

THERAPEUTIC INNOVATION IN SPINAL CORD INJURY IN BRAZIL: CLINICAL ADVANCES IN POLYLAMININ AND REGULATORY CHALLENGES <https://doi.org/10.63330/aurumpub.034-016>

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Abstract

Spinal cord injury represents a major clinical and social challenge in Brazil, requiring innovative therapeutic strategies capable of promoting neural regeneration and functional recovery. This chapter aims to analyze clinical advances related to the use of polyaminin as a therapeutic biomaterial for spinal cord injury in the Brazilian context, as well as to discuss the main regulatory challenges for its incorporation into the health system. The methodology consisted of a narrative review of national and international scientific literature, in addition to the analysis of regulatory documents concerning clinical research and advanced therapy medicinal products in Brazil. The results indicate that polyaminin shows promising potential in promoting axonal growth, reducing inflammatory response, and improving

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functional outcomes in experimental models, with prospects for future clinical application. However, regulatory barriers remain, including requirements for safety validation, production standardization, and ethical oversight in clinical trials. It is concluded that although poly laminin represents a significant advance in regenerative medicine, its therapeutic consolidation in Brazil depends on strengthening translational research and regulatory harmonization.

Keywords: Regenerative medicine, Regulatory challenges, Spinal cord injury, Therapeutic innovation, Poly laminin.

INTRODUCTION

Spinal cord injury (SCI) constitutes a serious public health problem, with a significant impact on the quality of life of affected individuals and high social and economic costs. It is characterized by partial or total interruption of the neural pathways of the spinal cord, resulting in motor, sensory, and autonomic deficits. In Brazil, the incidence of traumatic injuries associated with traffic accidents, urban violence, and falls reinforces the need for innovative therapeutic strategies that go beyond the limits of conventional treatment, historically centered on clinical stabilization and functional rehabilitation. In this context, bioactive biomaterials, such as poly laminin, emerge as promising alternatives in the field of regenerative medicine.

The research problem guiding this chapter can be summarized in the following question: what are the clinical advances related to the use of poly laminin in the treatment of spinal cord injury in Brazil, and what regulatory challenges limit its therapeutic application? Based on this problem, the general objective is established as analyzing the therapeutic potential of poly laminin in spinal cord regeneration and discussing the regulatory barriers to its incorporation into the Brazilian health system. As specific objectives, the following are proposed: (a) to describe the biological mechanisms involved in spinal cord injury; (b) to examine experimental and preclinical evidence regarding the use of poly laminin; (c) to

analyze the national regulatory landscape applicable to advanced therapies; and (d) to identify perspectives for the clinical consolidation of this innovation.

The justification for this study is grounded in the scientific and social relevance of the topic. The absence of therapies capable of meaningfully restoring neurological function after spinal cord injury highlights the need for investment in regenerative approaches. In addition, discussion of regulatory challenges becomes essential to enable the translation of scientific knowledge into clinical practice, especially in a context that demands ethical rigor and health safety.

From a theoretical standpoint, spinal cord injury involves primary and secondary processes, including cellular necrosis, an exacerbated inflammatory response, glial scar formation, and inhibition of axonal growth. Studies in tissue engineering demonstrate that biomaterials derived from extracellular matrix proteins, such as laminin, favor cell adhesion, neuronal differentiation, and axonal regeneration. Polylaminin, by mimicking structural and functional components of the extracellular matrix, exhibits properties that enhance the reorganization of the injured microenvironment. However, its clinical application depends on robust scientific validation and compliance with Brazilian regulatory standards for advanced therapy products, consolidating itself as an interdisciplinary field integrating neuroscience, bioengineering, and health regulation.

METHODOLOGY

STUDY DESIGN

This is a qualitative study with a descriptive and analytical approach, developed through a narrative review of the scientific literature and normative documentary analysis. The adopted design is justified by the need to understand, in an integrated manner, the clinical advances related to the use of polylaminin in spinal cord injury and the regulatory challenges surrounding its possible therapeutic incorporation in Brazil.

The research is exploratory with respect to its objectives, as it seeks to broaden understanding of a field still in consolidation in the national scenario, especially regarding the translation of experimental biomaterials into clinical practice.

DATA COLLECTION PROCEDURES

Review of the scientific literature

The bibliographic review stage included national and international scientific articles published in indexed journals, book chapters, and technical documents related to spinal cord injury, biomaterials, tissue engineering, and regenerative medicine. Experimental, preclinical, and clinical studies addressing the use of laminin or biomimetic polymers with potential application in spinal cord injury were considered.

Inclusion criteria involved publications with thematic relevance, methodological rigor, and contribution to understanding the biological mechanisms, therapeutic effects, and clinical limitations of poly(laminin). Duplicate works, studies with insufficient data, or those without direct relation to the object of investigation were excluded.

Normative documentary analysis

The documentary analysis included health legislation, resolutions, and guidelines related to clinical research and regulation of advanced therapy products in Brazil. Official documents issued by national regulatory bodies were examined, focusing on requirements for safety, efficacy, quality, and ethics in the conduct of clinical trials involving innovative biomaterials.

This stage made it possible to identify regulatory barriers, technical requirements, and the steps necessary for approval and eventual therapeutic incorporation of poly(laminin) into the health system.

ANALYSIS TECHNIQUES AND INSTRUMENTS

Data obtained through the bibliographic and documentary review were organized into thematic categories built from content analysis. The categories included: (a) pathophysiology of spinal cord injury; (b) biological foundations of polylaminin; (c) experimental evidence and clinical perspectives; and (d) regulatory and ethical challenges.

