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Original Article

J Clin Med Res. 2024;16(1):8-14

Cold Agglutinin Disease and COVID-19: A Scoping Review of Treatments and Outcomes

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Abstract

Background: Reports suggest that patients with both acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and cold agglutinin disease (CAD) may experience poorer survival when treated with rituximab. We conducted a scoping review to evaluate severe outcomes, including intensive care unit (ICU) admission and mortality, in coronavirus disease 2019 (COVID-19) patients with CAD on various treatments, including rituximab.

Methods: This review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR). Four literature databases were searched on December 19, 2023, for studies reporting lab-confirmed SARS-CoV-2 and CAD, excluding rheumatological conditions.

Results: Of the 741 screened articles, 19 were included. Studies, predominantly case reports (17/19) or case series (2/19), were mainly from the USA (8/19) and India (3/19), with others across Europe and Asia. Among 23 patients (61% female, median age 61 years), 21/23 had a new CAD diagnosis; only two had pre-existing CAD. Overall, 74% recovered, 21% died, and outcomes for one were unreported. Nine (39%) were ICU-admitted. Of rituximab-treated patients (n = 4), 25% were ICU-admitted, none died. Non-rituximab treatments (n = 19) saw 42% ICU admissions and 26% mortality.

Conclusions: This review found no increased risk of severe outcomes in CAD and COVID-19 patients treated with rituximab.

Keywords: Cold agglutinin disease; COVID-19; Rituximab; Severe outcomes; SARS-CoV-2; Autoimmune cytopenia; Poor survival

Manuscript submitted January 5, 2024, accepted January 19, 2024
Published online January 31, 2024

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doi: https://doi.org/10.14740/jocmr5102

Introduction

Infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease 2019 (COVID-19), has been associated with several hematological disease processes, including cold agglutinin disease (CAD) [1]. CAD is a rare disorder accounting for 25-30% of autoimmune hemolytic anemias [2].

In CAD, autoantibodies (immunoglobulin (Ig)M and rarely IgA and IgM) bind on the I antigen on the surface of red blood cells and cause complement-mediated hemolysis [3]. Pathological cold agglutinin antibodies can cause this hemolysis even at temperatures close to room temperature [4, 5], which puts affected patients at risk of hemolysis during their day-to-day lives. CAD is commonly associated with autoimmune processes, lymphoid malignancy, or underlying infection such as Epstein-Barr virus, mycoplasma, and now SARS-CoV-2 infection [6, 7]. Current first-line treatment for CAD involves the use of rituximab as monotherapy or as duo therapy with bendamustine [8]. However, reports show poorer survival for SARS-CoV-2 infected patients who received rituximab [9]. Severe outcomes with risk ratios as high as 5.5 have been reported in COVID-19 patients treated with anti-CD20 therapy such as rituximab [10, 11]. These observations have been made among patients who were taking rituximab and had underlying autoimmune rheumatologic conditions. Whether the higher disease severity was due to the existing inflammatory disease versus rituximab treatment remains unclear. Our paper focuses on the effects of rituximab in patients who had CAD and COVID-19 without underlying rheumatological conditions. We decided to eliminate the confounding effect of immunosuppression that could have resulted from these primarily autoimmune rheumatological conditions. Due to the scarcity of data on this topic, we conducted a scoping review of the literature to assess severe outcomes, including intensive care unit (ICU) admission and mortality among COVID-19 patients with CAD on different treatments, including rituximab, and examined underlying comorbidities.

Materials and Methods

We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) in reporting this review [12].

Data sources and searches

The review team collaborated with a research librarian (LC) to develop and execute a comprehensive search of the literature. This search used controlled vocabulary and keywords to find studies related to rituximab therapy in patients with SARS-CoV-2 infection and CAD (Supplementary Material 1, www.jocmr.org). A search was developed in PubMed and translated into Scopus (Elsevier) and Web of Science Core Collection (Clarivate) as a multi-file search of Science Citation Index-Expanded and Emerging Sources Citation Index. All searches were performed on December 19, 2023. A date limit of November 1, 2019, to present was applied to eliminate studies prior to the emergence of COVID-19. No other limits or filters were used. A Google Scholar search was executed on December 19, 2023, and the first 200 results, sorted by relevance, were exported for screening.

Study selection

Results were downloaded to a citation management software (EndNote) and underwent manual de-duplication by the research librarian. Unique records were uploaded into Covidence (Veritas Health Information, Melbourne, Australia) for independent review by three team members using pre-determined inclusion/exclusion criteria.

