Report on the EUGenMed final conference "European Roadmap for Implementation of Sex and Gender in biomedicine and health research".

Report Workshop 1: Sex and Gender in clinical research and pharmacology.

Clinical research

The report on clinical research was given by Angela Maas from Nijmegen, the Netherlands. She summarized the workshop that took place in December 2014 in Berlin and mentioned that this workshop focused on cardiovascular issues. She it made quite clear that cardiovascular was only taken as an example for many different clinical areas where sex and gender do play a role.

Fig 1 workshop particapants

Angela Maas discussed gender issues in aortic stenosis, microvascular disease, coronary heart disease, hypertension, heart failure and its pharmacological and interventional therapy. She mentioned that S&G differences in coronary artery disease are frequently due to unhealthy life style, stressful life, and subsequently obesity and hypertension. She also mentioned that acute coronary syndromes manifest quite frequently differently in women and men. Certain coronary artery dissection is much more frequent in women and particular in pregnant women or immediately postpartum. She also mentioned that women do have much more Tako tsubo syndromes than men, that they do have increased 30 day and one year mortality after acute coronary syndromes, that they have a greater risk factor profile with more heart failure with preserved ejection fraction. She mentioned that microvascular disease is a great problem in women and that the main gold standard of coronary angiography is not suitable for diagnosis in women. There is also more comorbidity and

symptoms after PCI and in coronary bypass surgery. She discussed heart failure with preserved ejection fraction that is particularly frequent in older women and is supported by diabetes, hypertension and arterial fibrillation. In heart failure with reduced ejection fraction men are frequently more strongly affected. They do have a higher mortality and they are more frequently recipients for transplanted hearts. In valvular heart disease there are interesting new developments. Women and men behave differently if they have a valvular aortic stenosis. Interestingly enough, women respond better than men to transcatheter aortic valve implantation (TAVI). The reason for the better outcome of women after TAVI is not clear yet. The implementation of sex and gender in cardiovascular disease as Prof. Maas concluded, requires contributions from many different stakeholders, governmental support, public health and more multi-disciplinary interaction.

Pharmacology and drug development

Karin Schenck-Gustafsson gave a best practise example on sex, gender, and drugs and reported on the building of a web-based knowledge database. She started by describing the well-known differences in pharmacokinetics and pharmacodynamics in women and men, the different absorption distribution metabolism and elimination of drugs, and described the body composition differences between women and men. She reported on some well-known differences in drug adverse effects between women and men including digitalis, ACE inhibitors, calcium channel blockers, clopidogrel, zolpidem and Lamotrigine for epilepsia and bipolar disorder. She discussed the GAO report that mentioned that a number of six of eight major drugs that were withdrawn from the market in the US had greater evidence for health risks in women than in men. She reported that Swedish women take more drugs than Swedish men and reported on an effort to facilitate considering gender in drug use in women and men. For this purpose a database is constructed at the Karolinska Institute that lists major differences for all known drugs that need women and men. She concluded that the benefit will be fewer drug complications, the use of right doses and right indications, saving money, more effective care, and better understanding of sex and gender aspects.

The talk was followed by a lively discussion focussing on the need of introducing a sex and gender database on drugs in as many countries as possible. Marek Glezerman mentioned the importance of a bottom up approach with versions for patients and doctors needed. Claudine Junien underlined how important it would be to go public with such a database also in France, and Eva Prescott asked if it would be possible to connect also to FDA. Hildrun Sundseth mentioned that the database is important for legislation and should be rephrased for patients. Giuseppe Seghieri asked about new drugs in diabetes and if it is possible that these are less prescribed to women.