

## Patient Reported Outcomes from CCTG CX.5 (SHAPE): Randomized Trial Comparing Radical Hysterectomy (RH) and Pelvic Node Dissection (PND) vs Simple Hysterectomy (SH) and PND in women with Low-Risk Early-Stage Cervical Cancer

**Background:** CX.5 (SHAPE) is a Canadian Cancer Trials Group (CCTG) led Gynecologic Cancer Intergroup international randomized phase III randomized non-inferiority trial comparing RH to SH in women with low-risk early-stage cervical cancer. The primary endpoint was pelvic recurrence rate at 3 years. Quality of Life (QoL) and Sexual Health are important survivorship issues for women undergoing this surgery and Patient Reported Outcomes (PROs) were important secondary endpoints in this trial.

**Methods:** PROs included QoL measured by EORTC QLQ-C30 with QLQ-CX24 and sexual health assessment (SHA) by the Female Sexual Function Index (FSFI) and the Female Sexual Distress Scale-Revised (FSDS-R). These were measured at baseline and at 3, 6, 12, 24, and 36 months after the surgery. Change scores from baseline were calculated and analyzed by linear mixed models.

**Results:** Among 700 patients randomized, 508 (73% of expected) and 432 (86% of expected) completed respectively baseline QoL and SHA. Compliance post-baseline was 56% to 69% for QoL and 63% to 79% for SHA with 58% of patients reporting QoL and 63% responding to the SHA at 36 months. Mean baseline scores were high for all EORTC QLQ-C30 functional scales. EORTC symptoms with the highest (worst) mean baseline scores were fatigue (24.5 on SH and 24.1 on RH) and sleep (29.9 on SH and 32.0 on RH). Mean baseline FSFI and FSDS-R total scores were respectively 27.1 and 10.9 on SH and 27.6 and 10.1 on RH. Significant differences in favor of treatment with SH was found for the following domains: EORTC QLQ-C30 pain scale; EORTC QLQ-CX24 symptom experiences, body image, sexual-vaginal functioning, and sexual worry, sexual activities, and sexual enjoyment scales; FSFI desire, arousal, lubrication, pain scales and total score; and FSDS-R total score.

**Conclusions:** Better quality of life and sexual health were observed with SH compared to RH.