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Case report

Bacteremia Due to *Bacillus clausii* (*Alkalihalobacillus clausii*): An Emerging Concern—Report of Two Cases

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Abstract

Background: The impact of probiotics on the control and management of diarrheal disease, both acute and chronic, has been significant in recent years. One example is the frequent use of *Bacillus clausii*, currently known as *Alkalihalobacillus clausii*, which is widely administered across diverse populations, from children to older adults. However, an emerging concern has arisen for which high-impact epidemiological data are lacking; few descriptive studies exist, and most reports consist of case reports, such as bacteremia caused by *B. clausii*. This bacterium exhibits a broad intrinsic resistance profile, complicating eradication and requiring prolonged antimicrobial regimens. **Case summary:** This report presents two cases, each with immunosuppressive conditions (invasive lung carcinoma and myelodysplastic neoplasm), who received treatment with *B. clausii* during medical care. Both developed systemic inflammatory response requiring vasoactive support, mechanical ventilation, and broad-spectrum antibiotics, with *B. clausii* isolated from peripheral blood cultures and identified by spectrophotometry. Despite treatment, both patients had unfavorable clinical outcomes, ultimately resulting in death. **Conclusion:** Mortality in these patients is extremely high, particularly among immunocompromised individuals, underscoring the need for prudent use of probiotics to prevent this complication.

Keywords

Bacillus clausii; bacteremia; infectious diarrheal disease; immunocompromised host.

INTRODUCTION

Probiotics are live microorganisms that, when administered in adequate amounts, confer a health benefit on the host[(1)], according to the definition established by the International Scientific Association for Probiotics and Prebiotics. Among the most widely consumed worldwide are *Lactobacillus spp., Bifidobacterium spp., Saccharomyces spp., Bacillus spp., Enterococcus spp.,* and *Streptococcus spp*[(2)].

In particular, the genus *Bacillus* is known for its ability to produce spores, allowing it to survive in diverse environments (water, air, food, and soil) under extreme conditions, such as pH variations, although it cannot reproduce until environmental conditions become favorable[(2,3)]. Within this group, *Bacillus clausii*, currently known as *Alkalihalobacillus clausii*, stands out. It has been identified in the gastrointestinal microbiota and is capable of surviving in this environment, as well as exhibiting intrinsic resistance to several antimicrobials, including macrolides, aminoglycosides, and beta-lactams[(4,5)].

The use of probiotics has been evaluated in various gastrointestinal disorders, such as acute gastroenteritis, antibiotic-associated diarrhea, inflammatory bowel disease, and infections caused by *Clostridioides difficile* and

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Helicobacter pylori. Their mechanisms of action include restoration of intestinal microbiome balance, production of antimicrobial substances, strengthening of the mucosal barrier, generation of short-chain fatty acids, and modulation of the immune system and the gut-brain axis[6].

Systematic reviews have reported that probiotics generally exhibit a favorable safety profile; however, rare adverse events have been described, including bacteremia and bloodstream infection, in both immunocompetent and immunocompromised patients[7]. In the specific case of *B. clausii*, toxicological and clinical studies have demonstrated a low rate of adverse events and the absence of toxin-producing genes or transferable resistance mechanisms, supporting its classification as a generally safe probiotic[8].

Nevertheless, although these events are uncommon, cases of bacteremia associated with the use of probiotics such as *A. clausii* have been reported, particularly in immunocompromised patients, raising concern because of the difficulty in controlling and eradicating these infections and the potential risk of fatal outcomes. These complications may require prolonged antimicrobial therapy and, in some cases, multiple therapeutic rotations[7,8].

In this context, clinical evidence supports the usefulness of *A. clausii* in acute colitis, acute gastroenteritis, antimicrobial-associated diarrhea, irritable bowel syndrome, and as an adjunctive therapy in *Helicobacter pylori* infection[6], as well as its efficacy in acute diarrhea demonstrated in controlled clinical trials[9]. However, its use should be carefully evaluated in high-risk populations.

