Innovative intradermal injection device for lymphoscintigraphy and sentinel lymph node mapping

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Introduction

Breast cancer ranks as the predominant malignancy diagnosed in females, representing over 10% of newly identified cancer cases annually. Globally, it stands as the second most prevalent cause of cancer-related mortality in women [1]. Precise disease staging, particularly the evaluation of lymph node involvement, plays a pivotal role in defining treatment strategies. The sentinel lymph node (SLN) is the initial recipient of direct drainage from the tumour, and its detection and subsequent histopathological analysis hold the potential to impact the scope and aggressiveness of oncological interventions [2].

Presently, SLN biopsy is considered the standard of care for nodal staging in breast cancer. This technique is deemed safe, characterized by a low false-negative rate, and associated with minimal morbidity [2]. The identification of the sentinel lymph node or lymphoscintigraphy is based on the fundamental principle that primary tumours typically drain to one or multiple nodes before disseminating extensively and is accomplished through the utilization of radioisotopes, fluorescent dyes, or a combination of both [3].

The methodology underlying lymphoscintigraphy

In the field of lymphatic mapping and imaging, lymphoscintigraphy has demonstrated an impressive technical performance, achieving a success rate that approaches a nearly perfect 100%. This impressive accuracy and reliability in identifying and tracing the SLN have solidified lymphoscintigraphy as a robust and widely adopted tool in the clinical management of various malignancies, including breast cancer [3,4].

In the context of breast malignancy, various procedures are available for lymphatic mapping. The prevailing method involves a superficial or deep perilesional injection, wherein 3-4 mL is injected with a total radioactivity ranging from 200 to 3,000 microcuries. An alternative technique entails intradermal or subcutaneous injection superficial to the lesion, employing 0.2 to 1 mL of technetium 99m with a total radioactivity ranging between 150-2,000 microcuries. Additional strategies encompass injection in the peri-areolar region and intralesional injection, each contributing to the comprehensive range of lymphatic mapping methods for breast cancer management [3].

Intradermal SNL mapping - Advantages & Challenges

The comparative efficacy of intradermal (ID) injection with other Routes of Administration (RoA) for SLN mapping and biopsy in breast cancer has been the subject of clinical investigation, particularly in early-stage patients.

Povoski et al. conducted a prospective randomized clinical trial to assess the reliability of the ID route for preoperative lymphoscintigraphy and intraoperative identification in comparison to alternative RoAs including the Intraparenchymal (IP) and subareolar [5].
The ID injection route exhibited a significantly higher frequency of successful localization, reduced time to initial localization through preoperative lymphoscintigraphy, and decreased time for harvesting the first SLN. This study stands as the inaugural prospective randomized clinical trial to validate the superiority of the ID route for the administration of 99mTc-sulfur colloid during SLN mapping and biopsy in breast cancer [5].

Fleming et al. conducted a study involving 125 patients diagnosed with invasive breast cancer, employing SLN mapping through radioisotope and isosulphan blue dye administration, followed by axillary dissection if necessary. Among these patients, the initial 80 underwent IP injection, while the remaining 45 received an ID injection directly above the tumour site [6]. The preoperative lymphoscintigram (LSG) analysis revealed a notably higher occurrence of SLN identification in the ID isotope group compared to the IP isotope group.

Furthermore, a study by Motomura et al. aimed to assess the potential enhancement in sentinel node identification rates by employing ID injection of radiocolloids compared to subdermal injection in T2 breast cancer patients with clinically negative nodes [7]. In this investigation, 55 patients received subdermal radiocolloid injection, while 61 patients underwent ID radiocolloid injection for sentinel node biopsy. The findings distinctly indicate that ID injection of Tc-99m tin colloid with a larger particle size yields a notably superior rate of sentinel node biopsy and lymphoscintigraphy identification compared to subdermal injection with the same substance [7].

While the ID route offers as a promising option for sentinel lymph node (SLN) mapping, its effective implementation necessitates the involvement of proficient operators with a wealth of experience in injection procedures. Intradermal injections, conventionally administered utilizing the Mantoux technique, are frequently regarded as intricate, demand practice, lack standardization, and are susceptible to errors [8]. Therefore, ongoing research endeavours and emerging innovations seek to augment the efficacy of the ID route and mitigate constraints seen with the Mantoux technique.

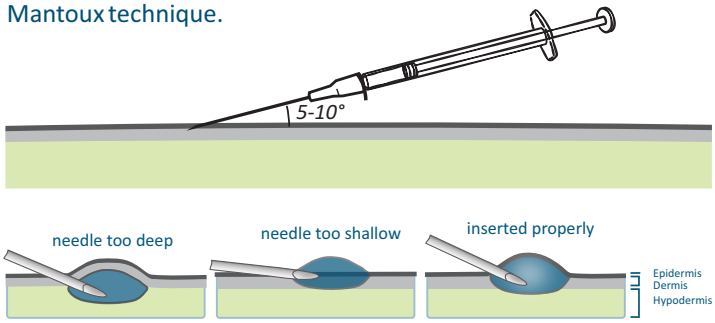

Figure 1: Challenges with Mantoux Technique

VAX-ID® for reliable intradermal SLN mapping

IDEVAX has developed VAX-ID®, a pioneering intradermal drug delivery device acknowledged for its user-friendly design and reliability. Tailored for standardized, precise, and reliable ID injections, VAX-ID® is placed perpendicular to the skin by healthcare practitioners.

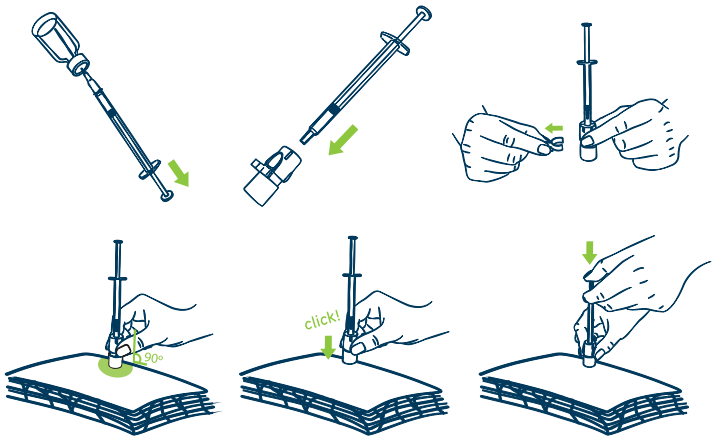

Figure 2: Instructions for Use of VAX-ID

The device's needle protruding length is predefined to allow for a high accuracy in skin penetration depth, considering the limited thickness of the dermal layer, and based on comprehensive skin thickness evaluations in adults, adolescents, and children [9, 10]. Demonstrating minimal dead volume and high dose accuracy, VAX-ID® consistently achieves successful injections at the designated dermal depth, while making ID injections safe and easy for healthcare professionals [11].

VAX-ID®'s benefits offer the possibility to standardize the ID administration of radioisotopes and fluorescent dyes used for lymphoscintigraphy and SLN mapping making the visualization more efficient and reliable. Moreover, VAX-ID® can make the ID injection easier and safer for the healthcare professional.

Figure 3: VAX-ID® Device

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