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PRESS RELEASE
10 STORIES WITH DATA ANNOUNCEMENTS

GYNAECOLOGICAL CANCER TREATMENT ENTERS NEW ERA OF PATIENT-TAILORED CARE

Advances in cancer prevention and treatment reported at this week's premier European congress for specialists in gynaecological cancers show that care is being more effectively tailored to the needs of individual women, so that survival can be improved without the cost of added complications and reduced quality of life.

Speaking at this week's 16th International Meeting of the European Society of Gynaecological Oncology (ESGO) in Belgrade, Serbia, the Society's new President, Professor Ate van der Zee, from the Netherlands, stressed the value of this new approach:

"Our latest treatments take account of the fact that every woman is different, and it isn't enough just to try to improve life expectancy. We need to try to minimise the effects of treatment on a woman's working and family life, and to take more account of whether she still wants to have children.

"We have also learned how important it is to concentrate our expertise in specialist centres, especially when we are treating the rarer gynaecological cancers, so that women have access to the most up to date knowledge and expertise that doctors specifically trained in gynaecological cancer can provide.

"By building this expertise we can also ensure that new discoveries made in laboratories across Europe are translated into clinical treatments as efficiently as possible as we develop ever more refined therapies tailored to the unique genetic and other characteristics of our patients."

Notes for Editors:

Summaries of key advances in gynaecological oncology announced at this year's ESGO congress are summarised in the following series of short reports.

NOBEL SCIENTIST URGES WIDER VACCINATION AGAINST HPV INFECTION TO ACHIEVE ERADICATION

A global vaccination programme against human papilloma virus (HPV), to include boys as well as girls, could lead to eradication of the virus and virtual disappearance of cervical cancer, predicted Nobel Prize winner, Professor Harald zur Hausen, after delivering the key-note lecture at the 16th International Meeting of the European Society of Gynaecological Oncology (ESGO) in Belgrade, Serbia, this week.

Professor zur Hausen, who was awarded the Nobel Prize in Physiology or Medicine in 2008 for his discovery of HPV as the cause of cervical cancer, explained that although HPV prevention will impact mainly on women's health, it also has important implications for men's health:

"If we wish to achieve eradication within a reasonable period of time, we will need to vaccinate both sexes, and research has shown that boys respond to vaccination in the same way as girls. The main risk of developing cancer after HPV infection is with women and, because of the cost of vaccines, it has been decided to start with girls. But other cancers associated with HPV infection, such as anal and oral cancer, are more common in men, and genital warts occur in both sexes. So there is good reason to vaccinate boys before the onset of sexual activity as well," said Professor zur Hausen.

He suggested that future reductions in production costs and development of cheaper vaccines will make wider vaccination a realistic option, and added that a major reduction in HPV 16 and 18 – the viruses which cause 70-80% of human papilloma infections – would probably enable the interval between currently used cervical screening tests to be extended. The introduction of self sampling by women, using new tests for HPV DNA, would also help to simplify screening procedures.

"A therapeutic intervention is also needed to protect people after they have acquired HPV infection, and it would be a great advantage to have targeted chemotherapy that would block viral functions that are responsible for development of precursor and malignant lesions. A lot of laboratories are working on this and, although I know of nothing yet, it will hopefully not be too long before we see progress," concluded Professor zur Hausen.

HPV vaccines indicate further benefits for cervical cancer protection

New human papilloma virus (HPV) vaccine studies presented at the 16th International Meeting of the European Society of Gynaecological Oncology (ESGO) in Belgrade, Serbia, this week have confirmed sustained protection against precancerous cervical lesions in healthy young women, as well as beneficial effects for women previously treated for cervical, vulvar or vaginal precancers or genital warts. Latest safety data also confirm the low levels of adverse events associated with the vaccines.

