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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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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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, CRT) 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 Mycoplasma 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
same prognostic value as macrometastases. This has implications for CC tertiary prevention approaches. The purpose of this study was to indicate how gynecologic oncologists can adapt to evolutions in tertiary prevention for MIC-positive (MIC+) CC patients.

Methodology Employing two previous studies – a meta-analysis on the prognostic role of MICs in early CC and a review of screening levels in CC prevention in Poland – we identified the need to balance following general clinical guidelines with personalized follow-up. Following PRISMA guidelines, we addressed the impact of MIC+ on prognosis of CC patients and risk control of recurrence associated with MIC+ cases. US Clinical Trials Registry, EBSCO/Ovid, ISRCTN Registry, MEDLINE/Pubmed, Cochrane databases and Google Scholar for English-language literature published over past 10 years (since 2012), with MeSH keywords ‘micrometastases’ AND ‘cervical cancer’ AND ‘follow up’ OR ‘tertiary prevention’ were analyzed. Results were graded according to the level of evidence. We presented process and critical analysis of the end data in a flow chart and algorithmic model.

Results Fifteen studies were included in this systematic review, with a total of 4700 subjects. While the MIC significantly worsens prognosis in early CC, the ITC remains unclassified. One study varied the prognosis by MIC size, but all studies followed a standard approach. A tertiary prevention algorithm stratifies follow-up by the burden of nodal disease, manages data to improve the follow-up performance, and integrates it in a useful form for clinicians by providing all the necessary information on the follow-up schedule of a patient.

Conclusion Healthcare systems should be prepared for forthcoming changes in prevention to improve the diagnosis and understanding of cancer biology and acknowledge the public health benefits of tertiary prevention.

Disclosures The Authors declare no conflict of interest.

Figure A prototype of an algorithmic model concerning optimal standard of patient management in case of low volume lymph node disease in the early cervical cancer of <2 cm

Legend: CT = computed tomography; ITC = isolated tumor cells; LBC = liquid-based cytology; MAC = macrometastasis; MIC = micrometastasis; OB/GYN = obstetrician-gynecologist; PET-CT = positron emission tomography-computed tomography

- This threshold value is not specified. The suggested size of 0.4 mm by Dostalek et al. (Dostalék L, et al. Gynecol Oncol 2023; 168: 151-156) may be changed or there may be several size limits with different predictive values
- PET/CT is not able to detect lymph nodes metastases less than 5 mm in size (Sironi S, et al. Radiology 2006; 238: 272-279; Driscoll DO, et al. Abdom Imaging 2015; 40: 127-133)
- PET has been shown to be prognostic of long-term progression-free survival outcome (Schwarz JK, et al. JAMA 2007; 298: 2289-2295), both PET and PET-CT can be used in follow up of patients with risk of nodal recurrence with similar diagnostic outcomes (Ding XP, et al. Arch Gynecol Obstet 2014; 390: 741-747.)