the different inclusion and exclusion criteria, we obtained 1156 patients, 733 CC patients and 423 non-CC patients. Subsequently, and after analyzing the first results, we decided to homogenize our database by means of a PMS analysis, by this way, we obtained a new balanced population of 374 patients (187 CC patients and 187 non-CC patients).

**Results** In the general population, patients with CC present a 72% reduction in the risk of relapse compared to non-CC patients (HR: 0.28 95% CI (0.17–0.46) p = 0.000) and a 90% reduction in the risk of death (HR: 0.10 95% CI (0.03–0.33) p = 0.000), these differences may be due to the fact that both populations present different preferences.

After homogenizing our population using the PMS, we obtained that the reduction in the risk of relapse was 65% for patients who have CC (HR: 0.35 CI 95% (0.16–0.75) p = 0.007) and 75% for the risk of death for the same cohort (HR: 0.25 95% CI (0.07–0.90) p = 0.033).

Regarding the secondary objectives, we observed that the CC seems to have a protective effect in tumors between 2–4 cm (HR: 0.33 95% CI (0.11–0.99) p = 0.049). This same protective effect is observed in patients operated on by laparoscopy (HR: 0.35 95% CI (0.14–0.89) p = 0.028). Finally, the MIS patients who have CC do not present differences compared to those operated by the open approach, whether they are conized or non-conized (Log-Rank p = 0.439 and Log-Rank p = 0.346).

**Conclusion** Patients undergoing CC have a significantly lower risk of relapse and death, this effect is more evident in those patients with 2–4 cm tumors or in those who are operated under MIS.

**Disclosures** I have nothing to disclose.

**Design and Validation of a Recurrence Risk Predicting Score in Early Stage Cervical Cancer After Radical Hysterectomy**

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10.1136/ijgc-2020-EGSO.17

**Introduction/Background** After the LACC trial, the scientific evidence has focused on confirming and finding the cause of why the open route presents better results than minimally invasive surgery (MIS). Even though the independent factors involved in relapse has not been studied.

**Methodology**

**Primary objective** to know the independent clinical, surgical and anatomopathological factors involved in the relapse of patients with stage IB1 cervical cancer who underwent radical hysterectomy (2013–2014).

**Secondary objective** To create a risk predictive index (RPI) that allows us to better select and stratify patients with a higher probability of relapse.

**Methods** Starting from 1272 patients from the European database belonging to the SUCCOR study and after applying the different inclusion and exclusion criteria we obtained 1156 patients. We randomly divided our sample into a test group and a validation group in a proportion of 60% to 40%.

The test group was used to identify the variables independently associated with relapse and to define the relapse RPI. The RPI was applied to calculate a relapse risk score for each participant in the validation group. According to their risk of relapse, participants were classified into 3 risk groups.

**Results** Women who relapse are more likely to have tumours larger than 2 cm on imaging assessment (OR 2.15, 95% CI 1.33–3.5) and to undergo MIS (OR 1.61, 95% CI 1.00–2.57). On the other hand, conisation is inversely associated with the risk of relapse (OR 0.31, 95% CI 0.17–0.60).

The AUC in the validation group for RPI is (0.72; 95% CI 0.65–0.79).

Depending on their score, patients were classified at low, medium or high risk of relapse. The relapse rate observed in each group was 3.4%, 9.8% and 21.3% respectively.

With a median follow-up of 58 months, the mean DFS in the validation group for low, medium and high risk categories were 75.4 (95% CI 73.8–76.9), 75.5 (95% CI 72.4–78.5) and 64.1 (95% CI 59.4–68.9) months respectively (P < 0.001)

**Conclusion** Our risk predictor index proved to be valid and therefore may help to identify those patients who would benefit from adjuvant therapy and close follow-up after radical hysterectomy.

**Survival Outcomes of Patients with Clear Cell Carcinoma Cervix: A Single Institutional Retrospective Analysis**

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10.1136/ijgc-2020-ESGO.18

**Introduction/Background** Cervical cancer is the most prevalent cancer and the fifth most common cause of cancer death in Indian women. Clear cell carcinoma of the cervix (CCCC) is rare, accounting for only 4% of all adenocarcinomas. CCCC can occur sporadically or in association with in-utero diethylstilbestrol (DES) exposure. There are no clear-cut treatment recommendations for the management of CCCC. Early-stage disease is usually treated by surgery and more locally advanced stages by chemoradiation followed by brachytherapy.