In a study of 1113 healthy women aged 15-25 years vaccinated with the anti-HPV 16/18 vaccine, Cervarix, sustained immunogenicity and 100% efficacy against HPV 16 and 18 related cervical intraepithelial neoplasia 2 (CIN2+) lesions was reported at 7.3 years follow up – the longest to date with the vaccine. Medically significant adverse events occurred in 8.1% of vaccinated women and 6.2% of placebo-treated women, and serious adverse events occurred in 1.8% and 2.4% respectively.

Presenting the data at a late-breaker session of the congress, trial investigator Dr Newton De Carvalho, from the Hospital de Clínicas da Universidade Federal do Paraná, Curitiba – Paraná, Brazil, concluded that the vaccine was highly effective against HPV infection and cytohistological endpoints associated with HPV 16/18, and had similar safety to placebo.

In a second analysis, Dr Elmar Joura, from the Medical University of Vienna, Austria, showed efficacy data on 1350 women who took part in placebo controlled trials of the anti-HPV 6,11,16,18 vaccine, Gardasil, following treatment for cervical, vulvar or vaginal precancers or genital warts. These data, collected an average 1.5-1.6 years post therapy, showed efficacy of up to 74% in preventing HPV 6/11/16/18 associated CIN, and efficacy of up to 79% for prevention of further precancerous vulvar or vaginal lesions or genital warts.

Dr Joura concluded that women who have been treated for cervical, vulvar or vaginal pre-cancer or genital warts, and are therefore at increased risk of further disease, can be told that they too will benefit from HPV vaccination.

Kinder cervical cancer surgery reduces complications without jeopardising survival

Nerve-sparing radical hysterectomy for cervical cancer causes less bladder and colorectal dysfunction than standard techniques, but doesn't adversely affect survival. These are the reassuring findings from two studies carried out in Italy and the Czech Republic, and reported at the 16th International Meeting of the European Society of Gynaecological Oncology (ESGO) in Belgrade, Serbia, 11-14 October 2009.

In a study of 200 patients reported by Dr Francesco Raspagliesi, from the National Cancer Institute in Milan, Italy, two and five year disease free survival after nerve-sparing surgery was 89% and 81% respectively – comparable with survival rates commonly reported in studies of radical hysterectomy in which nerve-sparing techniques are not used. But the complication rate of 3.5% was lower than seen with conventional techniques.

The second study, carried out by Dr David Cibula and colleagues at the General Faculty Hospital of Charles University, Prague, Czech Republic, directly compared morbidity six months after nerve sparing surgery with that seen with two standard radical hysterectomy techniques in 87 women with cervical cancer. Those who had surgery which left key pelvic nerves intact had significantly less urinary incontinence, defecation irregularity, bladder emptying problems and nocturia than those had more invasive surgery ($p < 0.05$ all parameters).

Dr Cibula concluded that it was nerve-sparing techniques which made the difference to the complications that women experienced after surgery, rather than the extent of the hysterectomy itself, and Dr Raspagliesi recommended that nerve-sparing techniques should now be considered for all cervical cancer surgery.

CALYPSO trial shows new chemotherapy combination prolongs progression free survival in ovarian cancer

Treating women with relapsed platinum-sensitive ovarian cancer with combined carboplatin and pegylated liposomal doxorubicin prolongs progression free survival and is associated with a lower risk of severe, long lasting nerve damage than standard carboplatin/paclitaxel treatment.

This was the key conclusion from the international multicentre CALYPSO trial reported this week at the 16th International Meeting of the European Society of Gynaecological Oncology (ESGO) in Belgrade, Serbia, by Dr Mark Heywood, from the BCCA Vancouver Cancer Centre, Vancouver, Canada.

Data from 986 patients treated in 16 countries in Europe, North America, the Middle East, Australia and New Zealand showed progression free survival of 11.3 months and 9.4 months respectively ($p=0.005$) for the carboplatin/pegylated doxorubicin vs carboplatin/paclitaxel combinations in women with relapsed platinum sensitive disease (ovarian cancer that had relapsed more than six months after treatment with platinum-based chemotherapy).

