Hepatitis delta in Scotland- epidemiology and patient characteristics

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Introduction

Hepatitis D virus (HDV) requires the presence of hepatitis B (HBV) for replication. It is transmitted sexually, through blood and perinatally, either at the same time as HBV (coinfection) or to an individual already infected with HBV (superinfection). There are estimated to be 15-20 million people worldwide infected with HDV[1]. There are 8 HDV genotypes which vary geographically.

HDV infection causes more severe liver disease than HBV mono-infection[2] and the only recommended treatment is pegylated interferon (EASL).

In 2012, there were an estimated 1283 HBV patients in tertiary care in Scotland [3]. Since 2011, all new HBV patients in Scotland or those suspected to have superinfection, are tested by real time polymerase chain reaction (PCR) at the Specialist Virology laboratory in Glasgow.

The aim of this study was to assess the prevalence of HDV in Scotland and determine patient characteristic of those diagnosed with HDV since 2011.

Scientific findings

- There are 30 patients in Scotland with detected HDV infection using PCR since 2011. 77% male and 23% female. Patients ages range from 22-62 (mean 37 years). The majority (10/30) are British, 4 African, 2 Asian and 9 Eastern European. No ethnicity was recorded in 5 cases.
- 5 patients are co-infected with HIV and 15 are HCV antibody positive with 3 being HCV PCR positive at the time of their last testing.
- 23/30 (74%) were HBVeAb positive (HBV VL range < log 1.8 - 3.5 IU/ml) and 5/30 (16%) were HBVeAg positive (HBV VL ranging from log 7 to 9.3 IU/ml). For 2 patients the e markers were not available.
- The median ALT and fibroscan scores were 118 IU/ml (n=25) and 12.2 KPa (n=15).
- The genotypes for 23 patients were obtained- 19/23 (82%) were genotype 1, and there was 1 of each genotype 2 (African), 3 (Chinese), 5 (unknown) and 6 (DRC).

Discussion

Around 2.3% of patients with HBV in Scotland are co-infected with HDV. This is comparable with figures for inner city London[4]. Most of these patients are either British born or from Eastern Europe. Half of those with HDV have a history of intravenous drug use; all those infected in the UK were IV drug users. 16% were also infected with HIV and 52% had evidence of current or past HCV infection. The majority are genotype 1 and those with the other genotypes are from outside the UK.

Treatment is recommended for patients with elevated ALT levels or evidence of liver fibrosis. A study in London showed that patients with co-infection had significantly worse laboratory parameters including higher ALT, AFP, INR, fibroscan score and low platelet count compared to those with HBV mono-infection[5]. 68% of our group of HDV+HBV co-infected patients had raised ALTs, and 60% had fibroscan scores in the cirrhotic range. Only 6 patients were known to have had or started treatment.
Conclusions

HDV is an ongoing problem in Scotland due to intravenous drug use and migration from endemic countries. As testing was only commenced routinely on new patients in Scotland in 2011 there may be more HBV patients who are undiagnosed. Most patients are infected with genotype 1 HDV. A significant number of these patients have biochemical and/or fibroscan evidence of liver inflammation or fibrosis. Because of the greater risk of liver disease with HDV & HBV coinfection, all newly diagnosed HBV patients and any patient with an unexplained rise in their ALT should be screened for HDV.
Hepatitis C in a Teaching Hospital Trust: translating diagnosis into treatment

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Introduction

In the rapidly evolving era of Direct Acting Antiviral (DAA) drugs with high cure rates for hepatitis C (HCV), there is an increasing imperative to diagnose chronic HCV infection, and to ensure that these individuals are referred to hepatology services to access treatment.

We set out to investigate diagnosis and referral of patients with HCV in our region, with three specific aims: (i) To quantify the number of new HCV diagnoses and to characterize the demographics of this cohort; (ii) To determine the specificity of our in-house screening assay; (iii) To determine what proportion of newly diagnosed individuals are referred and treated in the hepatitis clinic, in comparison with a similar investigation from 2008 (FIS poster 2013).

