UNIVERSIDADE ESTADUAL DE CAMPINAS
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Danielle Martins Startari Fialkowski

CAMINHOS LEGAIS E JURISPRUDÊNCIA SOBRE A FOTOBIOMODULAÇÃO PARA MUCOSITE ORAL NO TRATAMENTO DE CÂNCER NO BRASIL

LEGAL PATHWAYS AND CASE LAW ON PHOTOBIOMODULATION THERAPY FOR ORAL MUCOSITIS IN BRAZILIAN CANCER CARE

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Dissertação apresentada à Faculdade de Odontologia de Piracicaba da Universidade Estadual de Campinas como parte dos requisitos exigidos para a obtenção do título de Mestra em Estomatopatologia, na Área de Estomatologia.

Dissertation presented to the Piracicaba Dental School of the University of Campinas in partial fulfillment of the requirements for the degree of Master in Stomatopathology, in Stomatology area.

Orientador: Prof. Dr. Alan Roger dos Santos Silva

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RESUMO

A mucosite oral (MO) é uma toxicidade frequentemente associada ao tratamento oncológico e que pode impactar negativamente a qualidade de vida e o curso do tratamento oncológico dos pacientes. A fotobiomodulação (FBM) é uma terapia de luz recomendada internacionalmente para a prevenção da MO em diferentes cenários médicos. O objetivo deste estudo transversal foi identificar os caminhos legais para o acesso dos pacientes com MO à FBM no sistema de saúde brasileiro, no contexto público e privado. Foram realizadas buscas eletrônicas nas bases dos Tribunais de Justiça (TJ) dos estados brasileiros, no Superior Tribunal de Justiça e no Supremo Tribunal Federal, utilizando o termo "mucosite". Dentre as 180 decisões judiciais identificadas na busca, 50 preencheram os critérios de elegibilidade. Foram coletadas informações sobre o perfil demográfico e clínico dos pacientes, bem como dados qualitativos dos processos judiciais. As 50 decisões judiciais se originaram de 13 estados brasileiros, das cinco regiões administrativas do Brasil. As decisões judiciais foram totalmente procedentes em 41 casos (82%) e parcialmente procedentes em 9 casos (18%). Em 47 casos (94%), as decisões foram dirigidas à saúde suplementar (operadoras de planos de saúde), enquanto em 3 casos (6%) foram dirigidas ao Sistema Único de Saúde (SUS). Os resultados deste estudo, pioneiro em analisar a jurisprudência disponível sobre o acesso à FBM por parte de pacientes com MO, demonstram uma posição judicial consistente que afirma os direitos dos pacientes com câncer a este tratamento baseado em evidências em todas as regiões do país. Esse alinhamento entre a evidência científica para a prevenção e o tratamento da MO e o sistema judiciário brasileiro estabelece um precedente legal que pode influenciar a resolução de futuros casos de judicialização em saúde no Brasil.

Palavras-chave: Jurisprudência; Mucosite Oral; Fotobiomodulação; Brasil.

ABSTRACT

Oral mucositis (OM) is a toxicity frequently associated with cancer treatment and can have a significant negative impact on patients' quality of life and the course of treatment. Photobiomodulation therapy (PBMT) is an internationally recommended light therapy for the prevention of OM in different medical settings. This cross-sectional study aimed to identify the legal pathways to PBMT access for MO patients in Brazilian healthcare, in the public and private context. Electronic searches were performed in the databases of the Courts of Justice (TJ) of the Brazilian states, the Superior Court of Justice and the Supreme Federal Court, using the term "mucositis". Of the 180 court rulings identified in the search, 50 met the eligibility criteria. Information was collected on the demographic and clinical profile of the patients, as well as qualitative data from the court cases. The 50 court rulings originated from 13 Brazilian states, from the five administrative regions of Brazil. The court decisions were fully granted in 41 cases (82%) and partially granted in 9 cases (18%). In 47 cases (94%), the decisions were directed at the supplementary healthcare (health insurance providers), while in 3 cases (6%) they were directed at the Unified Health System (SUS) (public health). The results of this study, a pioneering analysis of available case law on access to PBMT for OM patients, show a consistent judicial position affirming the rights of cancer patients to this evidence-based treatment in all regions of the country. This alignment between the scientific evidence for OM management and the Brazilian judicial system establishes a legal precedent that could influence the resolution of future health justice cases in Brazil.

Key words: Jurisprudence; Oral Mucositis; Photobiomodulation Therapy; Brazil.

SUMÁRIO

1 INTRODUÇÃO

A mucosite oral (MO) é uma reação adversa frequente em pacientes submetidos à radioterapia na região de cabeça e pescoço, quimioterapia, ou à combinação dessas terapias, bem como em tratamentos que incluem o transplante de células-tronco hematopoiéticas. Essa condição é grave, causando dor intensa, dificuldade de deglutição, muitas vezes requerendo suporte nutricional via enteral ou parenteral e controle da dor com opióides. Em casos críticos, pode ser necessária a interrupção do tratamento oncológico. Em pacientes imunossuprimidos, a MO aumenta o risco de infecções, prolonga a hospitalização e está associada a uma maior taxa de mortalidade (Zadik et al., 2019; Elad et al., 2020).

