

It's The Dimples That Give The Ball Stability

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Section 1

Introduction

At the beginning of 1992, Boots Pharmaceuticals were preparing for the worldwide launch of Manoplax, a new therapy for the treatment of congestive heart failure. It was apparent from the extensive international pre-launch market research programme we had conducted that, although significant advances have been brought about by ACE inhibitors in the management of this condition, many patients remain symptomatic, despite multiple therapy. However, it was also evident from our data that only a small proportion of these patients currently receive any additional therapy as a result. Our hypothesis for this apparent anomaly, based on previous research findings, was that :-

- ◆ firstly physicians are not fully aware of the extent to which patients are affected by their condition.
- ◆ secondly, doctors are reluctant to actively identify patients who remain symptomatic on conventional therapy, as they believe there is, currently, little more that can be done to improve their situation.
- ◆ and finally, there is genuine lack of viable therapeutic options available in these circumstances.

Therefore, we decided to try to substantiate these hypotheses with a view to :-

- ◆ raising physician's awareness that there is a need to do more to improve the symptoms and quality of life of CHF patients.
- ◆ encouraging them to assess their patients more critically, possibly through the development of an instrument which could be used, for example, in a clinical trial setting.

In order to achieve these objectives it was necessary to conduct an in-depth investigation of CHF from the patient's own perspective to gain a fuller understanding of the physical and psychological consequences of the condition. However, evaluating the patient's viewpoint in isolation, does not give a true picture of the degree to which their lifestyle is affected. To a certain extent, CHF patients adapt the scale and nature of their activities in order to minimise the impact of the condition on their daily routine. As a result, they may not be actively aware of any improvement or deterioration which takes place over time as the changes they make in their behaviour tend to occur gradually.

Therefore, it was appropriate to widen the scope of the study to include :-

- ◆ the patient's spouse, as a more objective observer of the patient's condition
- ◆ and the patient's doctor, to provide an assessment of the patient from a clinical perspective.

This multi-faceted approach would, thus, enable us to:-

- ◆ gain a more accurate view of the patient's quality of life
- ◆ compare and contrast any differences within the patient/doctor and the patient/spouse perspectives

Due to inter-country variations in physicians' approach to the treatment of CHF, and the differences in the terminology used to describe the condition, it was apparent that the study would need to be conducted on an international scale. France, Italy, Germany and the UK and USA were selected for inclusion.

Methodology

Quality of life studies have been published which show a marked deterioration in the physical and emotional well being of heart failure patients compared to healthy subjects, and also to those with other chronic conditions such as arthritis and angina. We wished to explore beyond this and investigate the nature of the deterioration in heart failure patients' health status in more detail.

We therefore decided to include an established quality of life instrument that had been validated in international use, was suitable for between-group comparisons, and had also been used in chronic conditions including heart failure.

After reviewing a number of quality of life instruments, the SF-20 questionnaire from the Medical Outcome Study(1^{*}) with 2 additional items, also from the MOS, was selected.

This self completion questionnaire, which we call SF-20+2, was followed by a subsequent interview which included both supervised self-completion questions and more probing questions asked by an experienced market research interviewer. In this way, we had the benefits of a general health assessment instrument, allowing us to compare our scores with those of other chronic patient groups, together with detailed information specific to heart failure itself.

Patients who qualified for interview were recruited through specialists with office or out-patient practice - GPs were not included in the study.

Patient, spouse and doctor were interviewed separately and confidentially. All were asked questions which were identical apart from necessary changes in tense and gender, and the doctor questionnaire was modified for self-completion throughout.

After the SF20+2 questionnaire had been completed, the subsequent interview then covered the following seven broad areas,

- ◆ impact of heart failure on daily life,
- ◆ physical symptoms of heart failure,
- ◆ other associated physical problems,
- ◆ emotional impact of heart failure,
- ◆ financial impact of heart failure,
- ◆ expectations from/satisfaction with therapy,
- ◆ the patient/doctor interaction.

¹ Stewart AL, Hays RD, Ware JE Jr. The MOS Short-form General Health Survey,

Medical Care 1988; 26 (7) : 724-735

Patient and spouse were interviewed separately, usually in their own homes and each interview typically occupied up to 45 minutes.

Our study was designed to be pilot scale and therefore the tests for statistical significance that would be applied to a larger clinical study were not applied to the data gathered on this occasion.

The scope of the study was 175 heart failure patients from 86 doctors together with 87 spouses across five countries - France, Germany, Italy, UK and the USA. A sample of 50 patients suffering from hypertension, without heart failure or angina, were also included in the USA for comparison purposes.

To be eligible for inclusion, the heart failure patients had to be aged between 55 and 75, have confirmed left ventricular dysfunction and be being treated for the symptoms of heart failure.

Patients with severe heart failure were excluded. We did not include patients whose cardiovascular condition or therapy had changed recently and we also excluded those whose situation or concomitant illness could be expected in themselves to have an impact on the dimensions we were measuring.