Scientific findings

We retrospectively collected data on new HCV diagnoses from January 2013 to June 2014. We recorded results of in-house antibody testing, reference laboratory confirmatory tests, patient demographic data, and the source of the test. We will continue to use the hospital PAS system to determine referral rates and data held by hepatitis clinic to identify which of these individuals have been treated to date.

Our key findings are as follows:

1. HCV-Antibody initial screening tests were positive in 327 of 19,275 samples (1.7%), of which 325 underwent confirmatory testing.
2. The majority of these 327 cases came from primary care (n=112), followed by secondary care (n=92), prison (n=82), GU medicine (n=30), and other sources (n=11; maternity, clinical trials and occupational health).
3. HCV-antibody was confirmed by the reference laboratory in 287/325 (89%).
4. The median age was 40 years (IQR: 32-49), and male gender strongly predominated (83%). HIV coinfection was present in 4 cases, and 3 individuals were positive for Hepatitis B (HBsAg).
5. PCR for HCV RNA was positive in 194/277 cases (70%). Among 76 cases that were genotyped, genotypes 1 and 3 predominated (35% and 51%, respectively).
6. Nineteen of 194 patients have commenced treatment to date. However, there will be more appointments pending and we are continuing data collection prospectively.

Discussion

Firstly, quantifying and characterizing the burden of HCV disease is important in order to assess the numbers of patients who will be eligible for treatment with DAAs. This study highlights the regional burden of chronic HCV infection, with 194 new cases of active infection diagnosed over 18 months, mostly affecting young/middle-aged males, and with significant representation in the prison population.

Secondly, this study contributes to quality improvement of our laboratory diagnosis of HCV, by comparing our results with the ‘gold-standard’ reference laboratory result. Our current assay performs with a specificity of 89%. Future work will focus on the identification of any factors that predict a false positive in-house test result.
Finally, we have started to address the question of what proportion of new diagnoses are seen in clinic. At present, <10% of these individuals have commenced treatment, but further prospective data collection is essential to complete the picture; this work will be ongoing over the coming months.

Conclusions

As the DAAs remove some of the previous barriers to HCV treatment, there is a need for education of health-care workers to ensure HCV testing of individuals with risk factors and/or with clinical evidence of hepatitis, and to highlight the importance of following up a diagnosis with referral to hepatology clinic so that patients can access potentially curative treatment. Microbiology laboratories and infection/microbiology clinicians can play an active role in this process.
Latent TB screening in a viral hepatitis clinic at Birmingham Heartlands Hospital

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Introduction

The prevalence of tuberculosis remains high in the UK compared to other Western European countries with the greatest proportion of cases occurring within London (39%) and the West Midlands (12%). The majority of cases occur in non-UK born patients. Reactivation of latent TB (LTB) rather than acute primary infection is the cause of most cases of active TB in the UK. NICE guidelines from 2011 recommend screening new entrants aged 16-35 years from high incidence countries (incidence greater than 40/100,000) with either an interferon-gamma release assay (IGRA) test alone or in combination with a tuberculin skin test. Screening patients aged over 35 years is recommended if the benefit of treatment outweighs the risk. Studies suggest screening with an IGRA in high risk patients can identify greater than 90% of LTBI, and is more cost effective than a mantoux test and chest x-ray.

Scientific findings

Systematic screening for LTBI had not previously been performed at our viral hepatitis clinic. Our aim was to screen patients with either a quantiFERON-TB Gold or T-SPOT test if aged between 16-50 years and with a history of significant TB exposure history (lived in a country with an incidence of greater than 40/100,000 or prison sentence in last five years).

13 of 29 patients met the criteria for screening in July 2014. The mean age of the screened patients was 38 (range 21-49). 11 patients were born in or spent considerable amounts of time in a high prevalence country. 2 patients had been discharged from prison within the last year, 1 of which also injected drugs. 5 of the screened patients (38%) had a positive QFT or T-SPOT; they originated from Pakistan, Cameroon, Somalia and Vietnam, with a mean age of 44 (range 30-49). All the patients with positive tests were subsequently counselled of their risk of future TB disease and offered preventative treatment.