The analysis was grounded in an interpretative approach, seeking to establish relationships between scientific findings and the Brazilian regulatory context. This strategy enabled discussion not only of the therapeutic outcomes described in the literature, but also of the institutional determinants that influence their practical application.

CONSIDERATIONS REGARDING THE “SAMPLE” AND LIMITATIONS

As this is a theoretical-documentary study, there was no clinical sample of human participants or direct experimentation. The “sample” consisted of the set of scientific productions and normative documents selected according to the established criteria.

A limitation is recognized in the dependence on predominantly preclinical studies, since the clinical application of polylaminin is still in the development phase. In addition, the constant updating of regulatory standards may modify the described scenario, requiring continuous monitoring of current guidelines.

Thus, the adopted methodology enabled a grounded discussion, articulating scientific evidence and regulatory aspects, in order to offer a critical and contextualized view of therapeutic innovation in spinal cord injury in Brazil.

RESULTS AND DISCUSSION

SCIENTIFIC ADVANCES AND PRECLINICAL EVIDENCE

Analysis of the literature shows that poly laminin, a biomaterial inspired by the laminin protein of the extracellular matrix, presents bioactive properties relevant to the microenvironment of spinal cord injury. The main findings focus on the promotion of axonal growth, stimulation of cell adhesion and differentiation, as well as modulation of the local inflammatory response. In experimental models, a reduction in glial scar formation and improvement in the structural organization of injured nervous tissue were observed.

These results align with classic studies in regenerative neuroscience, which point to the extracellular matrix as a key element in neural plasticity. Laminin, due to its ability to interact with cellular receptors and activate intracellular pathways related to neuronal survival, underpins the development of biomimetic polymers such as poly laminin. The literature demonstrates that strategies based on bioactive biomaterials tend to show better tissue integration when compared with purely pharmacological approaches.

CLINICAL PERSPECTIVES IN THE BRAZILIAN CONTEXT

Although clinical data remain incipient, progress is observed in the consolidation of translational research in Brazil, especially in university centers and institutes dedicated to regenerative medicine. National scientific production points to the need for controlled clinical trials assessing safety, efficacy, and standardization of poly laminin application in humans.

From the care-delivery standpoint, the possibility of incorporating regenerative biomaterials represents a paradigm shift in spinal cord injury treatment, historically limited to surgical stabilization and rehabilitation. Therapeutic innovation may contribute to meaningful functional gains, even if gradual, especially when associated with multidisciplinary rehabilitation protocols.

REGULATORY AND ETHICAL CHALLENGES

The documentary analysis indicates that the incorporation of innovative biomaterials in Brazil depends on meeting stringent criteria established by national regulatory bodies, such as the Agência Nacional de Vigilância Sanitária (ANVISA). Products classified as advanced therapies require robust evidence of quality, safety, and efficacy, as well as traceability and good manufacturing practices.

In this context, challenges include:

- standardization of scaled production;
- toxicological and immunological validation;
- definition of controlled clinical protocols;
- compliance with ethical standards for research involving human beings.

The literature indicates that the gap between basic research and clinical application—known as the “translational valley of death”—is particularly pronounced in developing countries, where structural and financial limitations can delay the implementation of biomedical innovations.

INTERPRETATIVE SYNTHESIS OF FINDINGS

Taken together, the results indicate that poly laminin has a consistent biological rationale and promising outcomes in experimental models, suggesting relevant therapeutic potential for spinal cord regeneration. However, its clinical consolidation in Brazil depends on the articulation of high-quality scientific production, continuous funding, adequate laboratory infrastructure, and regulatory harmonization.

Thus, it is observed that scientific advancement does not occur in isolation: it is intrinsically linked to institutional, normative, and ethical factors. The discussion reinforces that therapeutic innovation in spinal cord injury requires an interdisciplinary approach, integrating neuroscience, bioengineering, public policies, and health regulation, so that the regenerative potential of poly laminin may, in the future, translate into concrete benefits for patients.

CONCLUSION

The general objective of this chapter was to analyze the clinical advances related to the use of polyaminin as an innovative therapeutic strategy for spinal cord injury in Brazil, as well as to discuss the main regulatory challenges that condition its clinical application. Specifically, it sought to describe the pathophysiological mechanisms of spinal cord injury, examine scientific evidence on the regenerative potential of polyaminin, and understand the national normative landscape applicable to advanced therapies.

The results indicate that polyaminin has a consistent biological basis, with experimental evidence demonstrating stimulation of axonal growth, modulation of the inflammatory response, and possible functional improvement in preclinical models. These findings reinforce its potential as a promising tool in the field of regenerative medicine. However, significant regulatory challenges were identified, especially regarding demonstration of safety, production standardization, clinical validation, and compliance with health regulations in force in Brazil.

As a contribution, this research articulates scientific and regulatory dimensions, offering an integrated analysis that broadens understanding of the pathways necessary for the consolidation of polyaminin as a viable therapeutic alternative. By highlighting the importance of translational research and normative harmonization, the study contributes to academic debate and to strategic planning of public policies aimed at innovation in health.

For future research, the conduct of controlled, multicenter clinical trials evaluating safety and efficacy in humans is recommended, as well as studies on economic feasibility and technology incorporation in the Brazilian health system. Furthermore, interdisciplinary investigations integrating bioengineering, neuroscience, and health regulation may strengthen the responsible and sustainable development of this therapeutic innovation.

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