

EDITORIAL

Menopause and quality of life

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Menopause is a universal event in midlife, occurring around the age of 50 years in most developed countries [1]. World-wide, the life expectancy of women is increasing. In most countries women who reach the age of 50 will have another 30 or 40 more years of life [1]. Adult women will therefore be living almost as long after the menopause as they do before. Thus this population is of growing interest in a number of contexts including those of political influence and health.

Although menopause has been described as a period of crisis, this is now debatable. The perception of the menopausal transition in women is strongly influenced by socio-cultural and lifestyle factors [2, 3]. This phase often coincides with other changes in women's lives such as retirement of self or spouse and children leaving home. Thus, it may be a time of great opportunity and freedom, but also requiring, for some women, much adjustment to a different way of life.

Menopause can be associated with vasomotor symptoms such as hot flushes, and sweats [3], that can be intensive enough to lead to distress, insomnia and fatigue. The frequency of these symptoms is poorly documented, with estimates ranging from 0 to 80% [1]. In addition, epidemiological studies indicate that menopause is associated with an increased risk of medium and long term illnesses (atrophic urogenital disorders, osteoporotic fractures and coronary heart disease) [1]. Atrophic symptoms begin to increase in close time association with the menopause. The prevalence of severe urogenital diseases in women after the age of 60 in Europe is as high as 20–26% [4]. Osteoporosis is a major health problem in western countries and in Japan, with the majority of those affected being postmenopausal women. It is estimated that, after the age of 50, as many as 15% of women will suffer from osteoporotic fractures [5].

Furthermore this incidence may be increasing due to western lifestyles which tend to emphasize ease rather than physical activity. In almost all parts of the world cardiovascular diseases are one of the most common causes of death among both women and men [1]. Cardiovascular disease shows a well-documented gender difference with men having an earlier incidence of clinically significant atherosclerosis [6]. The prevalence of cardiovascular disease increases more dramatically in older postmenopausal women, potentially attributable to the decline in sex steroids [7].

Treatment of menopause-associated problems implies either treatment of vasomotor or atrophic symptoms or prevention of induced risk. The treatment of symptoms focuses almost exclusively on hormone replacement therapy (HRT). In the prevention of osteoporosis, several drugs are approved in addition to HRT, such as calcitonin, bisphosphonates and Selective Estrogen Receptor Modulators (SERMs). HRT is extremely effective in the treatment of menopausal symptoms. However, very low compliance has been reported with HRT [8–10], especially in the long term (in some studies, 60% of women discontinue treatment before 6 months while only 10% continue treatment after 1 year). Reasons for discontinuation include lack of motivation for preventive measures, side-effects (especially bleeding, breast swelling and tenderness), and fears of cancer (breast and endometrium). Noticeably, the compliance is better in women who have low bone mass (a risk factor of osteoporosis). The compliance to bisphosphonates is also impaired by the difficulty of administration, and currently available SERMs may increase menopausal symptoms. Noncompliance may be a well-reasoned decision indicative of prioritization of risk and symptoms and the balance between treatment costs and benefits, tangible and intangible.

All the therapies mentioned above may have different consequences on quality of life, however these have been only partially evaluated and more studies are warranted. Patient-centred outcomes are therefore important to measure, in order to be able to provide information on how different aspects of quality of life (QOL) are affected by the treatments proposed. This will allow improvement of therapeutic choice and, possibly, compliance. The impact of short term as well as long term consequences of menopause on quality of life has been poorly explored. This poses methodological challenges: it is difficult to disentangle the short term consequences of menopause from the concomitant associated factors, both positive and negative. Moreover, whether an associated factor, say, children leaving home is experienced as positive or negative is very much an individual and culture-bound perception. Long term consequences are of very disparate nature and it is difficult to evaluate their global impact or to attribute them directly to menopause.

Quality of life and subjective health define a subject's perception and assessment of multiple areas of health that can be affected by a medical treatment. To evaluate treatments and interventions, subjective health is typically assessed via a series of questions that focus on the subjective impact of a specific condition.

Quality of life instruments have become essential components of the clinical testing process for preventive compounds. QOL assessment has become a necessity for public health research and to evaluate new treatments. Therefore, a timely review of existing questionnaires and scales should be undertaken to determine those which address most appropriately the issues faced by some postmenopausal women and which are likely to demonstrate sensitivity to the woman's perception of change in health status and well-being as validated by surrogate and clinical markers of disease.

