Clinical Spotlight

Patient Profiles in the Utilization of the CanGaroo® Envelope

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Abstract:

Background: The CanGaroo® Envelope (Aziyo Biologics, Silver Spring, MD) is intended to securely hold a cardiovascular implantable electronic device (CIED) to create a stable environment when implanted in the body. Data on the utilization of this newly available product are limited.

Objective: In this study, our objective was to describe the specific profiles of patients who may benefit from the use of the CanGaroo Envelope at the time of CIED implantation.

Methods: The utilization of the CanGaroo Envelope was assessed from January 2019 to October 2019 among a series of patients who were either undergoing de-novo CIED implantation or replacement.

Results: Among a total of 50 patients, the CanGaroo Envelope was utilized in 15 (30%). Three distinct patient profiles were identified: profile 1: elderly patients with poor tissue turgor at risk of wound dehiscence or erosion; profile 2: patients with a history of previous device infection; and profile 3: patients at high risk of device infection having one or more of the following risk factors - chronic kidney disease, immunocompromised state, or diabetes mellitus. At a mean follow-up of 18 ± 3 months, no CIED pocket erosion, dehiscence, or infection was noted.

Conclusions: Three distinct profiles of patients who could potentially benefit from the use of the CanGaroo Envelope were identified by the implanting physicians. Long-term follow-up data, including infection and wound dehiscence rates, are necessary to further analyze the optimal utilization of the device.

Nayak H, et al. *Cureus.* 2021 Jan 14;13(1):e12702

Key Messages:

- Interventions to reduce the risk of pocket complications such as dehiscence and erosion all focus on aiding wound healing.
- Elderly patients are particularly at high risk of poor wound healing, as age-related alterations in wound healing can negatively impact or delay healing in elderly patients, including delayed angiogenesis, delayed collagen deposition, and delayed re-epithelialization.
- CanGaroo Envelope is derived from natural extracellular matrix material. ECM has properties that may aid in wound healing: in vitro and in vivo animal studies show that the extracellular matrix may facilitate angiogenesis, recruit macrophages, and induce reconstructive remodeling.[1]

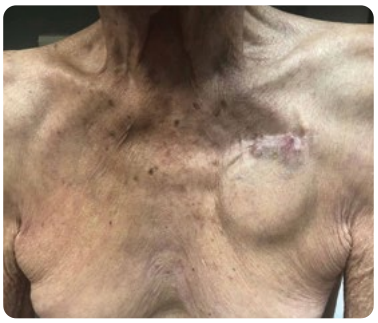

FIGURE 2: Example of a patient at high risk for erosion
A 77-year-old man with complete heart block presented for permanent pacemaker generator change secondary to elective replacement indication. He reported that the skin and soft tissue over his pacemaker had thinned over the last year, and he attributed this to a 10-pound weight loss he had suffered as a result of a chronic gastrointestinal illness. The outline of the generator was visible as were the edges of the header. The skin overlying the header was not discolored, indurated, or fixed but appeared thin. His risk of poor wound healing and erosion was high. This patient underwent a pacemaker generator change without incident and a CanGaroo Envelope was utilized to reinforce the pocket.
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Expert Editorial Opinion

By: Benjamin A. D'Souza MD, FACC, FHRS
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The use of cardiac implantable electronic devices (CIEDs) has continued to grow over the last few decades, with over 600,000 implants noted per year in the US.[2] This is largely due to clinical trials showing benefits of implantable defibrillators in our heart failure patients as well as a growing aging population requiring pacemaker implantation.

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Expert Editorial Opinion

The Future of CIED Implant Site Health

By: Benjamin A. D'Souza MD, FACC, FHRS
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The use of cardiac implantable electronic devices (CIEDs) has continued to grow over the last few decades, with over 600,000 implants noted per year in the US.[2] This is largely due to clinical trials showing benefits of implantable defibrillators in our heart failure patients as well as a growing aging population requiring pacemaker implantation. However, this aging population continues to grow, as do concerns for complications related to CIED implantation. Device infection is one of the most devastating complications regarding CIED implant, and numerous risk factors including low body mass index, a common characteristic in the elderly, can also contribute. Certain comorbidities (diabetes, end-stage renal disease, immunocompromised state) have also previously been identified as risk factors.[3] These comorbidities have been linked to poor wound healing, a factor associated with age.[4]

In addition to infection, there are other CIED complications that can occur in our growing population. Device migration or worse, device erosion, continue to be a concern at time of implant. The overall risk of complications associated with CIED implantation in most large studies has been reported to be up to 4%.[5] Minimizing these life-threatening complications remains paramount to successful long-term CIED implantation, as well as reducing morbidity and improved quality of life.

More recently there has been an option to minimize these complications, a novel pouch used for CIED implant, the CanGaroo Envelope, which provides a reinforced support structure for CIED. Based on its composition of small intestine submucosa (SIS) extracellular matrix (ECM), it has been shown to exhibit both a regenerative healing response by altering the normal foreign body reaction with a more cellular and less fibrotic healing response, and supporting angiogenesis.[6] While the use of SIS ECM is widely used in other parts of regenerative medicine, its adoption in use of CIED implants is relatively new.

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Nayak et al.[7] sought out to define patients that may derive the most benefit from SIS ECM and the use of a CanGaroo Envelope. Over a 10-month period, 50 patients with either de novo CIED implant or generator change were implanted, with a CanGaroo Envelope used in 15 (30%). Patients were then followed over an 18 ± 3 month follow-up.

The study noted no evidence of device erosion or infection in any patients who utilized the CanGaroo Envelope. Patient profiles which implanting physicians tended to utilize CanGaroo Envelope included elderly patients with poor skin turgor, previous CIED infection, or those who were at high risk of infection including diabetes or end-stage renal disease. This is in line with previous publications identifying patients at highest risk of CIED complications.

Although the study results are promising in that no patients had complications related to the use of CanGaroo Envelope, larger clinical trials with longer follow-up will be necessary to confirm these findings. This study is helpful in further identifying high-risk patients for CIED complications where use of CanGaroo Envelope would be beneficial. Both future retrospective and prospective studies involving the use of CanGaroo Envelope would be advantageous in determining who would most benefit from this novel technology.

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.

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