Neste contexto, a *Multinational Association of Supportive Care in Cancer and International Society of Oral Oncology* (MASCC/ISOO) recomenda a fotobiomodulação (FBM) como estratégia de primeira linha para a prevenção MO em pacientes oncológicos. Essa recomendação baseia-se em evidências científicas robustas que demonstram a eficácia da FBM na redução da gravidade das lesões, alívio da dor e aceleração do reparo tecidual (Lalla et al., 2014; Elad et al., 2020). Ao longo dos últimos trinta anos, a FBM consolidou-se como uma abordagem segura e eficaz no manejo da MO em pacientes oncológicos. Desde o primeiro estudo em 1992, o uso da FBM evoluiu significativamente, ganhando destaque em serviços de saúde ao redor do mundo. Além de todos os benefícios apontados, a FBM é considerada uma estratégia viável e sustentável, sendo amplamente recomendada como parte essencial de uma abordagem no cuidado integral ao paciente oncológico (Antunes et l., 2017; Brandão et al., 2018; Kauark-Fontes et al., 2022).

Neste cenário clínico, a atuação do cirurgião-dentista transcende a prevenção da MO, englobando a compreensão das necessidades individuais relacionadas à adequação bucal pré-tratamento oncológico e a reabilitação oral (Santos-Silva et al., 2022). Naturalmente, é imprescindível que os profissionais que atuam neste campo compreendam os aspectos legais relacionados ao suporte odontológico com a FBM tanto no setor público quanto no privado.

No Brasil, a Agência Nacional de Saúde Suplementar (ANS), órgão regulador vinculado ao Ministério da Saúde, é responsável pela regulamentação, normatização, controle e fiscalização dos serviços de saúde suplementar. Em 2015, o Comitê Nacional de Incorporação de Tecnologias no Sistema Único de Saúde (CONITEC) e a ANS introduziram a obrigatoriedade de cobertura da FBM como tratamento para MO. Contudo, essa cobertura se aplica exclusivamente a três perfis de risco específicos: pacientes com câncer de cabeça e pescoço, candidatos a transplante de medula óssea e pacientes com câncer hematopoiético (Brasil, 2017). Assim, no Brasil e na América Latina, a judicialização da saúde tem emergido

como uma resposta significativa às deficiências sistêmicas nos serviços de saúde, tanto no setor público quanto no privado. Essa intervenção judicial frequentemente aborda lacunas críticas no acesso a tratamentos, medicamentos e procedimentos (Iunes e Guerra Junior, 2023).

O sistema de saúde brasileiro opera em um modelo misto, integrando o Sistema Único de Saúde (SUS), que oferece atendimento integral e gratuito a todos os cidadãos, com o setor de saúde suplementar (Paim et al., 2011). No entanto, os limites do sistema público abriram espaço para a atuação do setor privado sendo que, no Brasil, os litígios relacionados à saúde frequentemente envolvem medicamentos de alto custo, incluindo aqueles utilizados no tratamento do câncer (Salha et al., 2022; De Castro et al., 2023).

Tendo em vista o exposto, esta dissertação teve o objetivo de identificar os caminhos legais para o acesso à FBM entre pacientes com MO por meio da análise detalhada da jurisprudência disponível nos tribunais de justiça dos estados brasileiros.

2 ARTIGO. Legal Pathways and Case Law on Photobiomodulation Therapy for Oral Mucositis in Cancer Care: a retrospective cross-sectional study

Este artigo foi submetido e está em revisão no periódico *Oral Surgery, Oral Medicine, Oral Pathology and Oral Radiology* (Anexo 1).

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Statement of Clinical Relevance

This study underscores the establishment of legal pathways ensuring cancer patients' right to PBMT for OM. The consistent stance of the Brazilian judiciary on this matter may influence future case law and shape healthcare-related litigation globally.

Abstract

Objectives: To identify the legal pathways to patient access to photobiomodulation therapy (PBMT) for oral mucositis (OM) management in Brazilian cancer care. **Study design:** This retrospective cross-sectional study assessed electronic databases of the Courts of Justice from all Brazilian states, the Superior Court of Justice and the Federal Supreme Court, yielding 180 court rulings for 'mucositis'. **Results:** A total of 50 court rulings, adjudicated between 2005 and 2024, met the eligibility criteria. The rulings were fully granted in 41 cases (82%) and partially granted in 9 cases (18%). Partially granted rulings typically involved the denial of compensation for moral damages. In 47 cases (94%), the rulings were directed to health insurance providers, while 3 cases (6%) involved public healthcare (SUS). The mean time elapsed between the filing date and the interim relief decision was 13.3 days (SD = 28.3; range: 1–115 days). Chemotherapy was the most common cancer treatment modality, followed by radiotherapy and candidates for hematopoietic stem cells transplantation. **Conclusions:** This pioneer study in the field of health law demonstrated a consistent legal framework supporting access to PBMT for the management of OM in cancer patients across various regions of Brazil.

