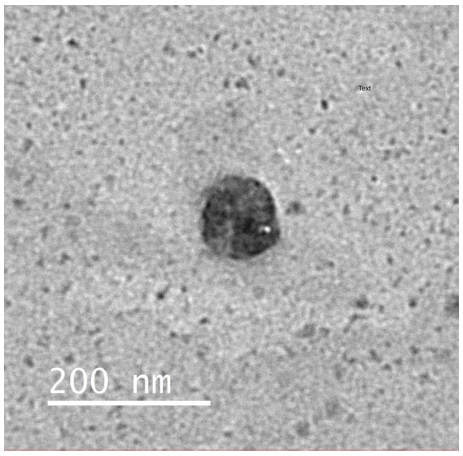

Novel Self-Assembling Nanoparticles for Extended Duration Local Anesthetics

Unmet Need

An estimated 40 million surgeries are performed every year in the United States. Out of this population, an estimated 80% had post-operative pain with 75% reporting it as moderate to extreme. Local anesthetics are commonly used to reduce the risk of postoperative chronic pain, decrease opioid consumption, and offer a fast postoperative recovery. However, their duration of action is insufficient to manage pain relief for the duration of post-operative pain, establishing a need for a novel local anesthetic formulation that provides adequate and extended pain management for patients.

Technology

Duke inventors from the Biomedical Engineering and Anesthesiology Departments have developed a nanoparticle based local anesthetic using machine learning. This is intended to be a simple to manufacture and extended duration injectable post-operative anesthetic. A computational decision system combining machine learning and molecular simulations was used to aid in the selection of the suitable combination of excipient molecules and local anesthetics. In one combination, the nanoparticles are formed by combining bupivacaine, an injectable local anesthetic, with Congo Red. The resulting nanoparticles are highly stable, have a radius of 60-70 nm, and can achieve over 60% drug loading. This has been demonstrated by characterizing the size of the resulting nanoparticles over weeks to months. In mouse models, the nanoparticle formulation was perineurally injected, and demonstrated significantly prolonged pain relief compared to drug alone with full sensory recovery in both groups. Furthermore, early motor, sensory, and histological mouse data suggest no major differences compared to drug alone once effects have subsided.

Other Applications

This technology could be used for single-shot regional anesthesia, infiltration, or nerve blocks as an alternative to catheter-based pain management approaches.

Advantages

- Simple and self-assembled nanoparticle formation without need for further purification
- High and consistent drug loading around 60-80% for top candidates
- Small particle size (~120-140 nm in diameter) enables delivery to target sites
- Provide significantly prolonged analgesia versus free drug in animal models
- Potential to reduce local anesthetic toxicity and dosage requirements
- Potential to allow redosing or multi-site dosing compared to rupturable liposomal formulations
- Highly stable for >48 hours and potentially weeks at room temperature

Duke File (IDF) Number

IDF #:T-008487

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