Palliative care

163 SUPPORTIVE FUNCTION OF PEGTEOGRASTIM AND PEGFILGRASTIM ON CHEMOTHERAPY-INDUCED NEUTROPENIA IN OVARY CANCER PATIENTS

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Introduction/Background Critical complication during chemotherapy is febrile neutropenia.. Granulocyte-colony-stimulating factor(G-CSF) is used to prevent febrile neutropenia associated with myelosuppression. Pegfilgrastim, a pegylated form of filgrastim, has an increased half-life. Pegteograstim is novel recombination human G-CSF of another form of pegylated filgrastim.We undertook investigation to evaluate efficacy and safety of pegteograstim and pegfilgrastim women with ovarian carcinoma that are treated with paclitaxel/carboplatin.

Methodology After chemotherapy minimum 24 hours, pegteograstim or pegfilgrastim was given a single subcutaneous injection of 6 mg during each chemotherapy cycle. We evaluated to ANC (absolute neutrophil count) change and febrile neutropenia incidence.

Results There were 30 of pegteograstim cases and 12 pegfilgrastim.Median ANC between pegteostim were 2960.pegfilgrastim was 2396.After pegteograstim, ANC was elevated till 13847 from 2960 (difference was 10,887)in case of pegteograstim. In pegfilgrastim, ANC increased to 12933 (difference was 10537).There was no febrile neutropenia in both cases. Safety profiles of two groups did not differ significantly.

Conclusion We conclude Pegteograstim and pegfilgrastim have similar efficacy and safety profile in the reduction of chemotherapy-induced neutropenia in the ovary cancer patients who were undergoing chemotherapy.

Disclosures NO COI.

388 EFFICACY OF INDIVIDUALISED STARTING DOSE (ISD) AND FIXED STARTING DOSE (FSD) OF NIRAPARIB PER INVESTIGATOR ASSESSMENT (IA) IN NEWLY DIAGNOSED ADVANCED OVARIAN CANCER (OC) PATIENTS

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Introduction Niraparib is a poly(ADP-ribose) polymerase inhibitor approved for maintenance treatment of patients with newly diagnosed or recurrent OC that responded to platinum-based chemotherapy and treatment in heavily-pretreated recurrent OC. Here we report efficacy in patients receiving the FSD and ISD in the PRIMA/ENGOT-OV26/GOG-3012 trial (NCT02655016).

Methods This double-blind, placebo-controlled, phase 3 study randomised 733 patients to receive niraparib or placebo for 36 months or until disease progression/toxicity. A protocol amendment introduced ISD: 200 mg in patients with body weight <77 kg or platelets <150,000/μL, or 300 mg in all others. The primary endpoint was PFS by blinded independent central review (BICR). IA PFS was a sensitivity analysis. At the primary analysis data cut, follow-up was 11.2 months and 17.1 months in the ISD and FSD subgroups, respectively. An ad hoc analysis of IA PFS was performed using an updated data cut with additional 6 months follow-up.

Results BICR and IA PFS were highly concordant in the overall population. Efficacy of niraparib based on IA PFS in FSD vs ISD subgroups for each data cut were similar (table 1). Dose interruptions, modifications, and haematologic toxicity were lower with the ISD. Exposure–response data supported the clinical data.

Conclusion The 200- or 300-mg ISD by baseline body weight and platelet counts demonstrated comparable efficacy while improving the safety profile of niraparib. Use of this regimen for first-line maintenance of advanced OC patients is approved by the US FDA.

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Abstract 388 Table 1

Median PFS	IA PFS in the overall population and the ISD and FSD subgroups, HR (95% CI)	
	Original data cut 17 May 2019	Updated data cut 17 Nov 2019
Overall, N=733	0.63 (0.51, 0.76) ***P*<0.0001**	0.64 (0.53, 0.77) ***P*<0.0001**
FSD, n=487	0.60 (0.47, 0.77)	0.62 (0.49, 0.78)
ISD, n=246	0.68 (0.48, 0.96)	0.68 (0.49, 0.94)

FSD, fixed starting dose; HR, hazard ratio; IA, investigator assessment; ISD, individualised starting dose; PFS, progression-free survival.

