International Journal of Recent Development in Engineering and Technology
Website: www.ijrdet.com (ISSN 2347-6435 (Online) Volume 15, Issue 08, August 2026)

Review on Targeted Drugs Delivery for Boron Neutron Capture Therapy (BNCT) of Cancer

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***Abstract*— BNCT is a radio therapeutic method which is divided into two parts. Process starts with the capturing of neutron by the 10B boron isotope and subsequent nuclear fission of boron. Recently, BSH and BPA are two boronated drugs which are being used for the therapy. Both of these approved drugs have very limited efficacy.**

To overcome this limitation, many potential studies are carried out to develop novel boronated drugs that have selectivity for cancer cells over normal cells. Newer boronated drugs need to deliver the therapeutic amounts of boron into cancerous cells with high specificity and low toxicity to normal cells.

In this review, we will focus on tumor-targeting technique and novel boron delivering agents. Many novel boron containing compounds have been synthesized and proposed for boron neutron capture therapy for cancers. However, none of these have reached the stage of clinical trials yet. Further evaluation of these newer agents in clinical trials is required to determine their therapeutics potential for BNCT cancer treatment.

***Keywords*— Boron Neutron Capture Therapy (BNCT), Boronophenylalanine (BPA), Sodium borocaptate (BSH), Novel boron delivering agents, Tumor-targeted drug delivery.**

I. INTRODUCTION

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Working Principle of Boron Neutron Capture Therapy:

- Irradiation of low-energy (0.025 eV) thermal neutrons or epithermal neutrons (10,000 eV) to stable isotope boron-10 (10B).
- These irradiated neutrons will be captured by the Boron and
- Neutron capture leads to nuclear fission which produce high-linear energy transfer (LET) alpha (α) particles (4He) and recoiling lithium-7 (7Li) nuclei.
- This cell killing radiation will penetrate into the tissue.

α-particles that are produced during nuclear fission have very short pathlengths (5–9 μm), hence their destructive effects are limited to boron-containing cells. Therefore, we can selectively destroy tumor cells and spare adjacent normal cells. That is how BNCT minimizes damage to surrounding non-tumour healthy tissues. With BNCT it should be possible to selectively destroy tumor cells infiltrating normal tissue.

Radiation generated following by the fission reaction, is having a short path length of the high energy particles, guarantees their destructive effect is kept within the cellular confines and making BNCT a safe therapeutic approach.

Sufficient amounts of boron and thermal neutrons need to be selectively delivered to the site of the tumor cells (~ 20 μg/g of Boron per weight of tumor, ~ 109 atoms/cell). So, Boron which present in cancer cells will absorb the required amount of neutrons and it sustain the release of optimum amount of radiation to kill cancer cells [1].

1. Blood–Brain Barrier (BBB) and BNCT

For the treatment of brain tumors, boronated drugs need to be permeable through Blood-brain barrier (BBB). It is desirable that the boron delivering agent has to be combine with brain barrier disrupting drugs to permeate across the blood–brain barrier (BBB). It is difficult for the high molecular boronated drugs to cross this barrier because it effectively excludes agents with molecular weights higher than 200 Da [2]. In line with this, highly infiltrative properties of glioma cells and their genomic heterogeneity is another major hurdle in the treatment.

Secondary Ion Mass Spectrometry [3] or Alpha Track Autoradiography can be used for the determination of cellular and sub-cellular level of boron [4]. These techniques allow more accurate dosimetry, but less applied for real time.

2. Marker & Detection in BNCT

Radiopharmaceuticals have to deliver excess amount of boron in cell so that tumour can be detect by radio-diagnostic modalities such as single photon emission computerized tomography and PET.

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Along with this, these radiopharmaceuticals should have slow rate of bioclearance from the body and need to attain the boron ratio for tumor:normal tissue of 3 to 4:1.

3. Clinical application of BNCT therapy

It is primarily applied to the patients who have failed the conventional cancer therapy. Patients with having high grade gliomas [5], recurrent tumors of the head and neck region [6] and cutaneous [7] or extra-cutaneous [8] melanomas can be treated by using this method.

Limitation of BNCT are:

(1) limited access to neutron sources

(2) limited effectiveness of current 10B isotope containing compounds

II. Method Of Bnct Technique

1. Neutron Source

Previously BNCT find its difficulties due to high cost of neutron sources. Thermal (< 0.5 eV) or epithermal (0.5 eV to 10 keV) neutrons could be produced by specially designed nuclear reactors for BNCT trials. Until 2014, specially designed and modified nuclear reactors were used to produce neutrons.

However, with advancement of engineering techniques, accelerator-based neutron sources have been developed. These accelerator based reactors are installed in laboratories and hospitals facilities for pre-clinical evaluation of boronated drugs as well as patient treatment.

TAE Life Science has developed Alpha-beam Neutron System (ANS). It is a positive ion-based electrostatic accelerator device. It will provide the most compact, reliable and economical solution for the clinical implementation of BNCT [9].

Several companies have developed the Accelerator-based neutron sources [10]. All of them are in Phase I/II clinical trials.

