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Use of Sf-36 Questionnaire in Evaluating the Quality Of Life of Hepatitis C Patients on Antiviral Therapy - Pilot Study

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Abstract

This article presents some relevant data derived from a pilot study aimed primarily at investigating the quality of life of hepatitis C patients by the use of the standardized SF-36 questionnaire. HCV infection is an asymptomatic disease, studies demonstrating its significant impact on patients' quality of life. At the same time, antiviral therapy may precipitate or exacerbate extrahepatic manifestations in patients with hepatitis C. Piloting the SF-36 questionnaire and re/formulation of some hypotheses based on preliminary data. Considerations on a series of 30 patients about to start antiviral therapy investigated using the standardized SF-36 quality of life questionnaire. Although the results are preliminary, they seem to confirm the hypothesis that the disease and its treatment have a major impact on patients' quality of life, exceeding in frequency and magnitude the initial predictions particularly in the mental and social domains, in terms of role and function, and also of the risk for depression. The manual and accompanying software have facilitated data processing and interpretation. Methodologically, the questionnaire proved easy to administer and accepted by subjects. The questionnaire scales, physical functioning, mental health and social functioning, fully covered all areas the disease has a major impact on. The results of the pilot study point out that in the following study phases more clear evidence on the relationship between physical and mental domains of quality of life in hepatitis C patients is needed.

Keywords: hepatitis C; treatment; pilot study, SF-36; questionnaire, quality of life.

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Introduction

Numerous international studies indicate that hepatitis C is a major health problem and emphasize the importance of early antiviral therapy. Because current therapy offers patients a chance to heal, but encumbered by adverse effects, some hard to overcome, the impact of therapy on quality of life must be discussed with the patient both at the start of therapy, as well as during it. Clinicians believe that in patients with hepatitis C the greatest difficulty is to maintain optimal therapeutic dose throughout treatment, as pegylated interferon and ribavirin have notable side effects that can drastically reduce quality of life during treatment. Low adherence to treatment results in a lower virological response rate (Franciscus & Porter, 2012). It is one of the reasons why the authors of this paper believe that in monitoring hepatitis C patients use qualitative methods for capturing a complete patient perspective are required. All studies measuring the impact of treatment with interferon alone or in combination with ribavirin showed that there is a decline in quality of life during treatment and a return to baseline levels after therapy. Currently, treatment can have positive effects on quality of life, and consequently post-treatment evaluation in terms of cost-effectiveness is useful. Patients with adequate antiviral response to interferon alfa-2b in combination with ribavirin report a better quality of life, a significant improvement in work capacity and productivity (Kaplan *et al*., 1982).

The main objective of this study was to pilot one of the main tools, the standardized SF-36 quality of life questionnaire, in view of making some critical considerations on it. One of the practical goals of the above mentioned paper is to facilitate the introduction of qualitative methods in the management of patients with hepatitis C, especially during treatment. SF-36 questionnaire is a registered trademark of the Medical Outcome Trust, USA, and was licensed free of charge for use in this paper exclusively for scientific purposes. The most common side effects of treatment with impact on quality of life are flu-like symptoms, fatigue, anxiety, depression, insomnia, irritability, lack of libido, decreased concentration, anemia, itching, muscle pain, fever, and anemia. In addition to the inherent discomfort caused by the disease and social problems the patient experiences, , difficulties in fulfilling social, professional, family obligations, up to temporary or permanent work incapacity (Cojocaru & Popa, 2013).

From a legal and ethical standpoint (Gavrilovici & Oprea, 2013), it is important to note that before the initiation of antiviral therapy the patient gives a written consent certifying that he/she has been informed about the side effects that may occur during treatment. At the same time, patients who do not respond to interferon and ribavirin therapy do not also show any improvement in their quality of life (Groessl *et al*., 2008). Given the complexity of quality of life issues in patients with hepatitis C, particularly during treatment, a tool able to highlight the qualitative aspects in as many physical and mental domains as possible was preferred. The major difficulty was choosing between specific quality of life questionnaires, extremely useful in clinical practice, questionnaires in which all included items are relevant to the disease under investigation, and generic questionnaires that allow comparisons with other diseases, but that should be, at the same time, adequate to hepatitis C problems.

