

IMPACT OF A THERAPEUTIC EDUCATION PROGRAM OF MODIFICATION LIFE STYLE ON KNOWLEDGE, COMPLIANCE AND SATISFACTION OF PATIENTS TREATED FOR CHRONIC VIRAL HEPATITIS C

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Abstract

Introduction: to help patients with chronic hepatitis C to modify their life style we need to therapeutic patient education (TPE) aiming to assess satisfaction and compliance of these patients with antiviral treatment.

Objectives: to assess the impact after eight months of TPE program on the satisfaction and compliance of the patients treated for viral chronic hepatitis vs.

Methods: through using questionnaire which distributed to 32 patients participated in at least one TPE consultation. 17 questions on knowledge and 20 patients was satisfied to answer the questionnaire

Results: 65% of the patients didn't not know answer to the questions before the first session of the program but after four TPE sessions, 76% of the patients give a precise answer about their knowledge and treatment sign scantly (0 . 01)), the viral load of 12 patients becomes negative during their treatment while 90.6% have good adherence to drug therapy. The patients were satisfied with the TPE consultations. the program had positive impact on their everyday life

Conclusions: TPE has a good an impact on the knowledge of the patients, it facilitate giving advice to the patients regarding the modification of their life style and medicinal treatment.

Introduction

Hepatitis C is an affection hepatic of viral origin at parenteral transmission. The prevalence in France of adults with antibodies anti-HCV is currently estimated to be between 1.1 and 1.2% of population, i.e. 500,000 to 650,000 individuals; about 8% are viraemic [1 - 4]. However, it is estimated that nearly 40% of those affected do not know their disease, have no symptoms, but can transmit sickness.

Liver infection begins with acute hepatitis on more often with little or no symptoms in 80% of cases. L'average incubation ranges from 4 to 12 weeks. The nice tomes are not speci fi c, thus explaining that the clinical history of hepacute viral C erarely done. The spontaneous recovery from acute hepatitis C within the first six first months after the idiotinitial tact is observed in 15 in 40% of cases. The frequency of the transition to chronicity ist of around 80%.

HCV infection is responsible for 70% of case chronic hepatitis [5]. Chronic hepatitis is general- asymptomatic, progressing towards cirrhosis then a car- hepatocellular carcinoma within a period which varies from a few years to several decades. This is almost exclusively at stage of cirrhosis that occursthe complications responsible sands of morbidity and mortality (2 to 5% per year) of the disease [4]. Antiviral treatment of this chronic disease has rested successively on standard interferon, dual therapy interferes with ribavirin and today pegylated interferon and ribavirine. These treatments generate many unwanted effects risks that the patient must anticipate, recognize and know how to manage and require knowledge of the precautions to be taken with this treatment.

Therapeutic failure often linked to failure to observe advance, justifies active participation of the patient. Therapeutic patient education (FTE) makes so here all its sense, because the definitive eradication of the virus and

therefore a cure is possible in more than half of the cases.

The objective

Is to assess, on the one hand, the impact educational support, in patients with of chronic viral hepatitis C on the evolution of sessions (on pathology and treatment management) and on adherence to treatment and on the other hand, the satisfaction of these patients with therapeutic education consultations.

Methods

This work was carried out in the consultation service of hepato-gastroenterology between January to September 2008.

Implementation and progress of the ETP program, patient with hepatitis C started a dual therapy is, if desired, covered at the ETP consultation; patients undergoing treatment may also, if they wish, participate in these consultations.

The therapeutic education file used at the consultations was addressed between doctors, pharmacists

The patient starting dual therapy with interferon and ribavirine is seen in consultation " pre-therapeutic. This individual interview lasts en average 1 hour to 1 hour 30 minutes. The goal of this interview is to get a maximum information about the patient, his experience, the history of his illness, his knowledge, his current concerns and its needs, in order to achieve a educational diagnosis and identify its objectives. During this interview, several points are discussed: evaluation and reminder basic knowledge of hepatitis C, the value of treatment the notion compliance, management of undesirable effects, the repercussion of the disease in everyday life, difficulties with disease and resources. At the end of this session, the educational diagnosis is set and the objectives of next sessions are defined and accepted by the patient.

If the patient has already started treatment, this session will be much shorter than that described above, because the patient has already familiarized himself with his treatment. The discussion will be the same as those of the pre-therapeutic but centered on the experience of treatment with the is holding. This session (approximately 30 min) is intended for patients from 1 to their re interferon injection day hospital.

