



## **Profile of Autoimmune Hepatitis in a Tertiary Care Hospital- A Retrospective Study**

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## Introduction

Autoimmune hepatitis (AIH) is an unsolved, unknown cause of hepatocellular inflammation categorised by the occurrence of periportal hepatitis or piecemeal necrosis on histology, liver associated autoantibodies in serum and hyper gamma globulinemia. (1) Though its etiology is unknown, its pathogenesis is partially based on abnormal autoreactivity. The classical phenotype have been categorised by serological markers, mainly antinuclear antibodies (ANA), smooth muscle antibodies (SMAs), and antibodies to liver kidney microsome type1 (anti-LKM1s), irrespective of association with anti-liver cytosol type 1 antibodies, hypergammaglobulinemia, increased serum immunoglobulin (IgG) levels, interface hepatitis on histological investigation, and corticosteroid therapy responsiveness. (2-4)

As limited data is available on epidemiology of AIH. Prevalence of AIH in Western and North America lies between 15 to 200 cases per 1 million people. (5) Still, AIH is considered rare in Asia due to major burden of chronic viral hepatitis. (6) Around 5% prevalence among all patients with chronic liver disease has been reported by Indian studies. (7-13) Clinically it differs from acute severe presentation, mild inflammatory, autoantibody negative disease and atypical histology and overlap syndromes.

Trials published in 1970 stated that AIH have been the first chronic liver disease to respond to corticosteroids. (14) Later, azathioprine and various other immunosuppressants has been shown to have significant result in changing the natural history of the disease. [15-17] In decompensated AIH associated cirrhosis, liver transplantation is the most effective treatment, with five year survival rates accounts from 83-92% and usually offered treatment in western countries. (18) Early diagnosis, appropriate treatment with immunosuppressants and management of cirrhosis forms the core of treatment in India. Among patients with chronic liver disease, liver transplantation as a treatment modality is low in India. (19) However as there is increasing awareness of AIH, data relating to long term outcome is limited. So our objective was to evaluate the profile of AIH and its treatment outcomes in patients.

## Methodology

A retrospective study was conducted to assess the profile of AIH and its treatment outcomes in diagnosed long-term AIH patients from January 2017 to May 2023. Autoimmune hepatitis had been diagnosed according to the criteria of the International Autoimmune Hepatitis Group and categorized as being definite or probable.<sup>2</sup> This study was approved by Institutional review board. Data was assessed from the records of patients who had been diagnosed and treated as autoimmune hepatitis during the mentioned period. 61 patients fulfilled the AIH International Study Group criteria and were included in the study. Patients who have not fulfilled the

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International Autoimmune Hepatitis Group criteria were excluded.

Data such as demographic, sign & symptoms, co-morbidity, laboratory investigations, histological investigations, Antibody positivity, treatment outcomes, follow up duration, mortality and remission were collected. Laboratory investigations included Hb, TLC, platelet, creatinine, Total Bilirubin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), ALP, Albumin, Globulin, PT and IgG. Serological tests for autoimmune autoantibodies included anti-nuclear antibodies (ANA), anti-smooth muscle antibodies (ASMA), anti-smooth muscle fibres and anti-liver kidney microsomal types I (anti LKM1) antibodies, both ANA & ASMA and AMA. Hepatitis B surface antigen (HBsAg) was tested in each patient. Histological parameters included portal infiltrates; liver necrosis, such as focal (spotty) lyticnecrosis and periportal or periseptal interface hepatitis (piecemeal necrosis); confluent necrosis; bridging necrosis and submassive necrosis. Treatment given was categorised in to immunosuppressant, steroids and others.

SPSS v. 20 was used for the statistical analysis. Kolmogorov-Smirnov test was used for Normal distribution of data. Categorical data were expressed in the form of frequencies and percentages, while continuous data as mean and standard deviation. For categorical data, chi-square and fisher exact test were applied as necessary while for continuous data, independent t- test or Mann Whitney test were performed on the basis of normal distribution of data.  $P < 0.001$  was considered statistically significant.

## Result

Demographic, clinical, biochemical profile, treatment and mortality of AIH –

The mean age of AIH patients was  $48.49 \pm 13.70$  years while Type I AIH found to be the most common AIH type. Over all mean time for remission in AIH patients was to be  $10.91 \pm 5.664$  months. Demographic, clinical, biochemical profile, treatment and mortality of AIH patients enrolled in the study is described in Table 1.