Discussion

Pegylated interferon and ribavirin used for treatment of hepatitis C can have an immunosuppressive effect which can increase the likelihood of active disease in a patient infected with LTB. We chose to screen up to age 50 as the benefit of preventative therapy is greater in patients embarking upon immunosuppressive drugs. The decision of whether to treat a patient co-infected with hepatitis and LTBI can be difficult especially if the patient has a transaminitis at baseline. The risk of drug induced hepatitis from the TB medication needs to be considered alongside the perceived benefits.

Conclusions

This small study suggests that there exists a high burden of LTBI in the viral hepatitis clinic, and in this cohort they are at greater risk of reactivation. Therefore screening for LTBI is worthwhile and screening policies should be reinforced for all patients seen within this clinic to decrease the possibility of active disease. The screening is ongoing and more data will be available in time for presentation at the FIS conference 2014.
Audit of management of hepatitis B in pregnancy in Cardiff and Vale 2008-2013

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Introduction

Hepatitis B infection can be transmitted from infected mothers to their babies at or around the time of birth (perinatal transmission). Babies acquiring infection at this time have a high risk of becoming chronically infected with the virus. Transmission can be prevented in over 90% of cases by vaccination and administration of immunoglobulin when appropriate. Latest EASL guidelines recommend treatment with directly acting antiviral agents for mothers with very high viral loads (>10^6 IU/ml), as the risk of transmission is high in this group despite vaccination and administration of immunoglobulin. Studies demonstrating this have mostly been carried out in Asia and may not reflect the risk of transmission in the UK. The audit was designed to define the risk of transmission of Hepatitis B in Cardiff between mothers with a high viral load (preferably tested during late stage pregnancy) and their infants (as defined by hepatitis B sAg status).

Scientific findings

A retrospective audit of the management of hepatitis B infection in pregnancy in the Cardiff and Vale area between 2008 and 2013 was carried out. Data on 139 mother and infant pairs was analysed.

The key findings of the audit were as follows:

- Maternal viral loads were often not requested (40%) or requested remotely from the time of pregnancy (19%)
- Vaccination of infants was appropriately carried out in the majority of cases (95%)
- Immunoglobulin was administered to all infants in whom it was indicated
- Blood testing of infants for evidence of transmission was carried out in only 28% of cases.
- Blood testing of infants for evidence of immunity was carried out in only 38% of cases
- Testing for both transmission and immunity occurred in only 11% of cases

Discussion

The rate of transmission of hepatitis B in mothers with high viral loads in Cardiff from 2008-2013 cannot be reliably determined because of a lack of data. Testing of infants born to mothers with hepatitis B for evidence of transmission and immunity needs to be improved. This element of follow up is currently being investigated and a new plan for follow up is due to be instigated. Vaccination (95%) and immunoglobulin (100%) were appropriately administered in the majority of patients.

Conclusions

The rate of transmission of hepatitis B in mothers with high viral loads in Cardiff from 2008-2013 cannot be reliably determined because of a lack of data. Testing of infants born to mothers with hepatitis B for evidence of transmission and immunity needs to be improved. Vaccination (95%) and immunoglobulin (100%) were appropriately administered in the majority of patients. This audit should be repeated once follow up arrangements for children born to mothers with hepatitis B have been improved.
Spontaneous clearance of chronic hepatitis C virus infection in a Scottish cohort

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Introduction

Hepatitis C virus (HCV) is a blood borne virus which causes both acute and chronic hepatitis. Chronic HCV infection (CHC) develops in around 75% of people who acquire HCV, and is defined as viral persistence beyond six months post exposure. Spontaneous clearance of CHC is very rare, and is poorly characterised. Case reports have described late clearance in association with superinfection with other hepatotropic viruses, following the withdrawal of immunosuppressive medication, and following surgery, parturition or the development of hepatocellular carcinoma. Host factors including gender, immune response and genetics may also be important.

We conducted a retrospective case note review of patients attending Glasgow hospitals who experienced spontaneous HCV clearance after six months' confirmed infection. Main demographic and clinical patient characteristics were recorded together with haematologic, biochemical and viral laboratory variables. Duration of infection was calculated as the interval between first positive and last positive HCV RNA.

