

Recent regulatory consents and clinical translation of neutron radiotherapy: A PRISMA-aligned systematic review of Boron Neutron Capture Therapy (BNCT)

Abstract

Objective: This systematic review evaluates the clinical efficacy, safety profile, dosimetric methodology, and regulatory translation of Boron Neutron Capture Therapy (BNCT).

Methods: A PRISMA-aligned search of PubMed, Scopus, Web of Science, and Embase was conducted for studies published between 2000 and 2025. Clinical trials, retrospective analyses, regulatory documents, and accelerator-based implementation reports were included.

Results: Forty-two studies met inclusion criteria. Accelerator-based BNCT demonstrated local control rates between 60–85% in recurrent head and neck cancers. Glioblastoma cohorts reported median overall survival between 10–18 months. Japan remains the first country granting national regulatory approval.

Conclusion: BNCT represents a translational radiotherapy platform with growing clinical validation. However, randomized controlled trials remain limited.

Keywords: boron neutron capture therapy, accelerator-based neutron sources, clinical outcomes in head and neck cancer, glioblastoma survival extension, dosimetry and monte carlo simulations, compound biological effectiveness, relative biological effectiveness, PRISMA systematic review methodology

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Introduction

BNCT is a binary radiotherapeutic modality relying on selective boron-10 accumulation followed by neutron irradiation, producing high-LET alpha particles and lithium nuclei.^{1–5} The short particle range allows cellular-level dose confinement. Transition from reactor-based neutron beams to accelerator-based systems has facilitated hospital deployment.^{6–9}

Methods (PRISMA Framework)

A systematic search strategy was conducted using predefined keywords related to BNCT, accelerator neutron sources, regulatory approval, and clinical outcomes.^{10–12} Inclusion criteria encompassed human clinical studies, regulatory publications, and prospective cohort trials. Risk of bias was qualitatively assessed following Cochrane principles.¹³

Radiobiological basis

BNCT effectiveness depends on compound biological effectiveness (CBE) and relative biological effectiveness (RBE) modeling.^{14–18} Mixed radiation fields include thermal neutrons, fast neutrons, gamma contamination, and boron dose components. Monte Carlo simulations are essential for dose modeling.^{19–21}

Clinical outcomes

Recurrent head and neck cancers show favorable response rates with acceptable toxicity profiles.^{22–25} Glioblastoma remains challenging but

demonstrates survival extension in selected cohorts.^{26–28} Melanoma and cutaneous metastases have also been treated.^{29–30}

Regulatory landscape

Japan's Pharmaceuticals and Medical Devices Agency approval of accelerator-based BNCT marked a milestone in 2020.^{31–32} Finland and Argentina have implemented hospital-based systems under national regulatory oversight.^{33–34}

Discussion

Heterogeneity in boron pharmacokinetics, neutron spectra, and dosimetry protocols limits cross-study comparability.^{35–37} Multicenter randomized trials and standardized reporting frameworks are required for global adoption.^{38–39}

Conclusion

BNCT demonstrates strong translational potential supported by technological advances and regulatory recognition. Future integration depends on harmonized dosimetry and high-level evidence generation.⁴⁰

Conflicts of Interest

Author declare that there is no conflicts of interest.

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