

Clinical and laboratory correlation of a screening reactive Hepatitis A IgM antibody

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Background

- Hepatitis A is an infection of the liver caused by hepatitis A virus (HAV).
- The disease is generally mild, but severity tends to increase with age.
- Asymptomatic disease is common in children. Rarely fulminant hepatitis A can occur.
- Jaundice may occur in 70–80% of those infected as adults.
- Hepatitis A infection acquired in the UK may either present as sporadic cases, as community-wide outbreaks resulting from person-to-person transmission or, uncommonly, as point of source outbreaks related to contaminated food

Aims and objectives

- Audit will investigate if the screening IgM HAV antibody detection represents evidence of acute or recent infection with HAV.
- Audit will correlate clinical conditions that are associated with a low level IgM HAV antibody detection in the screening assay.

Test Standard

Pennine Acute NHS Trust : Clinical virology MC-SOP-168
 IgM HAV (S/CO <0.80) = Non Reactive
 IgM HAV (S/CO 0.8 to 1.2) = Equivocal
 IgM HAV (S/CO >1.2) = Reactive

Local standard of clinical virology practice involves further classification as follows

IgM HAV (S/CO >1.2 to 3.0) = Reactive (low level detected)
 IgM HAV (S/CO >3.0) = Reactive (high level detected)

National Standard

Hepatitis A IgM assay REACTIVE

References:
 UK Standards for Microbiology Investigations | Issued by the Standards Unit, Public Health England. Virology | V 27 |
 Issue no: 3 | Issue date: 12.05.14
 PHE: Public health control and management of hepatitis A - 2017 Guidelines

Serology index and clinical picture in keeping with diagnosis of acute HAV infection

REPORT: DETECTED - Consistent with recent HAV infection

Serology index and clinical picture not in keeping with diagnosis of HAV infection

REPORT: DETECTED - Does not suggest recent HAV infection. Probably non-specific IgM reactivity

Methods

All patients investigated during the period April 2015 - April 2018 at the microbiology department in Pennine Acute NHS Trust and found to have an equivocal or reactive HAV IgM antibody were included in this audit. The screening IgM HAV antibody assay is tested using the Abbott Architect i2000 which uses a signal to cut-off ratio (S/CO) to report as not reactive, equivocal or reactive. The patients with these results were divided into two groups as follows:

Group I = 28 patients

Equivocal (S/CO of 0.8 to 1.2) & low level detected (S/CO of 1.2 to 3.0) for IgM HAV antibody

