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Which clinical features are linked with severe presentation in people tested for anti-GBM (glomerular basement membrane) antibodies?

Submission date
28/09/2026

Recruitment status
No longer recruiting

Registration date
28/09/2026

Overall study status
Completed

Last Edited
28/09/2026

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Anti-glomerular basement membrane (anti-GBM) antibodies can be associated with a rare autoimmune condition that may damage the kidneys and sometimes the lungs. Some people have severe kidney failure, need dialysis, or develop bleeding into the lungs when they first come to hospital, while others have a less severe presentation. Doctors use blood tests, kidney-function tests, scans, and sometimes kidney biopsy findings to understand how severe the illness is.
This study used existing hospital records to describe adults who were tested for anti-GBM antibodies and to examine a structured classification called Clinical Risk Integration (CRI). Among patients with a positive anti-GBM result, CRI classifies presentation as high risk when at least one major severity feature is present: very low kidney filtration (eGFR below 15 mL/min/1.73 m^2), dialysis dependence, pulmonary hemorrhage, or simultaneous anti-GBM and ANCA antibody positivity. The study also describes kidney, lung, antibody, and biopsy findings and explores how other severity markers differ between the CRI groups.

Who can participate?
This was a retrospective study of existing medical records, so patients were not newly approached or asked to attend study visits. Eligible records were from adults aged 18 years or older who had an anti-GBM antibody test as part of routine clinical care between 1 January 2021 and 31 December 2025 and had enough information to assess kidney function and renal or pulmonary involvement. Repeat encounters and records missing the core information needed for CRI classification were excluded.

What does the study involve?
Researchers linked the first eligible record for each patient across the hospital anti-GBM laboratory registry and relevant nephrology, blood-test, urine-test, imaging, dialysis, and renal pathology records. No new treatment, blood sample, scan, biopsy, appointment, questionnaire, or other procedure was required for this research. Records were de-identified for analysis.
The study first describes patients according to whether the anti-GBM antibody result was positive or negative. Within the anti-GBM-positive group, the CRI rule is used once at the index

presentation to classify high-risk or lower-risk presentation. Kidney, pulmonary, serologic, and biopsy features are then summarized and compared. Because the variables used to define CRI high risk are part of the classification itself, they are not treated as independent predictors of CRI risk class.

What are the possible benefits and risks of participating?
There is no direct clinical benefit to an individual whose historical record is included, because the research does not change their care. The study may help researchers describe the different ways anti-GBM disease presents and may guide future prospective research on early risk assessment. The main research risk is loss of confidentiality. The study minimizes this risk by using de-identified data, restricting access to authorized research personnel, and reporting results only in aggregate so that individuals are not identified. There are no additional medical or procedural risks because no new intervention or study procedure is performed.

Where is the study run from?
The study is run from the Medical Laboratory Department of Baoding No.1 Central Hospital (China).

When is the study starting and how long is it expected to run for?
The historical clinical records cover 1 January 2021 to 31 December 2025. Retrospective record collection began on 1 February 2026, the final eligible record set was completed on 30 April 2026, and the study analysis was completed on 31 August 2026.

Who is funding the study?
Medical Science Research Project of Hebei Province (Project No. 20251434) (China).

Who is the main contact?
Wenjie Song
18132745298@163.com

Contact information

Type(s)
Public, Principal investigator, Scientific

Contact name
Dr Wenjie Song

Contact details
Medical Laboratory Department, Baoding No.1 Central Hospital, No. 320 Changcheng North Street, Lianchi District
Baoding
China
071000
+86 312 5976789
18132745298@163.com

Type(s)
Scientific

Contact name

Dr Wenjing Song

Contact details
Department of Ultrasound, Fourth Medical Center of PLA General Hospital, No. 51 Fucheng Road, Haidian District
Beijing
China
100048
+86 10 66867399
dasong.wangchao@163.com

Type(s)
Scientific

Contact name
Dr Xiaotong Shen

Contact details
Medical Laboratory Department, Baoding No.1 Central Hospital, No. 320 Changcheng North Street, Lianchi District
Baoding
China
071000
+86 312 5976789
sdf0323@126.com

Type(s)
Scientific

Contact name
None Hongbin Liang

Contact details
Medical Laboratory Department, Baoding No.1 Central Hospital, No. 320 Changcheng North Street, Lianchi District
Baoding
China
071000
86 312 5976789
1311207076@qq.com

Type(s)
Scientific

Contact name
None Chen Liu

Contact details
Medical Laboratory Department, Baoding No.1 Central Hospital, No. 320 Changcheng North Street, Lianchi District
Baoding

China
071000
+86 312 5976789
songwenjie1201@sina.com

Additional identifiers

Study information

Scientific Title
Clinical characteristics and CRI-defined high-risk presentation among adults evaluated for anti-glomerular basement membrane antibodies: a retrospective cross-sectional analytical study at Baoding No.1 Central Hospital

Acronym
CRI-GBM

Study objectives
The study aims to characterize the demographic, clinical, laboratory, serologic, imaging and histopathologic features of adults evaluated for anti-glomerular basement membrane (anti-GBM) antibodies at index presentation; compare anti-GBM-positive with anti-GBM-negative patients; classify anti-GBM-positive patients according to Clinical Risk Integration (CRI) as high-risk or lower-risk presentation; and identify clinical, laboratory, serologic and histopathologic features associated with CRI-defined high-risk presentation. Prespecified subgroup analyses assess differences according to symptom status, anti-GBM/ANCA overlap serology and anti-GBM antibody titer category.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/01/2026, Medical Ethics Committee of Baoding First Central Hospital (No. 320 Changcheng North Street, Lianchi District, Baoding, 071000, China; +86 312 5976679; bdyzxirb@163.com), ref: IRB-A27N5-2026

