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Management of osteoradionecrosis of the head and neck region using microvascular free flaps: a systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

Support - No support.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202420022

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 February 2024 and was last updated on 05 February 2024.

INTRODUCTION

Review question / Objective Are microvascular free flaps a predictable option in managing osteoradionecrosis of the head and neck region?

Rationale Osteoradionecrosis (ORN) is a serious late complication of radiotherapy (RT) for head and neck cancer. Over the years several theories have emerged describing the pathophysiology of ORN. The ORN presentation varies, and can range from areas of asymptomatic exposed bone to severe and progressive necrosis. The latter might present with patients experiencing severe pain, trismus, dysphagia, pathological fractures, or orocutaneous fistulas. Consequently, repeated hospital visits and sometimes extensive surgical reconstructions are needed to manage these sequelae. Depending on the severity, ORN can have a debilitating impact on

patients' quality of life. The aim of this review is to analyse the quality of the evidence in managing osteoradionecrosis of the jaw using free flaps.

Condition being studied Osteoradionecrosis and the surgical management in advanced stage of necrosis.

METHODS

Participant or population Any (no limits of age) patients affected with ORN of the head and neck.

Intervention Any type of microvascular free flaps.

Comparator conservative management and or surgical debridement.

Study designs to be included Any type of studies included in the research strategy published from

1970 until January 2024: Randomized controlled trials, Case-controlled trials, Cohort studies (prospective and or retrospective), Case series, and Case report studies.

Eligibility criteria - Original articles published - Studies involving human subjects - All study designs with a clearly defined method.

Information sources The intended information sources for the current systematic review are:
 - Electronic databases (PubMed, MEDLINE, EMBASE, CINAHL)
 - Contact with authors where further information is required
 - References of included studies.

Main outcome(s) Primary outcome - Evaluate the success rate of microvascular free flaps in ORN cases in the head and neck region.
 Secondary outcome - Evaluate the contributing factors:
 Most common type of radiotherapy associated to ORN;
 Most common site of the necrosis in the head and neck region;
 Most common post-operative complications.

Quality assessment / Risk of bias analysis A quality assessment checklist from Risk Of Bias In Non-randomized Studies - of Interventions (ROBINS-I) will be used to assess all primary studies included in the systematic review. Alternative a Version 2 of the Cochrane risk-of-bias tool for randomized trials (RoB 2) will be used for RCT studies.
 Additionally we a descriptive quality components will be used. We will evaluate what the authors of the primary studies report regarding quality assessment of their studies. Two review authors will appraise the risk of bias in the included studies with the mentioned tools. Any disagreements in risk of bias assessments will be referred to another author of the review team and will be resolved by discussion.

Strategy of data synthesis This systematic review will not adopt any restrictions on minimum number of studies or heterogeneity of the studies. In case of heterogeneity of the cohort of patients and studies, descriptive statistics will be used to analyse and present the data.

Subgroup analysis All participants will be included in the final analysis. If data permits, a subgroup analysis will be included in this review.

Sensitivity analysis If sufficient data are extracted, a sensitivity analysis will be conducted to check the stability of the outcome results by excluding low methodological quality or high risk of bias studies.

Language restriction If sufficient data are extracted, a sensitivity analysis will be conducted to check the stability of the outcome results by excluding low methodological quality or high risk of bias studies.

Country(ies) involved Italy and United Kingdom.

Keywords Osteoradionecrosis, Radiation, Microvascular free flaps, Complications.

Contributions of each author

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