The following report presents two isolated cases of bloodstream infection in which *A. clausii* was isolated in immunocompromised patients, both with fatal outcomes.

CASE DESCRIPTION

Case 1

This was a 41-year-old male patient with a history of hospitalization for two months at a medium-complexity healthcare center due to respiratory symptoms, chest pain, and deterioration in functional class. He was diagnosed with septic shock of pulmonary origin, requiring invasive ventilatory support, antimicrobial therapy with linezolid and meropenem for 14 days, vasoactive support, and multiple procedures, including video-assisted thoracoscopy, thoracostomy, decortication, and biopsy collection. Vasoactive support was de-escalated on day 5, the patient was extubated on day 10, and, 20 days after the biopsy, a result suggestive of early invasive lung carcinoma was obtained, prompting transfer to a higher-complexity center for evaluation by clinical oncology.

Upon admission to the new hospital center, the patient presented signs of systemic inflammatory response with fever spikes above 38 °C, chills, and dyspnea. Chest radiography (**Figure 1**) and paraclinical findings suggested pulmonary empyema; therefore, he was transferred to the intensive care unit (ICU) due to hemodynamic instability with tachycardia, tachypnea, peripheral desaturation, and hypotension. Management was initiated with vasoactive support, antimicrobial therapy with a carbapenem and an oxazolidinone, and collection of two peripheral blood cultures.

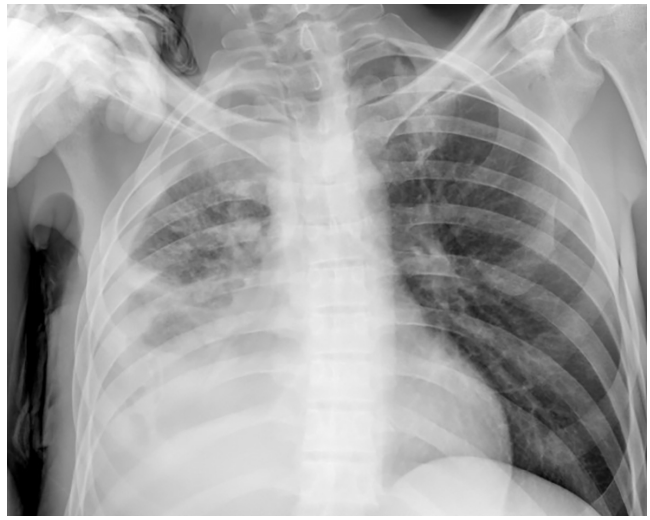


Figure 1. Chest radiograph showing blunting of the right costophrenic angle with decreased pulmonary parenchyma and right pleural effusion with interlobar effusion. Author's file.

On the second day in the ICU, the thoracic surgery service evaluated the patient and proposed abscessed lung carcinoma as the main diagnosis, requesting contrast-enhanced computed tomography (CT) of the chest (**Figure 2**). At 25 hours, blood cultures reported gram-positive bacilli identified as *B. clausii* by spectrophotometry. During rounds on the third day, questioning of both the patient and family members revealed that, during his stay at the referring institution, he had experienced high-output diarrheal stools treated with loperamide and *B. clausii*-type probiotics, with subsequent improvement.

The infectious diseases service evaluated the patient on the fourth day of hospitalization, considering the finding to be probable contamination; therefore, repeat blood cultures were ordered for follow-up and evaluation of antimicrobial rotation. On the fifth day, vasoactive support was successfully de-escalated, maintaining a mean arterial pressure above 65 mm Hg for 48 hours, and the patient was transferred to the general ward on the seventh day.

