Panel discussion: A new pill scare? How did it come about and how should we tackle it?

During the last day of the First Global Conference on Contraception, Reproductive and Sexual Health a panel discussion about the risk of venous thromboembolism (VTE) associated with the intake of combined oral contraceptives (COCs) was held. This session was chaired by Sven O. Skouby and Carolyn Westhoff, and included three lectures followed by constructive discussion.

Johannes Bitzer presented the source of the scientific controversy around this topic, with special focus on the hypothetical explanation of several registry-based studies, which indicated that there is an increased risk of VTE associated with the intake of third- and fourth-generation COCs compared to preparations containing the progestogen levonorgestrel (LNG). He stressed that these results contrast with those of published prospective cohort studies, sponsored by Bayer HealthCare, at the request of the European Medicine Agency (EMA) and the Food and Drug Administration (FDA) for an expanded post-marketing surveillance, which did not find such differences. Consequently, this discrepancy led to an intensive scientific discussion among epidemiologists about possible confounders and biases in the published studies, and reached a highly emotional political dimension in which all those who are professionally responsible for women’s health are involved: the national health authorities, the pharmaceutical companies, the professional organisations, the prescribers, the media and the public (i.e. the current or potential users of CHCs). He emphasized that all parties involved must be interested in conducting well-designed prospective studies addressing the relevant outcomes of the use of contraceptive methods (efficacy, safety, side effects, non-contraceptive benefits, and so on). This will require the collaboration of health authorities, industry, epidemiologists, physicians and women’s organisations.

Øjvind Lidegaard presented data from studies based on the Danish Registry concerning increased risk of third- and fourth-generation contraceptives and cyproterone acetate-containing pills. Additionally, data from another study, based on the Danish Registry, were shown which indicated that treatment with the transdermal patch and the vaginal ring was linked with a greater risk of VTE whereas the LNG releasing-intrauterine system (LNG-IUS) did not, and maybe even decreased that risk, compared to non-users. He expressed his belief that a serum level of sex hormone binding globulin (SHBG) is a reliable marker for assessment of VTE risk associated with the combined hormonal contraceptives (CHC) use. Finally, as a proof for his scientific observations, Øjvind Lidegaard showed the most recent and unpublished data on the reduction of the incidence of VTE in women in Denmark during the period when women began to replace third- and fourth-generation COCs with second-generation or LNG-containing COCs.

The third speaker was Jeffrey Jensen, who stressed the fact that many questions related to this scientific controversy, particularly conflicting results of various studies, have not been elucidated, so far. Many factors contribute to VTE risk (e.g. age, duration of use, weight, family history, etc.), which makes epidemiological studies vulnerable to bias and confounders, and may explain contradictory results. The inherent inability of database studies to adequately control for baseline confounders render this design less suitable for providing further clarification. He questioned whether the relative risk (RR) increase of around 2 described in the studies based on the Danish Registry and some other case-control studies reflects a clinically relevant difference. Expressing a fear that a rise of this new ‘pill scare’ might leave many women without reliable contraception, thus resulting in the increase of unplanned pregnancies, he stated that several studies have shown that the risk of VTE during pregnancy and the postpartum period is considerably higher (29–300 per 10 000 users) than during use of a CHC.

Practical recommendations: In order to reduce the VTE risk it is most important to avoid prescribing
CHCs to women at elevated risk for VTE. The World Health Organization Medical Eligibility Criteria for Contraceptive Use should serve as a first point of guidance for prescribers. Women who have a higher risk of VTE due to obesity, smoking, family history of VTE or cardiovascular disease should undergo a personal risk assessment and be advised appropriately.

The hormonal contraceptive methods with the lowest VTE risk are progestogen-only contraceptives. While there is some evidence from registry studies that CHCs containing LNG are associated with less risk than those containing third- and fourth-generation progestogens, large, well-designed cohort studies have not confirmed this difference in risk, and the controversy is not yet resolved. Even if third- and fourth-generation pills are associated with a higher RR, the absolute difference in risk is small, and is estimated by some authors to be of the order of 4–6 attributable cases per 10 000 users per year.

The risk of death from VTE is low. Based on a RR of 2, the excess risk of death for a woman taking modern pills is 1 in 100 000, which is much lower than the risk of everyday activities such as cycling.

In the decision-making process regarding the choice of a contraceptive method by the individual patient, VTE risk is but one element in the equation. Other elements are efficacy, tolerability, additional health benefits, and whether or not the patient can/will use an alternative method. These factors must be taken into account and discussed with the individual patient. Results from long-term cohort studies on the positive impact of the use of hormonal contraceptives on global health parameters of women should be part of the information given to women.