### Symptoms and signs of AIH

Abdominal pain were the common symptom present in 27.8% patients followed by jaundice and vomiting in 5 patients. Rest symptoms described in table 2.

In signs of AIH, Icterus was the most common signs in 50.8% of patients followed by abdominal distension in 9 and weight loss in 6 patients. Signs of AIH presented in table 2.

| <b>Variables</b>   | <b>Results</b>              |
|--|-----------------------------|
| <b>AGE</b> (Mean $\pm$ Standard Deviation)                       | 48.49 $\pm$ 13.70           |
| <b>Sex</b> N (%)   |                             |
| Female   | 45 (73.8%)                  |
| Male   | 16 (26.2%)                  |
| <b>Type of AIH</b> N (%)   |                             |
| AIH 1  | 57 (93.4%)                  |
| AIH 2  | 4 (6.6%)                    |
| <b>Laboratory Investigations</b> (Mean $\pm$ Standard Deviation) |                             |
| HB   | 11.103 $\pm$ 1.788          |
| TLC  | 8792.31 $\pm$ 5899.861      |
| PLATELET   | 220639.344 $\pm$ 142195.761 |
| CREATININE   | 0.8230 $\pm$ 0.84701        |
| TOTAL BILIRUBIN  | 9.6274 $\pm$ 9.91737        |
| ALT  | 244.21 $\pm$ 368.5289       |
| AST  | 278.59 $\pm$ 383.442        |
| ALP  | 156.79 $\pm$ 107.714        |
| ALBUMIN  | 3.1885 $\pm$ 0.68120        |
| GLOBULIN   | 3.3211 $\pm$ 1.10665        |
| PT   | 16.198 $\pm$ 4.4881         |
| IgG TOTAL  | 2040 $\pm$ 846.968          |
| <b>HbsAg</b> N (%)   |                             |
| NEGATIVE   | 56 (91.8%)                  |
| POSITIVE   | 5 (8.2%)                    |
| <b>ANA</b> N (%)   |                             |
| NEGATIVE   | 7 (11.5%)                   |
| POSITIVE   | 54 (88.5%)                  |
| <b>ASMA</b> N (%)  |                             |
| NEGATIVE   | 31 (50.8%)                  |
| POSITIVE   | 30 (49.2%)                  |
| <b>AMA</b> N (%)   |                             |
| NEGATIVE   | 60 (98.4%)                  |
| POSITIVE   | 1 (1.6%)                    |
| <b>ANA + ASMA</b> N (%)  |                             |
| POSITIVE   | 19 (31.1%)                  |
| NEGATIVE   | 42 (68.9%)                  |
| <b>TREATMENT Given</b> N (%)                                     |                             |
| IMMUNOSUPPRESSANT  | 6 (9.8%)                    |
| OTHERS   | 22 (36.1%)                  |
| STEROIDS   | 33 (54.1%)                  |

| <b>TREATMENT DISCONTINUATION N (%)</b>                             |                    |
|--|--------------------|
| NO   | 37 (60.7%)         |
| YES  | 24 (39.3%)         |
| <b>REMISSION N (%)</b>   |                    |
| NO   | 26 (42.6%)         |
| YES  | 35 (57.4)          |
| <b>TIME TO REMISSION (MONTHS)</b><br>Mean $\pm$ SD (N=35)          | 10.91 $\pm$ 5.664  |
| <b>History of Drug causing AIH N (%)</b>                           |                    |
| Ayurvedic  | 3 (4.9%)           |
| <b>FLARE WITH STEROID PLUSE N (%)</b>                              |                    |
| NO   | 48 (78.7%)         |
| YES  | 13 (21.3%)         |
| <b>DURATION OF FLU (MONTHS)</b><br>(Mean $\pm$ Standard Deviation) | 18.79 $\pm$ 15.544 |
| <b>Mortality N (%)</b>   |                    |
| NO   | 55 (90.2%)         |
| YES  | 6 (9.8%)           |

