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8 | Electronic Pneumatic Injection-Assisted Dermal Drug Delivery Visualized by Ex Vivo Confocal Microscopy

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ABSTRACT

Background and objectives: Electronic pneumatic injection (EPI) is a technique for dermal drug delivery, which is increasingly being used in clinical practice. However, only few studies have been reported on cutaneous drug distribution and related clinical endpoints. We aimed to visualize the immediate cutaneous drug distribution, changes in skin architecture, and related clinical endpoint of EPI. Study design/materials and methods: Acridine orange (AO) solution was administered to ex vivo porcine skin by EPI at pressure levels from 4 to 6 bar with a fixed injection volume of 50 µl and nozzle size of 200 µm. Immediate cutaneous distribution was visualized using ex vivo confocal microscopy (EVCM). Changes in skin architecture were visualized using both EVCM and hematoxylin and eosin-stained cryosections. Results: The defined immediate endpoint was a clinically visible papule formation on the skin. The pressure threshold to consistently induce a papule was 4 bar, achieving delivery of AO to the deep dermis (2319 µm axial and 5944 µm lateral distribution). Increasing the pressure level to 6 bar did not lead to significant differences in axial and lateral dispersion (P = 0.842, P = 0.905; respectively). A distinctively hemispherical distribution pattern was identified. Disruption of skin architecture occurred independently of pressure level, and consisted of subepidermal clefts, dermal vacuoles, and fragmented collagen. Conclusions: This is the first study to relate a reproducible clinical endpoint to EPI-assisted immediate drug delivery using EVCM. An EPI-induced skin papule indicates dermal drug delivery throughout all layers of the dermis, independent of pressure level settings. Keywords: biodistribution; dermatology; device; drug delivery; electronically-controlled; ex vivo confocal microscopy; needle-free injection; pneumatic device; skin. PMID: 32515075 PMCID: PMC7891353 DOI: 10.1002/lsm.23279 Free PMC article