Performance and usability of a novel intradermal drug delivery device

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INTRODUCTION & AIMS

In light of recent pandemics and health care emergencies, intradermal vaccination has gained renewed interest. Although, this route of vaccines administration has quite a few usability and acceptability challenges, some important advantages have been associated with intradermal vaccination[1]. Not in the least, the dose sparing properties whereby 1/5th to 1/10th of the dose can elicit a non-inferior immune response compared to intramuscular or subcutaneous vaccination as shown for vaccines like Influenza[2], Hepatitis B[3], and recently SARS-Cov-2[4] and mpox[5].

Idevax has developed VAX-ID®, an intradermal drug delivery device allowing for reliable intradermal injection with a high ease of use. The aim of the study was twofold (1) to assess the performance and usability of VAX-ID® in piglets; (2) to assess the usability by healthcare professionals in a living lab setting.

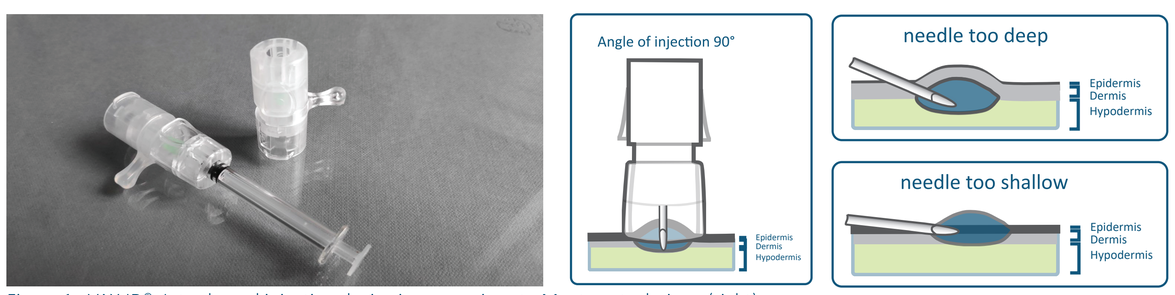

Figure 1: VAX-ID®, Intradermal injection device in comparison to Mantoux technique (right)

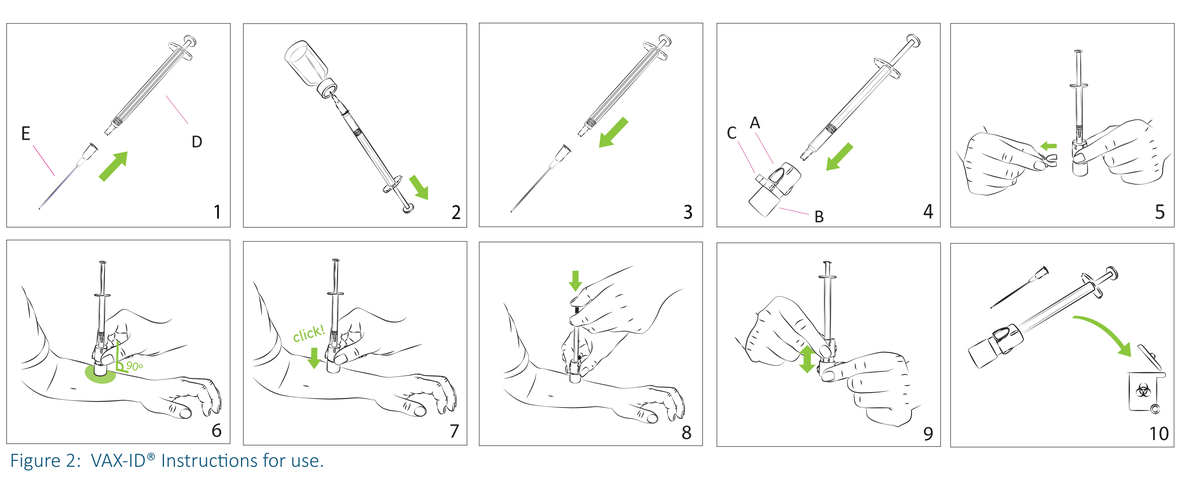

Figure 2: VAX-ID® Instructions for use.

MATERIALS & METHODS

Preclinical performance

Two piglets (12kg) received 19 injections using VAX-ID® preconfigured with a 32G needle having a predefined penetration depth of 0.85mm. An injection mixture of NaCl 0.9% and Chinese ink 1:0.15 ratio was injected in triplicate at 3 injection sites: neck, back, and abdomen. Visual inspection was performed for the evaluation of bleb formation, leakage, and adverse effects. A total of 19 tissue samples were collected and stained with hematoxylin and eosin (H&E) for histological analysis to assess liquid deposit and injection depth.

Figure 3: Study methodology and materials.

Usability

Usability of VAX-ID® was assessed by 15 healthcare professionals from Belgium and the Netherlands by means of injections using VAX-ID® in a tangerine, a commonly used simulation method for injection training[6], and a questionnaire. The questionnaire was a combination of open, yes-no and scoring questions (rating from 1 fully disagree to 10 fully agree).

RESULTS

Preclinical performance

Deposition of the dye was shown to reach both the papillary and reticular dermis in 100% of the samples (3 injections in the neck of 1 piglet were not successful as the dye was not injected in the skin). Visual inspection showed bleb formation in 14 out of 15 (93%) of the samples with an average bleb diameter of 0.56cm. As for adverse events, transient erythema was observed at the injection site. Only two samples showed micro bleeding and none of the samples showed macro bleeding.