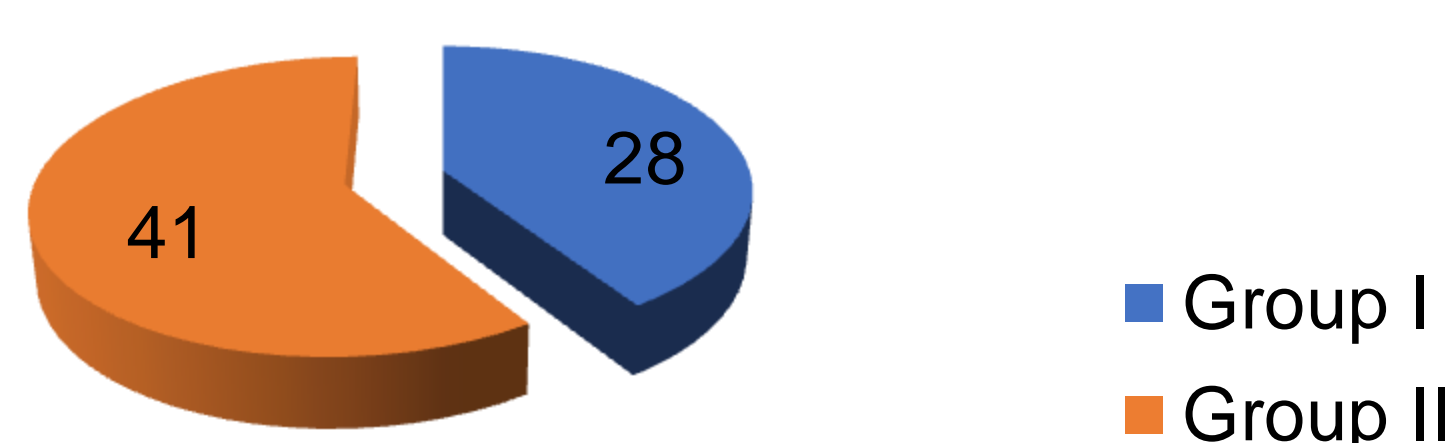
Group II = 41 patients

Detected at high level IgM HAV antibody (S/CO of >3.0)

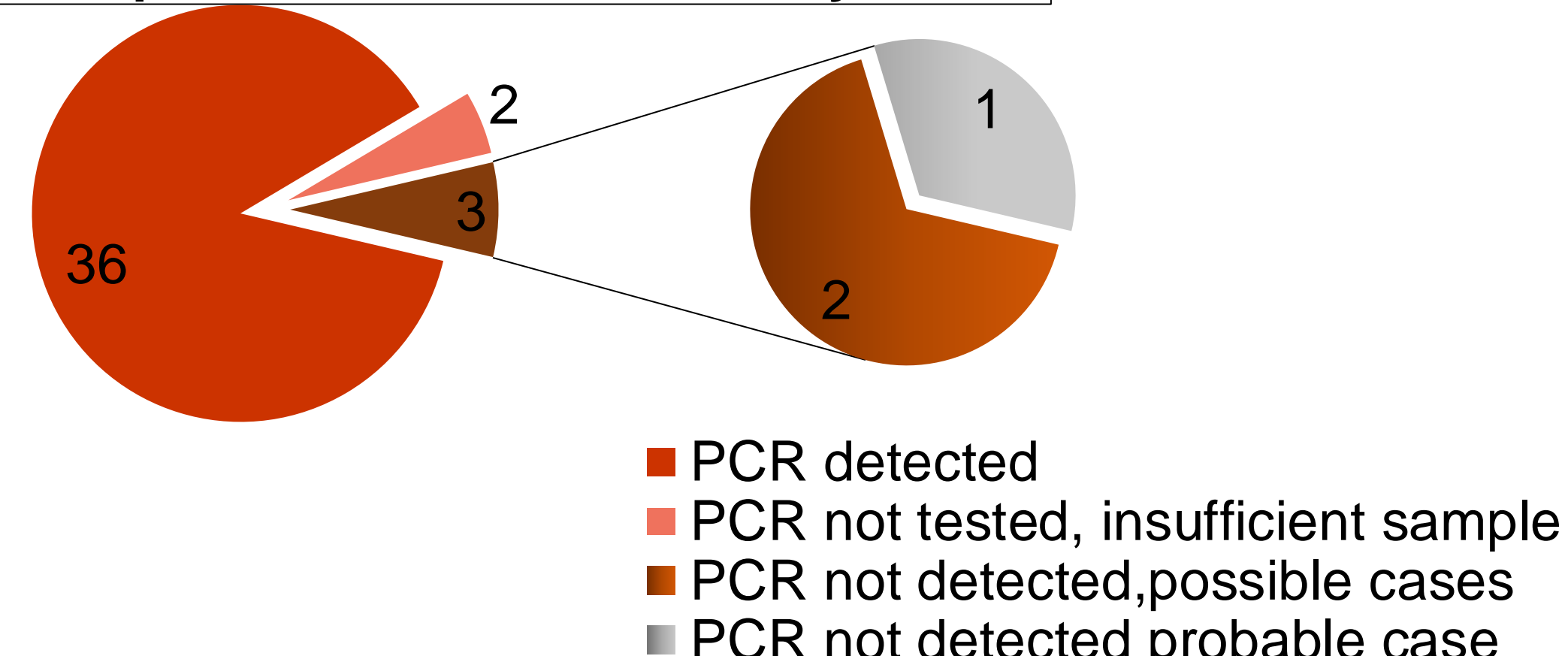
Results

- A total of 69 patients were screening test reactive for HAV IgM antibody: 28 patients belonged to Group I and 41 patients belonged to Group II.
- All patients' blood samples were sent to the Reference lab for confirmation of IgM antibody and further HAV RNA PCR and genotyping as per the reference laboratory protocol.

