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Original articles

The need to consider quality of life as an outcome of antidepressant therapy

JENNY MORRIS, Research Fellow, Centre for Health Economics, University of York, York YO1 5DD

Depression is a very common disorder. It has been estimated that 20% of all women and 13% of all men will develop depression at some time during their lifetime, although much of the depression which exists in the community is unrecognised and untreated. Approximately 75% of the female population and over 50% of the male population attend their general practitioners at least once with a psychiatric complaint, of whom 70% of the women and 34% of the men have a depressive episode. While treatment for some patients will be successful following the acute phase of the depressive episode, it will generally take at least three months and in some instances six months or more to treat an episode. The risk of relapse following treatment is high, affecting approximately 50% of patients treated; furthermore, there is no evidence to suggest that those patients being treated for their first episode of depression are less vulnerable to relapse following response to treatment than those who have suffered previous episodes of depression.

It can be appreciated, therefore, that there are various costs associated with depression. These include direct costs such as the costs of antidepressants and the costs of treatment for adverse side effects and/or for the consequences of overdose, and indirect costs to society which can be measured in terms of days lost from work, sickness benefit etc.

The success of treatment is generally measured in terms of clinical efficacy during the acute illness with long term effectiveness being largely ignored. Measures of efficacy include observer rating scales for depression such as the Hamilton Rating Scale and the Montgomery Asberg Depression Rating Scale, as well as tests designed to measure psychomotor functioning and cognitive processing.

Given the knowledge about the nature of depression and how depressive episodes adversely effect quality of life, together with the known side effects associated with antidepressant treatment, it is surprising that there has been little investigation of the patients' *quality of life* both during and following treatment. While a reduction in the signs and symptoms of depression will result in an improvement in some aspects of the patient's quality of life (e.g. cognitive processing, psychomotor functioning), the side effects commonly reported with the use of the tricyclic antidepressants (e.g. dry mouth, sweating, tremor, restlessness, dizziness, cardiotoxicity with overdose) and the monoamine oxidase inhibitors (MAOI) may diminish the patient's quality of life in other respects such as physical functioning, the ability to undertake work and/or social activities and, with some irreversible MAOIs, the need to adapt dietary habits. Furthermore, as well as adding to what might be considered an impaired quality of life because of the depressive episode, such adverse effects may also influence the likelihood of compliance with treatment, and increase the risk of overdose.

The lack of quality of life data vis-à-vis treatment for depression is striking when compared with the documentation on patients who have been treated for chronic diseases such as heart disease, cancer and renal disease. Some of the cancer clinical trials are of particular relevance, especially those which compare the toxicity of chemotherapy regimes, a form of treatment which both impinges upon quality of life and may influence compliance rates.

The few quality of life studies which have been undertaken in the psychiatric domain have focused on the severely mentally ill which has necessitated the use of structured or semi-structured interviews to collect the data, and the quality of life of the chronically mentally ill in the community.

The first major study to investigate the effect of a pharmaceutical product upon quality of life was that undertaken by Croog *et al* (1986) on antihypertensive therapy. However, the large number of instruments used in this study, together with the need for trained interviewers, limits the extent to which this study can serve as a useful model for incorporating quality of life assessments in clinical trials in psychiatry. A further study examined the impact of anxiolytic drugs on quality of life but focused largely on cognitive and psychomotor function with no information provided about life satisfaction, nor the ability to undertake usual activities.

However, it is not just within the context of clinical trials that quality of life is of relevance as an indicator of outcome. Following the implementation of the White Paper *Working for Patients* on 1 April 1991, all health care professionals will need to be versed in measures of outcome which provide more patient centred information than that currently provided by traditional measures such as morbidity and mortality. This will aid quality assurance, audit and, together with economic evaluations, help determine the most cost-effective treatment.

Given the lack of available literature upon which to design quality of life studies in this area, it is likely that studies published in the near future will become the standard. Thus there is a need to ensure that the following issues are addressed in order that the studies viewed as 'standard' are adequate models upon which to base future research: the homogeneity of the population being studied and the suitability of comparison groups; the appropriateness of the data collection method; and the reliability, validity and discriminant ability of the instruments used.

The choice of a suitable test instrument is crucial both to the success of a research project, and also to the likelihood of quality of life measures being used in clinical practice. Current measures of quality of life include generic instruments such as the Quality of Well Being Scale (QWB, Kaplan & Bush, 1982), the Nottingham Health Profile (NHP, Hunt *et al*, 1980), and the Sickness Impact Profile (SIP, Bergner *et al*, 1981), and those designed for use with specific physical diseases such as cancer, arthritis and cardiovascular diseases. Generic instruments have a useful part to play in quality of life studies if comparisons need to be made between different diseases, or if cost-utility analyses (e.g. where health outcomes are measured in quality adjusted life years) need to be undertaken. However, one of the limitations of these instruments is that the items or response categories may not be sufficiently sensitive to detect the changes in quality of life functioning in patients with specific diseases. Furthermore, the NHP only examines negative aspects of health which makes it impossible to obtain an accurate assessment of patient well-being; the length of the SIP 136 items) makes it less acceptable in studies which require assessments to be made over time; and the QWB is a complex instrument requiring the use of trained interviewers. McDowell & Newell (1987) cite the social adjustment scale as being designed as an outcome measure to evaluate drug treatment and psychotherapy for depressed patients. However, this instrument focuses entirely upon interpersonal relationships which precludes its suitability as a quality of life instrument as it ignores key domains such as physical functioning which can be impaired both as a result of the depressive illness and as a consequence of the side effects of the antidepressants.

Thus there is a need to either modify existing instruments or develop a new instrument which contains concepts of quality of life appropriate for the assessment of patients being treated with antidepressants. While the Hospital Anxiety and Depression Scale is widely used for measuring levels of anxiety and depression and could be used as a proxy measure for psychological functioning in some patient groups, this would need to be supplemented by a more detailed questionnaire to measure quality of life in the domains which are relevant to patients being treated with antidepressants. Areas which should be considered include physical functioning, cognitive functioning, social and physical activities, and family relationships. Cognitive functioning is probably the domain least well covered in existing quality of life instruments, although this is probably more central to the effects of depression upon quality of life rather than the side effects of treatment.

In conclusion, as well as providing a more patient centred measure of outcome, quality of life data can also add significant weight to the traditionally reported safety and efficacy data by: providing regulatory and prescribing bodies with the information necessary to differentiate products which are similar in terms of clinical efficacy and safety; informing clinicians about the subjective benefits which patients may derive from treatment; and assisting pharmaceutical companies in the pricing and marketing of products by including quality of life data as an outcome in cost-effectiveness analyses, and thereby providing clinicians with information on the cost-effectiveness of different drugs.

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