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## Transdermal Delivery of Botulinum Neurotoxin A: A Novel Formulation with Therapeutic Potential

**Abstract:**

**Background:** BoNTs are secreted from the Clostridium botulinum in the form of multimeric complexes, with a set of non-toxic proteins encoded for by a set of genes adjacent to the neurotoxin gene. Botulinum toxin A complex is the most lethal substance known to humans, with a LD50 in mice (1unit) ranging from 25 – 50 picograms. In spite of its toxic effects, botulinum toxin is considered as a wonder drug. Other than approved indications, botulinum toxin is frequently used for more than 800 off label neuro-muscular indications. Botulinum toxin is frequently administered to patients for treatment by injecting a composition containing botulinum toxin into affected the muscles and glands. Generally, the effective dose depends on the mass of muscle being injected. Other modes of administration have been considered, such as topical administration. Although major focus for topical administration has been to deliver small molecules, delivering large molecules, such as proteins, could be quite challenging. Several formulations and techniques are available to increase the permeability of molecules through the skin. However, permeability of big molecules, such as proteins, through skin is difficult. In addition, delivery of large molecules frequently requires other mediative techniques such as iontophoresis, ultrasound or microneedle. Skin is the largest organ of the body, protects humans from microbes, external pathogens, and other external environmental threats. Skin has three layers, a) the epidermis (the outermost layer of skin), b) the dermis (beneath the epidermis), and c) the hypodermis (the deeper subcutaneous dermis). One of the important functions of skin is to prevent the water loss and provides barrier for the entry of the molecules. No formulation exists which delivers the botulinum toxin without the help of any mediative techniques. What is needed therefore is a formulation or composition containing therapeutically effective amount of botulinum toxin which will permeate the toxin through the skin to demonstrate its efficacy in exerting the desired therapeutic effect.

**Methods:** The current work includes a method for formulating the toxin for topical applications, and a method for efficient delivery of botulinum toxin through skin as a topical medicine. Analytical methods were used for the characterization of a delivery vehicle. Efficacy of the delivery method was assessed by evaluating the Digital abduction score (DAS) after topical administration in gastrocnemius muscles of mice. Efficacy of topical delivery was also assessed in a mice model of hyperhidrosis.

**Results:** We have created four different variants of topical formulation with varying efficacies. Out of four formulations, we present the data for our best formulation. We were able to demonstrate the topical delivery of toxin using our nano-emulsion formulation in mice. We were able to get the efficacy in the range of 25 -100 units, showing asignificant reduction in sweating in mice.



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**Conclusions:** This is the first ever formulation for topical delivery of botulinum toxin without any aid of external technique or modification in the toxin. Studies related to mechanism of this delivery, and Franz cell assay are on-going. However, we have been able to successfully demonstrate the efficacy of the proposed formulation which is comparable to intramuscular administration.

**Biography:** Dr. Raj Kumar, PhD is an Associate Professor and Director of Academic Advisement and the Research Program at the Institute of Advanced Sciences in Dartmouth, Massachusetts, USA. With a strong academic background in biomedical sciences, Dr. Kumar has dedicated his career to advancing interdisciplinary research and mentoring emerging scholars. His leadership in academic advisement has significantly enhanced student engagement, curriculum development, and research innovation. Dr. Kumar's research interests span molecular biology, regenerative medicine, and translational research, where he has contributed numerous peer-reviewed publications and conference presentations. He is actively involved in international scientific collaborations and has served on various academic and editorial boards. Known for his commitment to academic excellence and scientific integrity, Dr. Kumar plays a key role in fostering a dynamic research environment. His work continues to shape the next generation of researchers while promoting global scientific dialogue and innovation.



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