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Prevention of gynaecologic cancer

47 PERFORMANCE OF CONE BIOPSY EXCISION FOR TREATMENT OF CERVICAL INTRAEPITHELIAL NEOPLASIA

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Introduction/Background Cervical cancer is to a great extent preventable disease through detection and treatment of cervical intraepithelial neoplasia (CIN). All local treatment modalities are efficient in preventing CIN. The influence of different techniques on the risk of recurrence remains therefore unclear. The minimum radicality of treatment to prevent treatment-induced morbidity and the increased risk of future invasion is required. The aim of the study was to assess the adequacy of cone biopsy excision of naked eye lesions as a method of treatment of cervical intraepithelial neoplasia (CIN). Women treated with LEEP were used as control.

Methodology The current study was randomized clinical trial. Cone biopsy excision of naked eye lesions was compared to LEEP of the transformation zone in women undergoing surgical treatment of CIN. The primary outcome was involvement status of the margin of the resected cone. Secondary outcomes were procedure time, blood loss, hemostasis time, intraoperative and postoperative complications, size of the resected area and postoperative pain, validated by visual analog scale (VAS).

Results Ninety women were evaluated for disease persistence after excision of the naked eye lesions using cone biopsy excision. Eighty-five cases treated with excision of the transformation zone using LEEP. There is no statistically significant difference as regarding the margin involvement of the resected cone, the primary outcome, was observed between cone biopsy excision and LEEP (11/90 [12%] vs 8/85 [9.4%], respectively; p = 0.55, OR=1.34 95% CI: 0.5115). Postoperative pain was lower after cone biopsy excision (VAS: 0 [0–2] vs1 [0–3]; p = 0.02). The secondary outcome parameters; procedure time, blood loss, hemostasis time, intraoperative and postoperative complications and size of the resected area were not different between the study groups. Age, parity, contraception method and body mass index did not influence the primary and secondary outcome parameters using multivariate analysis.

Conclusion Cone biopsy excision and LEEP are evenly effective and safe procedures.

Disclosures No conflict of interest related to this research.

93 PROPHYLACTIC HUMAN PAPILLOMAVIRUS HPV VACCINATION TO PREVENT RECURRENCE OF CERVICAL INTRAEPITHELIAL NEOPLASIA : A META-ANALYSIS

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Introduction/Background The aim of this systematic review and meta-analysis was to review evidence supporting the use of prophylactic human papillomavirus vaccines to influence the risk of recurrence of cervical intraepithelial neoplasia after surgical treatment.

Methodology A systematic literature search was performed for publications reporting risk of recurrence of cervical intraepithelial neoplasia after surgical treatment in patients receiving human papillomavirus vaccination (either in the prophylactic or adjuvant setting). Comprehensive searches of 6 electronic databases (MEDLINE, Embase, Web of Science, PubMed, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, and references of identified studies) from their inceptions were performed (English language only), and hand search reference lists were performed. Two independent reviewers applied inclusion and exclusion criteria to select included papers, with differences agreed by consensus. The literature search was performed using Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Results were reported as mean differences or pooled odds ratios (OR) with 95% confidence intervals (95% CI).

Results A total of 5744 citations were reviewed; 5 studies comprising 3562 patients were selected for the analysis. There were 1453 patients in the vaccinated group and 2109 in the placebo or unvaccinated group. The incidence of histologically confirmed cervical intraepithelial neoplasia 2+ was reduced in the vaccinated compared to the unvaccinated group (OR 0.51, 95% CI 0.35 – 0.74, p = 0.0003). The number needed to treat (NNT) to prevent one recurrence was 43. Both pre-treatment vaccination (OR 0.48, 95%CI 0.25–0.94, p=0.03, NNT-40) and adjuvant vaccination (OR 0.53, 95%CI 0.34–0.81, p=0.004, NNT–38) reduced recurrence rates.

Conclusion Prophylactic or adjuvant human papillomavirus vaccination reduces the risk of recurrent cervical intraepithelial neoplasia 2+. These data support further investigation of its role as an adjuvant to surgical treatment.

Disclosures No conflict of interest to declare.

194 ATAXIA-TELEANGIECTASIA FOLLOWED UP IN A HEREDITARY GYNAECOLOGICAL CANCER UNIT OF A TERTIARY HOSPITAL

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