A generic questionnaire is distinct from specific measurements and represents a category of health measurement tools the validity and reliability of which are achieved in populations with different characteristics (Häuser *et al*., 2004). In the construction of SF-36 quality of life questionnaire basic was the definition according to which quality of life an exhaustive assessment is made by a person on all aspects of his/her life· (Saris-Baglama *et al*., 2011). The definition is extremely comprehensive, and the resulting questionnaire is broad in content and synthetic in form.

One of the secondary objectives of the study, namely to facilitate the use of the results in health policies and population-based hepatitis C programs, required a standardized quality of life questionnaire which to enable multiple comparisons not only over time, but also with other diseases. Given the novelty of using a qualitative tool in hepatitis C in Romania, we chose SF-36 as it is the most used quality of life questionnaire worldwide, this fact allowing, by means of meta-analysis, the comparison of the results of this study with those obtained by clinicians and researchers with a longer history in the use of such tools in patient monitoring. As mentioned by a number of international studies, SF-36 proved to be valid and reliable both in primary care studies, as well as in studies on patients with chronic diseases, hepatitis C included (Thein *et al*., 2005, Häuser *et al*., 2004). SF-36 is a health status measure consisting of 36 questions. The 36 questions measure eight domains: physical functioning (PF), role limitations due to physical health (RP), bodily pain (BP), general health perceptions (GH), vitality (VT), social functioning (SF), role limitations due to emotional problems (RE), and general mental health (MH).

For each of the 8 domains the item scores were transformed into a scale from 0 (worst possible health status) to 100 (best possible health status).

The questionnaire allows the additional calculation of two subscores assessing physical and mental health summary scores (Physical Component Summary, PCS, and Mental Component Summary, MCS) (Saris-Baglama 2011).

Methodology

Type of study: longitudinal, predominantly prospective.

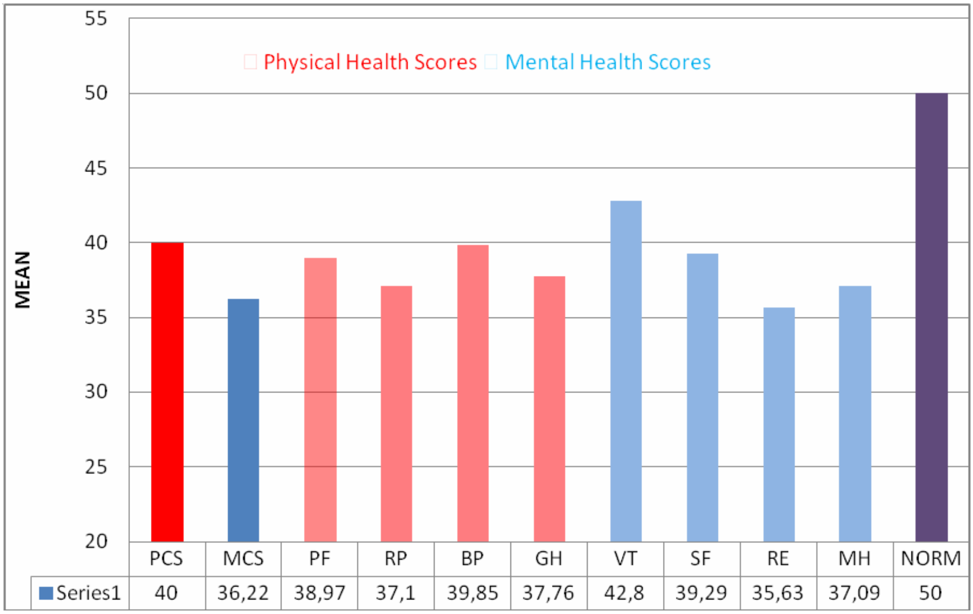
Study group: 30 treatment-naive patients (never treated before with antiviral therapy) – initiating antiviral therapy.

Case: Patient diagnosed with hepatitis C according to standard clinical and laboratory criteria: presence of HCV antibodies, detectable viremia, hepatic cytolysis syndrome, initiating the treatment, moderate liver fibrosis and necroinflammatory score present or absent. Data collected at treatment initiation would be used as the main database for comparisons with respect to patient course throughout monitoring.