2. Boron Delivering Agents

First boron delivering agent was discovered on 50 years ago [11]. Sodium borocaptate or BSH [12] was a first compound of BNCT. Clinically, BSH was first used for the treatment of high grade gliomas patients.

Second boron compound [13] was boronphenylalanine or BPA [14]. Untill now, BSH and BPA are only two compounds which are clinically approved for BNCT.

BSH having the high boron content (60 %), but is has a low tumour specificity. BSH was found to have low BNCT therapeutic efficacy with compared to BPA [15]. Indicating the therapeutic superiority of BPA over BSH.

Despite of having a low boron content (5 %) in BPA. L-BPA is preferentially taken up in tumor cells by L-type amino acid transporter 1 (LAT1, SLC7A5). Even though L-BPA shows promising results, it has some limitation like it required a high dosage for tumour therapy, less water solubility and lower ability to target the tumour.

A. Limitation of BSH and BPA

The major problem with first generation boronated drugs (BSH, BPA) is that they have very low uptake in cancer cells, as in the case of brain tumors.

Both compounds low tumour uptake is because of their inter-tumoral variability from one patient to another. And due to the marked and complex intra-tumoral histologic, genomic and epigenomic heterogeneity within high grade gliomas [16]

Low uptake and micro-distribution of boronated drugs will result into the broad range in mean survival time (MST) [17]. So, it need to require the advance boronated drugs.

III. Development Of Novel Boron Delivering Agents

Research motive of novel boron drugs is to develop novel boronated drugs which have better cancer cell selectivity. With compare to current drugs these novel agents are requires to deliver 10B loads in higher concentration to the target cells.

1. Criteria for Novel Boron Delivering Agents

- low intrinsic toxicity
- high tumor uptake (~ 20–50 μg boron) and low normal tissue uptake
- Ratio of tumor:normal tissue and tumor:blood boron concentration of greater than 3:1
- Rapid clearance from blood and normal tissues

Primary requirement for their development has been a delivery of therapeutic concentrations of boron with minimal normal tissue uptake and retention. To maximize the effectiveness of BNCT, the 10B load per cell must be improved. It is estimated that a novel boronated drug should deliver at least 20 g of 10B per gram of tumor.

IV. Targeted Drug Delivery For BNCT

Primary object of novel drug development for BNCT is more selectivity towards cancer cells and less cellular uptake in normal cells. It must have to deliver therapeutics concentration of boron into the tumor cells.

Novel boronated compounds need to have specificity for the cancel cells. They need to fulfill the 3:1 boron ratio for cancel cells to normal cells.

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For the better tumor specificity, boronated drugs can be linked to a tumor-targeting moiety. Various approached like incorporating boronated drugs with tumor-targeting moieties, such as unnatural amino acids, polyamines, peptides, proteins, antibodies, nucleosides, sugars, porphyrins, liposomes and nanoparticles can be used for selective delivery [18].

Several newer boron delivering agents have emerged with time. In this review, we will cover the novel low and high molecular weight boron delivery agents that have been evaluated in-vitro, but have not been evaluated clinically.

1. . Boronated natural Amino acids

One of the approach for the selective delivery is boronated natural amino acids. It is the natural amino acids linked with the boron compounds. They are lower molecular weight compounds. This type of compounds are boronated derivatives of amino acids such as serine, cysteine, tyrosine, methionine and aspartic acid [19].

Boron containing derivatives of naturally occurring amino acids such as L-dopa and L-tyrosine were synthesized and they shows the higher selectivity towards SK-23 melanoma cells [20]. These both are precursor amino acids of melanin and substrate for tyrosine.

Some of the boron containing synthetic amino acids have also been developed and studied. Boronated derivatives of synthetic amino acids are investigated because of their higher metabolic stability with compare to natural amino acids [21].

TAE Life Science is developing a novel lead molecule, named as TDP-747. It is an amino acid analogue that is taken up by the large neutral amino acid transporter (LAT-1), which is upregulated in many cancers. For TDP-747, tumour to healthy cell ration for boron is 13:1. It indicates the higher improvement over the 3:1 ratio usually seen with BPA.

2. Boronated Peptides

These are the compounds which contains the conjugation of sodium borocaptate with cyclic and linear peptides. Usually they have been studied and evaluated because they are easy to synthesize and they are non-immunogenic in nature. They have increased tissue penetration properties and low toxicity [22] with compare to other boronated drugs.

Peptide-boron conjugation can easily identify and target the specific protein receptors which are over-expressed in cancer cells. Boron-containing cyclic/linear peptides and cell-penetrating peptides (CPPs) with multiple arginine residues can potentially deliver the required high boron amount to cancer cells with higher T/N ratio.

In results, boronated derivatives of cell-penetrating peptides have less tumor cell selectivity with compared to receptor-specific targeting peptides [23].

3. Boron-containing Nucleosides and Nucleotides

Boron compound conjugated with nucleosides, nucleotides, thymidines, purines and pyrimidines have also been utilized for the selective delivery in BNCT.

4. . Convection enhanced delivery (CED)

It is an effective way to deliver some boron compounds and high molecular weight bio-conjugates to brain [24]. By using this method, therapeutic agents are delivered directly to the brain and completely bypass the BBB [25].

