($p < 0.005$). Finally, the correlation between disease stage and positive HPV DNA testing in the lymph nodes was also significant ($p < 0.05$). The presence of HPV DNA in cancer free pelvic lymph nodes was significantly correlated to the concomitant manifestation of pelvic lymph node metastases Specificity of the test for detection of metastatic lesion in the pelvic lymph nodes was 95.9% (95% CI: 89−100%), sensitivity was 81.8% (95% CI: 65−93%). The presence of HPV DNA in cancer free pelvic lymph nodes was significantly correlated to the recurrence. Specificity of the test for prognosis of recurrence was 43.6% (95% CI: 28−60%), sensitivity was 79.7% (95% CI: 67−89%).
Conclusion: The presence of HPV DNA in the lymph nodes is probably an early indicator of metastasis and could predict poor prognosis and should be treated as such in the follow up and planning the adjuvant therapy.

8025 POSTER

National Clinical Nursing Database for Patients Who Have Undergone Surgery for Ovarian Cancer

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Background: In 2005 in Denmark a national multidisciplinary evidence-based clinical guideline for fast track ovarian surgury was developed. The goal was to optimize the postoperative outcome of care and treatment for the ovarian cancer patients. The guideline contained recommendations for nursing actions before and after surgery. In 2008 a national audit of nursing data showed inadequate achievement in terms of: nutrition, mobilisation, pain treatment. nausea treatment and the extent of surgical intervention had an impact on hospitalization time.
In 2009 at a national multidisciplinary workshop, four work groups with representives from the largest surgical gynecological cancer departments in Denmark, were established. Three groups were tasked to review the clinical guidelines in nutrition, pain treatment, fluid therapy, respectively, the fourth group was tasked to develop a national clinical nursing database for patients who had undergone surgury for ovarian cancer. The nursing database was connected to the already existing medical database DGCD (Danish Gynecological Cancer Database). Registration was divided into pre, peri, and post operative care and rehabilitation plan. Nursing variables were based on the targets in the national clinical guidelines and based on consensus decisions in the workgroup. From June 2010 the nursing database was tested and continuously adjusted before being implemented in its current form in February 2011.
Results: The nationwide nursing database of patients who have undergone surgury for ovarian cancer is now implemented in Denmark and ensures a systematic documentation of selected nursing variables that support the continuous quality work. The data entry is individually organized to the various departments. Current data material is not large enough to represent a quatily measurement on a given nursing variable. This will be available at the conference in Stockholm September 2011.
Conclusion/Perspective: In 2012 the database is expected to include patients who have undergone surgury for corpus uteri cancer and in future all gynecological cancers.

8026 POSTER

The Optimal Surgical Management of Uterine Leiomyosarcoma − Should Ovaries Be Removed in Premenopausaul Patients?

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Background: Uterine leiomyosarcoma (LMS) is a rare malignant tumour of uterus. The main method of treatment of LMS is surgery. The efficacy of chemotherapy and radiotherapy is questionable. The aim of our study is to establish the optimal extent of surgery for uterine leiomyosarcoma in patients of different age groups.
Methods: A retrospective chart review was done to 198 patients with LMS treated at the N.N. Blokhin Russian Cancer Research Center, Moscow, Russia from 1970 to 2009. Patients with LMS had a median age of diagnosis 48.16 ± 0.7 years. Surgical treatment, as independent method, was performed to 126 patients (63.6%). Combined treatment, including surgery+postoperative chemotherapy or surgery + radiotherapy was performed to 60 patients (30.3%). Complex treatment (surgery + chemotherapy + radiotherapy) was performed to 13 (6.5%) patients.
Results: We observed association between ovarian preservation and improved survival: overall 5 year survival in patients with ovarian preservation and those who underwent oophorectomy is $87.3 \pm 8.4\%$ and $49.0 \pm 5.3\%$, respectively ($p < 0.05$). We didn't observe metastases in ovaries in any of 198 patients included in this study. Furthermore, we observed that in radically treated patients the frequency of distant metastases was 22.2% higher in patients with ovaries removed compared to patients with ovarian preservation during the primary surgery(59.7% and 37.5% respectively) ($p < 0.05$).
Conclusion: According to our data, the optimal surgery for LMS is total abdominal hysterectomy in the reproductive age and total abdominal hysterectomy with bilateral salpingo oophorectomy in the postmenopausal period.

