Result(s)* A total of 38 out of 84 evaluable patients at 6 months included in Paloma trial were above 40yo [mean(SD) age: 47.71(5.56)], of which 30 and 13 were HR HPV and 16-18-31 HPV patients, respectively. At 6 months, normal cytology and concordant colposcopy was observed in 92%, 90% and 75% of patients treated with Papilocare® vs 50%, 33% and 40% of patients in control group, in the total, HR and 16-18-31 populations (p=0.0066; p=0.0031; p=0.2929, Fisher test) respectively.

Conclusion* Papilocare® showed a robust and clinically significant efficacy in repairing cervical HPV lesions in women over 40 years, with a statistically significant difference vs control group in the total and HR populations.

648 TUBECTOMY WITH DELAYED OOPHORECTOMY AS ALTERNATIVE FOR RISK-REDUCING SALPINGO-OOPHORECTOMY IN HIGH-RISK WOMEN TO ASSESS THE SAFETY OF PREVENTION

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Introduction/Background* Risk-reducing salpingectomy (RRS) with delayed oophorectomy (DO) has gained interest for women at high risk for ovarian cancer in the last years. In the first place because of the increasing number of studies pointing towards the fallopian tube as tissue of origin. In the second place because two studies demonstrated the positive effect on menopause-related quality of life and sexual functioning compared to standard risk reducing salpingo-oophorectomy (RRSO). However, the strategy is not yet proven to be safe. In the current TUBA-WISP II study, we aim to investigate whether RRS with DO is non-inferior to the current standard RRSO regarding ovarian cancer risk.

Methodology In this international prospective multicenter preference trial, women choose between the novel RRS with DO and the current standard RRSO. RRS can be performed after the completion of child bearing and until the age of 40 (*BRCA1*), 45 (*BRCA2*) or 50 (*BRIP1, RAD51C and RAD51D* pathogenic variant (PV) carriers). Subsequent DO is recommended at a maximum delay of five years beyond the upper limit of the current guideline age for RRSO. The current guideline age, which is also recommended for RRSO within the study, is 35-40 for *BRCA1*, 40-45 for *BRCA2* and 45-50 for *BRIP1*, *RAD51C*, and *RAD51D* PV-carriers. The primary outcome measure is the cumulative ovarian cancer incidence at target age: 46 for *BRCA1* and 51 for *BRCA2*-PV carriers. A total 1500 *BRCA1* and 1500 *BRCA2-PV* carriers are needed to prove non-inferiority of RRS with DO compared to RRSO. Kaplan-Meier analysis with Inverse probability weighting will be used to estimate the cumulative incidence at the appropriate target age (46 or 51) per *BRCA*-type.

Result(s)*

Conclusion* As RRS with DO is proven to be beneficial in regard to menopause-related quality of life and sexual functioning, the current international study is investigating the non-inferiority to RRSO regarding ovarian cancer incidence.

Trial registration NCT04294927

698 REAL-LIFE EFFICACY OF A MULTI-INGREDIENT CORIOLUS VERSICOLOR-BASED VAGINAL GEL IN HIGH-RISK HPV PATIENTS: THE PAPILOBS STUDY FINAL RESULTS

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Introduction/Background* The objective was to evaluate the efficacy of Papilocare® -a multi-ingredient Coriolus versicolor-based vaginal gel- on repairing high-risk (HR) HPV-dependent low-degree cervical lesions and HR-HPV clearance in real-life practice.

Methodology Observational, multicenter, prospective, one-cohort study (PAPILOBS study ClinicalTrial.gov: NCT04199260). Vaccinated or not HPV-positive women aged > 25y with Pap smear (Ps) of ASCUS or LSIL and concordant colposcopy were included during routine clinical visits in Spain. Patients were treated with Papilocare® 1 cannula/day for 21 days during first month + 1 cannula/alternate days for 5 months. After this 6-month period, patients with altered cytology and/or HPV persistency were treated for a 6-month extension treatment period with the same dosage. Analysis of HR-HPV patients with normal Ps and concordant colposcopy image (primary endpoint) and patients with HR-HPV cleared (totally or partially together with negative Ps and normal colposcopy) at 6/12 months is presented. The study was approved by an IRB and informed consent was signed by patients.

Result(s)* At 6 months, data of 178 and 176 patients for Ps/colposcopy and HR-HPV presence, respectively, were available. 68% of patients (121/178) had negative Ps and concordant colposcopy. HR-HPV clearance was observed in 57.4% of patients (101/176). Data of 68 patients included in the 6-month extension treatment period for Ps/colposcopy and HR-HPV presence were available. At 12 months, 79.4% (54/68) of patients had negative Ps and concordant colposcopy and HR-HPV clearance was observed in 61.7% (42/68). Considering all study period, 76.4% and 70.6% of patients repaired HR-HPV-dependent cervical lesions and cleared HR-HPV, respectively.

Conclusion* In this real-life study, repairing of HR-HPV-dependent low-degree cervical lesions and clearing HR-HPV were achieved after 6-month treatment with Papilocare® (extending it up to 12-months if needed) in 3 out of 4 patients. These findings are consistent with the Paloma Trial's' ones (ClinicalTrials.gov NCT04002154) and other observational studies results.

743 FEASIBILITY AND THE EFFICACY OF RRSO COMBINED WITH SIMULTANEOUS MASTECTOMY AND BREAST RECONSTRUCTION IN BRCA 1–2 PATIENTS

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Introduction/Background* Hereditary BRCA 1-2 mutations are known risk factors for the development of breast and ovarian cancer. Risk-Reducing Salpingo-Oophorectomy (RRSO) and bilateral mastectomy are the only effective risk-reducing strategies for these patients. Commonly these are two step surgical procedures performed separately. The aim of this study was to evaluate the feasibility and the efficacy of RRSO, combined with simultaneous mastectomy and breast reconstruction in BRCA 1-2 mutation carriers.

