Clinical Infectious Diseases

IDSA FEATURES

Clinical Practice Guidelines by the Infectious Diseases Society of America (IDSA): 2020 Guideline on Diagnosis and Management of Babesiosis

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The purpose of this guideline is to provide evidence-based guidance for the most effective strategies for the diagnosis and management of babesiosis. The diagnosis and treatment of co-infection with babesiosis and Lyme disease will be addressed in a separate Infectious Diseases Society of America (IDSA), American Academy of Neurology (AAN), and American College of Rheumatology (ACR) guideline [1]. Recommendations for the diagnosis and treatment of human granulocytic anaplasmosis can be found in the recent rickettsial disease guideline developed by the Centers for Disease Control and Prevention [2]. The target audience for the babesiosis guideline includes primary care physicians and specialists caring for this condition, such as infectious diseases specialists, emergency physicians, intensivists, internists, pediatricians, hematologists, and transfusion medicine specialists.

EXECUTIVE SUMMARY

Summarized below are the 2020 recommendations for the diagnosis and management of babesiosis. The panel followed a systematic process used in the development of other IDSA clinical practice guidelines, which included a standardized methodology for rating the certainty of the evidence and strength of recommendation using the GRADE approach (Grading of Recommendations Assessment, Development, and Evaluation) (Figure 1). A detailed description of background, methods, evidence summary, and rationale that support each recommendation, and knowledge gaps can be found online in the full text.

I. How Should the Diagnosis of Babesiosis Be Confirmed?

Recommendation:

1. For diagnostic confirmation of acute babesiosis, we recommend peripheral blood smear examination or polymerase chain reaction (PCR) rather than antibody testing *(strong recommendation, moderate-quality evidence)*. **Comment:** The diagnosis of babesiosis should be based on epidemiological risk factors and clinical evidence, and confirmed by blood smear examination or PCR.

II. Can an Active Case of Babesiosis Be Diagnosed Based on a Single Positive Antibody Test or Is a Blood Smear, PCR, or a Four-fold Rise in Antibody Necessary for Confirmation?

Recommendation:

1. For patients with a positive *Babesia* antibody test, we recommend confirmation with blood smear or PCR before treatment is considered *(strong recommendation, moderate-quality evidence)*. **Comment**: A single positive antibody test is not sufficient to establish a diagnosis of babesiosis because *Babesia* antibodies can persist in blood for a year or more following apparent clearance of infection, with or without treatment.

III. What Are the Preferred Treatment Regimens for Babesiosis?

Recommendation:

1. We recommend treating babesiosis with the combination of atovaquone plus azithromycin or the combination of clindamycin plus quinine *(strong recommendation, moderate-quality evidence)*. **Comment:** Atovaquone plus azithromycin is the preferred antimicrobial combination for patients experiencing babesiosis, while clindamycin plus quinine is the alternative choice. The duration of treatment is 7 to 10 days in immunocompetent patients but often is extended when the patient is immunocompromised (Tables 1 and 2).

