Late Breaking Abstracts

01. Cervical cancer

### #142 AN INTERNATIONAL RANDOMIZED PHASE III TRIAL COMPARING RADICAL HYSTERECTOMY AND PELVIC NODE DISSECTION (RH) VS SIMPLE HYSTERECTOMY AND PELVIC NODE DISSECTION (SH) IN PATIENTS WITH LOW-RISK EARLY-STAGE CERVICAL CANCER (LRESCC)

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10.1136/ijgc-2023-ESGO.883

Introduction/Background The objective of this non-inferiority phase III prospective 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 relapse-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

### #422 CERVICAL MICROBIOTA – POSSIBLE TARGET TO PREVENT CERVICAL CANCER DEVELOPMENT – A PRELIMINARY STUDY

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10.1136/ijgc-2023-ESGO.884

Introduction/Background The aim of this study is to evaluate the presence of specific microbiota in cervical cancer patient in material collected from endocervical canal (cervical microbiota). The results will be a basis for further research on cervical cancer co-factors which may stimulate carcinogenesis.

Methodology 20 women diagnosed with cervical cancer independently of FIGO stage, were included in the study. Before the treatment (surgery, CRTH) sample from the endocervical canal was collected using cytology brush and preserved in Liquid-Based Cytology container. All collected samples were analyzed to isolate DNA with a NucleoSpin® Tissue kit. DNA isolates were subjected to qualitative and quantitative evaluation, using libraries based on the Illumina-16S Metagenomic Sequencing Library Preparation (16S Sequencing) protocol.

Results The mean age of participant was 54.23 years (range: 32-89 years, median 51 years). Nine women were postmenopausal, eleven were in reproductive age. In both groups bacterial vaginosis associated bacteria (Prevotella spp., Gardnerella vaginalis group, Atopobium vaginae) were dominant part of vaginal microbiota. In two patients in reproductive age with rapid progression and advanced stage Fusobacterium nucleatum was dominating. Interestingly, the prevalence of Ureaplasma spp and Mycoplasa spp in this group was low.

Conclusion In the population of premenopausal women diagnosed with cervical cancer presence of Fusobacterium nucleatum in cervical microbiota might be an indicator of rapid progression and poor prognosis. Further studies are need to confirm that observation.

Disclosures None