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Zopiclone: from clinical practice to quality of life
(satellite symposium Rhône-Poulenc Rorer)

1. Zopiclone, sleep and health-related quality of life

QUALITY OF LIFE MEASUREMENT IN THE MEDICAL SETTING

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Of the many publications on quality of life in the medical setting over the last two decades only a minor fraction has been devoted to the measurement of outcome in randomized clinical trials (RCTs). Most frequently such measurements have been performed in cancer disorders and in mild to moderate hypertension.

The components of quality of life measurements have been within the PCASEE model (physical, cognitive, affective, social, economic-social stressors, and ego or personality problems). Most variance has been in the cognitive and affective components.

Health-related quality of life measurement in the medical setting has extended the outcome evaluation in drug trials (RCTs) from the cost-effectiveness level (efficacy of drugs) into the cost-utility level (the patient's own efficiency assessment), therefore identifying the point (or points) at which treatment begins to do more good than harm.

QUALITY OF LIFE AND INSOMNIA

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Quality of life can be defined as the perception an individual has of his own life. Numerous factors may influence an individual's quality of life including health.
Quality of life studies analyse the relationship between health and quality of life and, by extension, the effect of treatment on the quality of life. The quality of life approach is a global one and has, therefore, to be multi-dimensional; generally 5 major dimensions can be identified: physical, intellectual, affective-emotional, well-being and social relations.
The field covered is very broad and may be defined as that of any pathology or therapeutic intervention likely to modify the quality of life of patients either as a result of the traumatisms generated or of their chronic nature and/or their repercussions in the medium or long term.
Why a quality of life study of insomnia?
Most work carried out to date in this area has attempted to interpret this highly subjective symptom through objective parameters.
The evaluation of quality of life requires use of an appropriate and reliable measurement instrument. From bibliographical research and interviews with experts it was possible to define those quality of life dimensions disturbed (or likely to be disturbed) by insomnia. The measurement instrument was developed from existing standard questionnaires (Psychological Well-Being Index, Sleep Evaluation Questionnaire, Leeds Sleep Evaluation Questionnaire), and from specific questions evaluating the repercussions of sleep on daytime activities, and of health on social and professional life.
As the study has to be multi-national, the quality of life instrument has been the subject of cross-cultural, linguistic validation in 5 languages (English, Danish, Finnish, French and Dutch). The translations were made on a translation/back-translation basis and each of the versions was tested with a panel of experts in each country.
The psychometric properties of the measurement instrument have been studied with 3 groups of patients. Its acceptability, internal reliability and reproducibility have been analysed on a population of insomniac patients having been treated effectively and the sensitivity of the instrument has been tested by a comparison of results obtained with untreated insomniac patients and with subjects not suffering from insomnia.
The quality of life measurement instrument has proved to be appropriate, reliable, with good internal coherence, replicable over time and sensitive.

ZOPICLONE, SLEEP AND HEALTH-RELATED QUALITY OF LIFE

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Four hundred and fifty-eight insomniac patients participated in a multinational, randomised, double blind, parallel groups study of zopiclone 7.5 mg versus placebo.
Patients received the drug or matched placebo nightly for 14 days and for a further six weeks on demand. Sleep characteristics and Quality of Life measures were assessed at 14, 28 and 56 days after admission. The assessments included the Sleep Evaluation Questionnaire and the Leeds Sleep Evaluation Questionnaire. Quality of Life was measured using a scale which assesses daily activities, social and professional life, and which has previously been shown to be valid and reliable.[1] Both groups of patients improved on the measures of sleep and Quality of Life, but the patients on the active treatment showed significantly greater improvement compared to placebo, both after 14 days and at the end of the trial. The rate of reported side effects was low, both after 14 days and at the end of the trial. The rate of reported side effects was low, and the number of dropouts due to adverse effects was similar in the zopiclone and placebo groups.[2] It is concluded that zopiclone is a well-tolerated and effective hypnotic agent which has beneficial effects upon Quality of Life of insomniacs.

[1]Rombaut, N.E.R. *et al.* (1990) The Quality of Life of Insomniacs Questionnaire (QOLI). *Medical Science Research,* **18,** 845-847.

[2]Goldenberg, F. *et al.* (1994) Zopiclone, sleep and health-related Quality of Life. *Human Psychopharmacology.* In press.

QUALITY OF LIFE OF SUBJECTS TREATED WITH ZOPICLONE AND OF GOOD SLEEPERS - Study comparing 296 patients and 528 controls.

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METHOD : From 20,000 households regularly surveyed by a national survey institute (SOFRES), two groups of subjects were selected : Group 1 = subjects using Zopiclone for the last 12 months (296 subjects), Group 2 = subjects not on any hypnotic treatment for 12 months (528 subjects).
The two groups were questioned about their sleep, vigilance and quality of life using a 23-item questionnaire. The questionnaire was returned by post to the survey company.
In the two groups, only those subjects not taking other treatments with known effects on vigilance were retained : 167 subjects in group 1 and 462 in group 2.
From group 2, 381 good natural sleepers were selected as having no sleeping troubles from the following list : difficulty in falling asleep, waking up during the night or too early.
The two groups were matched regarding sex and age and their replies to the questions on vigilance and quality of life compared using a "parametric test according to standardised normal distribution" (Laplace-Gauss).