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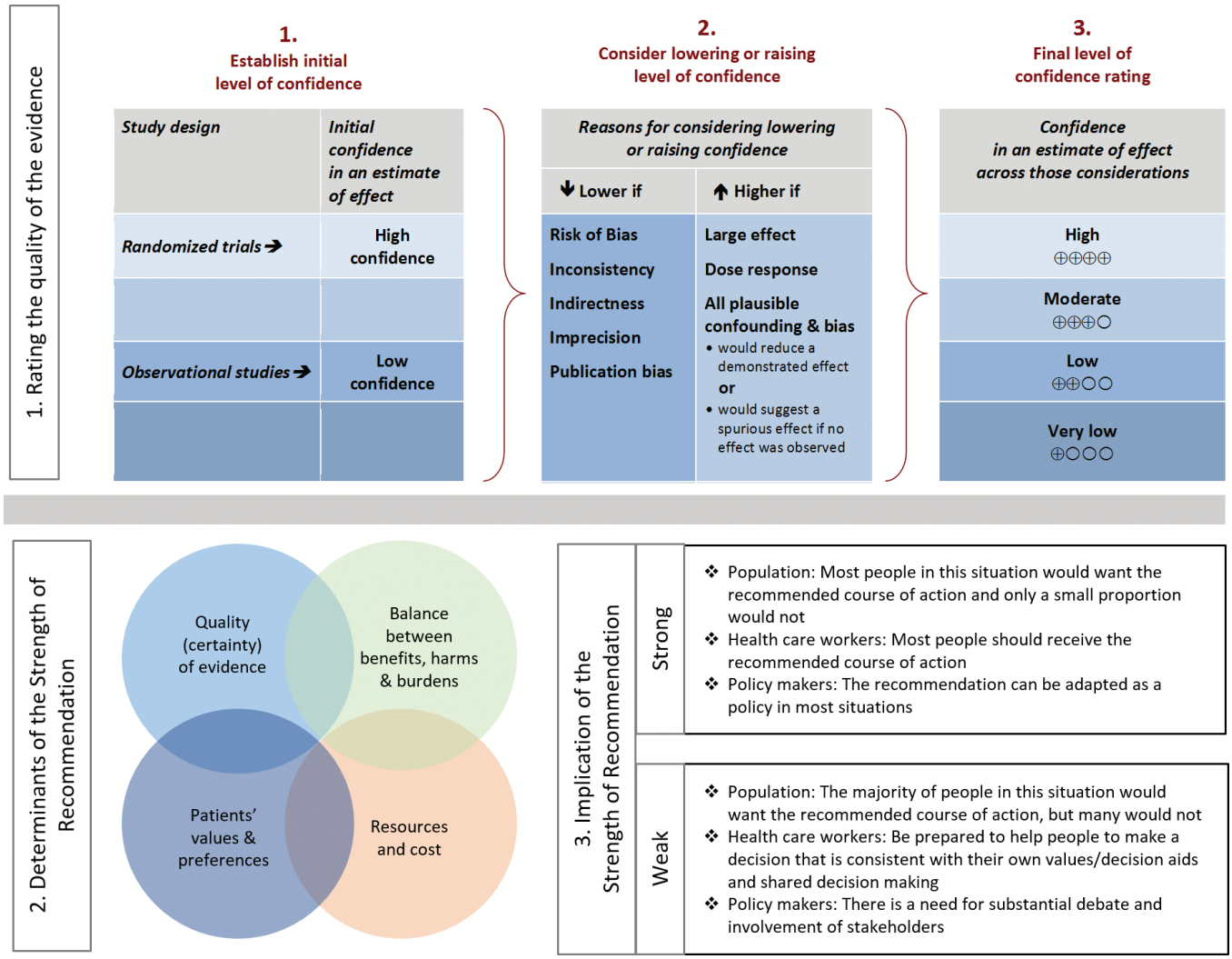

Figure 1. Approach and implications to rating the quality of evidence and strength of recommendations using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) methodology. Unrestricted use of the figure granted by the U.S. GRADE Network (Approach and implications to rating the quality of evidence and strength of recommendations using the GRADE methodology, 2015. url: http://www.gradeworkinggroup.org).

IV. Is Exchange Transfusion Indicated for Severe Babesiosis?

Recommendation:

1. In selected patients with severe babesiosis, we suggest exchange transfusion using red blood cells *(weak recommendation, low-quality evidence)*. **Comment**: Exchange transfusion may be considered for patients with high-grade parasitemia (>10%) or who have any one or more of the following: severe hemolytic anemia and/or severe pulmonary, renal, or hepatic compromise. Expert consultation with a transfusion services physician or hematologist in conjunction with an infectious diseases specialist is strongly advised.

V. How Should Immunocompetent and Immunocompromised Patients Be Monitored After Babesiosis Therapy Is Initiated? How Frequently and for How Long?

Recommendations:

1. For immunocompetent patients, we recommend monitoring *Babesia* parasitemia during treatment of acute illness using peripheral blood smears but recommend against testing for parasitemia once symptoms have resolved *(strong recommendation, moderate-quality evidence)*.
2. For immunocompromised patients, we suggest monitoring *Babesia* parasitemia using peripheral blood smears even after they become asymptomatic and until blood smears are negative. PCR testing should be considered if blood smears have become negative but symptoms persist *(weak recommendation, moderate-quality evidence)*.

Notes

Disclaimer. It is important to realize that guidelines cannot always account for individual variation among patients. They are assessments of current scientific and clinical information provided as an educational