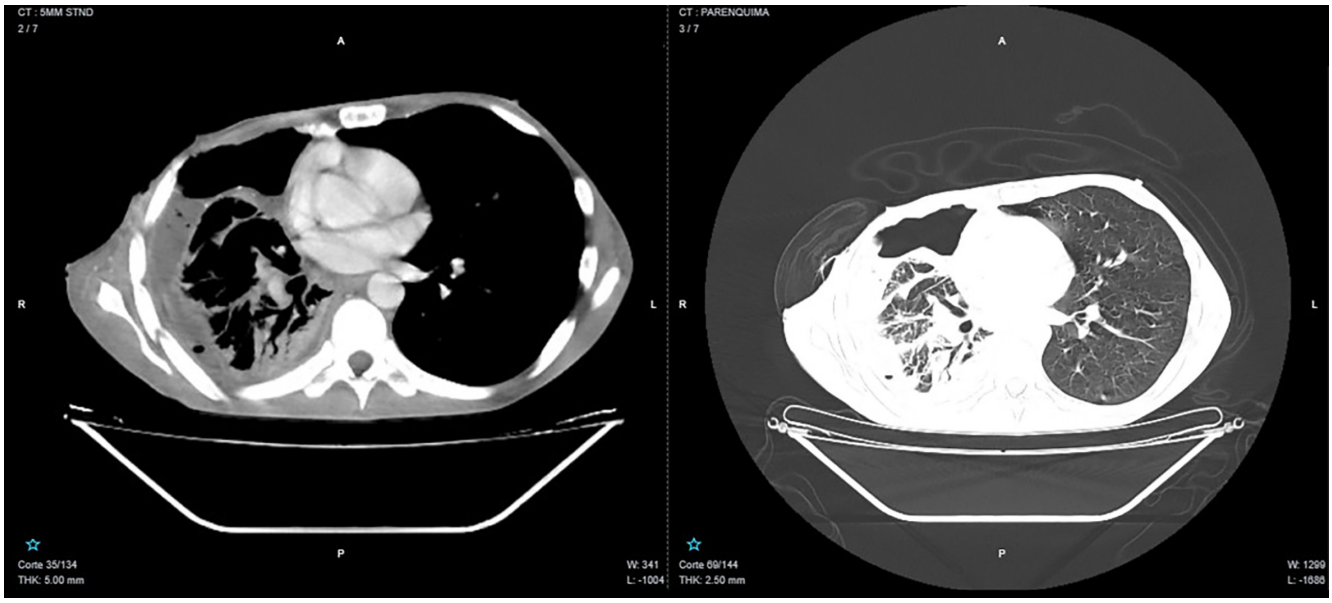


Figure 2. Contrast-enhanced chest CT with findings suggestive of multiple collections and loculated pleural effusion with residual pneumothorax. Author's file.

During the eleventh hospital day, thoracic surgery proposed a new thoracoscopy with decortication and biopsy, while clinical oncology requested a new sample to confirm the diagnosis and control the infectious source. At the end of the thirteenth hospital day, the patient again developed hemodynamic instability and impairment of respiratory mechanics and oxygenation indices, requiring high-flow oxygen therapy and readmission to the ICU. Follow-up blood cultures remained positive for *B. clausii* (**Figure 3**). The infectious diseases service indicated discontinuation of the oxazolidinone and carbapenem and initiation of therapy with a fluoroquinolone and a glycopeptide. However, the patient progressed to septic shock with multiple organ failure, requiring mechanical ventilation, continuous venovenous hemodiafiltration, and triple vasoactive support. The family signed a do-not-resuscitate order, and the patient subsequently died.

Case 2

A 68-year-old female patient with a history of myelodysplastic/myeloproliferative neoplasm was admitted due to a clinical presentation characterized by adynamia, asthenia, dizziness, and ecchymotic lesions on the upper extremities that had evolved over one month. She was evaluated by the hematology service and considered a candidate for hypomethylating therapy; therefore, hospitalization and initiation of azacitidine were indicated. On the fourth day of treatment, she developed liquid diarrheal stools and fever spikes, initially treated with loperamide plus *B. clausii*-type probiotics. However, due to persistence of symptoms, she received intravenous fluid therapy, antibiotic coverage with metronidazole, and total abdominal ultrasound, which demonstrated distended bowel loops with a large amount of fecal material, leading to the conclusion that she had intestinal obstruction.