The nurse performing the injection shows the patient the method adequate IFN injection. She assessed the behavior and established a diagnosis of needs, gives explanations on the terms

The patient is seen again 2, 4, 8, 12, 16 and 20 weeks after the start of treatment. These sessions (lasting an

average of 45–50 min) are dedicated to listening to the patient and providing advice so that he can live better before his illness and treatment is lying. The knowledge assessment questionnaire allows to take the points not acquired during previous consultations.

At the end of the treatment, the nurse completes the assessment questionnaire knowledge. She also submits a questionnaire the satisfaction that the patient will give during one of the 3 sessions post-treatment. These sessions take place 1, 3 and 6 months after stopping the treatment is lying. They aim to continue the support and of monitor the patient after stopping treatment using the plug " post-therapy ".

Study tools

Knowledge assessment questionnaire. The impact of the TVE program was assessed using a knowledge assessment questionnaire developed by pharmacists and ETP nurse. It allows to evaluate the patient knowledge before the start of its treatment and target the themes to be addressed in the consultations of ETP. This questionnaire so long, it can be filled by the FTE nurse or the pharmacy intern during the two first TVE sessions. The questionnaire is distributed by two columns to be completed "before FTE" and "after minimum of four sessions "evaluating the answers according to three opportunities

Response criteria have been listed to differentiate the patient s knowing totally or partially answer the questions.

The 36 questions were grouped into 5 main themes:

- General knowledge about hepatitis C: 6 questions
- Illness and life daily with the disease:

4 questions

- Treatment knowledge: 22 questions
- Knowledge of monitoring biologique: 2 questions (the patient knows the frequency and interest of biological monitoring).
- Identification of the care network: 2 questions.

Questionnaire started in March 2008 and the last questionnaire was completed on 8 September 2008.

Results

Between January 7 (start date of the TPE consultations) and September 8, 2008, 32 patients participated in at least one TTE consultation. Fifteen patients were excluded from the analysis:

Five patients stopped consultations for the following reasons:

- Treatment not started for personal reasons;
- Relocation to the Paris region after 5 weeks of treatment;
- Death of a patient after 8 weeks of treatment;

- Discontinuation of treatment because the patient was not responding after 18 weeks of treatment for one patient and after 22 weeks for another Six patients participated in less than four TTE sessions and four patients did not wish to answer the questionnaire after FTE for lack of time on the day of the assessment Seventeen patients were therefore included in the analysis and participated in an average of 5.6 TTE sessions (1 to 9 depending on the patient)

Patient characteristics

Patients, 11 men and 6 women, were on average 56 years old (40 to 73 years old). Seven patients were naive to dual therapy and 14 chose to self-inject interferon.

Evolution of the viral load and adherence to the treatment

Biological data on the viral load (VL) were found in the charts of the 17 patients. Twelve patients were negative for their CV during their treatment. (70.6%): four at W4, six at W12, one at W24 and one after S60 explained by an absence of previous data. The evolution of the number of patients with an undetectable CV is shown in the table below. On questioning and in view of the treatments given at each session, 16 of the 17 patients (94.1%) followed at the TPE consultations were observant with regard to their treatment (one patient forgot to take a ribavirin tablet) confirmed by viral load monitoring

Table 1: Evolution of the number of patients with undetected CVable. - Evolution of the number of patients having a undetectable VC

	Naive patients of Dual therapy N= 7	Patients in dual therapy N=10	Set of reprocessing patients N=17
Treatment week S4 (n = 15)			
Undetectable CV	2	1	4
Decrease in CV of more than 2 log	2	4	6
Decrease in CV of less than 2 log	2	3	5
Treatment week W12 (n = 14)			
Undetectable CV	5	5	10
Decrease in CV of more than 2 log	0	2	2
Decrease in CV of less than 2 log	1	1	2
Treatment week W24 (n = 10)			
Undetectable CV	4	5	9
Decrease in CV of more than 2 log	1	0	1
Decrease in CV of less than 2 log	0	0	0
Treatment week W28 (n = 7)			
Undetectable CV	2	5	7
Treatment week W36 (n = 3)			
Undetectable CV	0	3	3
Treatment week W48 (n = 3)			
Undetectable CV	0	3	3
Treatment week > W48 (n = 3)			
Undetectable CV	0	3	3

Analysis of knowledge assessment questionnaires

Before the 1st TPE session, 11/17 patients could not or only partially answer the questions asked. After a minimum of 4 TPE sessions, 13/17 patients give a precise answer to the questions. There is a significant difference between the patients' knowledge before and after a minimum of 4 TTE sessions ($p = 0.01$).

