Side effects of treatment in patients with hepatitis C - implications for nurse specialist practice

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KEY WORDS

hepatitis C, nurse specialist, nursing, symptoms, needs

ABSTRACT

Objective
To identify patients' perceptions of the side effects of Hepatitis C treatment.

Design
The research used a self-reporting postal survey design to identify reported side effects, related to hepatitis C treatment, suffered by patients attending a specialist nurse clinic.

Setting
The setting for this study was an outpatient hepatology clinic in a large general hospital in Ireland.

Subjects
The questionnaire was distributed to a convenience sample of 201 patients receiving hepatitis C treatment at the hospital.

Main outcome measure(s)
To determine what side effects are most common during hepatitis C treatment; to identify whether or not patients are satisfied with the nurse specialist/nurse led service and to identify the unmet support needs of patients on treatment.

Results
Several side effects were reported, including fatigue, sleep disturbances and weight loss. Another high scoring side effect was sexual dysfunction. Patients reported a high satisfaction with nurse specialist services.

Conclusions
Manifestations of treatment have implications for care management of this group. Routine assessment of quality of life or symptom related needs is suggested in addition to personalised support from nurse specialists. Raising patients' awareness of the potential side effects is very important in the approach to care, particularly in relation to compliance. In addition, providing information and advice to patients about how to manage their symptoms is essential.

INTRODUCTION

The high incidence of hepatitis C virus (HCV) makes it one of the greatest health threats facing the world today (Rhoads 2003). Hepatitis C is a treatable disease, and over the last few years increasing numbers of patients have been offered antiviral treatment to eradicate the virus. However, treatment is cytotoxic and associated with a multitude of adverse side effects (Zucker and Miller 2001). A combination of drug treatment and informational and psychological support, aimed at managing HCV symptoms and lifestyle, is often performed on an outpatient basis and in most cases led or supported by nurses. Nurses need to be highly skilled in this area, ideally nurse specialists (Zic 2005) and increasingly nurse specialists are at the forefront of care delivery: supervising patient treatment and monitoring side effects; providing patient education, counseling and support; maintaining records and clinical databases and participating in consultations (Ewart et al 2004).

The treatment for HCV involves a combination of two drugs: Pegylated Interferon (a subcutaneous injection that is given once weekly) and Ribavirin tablets that are taken orally each day (Fried 2002). In some patients (depending on genotype), this treatment has been shown to induce a sustained viral response (SVR), defined as undetectable hepatitis C PCR for six months after the end of treatment (Zic 2005). Poynard et al (2002) demonstrate that treatment of HCV resulting in an SVR prevents progression of liver fibrosis and may improve life expectancy. Studies have also found that patients who do not experience an SVR may benefit from the temporary decrease in liver inflammation and fibrosis while taking treatment (Shiffman et al 1999). Thus, adherence of patients to therapy is important because it can slow down the disease process.

There are more than six genotypes of HCV identified and genotype determines the duration of treatment (Fried 2002). The most common genotypes of HCV in Ireland are genotypes 1, 2 and 3 (Brennan et al 2004). Genotypes 2 and 3, on the other hand, are more common among intravenous drug users (IVDU). Other genotypes 4, 5 and 6, are uncommon, but with the increasing number of foreign national immigrants into Ireland, these genotypes are becoming more prevalent. In relation to treatment, genotypes 2 and 3 have similar traits and have the highest response rates; usually about 80% of cases clear the virus. These genotypes of HCV require 24 weeks of antiviral treatment. Conversely, genotypes 1, 4, 5 and 6 require 48 weeks of treatment but have poorer response rates; usually about a 48% chance of clearing the virus (Levine and Ghalib 2005).

HCV can affect individuals in many different ways. Fatigue is the primary symptom, often leading to poor quality of life (Ewart et al 2004; Glacken et al 2001). Nurses can offer advice to patients to manage fatigue symptoms focused on sleep management, energy conservation and exercise. Other symptoms include nausea, pain and depression, which can also have a serious impact on the ability to work and on quality of life (Temple-Smith et al 2004; Lawrence 2000). Unfortunately HCV treatment can initially compound and worsen these effects. Side effects such as worsening fatigue, insomnia, alopecia and arthralgia are common (Zucker and Miller 2001). Side effects can appear in clusters at different times during patient's therapy, regardless of their genotype or length of treatment (Zucker and Miller 2001). Other side effects include anorexia (Zucker and Miller 2001; Mulhall and Younossi 2005; Seyam et al 2005) depression (Zucker and Miller 2001; Bonaccorso et al 2002; Cornberg et al 2002; Leone 2002; Mulhall and Younossi 2005; Seyam et al 2005) skin irritations, anaemia , neutropenia and flu like symptoms (Zucker and Miller 2001) and myalgia (Mulhall and Younossi 2005). In some cases the side effects produced by therapy are so intense, patients feel forced to give up on treatment or doctors may even recommended this (Mulhall and Younossi 2005). Furthermore, depression can also increase the risk for patient non-compliance with antiviral therapy (Maddrey 1999). Although some basic description of side effects of HCV antiviral treatment appears in the literature, there is little documented evidence of the impact of specialist nursing services or patients' perceptions of their symptoms and side effects, their relative severity and whether or not their needs in relation to the symptoms are currently being met.

