Non-inferiority prospective randomized controlled trial on simple hysterectomy versus modified radical hysterectomy in early stage cervical cancer. An interim analysis of LESSER trial. (IGCS19-0183)

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Objectives

To analyze if simple hysterectomy does not have less efficacy and safety compared to modified radical hysterectomy in treatment of early stage cervical cancer.

Methods

An open label non-inferiority prospective randomized controlled trial included 40 patients with stages IA2 to IB1 ($\leq 2\text{cm}$) cervical cancer. The patients were randomized 1:1 in simple hysterectomy or modified radical hysterectomy and pelvic lymphadenectomy between May 2015 and April 2018. Health-related quality of life was assessed (EORTC QLQ-C30). Primary endpoint was disease free survival in 3 years and secondary endpoints was overall survival, morbidity, and quality of life.

Clinical and pathological characteristics were well balanced between treatment groups.

(150 vs. 199.5 minutes; $p=0.003$).

Postoperative bladder catheterization days were also higher after radical hysterectomy ($p=0.043$). There was no postoperative mortality and postoperative complication rate was not statistically different (15% and 20%; $p=1,0$). Global health, quality of life and physical functioning scores were not different between groups until 6 months of follow-up. There was no difference in adjuvant treatment between groups (30% and 20%; $p=0.48$). The median follow-up time was 16.2 months and the 2-year disease free survival was 95% and 100% for the simple hysterectomy and modified radical groups, respectively ($p=0.405$)(graphic 1). There was only 1 death due to cancer in the simple hysterectomy arm.

Graphic 1: Disease free survival curve .

Results

Thirty-two (80%) patients were squamous cell carcinomas and 3 (7.5%) cases had metastatic lymph node. The median surgical time was greater for the radical hysterectomy group

Conclusions

This interim analysis suggests low morbidity and safety for simple hysterectomy for early stage cervical cancer compared to radical hysterectomy.