Published in final edited form as:

Gynecol Oncol. 2009 June ; 113(3): 299–300. doi:10.1016/j.ygyno.2009.04.015.

Patient-reported outcomes in sentinel lymph node procedure versus inguinofemoral lymphadenectomy—What is the next step?

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Treatments for vulvar cancer have been associated with significant quality of life disruption, including sexual dysfunction, vulvar pain or numbness, and lymphedema [1,2]. However, the literature is sparse with details needed to guide treatment protocols, which could improve quality of life, or decrease the level of disruption associated with this disease and treatment. In this issue of the Journal, Oonk and colleagues provide valuable new perspectives from which to view the treatment for vulvar cancer. [3] The quality of life comparisons between the sentinel lymph node (SLN) procedure-only patients and the inguinofemoral lymphadenectomy (IFLA) patients in this descriptive study of longer term sequelae of these procedures offer insights into patient-reported outcomes on physical functioning, body image, satisfaction with treatment, sexual functioning, lymphedema, overall quality of life, and opinions regarding whether the sentinel lymph node procedure should be advocated for others.

In this study, patients were asked their opinion about whether they would advise relatives and friends to utilize the SLN procedure in light of its potential false-negative rate. One can appreciate the importance of this question given the possibility that a metastasis may be missed with this new procedure, thereby negatively influencing disease course. However, the inherent requirements of asking this line of questioning among both patient groups (SLN only or IFLA $\pm$ SLN) produces a psychologically healthy imperative to advocate for the procedure they actually had, allowing responses consistent with prior decision making. This ‘cognitive set’ could account for some of the differences in responses between groups, with SLN-only patients resoundingly advocating for their own procedure. As authors indicate, understandably, responses from those who had the more extensive procedure also recognized benefit, despite complications.

With respect to the overall quality of life score between-group differences, several caveats exist when interpreting nonsignificant differences in this study. First, as authors aptly noted, the study was likely underpowered to detect global QOL score differences. Two examples from similar studies examining SLN or axillary node dissection in breast cancer were provided, in which with larger sample sizes, a significant overall QOL difference was observed. Furthermore, significant overall QOL differences may well have been observed if questionnaires had been administered earlier in the recovery period. It is likely that with a median follow-up of 33 months from surgery, much of the psychological adaptation has

occurred. If that is the case, only the most persistent and troublesome morbidities would be observed 2 to 4 years post procedure. In short, the lack of a significant difference in global QOL should not diminish the importance of differences in other patient-reported outcomes. Specifically, the authors have provided compelling data noting that even after a long period of potential recovery significant differences are observed in patient-reported outcomes, which are associated with lymphedema in the IFLA patients (i.e., more discomfort in groin, vulva, and legs; complaints of edema and use of stockings; less content with the procedure).

Many cancer survivors are living with disfigurement, discomfort, and disruption of activities due to limb swelling following cancer treatment. To date, the preponderance of research on lymphedema within the field of oncology has focused on the development of upper extremity lymphedema occurring in patients treated for breast cancer. These data have helped to explore mechanisms for diagnosis and strategies for treatment of lymphedema, and have altered the clinical care of breast cancer patients with the incorporation of sentinel lymph node dissection. Investigations in gynecologic cancer patients are limited, with minimal information on the incidence of lower extremity lymphedema, potential risk factors for its development, or associated effects on quality of life. Oonk and colleagues have identified a powerful and robust set of symptoms and complaints associated with lymphedema in the IFLA patients, thereby providing additional justification to carefully examine the development of and treatment for lymphedema longitudinally in this population.

Lymphedema is one of the most problematic potential difficulties facing vulvar cancer patients due to the chronicity of symptom clusters, which require long-term management. Lower extremity lymphedema has previously been associated with decreased quality of life in response to loss of work, decreased socialization, and decreased self- and social confidence [1]. The chronic nature of this condition also serves as a constant reminder of one's cancer history, possibly heightening anxiety and fear of recurrence or advancing disease [4,5]. Women treated for gynecologic malignancies with resultant lymphedema have reported financial burdens (27%) (due to the cost of compression garments, medications, and bandages of responders), limitations in clothing options (79%), and modification in activities due to appearance and restriction from swollen legs (51%) [6]. This information provides a context when interpreting one of the most salient results from the EORTC QLQ-C30 questionnaire (Table 2), in which the authors report significantly greater financial difficulties by patients who underwent inguinofemoral lymphadenectomy compared to those with sentinel lymph node procedure. The results reported by Ryan and colleagues, and Janda et al. provide a parsimonious explanation for the spurious finding in Oonk's study.

Oonk and colleagues have provided an important justification to continue to pursue this work with rigor in a prospective trial, with assessment of overall quality of life and symptom-specific outcomes [2] initiated during post-operative recovery and assessed at regular intervals to 48 months. A recent study conducted through the Gynecologic Oncology Group noted that lymphedema was observed in 60–67% of the 137 IFLA study participants 6 months postoperatively [7]. These data reinforce the necessity for the next step in this research trajectory. A longitudinally designed study would permit a rigorous comparison of SLN versus IFLA oncologic and patient-reported outcomes, and an opportunity to examine

health practices offered and utilized during this time period, which might influence these outcomes.

Acknowledgments

I wish to thank Dr. Rich Barakat for his valuable discussion, and Dr. Jeanne Carter for her contributions.

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