METHODOLOGY

This study aimed to determine what side effects are most common during hepatitis C treatment; to identify whether or not patients are satisfied with the nurse specialist/nurse led service and to identify the unmet support needs of patients on treatment. A convenience sample of HCV patients from a large urban general hospital completed a 59-item self-reporting postal questionnaire, developed for the purposes of this study. The sample included all the patients who attended a nurse-led hepatitis C treatment clinic and were cared for by a nurse specialist. The sample size was two hundred and one patients and inclusion criteria was defined as all the hepatitis C patients, over the age of eighteen years, who attended the hospital for antiviral treatment of hepatitis C from January 2004 to January 2007. Those under the age of eighteen were excluded. The response rate was 53% (n=106). Data were analysed using SPSS version 14.0. Frequency descriptive statistics were used to describe; the demographics of the sample, the most common side effects of treatment and the scores on patient's perceptions of support. The Chi-Square test where appropriate, was used to compare the demographic characteristics of responders. The Mann Whitney U-tests were used to compare satisfaction scores between patient groups and the Spearman's rank correlation was used to determine the linear association between perception scores and the variables of gender, age, genotype and risk factor.

FINDINGS

Sixty eight percent of the respondents were male the remainder was female. The majority of respondents (n=41, 39%) were aged between 26 and 35. Twenty five percent (n=27) were between the ages of 46 and 55 years, and twenty-three (n=24) were aged 36-45 years. There were thirteen respondents aged 55 or over and only one respondent aged between 18-25 years.

Over half (n=55, 52%) of the respondents had contracted HCV through intravenous drug use (IVDU). A further twenty two (22%) respondents did not know how they contracted the virus and while fifteen (14%) respondents state they got infected through a blood transfusion. Thirteen (12%) respondents stated they got the virus from other infected blood products. One person reported sexual contraction from an infected partner.

Genotypes 1, 2 and 3 made up for almost 80% of cases. The most common type of hepatitis C was Genotype 3 (n=47, 44%), followed by Genotype 1 (n=28, 26%). Nine (9%) respondents reported having Genotype 2 and only three (3%) respondents reported Genotype 5 and two (2%) Genotype 4. A further seventeen (16%) respondents were unsure of their genotype. There were no reports of Genotype 6.

There was almost an even amount of respondents who undertook either 24 (n=52, 49%) or 48 (n=53, 46%) week treatment. The majority of patients (n=94, 89%) completed the full course of recommended antiviral treatment while ten (9%) respondents did not.

Sixty-five (61%) respondents had a negative PCR result six months after completing treatment while twenty-two (21%) respondents did not. Twelve (11%) respondents were still awaiting results and seven (7%) were unsure whether they had cleared the virus or not.

Thirty-eight (81%) respondents with genotype 2 or 3 had a negative PCR result post treatment while nine (19%) respondents did not. Of those with genotype 1, 4, or 5, fourteen (52%) had a negative PCR result and thirteen (48%) did not. The proportion of genotypes 2 or 3 that cleared the virus was significantly different to the proportion of genotypes 1, 4 or 5 that cleared the virus (p =0.018, df =1). Similarly, route of contraction influence results, as those who reported contracting HCV through intravenous drug use were more likely to have cleared the virus (p= 0.013, df =1). The proportion of younger respondents that cleared the virus was also significantly different (p=0.001, df =1). Of those respondents who knew their PCR status post treatment (n=87), fifty-two were aged 45 years or younger, of which 72% cleared the virus, whereas only 26% of those over 46 years did.

The ten most commonly reported side effects are outlined in table 1. There were no statistically significant differences in the side effects scores according to genotypes. Similarly there were no statistically significant differences in scores according to gender.

