Introduction/Background The objective of this non-inferiority phase III randomized trial was to compare RH to SH in women with LRESCC.

Methodology Women with LRESCC defined as stage IA2 or IB1 disease with lesions ≤2cm were randomized to RH or SH. The primary endpoint was pelvic recurrence rate at 3 years (PRR3). Primary intention to treat (ITT) analysis included all patients randomized. Secondary endpoints included extra-pelvic recurrence-free survival (EPRFS), overall survival (OS) and patient reported outcome.

Results 700 women were enrolled from December 2012 to November 2019. Median age was 44 (24-80); 91.7% were stage IB1 and 61.7% were squamous histology. On final pathology, lymph node metastasis occurred in 3.7% (3.3% SH and 4.4% RH), positive margins in 2.5% (2.1% SH and 2.9% RH), and lesions >2cm in 4.25% (4.4% SH and 4.1% RH). A total of 8.8% of women received post-surgical adjuvant therapy (9.2% SH and 8.4% RH). With a median follow-up of 4.5 years, 21 pelvic recurrences occurred (11 SH and 10 RH). The PRR3 was 2.52% with SH and 2.17% with RH (difference 0.35% with 95% upper confidence limit 2.32%) in ITT analysis. The 3-year EPRFS and OS were respectively 98.1% and 99.1% with SH; 99.7% and 99.4% with RH. SH had less bladder (9 vs 3) and ureteral injuries (5 vs 3) and significantly less urinary incontinence (4.7% vs. 11.0%) (p=0.003) and urinary retention (0.6% vs. 9.9%) (p<0.0001) compared to RH. QoL scales with significant difference between the two groups over time were all in favor of SH.

Conclusion The pelvic recurrence rate at 3 years in women with LRESCC who underwent SH was not inferior to RH and was associated with fewer surgical complications and better QoL. SH should be considered the new standard of care.

Disclosures None