

with Papilocare® (or extending it up to 12-months if needed) in 3 out of 4 patients. These findings need to be confirmed upon study completion.

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#### EFFICACY OF A MULTI-INGREDIENT CORIOLUS VERSICOLOR-BASED VAGINAL GEL IN HIGH-RISK HPV+ PATIENTS: RESULTS OF DIFFERENT STUDIES

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**Introduction/Background** To evaluate the consistency of the efficacy of a non-hormonal multi-ingredient *Coriolus versicolor*-based vaginal gel, Papilocare®, on HPV clearance in patients infected by high-risk HPV (HR-HPV) in several studies.

**Methodology** Results at 6 months from independent observational non-comparative studies carried out in three different public centers and in a one private center were compared to results from both a randomized, open, parallel and controlled clinical trial comparing the Papilocare® vs wait and see approach (The Paloma RCT) and a observational, multicenter, prospective, one-cohort study (Papilobs real-life study). Two prospective (Vigo and Bari studies) and two retrospective studies (Coruña and Hospitalet studies) have been performed.

Vigo study: HPV clearance of 25 patients infected by HPV 16 and/or 18 was evaluated as a secondary endpoint.

Bari study: HPV clearance of 98 HR-HPV patients was evaluated as primary endpoint.

Coruña study: 57 medical records of patients with HR-HPV were analyzed. HPV clearance was evaluated as primary endpoint.

Hospitalet study: Data of 91 HR-HPV patients were evaluated. Primary endpoint: composite efficacy variable (percentage of patients with normal cytology and/or HPV clearance).

Papilobs study: Interim data of 148 HR-HPV patients is presented. HR-HPV clearance was evaluated as secondary endpoint.

Paloma RCT: 66 HR-HPV patients were evaluated. Percentage of patients with HR-HPV clearance was assessed as a secondary endpoint.

**Results** After the 6-month treatment period, 48% and 57% of patients cleared HPV 16–18 and HR-HPV in Vigo and Bari studies, respectively. A reduction of 58% was observed in number of HR-HPV patients (Coruña) and 72.5% of patients negativized cytology and/or cleared HR-HPV (Hospitalet) ( $p \leq 0.0001$  vs baseline for all results, Chi-square). In the Paloma RCT, HR-HPV clearance was observed in 63% of patients treated with Papilocare® vs 40% in the control group. Similar rate of 59% HR-HPV clearance was observed in the interim analysis of the Papilobs study.

**Conclusion** Papilocare® has shown significant and consistent rates of HR-HPV clearance ranging from 50% to 70% in the 6 different studies. This high consistently rate of HR-

HPV clearance should be further confirmed in ongoing studies.

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#### RATIONALE AND EVIDENCE FOR EMERGING ANTIBODY-DRUG CONJUGATES IN GYNECOLOGICAL CANCERS: EFFECT OF ONLINE EDUCATION ON CLINICIAN KNOWLEDGE

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**Introduction/Background** A number of targeted antibody drug conjugates (ADCs) are emerging with the potential to become important new treatment strategies for gynecological cancers, including recurrent/resistant ovarian and cervical cancers. This study determined whether online continuing medical education could improve the knowledge of oncologists and obstetricians/gynaecologists (obs/gyns) on the rationale and evidence for emerging ADCs.

**Methodology** A 30-minute online video lecture was launched for physicians outside the USA in December 2019. Data was collected to March 2020. Educational effect assessed with repeated-pairs pre-/post-activity, where individual participants served as their own control. 3 multiple-choice, knowledge questions and 1 self-efficacy, 5-point Likert scale confidence question were analyzed. Chi-squared test assessed pre- to post-activity change (5% significance level,  $P < .05$ ). Magnitude of change in total number of correct responses overall, and for each question, were determined with Cramer's V ( $< .06$ =Modest,  $0.06$ – $0.15$ =Noticeable,  $.16$ – $.26$ =Considerable,  $> .26$ =Extensive).

**Results** 49 oncologists and 154 obs/gyns completed pre- and post-activity questions. A positive educational effect was observed for oncologists (considerable effect,  $V = .217$ ,  $P = .0002$ ) and obs/gyns (noticeable effect,  $V = .097$ ,  $p = .0028$ ) with average% of correct responses increasing 40 to 62% for oncologists and 34 to 43%, for obs/gyns. Participants with 3/3 answers correct increased from pre- to post-activity (6 to 35% for oncologists and 6 to 12%, for obs/gyns). Improvements in % of correct responses post-activity were seen for all 3 knowledge-based questions on antigen targets, and key trial data for tisotumab vedotin and mirvetuximab vedotin (88%, 39%, 45% improvements for oncologists; 70%, 15%, 16% improvements for obs/gyns). Confidence in knowledge of ADCs also improved post-activity with a total average confidence shift of 38% for oncologists and 32% for obs/gyn. 62% of oncologists' and 44% of obs/gyns' responses were reinforced or improved post-activity. 34% of all participants stated they would modify treatment plans as a result of participation in the activity.