The patient continued to deteriorate clinically, requiring vasopressor support and expansion of antibiotic coverage with meropenem and vancomycin. The general surgery service indicated emergency exploratory laparotomy, during which turbid peritoneal fluid (800 mL) was found, without other significant findings. Postoperatively, she was transferred to the intensive care unit (ICU) with a diagnosis of mixed septic and hypovolemic shock, with organ involvement evidenced by paraclinical findings, requiring vasoactive support, mechanical ventilation, and rotation to broad-spectrum antibiotics with meropenem and vancomycin. Prior to initiation of antimicrobial therapy, peripheral blood cultures and urine culture had been obtained upon admission.

The initial clinical course was favorable, and ventilatory weaning and withdrawal of support were achieved within 48 hours. However, clinical deterioration occurred during the following 24 hours, with respiratory distress and severe hypoxemia in a clinical picture compatible with acute pulmonary edema and bronchospasm. Noninvasive mechanical ventilation was required, but the response was poor, and she was intubated 20 hours after ventilatory weaning.

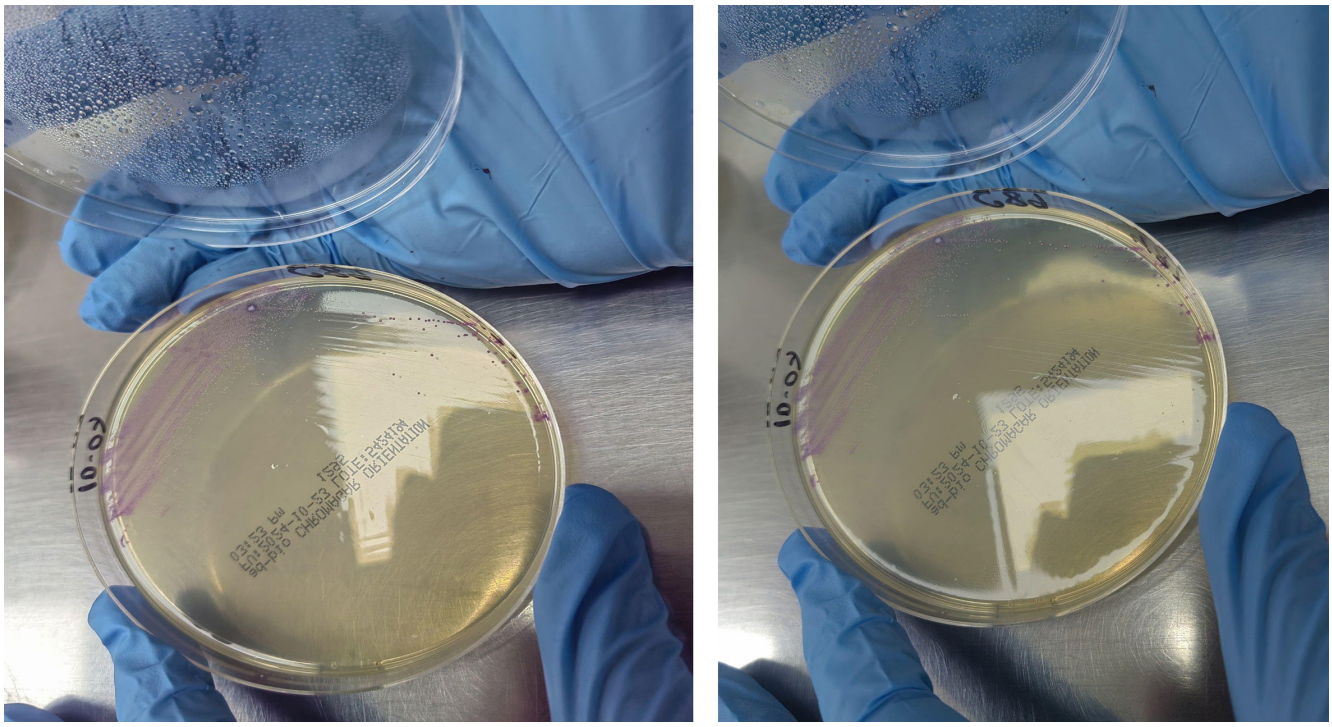


Figure 3. Chromogenic agar orientation medium showing small, round, violet-colored colonies of *B. clausii*. Author's file.

