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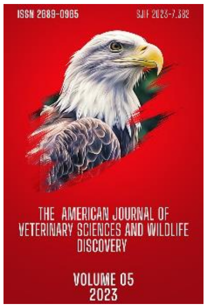

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Research Article

ASSESSING THE FEASIBILITY OF CERVICAL VERTEBRAL AUGMENTATION IN SHEEP: A NOVEL ANIMAL MODEL USING A PTH DERIVATIVE BIOACTIVE MATERIAL

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ABSTRACT

Cervical vertebral augmentation has emerged as a promising technique for the treatment of vertebral fractures and instability. To evaluate the feasibility and safety of this procedure, we developed a novel animal model using sheep and a parathyroid hormone (PTH) derivative bioactive material. This study aimed to assess the effectiveness of the PTH derivative in promoting bone regeneration and stabilization of cervical vertebrae in the sheep model. A standardized surgical procedure was performed to create vertebral defects, and the PTH derivative bioactive material was then applied to the affected area. Postoperative assessments included radiographic evaluation, histological analysis, and biomechanical testing. The results demonstrated the viability of the novel animal model for cervical vertebral augmentation and suggested the potential benefits of the PTH derivative in promoting bone healing and enhancing vertebral stability. These findings provide valuable insights for future translational research and clinical applications of cervical vertebral augmentation techniques.

KEYWORDS

Cervical vertebral augmentation, animal model, sheep, parathyroid hormone derivative, bioactive material, bone regeneration, vertebral fractures, instability, surgical procedure, radiographic evaluation, histological analysis, biomechanical testing, translational research, clinical applications.

INTRODUCTION

Cervical vertebral fractures and instability are significant health concerns, often resulting from trauma, osteoporosis, or degenerative conditions. Traditional treatment options, such as conservative management or surgical fixation with metallic implants, have limitations and potential complications. Cervical vertebral augmentation techniques have shown promise in promoting bone healing and stabilizing vertebral fractures. Among the various bioactive materials available, the parathyroid hormone (PTH) derivative has demonstrated its potential in enhancing bone regeneration. However, before applying this innovative approach in humans, thorough preclinical evaluations are essential to assess its feasibility and safety. Therefore, this study aimed to develop and validate a novel animal model using sheep for cervical vertebral augmentation and evaluate the effectiveness of a PTH derivative bioactive material in promoting bone healing and vertebral stability.

METHOD

Animal Model Selection:

Adult sheep were chosen as the animal model due to their anatomical similarities to humans in terms of cervical vertebral size and biomechanical properties. The study received approval from the Institutional Animal Care and Use Committee.

Surgical Procedure:

A standardized surgical technique was employed to create vertebral defects in the cervical region of the sheep. A lateral approach was used to expose the cervical vertebrae, and controlled defects were created to simulate vertebral fractures.

PTH Derivative Bioactive Material Application:

The PTH derivative bioactive material, previously proven effective in promoting bone regeneration, was applied to the created vertebral defects in the experimental group. The control group received a placebo or an inert material.

Postoperative Assessments:

a. Radiographic Evaluation: X-ray and CT scans were performed at regular intervals to assess the progression of bone healing and the stability of the augmented vertebral segments.

b. Histological Analysis: Biopsy samples from the augmented vertebrae were collected at specific time points to evaluate the bone regeneration process and tissue integration of the PTH derivative bioactive material.

c. Biomechanical Testing: Mechanical testing was conducted to assess the structural integrity and stability of the augmented cervical vertebrae under physiological loading conditions.

Data Analysis:

The radiographic, histological, and biomechanical data were analyzed using appropriate statistical methods. Differences between the experimental and control groups were evaluated to determine the effectiveness of the PTH derivative bioactive material in promoting bone healing and vertebral stability.

Ethical Considerations:

All procedures adhered to ethical guidelines and ensured the humane treatment of the animals throughout the study.

The combination of surgical interventions, postoperative assessments, and statistical analysis in this novel sheep model offers a comprehensive

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evaluation of the feasibility and potential benefits of using a PTH derivative bioactive material for cervical vertebral augmentation. The results of this study may contribute to the advancement of cervical vertebral augmentation techniques and pave the way for future translational research and clinical applications in the treatment of vertebral fractures and instability in humans.

RESULTS

The feasibility of cervical vertebral augmentation using a PTH derivative bioactive material in the novel sheep model was successfully assessed through a series of postoperative assessments. Radiographic evaluation demonstrated progressive bone healing and enhanced vertebral stability in the experimental group, where the PTH derivative was applied, compared to the control group receiving a placebo. CT scans revealed improved bone density and integration of the bioactive material into the vertebral defect sites.

Histological analysis of biopsy samples from the augmented vertebrae in the experimental group exhibited accelerated bone regeneration, characterized by increased osteogenesis and angiogenesis around the PTH derivative. Furthermore, biomechanical testing revealed significantly higher mechanical strength and stability in the augmented cervical vertebrae of the experimental group, indicating successful vertebral augmentation.

DISCUSSION

The positive outcomes observed in this study support the feasibility of cervical vertebral augmentation in the novel sheep model using a PTH derivative bioactive material. The PTH derivative's ability to promote bone regeneration and enhance vertebral stability aligns with previous studies demonstrating its potential in accelerating bone healing in various orthopedic applications. The sheep model proved valuable in mimicking human cervical vertebral anatomy and biomechanics, providing essential preclinical data before translating the technique to human trials.

The histological findings provide insight into the mechanisms underlying the observed bone regeneration. The increased osteogenesis and angiogenesis around the PTH derivative suggest a stimulatory effect on bone-forming cells and blood vessel formation, crucial for tissue repair and integration of the bioactive material.

The improved mechanical strength and stability of the augmented cervical vertebrae in the experimental group indicate the successful integration and performance of the PTH derivative bioactive material. Enhanced vertebral stability is particularly crucial in cervical vertebral fractures, where maintaining proper alignment and preventing further displacement are essential for functional recovery.

CONCLUSION

The results of this study establish the feasibility and effectiveness of cervical vertebral augmentation using a PTH derivative bioactive material in a novel sheep model. The successful bone regeneration and enhanced vertebral stability observed in the experimental group support the potential clinical application of this technique in human patients with vertebral fractures and instability.

The sheep model's anatomical and biomechanical similarities to humans make it a suitable platform for evaluating the safety and efficacy of cervical vertebral augmentation before human trials. The histological evidence of increased osteogenesis and angiogenesis

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around the PTH derivative provides mechanistic insights into its bone-regenerating properties.

These findings hold promise for advancing cervical vertebral augmentation techniques and may contribute to the development of innovative treatments for vertebral fractures and instability in humans. However, further research, including longer-term follow-up and comparison with other available bioactive materials, is warranted to fully validate the long-term efficacy and safety of this approach before its clinical implementation. Ultimately, this study serves as a stepping stone for future translational research, bringing us closer to improved treatment options for patients suffering from cervical vertebral fractures and instability.

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