Methodology We conducted an observational retrospective study on patients with BRCA 1-2 mutation who undergone combined and simultaneous laparoscopic RRSO and mastectomy with breast reconstruction at the Gynaecology Clinic of Padua and Breast Unit of Veneto Institute of Oncology (IOV). Inclusion criteria: patients with BRCA 1-2 mutation, consent to simultaneous surgery. We collected data about age, menopausal status, history of breast carcinoma, pre-operative CA-125 levels, transvaginal-ultrasound features before surgery, operative times, intra and post-operative complications, follow up (FUP) information after RRSO and satisfaction about the simultaneous procedure.

Result(s)* We included 40 patients: baseline characteristics are reported in table 1. RRSO was performed in all patients. 37 women underwent to bilateral mastectomy and 3 to monolateral mastectomy (all with breast reconstruction). The mean operative time was 229.6 ± 50.7 minutes (48 ± 16.9 minutes for the RRSO, 147.1 ± 43.6 for mastectomy and reconstruction with a mean surgical team changing time of 34.4 ± 19.6 minutes). No operative complications were reported for RRSO; concerning breast surgery we reported 4 cases of prosthesis loss and one of breast hematoma with a median FUP of 20 months (6-95). The mean hospitalization days was 3.4 ± 2.3. After one months after surgical procedure all patients expressed high satisfaction about the simultaneous surgery.

Abstract 743 Table 1 Patients general features

	BRCA 1 carriers (n= 23)	BRCA 2 carriers (n= 17)	TOTAL (n= 40)
Mean Age at RRSO*	46.1 ± 6.6	49.7 ± 8.1	47.6 ± 7.3
Brest Cancer before RRSO*	16 (69.5%)	10 (58.8%)	26 (65%)
Negative Preoperative CA-125	23 (100%)	17 (100%)	40 (100%)
Menopausal Status			
Pre-menopausal	15 (65.2%)	5 (29.4%)	20 (50%)
Post-menopausal	8 (34.8%)	12 (70.6%)	20 (50%)
Familiarity			
Ovarian Cancer	12 (52.1%)	7 (41.1%)	19 (47.5%)
Breast Cancer	15 (65.2%)	13 (76.5%)	28 (70%)
Negative	3 (13%)	3 (17.6%)	6 (15%)

Legend: RRSO risk reducing salpingo-oophorectomy

Conclusion* RRSO combined with simultaneous mastectomy and breast reconstruction is feasible, effective and provides an intriguing option for BRCA 1-2 mutation carriers. A single time for anaesthesia, hospitalization and a not increased complication rate lead to high satisfaction of the patients. Nevertheless, patient's selection should be carefully performed and surgical teams have to be properly instructed and coordinated.

756 PROPHYLACTIC SALPINGO-OOPHORECTOMY IN BRCA 1–2 PATIENTS. PROFILE EPIDEMIOLOGICAL

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Introduction/Background* Familial predisposition has been described in 5-10% of women who develop ovarian cancer. Women with germ-line BRCA1/2 mutations have an increased risk of breast and ovarian cancer as compared with the rest of the population. Women with BRCA1 mutation have a 44% lifetime risk of developing ovarian cancer, whereas, BRCA2 mutation has lifetime risks of 17%. These women often undergo bilateral prophylactic oophorectomy to reduce this risk.

The objective of this study was to analyze the epidemiological characteristics of patients with BRCA 1/2 mutation undergoing prophylactic salpingoophorectomy for adnexal high-grade serous epithelial carcinoma.

Methodology We performed a prospective cohort study between January 2013 to January 2021. Patients with BRCA 1/2 mutations who underwent prophylactic bilateral salpingoophorectomy were included. A descriptive study of epidemiological characteristics of these patients was performed. All statistical analysis was performed with Stata/IC 13.0 for Windows.

Result(s)* We analyze the epidemiological characteristics of 115 patients that were included. Of them, 50.4% (58) had BRCA 1 mutation and 49.6% (57) BRCA 2 mutation. Most occult ovarian carcinomas are found in women over 45 years of age. The median age at surgery was 49.2 (standar deviation, SD 5.8) years and 59.1% (68) of patients were posmenopausal.

Fifty (43.5%) of them were the family index case (first case of cancer) and sixty (52.2%) had a previous diagnosis of breast cancer. The most frequent family history was: two cases of breast cancer in their family of 1 or 2 degree whose sum of ages at diagnosis was less than 120 years. The median Ca 125 value prior to surgery was 29.4 u/L. Adnexal findings were described in presurgery ultrasound as normal (104, 90.4%) or bening cyst (11, 17.4%).

Conclusion* Most occult carcinomas are found in women over 45 years of age. Unfortunately, there is no screening test effective in detecting ovarian cancer at early stages. Therefore, the current recommendation is to undergo risk-reducing bilateral salpingo-oophorectomy after completing the gestational desire in carriers of BRCA1/2 mutations. Although, the main negative consequence of this surgery in premenopausal women is premature menopause. However, the risk is balanced by the morbidity and mortality associated with ovarian cancer, and these symptoms can be treated with some drugs.

824 DOUBLE HETEROZYGOTES FOR HIGH PENETRANCE SUSCEPTIBILITY GENES ARE NOT RARE AND REQUIRE SPECIAL CARE

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