Three authors (JSM, GRK, and AH) independently screened titles and abstracts and read the full texts to assess if they met the inclusion criteria. The authors met and discussed any articles where there was conflict and decided to either include or exclude such articles. Inclusion criteria were any study design (all were case reports/series) in which patients had both SARS-CoV-2 (laboratory-confirmed) and CAD. We excluded studies in pediatric populations, editorials, reviews, those published in a non-English language, articles where full texts were not available, and non-peer-reviewed preprints.

Data extraction

Using a standardized template, two reviewers (JSM and SK) independently abstracted data from individual studies. We abstracted data on the study author, year, country, study design, study population, CAD status, clinical presentation, comorbidities, rituximab treatment status, COVID-19 treatment, CAD treatment and mortality, and ICU admission status. Discrepancies were resolved by discussion between the two abstractors.

Data synthesis and analysis

In this scoping review, we assessed severe outcomes, including ICU admission and mortality among COVID-19 patients with CAD on different treatments, including rituximab, and examined underlying comorbidities. We calculated the proportions of patients treated with rituximab or other therapies who died or who were admitted to the ICU. In addition, we presented data on underlying comorbidities and demographics. Analyses were performed in SAS 9.4 (SAS Institute, Cary, NC). We did not register this study with PROSPERO nor conduct a quality assessment of the included studies, as these are unnecessary for a scoping review. This study was conducted in compliance with the ethical standards of the responsible institution on human subjects as well as with the Helsinki Declaration. In addition, this scoping review was exempt from institutional review board approval.

Results

Our search yielded 1,065 records; we excluded 324 duplicates and screened 741 articles. At the abstract and title review stage, we excluded 716 articles, leaving 25 articles for full-text review. Of these, 19 met the inclusion criteria and were included in the scoping review. The most frequent reason for excluding studies at the full-text review stage was the study being in the wrong patient population, i.e., patients who had COVID-19 and were receiving rituximab for rheumatologic conditions but did not have CAD (Fig. 1). While the main reasons for exclusion at the abstract stage were studies about COVID-19 vaccinations, review articles such as systematic reviews or meta-analyses, studies on topics of other hemolytic anemias (but not CAD) and COVID-19, studies on the pathogenesis of CAD, but not treatment.

Characteristics of included studies are reported in Table 1 [13-31]. All the studies were case reports (17/19) or case series (2/19). Most of the studies were conducted in the USA (42% (8/19)) and India (15% (3/19)). The rest were conducted in various countries in Europe and Asia. Most of the patients were females (61% (14/23)), and the median age was 61 years (interquartile range (IQR): 24).

Most of the patients had a new diagnosis of CAD (21/23), and only two had pre-existing CAD before acquiring COVID-19. Anemia (7/23) and severe pneumonia (7/23) were the common diagnoses that the patients initially presented with. The other clinical presentations were thrombocytopenia, mild pneumonia, hypoxic respiratory failure, and nonspecific symptoms.

Examples of comorbidities included hypertension, type 2 diabetes mellitus, end-stage renal disease, cirrhosis, chronic obstructive airway disease, chronic lymphocytic leukemia, etc. Patients mostly presented with a combination of comorbidities co-existing. There was no difference in comorbidity prevalence among patients treated with rituximab compared to those treated with other therapies.

Treatments for CAD included the use of rituximab, packed red blood cell transfusions, plasma exchange, and steroids. These treatments were in combination; however, rituximab use occurred in only 4/23 patients.

Overall, 74% (17/23) of the patients recovered, while 21% (5/23) died, and no outcome was reported for one patient. Nine patients (39%) were admitted to the ICU. Among the four patients who were treated with rituximab, only one (25%) was admitted to the ICU, and none died. Among those treated with other treatments without rituximab, 42% (8/19)

