



Original Article

Safety of Lead Repair Compared to Lead Revision for Visible Lead Insulation Defects in Patients With Cardiac Implantable Electronic Devices

Yehia Fanous, MD, Lorne Gula, MD, FHRS, Allan Skanes, MD, FHRS, Anthony Tang, MD, FHRS, Raymond Yee, MD, FHRS, and Habib R. Khan, MBBS, MRCP, PhD

London Health Sciences Centre, University of Western Ontario, London, Ontario, Canada

ABSTRACT

Background: Cardiac implantable electronic devices deliver life-sustaining therapy and may be prone to hardware degeneration over time. Functioning transvenous endocardial leads with visible insulation breaks are amenable to lead revision (LRV) or lead repair (LRP), with medical adhesive. The latter is a less invasive and more cost-effective strategy. However, data are sparse on the overall safety of such an approach.

Methods: This is a retrospective cohort study of patients with lead insulation defects managed by either LRV or LRP with medical adhesive. The data analyzed were from January 2010 to January 2021.

RÉSUMÉ

Introduction : Les dispositifs cardiaques électroniques implantables offrent un traitement essentiel au maintien de la vie, mais peuvent subir une détérioration de leur matériel au fil du temps. Le fonctionnement des sondes endocavitaires transveineuses ayant des ruptures visibles de l'isolant se prête à la révision de sonde (RVS) ou à la réparation de sonde (RPS) au moyen d'un adhésif médical. Cette dernière stratégie est moins invasive et plus efficace. Toutefois, les données sur l'innocuité générale d'une telle approche sont rares.

Méthodes : Il s'agit d'une étude de cohorte rétrospective de patients dont les sondes montrent des défaillances de l'isolant prises en charge

The life-sustaining function of cardiovascular implantable electronic devices (CIEDs) depends on the lead component's structural and functional integrity. Transvenous leads are composed of a metallic conductor housed within an insulating layer of silicone or other polymers. Loss of insulation integrity may lead to nonphysiological sensing, resulting in inappropriate therapy from defibrillators or failure to deliver therapy due to inhibition.^{1,2} Insulation defects occur with an incidence of 4%–13% over 4 years and are the most common cause of lead failure.^{3,4} Even in the absence of electrical failure, abrasions to the outside insulator may contribute to morbidity by acting as a nidus for infection and are associated with an increased risk of infective endocarditis.⁵

A number of strategies are used in the management of lead insulation defects. In the past, a damaged lead was often abandoned and a new one implanted. However, insulation

defects may be amenable to repair with silicone adhesive and an anchoring sleeve in certain circumstances. This approach preserves the lead and may offer a safer, less invasive, and more economical alternative.⁴ Data are sparse on the relative safety of such an approach. In this study, we sought to evaluate the safety and durability of lead repair with a medical adhesive, compared with lead revision, for the management of visible lead insulation defects.

Methods

Study participants were identified from the electrophysiology health administrative database in London, Ontario. This electronic database was established in 2009 at the London Health Sciences Centre as the sole repository of all CIED implant and follow-up data. A computerized search for all adult patients with CIEDs with transvenous endocardial leads and visible lead insulation defects was conducted using the following keywords and Boolean operators: “insulation defect” AND “repair” OR “silicone” OR “adhesive” OR “glue” OR “revision” OR “replacement.” Patients were enrolled from January 2010 to January 2021.

All patients retrieved by the database search within the enrollment period were evaluated. Patients were excluded if the lead insulation defect had been determined to not require intervention at the assessment time. We also excluded patients

Received for publication July 8, 2021. Accepted July 27, 2021.

Ethics Statement: This research adhered to the ethical guidelines.

Corresponding author: Dr Habib Khan, London Health Sciences Centre, University of Western Ontario, 339 Windermere Rd, Room C6-117A, London, Ontario N6A 5A5, Canada. Tel.: +1-519-663-3746, ext. 33746; fax: +1-519-663-3782.

E-mail: habib.khan@lhsc.on.ca

See page 1494 for disclosure information.

All-cause mortality, and both early and late complications, was ascertained for all cases.


Results: A total of 57 cases were identified, with a mean age (standard deviation) of 75 (± 11.8) years; 18 (31.6%) were women. A total of 35 patients (62.5%) underwent LRV for an insulation defect, and 21 (37.5%) underwent LRP. There was no statistical difference in the rate of early and late complications between the 2 groups over a mean follow-up period of 1.15 (± 0.78) years [3 (8%)] LRV vs 1 (5%) LRP, $P = 0.88$. One death was identified in each group, unrelated to either the device or a device-related procedure. There was no association between device type and the likelihood of LRP vs LRV as an attempted strategy ($\chi^2 = 2.25$, $P = 0.53$).