**Table 1-** Demographic, clinical, biochemical profile, treatment and mortality of AIH patients

| <b>SYMPTOMS</b>    | <b>Frequency</b> | <b>Percent</b> |
|--------------------|------------------|----------------|
| LOSS OF APPETITE   | 1                | 1.6            |
| ABDOMEN PAIN       | 17               | 27.8           |
| ANOREXIA           | 3                | 4.9            |
| ASCITES            | 3                | 4.9            |
| ASYMPTOMATIC       | 6                | 9.8            |
| DERANGED LFT       | 1                | 1.6            |
| DIARRHEA           | 1                | 1.6            |
| DYSPNEA            | 1                | 1.6            |
| ENCEPHALOPATHY     | 1                | 1.6            |
| FEVER              | 3                | 4.9            |
| HEMETEMESIS        | 1                | 1.6            |
| ITCHING            | 2                | 3.3            |
| JAUNDICE           | 5                | 8.2            |
| LOOSE MOTION       | 3                | 4.9            |
| LOOSE MOTION (SLE) | 1                | 1.6            |
| NAUSEA             | 2                | 3.3            |
| VOMITING           | 5                | 8.2            |
| <b>Total</b>       | <b>61</b>        | <b>100.0</b>   |

| <b>SIGNS</b>         | Frequency | Percent      |
|----------------------|-----------|--------------|
| ABDOMINAL DISTENSION | 9         | 14.8         |
| ASCITES              | 1         | 1.6          |
| FEVER                | 1         | 1.6          |
| FEVER WITH CHILLS    | 2         | 3.3          |
| HEMATEMSIS           | 2         | 3.3          |
| ICTERUS              | 31        | 50.8         |
| JOINT SWELLING       | 1         | 1.6          |
| MALENA               | 1         | 1.6          |
| NA                   | 1         | 1.6          |
| PEDAL EDEMA          | 2         | 3.3          |
| PR BLEED             | 2         | 3.3          |
| UGI BLEED            | 1         | 1.6          |
| WEIGHT LOSS          | 6         | 9.8          |
| WEIGHT LOSS (SLE)    | 1         | 1.6          |
| <b>Total</b>         | <b>61</b> | <b>100.0</b> |

**Table 2-** Symptoms and Signs of AIH patients

#### Comorbidity in AIH

Among the comorbidity, diabetes mellitus was found in 8 patients followed by 6 hypothyroidism, 5 combined DM + HTN, DM+ Hypothyroidism and HTN + Hypothyroidism in 2 patients while BRONCHIAL ASTHMA, DM + RHEUMOTOID ARTHRITIS, and HTN were seen in 1 patients. (Table 3)

| Comorbidity              | Frequency | Percent |
|--------------------------|-----------|---------|
| BRONCHIAL ASTHMA         | 1         | 1.6     |
| DM                       | 8         | 13.1    |
| DM, HTN                  | 5         | 8.2     |
| DM, HYPOTHYROIDISM       | 2         | 3.3     |
| DM, RHEUMOTOID ARTHRITIS | 1         | 1.6     |
| HTN                      | 1         | 1.6     |
| HTN, HYPOTHYROIDISM      | 2         | 3.3     |
| HYPOTHYROIDISM           | 6         | 9.8     |
| NA                       | 35        | 57.4    |
| Total                    | 61        | 100.0   |

**Table 3-** Comorbidity of AIH patients

Comparison of AIH patients with remission amongst demographic, clinical, biochemical profile, treatment and mortality-

We compared separately various factors like age, gender, Laboratory investigations, biochemical profile, treatment regimen, time to remission, duration of follow-up, treatment discontinuation, flare with steroid and mortality to determine whether any factor predicted remission (Table 4). However platelet count and flare with steroid found to be statistically significant with  $P < 0.05$ . While in rest of the factors, no statistical difference was found.