**Methodology**

**Aim:** This study aimed to assess the survival outcomes and patterns of failure of patients with CCCC.

**Settings and Design:** Retrospective study done at Regional Cancer Centre, Thiruvananthapuram, Kerala, India

**Material and Methods:** Case records of all the patients with CCCC who were diagnosed and treated between 1995 and 2015 were reviewed for clinical, pathological and treatment characteristics.

**Statistical analysis:** Disease-free survival (DFS) and overall survival (OS) were estimated using the Kaplan-Meier method.

**Results** The diagnosis of clear cell carcinoma of the cervix was confirmed in 15 patients. The median age was 53 years. 20% of the patients were in the International Federation of Gynaecology and Obstetrics (FIGO) stage I, 60% in stage II, 7% in Stage III and 13% in stage IVA. Stage IB and IVA patients were managed surgically, and adjuvant therapy depended on the tumour pathology. Stage IB and IIIB
patients were treated with concurrent chemoradiation followed by brachytherapy. The median follow-up period was 47 months. The three-year DFS and OS were 13.3% and 13.3% respectively.

Conclusion CCCC has a poor prognosis, stage for stage compared to other histologies. The FIGO stage, tumour size, lymphovascular space invasion and pelvic node status were factors that predicted the prognosis. Adjuvant radiotherapy or chemoradiotherapy have a limited role in the treatment of this rare cancer.

Disclosures The authors have no potential conflict of interest to disclose.

Efficacy of a multi-ingredient Coriolus versicolor-based vaginal gel in HPV+ women older than 40 years: sub-analysis of Paloma clinical trial

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Introduction/Background HPV clearance and resolution of cervical HPV-dependent lesions become important in peri- and postmenopausal women. The objective of this sub-analysis was to evaluate the efficacy of the Papilocare®[1], a multi-ingredient Coriolus versicolor-based vaginal gel, on the normalization of cervical HPV-dependent atypia (ASCUS and LSIL) and associated colposcopic alterations in women older than 40 years.

Methodology Paloma clinical trial (ClinicalTrials.gov NCT04002154) was a multicenter, randomized, open-label, parallel-group, usual practice-controlled clinical trial. Unvaccinated HPV positive women aged between 30–65 with cytology of ASCUS or LSIL and concordant colposcopic 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: no treatment.

Results A total of 41 out of 84 evaluated patients included in the 6-month extension treatment period for Papilocare® showed a robust efficacy in normalizing cervical HPV lesions in women older than 40 years, with a statistically significant difference vs control group in the total and high-risk populations.

Conclusion Papilocare® showed a robust efficacy in normalizing cervical HPV lesions in women older than 40 years, with a statistically significant difference vs control group in the total and high-risk populations.


All other authors have declared no conflicts of interest.

287 REAL-LIFE EFFICACY OF A MULTI-INGREDIENT CORIOLUS VERSICOLOR-BASED VAGINAL GEL IN HIGH-RISK HPV PATIENTS: INTERIM ANALYSIS

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Introduction/Background Real-life studies inform on the ‘effectiveness’ of a treatment what is intended to do in routine circumstances. The aim of this study is 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). Currently recruiting 300 vaccinated or not HPV-positive women aged > 25y with Pap smear of ASCUS or LSIL and concordant colposcopy during routine clinical visit in Spain. Patients are treated with Papilocare® 1 cannula/day for 21 days the first month + 1 cannula/alternate days for 5 months. After this 6-month period, patients with altered cytology or HPV persistency are treated for a 6-month extension treatment period with the same dosage.

Interim analysis of HR-HPV patients with normal Pap smear and concordant colposcopy image (primary endpoint) and patient with HR-HPV cleared (patients with total clearance or partial clearance together with negative Pap smear and normal colposcopy) at 6/12 months is presented. The study was approved by the ethical committee of Public University Hospital of Puerta de Hierro (Madrid). Informed consent was signed by all patients.

Results At 6 months, data of 148 and 146 patients for Pap smear/colposcopy and HR-HPV presence, respectively, were available. 67.6% of patients (100/148) had negative Pap smear and concordant colposcopy. HR-HPV clearance was observed in 38.9% of patients (86/146). Data of 46 and 44 patients included in the 6-month extension treatment period for Pap smear/colposcopy and HR-HPV presence, respectively, were available. At 12 months, 78.3% (36/46) of patients had negative Pap smear and concordant colposcopy and HR-HPV clearance was observed in 70.5% (31/44). Considering all study period, 77% (114/148) and 72.6% (106/146) of patients repaired HR-HPV-dependent cervical lesions and cleared HR-HPV, respectively.

Conclusion In this interim analysis, repairing of HR-HPV-dependent low-degree cervical lesions and clearing HR-HPV, in real life conditions, was achieved after 6-month treatment.