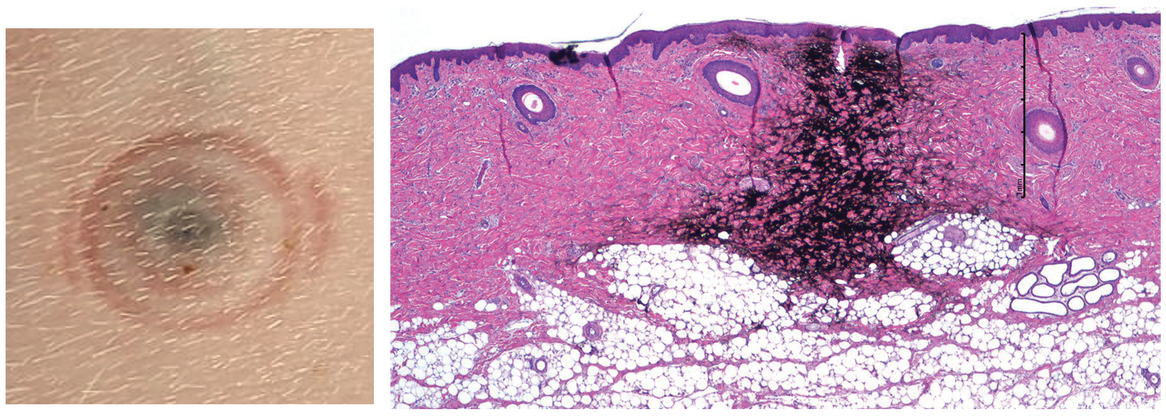

Figure 4: Bleb formation (left) and dye deposition using H&E stain 20x (right) following injection of 100 µL dye using VAX-ID® 2200 32G.

Usability

Out of the 15 healthcare professionals, 13 were females and 2 males, 1 left-handed and 14 right-handed. The overall score of the device for user friendliness was 8.16/10 and 8.39/10 for look and feel. Activation of the device was clearer (7.72/10) than deactivation of the device (6.07/10). The risk of needle-stick injuries was rated as rather low (1.71/10). All participants agreed on the need for Instructions for Use (IFU) for (first time) usage of the device.

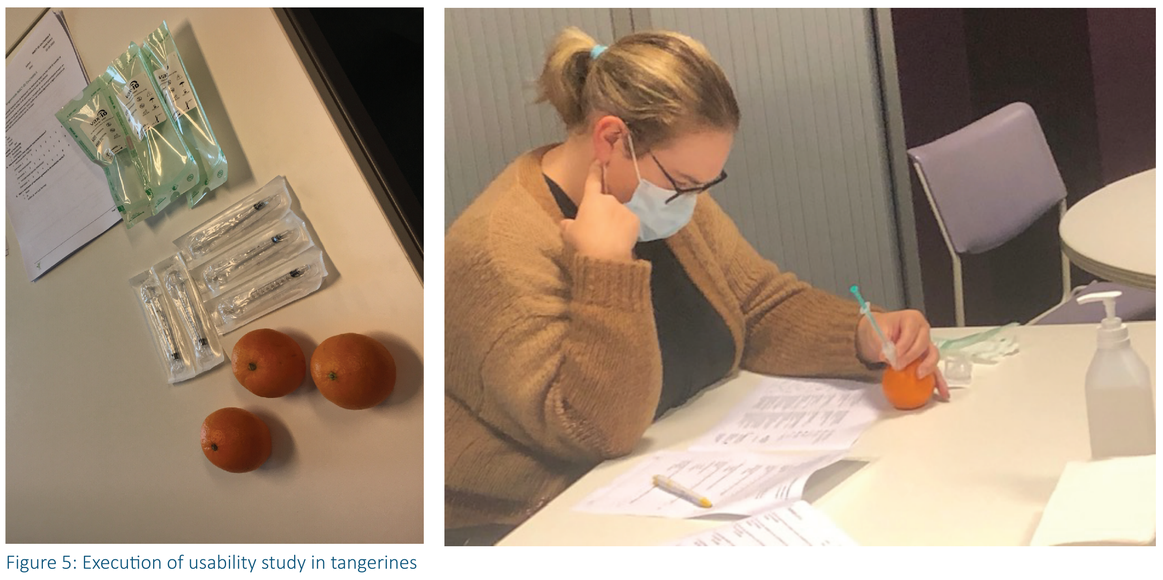

Figure 5: Execution of usability study in tangerines

CONCLUSION

In conclusion, VAX-ID® preconfigured with a 32G needle was able to successfully inject in the dermal layer of the skin in a preclinical setting. Furthermore, the injections induced bleb formation, a visual check of a successful intradermal delivery.

Furthermore, the usability study showed that most of the participants were convinced the device was user-friendly and they liked the look and feel of VAX-ID®. All participants agreed that having the IFU is necessary as a guidance to get acquainted with this novel device.

References

[1]Hickling JK et al. World Health Organ. 2011; [2]Vankerckhoven & Van Damme Expert Opinion Drug Delivery 2010; [3]Van Mulder et al. Vaccine 2018; [4]Geert V.T.R. et al. Vaccine 2021; [5]Frey et al. Vaccine 2015; [6]Lorene Payne. The Nursing Student's Guide to Clinical Success, Chapter 10: Simulation – An alternate clinical practice.

VAX-ID®

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