5. Boron-containing Porphyrin derivatives

Chlorins, bacteriochlorins, tetrabenzoporphyrins, and phthalocyanines are some of the examples of Boron containing porphyrins. This class of compounds finds its applications in BNCT because of their low toxicity and natural affinity for tumors [26].

Porphyrin-based compounds have an intrinsic fluorescence property. Therefore, they can be used for fluorescence-based detection and quantification of boron accumulated in blood, tumors and other tissues.

A detailed synthetic study will be required for the development of pophyrin containing compounds which have low affinity for macrophages and increased tumor cell uptake. However, Enhanced tumor cell uptake of boron-containing porphyrins can be achieved by conjugating a cell-penetrating peptide to the porphyrin ring.

6. Boron-Containing Nanoparticles

Since boron-containing nanoparticles have high amount of boron content, they can deliver therapeutic amounts of boron into cancer cells for BNCT [27].

Some limiting factors of Boron-containing nanoparticles are their lack of tumor-targeting ability and their frequent aggregation in aqueous solutions.

7. Boron-containing Sugars

These are the low toxicity molecules which can be used in BNCT. Various sugar containing compounds like derivatives of glucose, mannose, ribose, galactose, maltose and lactose [28] are comes under this category.

These types of compounds are more hydrophilic in nature so they tend to have lower tumour uptake. They also have rapid clearance from tissue. These are some limiting factors for their application in BNCT.

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8. Antibody-Boron conjugates

Antibody boron conjugates (ABCs) contain an antibody moiety and a boron-containing payload. ABCs having an improved differential penetration into cancer cells. They have better tumor cell specificity along with longer serum half-life.

By having a high boron concentration, they can help to improve the efficacy of BNCT. They can also expand the spectrum of cancer indications treatable with BNCT.

9. Boronated Monoclonal antibodies

Mono-clonal Anti-bodies (MoAbs) are higher molecular weight boronated agents. MoAbs are promising tumor-targeting agents due to their high specificity for molecular targets such as EGFR and EGFRvIII [29] and the ligands EGF [30] and VEGF [31].

Tumours like gliomas have overexpressed EGFR. So, we can specifically target the EGFR-overexpressing cancer cells with the help of MoAbs [32].

Disadvantage includes their difficulties to produce and derivatize the antibodies. And they have poor tumor cell internalization.

10. Boron-Containing Liposomes

Other potential carriers are vesicles like liposomes. It consists of an aqueous volume entirely enclosed by a lipid bilayer [33]. Liposomes are having the high loading efficiency [34]. Liposome can carry high concentration of boron by encapsulating large amounts of boronated drugs within their closed lipid bilayers and the aqueous core.

This bilayer mechanism helps in controlled release of the boronated drugs. The enhanced permeability and retention effect (EPR) of liposomes ensures the therapeutic accumulation of boron into the target tumor tissues. The average boron concentration of the liposomes in cancer cells was found to be the 30 µg 10B/g considered sufficient for effective BNCT [35].

11. Small Organic molecules

Small organic molecules are having the wide range of applications in treatment of diseases. These compounds can be effectively used in the treatment of brain tumour by using BNCT. These are the low molecular weight synthetic compounds, which can cross the blood–brain barrier and engage targets in the brain.

12. Polymer linkage to Boronated drugs

Solubility and pharmacokinetic properties of high molecular weight boron delivery agents can be improved by Polymers carriers. Polymer linkage could increase their circulation half-life in the body and their accumulation in the tumour [36].

BPA is a hydrophobic boronated drug, whose cellular uptake is dependent upon the l-amino acid transporter system [37]. So, conjugation to polymers might also increase its solubility [38].

13. Boron-containing DNA binding molecules

DNA intercalators, polyamines and alkylating agents are comes under this class [39]. Despite all potential advantages of novel boronated drugs (targeted delivery), They all have yet to be evaluated for clinical use [40].

V. Conclusion

There are two drugs which are clinically used for BNCT, but both two drugs can not able to deliver the required boron concentration to tumour cells. In line with this, they also deliver the high amount of boron in healthy tissue as well. Which end in severe side effects to healthy tissues.

Specificity of the boronated drugs can be increased by utilizing and targeting the cell wall receptors presents on tumour cells. Conjugation of boronated drugs with Peptides and Mono-clonal anti-bodies can help in amplification of effectiveness. In a similar way, peptides have been functionalized and conjugates with boronated drugs shows remarkable In-vivo properties with compared to the clinically approved BNCT drugs.

Although synthesis of the Peptides is quite easy, they can be rapidly cleared from blood and tissues by proteolytic enzymes. Many studies indicated that nanoparticles and liposomes can carry large boron loads so they proved to be potential agents for selective and targeted drug deliver for BNCT.

Cellular uptake of 10B atoms and high tumor–boron accumulation in cancer cells can be achieved by using the targeted drug delivery for BNCT. With the help of targeted drug delivery we can overcome the current challenges of BPA and BSH. And hope that further research will identify new and better boron delivery agents for clinical use.

Conflict Of Interest

The authors claim they have no competing interests.

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