2022-RA-1191-ESGO EFFICACY OF A MULTI-INGREDIENT CORIOLUS VERSICOLOR-BASED VAGINAL GEL IN HIGH-RISK HPV WOMEN OVER 40: SUB-ANALYSIS OF THE PALOMA CLINICAL TRIAL & PAPILOBS REAL-LIFE STUDY

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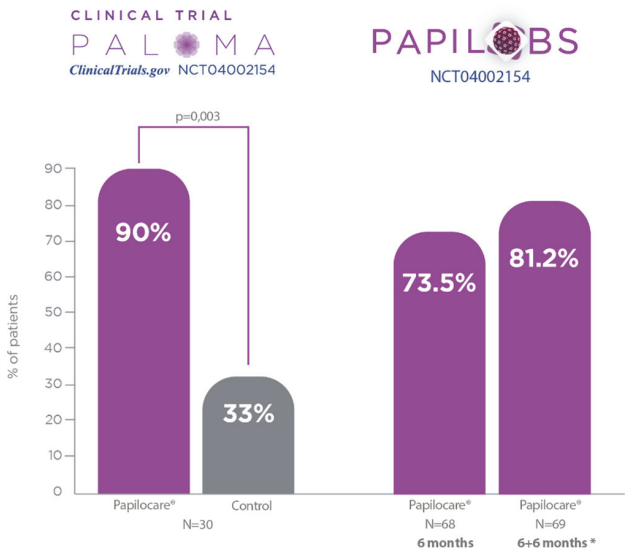
Introduction/Background HPV clearance and resolution of cervical HPV-dependent lesions become difficult in peri and postmenopausal women. The objective of this analysis was to evaluate the effect of the Papilocare®, a multi-ingredient Coriolus versicolor-based vaginal gel in repairing the high-risk (HR) HPV-dependent low-grade cervical lesions in women over 40 years

Methodology Paloma study (ClinicalTrials.gov NCT04002154) was a multicenter, randomized, open-label, parallel-group, watchful waiting approach-controlled clinical trial. Unvaccinated HPV positive women aged between 30–65 with cytology of ASCUS or LSIL and concordant colposcopy image were randomized into 3 groups: A) Papilocare® 1 cannula/day for 1 month + 1 cannula/alternate days for 5 months; B) Papilocare® 1 cannula/day for 3 months + 1 cannula/alternate days for 3 months; C) Control group: watchful waiting approach. Papilobs study (ClinicalTrial.gov: NCT04199260) was an observational, multicenter, prospective, one-cohort study. Vaccinated or not HPV-positive women aged > 25 y with cytology of ASCUS or LSIL and concordant colposcopy were included. Patients were treated with Papilocare® 1 cannula/day for 21 days during first month + 1 cannula/alternate days for 5 or 11 months. Percentages of patients with normal cytology and concordant colposcopy are presented.

Results A total of 30 and 68 HR-HPV patients above 40yo were evaluated in Paloma and Papilobs studies, respectively. In the Paloma trial, normal cytology and concordant colposcopy was observed in 90% vs 33% patients in A+B Papilocare® and control groups, respectively, (p=0.003, Fisher test). Overall, throughout the Papilobs study normal cytology and concordant colposcopy was achieved in 81.2% patients (73.5% at 6 months).



Abstract 2022-RA-1191-ESGO Figure 1

Conclusion After a 6 month treatment period, Papilocare® showed a clinically robust and statistically significant efficacy in repairing cervical HR-HPV lesions in women over 40 years vs watchful waiting approach. This efficacy was corroborated in the real-life study in more than 2/3 of the HR-HPV patients above 40.

2022-RA-1264-ESGO EVALUATION OF MANAGING CIN 3 PLUS DIAGNOSED PREGNANT WOMEN BY METHYLATION ASSESSMENT USING FAM19A4/MIR124 METHYLATION TEST

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Introduction/Background Pregnant women diagnosed with CIN3 (cervical intraepithelial neoplasia) have high regression rates after delivery. Biomarkers are needed to only identify pregnant women with progressive CIN requiring treatment to reduce over referral and overtreatment.

Methodology In this study we evaluated the performance of the FAM19A4/miR124–2 methylation test for molecular triage on formalin fixed samples of CIN3+-diagnosed pregnant women with known clinical course over time as well in a cross-sectional setting. In this German multicenter retrospective study biopsy material was collected from pregnant women diagnosed with cervical cancer (n=16), with CIN3 that progressed to cancer during pregnancy (n=7), with CIN3 that

regressed to CIN1 or less within 6 months after delivery (n=41), without CIN (n=16), CIN3 covering 3–4 quadrants (n=14) and randomly selected CIN3 (n=41). *FAM19A4/miR124–2* methylation analysis was performed blinded on first diagnosis.

Results All pregnant women with cervical cancer and with CIN3 progressing to cancer tested positive for *FAM19A4/miR124–2* methylation (100%, 22/22). In the regressing CIN3 group 47.5% and in the group without CIN 21.6% tested methylation positive. High-volume CIN3 and random selected CIN3 were methylation-positive in 91.7% and 82.1%. Methylation levels were significantly higher in progressive CIN3 and cancer compared to the controls (P<0.0005). The likelihood ratio of a negative methylation test (LR-) for progressive CIN3+ was 0 (95%CI:0–0.208).