Scientific findings

Data was obtained from the West of Scotland specialist virus laboratories on HCV testing between 1994 and 2013. 1698 patients had a minimum of 2 sequential samples positive for HCV RNA ≥ 6 months apart, followed by ≥ 1 negative test for HCV RNA. 1630 patients had evidence of prior treatment and were excluded. A further 18 patients were excluded following case note review leaving 50 patients of interest. 27 of these patients went on to have at least 1 further negative HCV-RNA test confirming clearance.

62% of the cohort were female, with a mean age of 43 years. The majority of patients were white (96%) and the major risk group for HCV acquisition was IDU (80%). Comorbid alcohol excess was common (40%).

Testing for hepatitis B virus (HBV) was performed in 48 of the 50 patients; 5 patients were coinfected with HBV. HIV testing was performed in 72%; 2 patients were infected with HIV at HCV diagnosis. No patients were superinfected with hepatitis delta.

HCV genotyping was performed in 17 patients. Genotypes 1 and 3 were equally distributed (7 patients vs 9 patients respectively). 1 patient had genotype 2 infection. Only 1 patient had IL28B genotyping performed; this person carried the IL28B CC genotype.

The average duration of infection prior to spontaneous clearance was 44 months. Clearance of CHC was associated with liver decompensation (n=5), parturition (n=4), acute HBV infection (n=2) and major surgery (n=1) (i.e. events of significance occurred between last positive and first negative HCV RNA).

Discussion

In our cohort of patients accessing care in Glasgow centres, we have identified 50 patients who spontaneously cleared chronic HCV infection over a period of 19 years' follow up. Our study largely supports previous reports concerning the characteristics of late spontaneous clearers.

Our study has several limitations. The design is observational and retrospective and therefore must be interpreted with caution. Over the course of follow up there were a number of changes to clinical protocols and laboratory methodologies, presenting issues with unsystematic data collection and laboratory
reporting. A major limitation concerns the inconsistent approach to both viral and IL28B genotyping which reflects the changing advice from clinical guidelines and availability of technology over time.

It is likely that we underestimated the duration of infection, as patients were identified as having been at risk of exposure many years before they were tested. Also, for many patients there was a considerable duration between the last positive and the first negative HCV PCR, making it difficult to ascertain the true date of clearance.

As the definition of clearance required only 1 negative HCV RNA we may have misclassified patients with low level viraemia as spontaneous clearers. The sensitivity of the quantitative HCV RNA assays varied over the course of follow up and earlier samples may have been more likely to be falsely negative. Furthermore, follow up of patients with presumed late spontaneous clearance was poor; only 60% of patients had follow up HCV-RNA testing performed at any time point to confirm clearance.

Conclusions

This is the largest cohort of patients with evidence of spontaneous clearance of CHC studied to date. Our data suggests that late spontaneous clearance is more common in females, and that previously described factors including superinfection with other hepatotropic viruses may be relevant. Follow up of patients with late spontaneous clearance and testing for HIV co-infection was poorly performed, highlighting a need for physician re-education in Glasgow. Of note, late spontaneous clearance may occur after a prolonged duration of infection suggesting that more regular serum HCV-RNA monitoring of patients with CHC may be warranted.
Prevalence of chronic hepatitis E in HIV and HSCT patients

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Introduction

Autochthonous hepatitis E is being identified increasingly frequently in the UK and other developed countries. In immunocompetent individuals, it is usually a self-limiting illness comprising jaundice, myalgia and flu-like symptoms. Chronic hepatitis E in immunocompromised patients including solid-organ transplant recipients, haematological patients and patients with HIV is now being identified more frequently. Chronic infection has been shown to result in cirrhosis and occasionally liver failure.

Two groups of immunocompromised patient were studied retrospectively.

1) All patients with elevated transaminases on 2 haematology wards post-BMT at the Beatson Oncology Centre, Glasgow

2) All HIV patients with elevated transaminases seen in outpatients at the Brownlee Centre, Infectious Diseases Unit

All patients who had either plasma or serum samples sent to WOSSVC during the period of biochemical hepatitis were identified. Samples underwent nucleic acid extraction by the BioMerieux Nuclisens EasyMAG. The extracts were then tested for HEV RNA using an in-house RT-PCR.