Tools: SF-36 consists of the following scales that measure both the physical and mental domains of patients, plus two summary scores: PCS - physical component summary, MCS- mental component summary, PF- physical functioning (ability to perform such physical activities as self-care, walking and hard physical activities), PF- role-physical (the extent to which physical health of a person limits him in performing usual activities (child care, professional activities), BP- bodily pains (intensity, duration and frequency of bodily pains and the extent to which they limits them in usual activities), GH- general health(what a persons thinks about his own health, rating of current health status overall), VT- vitality (available energy as felt by the subject, absence of fatigue), SF - social functioning(the extent to which a person is able to develop and maintain social relationships: family, friends, etc), RE- role emotional (the extent to which emotional problems of a person limit him in usual activities such as child caring, professional activities, etc.), MH- mental health (emotional, cognitive and intellectual state of a person). Population norm used to compare individual or group scores. Population norm is actually a limit of statistical normality (Ware, 2001). For all scales, population norm is 50. There are also population norms by sex and age groups. Low scores signal a state of poor health.

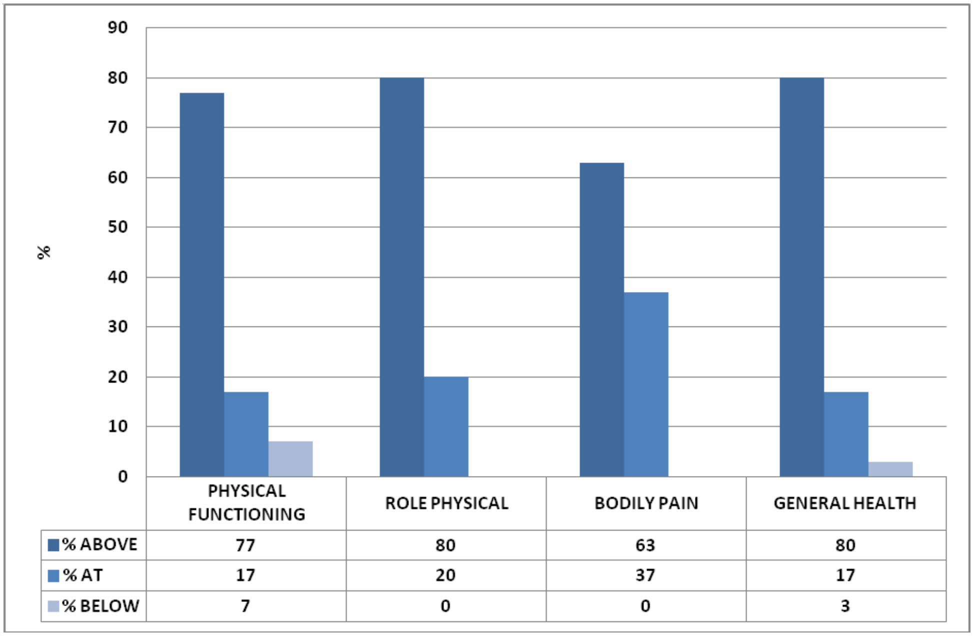
Results and conclusions

The additional software offered by the authors of this questionnaire allows a first report on pilot study data, so that the users to become familiar with what this tool facilitates. This report allows (Thein *et al*., 2005): (1) Comparisons for the entire group; (2) scores by age groups; (3) scores by sex; (4) data table. The number of subjects in the pilot study being relatively small, we will present preliminary data only on the entire group and by sex. As shown in *Graph 1*, the mean scores on all scales for the whole group were below the population norm, proving that the investigated hepatitis C patients had a poorer health status for both components, physical and mental, compared with the general population.