Severe neutropenia occurred in 35% and 46% respectively of patients in the two groups, severe neuropathy in 5% and 28% and alopecia in 7% and 84%. Hand-foot syndrome – a well documented inflammatory condition associated with pegylated doxorubicin was more common in the carboplatin/pegylated doxorubicin group (13% vs 2%) and severe thrombocytopenia was also more common (16% vs 6%). Treatment needed to be discontinued early in 4.3% of patients in the carboplatin/pegylated doxorubicin group, compared to 14% of those on the standard regime.

Dr Heywood pointed out that an unexpected advantage of adding doxorubicin to carboplatin was the reduction in sensitivity reactions to carboplatin seen in the novel treatment group compared to that normally seen with carboplatin alone or in other combinations.

He concluded that the carboplatin/pegylated doxorubicin combination provided a superior risk benefit ratio compared with carboplatin/paclitaxel for women with relapsed, platinum sensitive ovarian cancer.

Keyhole surgery shows quality of life benefits for women with early endometrial cancer

Women who have laparoscopic surgery for early stage endometrial cancer have a shorter hospital stay, less pain and faster recovery within the first six weeks after surgery, according to preliminary results of a comparative study of laparoscopic and open surgery, reported by Dr Claudia Bijen, at the 16th International Meeting of the European Society of Gynaecological Oncology (ESGO) in Belgrade, Serbia.

Dr Bijen, from the University of Groningen, the Netherlands, presented data from 185 women with early endometrial cancer who underwent laparoscopic surgery and 94 who had open surgery. While there was no significant difference in major complications between patients in the two groups, those undergoing laparoscopic surgery had significantly better quality of life scores six weeks after surgery, less pain and were able to return to work more quickly than those who had open procedures.

Dr Bijen stressed that the study design ensured that laparoscopic surgery was carried out by skilled surgeons – something which would be important if the laparoscopic technique is taken up more generally in clinical practice.

Ovarian cancer patients have lower death risk when treated by experts

Women with ovarian cancer are less likely to die from their disease if they are treated by specialist gynaecological oncologists than if they are cared for by general gynaecologists, according to the results of a study carried out in Scotland, UK, and reported at this week's 16th International Meeting of the European Society of Gynaecological Oncology (ESGO) in Belgrade, Serbia.

An analysis of survival data from a cohort of 912 ovarian cancer patients treated in the West of Scotland Managed Clinical Network showed a 24% lower risk of death in women treated by gynaecological oncologists who specialise in the treatment of gynaecological cancer than by general gynaecologists who treat the full range of gynaecological problems that women can experience.

Reporting her findings at a late breaker session of the congress, Dr Alex Stirling, from the West of Scotland Cancer Surveillance Unit, explained that recent reorganisation of cancer services in Scotland was designed to provide equal standards of care for patients wherever they lived. However, some women continue to be treated away from larger cancer centres, and do not therefore have access to gynaecological oncologists.

Dr Stirling added that, by the end of the year, cancer services in the area will be centralised, and selection of cases for surgery will be decided by a specialist multidisciplinary team – hopefully helping to reduce remaining inequalities of care and ensuring that more difficult cases are treated by gynaecological oncologists.

High dose folate and B vitamin supplements increase uterine cancer risk

Women who take large amounts of folate, vitamin B2, B6 or B12 supplements may be increasing their risk of uterine cancer, according to research presented at the 16th International Meeting of the European Society of Gynaecological Oncology (ESGO) in Belgrade, Serbia, 11-14 October 2009.

Results from a 20 year follow up of dietary intake in over 23,000 postmenopausal women taking part in the Iowa Women's Health Study, have shown that women who consumed large amounts of the supplements were twice as likely to get type II uterine cancer than women who had normal intakes, although there was no effect on type I uterine cancer.

Dr S Uccella, from the department of gynaecologic surgery at the Mayo Clinic, Rochester, USA., explained that the results contrasted with the expected protective effects of the supplements and further investigation showed that, while a folate intake of 200-600mcg/day did have a protective effect, taking higher levels nearer 1000mcg/day increased the risk of uterine cancer.