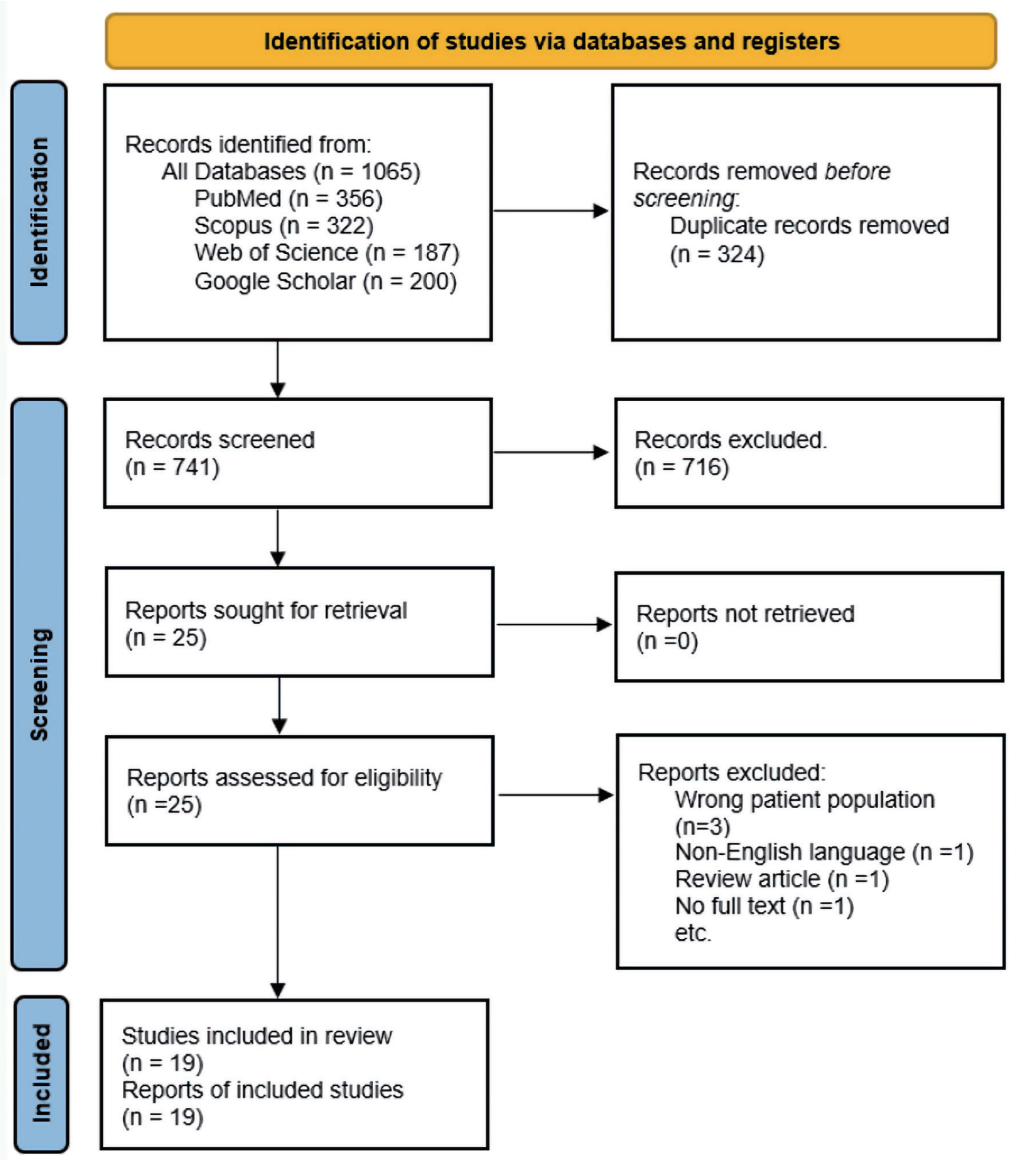

Figure 1. Study selection flow diagram: adapted from the PRISMA. PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

patients were admitted to the ICU, and 26% (5/19) died.

Discussion

We did not find an increased risk of severe outcomes among patients with CAD infected with COVID-19 who were treated with rituximab compared to those treated with other therapies. No difference in comorbidity prevalence among these two groups of patients (treated with rituximab vs. those treated with other therapies) was identified.

Previous studies showed that there was an increased risk of severe outcomes among patients with underlying rheumatological conditions presenting with COVID-19 and CAD and being treated with rituximab [9, 11, 32, 33]. Hence, a confounding effect of immunosuppression that could have resulted from these primary autoimmune rheumatological conditions could have erroneously attributed the increased risk of severe outcomes to rituximab therapy.

As seen in our systematic literature search, there is a paucity of studies specifically describing the effect of rituximab use among COVID-19 patients with CAD. We speculate that this is likely because after the publication of the rheumatological studies as mentioned above, the use of rituximab for CAD among COVID-19 patients might have decreased.