Introduction

Oral mucositis (OM) is a common and debilitating adverse effect of cancer treatment, frequently associated with head and neck radiotherapy, chemotherapy, or concurrent chemoradiotherapy, and is also a well-recognized complication in protocols involving hematopoietic stem cell transplantation.OM manifests in the oral mucosa with erythema and ulcerations, often causing pain, difficulty in eating and swallowing, and in some cases, demanding the suspension of cancer treatment leading to a negative impact on cancer prognosis. [1] Consequences of this severe toxicity include the potential need for nutritional support through enteral or parenteral routes, pain management with opioids, prolonged hospitalization, and multiple consultations with the multidisciplinary intensive care team, which collectively increase healthcare system costs and burden patients financially. [1,2]

The Multinational Association of Supportive Care in Cancer and International Society of Oral Oncology (MASCC/ISOO), [1] the European Society for Medical Oncology (ESMO) [3] and the Children's Oncology Group (COG) [4] have published clinical practice guidelines for OM management. These guidelines provide recommendations on basic oral care, OM severity and anti-inflammatory agents, photobiomodulation therapy (PBMT), alongside other approaches such as cryotherapy, growth factors, cytokines, and natural agents. [1] PBMT, previously known as low-level laser therapy, is a non-invasive light-emitting therapy employed in the supportive care of cancer patients. Its efficacy in reducing inflammation, providing analgesia, and promoting wound healing is well-documented, making it a safe and cost-effective option for managing OM and other treatment-related side effects. [5]

Dental support for cancer patients extends beyond PBMT alone. The scientific and technical expertise of the dental team encompasses pain prevention, oral function maintenance, management of treatment-related oral complications, and quality of life improvement. [1,6] Access to dental care should be available to patients at all stages of treatment – pre-, during, and post-therapy, across both private and public healthcare settings. High-risk patients for OM should receive both dental care and PBMT to prevent and manage cancer therapy-related toxicities. In this clinical context, robust evidence supports PBMT as accessible intervention that prevents OM and enhances patients' quality of life. By reducing the severity and duration of OM, PBMT facilitates uninterrupted cancer treatment, ultimately improving overall survival rates. [7,8] From an economic standpoint, PBMT represents a practical and sustainable option within the multidisciplinary care framework for cancer patients. [9] In Brazil, PBMT has been established as the standard of care for OM prevention and treatment and is endorsed by the Unified Health System (SUS). [10]

The National Supplementary Health Agency (ANS), the Brazilian regulatory body operating under the Ministry of Health, is responsible for the regulation, standardization, control, and oversight of health insurance services. In 2015, the National Committee for Health Technology Incorporation (CONITEC) and ANS introduced mandatory coverage for PBMT as a treatment for OM. However, this coverage applies solely to three specific risk profiles: patients with head and neck cancer (HNC), candidates for hematopoietic stem cell transplantation (cHSCT), or patients with hematopoietic cancer (HC). [11]

In Latin America, the judicialization of health has emerged as a significant response to systemic deficiencies in healthcare services, both in public and private sectors. This judicial intervention often addresses critical gaps in access to treatments, medications, and procedures, positioning courts as pivotal defenders of individual health rights. Latin American countries now report some of the highest rates of health-related litigation worldwide. [12]

The Brazilian healthcare system operates as a mixed model, integrating the SUS, which offers comprehensive, no-cost healthcare to all citizens, along with private healthcare subsectors. This system provides diverse healthcare access options, primarily based on financial capacity and accessibility. [13] Health, as stipulated by Article 196 of the Brazilian Federal Constitution, is recognized as a universal right and State duty. [14] However, healthcare limitations have opened the door for private sector involvement. In Brazil, health-related litigation often concerns high-cost medications, including those used in cancer treatment. [15,16] In this context, right-to-health lawsuits increased by 130% between 2008 and 2017 – a rate significantly outpacing the overall growth in legal actions during the same period – demonstrating the judiciary's expanding role in influencing healthcare access and resource distribution. [17]

The ANS has announced that the net profit of Brazilian health insurance companies in 2023 was R$2.985 billion. The sector provides coverage to over 50 million beneficiaries, representing approximately 25% of the Brazilian population. [18] Notwithstanding the considerable number of beneficiaries, only a modest proportion of individuals pursue recourse to the courts to address matters pertaining to health plans. In 2023, over 220,000 supplementary health court cases were registered with the National Council of Justice (CNJ), [19] which corresponds to around 0·5% of beneficiaries pursuing legal recourse to assert their rights.

The promulgation of the 1988 Federal Constitution of Brazil [14] and the enactment of the new Code of Civil Procedure (CPC) [20] gave rise to a new era in Brazilian case law. These legal milestones served to enhance the importance of case laws as sources of law and to establish guidelines that directly influence judicial conduct. The CPC, established by Law No.