He concluded that the research could have implications for women's health in countries such as the USA and Canada, where folate and B vitamins are added to foodstuffs, and other countries considering similar action.

Broader age range recommended for cervical screening

Cervical cancer screening programmes that limit tests to women aged 30-60 years are missing a significant proportion of women who are at risk of getting the disease. An analysis of 401 cases of cervical cancer diagnosed in the Netherlands, where screening is only offered to women aged 30-60, has shown that 19% were in women aged under 30 and 12% were in women over 60.

The analysis, reported by Dr Roosmarie de Bie at the 16th International Meeting of the European Society of Gynaecological Oncology (ESGO) in Belgrade, Serbia, 11-14 October 2009, also showed that 40% of cervical cancer cases were in women who had regular screening tests, and 25% had a normal smear within the five years before their diagnosis, suggesting a need for more sensitive tests.

Dr de Bie, from Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands, concluded that underscreening together with insufficient sensitivity are the main problems of the national screening programme, and its effectiveness can be improved by interventions to increase the participation rate and the sensitivity of the screening test. She recommended that the target age-range of the current programme should be re-evaluated.

Dr de Bie also told delegates that a project underway in Nijmegen is piloting the use of home HPV DNA tests in an effort to reach more women who are currently missing out on conventional smear tests.

Currently in the Netherlands, there are 600 new cases of cervical cancer each year despite the presence of an established national screening programme.

Serbian women missing out on cervical cancer prevention

Three quarters of sexually active students who took part in a survey of cervical screening had never had a Pap smear, despite being aware of the importance of such tests, according to results of a study carried out in Serbia – the country with the highest incidence and mortality from cervical cancer in Europe.

Speaking at the 16th International Meeting of the European Society of Gynaecological Oncology (ESGO) in Belgrade, Serbia, 11-14 October 2009, Dr Olivera Těsić, from the Oncology Institute of Vojvodina, Serbia, described data from a questionnaire administered to 727 female students, 294 students aged younger than 21 years old and 433 students aged 21-24 years old. Although 82% of the women were sexually active, 77% had never had a smear, despite the fact that over 70% of students knew the importance of regular smears. In contrast, 73% were unaware of the role of HPV in cervical cancer – even though about half of the students were medical students.

Dr Těsić concluded that if such well educated young women were missing out on regular smears and were unaware of the role of HPV, this raised significant doubts about awareness and uptake in other young women in Serbia. In May 2008, the Serbian government agreed that a national cervical cancer screening programme should be implemented.

Cancer treatment during pregnancy need not risk baby's health

Many women who discover they have cancer while pregnant risk their own health by postponing treatment. But an international collaborative study carried out in Belgium, the Netherlands and the Czech Republic, has shown that, while babies born to women who undergo cytotoxic treatment during pregnancy tend to be born prematurely and are small for gestational age, most achieve a good outcome and the incidence of congenital malformations is comparable to the general population.

The analysis, reported at the 16th International Meeting of the European Society of Gynaecological Oncology (ESGO) in Belgrade, Serbia, 11-14 October 2009, followed up 215 pregnancies in women diagnosed with invasive cancer between 1998 and 2008. Cancer treatment was started during pregnancy in 57% of cases, and it was delayed until after the birth in 27% of pregnancies. The remainder ended in spontaneous miscarriage or were terminated. Delivery was induced in 72% of pregnancies and 54% of children were born preterm.

Babies exposed to cytotoxic treatment in the womb were more likely to be born prematurely (12%, $p=0.012$), and to be small for gestational age children (24%, $p=0.001$). However, the incidence of congenital malformations was comparable to the general population.

Dr Kristel Van Kalsteren, from the Katholieke Universiteit Leuven, Leuven, Belgium, concluded that pregnancies complicated by maternal cancer have an overall satisfactory outcome, though the prevention of iatrogenic prematurity deserves attention. She recommended that such women who are diagnosed with cancer while pregnant should be treated in a multidisciplinary setting with access to a maternal and neonatal intensive care unit.