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β-Tricalcium Phosphate as Alveolar Bone Grafting in Cleft Lip/Palate: A Systematic Review

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ADMINISTRATIVE INFORMATION

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 August 2023 and was last updated on 26 August 2023.

INTRODUCTION

Review question / Objective The aim of this systematic review is to describe and to identify prospect of β-Tricalcium Phosphate (β-TCP) as Alveolar Bone Grafting (ABG) in Cleft Lip/Palate (CL/P) or alveolar bone cleft defect. What is the prospect β-TCP as ABG to stimulate the regeneration of CL/P or alveolar bone cleft defects?

Rationale Cleft Lip with or without cleft Palate (CL/P) is a major congenital birth defect in the craniofacial structure caused by a defect in palatogenesis during the embryonic phase. CL/P etiology is impacted by genetic, environmental, and a mixture of both factors. CL/P is shown clinically as a cleft in the lip, alveolar bone, palate, and nasal septum. The patients have cosmetic and functional deficiencies.. CL/P is one of the most frequent orofacial congenital abnormalities worldwide.. The epidemiology of cleft lip, cleft palate, and cleft lip and palate (CL/P) has been recorded at roughly 1 in 700 per birth, but it has also been reported at 1 in 500 to 1 in 2,500 per birth in other parts of the world. The prevalence of CL/P was estimated to be 10.8 million people in 2017, with a disease burden of 652.084 disability-adjusted life years, with low- and middle-income countries (94.1%) of this disease burden. CL/P is highly common in the Asia area, particularly in Japan, China, and Indonesia, which are high-risk nations for CL/P.

Lifetime costs, loss of productivity, lack of self-confidence due to facial, aesthetic, or cosmetic aspects, increased utilization of mental health services, speech and hearing impairment, risk of infection, and increased morbidity and mortality at all stages of life are all the negative impacts of CL/P on the individual and society. Furthermore, it may affect the oral health related quality of life of CL/P patients [9]. In individuals with CL/P, dental malformations are more prevalent due to anatomical abnormalities in the alveolar process. Approximately 83.3% of the individuals with CL/P had at least one dental anomaly, with tooth

agenesis being the most prevalent abnormality observed. Fur-thermore, the group with unilateral CL/P had the greatest number of dental abnormalities. These anomalies can create serious issues that can be avoided or mitigated by early detection and treatment.

The alveolar cleft volume increased with age in CL/P patients, which is related to an increasing breadth of the lip-palatal defect. Patients under the age of 18 had significantly higher rates of ipsilateral maxillary sinusitis, which may increase the risk of bone infection. Alveolar process has the important role as the dentition host. Therefore, Alveolar cleft that occurred in the CL/P is necessary to be closed. Alveolar bone grafting (ABG) and periosteoplasty are the two most frequent surgical methods that have been established for CL/P treatment. Regeneration of alveolar cleft and continuous alveolar process for tooth can erupt be moved by means of orthodontics are the main objective of ABG or perios-teoplasty in CL/P patients. Secondary alveolar bone grafting (SABG) reconstructs the alveolus, supports permanent teeth, closes any residual anterior palatal fistulas, and supports the alar base and lip on the cleft side. Restoring maxillary integrity is also advantageous if future orthognathic surgery is necessary. The optimal period for alveolar bone grafting (ABG), according to the European and North American Cleft Association, is before canine eruption. However, various concerns remain, including the nature of the surgical and orthodontic techniques, the kind of bone and donor location, and the op-timum approach to managing the space in the dental arch. Although the most typical age range for performing a bone graft is between the ages of 8 and 11, some hospitals have started to perform alveolar bone grafts at a younger age in the expectation of achieving better outcomes for unerupted incisors. A variety of donor sites have been used, but the iliac crest remains the most preferred, although it may pose challenges for some patients with medical conditions.

Condition being studied Rapid integration of ABG is crucial for achieving structural stiffness. Structural and nonstructural ABG procedures modify alignment, function, and appearance by adding length, height, and volume. Corticocancellous autografts, allografts, xenografts, and synthetic grafts are all kinds of ABG. Autogenic grafts, which are harvested from the patient, are less likely to be rejected. However, the harvesting process adds an additional step, and donor site morbidity is prevalent. Secondary operations and donor site problems are avoided with allografts, xenografts, and synthetic grafts. Stringent regulations are projected to significantly limit the allograft industry in the future. The use of xenograft or synthetic ABG, such as Beta (β)-tricalcium phosphate (β-TCP), a bioceramic biomaterial, is expected to be promising and helpful for clinical results in CL/P therapy. β-TCP materials, followed by xenograft biomaterials, which regrettably still lack established predictability and clinical efficacy, dominate the cranio-maxillofacial market. Despite numerous efforts made to investigate the ABG in the field of cra-nio-maxillofacial medicine, the regenerative prospect of β-TCP as ABG in CL/P has not yet been fully elucidated and remains limited.

METHODS

Search strategy A systematic review protocol based on PRISMA 2020 was drafted. In addition, reporting was based on the PRISMA 2020 checklist [16,17]. The following databases were searched: MEDLINE/ PubMed (https://pubmed.ncbi.nlm.nih.gov), Web of Science/ ISI-Web of Knowledge (https://www.webofscience.com/), Scopus (https://www.scopus.com/), and the Cochrane Library (https://www.cochranelibrary.com/advanced-search). Manual searches were undertaken to supplement the completed searches. Furthermore, the gray literature in The New York Academy of Medicine Gray Literature Report (http://www.greylit.org) and the European System for Information on Gray Literature (http://www.opengrey.eu) was screened.