13.105/2015, [20] underscores the significance of legal precedents, case laws, and binding summaries in fostering uniformity and predictability in judicial decisions, thereby guaranteeing enhanced legal security and equal treatment in analogous cases. Understanding judicial decisions is particularly relevant in the context of health judicialization, as it provides insights into how legal precedents and case law can shape access to healthcare.

Considering the public and supplementary health landscape in Brazil and the limited access to PBMT for OM management, this study aimed to identify the legal pathways to the access to PBMT for OM patients, analyze court rulings, and determine how case law can be utilized to support supportive care practices for cancer patients.

Methods

Study design

This cross-sectional study was approved by the Research Ethics Committee of the Piracicaba Dental School at the University of Campinas (protocol 69684123.0.0000.5418) and complied with Declaration of Helsinki. Additionally, the study adhered to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines to ensure methodological rigor and transparency.

Setting

It is a retrospective cross-sectional study of court rulings regarding the use of PBMT for the prevention and treatment of OM, accessed through each Brazilian state's Courts of Justice (CJ) digital databases (Acre: https://esaj.tjac.jus.br/; Alagoas: https://www2.tjal.jus.br/; Amapá: https://www.tjap.jus.br/portal/; Amazonas: https://consultasaj.tjam.jus.br/; Bahia: http://esaj.tjba.jus.br/esaj/portal; Ceará: https://esaj.tjce.jus.br/ Distrito Federal: https://www.tjdft.jus.br/pje; Espírito Santo: https://www.tjes.jus.br/consultas/processos/ Goiás: https://www.tjgo.jus.br/; Maranhão: https://pje.tjma.jus.br/; Mato Grosso: https://pje.tjmt.jus.br/; Mato Grosso do Sul: https://esaj.tjms.jus.br/; Minas Gerais: https://www.tjmg.jus.br/portal-tjmg/processos/andamento-processual/; Pará: https://www.tjpa.jus.br/PortalExterno/index-consultas.xhtml; Paraíba: https://www.tjpb.jus.br/tags/consulta; Paraná: https://www.tjpr.jus.br/consulta-processual; Pernambuco: https://www.tjpe.jus.br/servicos/consulta-processual; Piauí: https://pje.tjpi.jus.br/1g/ConsultaPublica/listView.seam; Rio de Janeiro: https://www.tjrj.jus.br/consultas/endereco_telefones/esaj; Rio Grande do Norte: https://pje2gconsulta.tjrn.jus.br/consultapublica/ConsultaPublica/listView.seam; Rio Grande

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The initial search in the Jusbrasil database (https://www.jusbrasil.com.br/) and the CJ databases was performed using the terms "laser therapy" AND "mucositis." For the final search, performed between September 21 and 30, 2024, within the CJ databases of each Brazilian state, the STJ and the STF databases, only the term "mucositis" was used. Each lawsuit retrieved was assessed by a Juris Doctor (M.P.) and two researchers (D.M.S. and T.C.E.P.), who applied the eligibility criteria. Data collection was performed between October 1 and 20, 2024.

Participants

The eligibility criteria for this study included court rulings addressing access to PBMT for the management of OM in cancer patients within the Brazilian healthcare system, encompassing both the public and supplementary healthcare sectors. Rulings were included regardless of the year of issuance, provided they were publicly accessible through the CJ database of each Brazilian state. Cases were required to explicitly reference PBMT as a treatment modality for OM. Exclusion criteria encompassed rulings unrelated to PBMT or OM, those with incomplete records lacking essential legal or contextual information, non-final rulings still under appeal, and rulings under court-ordered secrecy.

The court decisions served solely as indicators of the medical-dental litigation landscape, with all involved parties' identities anonymized. While case identification numbers were collected, they are not disclosed and are instead replaced by alphanumeric codes in the data tabulation.

Variables and data sources

After identifying relevant cases, standardized data collection forms were completed, gathering information on treatment specifics, outcomes, and other pertinent details. Collected

data included case number, state CJ, ruling, PBMT prescription (Medical/Dental), recipient of the petition (Public Health System/Health Insurance Providers), denial of coverage (Yes/No), petition alignment with ANS guidelines (Yes/No), appeal status (Yes/No), judgment type (Reimbursement/ Mandatory provision of service without reimbursement), type of reimbursement (Partial/Total), moral damages (Yes/No), legal basis, time between the filing date and interim relief decision (days), age group (decade), main diagnosis (ICD-10), and treatment modality (Hematopoietic Stem Cell Transplantation/Chemotherapy/Radiotherapy).

Statistical analysis

Following collection, the data were organized in an Excel spreadsheet (Microsoft Corporation, Redmond, WA, USA) and analyzed using descriptive statistics. A significance level of 5% ($p \leq 0.05$) was adopted, and statistical analysis was conducted with jamovi® software, version 2.3 (Sydney, Australia).