Both epidemiological data and clinical trials must be taken into account when best practice is defined. Regulatory restrictions of previously registered methods should only be made after careful assessment of all the available evidence.

Johannes Bitzer, ESC President

The fruitful professional career of Leon Speroff

During the First Global Conference in Copenhagen, Prof. Leon Speroff during his very interesting keynote lecture on Historical Highlights in Oral Contraception led us to the time when the first contraceptive pill was introduced to the market. It was a vivid and interesting story about Gregory Pincus, Katharine McCormick, John Rock, Min Chueh Chang, and many others who contributed to one of the most important events in the modern history, the beginning of the controlled fertility, when it became possible to efficiently separate sexuality from procreation.

Such a story could have only been told by Prof. Leon Speroff, who is famous for his publishing activities. This remarkable man received his medical degree from Case Western Reserve University School of Medicine in Cleveland, Ohio, following which he completed his training in obstetrics and gynecology at Yale-New Haven Hospital. After two years in the Air Force, Dr. Speroff was a Fellow in the Training Program for Steroid Biochemistry at the Worcester Foundation for Experimental Biology in Shrewsbury, Massachusetts, and then a Research Associate with Dr. Raymond Vande Wiele in the Department of Obstetrics and Gynecology at Columbia University College of Physicians and Surgeons in New York City. Currently, Dr. Speroff is Professor Emeritus of Obstetrics and Gynecology at the Oregon Health & Science University in Portland. His previous appointments included Assistant Chairman and Director of the Gynecologic Endocrine Laboratory in the Department of Obstetrics and Gynecology at Yale University School of Medicine, Chairman of the Department of Obstetrics and Gynecology at Oregon Health Sciences University, and Chairman of the Department of Reproductive Biology at Case Western Reserve University.

Prof. Speroff has served as President of the American Fertility Society (now the American Society for Reproductive Medicine) and was the founding President of the Society of Reproductive Endocrinologists. His wide range of editorial activities has involved 14 specialty journals in obstetrics, gynecology, and reproductive medicine. He served as the host of the Lifetime Cable Television program on obstetrics and gynecology. Dr. Speroff is the senior author of Clinical Gynecologic Endocrinology and Infertility, now in its 8th edition, and A Clinical Guide for Contraception, now in its 5th edition. He has written the biography of Carlos Montezuma, an American Indian physician who was a prominent activist for Indian rights in the early 1900s. His latest works include the historical story of two railroads, competing with each other as they were built on opposite banks of the same river: The Deschutes River Railroad War; a journal of his rookie senior softball season: A Slow-Pitch Summer, and A Good Man, the biography of Gregory Pincus, the developer of the birth control pill.
Prize Winners at the Copenhagen Congress

Over 300 abstracts were submitted for this Copenhagen Global Congress with 5 sessions given over to free communications and two days of poster viewing. From Mexico to Sri Lanka and New Zealand to The Netherlands, we were inspired by innovative ideas, high quality research and an opportunity to share good practice. Unfortunately not everyone can win a prize, but to those who did not succeed this time, please consider submitting your work again for the next ESC congress in Portugal in 2014.

We had four categories of prizes worth 500 Euros each. The first was for the Young Scientist Award, which has to be written and presented by a first author who was less than 35 years old on 22 May 2013. The winner was Jenny Stern from Sweden for ‘Introducing the Reproductive Life Plan in midwifery counselling – a randomised controlled trial’ (Poster number 182). This plan included a semi-structured discussion with the midwife and a brochure. The results showed it increased women’s knowledge of reproductive health.

The prize for the best Free Communication went to Daniela Brawley from Glasgow, UK. Her presentation was entitled ‘Unplanned pregnancy and contraception choice in women living with HIV: a 12-year case review in a large urban centre’ (FC30). This work focused on the complexity of managing women living with HIV despite free access to long acting contraceptive methods. It showed that partners and other factors have to be taken into account.

There were two Poster prizes, one for each day, selected after an informal discussion at lunch time and then a formal presentation with slides in the afternoon. Raffaela Schiavon from Mexico won with her work entitled ‘Increasing abortion-related hospitalisation rates among adolescents in Mexico’ (Poster number 01). This study identified the number of abortion related admissions to hospital for girls aged 10-19 years. The rates were found to be increasing and pointed to a significant unmet need for sexual education and access to contraceptive services. The second prize went to Josephine Obel (Denmark) and Marcus Larsson (Sweden) for their work in Africa entitled ‘HIV and sexual and reproductive health in border districts affected by migration in Tanzania’ (Poster number 205). Many workers cross between the areas bordering Tanzania and the study showed an increase in the sexual risk-taking behaviour of this group of men compared to the general population. Access to sexual health services was limited and gaps in service provision needed to be improved.