Results of screening Hepatitis A serology

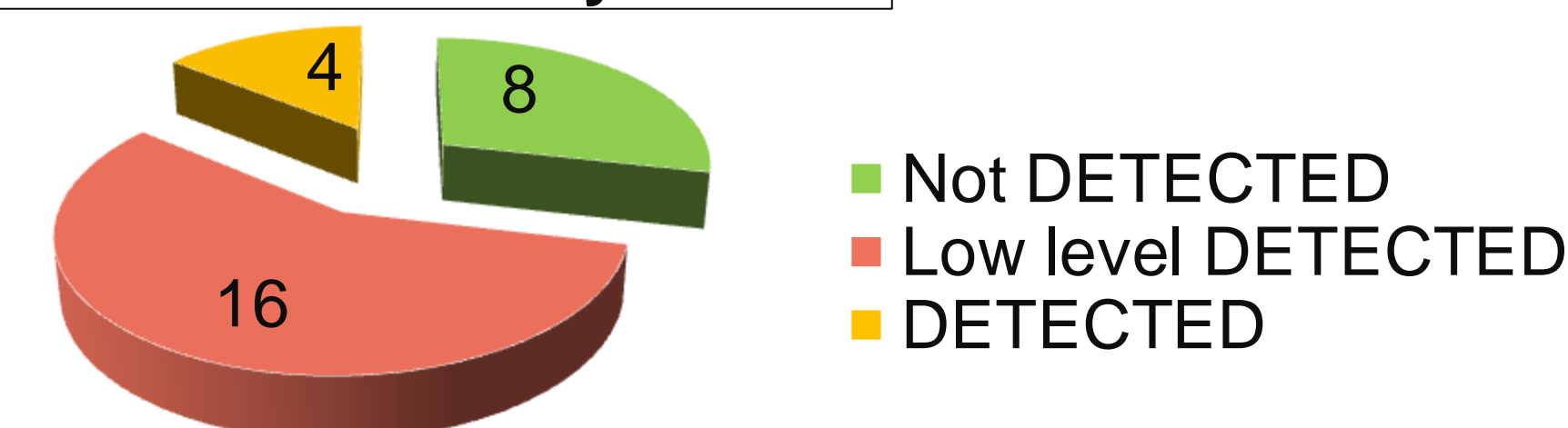


Group II - Reference Laboratory Result



Overall, **40/41 (~98%)** patients had acute hepatitis A infection confirmed either by a combination of epidemiology and clinical features or by the reference laboratory

Group I - Reference Laboratory Results



Overall, **3/28 (~10%)** patients had acute hepatitis A infection confirmed by the reference laboratory