At 48 hours, blood cultures reported isolation of *B. clausii*. Samples were repeated and the same result was confirmed; therefore, the condition was classified as *B. clausii* bacteremia. Despite the antimicrobial therapy instituted, the patient showed poor clinical progression with septic shock secondary to bacteremia, requiring dual vasoactive support, but progressed to multiple organ failure and died after 19 days of ICU stay.

DISCUSSION

Two cases of bacteremia caused by *B. clausii* (*A. clausii*), a gram-positive bacillus, were presented in immunocompromised patients who had received this probiotic as part of the treatment for acute diarrheal disease. Both cases had fatal outcomes, attributable to a torpid clinical course and multiple organ dysfunction. This is an entity for which there are no clear epidemiological data regarding incidence and prevalence, given that the available literature mainly consists of case reports and a few case series at the international level, with very few cases described nationally.

The first case reported in Colombia was described by García and colleagues in 2021, in an 87-year-old patient with upper gastrointestinal bleeding, diarrhea of infectious origin, and recent use of a proton pump inhibitor. The most recent report, in 2024, described by Corredor and colleagues, corresponded to two cases in critically ill patients: one with ulcerative colitis dependent on life support and another with septic shock of pulmonary and soft tissue origin, with a history of heart failure, hypertension, and hypothyroidism, both with fatal outcomes[10,11].

A common factor in all reports was prior use of *B. clausii*-type probiotics during hospitalization, a finding that was also observed in our patients. Shared predisposing factors included immunodeficiency (invasive lung cancer and hematologic neoplasm) and critical illness, conditions that promote gastrointestinal system dysfunction and disruption of the intestinal barrier, thereby facilitating bacterial translocation. These processes may be potentiated by the use of multiple medications, antibiotics, vasoactive agents, proton pump inhibitors, and prolonged hospitalizations[12,13].

Previously reported cases were described in two regions of Colombia; however, after searching databases such as PubMed, Ovid, Google Scholar, Cochrane, and Scopus, no documented reports were found in the Caribbean region.

This is not the first time such cases have been described in immunocompromised patients, as approximately two cases involving stage IV lung cancer patients presenting with pneumonia were reported by Gargar and colleagues

in 2019[14]. These authors observed that, when facing acute or chronic diarrhea in oncology patients, there are no standard protocols for the appropriate use of these probiotics. As described by Díaz-Madriz and colleagues, whose study analyzed cases of *B. clausii* bacteremia, the mean age of affected patients was 71 years, all patients had some degree of immunosuppression, and most received treatment with levofloxacin and vancomycin, with fatal outcomes in three of the four identified patients, leading to the conclusion that extreme caution should be exercised when administering these agents in immunocompromised and elderly patients[15]. Accordingly, for cases such as ours that meet these risk factors and conditions, safe probiotic administration protocols and standardized management protocols for acute diarrheal disease should be developed in the previously mentioned settings to prevent fatal outcomes.

In our cases, both patients had fatal outcomes despite receiving early antimicrobial therapy. Given the intrinsic resistance of *B. clausii*, future therapeutic strategies are required to optimize the management of these infections. Authors such as Corredor, García, Gargar, and Díaz[10,11,14,15] have documented the need for prolonged antimicrobial regimens (longer than four weeks) in surviving patients, with persistence of positive blood cultures. These data highlight the importance of strengthening clinical recognition of this entity and developing timely prevention and management strategies.

CONCLUSION

B. clausii bacteremia represents an emerging infection with high clinical impact, characterized by elevated mortality and difficulty in eradication, as observed in the cases described. Before indicating the use of probiotics, the therapeutic decision should be individualized by considering each patient's risk factors, especially in immunocompromised individuals. It is essential to promote studies that allow better understanding of this entity and to establish institutional and international protocols for the safe and rational use of probiotics in both outpatient and inpatient settings.

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