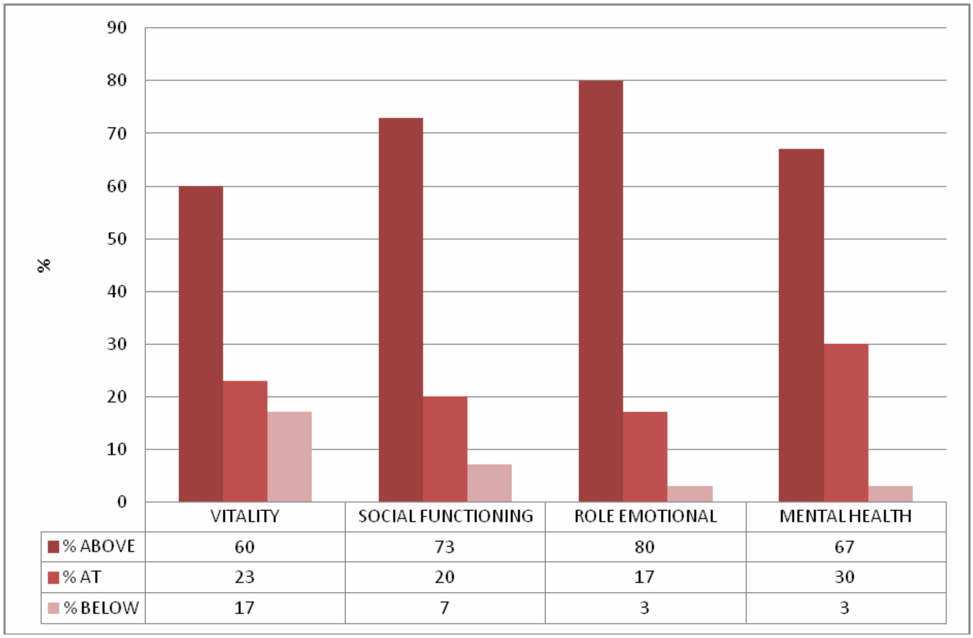
Graph 1. SF-36 Scale: Scores for total lot

The lowest mean score for the whole group was recorded on the RE scale (35.63) and the highest average score on the VT scale (42.8), but without reaching the normal levels in the general population. The low scores on role emotional (RE) scale show the extent to which emotional problems of a person limit him/her in usual activities, e.g. childcare professional activities, etc. (Ware *et al*., 2001). If vitality is defined by the authors as the available energy felt by the subject, absence of fatigue (Ware *et al*., 2001), we can conclude that a low score indicates the presence of fatigue and low energy. The report obtained using the software gives aggregate data for each scale and the percentage of patients below, within, or above population norm. The graphs below were constructed based on these data. The *Graph 2* presents physical component scale scores above, at, below the general population norm.



	PHYSICAL FUNCTIONING	ROLE PHYSICAL	BODILY PAIN	GENERAL HEALTH
■ % ABOVE	77	80	63	80
■ % AT	17	20	37	17
■ % BELOW	7	0	0	3

Graph 2. *Physical component scale scores above, at, below the general population norm*



	VITALITY	SOCIAL FUNCTIONING	ROLE EMOTIONAL	MENTAL HEALTH
■ % ABOVE	60	73	80	67
■ % AT	23	20	17	30
■ % BELOW	17	7	3	3

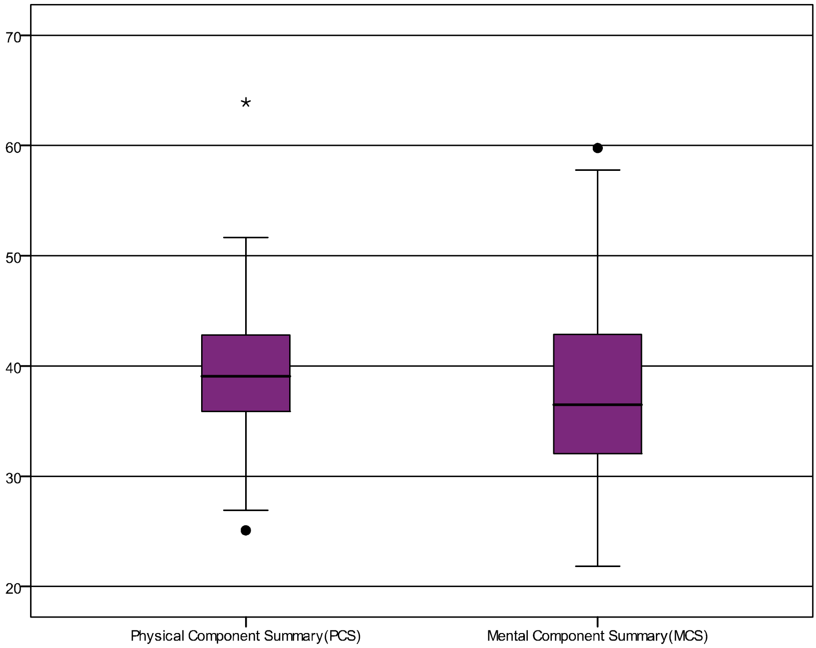
Graph 3. *Mental component scale scores above, at, below the general population norm*