8027 POSTER

Audit of Fertility-sparing Surgery for Early Stage Cervical Cancer

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Background: Carcinoma of the cervix is the second most common cancer in women worldwide after breast cancer, with a peak incidence in females of fertile age. It is important to offer a more conservative approach to surgical management, to minimise the previously accepted adverse effects of radical surgery, and to offer women more than just cure, but also preservation of their fertility. We analyse the oncological results, complications and fertility rates in a group of women who have undergone fertility-sparing surgery for early-stage cervical cancer.
Materials and Methods: From January 2000 to July 2010, 40 radical trachelectomy or radical cone biopsy procedures with pelvic lymphadenectomy were planned.
Results: A total of 40 women were followed up for a median period of 16 months. 21 women (52.5%) underwent a radical trachelectomy. One procedure was abandoned due to extensive disease at the time of surgery. A radical cone biopsy was performed in the remaining 18 women (45%). Three patients (7.5%) had completion treatment (one radical hysterectomy and two chemoradiotherapy) at the time of initial treatment. There was one recurrence among the women who had completion treatment and another recurrence in those who did not. The perioperative complication rate was low (2.5%) and 14 postoperative complications occurred in 10 women (25%). There was no bladder or urethral injury. Three women discovered they were pregnant pre-operatively and two delivered a live birth after a radical cone biopsy. 28 women attempted pregnancy post-operatively. There were eight pregnancies in seven women and four live births. There was one first trimester abortion and three continuing pregnancies.
Conclusions: Radical trachelectomy and radical cone biopsy with pelvic lymphadenectomy are oncologically safe procedures in selected patients with early stage cervical carcinoma. The morbidity is low and it allows fertility preservation.

8028 POSTER

The Post-surgery Symptom Experience of Women With Vulval Neoplasia − Development and Content Validity of a Patient Reported Outcome (PRO) Instrument

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Background: Women with vulval neoplasia (vulval intraepithelial neoplasia and vulval cancer) often experience severe postsurgical complications, but validated instruments for evaluating postsurgical symptoms and related distress are lacking. Therefore the aims of this study were (1) to develop a WOMen with vulvAl Neoplasia − Patient Reported Outcome (WOMAN-PRO) instrument to measure womens' post-vulval-surgery symptom experience, (2) to examine the content validity of the newly developed WOMAN-PRO instrument, (3) to describe modifications based on pilot-testing, and (4) to examine the content validity of the revised instrument (Clinical Trial ID: 01300663).
Methods: In this international, mixed methods multicenter study, a new instrument was developed according to the PRO guidelines, based on literature searches, patient interviews ($n = 20$) and expert feedback ($n = 9$). The 37 items instrument was pilot-tested first with a content validity index (CVI) rating by patients ($n = 6$) and experts ($n = 6$). The revised 36 items were pilot-tested again by patients ($n = 4$). Participants were recruited from one Swiss and two German University Hospitals.

Results: The initial pilot-tested WOMAN-PRO instrument had a scale CVI of 0.98 based on six patients rating and a scale CVI of 0.92 based on six clinical experts' assessment. Clinical experts' assessments of 34 items showed excellent CVI ranging from 0.83 (15 items) to 1.0 (19 items). The remaining 3 items had a low CVI of 0.66. Patients assessment of 36 items showed excellent CVI of 0.83 (3 items) to 1.0 (33 items). The remaining item had a low CVI of 0.66. The content validity index and the comments from the initial piloting of the provisional instrument resulted in the decision to delete two items, revise three items, add one item and reduce the response options from five to four categories. The revised WOMAN-PRO showed an excellent item and scale CVI of 1.0.
Conclusions: The potential use of the WOMAN-PRO instrument in clinical practice offers patients guidance in early recognizing and self-assessing symptoms and related distress. The instrument provides clinicians with systematic information about key symptoms from a patient perspective and women's unmet informational needs related to assessing and managing symptoms in daily live. If the results of further ongoing psychometric testing are promising, the WOMAN-PRO will provide a useful outcome measure for clinical trials examining the post-surgery symptom experience in women with vulval neoplasia.

8029 POSTER

Health-Related Quality of Life (HRQoL)/Patient Reported Outcomes (PRO) of Patients (pts) With Partially Platinum Sensitive (PPS) Recurrent Ovarian Cancer (ROC) Treated in a Randomized Phase III Trial of Trabectedin and Pegylated Liposomal Doxorubicin (PLD) Vs PLD Alone (OVA-301) − an Exploratory Analysis

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Background: OVA-301 is a large randomized trial that demonstrated OS benefit (Monk B. 2011) of trabectedin plus PLD (T+P) *vs* PLD in PPS ROC pts.
Methods: This analysis provides an evaluation of PRO in PPS pts, analyzing single domains and the global health status (GHS). EORTC-QLQ C30 and OV28 questionnaires were completed at screening and on Day 1 of every other treatment cycle (C) starting with C1, and at end of treatment (EoT). Comparisons are exploratory so no adjustments for multiplicity to control the overall Type I error rate were done.
Results: 214 pts had PPS ROC (PLD: 91/ T+P: 123 pts). Questionnaire completion was ~90% at baseline and well maintained up to 21 cycles (~83%). A median of 4 and 6 cycles of PLD and T+P were administered. The table shows the cross-sectional analysis of the mean score changes from baseline (MCB) of the functional, symptoms and GHS scales, including relevant findings at the corresponding timepoint.