Scopus β-tricalcium AND phosphate OR β-TCP or bone graft OR bone grafting OR alveolar AND bone AND graft AND alveolar AND bone AND cleft OR cleft AND palate AND (LIMIT-TO (PUBSTAGE, “final”)) AND (LIMIT-TO (OA, “all”)) AND (LIMIT-TO (DOCTYPE , "ar")) AND (LIMIT-TO (LANGUAGE , "English")) AND (LIMIT-TO (SRCTYPE , "j"))

PubMed β-tricalcium phosphate OR β-TCP OR bone graft OR bone grafting OR biomaterial OR alveolar bone graft AND alveolar bone cleft AND cleft palate

Filters applied: Free full text, Clinical Trial, Randomized Controlled Trial, English, Exclude preprints, MEDLINE.

Web of Science ((((((ALL= (β-tricalcium phosphate)) OR TS= (β-TCP)) OR TS= (bone graft)) OR TS= (bone grafting)) OR TS= (alveolar bone graft)) AND TS=(alveolar bone cleft)) OR TS=(cleft palate)

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Cochrane Library β-tricalcium phosphate OR β-TCP OR bone graft OR bone grafting OR alveolar bone graft AND alveolar bone cleft OR cleft palate in Title Abstract Keyword - in Trials, Clinical Answers (Word variations have been searched).

Participant or population CL/P or alveolar defect Animal Model Study and CL/P patient.

Intervention β-TCP ABG.

Comparator Autograft / Xenograft or no treatment/other regenerative materials.

Study designs to be included in vivo study, including CL/P animal studies and clinical studies.

Eligibility criteria The following categories of articles were included in this review: original articles that focused on the methodology of using β-TCP as an ABG in animal models or humans, to regenerate CL/P or alveolar bone cleft defects. Open access (accessed through Graduate School of Dentistry, Tohoku University's IP address) of full-text articles relevant to β-TCP ABG for CL/P or alveolar bone cleft defect were used as inclusion criteria. Reviews, short communication, editorial notes, processes, and recommendations were not considered and excluded. All types of experimental and observational studies in English were included. Nevertheless, no duplicate studies were included in the analysis. Adults or children of any gender or age are acceptable study subjects, as are any other objects of in vivo re-search. CL/P, alveolar cleft defect, β-TCP, and ABG, as well as any additional therapies involving tissue engineering, were included in the research as study factors or exposures. Bone regeneration, bone repair, bone volume, dentistry, bone remodeling, and any other measure of bone regeneration in CL/P were among the outcomes of the research ex-amined. Articles in languages other than English, letters to the editor, and all types of reviews and commentaries were excluded. There were no restrictions on the year of publication, but only free accessed full papers.

Information sources A systematic review protocol based on PRISMA 2020 was drafted. In addition, reporting was based on the PRISMA 2020 checklist [16,17]. The following databases were searched: MEDLINE/ PubMed (https://pubmed.ncbi.nlm.nih.gov), Web of Science/ ISI-Web of Knowledge (https://www.webofscience.com/), Scopus (https://www.scopus.com/), and the Cochrane Library (https://www.cochranelibrary.com/advanced-search). Manual searches were undertaken to supplement the completed searches. Furthermore, the gray literature in The New York Academy of Medicine Gray Literature Report (http://www.greylit.org) and the European System for Information on Gray Literature (http://www.opengrey.eu) was screened.

Main outcome(s) Bone regeneration or bone remodeling of CL/P or alveolar bone cleft defect.

Additional outcome(s) New bone formation, enhanced osteogenic markers, orthodontic tooth movement rate.

Data management Data relevant to methodology, sample size, duration of the studies, and the investigations carried out were extracted from each study. Results from the animal (in vivo) and human clinical studies were tabulated in the table using predetermined data collection forms by the two investigators independently . Microsoft Office Excel (2010, Microsoft) was used for descriptive statistics.

Quality assessment / Risk of bias analysis Depending on the type, each study was assessed individually and independently by investigators. It was decided that for the quality assessment of any randomized clinical trials, Consolidated Standards of Reporting Trials (CONSORT) would be used. The Animal Research: Reporting of In Vivo Experiments (ARRIVE) guidelines were selected for animal studies. Any disagreements were solved by discussion between investigators.
The risk of bias evaluation was carried out in accordance with a technique derived from prior systematic reviews. This assessment evaluated the description of several quality assessment parameters, including a well-defined β-TCP as ABG process, standardized sample or subject preparation, randomization of samples or subjects, tests conducted by a single blinded operator, a clear test method specification, and comprehensive reporting of results. The article was labeled "Y" for a given parameter if the authors reported it and "N" if the information could not be located. The articles were classified as having a high, medium, or low risk of bias based on the number of "Y" elements included (1-2, 3-4, or 5-6).

Strategy of data synthesis The keywords yielded a total of 5824 articles publication, with 90 papers from Scopus, 6 papers from PubMed, 4510 papers from Web of Science and 1218 papers from the Cochrane Library, respectively. The 3196 suitable articles to evaluate after removing duplicates and languages. We had 1315 studies left after doing title and abstract reading. Eighty-five full-articles

were assessed for eligibility. The read the complete texts of those papers and eventually chose 20 that matched the inclusion requirements. The reviewers (A.P.N, H.Y, J.C) independently performed critical evaluations utilizing JBI critical evaluation tools.

Subgroup analysis nil.

Sensitivity analysis nil.

Language restriction English.

Country(ies) involved Japan, Indonesia.

Other relevant information nil.

Keywords Medicine; β-Tricalcium Phosphate; Bonegraft; CL/P; Dental Material; Bioceramic.

Contributions of each author

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