PATIENT EXCLUSION CRITERIA

- ◆ "severe" CHF (NYHA IV) or housebound/hospitalised
- ◆ CHF diagnosed within the last six months
- ◆ MI within the last three months
- ◆ currently involved in any clinical trials for cardiovascular therapy.
- ◆ a new drug added for CHF at last consultation (a dosage change, however, is acceptable)
- ◆ any severe concomitant physical condition which may affect mobility (eg. advanced arthritis, arrhythmia, angina which is not controlled by the use of short-acting nitrate)
- ◆ any significant experience during the last year which could affect emotional state (eg. death of a spouse or close relative, divorce, etc.)

Analysis of the sf20 + 2 questionnaire

The SF20+2 questionnaire contains 22 scales which patients (or spouse or doctor) completed. In the analysis method developed within the MOS, these scales are grouped into six health dimensions. Each dimension is made up of between 1 and 6 of the scales.

The analysis programme assigns values or scores to the individual scale items and then aggregates them to produce a score for each health dimension. These scores range from 0 to 100, with higher scores indicating better health.

Due to time constraints, our paper today will include data from four of these six health dimensions.

- ◆ physical functioning
- ◆ social functioning
- ◆ mental health
- ◆ vitality

The scores for any given health dimension resulting from the doctor (or spouse) interviews can then be compared to the corresponding scores from the patient interviews. Pairs of results - eg. doctor and patient scores for each individual patient - can be plotted on a graph of the type shown overleaf.

The broken line shows the line of perfect agreement between doctor and patient. Any points in the lower right hand area indicate doctors scoring a patient's health, or quality of life, on the health dimension in question to be lower than the patient does him or herself.

Points in the upper left hand area indicate patients who score themselves low on the health dimension but whose doctors are assessing them to have a higher score - in other words, here the doctor is overestimating health status relative to the patient and presumably underestimating, again relative to the patient, the impact of heart failure on the patient's quality of life.

Summary of main results

The chart below shows the results for one health dimension in SF20+2 - physical functioning - and for all countries combined. The two lines are the regression lines through the points on the chart for patient/spouse and patient/doctor scores respectively.

Patient and spouse scores show a much closer level of agreement than patient and doctor scores.

This tendency towards closer agreement between patient and spouse scores than between patient and doctor scores is evident in all 5 countries, although the proximity of the regression lines to the line of perfect agreement does vary among countries. Overall, patient-physician agreement is closest in France and Italy and lowest in the USA.

The 3 remaining health dimensions included in our analysis of the SF20+2 questionnaire are:

- ◆ mental health
- ◆ social functioning and,
- ◆ vitality.

Again, we observed an overall closer agreement between patient and spouse scores than between patient and doctor scores although there is a tendency towards doctors overstating a poor score, relative to the patient, to a greater degree than the understating of a high patient score.

In other words, the differences between patient and doctor scores are greatest for patients whose quality of life, in their estimation, is most affected by their heart condition.

During the interview and after completing the SF20+2 questionnaire, both patients and spouses were questioned about the emotional impact of heart failure. As a group, spouses tend to rate the emotional impact of heart failure to be more severe than the patient does, mentioning that patients in particular become increasingly bad tempered, depressed, unsociable and worried about side-effects. Patients told us that this is not an area they discuss with their doctors, typically as they feel it is wasting the doctor's time or is something which the doctor cannot help with.

The interview also included some structured questions using rating scales. For example, patients were asked for each of 19 physical activities

- ◆ whether it is important for them to be able to do the activity, and, if so
- ◆ the extent that their heart failure has limited this activity over the last 3 months.

Over all countries, the activities (of the 19 listed) that were important to the most patients were sleeping, bathing/washing, dressing, walking, eating, getting in and out of a car, bending down, shopping and walking up stairs.

Each doctor/patient pairing was allocated to one of three categories.

- ◆ doctor and patient agree
- ◆ doctor rates the effect of heart failure on the activity to be greater than the patient does
- ◆ doctor rates the effect or impact of heart failure to be less than the patient does.

In a majority of cases, doctors and patient agree but, across the five countries, where they do not, the majority situation is for the doctor to rate heart failure as less limiting.

One of the areas where patients and doctors did not agree at all well is the rating of the severity of five main symptoms of heart failure that were included in the interview questionnaire. These five symptoms are:

- ◆ breathlessness on exertion
- ◆ lack of energy
- ◆ chest pains
- ◆ swollen ankles
- ◆ breathlessness at rest.

Again, every patient did not report all five symptoms, and only in those circumstances where a symptom was mentioned by a patient was that patient/doctor pairing included in the analysis.

Some explanations for this high level of non-agreement between doctor and patient emerge from comments made by the patients during the interview.

Around 3 out of 4 patients (or even a little higher proportion) said they can cope with their heart condition. It rules their lives but they manage the condition and accept the limitations their heart failure imposes on them.

With this limiting adjustment to their lifestyle patients consequently avoid such symptoms as breathlessness and chest pain.