Table 1: Ten Most Common Side Effects Experienced by Respondents

(n=106)	Very mild/mild n=	Moderate n=	Severe/very severe n=	Total (%)
Fatigue	12	27	55	94 (89%)
Sleep Difficulties	23	18	50	92 (87%)
Weight Loss	30	26	33	89 (84%)
Poor Concentration	24	30	34	88 (83%)
Depression	26	23	39	88 (83%)
Skin Irritation	27	25	32	84 (79%)
Flu-like Symptoms	28	29	26	83 (78%)
Loss of Appetite	29	20	33	82 (77%)
Forgetfulness	28	23	31	82 (77%)
Pain in the Liver Area	35	33	10	78 (74%)

n= number of respondents

Table 2: Ten Least Common Side Effects Experienced by Respondents

(n=106)	Very mild/mild n=	Moderate n=	Severe/very severe n=	Total (%)
Sexual Dysfunction	33	16	28	77 (73%)
Anxiety	30	16	30	76 (72%)
Muscle Aches	34	18	24	76 (72%)
Headaches	37	23	15	75 (71%)
Joint Pain	31	20	21	72 (68%)
Nausea	32	23	17	72 (68%)
Fever	38	20	8	66 (62%)
Hair Loss	35	11	19	65 (61%)
Low Red Cells	27	21	15	63 (59%)
Low White Cells	22	16	14	52 (49%)

n=number of respondents

Table 3: Other Side Effects Reported by Respondents

Side Effect	No. of Respondents
Anger	10
Nightmares	3
Paranoia	2
Mood Swings	1
Mouth Ulcers	6
Irritability	1
Eye Irritation	7
Tearful	1
Palpitations	1
Confusion	2
Hearing Problems	1

There were ten other side effects reported by respondents and these were identified as the ten less common effects of treatment (See table 2).

Patients were also asked to write down any other symptom(s) they experienced they believed might have been associated with HCV treatment. They were also asked to rate the severity of these symptoms (1=very mild and 5=very severe). This revealed 13 other side effects, which are listed in table 3.

Patients were later asked about their overall satisfaction in the HCV treatment clinic. The majority of respondents (n=69, 65%) answered 'very satisfied', thirty (28%) respondents said 'satisfied', two (2%) said 'dissatisfied' and four (4%) were 'very dissatisfied'. There were no statistically significant differences between these latter satisfaction scores according to gender, age, risk factor for developing HCV or genotype.

Patients were also asked to identify any needs they may have had while on treatment they felt were unsupported by the nurse specialist. Respondents described a total of fifteen unmet needs and table 4 lists these needs and the number of respondents who reported them.

Table 4: Unmet Support Needs reported by Respondents

	No. of respondents	%
Healthy Diet Information	2	3.8
Contact with others on treatment	2	3.8
More Phone Contact	4	7.7
Privacy during Consultations	3	5.8
	4	7.7
Advice on Mortgages/Life Assurance	2	3.8
More Counselling during treatment	6	11.5
More Nurse Specialists to reduce waiting times	4	7.7
More Support Post treatment	8	15.4
More Contact with the Doctor during treatment	1	1.9
Information to GP's about patient on treatment	2	3.8
Advice on Alternative Medications	1	1.9
An out of hours service helpline	4	7.7
More Social Worker Input	2	3.8
Less Judgmental of pts with history of IVDU	7	13.5
Total	52	100.0

DISCUSSION

Nurse specialists treating patients with HCV respond to a wide variety of patient needs given the very different range of clientele that may be affected by this condition (Fletcher 2003). Using expert skills, the specialist is able to provide a range of services aimed specifically at this group, and this study indicates that patients are indeed satisfied with at least one operation of this service. Given the elongated period of treatment, there is an opportunity for the nurse to build up a relationship with the client and personalise their support plan, and this is perhaps why satisfaction with services provided was so high. The high reported positive response to treatment is testament to the benefits of the medication management regimen, and these findings may provide reassurances to clients, particularly those with genotype 2 or 3 who are perhaps struggling to deal with the side effects at any given time. Although it is not clear from this study just how much information patients received, in other settings Hayter (2006) found that nurses were inclined to minimise side effect information in the belief that this may improve patient concordance with treatment compliance. However, Hayter's (2006) suggests that full details of side effects and other medication information should be provided; while initially this may be alarming, it will increasingly improve patients' confidence, as unprepared for side effects will have the opposite effect.

A relatively unique situation exists in the Republic of Ireland (ROI), currently, as there is no estimate of the prevalence of HCV among the general population (Brennan et al 2004). At the same time, there has been a highly publicised infection of an estimated 1,700 persons through the administration of blood and blood products contaminated with HCV (Consultative Council on Hepatitis 2005). These include women infected through anti-D immunoglobulin, persons with haemophilia, and recipients of blood transfusions and those who received treatment for renal disease (Consultative Council on Hepatitis 2005). This occurrence caused great upset to sufferers and their families, and many of these individuals are receiving treatment. An approximate 14% of the current sample report infection from this route. This issue obviously raises complex emotional and psychological needs that the nurse specialist must address in this setting. The higher reported clearing of the virus is however reassuring. Other issues that challenge nursing practice arise with almost half of the cohort reporting infection from IVDU, this group calls for a reduced stigmatisation of their condition, a factor which nurse specialists may need to address. The number reporting infection through sexual contact, although very low, needs further consideration in terms of education of both this population and the population in general.