As to the scores on the main physical health summary scales, a large percentage of the subjects were below the population norm on all scales. The highest percentage of subjects below normal limits in general population was found on scales Role Physical (RP 80%) and General Health (GH 80%). For the PCS component, a low score reveals major limitations in self-care, physical, social, and role activities, severe bodily pains, frequent states of fatigue, and poor health status (Ware *et al*., 2001).

From conversations with patients, we concluded that the self-rating of general health (GH) as poor is also due to the associated amorphous symptoms, depression, or flue-like symptoms, etc. The *Graph 3* put in evidence the mental component scale scores above, at, below the general population norm.

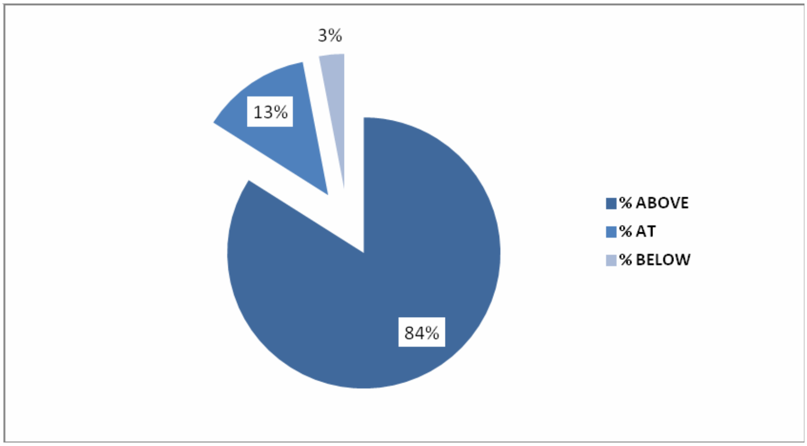
The analysis of the data in graph 3 on the mental health summary scales showed that a high percentage of the subjects presented role limitations due to emotional problems (RE 80%). Although below the percentages recorded on physical health summary scales, the percentage of patients below the normal limits in general population on mental health summary scales was still very high.

The *Graph 4* compares the physical and mental component scores distribution on total lot.