Results

The electronic search in all Brazilian states CJ databases identified 180 court rulings, of which 50 met the inclusion criteria, covering 13 Brazilian states. The 130 excluded court rulings included cases of gastrointestinal mucositis and cases of OM for which PBMT was not requested. No case law on this subject was found in the STJ or STF, indicating the absence of legal precedents in these higher courts.

Of the 50 cases analyzed, 27 (54%) originated from São Paulo, 4 (8%) from Pernambuco, 3 (6%) from Bahia, 3 (6%) from Minas Gerais, 3 (6%) from Rio de Janeiro, 2 (4%) from Alagoas, 2 (4%) from Paraná, 1 (2%) from Amazonas, 1 (2%) from Distrito Federal, 1 (2%) from Espírito Santo, 1 (2%) from Mato Grosso do Sul, 1 (2%) from Rio Grande do Sul, and 1 (2%) from Santa Catarina. The court rulings were adjudicated between 2005 and 2024.

In 44 cases (88%), the available information indicated the prescribing professional: 26 cases (52%) were attributed to a medical professional, while 18 cases (36%) were attributed to a dental professional. **Table I** displays the distribution frequency of petitions for PBMT access for OM patients to either supplementary healthcare (health insurance providers) or public healthcare (SUS), along with the rulings were granted fully or partially. The partially granted rulings involved cases where compensation for moral damages was sought, which the court did not award.

Depending on the court ruling, patients were either reimbursed for private PBMT sessions, had sessions covered directly by the health insurance provider/SUS, or were required

to receive PBMT sessions provided by the health insurance provider/SUS without reimbursement (mandatory provision of service without reimbursement). **Table II** presents the distribution frequency for these determinations.

Only 18 (36%) cases provided data on the time elapsed between the filing date and the interim relief decision. The mean time was 13.3 days (SD = 28.3), with a range of 1 to 115 days. Thirty-one ICD-10 codes were recorded across the lawsuits, although 8 (16%) cases lacked this information. **Table III** categorizes the primary diagnoses for the 42 cases with ICD-10 data (84%) in relation to whether they met the ANS profiles for PBMT coverage for OM (HNC, cHSCT, or HC), *versus* those who do not meet these profiles. Regarding cancer treatment modalities, chemotherapy was most common, appearing in 17 (34%) cases, followed by radiotherapy in 13 (26%) cases, and cHSCT in 7 (14%) cases. Treatment modality data was unavailable for 13 cases (26%).

Discussion

This cross-sectional study identified the legal pathways to the access to PBMT for OM patients, analyzed legal precedents, and demonstrated how case law can be utilized to support dental care practices for cancer patients. A total of 50 court rulings met the eligibility criteria for this study, spanning 13 different Brazilian states.

Healthcare judicialization in Brazil shows unique characteristics in public *versus* supplementary healthcare, each with distinct litigation focuses. In the supplementary sector, litigation primarily concerns contractual disputes and specific procedure coverage, underlining the specifics of health plan agreements and consumer rights. These cases often reference the Federal Constitution, [14] the Health Plans Law (Law No. 9.656/1998), [21] and the Consumer Protection Code (Law No. 8.078/1990), [22] ensuring both the adequacy of service provision and contractual transparency. An analysis of 6,090 lawsuits against a health plan provider in the Brazilian city of Belo Horizonte, MG, between 2010 and 2017, revealed that most claims involved contractual issues, denied procedures, and prosthetic/orthotic devices. [23] Conversely, in public healthcare, judicialization often involves the pursuit of access to medications and treatments not available in SUS. [24] All 50 court rulings (100%) analyzed in this study involved petitions requesting either reimbursement or mandatory provision of PBMT for OM in cancer patients. These findings highlight that PBMT is not currently available through SUS and is only mandated by ANS guidelines for patients meeting specific risk profiles. Judicialization, therefore, plays a significant role in enforcing social rights, but it also challenges Brazil's healthcare system's stability and sustainability.

A recent analysis of legal data from Brazil reveals that there are currently 801,720 health-related lawsuits in progress across the country. Of these, approximately 497,000 pertain to public health issues, while around 318,000 relate to supplementary healthcare. Thus far in 2024, 306,000 new lawsuits related to this theme have been filed, and by June of this year, 264,000 cases had been adjudicated, representing nearly 33% of the total. [19] In 2023, lawsuits addressed to SUS surpassed lawsuits addressed to health insurance providers. [24] Notably, our findings diverge from the existing literature, as the initial petition of the court rulings included in the present study were addressed to supplementary healthcare in 47 (94%) cases and to SUS in only 3 (6%) cases.