Table 1. Treatment Regimens for Babesiosis Patients

Patient Category	Treatment Regimen: Adult doses	Treatment Regimen: Pediatric doses
Ambulatory patients: mild to moderate disease[a]	**Preferred** Atovaquone 750 mg orally (with a fatty meal) Q12h plus azithromycin 500 mg orally on day 1, then 250 mg Q 24h for 7 to 10 days. **Alternative** [c]Clindamycin 600 mg orally Q8h plus quinine sulfate 542 mg base (which equals 650 mg salt) orally Q6h–8h for 7 to 10 days.	**Preferred** Atovaquone 20 mg/kg per dose (up to 750 mg) Q12h orally plus azithromycin 10 mg/kg (up to 500 mg) orally on day 1, then 5 mg/kg (up to 250 mg) Q24h for 7 to 10 days.[b] **Alternative** [c]Clindamycin 7–10 mg/kg (up to 600 mg/dose) orally Q8h plus quinine sulfate 6 mg base/kg (which equals 8 mg salt/kg) (up to 542 mg base or 650 mg salt/ dose) orally Q6–8h for 7 to 10 days.
Hospitalized patients: acute severe disease[d]	**Preferred** Atovaquone 750 mg orally Q12h plus azithromycin 500–1000 mg IV Q24h until symptoms abate, then convert to all oral therapy (see step-down therapy). **Alternative** [c]Clindamycin 600 mg IV Q6h plus quinine sulfate 542 mg base (which equals 650 mg salt) orally Q6h–8h until symptoms abate, then convert to all oral therapy (see step-down therapy). If infection relapses, consider one of the regimens listed in Table 3.	**Preferred** [e]Atovaquone 20 mg/kg per dose (up to 750 mg) Q12h orally plus azithromycin 10 mg/kg (up to 500 mg) Q24h IV until symptoms abate, then convert to all oral therapy (see step-down therapy). **Alternative** [c]Clindamycin 7–10 mg/kg IV (up to 600 mg/dose) IV plus quinine sulfate 6 mg base/kg (which equals 8 mg salt/kg) per dose (up to 542 mg base or 650 mg salt) Q6–8h orally until symptoms abate, then convert to all oral therapy (see step-down therapy). If infection relapses, consider one of the regimens listed in Table 3.
Hospitalized patients: step-down therapy (transition to oral therapy)	**Preferred** Atovaquone 750 mg orally Q12h plus azithromycin 250–500 mg orally Q24h. Treatment of acute disease plus step-down therapy typically lasts 7–10 days in total. A high dose of azithromycin (500–1000 mg) should be considered for immunocompromised patients. **Alternative** [c]Clindamycin 600 mg orally Q8h plus quinine sulfate 542 mg base (which equals 650 mg salt) orally Q6h–8h. Treatment of acute disease plus step-down therapy typically lasts 7–10 days in total.	**Preferred** Atovaquone 20 mg/kg per dose (up to 750 mg) orally Q12h plus azithromycin 10 mg/kg (maximum dose 500 mg) orally Q24h. Treatment of acute disease and step-down therapy typically last 7–10 days in total. **Alternative** [c]Clindamycin 7–10 mg/kg orally (up to 600 mg/dose) orally Q8h plus quinine sulfate 6 mg base/kg (which equals 8 mg salt/kg) (up to 542 mg base or 650 mg salt/ dose) orally Q6–8h. Treatment of acute disease plus step-down therapy typically lasts 7–10 days in total.
Highly immunocompromised patients	Start with one of the regimens recommended for hospitalized patients: acute severe disease and follow with step-down therapies but treat for at least 6 consecutive weeks, including 2 final weeks during which parasites are no longer detected on peripheral blood smear [3]. When oral azithromycin is used, a 500–1000 mg daily dose should be considered. If infection relapses, consider one of the regimens listed in Table 3.	

[a]These patients usually are immunocompetent, experience mild to moderate symptoms, have a parasitemia <4%, and do not require hospital admission.

[b]Azithromycin modestly increases the risk of pyloric stenosis for infants less than 6 weeks old [4].

[c]Clindamycin plus quinine is preferred when parasitemia and symptoms have failed to abate following initiation of atovaquone plus azithromycin. Some physicians have used parenteral quinidine instead of oral quinine; however, quinidine is no longer available in the United States.

[d]Exchange transfusion may be considered for patients with high-grade parasitemia (>10%) or moderate to high-grade parasitemia and any one or more of the following: severe hemolytic anemia or pulmonary, renal, or hepatic compromise. Expert consultation with a transfusion services physician or hematologist is strongly advised.

[e]This regimen has not yet been reported for treatment of children with severe babesiosis.