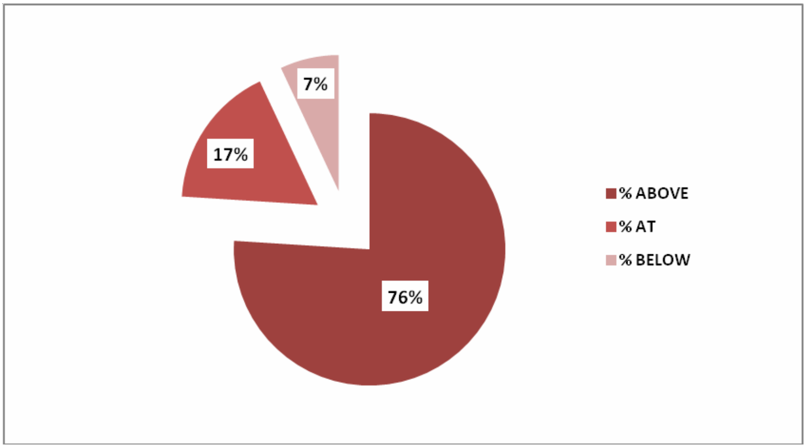


Graph 4. *Physical and mental component scores distribution-total lot*

The *Graph 4* shows the wide range of mental component scores (MCS) distribution (37.93) in the whole group, lowest score 21.84 and highest score 59.77, and the range of physical component subscale (PCS) scores (38.82), lowest score 25.09 and highest score 63.91. Apparently wider, the range of PCS subscale scores is due to an extreme case, the scores being in reality grouped around the average (39.99) with values relatively equal to those of the median (39.68) and trimmed mean (39.06). The left-shift distribution of MCS scores mean (38.22), median (36.48) and trimmed mean (37.93) in our subjects proved that low scores are most common. There is no significant differences between physical and mental component scores distribution on total lot (Paired Sample Test, t=0.826, df 29, p=0.416). The percentage of physical and mental component summary scores above, at, below the general population norm are presented in *Graph 5* and *Graph 6*.



Graph 5. *Physical component summary scores above, at, below the general population norm*

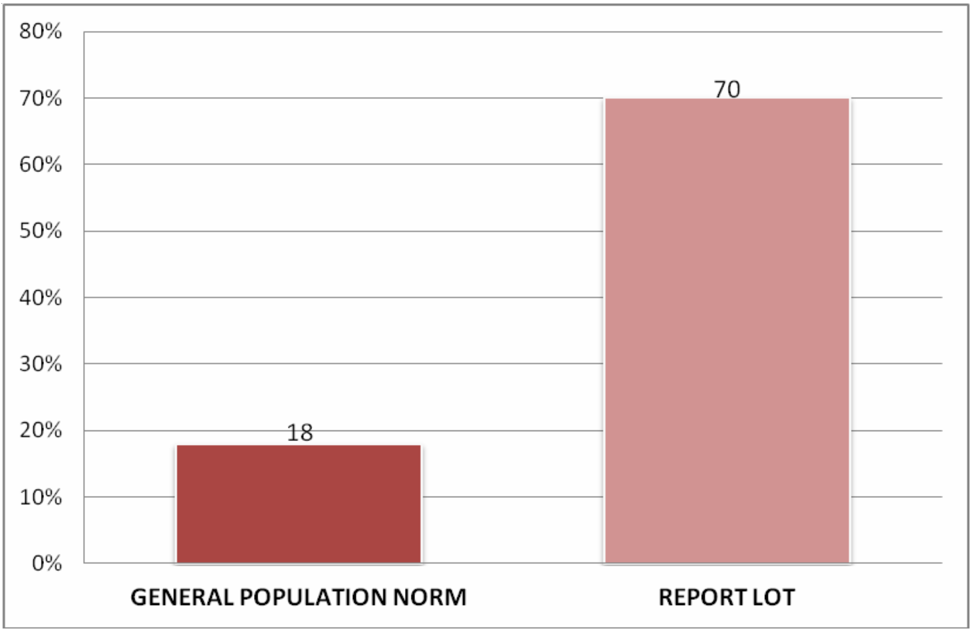


Graph 6. *Mental component summary scores above, at, below the general population norm*

As shown in *Graphs 5* and *6*, for both components, physical and mental, the frequency of subjects with scores lower than the norm was very high (77% and 84%, respectively, with a higher frequency for the physical component). An important finding that needs to be checked in the final phase of the study is that Pearson test reveals no significant correlations between PCS and MCS either in the whole group, or by sexes. At this time we have no scientific explanation for this inconsistency between these two components. It remains to be seen whether in the final analysis, on much larger subject groups, the relationship between PCS and MCS remains unchanged. On scales, the highest correlation between a physical health summary scale and a mental health summary scale is that between Role physical and Role emotional (Pearson correlation $r = 0.653$, $p < 0.001$).