Primary study design
Observational

Secondary study design
Cross sectional study

Study type(s)

Health condition(s) or problem(s) studied
Anti-glomerular basement membrane antibody positivity and anti-GBM disease / pulmonary-renal presentation

Interventions
This is a retrospective cross-sectional analytical study using existing routinely collected clinical records from Baoding No.1 Central Hospital, China. Adult patients who underwent anti-GBM

antibody testing during the study period were identified consecutively from the immunology laboratory registry. The first eligible index record for each patient was linked with nephrology, clinical chemistry, hematology, urinalysis, chest imaging, dialysis and renal pathology records. Records were eligible when patients were aged 18 years or older, had a verifiable anti-GBM antibody result, sufficient renal-function information to calculate estimated glomerular filtration rate, and adequate documentation of renal and pulmonary involvement. Duplicate encounters and records without sufficient information for classification were excluded. A total of 138 records were retrieved and 91 unique eligible records were included in the final analysis, comprising 64 anti-GBM-positive and 27 anti-GBM-negative patients.

Within the anti-GBM-positive cohort, CRI was used to classify presentation as high risk or lower risk at the index assessment. High-risk presentation was defined by the presence of at least one major severity feature: estimated glomerular filtration rate below 15 mL/min/1.73 m², dialysis dependence at presentation, clinically documented pulmonary hemorrhage, or concurrent anti-GBM and ANCA positivity. Anti-GBM-positive patients without these features were classified as lower risk. The primary outcome is CRI risk class at index presentation. Secondary outcomes include renal status, pulmonary status, serologic profile and renal histopathologic features, all measured from the index clinical record.

Data are summarized using means and standard deviations, medians and interquartile ranges, or frequencies and percentages as appropriate. Anti-GBM-positive and anti-GBM-negative patients are compared using independent-samples t tests, Mann-Whitney U tests, chi-square tests or Fisher's exact tests according to variable type. Within the anti-GBM-positive cohort, CRI high-risk and lower-risk groups are compared using corresponding parametric or non-parametric methods. Exploratory binary logistic regression evaluates non-defining clinical, laboratory, serologic and histopathologic factors associated with high-risk presentation. Prespecified subgroup analyses examine symptom status, single-positive versus double-positive serology and anti-GBM titer category. Statistical analyses are performed using IBM SPSS Statistics, with two-sided significance set at $p < 0.05$.

Intervention Type
Other

Primary outcome(s)
1. CRI-defined high-risk presentation measured using binary risk class among anti-GBM-positive patients using the first eligible index record. High risk is defined by at least one of: eGFR <15 mL /min/1.73 m², dialysis dependence at presentation, clinically defined pulmonary hemorrhage, or anti-GBM/ANCA co-positivity. Anti-GBM-positive patients with none of these criteria are classified as lower risk, at index presentation; measured once from the first eligible record within the historical source-record period

Key secondary outcome(s)
1. Renal status measured using serum creatinine, eGFR, blood urea nitrogen, serum albumin, dialysis dependence, proteinuria, hematuria, red cell casts, and active urinary sediment extracted from the index clinical/laboratory record at index presentation; measured once

2. Pulmonary status measured using hemoptysis, dyspnea, diffuse alveolar infiltrates, and pulmonary hemorrhage determined from respiratory review and chest-imaging records at index presentation; measured once

3. Serologic profile measured using anti-GBM titer, ANCA status, single-positive versus double-positive serology, and anti-GBM titer category (20 to <100 RU/mL versus >=100 RU/mL) extracted from the index immunology record at index presentation; measured once

4. Histopathologic status measured using crescent burden, necrotizing lesions, glomerulosclerosis, interstitial fibrosis or tubular atrophy, and tubular injury extracted from the final renal biopsy report when biopsy data are available at Index presentation / diagnostic biopsy; measured once

5. Exploratory association of non-defining severity markers with CRI risk class measured using univariable logistic regression for non-defining features including age, blood urea nitrogen, serum albumin, high anti-GBM titer, crescent burden >=50%, glomerulosclerosis, and tubular injury. CRI-defining variables are excluded from predictor modelling at index presentation; analysis performed after record abstraction was complete

Completion date
31/08/2026

Eligibility

Key inclusion criteria
1. Age 18 years or older at index evaluation
2. Documented anti-GBM antibody test performed during routine clinical care within the historical source-record period
3. Serum creatinine available at index presentation to permit eGFR calculation using the 2021 CKD-EPI creatinine equation
4. Sufficient clinical documentation to determine renal and pulmonary involvement at index presentation

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
91

Key exclusion criteria
1. Age younger than 18 years
2. Repeat encounter after the first eligible index presentation

3. Record lacking core CRI classification variables: antibody status, renal-function data, or organ-involvement documentation
4. Irretrievable or unverifiable serologic or clinical source documentation

Date of first enrolment
01/01/2026

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
China

Study participating centre
Baoding No.1 Central Hospital
No. 320 Changcheng North Street, Lianchi District
Baoding
China
071000

Sponsor information

Organisation
Medical Science Research Project of Hebei Province (Project No. 20251434)

Funder(s)

Funder type

Funder Name
Baoding No.1 Central Hospital

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Consent form version 1.0	28/09/2026	28/09/2026	No	No
Participant information sheet	version 1.0	28/09/2026	28/09/2026	No	Yes
Protocol file	version 1.0	28/09/2026	28/09/2026	No	No
Statistical Analysis Plan	version 1.0	28/09/2026	28/09/2026	No	No