In order to address these issues, Alain Leplege (INSERM U292, Le Kremlin-Bicetre, France), Anne Marciniak (Pfizer Central Research, Sandwich, UK), and Mauro Niero (University of Venice, Venice, Italy) organised a workshop in Venice, Italy on 9–10 November, 1998 with the valuable assistance of a scientific committee chaired by Sonja Hunt (Department of General Practice, University of Edinburgh, Scotland, UK)

and including Francine Caulin (Rhone Poulenc Rorer, Paris, France), Thomas Kohlman (University of Lubeck, Lubeck, Germany) and Hanne Thorsen (University of Copenhagen, Copenhagen, Denmark).

The objectives of this workshop were:

- to analyse the characteristics, relevance, conditions of use and limitations of currently available measuring tools in the domains of Women's Health and Osteoporosis,
- to present data on the evaluation of perceived health status in postmenopausal women (whether treated or not) obtained through these instruments and with other evaluation strategies,
- to identify the specific circumstances and subgroups in which each instrument may be appropriate,
- to consider study design and methodology.

The developers of the main instruments in the areas were invited to present their instruments and the validation data and results available. Papers were given by: Paul Cleary (University of Boston, Boston, MA, USA: The Functional Status Questionnaire – FSQ), Lorraine Dennerstein (Department of Psychiatry, The University of Melbourne, Australia: Methodologic issues in menopause research), Edward Helmes (Edith Cowan University, School of Psychology, Western Australia: The Osteoporosis Functional Disability Questionnaire – OFDQ), John Hilditch (Sunnybrook Health Science Centre, University of Toronto, Canada: The Menopause-Specific Quality of Life Questionnaire – MENQOL), Sonja Hunt (Department of General Practice, University of Edinburgh, Scotland, UK: Conceptual and methodological issues associated with measurement of subjective health in post menopausal women), Myra Hunter (University of London, London, UK: The Women's Health Questionnaire), Jean Pierre Le Floch (Clinique diététique de Villecresnes, Villecresnes, France: The Qualifemme), Paul Lips (Academisch Ziekenhuis, Vrije Universiteit, Amsterdam, The Netherlands: The Quality of Life Questionnaire of the European Foundation For Osteoporosis – QUALEFFO), Patrick Marquis (Mapi Research Institute, Lyon, France: The QUALIOST), Betsy Love McClung (Providence Medical Centre, Portland, Oregon, USA: The Osteoporosis-Targeted Quality of Life Questionnaire – OPTQOL –

and the Osteoporosis Quality of Life Questionnaire – OQLQ), Norma McCoy (Department of Psychology, San Francisco State University, San Francisco, USA: The Sexual Behaviour Questionnaire), Virginie Ringa (Inserm Unit149, Villejuif, France: Epidemiology and public health), Stuart Silverman (The Osteoporosis Medical Centre, Beverly Hills, CA, USA: The Osteoporosis Assessment Questionnaire – OPAQ), Katie Stone (UCSF, San Francisco, CA, USA: The Functional Disability Scale – FDS), Anna Tosteson (Dartmouth Medical School, Hanover, New Hampshire, USA: Utility assessment of Women Health Concerns), and Ingela Wiklund (Astra Hässle AB, Mölndal, Sweden: Responsiveness to change and placebo effect: The experience of administering a battery of measures).

Other participants at the meeting, including industry partners who have developed compounds in this area, were invited to share their experience. These included: Jennie Best (Roche Pharma, Palo Alto, USA), Olivier Chassany (CPMP – Agence du médicament, France), Sylvaine Corcaud (Institut de recherche Servier, Neuilly, France), Alison Dawson (Eli Lilly – Lilly Research Center, Windlesham, UK), Olivier Ethgen (Service d'Epidemiologie et de Sante Publique, CHU SARTILMAN, LIEGE, Belgium), Bertrand Gelas (Theramex, Monaco), Larry Gorkin (Pfizer Pharmaceutical Group, New York), Muriel Haim-Nemerson (Merck, Whitehouse Station, USA), Anne Marie Limouzin-Lamothe (Cabinet Monceau, Paris, France), Carolin Miltenburger (Shering, Berlin, Germany), and Emmanuel Picavet (University of Paris I, Paris, France). The discussion focused on the ability of current quality of life questionnaires to address the complex patient perspective.

The papers presented in this issue of quality of life research were based on the original contributions to the Venice meeting, but because of the time frame, new material became available to update and complement the original contributions. Alain Leplège and Lorraine Dennerstein jointly edited the submitted manuscripts for this issue. The first section of this issue reviews menopause-associated health experiences and effectiveness of treatments, contextualises these health experiences for women and considers some of the methodologic issues. The remainder of the

issue focuses on specific questionnaires which measure different aspects of QOL relevant to the menopause. These include measures of mid-aged women's emotional and physical health, measures of sexuality, and questionnaires assessing functional status, disability and the specific impact of osteoporosis.

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