Conclusion A negative *FAM19A4/miR124–2* methylation test can rule out progressive CIN disease in pregnant women diagnosed with CIN3. This can help the clinician by managing these pregnant women with conservative follow-up until after delivery. (Int J Cancer. 2022 Jun 6. doi: 10.1002/ijc.34153)

2022-RA-1270-ESGO QUALITY OF LIFE AFTER RISK-REDUCING SURGERY FOR BREAST AND OVARIAN CANCER PREVENTION: A SYSTEMATIC REVIEW AND META-ANALYSIS

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Introduction/Background RRS is the most-effective prevention for breast-cancer (BC) and ovarian-cancer (OC) in women with increased-risk. We aimed to assess the quality-of-life (QoL) impact of risk-reducing surgery (RRS) including risk-reducing-mastectomy (RRM), risk-reducing-salpingo-oophorectomy (RRSO) and risk-reducing early-salpingectomy and delayed-oophorectomy (RRESDO) through a systematic review and meta-analysis.

Methodology We searched major databases until December 2021 following a prospective protocol (PROSPERO-CRD42022319782). Qualitative-synthesis was performed to identify the impact of RRS on various QoL outcomes. Fixed-effects meta-analysis was performed to obtain pooled estimates of QoL outcomes.

Results Thirty-one studies were included (N=4151 post-RRS vs. N=3905 controls). 12/12 studies post-RRM (N=944) reported unchanged general-health QoL, and 10/16 (N=1911) post-RRSO reported unchanged/improved general-health QoL despite short-term deficits (N=578). 13/16 studies (N=1602) showed affected sexual-function post-RRSO. Meta-analysis showed a reduction (-1.21[-1.53,-0.89]; N=3070) in sexual-pleasure and an increase (1.12[0.93,1.31]; N=1400) in sexual-discomfort using the Sexual-Activity-Questionnaire. HRT in pre-menopausal RRSO was associated (on meta-analysis) with an increase (1.16 [0.17, 2.15]; N=291) in sexual-pleasure and a decrease (-1.20 [-1.75, -0.65]; N=157) in sexual-discomfort. 4/10 studies post-RRM (N=236) showed impacted sexual-function, while 6/10 (N=572) showed stable sexual-function. 5/10 studies post-RRM (N=514) reported no body-image problems, whereas 5/10 (N=344) showed otherwise. 12/13 studies (N=1871) reported increased menopause symptoms post-RRSO with a reduction (-1.96 [-2.81, -1.10]; N=1745) in Functional-Assessment-of-Cancer-Therapy-Endocrine Subscale on meta-analysis. 5/5 studies (N=365) post-RRM and 8/10 (N=1223) post-RRSO reported unchanged/decreased cancer-related-distress. RRESDO (2 studies, N=413) resulted in better sexual-function and menopause-specific QoL.

Conclusion RRM/RRSO reduced cancer-related distress with unaffected general-health QoL. Women/clinicians should be aware of the negative impact of sexual dysfunction and menopause related symptoms from RRSO, along-with potential detrimental impact of RRM on body-image. Early salpingectomy does not appear to increase sexual dysfunction or impact menopause symptoms and RRESDO may be a promising alternative to mitigate QoL-related risks.

2022-RA-1272-ESGO COST-EFFECTIVENESS OF RISK-REDUCING SURGERY FOR BREAST AND OVARIAN CANCER PREVENTION: A SYSTEMATIC REVIEW

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Introduction/Background Risk-reducing mastectomy (RRM) and salpingo-oophorectomy (RRSO) are the gold standard preventative strategies for women at high-risk of breast cancer (BC)/ovarian cancer (OC). Risk-reducing early-salpingectomy followed by delayed-oophorectomy (RRESDO) is being trialled as an alternative to RRSO. Opportunistic bilateral salpingectomy (OBS) during gynaecological surgery has been proposed as a potential approach to prevent OC in general population. We performed a systematic review of the published evidence on cost-effectiveness of RRM/RRSO/RRESDO for BC/OC prevention in intermediate/high-risk women, and OBS in baseline-risk.

Methodology We searched major databases to December 2021. We included economic evaluation studies reporting on cost-effectiveness/cost-utility outcomes in women at high-risk of BC/OC undergoing RRM/RRSO/RRESDO, or baseline OC risk undergoing OBS.

Results Our search yielded 5801 citations; 22 studies were included. Eight studies concluded that RRM/RRSO individually or in combination were cost-effective compared to surveillance/no surgery for unaffected *BRCA1/2* carriers, while one study found that RRESDO was cost-effective. Two studies on women at low/intermediate OC-risk specified that RRSO was cost-effective at OC lifetime risks of ≥4% (pre-menopausal) and ≥5% (post-menopausal women). These results were partially sensitive to initial age, uptake rates, cancer risk-reduction, and disutility following surgery. Four studies concluded that the addition of OBS to hysterectomy was cost-effective for OC prevention in the general population. Similarly, OBS was cost-effective as an alternative to