INPLASY PROTOCOL

To cite: Chen et al. An exhaustive system review and meta-analysis of surgery procedures used to treat Kümmell disease in combination with neurological deficits. Inplasy protocol 2020110113. doi: 10.37766/inplasy2020.11.0113

Received: 26 November 2020

Published: 26 November 2020

Corresponding author:
Xiaohong Fan

chen023028@163.com

Author Affiliation:
Hospital of Chengdu University of Traditional Chinese Medicine

Support: **N/A.**

Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
The authors have no potential conflicts of interest.

An exhaustive system review and meta-analysis of surgery procedures used to treat Kümmell disease in combination with neurological deficits

Chen, B[1]; Fan, X[2]; Li, T[3]; Li, Q[4]; Shi, Y[5]; Yu, Y[6]; Jiang, L[7].

Review question / Objective: **Kümmell disease with neurological deficits occurs after a traumatic injury and gives rise to vertebral collapse, spinal instability, and aggravated local kyphosis. Surgical treatment is strongly recommended. There is no consensus on an optimal surgical procedure for Kümmell's disease. we accumulated a high-quality evidence-based database to assess the effectiveness and safety of various surgical procedures used to treat Kümmell disease with accompanying neurological deficits.**
Condition being studied: **Kümmell disease, or ischemic necrosis of the vertebra, occurs after a traumatic injury and gives rise to vertebral collapse, spinal instability, and aggravated local kyphosis. In the presence of neurological deficits, surgical treatment is strongly recommended. Although multiple surgery procedures have been implicated in treating Kümmell's disease. There is no consensus on an optimal surgical procedure for Kümmell's disease, as most patients with this disease belong to the elderly population and, therefore, suffer from additional medical illnesses, experience frequent instrumentation failure due to reduced bone quality, and are likely to have a high death rate post-surgery. As such, it is crucial to examine all options and carefully determine the treatment protocol needed to provide the best opportunity to stabilize challenging patients safely and effectively.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 November 2020 and was last updated on 26 November 2020 (registration number INPLASY2020110113).

INTRODUCTION

Review question / Objective: **Kümmell disease with neurological deficits occurs after a traumatic injury and gives rise to vertebral collapse, spinal instability, and aggravated local kyphosis. Surgical treatment is strongly recommended. There is no consensus on an optimal surgical procedure for Kümmell's disease. we accumulated a high-quality evidence-based database to assess the effectiveness**

and safety of various surgical procedures used to treat Kümmell disease with accompanying neurological deficits.

Condition being studied: Kümmell disease, or ischemic necrosis of the vertebra, occurs after a traumatic injury and gives rise to vertebral collapse, spinal instability, and aggravated local kyphosis. In the presence of neurological deficits, surgical treatment is strongly recommended. Although multiple surgery procedures have been implicated in treating Kümmell's disease. There is no consensus on an optimal surgical procedure for Kümmell's disease, as most patients with this disease belong to the elderly population and, therefore, suffer from additional medical illnesses, experience frequent instrumentation failure due to reduced bone quality, and are likely to have a high death rate post-surgery. As such, it is crucial to examine all options and carefully determine the treatment protocol needed to provide the best opportunity to stabilize challenging patients safely and effectively.

METHODS

Search strategy: The scientific databases used in this study were as follows: PubMed, Embase, Web of Science, Cochrane Library, China Science and Technology Journal Database, Chinese Biomedical Literature Database, the China National Knowledge Infrastructure, and Wanfang Data. The timeline for the electronic database search was from 1958 to October 2020 ,which is not limited to language. Reference list of all selected articles will independently screened to identify additional studies left out in the initial search.

Participant or population: Participants were chosen based on the details of surgical methods of Kümmell's disease with neurological deficits. There were no restrictions on age, gender, or race.

Intervention: The surgical treatment included anterior neural decompression and posterior fusion, and cement-augmented anterior reconstruction with posterior decompression and internal fixation.

Comparator: Posterior vertebrectomy and fusion

Study designs to be included: All randomized and controlled studies, cohort trials, and case-control studies.