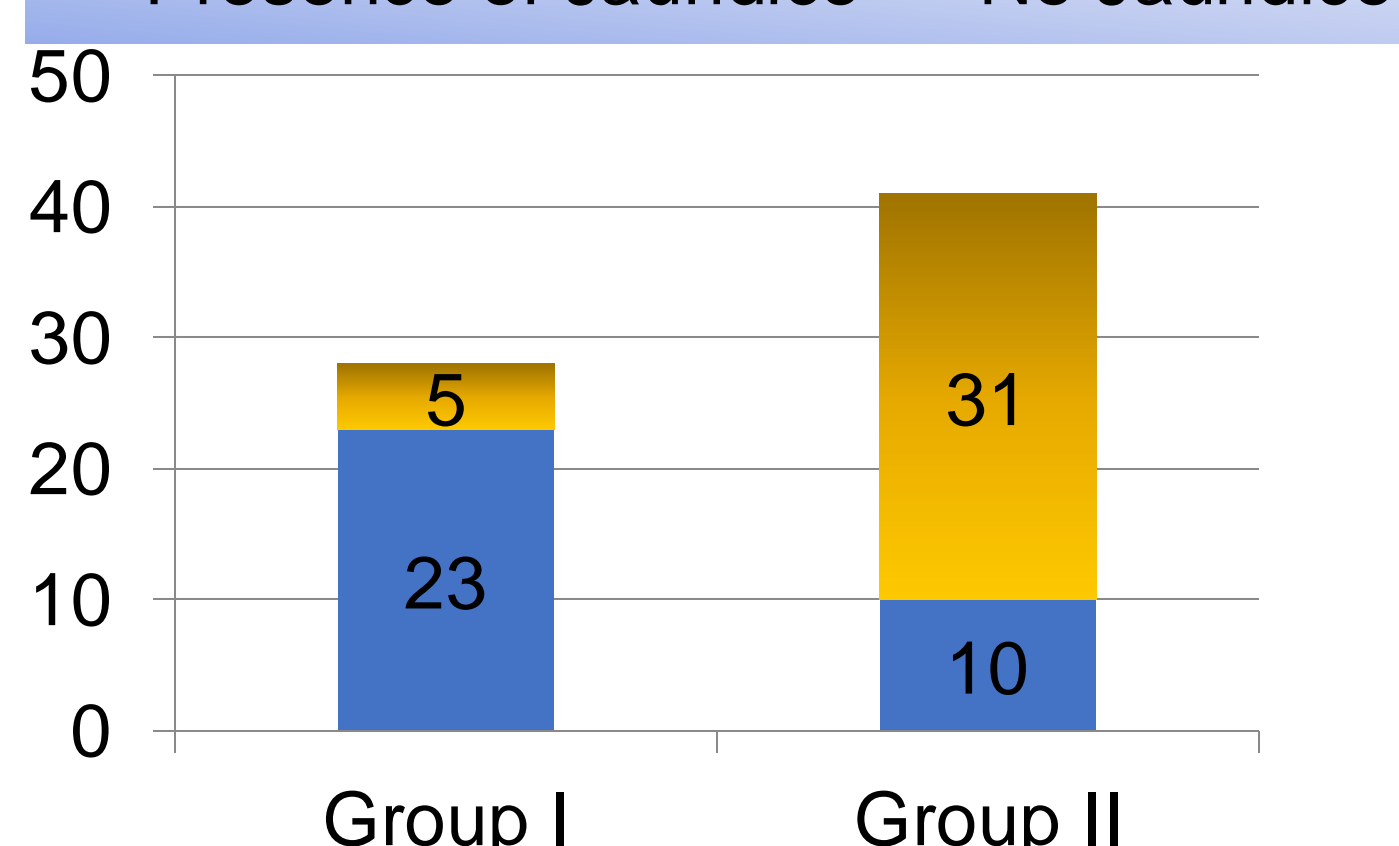
Of the Group I patients, 5/28 (18%) had jaundice as a presenting symptom.