Item/Domain	C3			C5			C7			C9		
	PLD	T+P	p[a]	PLD	T+P	p[a]	PLD	T+P	p[a]	PLD	T+P	p[a]
Appetite loss[1]	2.5	16.7	0.054	−1.4	7.0	0.975	−1.6	4.3	0.837	0	1.4	0.796
Dyspnea[1]	−1.3	4.3	0.024	1.4	5.0	0.195	−1.6	−0.7	0.750	−4.8	−2.9	0.932
Nausea/ Vomiting[1]	1.6	13.8	0.003	0.7	7.2	0.022	1.6	5.8	0.149	−1.2	6.9	0.114
Pain[1]	−3.4	−2.7	0.862	−0.4	−5.3	0.054	−1.6	−6.5	0.053	0	−8.3	0.053
Peripheral Neuropathy[1]	7.9	4.4	0.666	10.8	3.1	0.229	9.1	3.3	0.074	9.4	4.6	0.159
GHS/QoL[2]	−2.4	−6.6	0.352	−0.6	−3.1	0.909	0.9	−1.4	0.371	0.6	4.0	0.023

[1]Lower is better; [2]Higher is better; [a]T-test p-values comparing real scores.

Nausea/Vomiting favored PLD at C3 and C5, with a non significant trend across cycles. Meanwhile the pain scale favored T+P with improved results at C5 and beyond due to treatment.
Peripheral Neuropathy scale had a trend favoring T+P after 5 cycles, which was maintained.
In general the GHS scale had an important clinical difference in favor of T+P at C9, and was maintained for longer treated pts (EoT = MCB:PLD = −9.8, T+P = −3.4, p = 0.062).
Further findings will be discussed at the meeting.
Conclusions: Acknowledging the limitations of this analysis, differences were observed in different domains, characterizing the different profile of both treatments. The nausea/vomiting domain favored PLD, while T+P had better scores for pain and neuropathy, suggesting a non platinum/non-taxane treatment helps to recover from toxicities associated with prior therapies, which may offer new potential for following therapies. In general, addition of Trabectedin to PLD has no detriment in the global QoL and shows an improved outcome in the GHS for PPS ROC pts.

8030 POSTER

Phase II Study of NGR-hTNF Plus Doxorubicin in Relapsed Ovarian Cancer (OC)

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Background: NGR-hTNF consists of tumour necrosis factor fused with the peptide NGR, which selectively binds to a CD13 overexpressed on tumour blood vessels. NGR-hTNF is able to increase the intratumoral doxorubicin distribution by altering tumour vasculature.
Methods: OC patients failing at least one prior platinum-taxane line and with platinum-free interval either lower than 6 months (PFI <6) or between 6 to 12 months (PFI <12) received NGR-hTNF 0.8 $\mu g/m^2$ and doxorubicin 60 mg/m^2 on day 1 every 3 weeks. Doxorubicin was maintained up to 8 cycles and NGR-hTNF until disease progression. Primary endpoint was response rate. A 2-stage study design assumed that $\geqslant$2/17 and $\geqslant$6/37 patients with objective response would warrant further testing.
Results: Thirty-seven patients (25 with PFI <6; 12 with PFI <12) pretreated with 1 to 5 chemotherapy lines (median 1) were enrolled. Median age was 57 years (range 35−72) and 32 patients presented with a PS of 0. Median PFI was 4.6 months (95% CI 3.4−5.8).
Baseline CA125 ranged from 6 to 5,787 U/mL (median 549). Median baseline neutrophil-to-lymphocyte ratio (NLR), an index of systemic host immune response to tumour, was 2 (range 1−17). In total, 174 cycles were given (median 4; range 1−8). Neither increase of doxorubicin-related toxicities nor grade 3−4 NGR-hTNF related toxicity were registered.
Common grade 1−2 toxicity were transient chills (58%). After first study stage (n = 17), 6 patients showed partial response (2 with PFI <6; 4 with PFI <12) and the trial met its primary endpoint. After study completion (n = 37), a total of 17 patients had experienced stable disease (10 with PFI <6; 7 with PFI <12), yielding an overall disease control rate of 66% (92% in PFI <6; 48% in PFI <12). Median progression-free survival (PFS) was 4.9 months (95% CI 3.5−6.3) in overall population, 3.7 months in patients with PFI <6, and 8.2 months in patients with PFI <12. Moreover, median PFS was 7.8 vs 3.4 months (HR = 0.34; p = 0.01) in patients with baseline NLR lower or higher than the median value, respectively.
After a median follow-up of 10.8 months, 25 patients (68%) were still alive.
Conclusion: Tolerability and activity of NGR-hTNF plus doxorubicin deserve further randomized testing versus doxorubicin alone in platinum-resistant/refractory OC.

8031 POSTER

Prediction of Overall Survival (OS) Adjusted by Continuous Platinum-free Interval (PFI) at Fixed Timepoints in Patients With Recurrent Ovarian Cancer (ROC) − Results From OVA-301

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Background: OVA-301, a phase III study comparing trabectedin plus pegylated liposomal doxorubicin (PLD) *vs*. PLD alone in 672 patients progressing after one prior platinum-based regimen, showed significantly longer progression free survival and higher response rate for the combination, with acceptable tolerance (Monk et al; 2010). This study also showed longer OS in patients treated with the combination (Monk et al;