| <b>Remission</b>       |                            |                            |                    |
|------------------------|----------------------------|----------------------------|--------------------|
|                        | <b>NO</b>                  | <b>YES</b>                 | <b>P VALUE</b>     |
| <b>AGE</b>             |                            |                            |                    |
| Mean $\pm$ SD          | 48.23 $\pm$ 16.00          | 48.68 $\pm$ 11.95          | 0.924**            |
| <b>SEX</b>             |                            |                            |                    |
| Female                 | 20 (44.4%)                 | 25 (55.6%)                 | 0.629 <sup>†</sup> |
| Male                   | 6 (37.5%)                  | 10 (62.5%)                 |                    |
| <b>HB</b>              |                            |                            |                    |
| Mean $\pm$ SD          | 11.17 $\pm$ 1.58           | 11.05 $\pm$ 1.94           | 0.78*              |
| <b>TLC</b>             |                            |                            |                    |
| Mean $\pm$ SD          | 7699.23 $\pm$ 4404.77      | 9604.3 $\pm$ 6750.39       | 0.127**            |
| <b>PLC</b>             |                            |                            |                    |
| Mean $\pm$ SD          | 179461.53 $\pm$ 136623.345 | 251228.57 $\pm$ 140345.600 | <b>0.05*</b>       |
| <b>Creatinine</b>      |                            |                            |                    |
| Mean $\pm$ SD          | 0.71 $\pm$ 0.335           | 0.90 $\pm$ 1.080           | 0.06**             |
| <b>Total Bilirubin</b> |                            |                            |                    |
| Mean $\pm$ SD          | 7.47 $\pm$ 7.45            | 11.22 $\pm$ 11.25          | 0.354**            |
| <b>ALT</b>             |                            |                            |                    |
| Mean $\pm$ SD          | 243.11 $\pm$ 377.277       | 245.02 $\pm$ 367.435       | 0.793**            |
| <b>AST</b>             |                            |                            |                    |
| Mean $\pm$ SD          | 267.04 $\pm$ 342.386       | 287.17 $\pm$ 416.036       | 0.815**            |
| <b>ALP</b>             |                            |                            |                    |
| Mean $\pm$ SD          | 140.5 $\pm$ 83.00          | 168.89 $\pm$ 122.70        | 0.493**            |
| <b>Albumin</b>         |                            |                            |                    |
| Mean $\pm$ SD          | 3.12 $\pm$ 0.667           | 3.23 $\pm$ 0.697           | 0.53*              |
| <b>Globulin</b>        |                            |                            |                    |
| Mean $\pm$ SD          | 3.29 $\pm$ 1.201           | 3.33 $\pm$ 1.048           | 0.89*              |

|                                  |                   |                   |                    |
|----------------------------------|-------------------|-------------------|--------------------|
| <b>PT</b>                        |                   |                   |                    |
| Mean ± SD                        | 16.315 ± 4.329    | 16.111 ± 4.663    | 0.55**             |
| <b>IgG</b>                       |                   |                   |                    |
| Mean ± SD                        | 2113.13 ± 705.948 | 1966.87 ± 987.991 | 0.254**            |
| <b>ANA</b>                       |                   |                   |                    |
| NEGATIVE                         | 3 (42.9%)         | 4 (57.1%)         | 1.00 <sup>#</sup>  |
| POSITIVE                         | 23 (42.6%)        | 31 (57.4%)        |                    |
| <b>ASMA</b>                      |                   |                   |                    |
| NEGATIVE                         | 14 (45.2%)        | 17 (54.8%)        | 0.684 <sup>¶</sup> |
| POSITIVE                         | 12 (40%)          | 18 (60%)          |                    |
| <b>ANA+ASMA</b>                  |                   |                   |                    |
| NEGATIVE                         | 19 (45.2%)        | 23 (54.8%)        | 0.539 <sup>¶</sup> |
| POSITIVE                         | 7 (36.8%)         | 12 (63.2%)        |                    |
| <b>TREATMENT GIVEN</b>           |                   |                   |                    |
| IMMUNOSUPPRESSANT                | 3 (50%)           | 3 (50%)           | 0.09 <sup>¶</sup>  |
| OTHERS                           | 13 (59.1%)        | 9 (40.9%)         |                    |
| STEROIDS                         | 10 (30.3%)        | 23 (69.7%)        |                    |
| <b>Time to remission</b>         |                   |                   |                    |
| Mean ± SD                        | 12.17 ± 6.494     | 10.66 ± 5.570     | 0.581**            |
| <b>Duration of FLU</b>           |                   |                   |                    |
| Mean ± SD                        | 13.47 ± 14.035    | 21.28 ± 15.793    | 0.053**            |
| <b>TREATMENT DISCONTINUATION</b> |                   |                   |                    |
| NO                               | 15 (40.5%)        | 22 (59.5%)        | 0.683 <sup>¶</sup> |
| YES                              | 11 (45.8%)        | 13 (54.2%)        |                    |
| <b>FLARE WITH STEROID PLUSE</b>  |                   |                   |                    |
| NO                               | 25 (52.1%)        | 23 (47.9%)        | 0.004 <sup>¶</sup> |
| YES                              | 1 (7.7%)          | 12 (92.3%)        |                    |
| <b>MORTALITY</b>                 |                   |                   |                    |
| NO                               | 22 (40%)          | 33 (60%)          | 0.387 <sup>#</sup> |
| YES                              | 4 (66.7%)         | 2 (33.3%)         |                    |

\*- Independent T-Test, #- Fisher exact test, \*\*- Mann Whitney test, ¶- Chi-square test

**Table 4-** Comparison of AIH patients with remission amongst demographic, clinical, biochemical profile, treatment and mortality



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