One challenge of judicializing health care is balancing individual and collective rights with system priorities. In this context, courts often handle individual medical needs that may involve quality-of-life issues or life-threatening situations, while the State's actions are directed from a collective perspective. [12] A study conducted in the Brazilian state of Goiás analyzed 301 lawsuits requesting oncological medicines and reported an average time of 8.45 days (SD = 0.87) for the granting of requests by the Goiás CJ. [26] In contrast, our findings indicate that rulings for PBMT in OM patients took longer, with a mean interval of 13.3 days (SD = 28.3) between the filing date and the interim relief decision. To mitigate this discrepancy, the Judiciary can rely on recommendations from the CONITEC [7] and technical notes from the Health Technology Management Support Center (NATJUS). [27] These guidelines are of paramount importance for the judicial decision-making process, which is aimed at ensuring access to essential technologies and treatments for patients, such as PBMT for OM in cancer patients.

Since 2015, PBMT has been recommended by CONITEC and ANS for the prevention and treatment of OM, exclusively for specific profiles. [7] It is acknowledged, however, that a considerable number of patients will develop OM due to different modalities of cancer treatment, [28] many of which do not align with the risk profiles outlined by ANS guidelines. In the present study, an analysis was conducted on 42 (84%) cases to assess compliance with ANS profiles for OM PBMT coverage. Of these cases, only 16 (38.1%) did not meet the ANS profiles. In 2022, Federal Law No. 14,454 overturned the "exhaustive list" restriction of health insurance coverage, [29] signifying that health insurers may now be legally required to cover exams or treatments not listed in the supplemental health procedure catalog. ANS guidelines are now considered exemplary rather than restrictive. Consequently, dental professionals need to understand the legal pathways for securing access to PBMT, given their technical and

scientific qualification to assist patients in obtaining prevention and treatment for OM with PBMT.

An understanding of both legal precedent and case law is essential to comprehend the phenomenon of health judicialization in Brazil. Each plays a unique role in shaping access to healthcare through the judicial system. A legal precedent is a principle or rule established in a previous court decision, guiding future cases with similar facts. Court rulings serve as a conduit through which citizens can assert their legal rights on an individual basis, effectively transforming access to healthcare services through immediate judicial intervention. The term "case law" is used to describe the body of legal precedents that are created through the accumulation of legal precedents. As several rulings on analogous cases are handed down, case law is formed, establishing consistent standards that guide judicial decisions on healthcare-related disputes throughout the country. A case law serves to unify judicial responses and provide predictability in rulings, thereby ensuring a more uniform application of healthcare rights across Brazil. [30] Most of the court rulings addressed in this study were fully granted (82%), while those that were partially granted (18%) involved cases where compensation for moral damages was sought but not awarded by the court. The findings indicate that court rulings on PBMT for OM in the Brazilian judicial system have been met with a favorable response from magistrates, thereby contributing to an expansion of the legal precedents for this intervention, which addresses a common complication associated with cancer treatment.

Regarding the matter of access to PBMT for OM by cancer patients, the Brazilian state of São Paulo is at the vanguard in this regard. Precedent 102 of the CJ of the State of São Paulo states that "when there is an explicit medical recommendation, the refusal to cover the cost of treatment on the grounds that it is experimental or not included in the procedures approved by the ANS is considered abusive". However, it is only applicable to lawsuits in the São Paulo CJ. [31] Our findings indicate that the Brazilian state of São Paulo was the subject of more than half of the court rulings analyzed (54%). A positive association can be established between Precedent 102 and the court rulings of this state.

Furthermore, it is thus evident that dental professionals must be conversant with the legal pathways that guarantee access to PBMT. These professionals possess the requisite technical and scientific expertise to assist patients in receiving dental care before, during, and after cancer treatment. [1,5–9] In these instances, the service must be performed by dental professional trained in PBMT, typically an oral medicine specialist. The Brazilian Superior Court of Justice has established that it is the medical team, rather than the health insurance provider, who determines the course of treatment for the patient. [32] The court rulings analyzed

in this study showed that a medical professional prescribed PBMT support for OM in 26 (52%) cases, while a dental professional did so in 18 (36%) cases. Therefore, denials by health insurance companies of PBMT treatment prescribed by the medical team for cancer patients, based solely on the criteria defined in the ANS usage guidelines and the assertion that the patient does not meet these criteria, are unjustified. This underscores the value of multidisciplinary collaboration within cancer care teams.

One of the primary strengths of this study is its novel exploration of legal precedents as a potential avenue for understanding the judicialization of health in Brazil, particularly in the context of PBMT for OM. By analyzing court rulings, this study provides unique insight into how the legal system influences access to innovative therapies, emphasizing the role of judicial processes in safeguarding healthcare rights. The study's comprehensive approach, encompassing rulings from multiple Brazilian states, enhances its relevance by capturing a wide spectrum of judicial interpretations and applications of health law across different jurisdictions. Additionally, this research contributes to a broader understanding of systemic responses to unmet medical needs in cancer care, offering valuable data for policymakers and healthcare providers to address gaps in therapeutic coverage. Moreover, by concentrating on PBMT, an evidence-based intervention for OM, the study highlights the clinical significance of judicial actions that guarantee prompt and effective care, thereby promoting healthcare equity. It is important to note, however, that while this analysis reveals critical aspects of judicial intervention in healthcare access, the outcomes following the rulings remain unknown. Consequently, it is not possible to ascertain whether patients ultimately experienced positive health improvements following PBMT for OM.