Knowledge fully acquired before ETP predominates in patients undergoing retreatment 64% (i.e. 11 questions) vs. 14% in dual therapy patients.

The proportion of patients for whom knowledge is not acquired after a minimum of 4 TPE sessions is very low (<5%). This mainly involves knowledge of the virus and genotyping as well as knowledge and management of their treatment. Twelve patients were unable to give an example of interaction with their treatment after TPE.

Only 3 of the 17 patients thought of the pharmacist when asked to name a health professional (other than the specialist doctor or the TPE nurse) who could provide them with information about their disease, their

treatment and a single patient replied that they would contact the pharmacist if an adverse effect occurred during their treatment

Analysis of satisfaction questionnaires

Twenty patients included in the ETP consultations completed a questionnaire. It was returned to patients after a minimum of 4 TTE sessions. Seven patients were at the end of treatment and thirteen were undergoing treatment. All of the patients welcomed the TPE consultations with an average score of 9/10 given to the quality of these sessions.

The frequency of consultations seemed appropriate to them and twelve patients considered that the ideal duration of consultations would be 30 min. Only one patient wished to interrupt treatment, because trips to consultations accentuated his fatigue and his motivation was average. Nineteen patients feel in confidence with the nurse and understand the vocabulary used. All patients: - felt that confidentiality and their privacy were respected during consultations, - felt listened to by the nurse, - felt they had obtained the desired information, - were able to ask the questions they wanted and got their personal questions answered. Of the 44 patient-reported comments, clarity of explanation, support, listening and understanding came most prominently. Twelve of the fifteen patients who self-inject interferon felt that the TPE program helped them to carry out this gesture. On the other hand, three patients regret having seen the injection technique only once.

Discussion

Structure and content of the TPE program

Experiences relating to the implementation of TPE consultations for patients with chronic viral hepatitis C are little described in the literature, thus showing the innovative nature of our approach for this type of chronic disease. In fact, in other pathologies such as diabetes, arterial hypertension, asthma, HIV, etc., the therapeutic education of the patient is the subject of numerous publications, see even recommendations published by the 'ANAES in 2001 or a methodological guide from the HAS [6,7]. These recommendations can obviously be applied to all other chronic pathologies, but it would be interesting to have a methodological guide intended for the ETP of HCV patients. In 2006, the HAS issued recommendations on the management of patients with chronic hepatitis C; some of these recommendations are dedicated to treatment, but only a few lines on the patient's therapeutic education [8]

Some establishments have published their experience and described the different stages of implementation [9–14]. The structure and content of the therapeutic education program set up at the Tours University Hospital comprises

four main stages as described in the reference texts [7,8,15,16]. The different TVE programs described in the literature are no different from our organization. We systematically re-find the initial stage of the educational diagnosis and the determination of the skills to be acquired. In our case, it is the nurse competent in FTE who establishes this diagnosis with the patient. In the literature, we see that this diagnosis is drawn up either between the patient and a health professional competent in FTE (generally the nurse) or between the patient and several health actors. Even if the nurse communicates the educational diagnosis of the patients to the doctor, our program lacks multidisciplinary consultation meetings to validate the educational diagnoses of each patient and establish a distribution of skills to be acquired between the different actors of the TVE

The second step found in all programs is planning with the patient a personalized TPE program. There are two types of TVE sessions in the literature: individual sessions and group sessions. There is currently no study showing the benefit of one type of session over another. Our program consists exclusively of individual sessions. The lack of an adapted room, the ease of access to these sessions for patients and the desire to recruit as many patients as possible (patients having difficulties in being in a group) explains the orientation of our choice towards individual sessions. . On the other hand, it would be interesting to be able to offer patients these two types of session afterwards, because group sessions are conducive to sharing experience and may involve former patients. Depending on the results of the knowledge assessment questionnaire obtained during the first ETP consultation, the nurse will determine with the patient the skills to be acquired during individual sessions. In our program, contrary to the literature, the ETP nurse is almost the only interlocutor (except when the pharmacy intern is available). It would also be necessary to complete the group of educators by adding a psychologist and a dietician. The tools used are mainly educational tools provided by pharmaceutical laboratories. These tools are very well suited to individual sessions, on the other hand, if group sessions are envisaged, educational card-based games as is the case in rheumatoid arthritis, for example, would have to be created; role plays could be developed to make these sessions more interactive. Finally, as with any project, it is necessary to anticipate the evaluation of this program. Several reference texts have made proposals for the evaluation of therapeutic education [7,17–19]. The evaluation of our program covers three dimensions: knowledge (and indirectly self-care skills), adherence and patient satisfaction. These three dimensions are often found in the evaluations published in the literature. In our program, several dimensions are missing, for example, the evaluation of

the quality of life of patients (dimension often evaluated in the literature) or the evaluation of satisfaction but from the point of view of the products. fessional.

