

Device Pocket Challenges in Elderly and Thin Individuals

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Summary:

Background: In addition to having thin skin, elderly patients are more prone to developing cardiovascular disorders which may require surgical implantation of a cardiac implantable electronic device (CIED). Elderly, emaciated, and thin-skinned patients present unique challenges with regard to CIED implantations. The latter could lead to complications associated with increased cost and significant morbidity and mortality with this vulnerable patient population.

Purpose: The aim of this article is to explore strategies that can be utilized to promote cardiac device fixation in elderly thinned skinned patients undergoing CIED procedures. Cardiac implantable device techniques intended to minimize complications associated with CIED implantations in the elderly and thin patient population were reviewed and discussed.

Discussion: Both advantages and limitations were noted within the various procedural recommendations. Utilization of an extracellular matrix (ECM) material for tissue reinforcement has been previously reported as yielding encouraging results in thinned skin patients deemed at risk for device erosion. In this experience of 24 patients, implanted cardiac devices included 14 pacemakers and 10 implantable cardiac defibrillators. Only 1 of 24 patients developed an infection with clinical evidence of device erosion requiring system extraction. A decellularized extracellular dermal matrix (AlloDerm) was used in this case series; however, the CanGaroo® biologic envelope, an acellular matrix composed of porcine small intestinal submucosa could also serve in the same role.

Conclusions: Specific techniques can be utilized at the time of device implant planning and procedure to avoid complications in elderly, emaciated, and thin-skinned patients. The emergence of acellular matrix devices presents a promising new development in this direction.

Goel R. *Cureus*. 2021 Jan 5;13(1):e12902.

Key Messages:

- » Thin skinned, emaciated, and elderly patients may have metabolic changes in their tissues that can pose additional complications with CIED implantation.
- » Metabolic changes associated with thinning skin and loss of adipose tissue increases risk for progressive erosion.
- » Implantation of a foreign body, such as a CIED, may create challenges in these patients due to reductions in skin barrier integrity as well as loss of subcutaneous adipose tissues, which negatively affects mechanical cushioning and tissue healing around the device.
- » The addition of supplementary ECM material around the implanted device may help augment tissue loss and prevent complications that result in device erosion.

Expert Editorial Opinion

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The rate of cardiac electronic devices (CIED) implantation in elderly patients is increasing, and aging is one of the strongest risk factors for developing wound complications associated with CIED implantation.^{2,3} Frequently, the elderly present with malnutrition, immobilization, psychological stress, lack of subcutaneous tissue, and medications such as corticoids and immunosuppressors, all of which may limit wound healing. Pacemaker erosion or extrusion has been reported in 0.9% of patients receiving a device and are potentially lethal,² requiring the same level of attention as device infections. As a result, strategies to prevent device or lead migration and erosion in the elderly and thin patients with poor turgor are welcome in this field.

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Henrikson CA, et al. *Circulation*. 2004 Aug 31;110(9):e79.

“A significant number of the device erosion-related complications in thin individuals can be avoided with awareness and relatively simple interventions to decrease the risk of device component pressure against the skin.”

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A New Strategy to Reduce Pocket Complications in the Thin and Elderly: CanGaroo® Envelope

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Implantation of cardiac electronic devices (CIED) has increased significantly in the last decade due to broader indications. Patients are older with substantial underlying comorbidities, this coupled with a higher complexity of procedures has resulted in increased numbers of CIED infection-related hospitalizations that is out of proportion to rates of new device implantation (2.8 fold for PPM and 6.0 fold for ICD). Aging is one of the strongest risk factors for developing wound complications associated with CIED implantation.^{2,3} Frequently, the elderly present with malnutrition, immobilization, psychological stress, lack of subcutaneous tissue, and medications such as corticoids and immunosuppressors, all of which may limit wound healing. Pacemaker erosion or extrusion has been reported in 0.9% of patients receiving a device and are potentially lethal,² requiring the same level of attention as device infections. As a result, strategies to prevent device or lead migration and erosion in the elderly and thin patients with poor skin turgor are welcome in this field.

In this paper, Dr. Goel reviewed the pros and cons of current strategies to combat the lack of subcutaneous tissue at the time of CIED implantation. While placing a device subcutaneously may provide more cosmetic appeal, it requires additional surgical skills.⁴ Leadless pacemakers are not able to provide atrial pacing or cardiac resynchronization, therefore limiting the number of patients that could benefit from this utilization. The third option described in this paper is very attractive because it does not add time to the procedure, or require new surgical skills. This option involves the utilization of an acellular matrix. One such product is comprised of porcine small intestine

extracellular matrix (SIS ECM) under the trade name CanGaroo Envelope. In preclinical studies, this material has been utilized in numerous surgical conditions to stimulate vasculature growth, resulting in a healthy pocket while also providing device stabilization.⁵ CanGaroo, derived from decellularized SIS ECM, provides a natural biologic scaffold which stimulates wound healing, and has been shown to mitigate the formation of a fibrotic capsule.⁵ Utilization of CanGaroo for CIED implants poses many benefits, such as supporting angiogenesis, naturally reinforcing the pocket, and

immunomodulation of the innate healing process away from inflammation and towards that of tissue regeneration.^{5,6}

CanGaroo Envelope features and benefits:

- » CanGaroo regulates the biologic healing response post implant, reduces inflammation, and mitigates excessive scar tissue formation.
- » Due to the form factor, a multi-point anchoring strategy can be implemented to reduce device motion and migration that may lead to erosion.⁷

In summary, Dr. Goel reviewed the pros and cons of current therapeutic strategies to address a frequently observed problem encountered at the of device implantation in the thin and elderly patients at risk for device erosion. The novel CanGaroo Envelope stands out due to its ease of use and multiple potential benefits. It securely holds a CIED and creates a stable environment promoting healing and protection from migration when implanted. Clinical trials are needed to confirm this data but the initial results are very promising.

Pacemaker erosion or extrusion has been reported in 0.9% of patients receiving a device and are potentially lethal,² therefore requiring the same level of attention as device related infections. As a result, strategies to prevent device or lead migration and erosion in the elderly and thin patients with poor turgor tissue, are welcome in this field.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Material for the use only in countries with applicable health authority product registrations. This document is not for use or distribution in France.

References:

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