This precautionary use of rituximab for the treatment of CAD in patients with COVID-19 is likely to continue. Hence, there is a need for further studies examining the effect of rituximab use among COVID-19 patients with CAD and rheumatological conditions while adjusting for underlying immune

Table 1. Main Characteristics of Included Studies

Author, year	Country	Study type	Age (years)/ sex	CAD status (pre-existing/new diagnosis)	Clinical presentation	Comorbidity	Treatment with rituximab	COVID-19 treatment	CAD treatment	Time to AIHA	ICU admission	Overall outcome
Zagorski et al, 2020 [13]	USA	Case report	46/F	New	Anemia	Immune thrombocytopenic purpura (ITP), post splenectomy/iron deficiency anemia, asthma	No	Supportive only	Packed RBC transfusion	Concomitant	No	Died
Tsukamoto et al, 2022 [14]	Japan	Case report	72/F	New	Anemia	Not reported	No	Steroids	Steroids	Concomitant	Yes	Resolved
Ramos-Ruperto et al, 2021 [15]	Spain	Case series	54/M	New	Severe pneumonia	No significant medical history	No	Hydroxychloroquine and tocilizumab	Steroids and plasma exchange	Concomitant	No	Resolved
			72/F	New	Severe pneumonia	No significant medical history	No	Hydroxychloroquine, tocilizumab, and steroids	Steroids and packed RBC transfusion	Not reported	Yes	Resolved
			76/F	New	Severe pneumonia	Hypertension, hypothyroidism, chronic lymphocytic leukemia (no previous treatment)	No	Hydroxychloroquine and steroids	Steroids and packed RBC transfusion	Not reported	Yes	Resolved
Raghuwanshi et al, 2020 [16]	India	Case report	45/M	New	Pneumonia with anemia and thrombocytopenia	Not reported	No	Not reported	Packed RBC transfusion	Not reported	Yes	No reported outcome
Priyadarshini et al, 2022 [17]	India	Case report	43/M	New	Severe pneumonia	Not reported	No	Remdesivir and steroids	Packed RBC transfusion	2 days	Yes	Died
Patil et al, 2020 [18]	USA	Case report	51/F	New	Severe pneumonia	Breast ductal carcinoma status post lumpectomy/radiation therapy/tamoxifen	No	Hydroxychloroquine	Packed RBC transfusion	Concomitant	No	Resolved
Moonla et al, 2020 [19]	Thailand	Case report	24/F	New	Severe pneumonia	No significant medical history	No	Hydroxychloroquine	None	3 days	No	Resolved
Maslov et al, 2020 [20]	USA	Case report	48/M	New	Anemia	Hypertension, insulin-dependent diabetes mellitus, obesity/ESRD on hemodialysis	No	Supportive only	None	Concomitant	No	Died
Lazarian et al, 2020 [21]	French and Belgian	Case series	62/F	New	Severe pneumonia	Hypertension, cirrhosis	Yes	Not reported	Steroid and rituximab	4 days	No	Resolved
			69/F	New	Moderate pneumonia	Obesity	No	Not reported	Steroids	10 days	No	Resolved
			61/M	New	Mild pneumonia	Hypertension, chronic renal failure	No	Not reported	Packed RBC transfusion	11 days	No	Active hemolysis at publication

