Why aren't we treating the treatable?
An audit of all HIV/HCV co-infected individuals attending an HIV clinic

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Background

The progression of liver disease remains a significant problem in HIV/HCV co-infected individuals, and is a leading cause of morbidity and mortality within this population (Smit et al, 2008). These individuals have a more rapid progression of liver disease than the mono-infected cohort (e.g. Macias et al, 2010). Despite this, the uptake of HCV treatment in co-infected individuals remains poor and only limited data exists as to why this population infrequently accepts and completes treatment (Bova et al, 2010). The publication of the BHIVA Guidelines for the management of co-infection (Brook et al, 2010) prompted an audit of all HIV/HCV infected individuals attending the Regional Infectious Diseases Unit in Edinburgh, to assess current practice against the suggested audit standards. A number of factors were examined, however for the purposes of this report, the uptake of treatment and the staging of liver disease are the main focus.

Methods

A total of 219 individuals who are both HIV positive and anti-HCV positive were identified from the unit database. A retrospective audit of these individuals' case notes was then conducted. Only written entries made in the last three years were reviewed. Written entries included both clinical letters and also hand written entries in the outpatient clinical notes. Serology was audited using the laboratory computer system APEX which allowed access to results back to 1999. The design for the audit tool was based on the BHIVA audit standards for the management of co-infection (Brook et al, 2010). The first sets of case-notes were audited on the 15.02.2010 and the last set on the 31.12.2010. The average time between case notes being audited and the individual's last attendance in clinic was 49.1 days.

Results

Of the 219 individuals identified, 46 were excluded from the study for reasons shown in ***figure 1***. 3 patients died during the course of the audit. The remaining 173 sets of notes were audited and those individuals who were HCV RNA viraemic were identified. The following results pertain only to those 113 individuals who were anti-HCV and HCV RNA positive.

Audit Standard 5: All HCV-infected patients should have documented evidence in their case notes of a discussion on alcohol avoidance and how to reduce the risks of transmission.

Figure 2 demonstrates those individuals who had documented evidence of these discussions within the last three years.

Audit Standard 9: All HCV RNA-positive patients should have an HCV viral load and genotype determination performed.

Figure 3 demonstrates the genotypes of those individuals identified as HIV/HCV RNA positive.

Audit Standard 11: All patients with chronic HCV should be offered an assessment of liver fibrosis by liver biopsy, hepatic elastography or other validated noninvasive fibrosis test.

For the assessment of fibrosis and the staging of liver disease, hepatic elastography has only been available on a limited basis locally since June 2010, therefore liver biopsy has been the standard assessment tool used during the audit period. Overall, 39% of individuals had either evidence of being offered a biopsy within the last three years in the case-notes or had a biopsy result documented on the laboratory results system since 1999 (45% for genotypes 1 and 4, 33% for genotypes 2 and 3). Of those offered a biopsy, ***figure 4*** shows the relevant uptake rates. 29% (n=33) of the total cohort had documentation in the medical notes indicating they appear clinically cirrhotic. Of those, only 21% (n=7) had been confirmed by biopsy.

Audit Standard 13: All HCV RNA-positive patients should be considered for treatment unless there is a specific contraindication.

Of the 113 RNA-positive individuals, ***table 1*** illustrates the breakdown of their combined experience of HCV treatment. For the 72 individuals who had no experience of HCV treatment, ***table 2*** details the documented reasons as to why it had not yet been attempted. Multiple reasons were cited in some sets of notes.

48 out of 72 individuals had discussion of HCV treatment in the notes with documented reasons as to why they had declined therapy to date. A number of relative contraindications were also examined (see text box). Of the whole cohort of 72 patients with no experience of treatment, 23 had no relative contraindication to treatment documented in the notes. Of the 48 individuals who had declined treatment, 19 did not have any relative contraindications noted. Therefore, 4 individuals had neither discussion regarding HCV treatment documented in the last three years and no relative contraindication noted.

Relative Contraindications to HCV treatment as per RIDU treatment protocol

- CD4<200
- Chaotic drug use/ongoing unsafe IVDU
- Uncontrolled psychiatric/psychological symptoms
- Pregnant or planning a pregnancy
- Excessive alcohol intake
- Poor attendance record
- Lack of practical or emotional support
- Severe thrombocytopenia
- Advanced or decompensated cirrhosis
- Malignancy
- Autoimmune disease
- Uncontrolled hypertensive or diabetic retinopathy

Figure 1: Individuals excluded from HIV/HCV co-infection audit

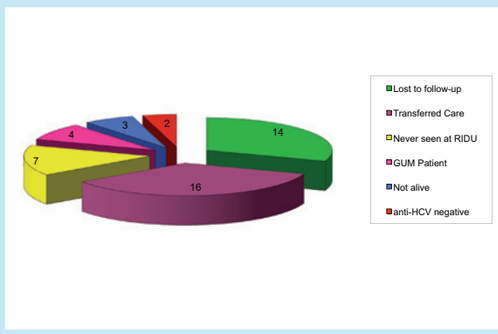

Figure 2: Percentage of patients with documented evidence of discussion within the last three years