Numbers of clients reporting side effects is high. In keeping with the literature on the topic, fatigue was reported as the most common side effect of HCV treatment (Zucker and Miller 2001). Sleeping difficulties also feature highly (Mulhall and Younossi 2005; Zucker and Miller 2001). Consistent with Seyam et al's (2005) findings, most clients suffered from weight loss. A much higher proportion of clients reported depression (83%) compared with previous findings of 41% (Bonaccorso et al 2002). Although this finding could be inflated due to self-reported, as opposed to clinical diagnosis in Bonaccorso et al's (2002) study, these findings need to be borne in mind when dealing with this client group. Other side effects, with the potential to significantly influence clients' quality of life are reported in this study. These include: poor concentration, skin irritation, flu-like symptoms, loss of appetite, forgetfulness and pain in the liver area. Although reported in the study as the ten least common side effects, the following were also commonly reported by the group: sexual dysfunction, anxiety, muscle aches, headaches, joint pain, nausea, fever and hair loss. All of these manifestations of treatment have implications for management of this group by nurse specialists. In the first instances raising clients' awareness to the potential effects is important and secondly providing information and advice to clients about how to manage their symptoms. Clients' express information needs related to symptom management more frequently that the requirement for technical information such as how their medication actually works. Although not hitherto reported, sexual dysfunction is a reported feature of this group. The exact nature and distribution of this problem needs further exploration from a research perspective. Nurse specialists at local level also need to become involved in assessing clients' difficulties in this area and encouraging them to report these. Referral to specific sexual dysfunction specialists may also be required.

Although not specifically explored in this study, all of the above symptoms may affect the health related quality of life (HLQL) of this client group. When discussing the range of similar symptoms, including fatigue, weight loss and nausea, associated with HIV and its treatment Webb and Norton (2004) suggest that the nurse has an essential role in the assessment and management of these to improve quality of life and further suggests the routine use of a HLQL assessment tool for this purpose. These authors discuss a range of both generic and disease specific quality of life assessment and suggest their usefulness as an adjunct to providing best quality of care to clients with chronic illness (Webb and Norton 2004). They suggest that this information would serve to monitor disease progression and response to treatment, help to identify physical and psychosocial problems and promote better treatment concordance.

Although patients' perceived support received from the nurse specialist to be satisfactory, some patients emphasised that aspects of support were lacking in terms of weight management, sleep management and support after treatment completion. The central issue here is that patient needs in these areas need to be swiftly identified by nurse specialists, perhaps through a quality of life measure as previously discussed or through the use of an alternative needs assessment tool.

CONCLUSIONS

Hepatology nurse specialists care needs to achieve a balance in services that offer not only clinically effective care, but which are also judged by patients as acceptable and beneficial. HCV treatment presents an enormous challenge for nurses due to individualised range of side effects and the impact they can have on a patient's quality of life. Many studies support the idea that supportive relationships between patients and nurse specialists facilitate patient well-being and physical comfort that contribute to both health and healing (Bousfield 1997). Therefore, nurse specialists' care can benefit from a clear understanding of the required support needs of this group. Further quantitative studies are required on the topic in relation to sexual dysfunction and the overall impact of side effects of HCV treatment of quality of life. Further qualitative approaches may be useful as this would help to obtain valuable information to understand the different factors that influence a patient's perception of nursing care (Cormier 2005; Tarkka at al 2003; Langford et al 1997). For example, additional qualitative studies focusing on the lived experience of individuals on HCV treatment could yield important information about the physical and psychological consequences of undergoing treatment for hepatitis C. At a time when nurse specialist roles are developing exponentially internationally it is important that hepatology nurse specialists begin to systematically gather research evidence on the patient's perspective that can positively influence their practice (Armstrong 1999).

RECOMMENDATIONS

Hepatology nurse specialists need to improve their skills in relation to counselling, weight management, sleep management and giving support in relation to sexual dysfunction. These important issues should be incorporated into continuing professional development programmes for this group to improve care provision. From a management perspective, hepatology units; hospitals; HCV support groups and national health authorities need to be aware of the detrimental effects of HCV treatment and the impact it can have on an individual's quality of life. They must strive to work together to provide services for HCV patients that address not only the physical but also the psychological and social problems that can arise as a result of HCV treatment. It could be suggested that members of HCV specialist groups join to provide a forum to discuss HCV management programs so as to ensure that there is a uniform understanding of the implications of HCV treatment for patients and the healthcare system.

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