Table 1. Main Characteristics of Included Studies - *(continued)*

Author, year	Country	Study type	Age (years)/ sex	CAD status (pre-existing/new diagnosis)	Clinical presentation	Comorbidity	Treatment with rituximab	COVID-19 treatment	CAD treatment	Time to AIHA	ICU admission	Overall outcome
Kaur et a, 2021 [22]	USA	Case report	61/M	New	Hypoxic respiratory failure	Hypertension, type 2 diabetes mellitus, hypercholesterolemia, ESRD, hemodialysis-dependent, anemia of chronic disease, coronary artery disease, paroxysmal atrial fibrillation, and obesity	No	Hydroxychloroquine, steroids, azithromycin	Packed RBC transfusion	21 days	Yes	Resolved
Jacobs et al, 2021 [23]	USA	Case report	33/F	New	Anemia	No significant medical history	Yes	Steroids and tocilizumab	Rituximab and packed RBC transfusion	Concomitant	Yes	Resolved
Gupta et al, 2021 [24]	USA	Case report	77/M	New	Pneumonia	COPD and glucose-6-phosphate dehydrogenase (G6PD)	No	Hydroxychloroquine, steroids, unspecified antibiotics	Packed RBC transfusion	9 days	Yes	Died
Chang et al, 2022 [25]	Malaysia	Case report	70/F	New	Pneumonia	Type 2 diabetes mellitus, hypertension, and dyslipidemia	No	Steroids	Packed RBC transfusion	3 days	Yes	Resolved
Capes et al, 2020 [26]	Belgium	Case report	62/M	New	Pneumonia	Oropharyngeal squamous cell carcinoma on radio chemotherapy	No	Intubation	Packed RBC transfusion	16 days	Yes	Resolved
Bhuyan et al, 2022 [27]	India	Case report	45/F	New	Anemia	No significant medical history	No	Supportive only	Packed RBC transfusion	Concomitant	Yes	Resolved
Bhagat et al, 2021 [28]	USA	Case report	83/F	Existing	Anemia	Cold agglutinin hemolytic anemia, chronic anemia, hypothyroidism, hypertension, deep vein thrombosis and chronic lymphedema	Yes	Remdesivir and steroids	Rituximab and packed RBC transfusion	Concomitant	No	Resolved
Aldaghlawi et al, 2021 [29]	USA	Case report	69/F	New	Nonspecific symptoms	Stage IV chronic lymphocytic leukemia on tirabrutinib	Yes	Levofloxacin, steroids	Rituximab, steroids	20 days	No	Resolved
Ahmed et al, 2021 [30]	Canada	Case report	70/M	Existing	Pneumonia	Cold agglutinin disease, gout, and chronic viral hepatitis B without cirrhosis	No	Steroids	Packed RBC transfusion and plasma exchange	Concomitant	Yes	Resolved
Ahmadnezhad et al, 2021 [31]	Iran	Case report	49/F	New	Anemia	Thalassemia	No	Supportive only	Packed RBC transfusion	Concomitant	No	Died

COVID-19: coronavirus disease 2019; CAD: cold agglutinin disease; AIHA: autoimmune hemolytic anemia; ICU: intensive care unit; F: female; M: male; RBC: red blood cell; ESRD: end-stage renal disease; COPD: chronic obstructive pulmonary disease.

suppression of these autoimmune conditions.

Our study faced limitations due to the scarcity of existing research on this topic, prompting us to conduct a scoping review. The included studies in this review primarily consisted of case reports or case series, as no retrospective or prospective studies (stronger studies) were published in the literature on this subject. Another limitation of our study is that we did not have data on confounding factors such as length of hospital stay and all the therapies the patients received while hospitalized. However, these risk factors are likely to have been more common among patients that required treatment with rituximab, and it would bias the results of our analysis towards the null.

In accordance with our scoping review, a multicenter observational study by Sorin et al did not show any discernible increase in the risk of severe COVID-19 among patients with autoimmune cytopenia undergoing rituximab treatment. This study evaluated the incidence and risk factors associated with severe COVID-19 in a cohort of patients and demonstrated a low occurrence. Out of the 308 patients studied, only 11 had COVID-19 necessitating oxygen therapy, and only two died [34].

Conclusions

This scoping review did not reveal an elevated risk of severe outcomes in CAD patients with COVID-19 treated with rituximab. Nonetheless, caution is advised when using rituximab in CAD patients with COVID-19 and underlying rheumatological conditions due to the heightened risk of severe outcomes in this subgroup, as reported in the literature.

Supplementary Material

Suppl 1. Search strategies.

Acknowledgments

Thanks to the Graduate Medical Education Department, White River Medical Center, Batesville, AR, USA.

Financial Disclosure

This work was not supported by any funding agency.

Conflict of Interest

Investigators will receive only normal scholarly gains from taking part in this study. The authors declare no competing interests.

Informed Consent

Not applicable.

Author Contributions

Conception and design: J.S. Musuuza, G.R. Kamoga. Literature search: L. Christensen, J.S Musuuza. Literature review and data abstraction from publications: J.S. Musuuza, S. Kumar, D.K. Posa, A. Hans, S. Nayyar, G.R. Kamoga. Analysis and interpretation of the data: J.S. Musuuza, G.R. Kamoga. Drafting of first draft: J.S. Musuuza, G.R. Kamoga. Critical revision for important intellectual content: all authors. Reading and final approval of the manuscript: all authors.

Data Availability

All data used in analysis of this manuscript are freely available by contacting the corresponding author.

Abbreviations

CAD: cold agglutinin disease; ICU: intensive care unit; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

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