Eligibility criteria: Surgeries conducted to treat Kümmell disease with neurological deficits were considered for inclusion. There were no language limitations. Any surgeries conducted in the absence of study groups, literature review, case reports, repeated studies, animal experiments, osteoporotic vertebral compression fracture, vertebral hemangioma, and primary or metastatic tumor fracture were not included in the study.

Information sources: PubMed, Embase, Web of Science, Cochrane Library, China Science and Technology Journal Database, Chinese Biomedical Literature Database, the China National Knowledge Infrastructure, and Wanfang Data.The timeline for the electronic database was from 1958 to Oct.2020.The search was not limited to language.In order to expand the scope of the search, the relevant references in the literature found in the reported databases were also retrieved manually and examined. Past reviews and meta-analyses were also scanned for supplemental information.

Main outcome(s): All studies included 1 or more of the following outcomes: visual analogue scale (VAS); Oswestry Disability Index (ODI); operation time, intraoperative blood loss, perioperative complications, and patient mortality.

Additional outcome(s): Other outcome data reported were patient characteristics, radiological (ex. anterior vertebral heights and kyphosis angle), neurological improvement (Frankel classification), instrumentation failure, events of new VCF.

Data management: Once the relevant literature was collected, two researchers independently extracted relevant data from each study. Any conflicts in their data extraction and conclusions were settled by a third reviewer. The extracted data included: first author, publication time, title of journal, study design, number of patients, average age, gender composition, treatment, duration of intervention, and outcome. In case of missing important information, the original authors were contacted for further details on their research.

Quality assessment / Risk of bias analysis: The study quality evaluation was carried out based on the quality evaluation criteria recommended by the Cochrane system. This included: (1) selection bias: determining the accuracy of the random method and the sufficiency of the randomization concealment; (2) implementation bias: whether the blind method of participants and subjects was in place; (3) measurement bias: whether the blind method of therapeutic effect evaluator was correct; (4) loss of follow-up bias, whether there were missing reports on follow-up, and whether the treatment was appropriate (incomplete outcome data processing). (5) Publication bias: whether there were selective reports. A bias value of "high," "unclear," or "low" was provided to each study. These criteria were examined independently by two researchers. The outcomes of these ratings were then cross-examined and any conflicts settled by a third reviewer.

Strategy of data synthesis: Review Manager 5.1.0 will be used for data synthesis, I2 quantitative and chi square tests were used to evaluate statistical heterogeneity, and the test standard was $p< 0.05$. In the absence of heterogeneity ($I2< 50\%$), the fixed effect model was used for meta-analysis; however, in the presence of statistical heterogeneity ($I2> 50\%$), the heterogeneity was analyzed. If clinical heterogeneity was excluded, the random effect model was used for the meta-analysis.

Subgroup analysis: If clinical heterogeneity was not excluded, a subgroup analysis was performed according to the clinical heterogeneity to determine the source of heterogeneity. Upon the existence of significant heterogeneity after subgroup analysis, the meta-analysis was not collected, and a descriptive summary was reported instead. However, in the presence of significant heterogeneity, subgroup analysis was performed according to the varying characteristics, treatment protocols, and outcome measurements.

Sensibility analysis: Sensitivity analysis was used to exclude low-quality studies and small-population studies. In addition, changes in the I2 value and combined effect quantity were used to analyze the stability of the results.

Language: There were no language limitations.

Country(ies) involved: China.

Keywords: Kümmell disease, systematic review, meta-analysis, protocol, neurological deficits, surgery.

Contributions of each author:

Author 1 - Botao Chen - Writing – review and editing the manuscript.
Email: 271114988@qq.com
Author 2 - Xiaohong Fan - Writing – review and editing the manuscript.
Email: chen023028@163.com
Author 3 - Tong Li - Data curation and formal analysis.
Email: 2816487188@qq.com
Author 4 - Qianchun Li - Resources and software.
Email: 1047565640@qq.com
Author 5 - Yin Shi - Formal analysis and software.
Email: wangshaochun88@163.com
Author 6 - Yang Yu - Investigation and supervision.
Email: yangyu@sina.com
Author 7 - Leiming Jiang - Investigation and supervision.
Email: leimingjiang@aliyun.com