Impact of the ETPDe program

Numerous studies have shown the impact of therapeutic education in reducing iatrogenic drug risk, especially in patients on oral anticoagulants for venous thromboembolism [20]. The first study on the effectiveness of therapeutic education dates from 1972, it concerned diabetic patients in disadvantaged areas of Los Angeles and reported a significant reduction in hospital days of between 1.5 and 5.5 days / patient [21]. A more recent study evaluating the impact of therapeutic education on the re-hospitalization of psychotic patients also highlights a decrease in the number of hospitalizations in patients who have benefited from TTE sessions [22]. Since then, many teams have been involved, in different fields of health, towards an evaluation process. The pathologies mainly found in the literature concern: the management of diabetes, hypertension or even the HIV patient [23]. The impact of TPE on treatment adherence is a subject often discussed. For example, the study by Cacoub *et al.* published in 2008, on adherence in the field of hepatitis C, found that adherence after 6 months of treatment was significantly higher in educated patients, these data were in agreement with a significantly higher virological response rate. important in these patients [24].

The shorter duration of our study, the small staff and the absence of groups without FTE explain the differences obtained with the Cacoub study even if we observe the same trends. In our study, a patient was considered observing if they took the correct dosage, at all times and for the entire duration of the treatment, whereas the study by Cacoub considers that the patients are observing if they take 80% of the dose for 80% of the treatment. expected duration. For the determination of the viral load, Cacoub analyzes the sustained virological response (CV undetectable 12 weeks or more after the end of the treatment), for our study the CV was analyzed only on the duration of the treatment. Too few patients had completed their treatment to obtain sufficient results. Few studies measuring the impact of PTE on patient knowledge are currently available in France [12,13,25–27]. In this perspective, the implementation of a post-ETP knowledge assessment questionnaire seems relevant. The published studies evaluating the evolution of patient knowledge after FTE all point in the same direction: a significant improvement in knowledge.

With the exception of a publication in which knowledge was assessed at each education session, the methodology chosen to assess the improvement in knowledge was a questionnaire given before the start of the TVE sessions

and at the end of the TVE program. In our study we arbitrarily chose to assess knowledge after a minimum of 4 TVE sessions. In fact, 8 months after the start of the program we did not have a sufficient number of patients who had completed the entire program. Even if the results of this questionnaire presented in our study are difficult to interpret from a purely statistical point of view, they can nevertheless give trends.

In fact, due to the heterogeneity of the population included in TPE consultations, knowledge of the disease, treatment and follow-up varies from one patient to another. Thus, a patient carrying out a first antiviral treatment will not have the same knowledge as a patient receiving the 3rd line of treatment.

Even if these two patients have been analyzed separately, the small size of our samples does not allow us to highlight significant differences with statistical tests. In addition, the number of TTE sessions, even if the minimum required was 4 sessions, varies from one patient to another. And finally, not all patients started the TTE sessions at the start of treatment. " all the questions asked (36 questions) to patients before the 1st TVE session and after a minimum of 4 sessions, 47% of the responses correspond to knowledge fully acquired after the TVE for all patients, 53% are made up of partially and fully acquired knowledge (with a higher percentage of "acquired" compared to "partially"). With the exception of the question on drug interactions with their treatment, where 75% of patients were unable to give an example, the proportion of patients for whom knowledge was not acquired after the TPE (9 items out of the 36 posed) corresponds to a small percentage (one patient out of 17 in 80% of cases). Only three patients think of the pharmacist when asked to nominate a health professional (other than the specialist doctor or the TPE nurse) who can provide them with information about their disease, their treatment and only one patient responded. that they would contact the pharmacist if any adverse effect occurred during treatment. This low proportion is directly linked to the fact that the pharmacist is not integrated into this program as a competent resource person. In addition, the three patients could not be influenced by the presence of the intern in the pharmacy, because the latter was absent during the cessations.