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Potential conflicts of interest. The following list is a reflection of what has been reported to the IDSA. To provide thorough transparency, the IDSA requires full disclosure of all relationships, regardless of relevancy to the guideline topic. Evaluation of such relationships as potential conflicts of interest is determined by a review process which includes assessment by the Board of Directors liaison to the Standards and Practice Guideline Committee and, if necessary, the Conflicts of Interest (COI) and Ethics Committee. The assessment of disclosed relationships for possible COI is based on the relative weight of the financial relationship (ie, monetary amount) and the relevance of the relationship (ie, the degree to which an association might reasonably be interpreted by an independent observer as related to the topic or recommendation of consideration). The reader of these guidelines should be mindful of this when the list of disclosures is reviewed. **P. J. K.** receives research funding from the National Institutes of Health (NIH), the Gordon and Llura Gund Foundation, and the Yale Emerging Infections Program; receives remuneration from Gold Standard Diagnostics for a collaborative research project; has stock in Gilead Sciences and First Trust NASDAQ Pharmaceuticals ETF; has received research funding from NIH, the Centers for Disease Control and Prevention (CDC), the Gordon and Llura Gund Foundation, and L2 Diagnostics for NIH-sponsored research; has served as a scientific consultant and provided medical education and training for Oxford Immunotec, Inc.; has a patent pending (Enhanced Chemiluminescent enzyme-linked immunosorbent assay for detection of antibodies against *Babesia microti*), for which U.S. Provisional Patent Application No. 62/580,588, was filed on November 2, 2017; serves on the Board of Directors for the American Lyme Disease Foundation and the Editorial Boards of *Pathogens* and *Plos Neglected Tropical Diseases*, the Editorial Advisory Board of *Clinical Infectious Diseases*; was on the Editorial Board of *Journal of Clinical Microbiology*, and will be on the Editorial Board of *Clinical Microbiology Reviews* starting January 2021. **P. G. A.** receives research funding from the Fisher Center for Environmental Infectious Diseases and the NIH; serves on the Board of Directors of the American Lyme Disease Foundation and as the Vice Chair of the Infectious Diseases Society of America (IDSA) Foundation; serves as a scientific advisor for DiaSorin, Adaptive Technologies and Shionogi; provides legal expert opinion testimony regarding Lyme disease; had stock in Johnson & Johnson; has served as an editor for John Hopkins POC-IT ABX Guide, an advisor for the Food and Drug Administration (FDA), Genentech, Dynavax, Aradigm, Cempra, BioMérieux, Cerexa, and Medscape; has received research funding from Cerexa; has served on the FDA Advisory Board, the Medscape Advisory Board, and the IDSA Board of Directors; and his spouse has equity interest in venture capital-funded Capricor. **J. A. B.** receives research funding from the Lyme Disease Biobank Foundation and Zeus Scientific; serves as a scientific advisor and consultant to DiaSorin, Inc.; has served as a scientific advisor and consultant for T2 Biosystems; has served on the scientific advisory board of Roche Diagnostics and AdvanDx; has received research funding from Karius, Inc., Alere, Inc., T2 Biosystems, BioMérieux. TBS Technologies, Immunetics, Inc., DiaSorin, Inc., Kephera Diagnostics, Inc., the Bay Area Lyme Foundation, the Lyme Disease; has participated in unfunded research collaborations with Karius Inc. and Kephera Diagnostics; was a member of the editorial board of the *Journal of Clinical Microbiology*; was a co-inventor on an application for a patent to protect intellectual property; and his spouse is an employee of Informed DNA. **Y. F. Y.** serves as director of the Evidence Foundation and the GRADE Network; conducts GRADE workshops with the Evidence Foundation; has served as the chair of the Guidelines Committee for the American Gastroenterological Association; and has received research funding from the Cleveland VA Medical Research and Education Foundation. **P. M. L.** has received research funding from the National Cytomegalovirus Foundation and from the NIH and educational funding from Duke University; and has served as a consultant and reviewed trial protocol for Frederick O'Connor Medical Consultants, LLC. **H. C. M.** is a current member of the CDC Workgroups; serves as a volunteer consultant on the American Academy of Pediatrics Committee on Infectious Diseases, and the NIH DSMB. **S. K. S.** has received research funding from the NIH; and has provided expert testimony for Danaher Lagnese, P.C. **E. V.** has stock in Abbott Laboratories; has filed a patent application related to compositions and methods for the prophylaxis and treatment of babesiosis (Application No: 62/939,808; has previously owned stock in AbbVie, Amgen, Baxter International, Bristol-Myers Squibb, Gilead Sciences, Johnson and Johnson, Novartis, Quest Diagnostics, and UnitedHealth Group; and received research funding from The Gordon and Llura Gund Foundation, the Dorothy Harrison Egan Foundation and the Global Lyme Alliance. **G. P. W.** receives research funding from Immunetics, Inc., Rarecyte, Inc., Institute for Systems Biology, and Quidel Corporation; serves on the Board of the American Lyme Disease Foundation; provides and has previously provided expert testimony in malpractice cases; has stock in AbbVie, Inc. and Abbott Laboratories; has received research funding from the CDC, NIH, BioMérieux, Bio-Rad Laboratories, and DiaSorin, Inc; has served as a scientific research advisor for Baxter International and as a Lyme disease advisor and expert for the Missouri Board of Registration for the Healing Arts; has a patent approved (U.S. Patent No. 10,669,567 B2) for High Sensitivity Method for Early Lyme Disease Detection; filed two patent applications related to early Lyme disease detection (Application No: 62/277,252) and Lyme arthritis and post-treatment Lyme disease syndrome (Application No: 62/725,745); and has served on the Editorial Boards for *Clinical Infectious Diseases*, *Vector-Borne and Zoonotic Diseases*, and *Ticks and*

Tick-Borne Diseases. All other authors report no potential conflicts. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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