**Conclusion** This on-demand, online video lecture resulted in a positive education effect for both oncologists and obs/gyns. However, persistent knowledge gaps are evident, especially amongst obs/gyns, suggesting there is a need for additional education as data on ADCs continues to emerge. Online medical education is valuable in establishing improved knowledge

of emerging therapies, such as ADCs, as well as identifying areas of continued educational need.

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### 316 'ARE THERE LIMITS TO CURATIVE TREATMENTS?' – THE IMPACT OF CHEMO-RADIATION IN CERVICAL CANCER PATIENTS

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**Introduction/Background** Cervical cancer (CC) is the second most frequent gynaecologic tumour and curative treatment often includes concomitant chemo-radiation (RT/ChT). The aim of this study was to assess the early and late impact on quality of life (QOL) of patients treated with this treatment modality.

**Methodology** Prospective study of patients, treated in a tertiary cancer centre, with RT/ChT (weekly cisplatin) between 2014–2016 with a median follow-up of 54.7 months. QOL was assessed using validated versions of EORTC QLQ-C30 and QLQ-Cx24 questionnaires, looking for 7 principle domains: global health, role function, physical function, social function, financial issues, sexual function and symptoms. For this evaluation two distinct moments were defined: the first one at the first day of treatment and the second one after at least 3.7 years (min-max: 3.7–5.9 years). To avoid bias in long-term questionnaires' answers (moment two) there were excluded patients that had persistent disease after RT/ChT or recurred after complete response. Patients' answers were converted, by linear transformation, into 0–100 score intervals. Paired Sample T-test and Wilcoxon Signed Rank Test were used to compare results.

**Results** 50 patients were included, with average age at diagnosis of 52 years (24–74 years) and stage disease II (FIGO 2009) in 32 (64%). First and second questionnaires were answered by 50 and 34 patients, respectively. There were no differences between the two moments concerning global health ( $p=.41$ ), role function ( $p=.72$ ), physical function ( $p=.21$ ), social function ( $p=.86$ ) and financial issues ( $p=.21$ ). An emotional improvement to second evaluation ( $p=.03$ ) and a decrease in cognitive function ( $p=.007$ ) were observed. Related to symptoms there were no differences, except for diarrhea that was worse ( $p=.006$ ) and lymphedema ( $p=.005$ ) that improved later in time. Although sexual dysfunction seemed similar ( $p=.21$ ), there were a progressive increase of sexual worry ( $p=.004$ ).

**Conclusion** Careful assessment and handling of treatment toxicities is imperative to minimize long term sequelae of curative treatments. Particularly in these survivor's cohort, focus on cognitive and sexual problems and diarrhea seems extremely important.

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### 327 RADICAL HYSTERECTOMY IN EARLY CERVICAL CANCER: CHARACTERISTICS AND OUTCOMES OF A LARGE-CONTROLLED EUROPEAN POPULATION

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**Introduction/Background** Radical hysterectomy has been for years the primary treatment for early cervical cancer.

Recently, a number of retrospective studies and a prospective randomized trial (LACC trial) revealed higher rates of recurrence and death in patients that underwent minimally invasive surgery.

In Europe, we did not counted with large-contrasted data. We designed the SUCCOR study, a multicenter, observational cohort study with the primary goal of validating the results of the LACC trial in Europe.

In this study we try to compile all the information obtained in the Succor study to offer a comprehensive picture of the characteristics and outcomes of the surgical treatment of early cervical cancer in this large European population.

**Methodology** Patients were eligible if they underwent a radical hysterectomy in a European Institution for stage IB1 cervical cancer (FIGO 2009), from January 1st, 2013 to December 31st, 2014.

**Results** From May 15th to November 15th, 2019, we received data from a total of 1272 patients. 116 patients were excluded. The final cohort was composed of 1156 patients.

The median age of the studied population was 47.12 yo (10.8). 36.6% of patients had undergone a cone biopsy before the radical hysterectomy. The mean preoperative maximum diameter measured by magnetic resonance imaging was 19.58 mm (13.3).

633 (54%) radical hysterectomies were done by laparotomy and all the other 523 (46%) by minimally invasive surgery.

Nerve sparing technique was carry out in 61.8% of cases. Only in 224 cases (19.4%) the sentinel lymph node biopsy was performed with a rate of bilateral identification of 79.7%.

The average length of stay in the hospital was 6.72 days (4.2).

The average number pelvic nodes retrieved was 25.51, showing 12.4% of patients, nodal metastasis.

510 patients (44.1) received any type of adjuvant therapy. Standard radiation plus braquitherapy were the most frequent used modality of adjuvant treatment (54.1 and 43.3% respectively) while concomitant chemoradiation was use in 34.1% of the cases.

After a median follow up of 58 months, the 5-y disease free survival rate was 88.3% and the overall survival rate at 5-y was 94.9%.

**Conclusion** In this study we have collected the most extensive amount of information ever obtained on radical hysterectomy for cervical cancer in our continent. Even though it is a retrospective registry, the meticulous design of the inclusion and exclusion criteria offers a high level of accuracy when evaluating the surgical outcome of patients with cervical cancer after radical hysterectomy.

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