Editorial

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The role of AI and ML in advancing electronically controlled drug delivery systems

Bappaditya Chatterjee*

Electronically controlled drug delivery systems (EDDS) provide better control over drug release in the body. A sustained drug delivery system releases the drug for a prolonged period at a first-order rate. A perfectly designed controlled drug delivery system releases the drug at a zero-order or constant rate. However, in both cases, conventionally, the release does not depend on any feedback mechanism or responses generated by the body. Therefore, the release remains an "open-loop" system. In the case of EDDS, the release can be controlled electronically by some articulated program based on the desired responses or feedback generated in the body. A perfect example is the MiniMed system™ developed by Medtronic [1]. This system delivers insulin to diabetic patients by a pump attached to the body surface. An in-built technology, named SmartGuard™, automatically controls the insulin delivery based on the glucose level of the body determined by a sensor. Another type of EDDS manages the drug release at the desired site. We might be familiar with Intellicap®, one of the early generation oral electronic capsules [2]. It comes with a pH and temperature sensor, a drug reservoir, a programmable microprocessor, and an edible battery. The capsule delivers its "cargo" at the desired sites after being activated by different gastrointestinal pH regions. Another interesting electronically activated drug-free capsule is Vibrant gastro®, the first FDA-approved drug-free capsule for chronic constipation, which needs to be activated by placing it in an activation module before ingestion [3]. The capsule creates a controlled vibration once it reaches the colon, which instigates bowel movement. Several other EDDS include iontophoretic transdermal patches or implants for delivering drugs through the spinal cord.

**School of Pharmacy, GITAM University-Hyderabad, Visakhapatnam, India. E-mail: bdpharmaju @ gmail.com*

The journey of EDDS started in the last century. In 1998, possibly the very first patent on microchip drug delivery devices was awarded to a team of researchers at MIT, USA [4]. Few delivery systems or drug-free systems have been approved in the last decade. However, the growth of such systems for the benefit of the end-users, i.e., patients, is not so impressive. Several "roadblocks" are ahead, which include regulatory challenges, safety of the system, robustness of the device, and cost and patients' apathy to administer electronic systems (orally). Artificial intelligence and machine learning (AI-ML) can help the development of EDDS and provide much better control over drug release at the desired rate and sites. AI-ML, often used together, are not exactly the same. AI refers to a broader approach to simulating the cognitive function of the human brain using a machine. ML is a subset of AI, which particularly focuses on data and algorithms, and helps AI in continuous learning in a similar way to the human brain. AI-ML can help the development of EDDS in many ways. AI-based predictive models are used in designing smart delivery systems. AI-based models can simulate the biological environment [5] that can be used to assess the safety and toxicity concerns of an EDDS. Microfabrication techniques are used to design implantable microchips. AI can enable the microchip to not only control the drug release but also collect and transfer the bio-environmental data to an external device. The mechanistic framework using AI-ML can analyze large datasets, identify what went wrong, refine the design, and evolve more advanced models. In the last decade, tremendous interest has grown in wirelessly controlled drug delivery systems using AI. The development of advanced nanocarriers or nanoparticulate systems has added a boost to it. Wirelessly controlled nanobots are being researched a lot in different theranostic areas [6,7]. For diagnostics, it is advantageous because we can control the movement of nanobots remotely to the desired sites. For therapeutic purposes, remotely controlled delivery of drugs can also be possible. AI-based technology can provide a feedback-based mechanism of drug release. As discussed earlier, what happens if my insulin pump stops delivering after getting a signal of reduced sugar level to a certain risk value? It sounds not only interesting but also reduces the chance of a potential adverse reaction. The most required application of AI in EDDS is probably in this feedback-mediated drug release. Few clinical trials have been conducted around the globe to determine the safety and efficacy of sensor/microchip-based drug delivery systems [8–10]. Such sensors and microchip-based systems can be more advanced and provide better "remote control" over drug delivery using AI-based technology. The major challenge is the development and continuous training of the AI-based model for maintaining accuracy and precision.

In this cutting-edge tech era, big development is possible by inter-disciplinary collaboration. In EDDS, the implementation of AI-based techniques can be successful only through effective collaboration between pharmacists, clinicians, formulation scientists, engineers, etc. The regulators are continuously updating the requirements for new drug product approval. Nevertheless, the regulations are becoming more stringent to ensure the safety of the patients. EDDS developers should give primary importance to this safety concern. Another concern, based on my opinion, is if the system is not fully automated, if the drug delivery can be controlled remotely using an "application," then whether an end-user or patient would be capable of handling it? If not, the monitoring/control will be with the clinicians, and might be remotely controlled. Will it be possible for a doctor/therapist to do maneuvers for many patients? These questions persist. But these will not be a problem in the case of feedback-regulated systems, where manual intervention will not be required. In the near future, we can expect more EDDS controlled by AI-ML technologies, especially in chronic or lifestyle-mediated diseases. The pharmaceutical researchers should immerse themselves in the collaborative developmental approach of EDDS to "hit the bullseye" of therapy.

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