Our conclusions, therefore, are that:

- ◆ patients change their frame of reference in order to feel that they are coping
- ◆ doctors and some spouses use the healthy person as their frame of reference or comparator
- ◆ patients consequently understate the severity of their heart failure symptoms.

The final set of evaluations or assessments made by the patients, doctors and spouses was the severity of what we have called "associated problems". These include other symptoms that may be attributable to the heart failure itself or to side-effects of drug therapy. A total of seventeen were included. Here we observed a very marked tendency for the doctor to rate the severity lower than the patient does him or herself. Patients seem to believe that their doctors are not able to help in these areas and that these are symptoms that they have to put up with. Other patients just do not want to cause additional work for their doctors and, like most of the physicians, all but a few patients expressed satisfaction with the benefit they - the patient that is - obtain from their drug therapy.

However, patients' expectations appear to be low and satisfaction is always conditioned by (or expressed relative to) expectations which, for patients with heart failure, are actually quite low.

Summary

Our findings from the study may be summarised as follows:

There are differences between patients, doctor and spouse perspectives on the impact of heart failure.

The extent of these disparities between patient/doctor and patients/spouse assessments vary among countries but generally the spouse is in closer agreement with the patient.

Patients, adjust their lifestyle to minimise or avoid exacerbating the symptoms of breathlessness, lack of energy and chest pain and have low expectations of drug therapy. In fact, when asked whether they could cope with their heart condition or if they felt that it ruled their lives, most patients answered both!

Patients tend not to report other symptoms or emotional feelings to their doctor (unless prompted to by the doctor) and doctors frequently estimate the incidence and severity of these to be far lower than the patient does.

This all means that focusing on the "classical" symptoms may hide the real impact of heart failure on the patients' physical and emotional well-being.

Conclusions

It is clear from these findings that Quality of Life can be measured on an international basis, not only over time, but that relative differences between individual patients can also be assessed at any given point.

By using marketing research techniques, a more accurate, detailed and also individual view of the patient's well-being can be obtained than would normally be apparent from clinical trial evaluations, or in the course of routine practice.

These results were presented at the "Controversies in Heart Failure Management" conference, in London, in April of this year, to an international Opinion Leader audience and will be subsequently published. As well as provoking a lively audience discussion, there was clear recognition from the expert panel that :-

- ◆ despite optimum use of existing therapies, a considerable number of patients remain significantly debilitated by their condition
- ◆ quality of life, or well-being, is not merely a function of the physical status or symptoms which are routinely measured in a clinical trial or using standard tests
- ◆ the true impact of CHF is not fully appreciated, as physicians themselves also adjust their expectations of what they can realistically achieve for their patients
- ◆ earlier intervention with existing treatments, or new therapies could offer significant patient benefits.

However, while there was a recognised need to do more to identify and comprehend the symptomatic patient, in reality it is difficult to find extra time to do so in a busy clinical practice. Therefore, we are presently investigating a number of practical applications resulting from this study which could be adapted to the specific national requirements we have already identified.

In this way, in addition to the obvious use of the data provided by this study in the development of promotional materials in a number of countries, the company has effectively employed marketing research to :-

- ◆ enhance the reputation of Boots as a new player in the cardiovascular arena
- ◆ raise physicians' awareness of the needs of the symptomatic patient
- ◆ potentially, provide a simple means of assessing patient well-being more accurately and, thereby,
- ◆ giving doctors an added opportunity to evaluate the potential benefits of intervention with a new treatment such as Manoplax

Roger Brice

Roger Brice will be celebrating 25 years in pharmaceutical marketing and marketing research later this year. He joined the UK market research department of Merck Sharp and Dohme as a statistician and enjoyed a number of positions in the UK subsidiary, including Marketing Research Manager and Group Product Manager, before moving to the international headquarters of Merck & Co. in the USA. Positions held there include Director of Marketing for Vaccines and Ophthalmics, Director of Health Economics and Director of Marketing and Sales Research. For the last five years he has been a supplier rather than a buyer of marketing research and is currently Research Director at the UK offices of Adelphi International Research.

Anne Marshall

Anne Marshall has worked in marketing research for the last 5 years. With a background in languages and business, she joined Boots Pharmaceuticals to specialise in international marketing research for new products in development. Anne is currently International Planning and Research Manager for the cardiovascular therapy area.

Bernard Jambon

Bernard Jambon founded MAPI 19 years ago, since when the company has established a reputation for providing specialised market research services for the pharmaceutical industry. About 6 years ago MAPI became involved in quality of life studies, at which time Bernard formed a new division within MAPI to carry out such studies worldwide. Bernard is known internationally as an expert in quality of life investigations having now conducted many studies varying in scope from one up to fifteen countries. He is a regular speaker at health economics and quality of life congresses, publishes regularly on these subjects – including the quarterly Quality of Life Newsletter with a circulation of 6,000 worldwide – and is now also involved in the International Society for Quality of Life.

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