The sub-group analysis indeed shows that patients who have already received dual therapy have more knowledge before TPE on issues relating to treatment and its follow-up than patients who have not received dual therapy. For the two other categories of questions (general knowledge about hepatitis C and identification of the care network) this difference is blurring. These data are of course only trends, because this study is non-comparative (absence

of a control group not having benefited from the TVE program). It would have been interesting to ask only patients starting dual therapy (only whether or not they have a history of treatment). Ultimately, this study could be carried out when all the patients undergoing treatment have benefited from the TPE sessions and only those starting dual therapy remain, ensuring that at least 30 patients are included per category of prior treatment. However, the impact of TPE consultations on patient knowledge will remain difficult to assess, as patients can obtain information outside of that provided during the sessions (internet, brochures, associations, etc.). It would also be interesting to ask these questions before the start of each TVE session in order to estimate the minimum number of consultations necessary to obtain, for example, 80% of acquired knowledge.

Place of the pharmacist in the TVET program

In view of the results, in particular on compliance and on questions concerning the drug, the role of pharmacists in the multidisciplinary team deserves to be discussed. The review of the literature published in 2005 by Van Wijk *et al.* shows that the actions described involve the involvement of pharmacists of origin [28]. Two articles confirm the pharmacist's place in optimizing the response to treatment of patients with hepatitis C [29,30].

In our study, the share of treatment-related advice alone accounts for 75% of all advice given by the TVE nurse. In addition, compliance affects not only compliance with the taking of prescribed drugs but also all aspects of treatment. The pharmacist, as a drug specialist, therefore has his place within these therapeutic education consultations with a view to complementary of knowledge. Thus, the pharmacist could provide (during dedicated pharmaceutical consultations or in collaboration with nursing consultations) advice relating to the mode of action, the intake plan, storage, drug stock management, but also the expected adverse effects, their management, self-medication, interactions with treatment and the importance of adherence. The nurse would bring her knowledge of the practice of care, daily life with the disease, ensure that the patient has sufficient personal and environmental resources to guarantee the success of the treatment, and would provide practical advice, hygiene and diet.

The doctor will of course accompany the patient from the announcement of the diagnosis until the end of his treatment and several months afterwards. He is the patient's first point of contact in therapeutic education. It provides, among other things, information on the disease, the principle and course of treatment, the monitoring methods to assess the tolerance and the efficacy of dual therapy. However, hospital pharmacists

are very rarely involved in TPE consultations. The involvement of hospital pharmacists in the TVE approach is progressive, in line with their establishment in care units and the development of clinical pharmacy. In fact, this pharmaceutical presence in care units makes it possible to optimize therapeutic management (dosage adjustment, proposal for a therapeutic alternative, specific pharmacological monitoring) and thus positions the pharmacist as a potential player in personalized patient monitoring. [31]. Thus, in our study, it would have been interesting to obtain, by means of a satisfaction questionnaire intended for the FTE nurse, the nurse's opinion on the FTE consultations carried out in conjunction with the intern. In our study, the hospital pharmacist positioned himself in the ETP, by participating in the development of educational programs

Conclusion

Since the identification of HCV, almost twenty years ago, the care has been the subject clinical studies to regularly improve therapeutic protocols, the advent of dual therapy, and very recently triple therapy combining interferon, ribavirin and antiprotease for genotype 1 patients, makes patient adherence to their treatment to guarantee its efficacy.

Therapeutic education sessions implemented in place at CHRU to assess impact on optimization of the patient by improving the knowledge, skills and satisfaction of patients. Even though the therapeutic education consultations of the patient are now registered in the activities routine venues of the hepato-gastroenterology department of the CHRU to ascertain the importance of these consultations and be able to extend them to patients with chronic hepatitis viral B. This lack is to poor compliance with treatment and the emergence in the case of triple therapies of HCV strains resistant to these antiproteases. However the law " Hospital, Patients, Health and Territory show the importance of Health with the development of such programs [32 - 36]. This will thus seem all health professionals to the same the goal of development massive therapeutic education easily, in town or in hospital, thus replacing the patient at the heart of the health-care system. A program of therapeutic education favor multidisciplinary actions, our program must be improved in this direction by creating sessions dedicated to medication management which would be led by a pharmacist.

Other studies including a greater number of patients will therefore be necessary in order to assess the impact of this biological status therapeutic education program patients, their level of compliance, their quality of life or still their knowledge about disease, treatment and prevention.

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