The limitations of this study lie in its reliance on publicly accessible databases of court rulings. Furthermore, case records may vary in detail across jurisdictions, with inconsistencies in reporting medical information, case outcomes, or legal justifications. This variability can hinder a comprehensive analysis of the frequency and nature of judicial decisions related to PBMT. Moreover, the retrospective design of this study precludes the possibility of capturing real-time trends in judicial outcomes and any subsequent impact on patient access or treatment quality. Ultimately, while court rulings offer valuable insight into the role of the judiciary in health policy, they may not fully capture the nuances of broader systemic issues within the healthcare system or the experiences of patients who do not pursue litigation.

In conclusion, this study underscores the pioneering significance of seeking case law on PBMT for OM in the Brazilian judiciary system. The results of our analysis of 50 court rulings indicate that cancer patients have a right to access evidence-based treatment for OM, with a

favorable judicial stance observed across all Brazilian geographical regions. The identification of 50 court rulings regarding PBMT for OM between 2005 and 2024 is relatively low given the significance of the issue and the high number of cancer patients affected by this complication. This finding suggests a low level of judicialization on the topic rather than an absence of the problem itself. The uniformity of the legal precedents reflects a progressive understanding within the judiciary, which not only strengthens patients' rights but also establishes the legal pathways for fair access to PBMT. This may set a case law for future healthcare-related judicial cases in Brazil. Further studies should investigate the outcomes of legal precedents on patient health and explore policy reforms that may strengthen healthcare universality of access and equity in Brazil.

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Data sharing: The data supporting the findings of this study are available from the corresponding author, A.R.S.S., upon reasonable request.

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Table 1. Distribution of fully or partially granted court rulings (n = 50).

Petition addressed to	Ruling	Counts	% of Total	Cumulative %
Health insurance providers	Granted	40	80 %	80 %
	Partially granted	7	14 %	94 %
Public healthcare	Granted	1	2 %	96 %
	Partially granted	2	4 %	100 %

Table 2. Court rulings (n = 50) for PBMT support for cancer patients with OM.

Judgment/Reimbursement	Counts	% of Total	Cumulative %
Mandatory provision of service without reimbursement	16	32 %	32 %
No	13	26 %	5 %
Yes	21	42 %	100 %

Legend: Mandatory provision of service without reimbursement: PBMT sessions provided by the health insurance provider/SUS without reimbursement; No: PBMT support covered directly by the health insurance provider/SUS; Yes: reimbursement for private PBMT sessions.

Table 3. Distribution of the available primary diagnoses (ICD-10 codes) (n = 42), categorized by compliance with ANS coverage profiles for PBMT in OM treatment.

ANS profile	Counts	% of Total	Cumulative %
HNC	16	38.1 %	38.1 %
No	16	38.1 %	76.2 %
HC	3	7.1 %	83.3 %
cHSCT	7	16.7 %	100.0 %

Legend: HNC: head and neck cancer; No: do not comply with ANS profiles; HC: hematopoietic cancer; cHSCT: candidates for hematopoietic stem cells transplantation.

3 CONCLUSÃO

Este estudo enfatiza a relevância pioneira da investigação de jurisprudência sobre FBM para o tratamento da MO no sistema judiciário brasileiro. A análise de 50 decisões judiciais evidenciou uma postura favorável dos tribunais em todas as regiões do país, estabelecendo uma base jurídica robusta para o acesso à FBM. A uniformidade observada nas decisões judiciais não apenas fortalece os direitos dos pacientes, mas também configura um precedente jurídico relevante, que pode contribuir para a redução da judicialização da saúde, diminuindo, assim, a sobrecarga do poder judiciário. O presente trabalho assume um papel crucial como referência para futuros casos relacionados ao acesso a terapias avançadas na saúde, ao identificar os caminhos legais para a obtenção de tratamentos essenciais de forma eficiente. A continuidade da pesquisa deve se concentrar na avaliação dos impactos das decisões judiciais à saúde dos pacientes oncológicos, bem como na exploração de reformas políticas que possam melhorar a equidade e a universalidade de acesso a terapias avançadas, como a FBM.