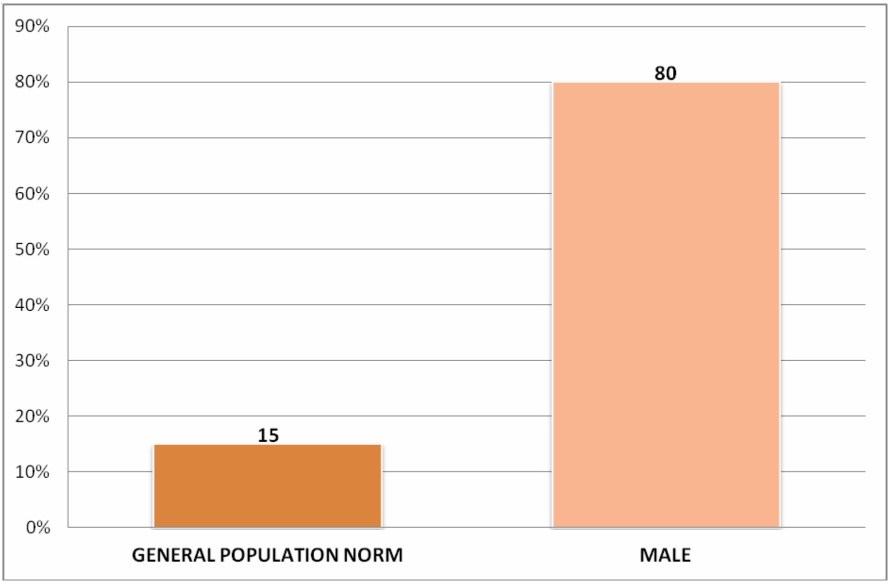
Some of the most important information provided by the analysis of SF-36 questionnaire data is those on the risk for depression. In patients who had depression prior to hepatitis C or initiation of treatment, episodes of anger and irritability occur once interferon is administered (Brooks *et al*., 2011). The questionnaire is designed to be a first-stage screen of depression in terms of risk. The score is defined by the authors as being a mental component summary (MCS) with a score of 42 or below (Ware *et al*., 2001).

A low score indicates frequent mental disturbances, marked limitation in social activities due to emotional problems, state of health generally self-ranked as poor (Ware *et al*., 2001).

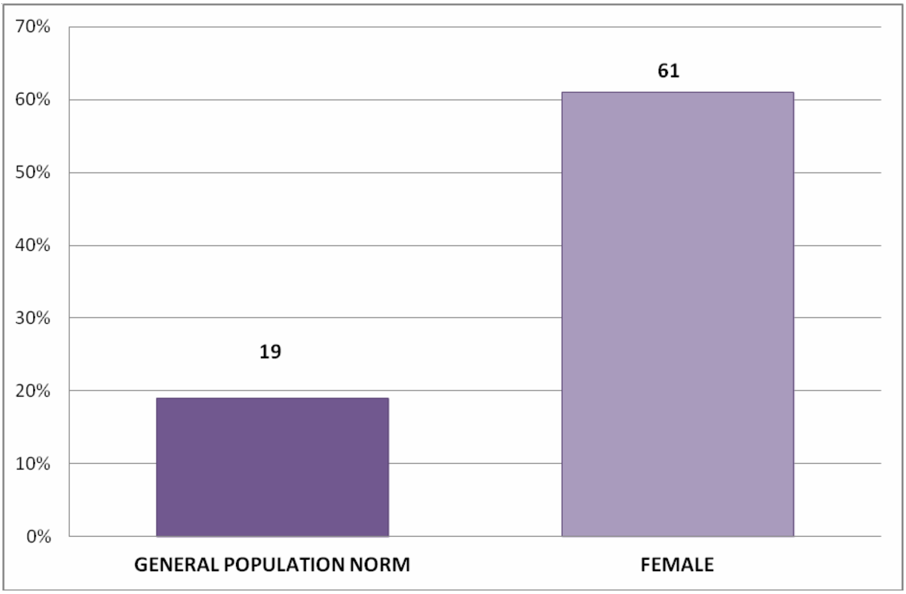


Graph 7. *First stage positive depression - total lot (% at risk)*

The data in the software-generated report, software that accompanies the SF-36 questionnaire offered by its authors and takes statistical normality into calculation, that is the population norm, different for men and women, are presented in the *Graphs 8* and *9*.



Graph 8. *First stage positive depression – male (% at risk)*



Graph 9. *First stage positive depression - female (% at risk)*

Men have a significantly higher risk for first-stage depression than women (Pearson Chi-Square = 32.000, df 3, p <0.001). The graphs show a significant percentage of subjects at risk for depression in the whole group and for the two sexes.