RESULTS : Five aspects on the quality of life of the participants were studied by the questionnaire :
- Professional aspect : There was no significant difference found in the appreciation of the quality of working life between good sleepers who worked (230) and working Zopiclone users (75). 14% of Zopiclone users and 18% of good sleepers had difficulties carrying out their work. 93% of Zopiclone users and 97% of good sleepers were happy with their work.
- Sentimental and relational aspect : 91% of patients taking Zopiclone felt content with their sentimental life (57% very well and 34% reasonably well). They were statistically equal to the good sleepers group, who felt 94% content with their sentimental life (58% very well and 36% reasonably well). Also, 59% of patients treated by Zopiclone against 64% of good sleepers went out in the evening. However, treated patients were less likely to receive visitors than the control group (77% vs 83%, not statistically significant).
- Domestic aspect : the treated patients have a domestic activity comparable to that of good sleepers : 69% vs 67% do their housework normally, 88% vs 81% go shopping, 61% vs 62% do odd jobs around the home or do gardening.
- Leisure aspect : Although as many patients do walking or sports as good sleepers, 77% vs 72%, fewer watch television, 90% vs 95%.
- Safety aspect : Finally with regards to driving : 6% of Zopiclone users vs 14% of good sleepers have had problems of drowsiness while driving. 5% against 10% of control subjects have had near accidents due to sleepiness.

MEASURING THE UNMEASURABLE - THE ROLE AND IMPORTANCE OF QUALITY OF LIVE MEASUREMENTS IN ECONOMIC EVALUATIONS

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The increased efforts to contain health care cost and the battle to receive share of the health expenditure budget have stimulated a considerable growth in the number of economic evaluative works over the past two decades. In addition, economic evaluations are already needed in many countries for price negotiations of drugs (F, SF, S), for inclusion in drug positive lists and reimbursement guidelines (B, SF, I, NL, P, S, CH) and to convince health services managers (nearly all). As a bibliography on economic evaluation studies covering 1906 references shows, most of these studies have been done in the past in the US (54.9 %) and GB (19.9 %). In addition, most of the studies are cost-studies or cost effectiveness studies, and only 3 % are cost-utility studies focusing on the quality of life of the patients as a major outcome of therapy. However, quality of life will be the main target of current and future economic evaluations of new therapies. This has two reasons. First, only few new therapeutical regimes can show a significant increase in survival. Second, society is nowadays less interested in the measurement and improvement of medical outcome indicators but have an increasing interest in quality of life of the patients. Over the past few years economist and clinical experts have developed powerful incidence specific and general tools (EuroQoL, Rosser & Kind, SF36, Nottingham Profile) to measure the unmeasurable quality of life.

QUALITY OF LIFE AND MANAGEMENT OF SLEEP DISORDERS IN JAPAN

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Undisturbed sleep is a sign of good health and good "Quality of Life" (QOL)". "Good appetite, regular bowels and sound sleep" have been considered to be a triumvirate of good health in Japan, as "proper nutrition, physical fitness, and good sleep" in other countries. Besides the physical health and peaceful mind, good interpersonal relationship in family and society has been an important factor for the QOL in Japan. However, increase of psychosocial stressors and disruption of the biological clock due to irregular sleep-wake schedules have resulted in an increase of sleep disorders, particularly insomnia. The number of people suffering from insomnia is increasing also due to the increase in the elderly population. The quality of sleep tends to get poorer even in apparently healthy elderly due to physiological aging process. Sleep apnea syndrome is also one of the causes of insomnia in the elderly. Insomnia disrupts not only the lives of older persons, but also those of their families and caregivers. In order to manage insomnia, the first thing to do is to identify the cause of insomnia and eliminate the cause as far as possible. Correction of poor sleep hygiene and habits is of primary importance. The search for the ideal hypnotic drug continues for many years, and now we have many good benzodiazpine receptor agonists such as benzodiazepines, cyclopyrrolones (zopiclone), etc. for use as hypnotics. To achieve the dual goals of hypnotic therapy, i.e., improvement of both sleep and restoration of daytime functioning, a short-acting benzodiazepine receptor agonist such as zopiclone, which exerts less distortion of sleep architecture and no worsening of mild sleep apnea syndrome, is generally preferable. Some patients are under therapeutic dose of hypnotic medication for a long time without any side effects, because they need the hypnotic to get sleep necessary for their daytime functionings. It may be allowed, particularly in the elderly population, to use a small amount of hypnotics to get a good sleep and live a happy life from the standpoint of QOL.

AN OVERVIEW OF THE REPORT OF THE NATIONAL COMMISSION ON *SLEEP DISORDERS RESEARCH*

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Millions of Americans Are Affected By Sleep Disorders. Forty million Americans are chronically ill with various sleep disorders; an additional 20 to 30 million experience intermittent sleep-related problems. Sleep apnea alone is the cause of excessive daytime sleepiness experienced by almost 20 million Americans. Millions more are severely sleep deprived as the result of demanding work schedules and various other lifestyle factors. Overwhelming evidence from testimony and specific surveys suggest that the vast majority of Americans with sleep disorders remain undiagnosed and untreated.

The consequences of sleep disorders and sleep deprivation are diverse. Some sleep disorders are potentially fatal; others are little more than an annoyance. Some are lifelong, with additional complex deleterious effects on family members; other are brief and non-recurring. Some can be treated effectively; others require more research. Falling asleep inappropriately, for example, can blot out a few minutes of television, or it can cause catastrophic damage to life and property. Patients often are misunderstood, are thought to be lazy, and socially isolated from family and friends. In sum, the consequences of sleep disorders, sleep deprivation, and sleepiness are significant and include reduced productivity in both school and workplace, serious morbidity, increased mortality, and decreased quality of family and social life.

The medical and socioeconomic consequences of Sleep Disorders will be presented and discussed.

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