaire pour un cancer du col utérin de stade précoce nouvellement diagnostiqué ont été recrutées de façon prospective pour subir une biopsie des GS réalisée au moyen de techniques combinées, suivie d'une lymphadénectomie pelvienne afin d'évaluer des indicateurs de la qualité clés, comme le TD, la sensibilité et la valeur prédictive négative des GS. Des chirurgiens ayant de l'expérience dans la biopsie des GS ont agi à titre de mentors auprès des chirurgiens n'ayant jamais effectué cette

intervention. Des analyses intermédiaires et des rondes multidisciplinaires ont régulièrement eu lieu pour mettre en évidence les échecs de la technique ou du protocole.

Résultats : Au total, 39 patientes (âge médian : 42 ans) ont été recrutées entre août 2010 et février 2014. Les nombres médians de GS et de nœuds lymphatiques pelviens excisés par patiente étaient respectivement de 3 et de 19. Le TD des GS était de 92 % par patiente (36/39), de 88,5 % par hémibassin (69/78) et de 85 % bilatéralement (33/39). La biopsie des GS a permis de détecter correctement sept des huit cas d'hémibassin présentant des métastases nodales; sa sensibilité était donc de 88 % (IC à 95 % : 0,47 à 1,00) et son taux de faux négatifs, de 12 % (IC à 95 % : 0 à 0,53). Les chirurgiens ayant eu un mentor (n = 3) ont eu des résultats aussi bons (TD = 100 %) que ceux des chirurgiens expérimentés (n = 2; TD = 85 %).

Conclusions : Cette étude fournit un modèle sur lequel les autres centres peuvent se baser pour élaborer et valider leurs protocoles de biopsie des GS cervicaux. La détection précise des métastases nodales et un TD élevé des GS peuvent être atteints en misant sur la collaboration multidisciplinaire, l'application des connaissances par la mise au point de protocoles fondés sur des données probantes, le mentorat par les pairs et l'évaluation continue de la qualité.

J Obstet Gynaecol Can 2017;39(8):659–667
https://doi.org/10.1016/j.jogc.2017.02.017

INTRODUCTION

Cervical cancer accounts for approximately 265 000 deaths annually worldwide.[1] Survival is most significantly affected by the presence of regional lymph node involvement, traditionally evaluated using pelvic lymphadenectomy.[2,3] However, only 15% to 20% of patients with early-stage disease (IA–IB2) have lymph node metastases, rendering lymphadenectomy and its associated morbidities unnecessary in up to 85% of patients.[2–4]

ABBREVIATIONS

99mTC	technetium
DR	detection rate
FN	false negative
FNR	false negative rate
H&E	hematoxylin/eosin
ITC	isolated tumour cells
LVSI	lymphovascular space invasion
NPV	negative predictive value
SLN	sentinel lymph node
SN	sensitivity
TN	true negative
TP	true positive

Sentinel lymph node biopsy is a less-invasive alternative for assessing nodal status.[5] The SLN concept identifies the first lymph node to receive lymphatic drainage from the primary tumour site and thus should accurately represent nodal status.[5] This principle has held in breast cancer,[6,7] melanoma,[8] and vulvar cancer,[9] for which SLN biopsy is now standard of care. There is a growing body of evidence confirming the safety and feasibility of SLN biopsy in early-stage cervical cancer as well.[10–12] However, heterogeneity observed in detection rates and false negative rates at individual institutions has prevented widespread use of cervical SLN biopsy in routine clinical practice.[13]

Numerous studies have demonstrated that the DRs and FNRs of cervical SLN biopsy can vary greatly depending on factors such as disease stage,[5,10,11] tumour size,[5,10,11] detection method,[5,10–12] type of pathological evaluation,[14,15] and surgeon experience.[16,17] Substantial differences observed in two landmark, prospective cohort studies of SLN biopsy in cervical cancer illustrate this well. Altgassen et al.[18] achieved a DR of 88% and an FNR of 22.6% in patients with all stages of disease (IA1–IVB) and use of routine pathology. In contrast, Lecuru et al.[19] achieved a DR of 98% and an FNR of 8% in patients with early-stage disease (IA1–IB1), one trained surgeon per site, and use of ultrastaging rather than routine pathology. Such studies demonstrate that attention to multiple factors is essential to maximize the success of this procedure.

We therefore developed an institutional program for SLN biopsy focused on these important variables. We did so in a stepwise fashion that involved multidisciplinary collaboration, knowledge translation, peer mentorship, and quality control measures. As SLN biopsy begins to replace full lymphadenectomy for pelvic lymph node assessment in early-stage cervical cancer, it is imperative that centres such as ours, without prior experience, can implement SLN biopsy successfully. Therefore, the objectives of the current study were to (1) describe the process of implementing a new SLN biopsy program and (2) assess post-program quality improvement metrics, including SLN DR and diagnostic parameters. The critical steps in implementation described here can be modelled by centres adopting either a combined technetium/blue dye technique or more novel methods (e.g., indocyanine green).

METHODS

Here we describe the development and implementation of our institutional cervical SLN biopsy program at Princess Margaret Cancer Centre. We also outline the methodology for the post-implementation validation study.