Of the Group II patients, 31/41 (76%) had jaundice as a presenting symptom

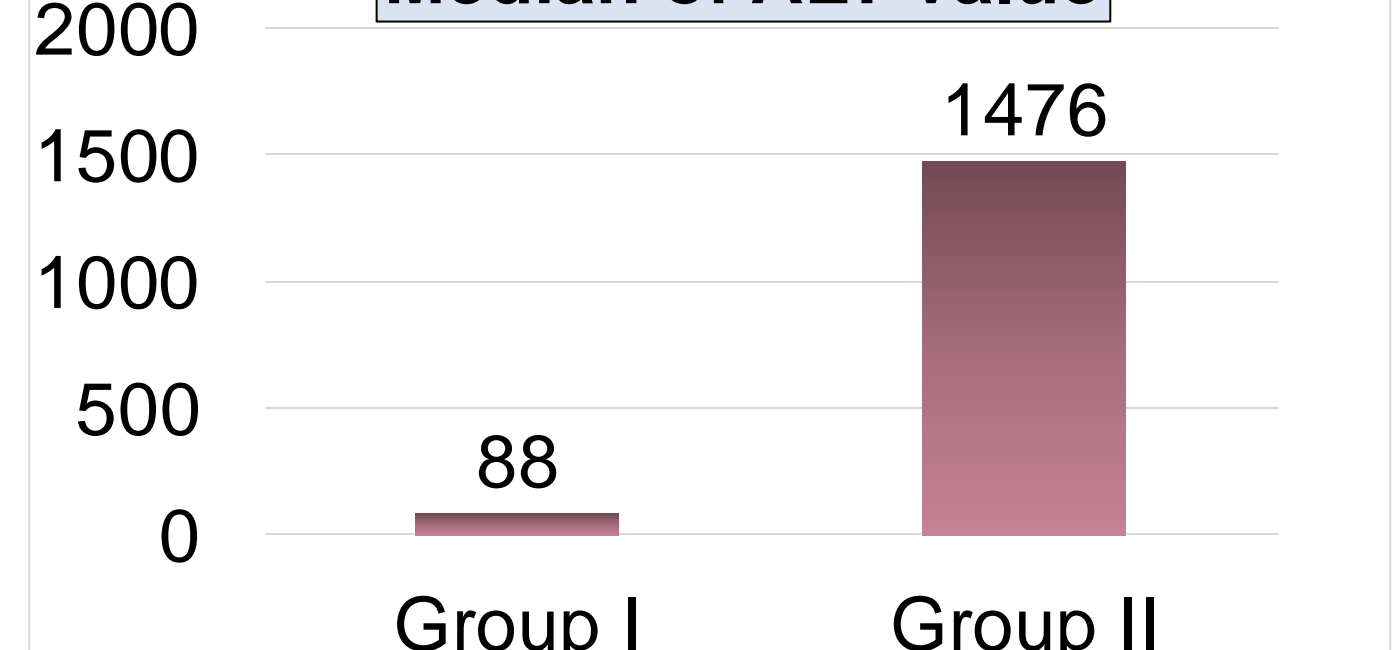
Of the Group I patients, ALT ranged from 20 to 3970 IU/ml with a median of 88 IU/ml

Of the Group II patients, the ALT ranged from 107 IU/ml to 6362 IU/ml with a median of 1476 IU/ml

Presence of Jaundice



Median of ALT value



Conclusions

- Patients in Group II had confirmed diagnoses of acute hepatitis A infection in **40/41 (~98%)** of patients which was confirmed either by a combination of epidemiology and clinical features or by the reference laboratory. One patient was found to have a false positive hepatitis A IgM
- Patients in Group I had a possible alternate clinical diagnoses in a significant number. A small proportion **3/28 (~10%)** of patients had a final diagnosis of acute hepatitis A infection that was confirmed by the reference laboratory.
- Screening reactive Hepatitis A IgM with an equivocal, low level or high level detected result did not show any significant difference in relation to age or gender.
- Jaundice was seen more likely in patients who were finally confirmed as acute hepatitis A infection in comparison with those not having acute hepatitis A - Group I (18%) in comparison to Group II patients (76%).
- ALT was definitely raised in the Group II in comparison to Group I.

Recommendations for Group I

HEPATITIS 'A' SEROLOGY COMMENT: The screening hepatitis A serology result is NOT highly suggestive of an acute hepatitis A infection. If patient has clinical and biochemical evidence of acute hepatitis, please send a repeat sample for a full viral hepatitis screen. Confirmatory reference lab results of this sample to follow. Please contact microbiology to discuss further, if needed.

Recommendations for Group II

HEPATITIS 'A' SEROLOGY COMMENT: The screening hepatitis A serology result is (highly) suggestive of an acute hepatitis A infection. If patient has clinical and biochemical evidence of acute hepatitis, please send a repeat sample for confirmation and notify Greater Manchester Health Protection Team. Confirmatory reference lab results of this sample to follow. Please contact microbiology to discuss further.