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ANEXOS

ANEXO 1: Comprovante de submissão do artigo

Oral Surgery, Oral Medicine, Oral Pathology and Oral Radiology

Legal Pathways and Case Law on Photobiomodulation Therapy for Oral Mucositis in Cancer Care: a retrospective cross-sectional study

--Manuscript Draft--

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	Alan Roger Santos-Silva, D.D.S., M.Sc., Ph.D.,FAAOM
Abstract:	Objectives To identify the legal pathways to patient access to photobiomodulation therapy (PBMT) for oral mucositis (OM) management in Brazilian cancer care. Study design This retrospective cross-sectional study assessed electronic databases of the Courts of Justice from all Brazilian states, the Superior Court of Justice and the Federal Supreme Court, yielding 180 court rulings for 'mucositis'. Results A total of 50 court rulings, adjudicated between 2005 and 2024, met the eligibility criteria. The rulings were fully granted in 41 cases (82%) and partially granted in 9 cases (18%). Partially granted rulings typically involved the denial of compensation for moral damages. In 47 cases (94%), the rulings were directed to health insurance providers, while 3 cases (6%) involved public healthcare (SUS). The mean time elapsed between the filing date and the interim relief decision was 13.3 days (SD = 28.3; range: 1–115 days). Chemotherapy was the most common cancer treatment modality, followed by radiotherapy and candidates for hematopoietic stem cells transplantation. Conclusions This pioneer study in the field of health law demonstrated a consistent legal framework supporting access to PBMT for the management of OM in cancer patients across various regions of Brazil.
Opposed Reviewers:	

ANEXO 2: Relatório de verificação de originalidade e prevenção de plágio

Dissertação Dani

ORIGINALITY REPORT

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ANEXO 3: Comprovante de aprovação no Comitê de Ética em Pesquisa

FACULDADE DE ODONTOLOGIA DE PIRACICABA DA UNIVERSIDADE DE CAMPINAS - FOP/UNICAMP

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: BARREIRAS JURÍDICAS PARA O ACESSO À FOTOBIOMODULAÇÃO POR PACIENTES COM CÂNCER: ANÁLISE NO CONTEXTO DA SAÚDE SUPLEMENTAR

Pesquisador: DANIELLE MARTINS STARTARI FIALKOWSKI

Área Temática:

Versão: 3

CAAE: 69684123.0.0000.5418

Instituição Proponente: Faculdade de Odontologia de Piracicaba - Unicamp

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 6.150.526

Apresentação do Projeto:

O parecer inicial é elaborado com base na transcrição editada do conteúdo do registro do protocolo na Plataforma Brasil e dos arquivos anexados à Plataforma Brasil. Os pareceres de retorno, emendas e notificações são elaborados a partir do último parecer e dos dados e arquivos da última versão apresentada.

Pendência 1 (atendida em 28/06/23). A EQUIPE DE PESQUISA citada na capa do projeto de pesquisa inclui DANIELLE MARTINS STARTARI FIALKOWSKI (Cirurgiã Dentista, Mestranda no PPG em Estomatopatologia da FOP-UNICAMP, Pesquisadora responsável), THAÍS CRISTINA ESTEVES PEREIRA (Cirurgiã Dentista, Mestranda no PPG em Estomatopatologia da FOP-UNICAMP), MARCELA PIRES PONTES (Advogada especialista em Direito Médico, Odontológico e da Saúde, Sem vínculo institucional), ALAN ROGER DOS SANTOS SILVA (Cirurgião Dentista, Professor da Área de Semiologia da FOP-UNICAMP) e o que é confirmado na declaração dos pesquisadores e na PB.

DELINEAMENTO DA PESQUISA: Trata-se de um estudo observacional retrospectivo com amostra de conveniência, que busca coletar informações sobre jurisprudências de 50 casos da base de dados digital Jusbrasil e que tratem do uso FBM no tratamento da MO. Objetivo: Este estudo pretende

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Bairro: Areião **CEP:** 13.414-903
UF: SP **Município:** PIRACICABA
Telefone: (19)2106-5349 **Fax:** (19)2106-5349 **E-mail:** cep@unicamp.br

do protocolo.

Conclusões ou Pendências e Lista de Inadequações:

Não há mais pendências por resolver (vide texto acima).

Considerações Finais a critério do CEP:

Parecer de aprovação de Protocolo emitido "ad referendum" conforme autorização do Colegiado na reunião de 01/02/2023. O parecer será submetido para homologação na reunião de 05/07/2023.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_2138293.pdf	28/06/2023 23:37:53		Aceito
Outros	CartaResposta2.pdf	28/06/2023 23:37:17	THAIS CRISTINA ESTEVES PEREIRA	Aceito
Projeto Detalhado / Brochura Investigador	ProjetoResposta2.pdf	28/06/2023 23:36:50	THAIS CRISTINA ESTEVES PEREIRA	Aceito
Outros	CartaResposta.pdf	23/06/2023 14:03:10	THAIS CRISTINA ESTEVES PEREIRA	Aceito
Declaração de Instituição e Infraestrutura	DeclInstituicaoAss.pdf	16/05/2023 12:56:59	THAIS CRISTINA ESTEVES PEREIRA	Aceito
Folha de Rosto	FolhaDeRostoAssinada.pdf	16/05/2023 12:55:09	THAIS CRISTINA ESTEVES PEREIRA	Aceito
Declaração de Pesquisadores	DeclPesquisadores.pdf	10/05/2023 22:37:54	THAIS CRISTINA ESTEVES PEREIRA	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não