The Global award which was chosen from all the free communications and posters went to Jane Feiberg from the United States for her presentation ‘Evidence-based modelling suggests improved maternal and child health through increased access to family planning in Pakistan’ (Poster number 151). This work was funded by the US Agency for International Development (USAID) and showed that maternal health was improved when the government introduced a new contraceptive supply chain which was found to be helping to meet the needs of Pakistani couples.

Overall, a very successful meeting and congratulations to all the winners and their colleagues involved with the presented studies.

Consult the book of abstracts (free of charge): www.escrh.eu/2013/awards

Dr. Sarah Randall, Convenor for Abstracts

CHALLENGES IN SEXUAL AND REPRODUCTIVE HEALTH
28 > 31 MAY 2014

13TH CONGRESS OF THE EUROPEAN SOCIETY OF CONTRACEPTION AND REPRODUCTIVE HEALTH
Report of the workshop of the expert group on sexual medicine and sex education

The workshop of the EG on sexual medicine and sex education was in an intimate conference room, which made interaction easy. There were participants from many countries, including Egypt, Ivory Coast, Australia, and Europe. Christine Winkelmann and Olaf Kapella first gave a short presentation on how to counsel when patients present themselves with sexual health complaints, especially if there seem more issues at stake than only the medical reason for the consultation. After the presentation there was a role play demonstrating how not to do such counselling. The participants were asked to advise the ‘doctor’ how to do this counselling with many good suggestions. It was remarkable however that when the ‘patient’ gave an indication of possibly having sexual problems, none of the participants reacted to this clue and stayed within the safe medical history. After the role play we exchanged tips on how to speak with a young girl without the parents. In some countries this appeared to be totally forbidden.

Many participants said afterwards that they enjoyed this type of workshop, since it is a good way to learn skills in counselling. The expert group hopes to have a pre-congress workshop next year to practice this more in depth, since it is very clear this type of workshop adds something valuable to the presentations.

Olga Loeber, Coordinator

Johannes Bitzer, ESC president, Honorary Fellow of the FSRH of the RCOG

On Thursday 6 June 2013, the UK Faculty of Sexual and Reproductive Healthcare of the Royal College of Obstetricians and Gynaecologists (FSRH) bestowed an Honorary Fellowship on Professor Johannes Bitzer, current President of the European Society of Contraception and Reproductive Health (ESC).

The citation was given by Dr Sarah Randall who informed the audience that Johannes is the Director and Chief Physician of the Department of Obstetrics and Gynaecology at the University Hospital in Basel. Living in Germany, working across the border in Switzerland and being close to France, Johannes, like so many of our ESC friends, switches between languages with enviable ease. Since its inception in 1988, the ESC has gradually changed as did the Faculty; widening its scope to encompass all aspects of sexual and reproductive health. Johannes had been key to this change with his long interest in the more psychosocial aspects of sexual health. She explained that Johannes’ practice is one of holistic care and multidisciplinary working which has now resulted in nurses and midwives having a greater role within the organisation of ESC.

Over the last few years, the ESC and the Faculty have worked more closely through joint educational projects in which Johannes has been involved. Johannes is due to retire from his hospital post this year and Sarah commented that he would be a great candidate for the next UK “Strictly Come Dancing” series as anyone who has attended an ESC congress dinner will know, he is a dancer par excellence.

The 7th Diczfalusy award lecture symposium on reproductive health

The Egon and Ann Diczfalusy Foundation for Supporting Research in Reproductive Health with their co-organisers the Association for Reproductive Health & University of Belgrade, School of Medicine are organising the 7th Diczfalusy award lecture symposium on reproductive health on 27-28 September 2013 at the Hotel Hyatt Regency, Belgrade, Serbia.

We are calling for nominees for the young scientist prize 2013 of the Diczfalusy Foundation (deadline 28 July). Go to: www.escrh.eu/about-esc/news/call-nominees-young-scientist-prize-2013-diczfalusy-foundation
For general information on the meeting go to: diczfalusy.shp.hu

All materials to be included in the ESC Newsletter should be submitted (electronically) to the:
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