There are a significant percentage of men experiencing depression symptoms, fact that requires more attention to the male patients who are more reluctant to report the occurrence of mental symptoms considering them "specific to women."

Discussions

SF-36 questionnaire is a valuable tool proving to be adequate to the goals and objectives of this pilot study phase, through data on both patient and target patient group. Although the calculation methodology of the scores obtained with the questionnaire includes an algorithm for incomplete data sets (Saris – Baglama *et al.*, 2011), we were interested in the items missing data. There were few such cases of missing data (insignificant in number), demonstrating that the subjects were familiar with the situations and problems described by the items in the questionnaire, and the items were relevant for rating their health. The average time to complete the questionnaire was 10 minutes and there were no cases in which the subjects did not understand the instructions for filling out the questionnaire or the true meaning of the question regardless of age or education level. Both items layout, as well the translation into Romanian in simple and clear words of this questionnaire have facilitated the complete and timely responses.

Pilot study data are a first confirmation of the hypothesis that hepatitis C patient monitoring team should always include a psychiatrist or psychologist, if possible both. The conclusion is based on the high percentage of patients experiencing depression (whole group 70%, women 61%, men 80%) with significant differences between women and men. Also, the average scores on all questionnaire scales are below population norm. The software of the SF-36 questionnaire provides a synthesis for each patient, compared with the general population in terms of physical functioning, pain and work capacity, emotional well-being, participation in social activities, and also an overall assessment, compared with people of the same sex in the general population. This way, the questionnaire is a useful tool for clinicians in the long-term monitoring of the disease course and assessment of treatment effectiveness. Once a license to use this questionnaire is obtained, available for purely scientific purposes free of charge, software that facilitates obtaining valid and reliable data and results is offered. The results obtained in this first pilot study are preliminary data fully support the main hypotheses of the study, particularly the drastically reduced quality of life of hepatitis C patients in general, and during the difficult period of treatment with interferon and ribavirin in particular.

Physical component subscale shows a significant percentage of patients with scores below the population norm (84%) and also a significant proportion of patients with scores below the population norm on the mental component subscale (76%). The importance of mental components in hepatitis C patients is proved by the fact that the lowest overall mean scores (35.65) was in the domain of role emotional (RE), mental component measuring the limitations in daily activities, such as childcare or professional activities, due to emotional problems. The association of psychological and physical problems in patients suffering from hepatitis C is demonstrated by the significant correlation between role emotional (RE), mentioned above, and role physical (RP) which measures the same limitations as RE but due to physical health (Pearson Correlation $r = 0.653$, $p < 0.001$).

We mention the fact that both the intensity of patients' psychological reactions to the disease and the intensity of physical symptoms are very diverse as shown by the distribution range of higher mental component summary scores (MCS = 37.93) in the whole group (lowest score = 21.84, highest score = 59.77) and physical component summary scores (PCS = 38.82) (lowest score = 25.09, highest score 63.91).

Conclusions

The severe impact of the illness on the patient with Hepatitis C in the pilot study is obvious and justifies future large and complex studies to background long-term support. In the same time, the lack of correlation between the physical and mental component summary scores and the large range of scores both in mental and physical area lead to the assumption that both psychological and physical reactions to disease and treatment have a low level of predictability, hence the need for monitoring each patient's health state, with emphasis on depression. A secondary objective of this pilot study was the formulation/re-formulation of some hypotheses issued in the methodology of the longitudinal study, the present pilot study being part of it. The obtained results did not require the reformulation of the basic hypotheses of the study. We believe the introduction of this type of qualitative assessment is very useful for health care providers, policy makers, etc., SF-36 meeting all practical and scientific requirements. We presume representative sample or/and large lots of patients enable comparisons in time and in space, some differences in quality of life may be due for illness itself, but lack of appropriate support may worsen the patients' health status. Patients were deeply interest in the issue of this pilot study, which demonstrate the need of both physical and psychological support. It is a good start for a longitudinal study in order to keep subjects in a long-term study. Since the pilot study included a relatively small group of patients, the analysis of other criteria and factors, such as age groups, was not possible.

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