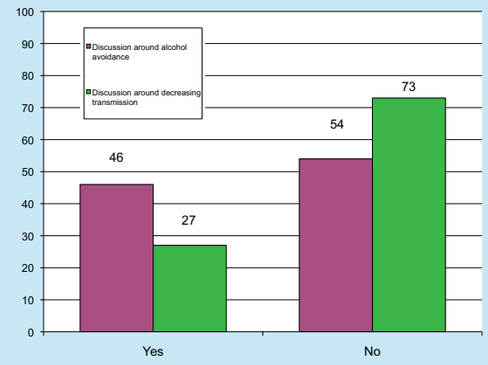

Figure 3: HCV RNA positive co-infected individuals by genotype (n=113)

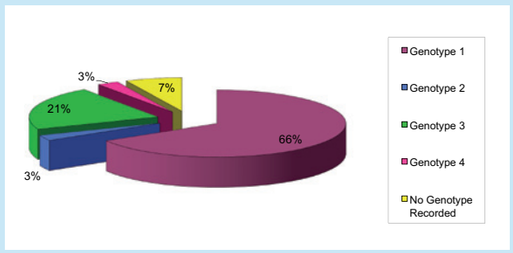

Figure 4: Percentage uptake for those HIV/HCV patients offered a liver biopsy by HCV genotype

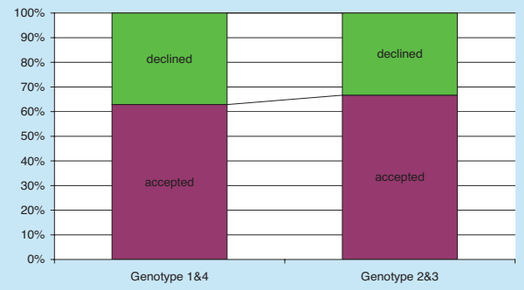

Table 1: The experience of HCV RNA-positive co-infected individuals of HCV treatment.

Experience of HCV treatment	Number of Individuals
Treated unsuccessfully in the past	21
On waiting list actively being considered/working up to treatment	12
Currently undertaking HCV treatment	8
No experience of HCV treatment to date	**72**

Table 2: Patient reasons for not wishing to pursue HCV treatment as recorded in clinical notes. Multiple reasons cited in some sets of case-notes.

Reason Documented	Number of References
Unknown/nothing documented	**24**
Worries regarding side effects and affect on quality of life	23
Wishes to postpone at present	12
Ambivalent/uninterested in treatment	10
Poor success rates with current treatment	9
Currently undergoing treatment for other condition	3
Reluctant to switch HAART	1
Awaiting CD4 count to rise	1

Discussion

The side effects associated with the current HCV treatment regime of pegylated interferon and ribavirin were the main reasons cited by patients for declining therapy. This is consistent with other studies which have looked at the factors influencing a decision to start HCV treatment (Osilla et al, 2009). There needs to be an awareness however, that individuals' attitudes, opinions and circumstances change. As the new drugs currently in development start to filter through to clinical practice, with the promise of increased SVR rates and shortened treatment times, these favourable factors may outweigh the significant side effect profile for a number of individuals. The topic of HCV treatment should therefore be revisited annually in clinic, and plans formulated to address obstacles to treatment, whether the individual is actively considering a course of therapy at that stage or not. Proactive management of other biopsychosocial issues which could hinder HCV treatment should be encouraged amongst clinicians in readiness for a period of therapy, so that when an individual does consent to treatment, any relative contraindications are already being addressed. The documentation of these discussions and subsequent plans of care are vital.

The confirmation of cirrhosis and staging of liver fibrosis have historically been poorly conducted within the unit. Approximately two thirds of those offered staging by biopsy in the past accepted however; therefore as hepatic elastography becomes more readily available locally the uptake of this non-invasive scan will hopefully improve these results. As more rapid progression of liver disease is frequently reported in this cohort (e.g. Macias et al, 2010), the repeated and regular use of staging tools should be a priority within this population to monitor progression of liver disease.

Conclusions

- The staging of liver disease has historically been poorly conducted within the unit. The arrival of hepatic elastography however should help to improve this. Clinicians have been made aware of the audit results to improve practice.
- 72 out of 113 HCV RNA positive co-infected individuals have no experience of treatment to date. Of these 72 individuals however, only 5.6% (n=4) have neither a discussion regarding HCV treatment and a reason for declining, or a relative contraindication documented in their notes.

References

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