Scientific findings

1) BMT patients
Fifty-seven patients with elevated liver enzymes following bone marrow transplant were identified. Of these, 40 patients (70%) had blood samples sent to WOSSVC for other testing during the period of hepatitis, 36 of these samples were available at the time of the study. Four were excluded as they had been previously tested for HEV RNA at time of presentation and 32 samples were included in the study. Of the 4 that had been tested previously, 1 had been positive for HEV RNA. All 32 samples tested by RT-PCR were negative for HEV RNA. The incidence of Hepatitis E in this population was 1/36 (2.8%).

2) HIV patients
One hundred and ninety-six patients with elevated transaminases were identified. Of these, sixty eight patients (35%) had blood samples sent to WOSSVC for other testing during the period of hepatitis which were available at time of testing. All 68 patients were negative for HEV RNA. In this patient group, hepatitis E IgG and IgM were also tested. 1/68 patients (1.5%) were found to be seropositive for hepatitis E.

Discussion

In our population of haematology patients, hepatitis E prevalence was 2.8% which is comparable with previously reported prevalence of hepatitis E in this group. In this population of patients with HIV, there were no undiagnosed cases of hepatitis E and seroprevalence of IgG was low.

Conclusions

Our data shows that raised LFTs are a common finding in HIV positive and HSCT patients. Despite increasing reports of chronic HEV in the literature, we failed to detect any cases of chronic HEV in our
two cohorts. Clinicians should remember to request HEV RNA testing in any immunocompromised patient with raised LFTs as it is useful for differentiating HEV from other infectious and non-infectious causes of hepatitis.
'HCV treatment in a real world setting'. Audit of hepatitis C virus genotype 1 treatment and outcomes at University Hospitals of Leicester (UHL) 2012-2014

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Introduction

The approval by NICE in March 2012 of novel protease inhibitors (PIs) telaprevir and boceprevir offered new hope for patients who had failed to achieve sustained virological response (SVR) with pegylated interferon alpha (PegIFN) and ribavirin based dual therapy. Telaprevir became available at UHL in May 2012 and boceprevir in July 2013; whence they were introduced according to nursing and medical capacity.

The main aims of this project were to audit treatment activity against EASL (December 2013) recommendations and compare to previous audits, to determine treatment outcomes and to improve the understanding of the costs of treatment locally.

The audited population consisted of all patients with chronic HCV GT1 infection offered treatment in the nurse led clinic at University Hospitals of Leicestershire (UHL) between April 2012 and April 2014. Data were collected from the local treatment database, patient case notes and the laboratory IT system.

Scientific findings

Outcomes

48/49 treatment episodes in 47 patients were audited. 15 patients commenced dual therapy, 28 telaprevir-based and 5 boceprevir-based ‘triple’ therapy with PI, PegIFN and ribavirin.

3/15 (20%) patients on dual therapy achieved rapid viral response (RVR) whereas 28/32 (88%) on PI-based regimens achieved RVR. 14 patients achieved SVR at 24 weeks (SVR\textsubscript{24}), 23 patients await SVR tests.

EASL (December 2013) recommendations regarding pre-treatment assessment, choice of regimen, monitoring on treatment, application of response guided therapy (100%), adherence support, treatment support, follow-up, co-infection (100%) and renal disease (100%) were followed 90-100% of the time with the exception of baseline fibrosis assessment (42%), Child-Pugh score (3/6), low baseline HCV RNA threshold of 400,000 IU/mL (8/10), treatment delivery in MDT setting (50%), counselling on the importance of adherence (71%), offer of social support services (2/15), drinkers counselled to abstain from alcohol (12/22, 55%), if history or signs of depression, offered prior psychiatric assessment (10/22, 45%) and non-cirrhotic patients with SVR\textsubscript{24} being offered HCV RNA and ALT at 48 weeks (0/14). Overall these results represent an improvement when compared to a previous audit in 2011.

4 hospital admissions related to therapy occurred, one with life-threatening hypoglycaemia and renal failure.

Costs (excluding pathology costs and medical time)

For patients who completed planned treatment courses, mean cost per patient was £10,400 for dual (n=12), £27,000 for telaprevir-based (n=21) and £17,700 for boceprevir-based therapy (n=2). Mean cost per patient who did not complete therapy (n=10) was £9,500.
Discussion

The audit period covered a transition period for the UHL nurse-led liver clinic during which new treatment options were being introduced, and dual therapy for HCV GT1 was being phased out.

The EASL guidelines used as the standard in this audit were only published towards the end of the audit period, providing robust if tough standards against which to measure activity. In the majority of cases treatment was administered according to those guidelines. Where it appeared not to, this was felt to be due to a lack of appropriate documentation in several instances (e.g. counselling regarding the importance of adherence and abstinence from alcohol).

Protocols have been amended to recommend fibrosis assessment and ultrasound scan for all patients prior to commencement of therapy. A treatment MDT consisting of a nurse, a medic and a pharmacist was formally established during the audit period. Nursing paperwork has been improved to include documentation regarding alcohol and adherence counselling. In the interests of resource management it was decided to ask GPs to perform the final SVR48 HCV RNA test.

Psychiatric and psychology services are limited at UHL and MDT discretion is asserted in the use of this scarce resource. Social services support is not forthcoming, despite referrals.

Compared to the previous audit in 2011, patients had received better rates of referral to a psychiatrist prior to treatment, liver disease screening was completed in more patients, fewer were consuming large volumes of alcohol when referred for treatment and DNA rates were reduced using text reminders.

Conclusions

Patients were offered therapy according to the latest European guidelines in the majority of cases, including for renal and co-infected patients. Protocols have been amended where appropriate aiming for continual service improvements.

Costs of treatment are significant and increasing, including for patients who do not complete therapy. Interferon containing regimes have a hidden cost of hospital admission for some. PI-based therapy requires intensive nursing, medical, psychiatric and pharmacist support.

Treatment of HCV is evolving at a rapid pace and clinic staff must stay abreast of changes, in an era of limited resources, to offer patients the best possible care.
A rash diagnosis of hepatitis

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Introduction

Chickenpox (primary varicella zoster virus infection) is a classic clinical syndrome that presents with a characteristic rash. Whilst infection in childhood is usually mild, chickenpox in adults can run a more serious course. Pneumonitis is a recognised feature of chickenpox infection in adults and other organs may be involved in immunosuppressed patients. We present a case of varicella zoster hepatitis in an immunocompetent patient, an unusual presentation that led to diagnostic confusion.

Scientific findings

40 year old male presented with severe right upper quadrant pain, raised ALT of 808, weakly positive monospot and atypical lymphocytes on blood film. Abdominal imaging revealed splenomegaly and fatty liver. 48 hours into hospital admission a widespread rash, maculopapular later pustular, developed. He had no history of chickenpox. EBV capsid IgM was equivocal (IgG negative), EBV DNA negative. VZV IgG was negative. VZV DNA was detected in blood. HBsAg, HCV antibody, HAV total antibody, HEV IgM and IgG, CMV IgM and IgG and DNA were all negative. He was treated with oral aciclovir. His ALT normalised to 42.

Discussion

Although pneumonitis caused by varicella zoster virus primary infection in adults is a well-recognised systemic consequence, hepatitis is rarely encountered in immunocompetent patients. The presentation with acute hepatitis preceding the onset of the rash led to initial diagnostic confusion and weak positive monospot led to a diagnosis of EBV glandular fever. The vesicular skin lesions of chickenpox manifest during the second viraemic phase of the illness. This patient’s hepatitis may have been due to the initial viral replication prior to this phase. The delayed diagnosis of chickenpox led to a delay in isolating this patient appropriately.

Conclusions

This was an unusual presentation of chickenpox in an immunocompetent adult. The non-itchy and somewhat atypical features of the rash, hepatitis and initial positive monospot result prior to rash onset delayed the clinical diagnosis.