Conclusions: The results of this study suggest that the use of a lead-repair strategy, with silicone adhesive glue and an anchoring sleeve, is not associated with an increased rate of early or late complications, compared with lead revision in the management of visible lead insulation defects with stable lead function.

with multiple concurrent lead malfunctions or additional damage to the lead extending beyond the insulator. The method by which the insulation defect was detected was not prespecified, and included were both detection at routine device follow-up, with changes in lead parameters, and visual detection during generator replacement.

Clinical and demographic information was collected for each patient. All procedure reports were abstracted for interventional details and complications. Adverse events were ascertained from the time of implant through January 2021. Outcomes included all-cause mortality, device-related complications, and abnormal lead parameters resulting in new-lead implant or additional procedures. Device-related complications included pocket infections, hematomas, pneumothorax, lead dislodgement, cardiac perforation, lead endocarditis, and recurrent lead dysfunction after initial intervention. Patients were classified into 2 groups: lead revision (LRV) and lead repair (LRP).

Lead repair

Briefly, the process of lead repair occurs as follows: After the visual identification of a defect, a 9-F suture (anchoring) sleeve is coated on the luminal side with silicone adhesive and applied over the length of the insulation break. Silk sutures are then tied over the sleeve to secure it over the repair site and prevent migration during lead manipulation. A cure time of 10 minutes for the silicone adhesive is allotted prior to manipulation of the lead back into the pocket and site closure. [Figure 1](#), [Figure 2](#) and [Video 1](#)  (view video online) illustrate the process.

Leads were tested for performance and parameter stability at the end of the procedure. This process included checks for threshold, impedance, sensing, and noise artifact. If lead performance was deemed suboptimal, the repair strategy was abandoned.

Statistical analysis

Baseline characteristics between the 2 groups were summarized with descriptive statistics. Unadjusted complication

par RVS ou par RPS au moyen d'un adhésif médical. Les données analysées s'échelonnaient de janvier 2010 à janvier 2021. La mortalité toutes causes confondues ainsi que les complications précoces et tardives étaient établies pour tous les cas.

Résultats : Nous avons trouvé un total de 57 cas, dont l'âge moyen (écart type) était de 75 ($\pm 11,8$) ans; 18 (31,6 %) étaient des femmes. Au total, 35 patients (62,5 %) avaient subi une RVS en raison d'une défaillance de l'isolant, et 21 (37,5 %) avaient subi une RPS. Il n'y avait aucune différence statistique dans le taux de complications précoces et tardives entre les deux groupes durant une période moyenne de suivi 1,15 ($\pm 0,78$) an [3 (8 %)] RVS vs un (5 %) RPS, $P = 0,88$. Dans chaque groupe, nous avons noté 1 décès non associé au dispositif ou à une intervention liée au dispositif. Il n'y avait aucune association entre le type de dispositif et la probabilité de tentative d'une stratégie de RPS vs d'une stratégie de RVS ($\chi^2 = 2,25$, $P = 0,53$).

Conclusions : Les résultats de cette étude montrent que l'utilisation d'une stratégie de RPS au moyen d'un adhésif de silicone et d'une douille d'ancrage n'est pas associée à un taux plus élevé de complications précoces ou tardives que la RVS dans la prise en charge des défaillances visibles de l'isolant de la sonde lors de fonctionnement stable de la sonde.

rates were compared using t-tests, χ^2 tests, and Fisher exact analysis where appropriate. Nominal P values were reported for tests of continuous and categorical measurements, with the assumption of a maximum α error of 5% as the threshold for statistical significance.

Results

A total of 57 cases were identified and included in this study, of which 39 (68.4%) were men, and 18 (31.6%) were women. The mean age of the study participants was 75.5 \pm 11.8 years. The mean time of lead implantation with an insulation defect was 100 \pm 85.6 months. Implanted devices included 14 (25%) implantable cardioverter-defibrillators, 19 (34%) cardiac resynchronization therapy defibrillators, 11 (18%) permanent pacemakers, and 13 (23%) cardiac resynchronization therapy pacemakers. [Table 1](#) outlines the patient characteristics. There was no difference in age between the LRP and the LRV groups (75.1 \pm 13.2 years vs 75.8 \pm 11.0 years, $P = 0.81$) or in lead implantation time (86.4 \pm 80.4 months vs 109.6 \pm 87.8 months, $P = 0.44$).

In 35 (62.5%) cases, the lead was revised, with the patient receiving a new lead, and for 21 (37.5%) patients, the defective lead underwent repair with silicone adhesive and an anchoring sleeve. In one case within the group undergoing repair, the lead was not visibly defective but was presumed to have sustained a microabrasion from accidental contact with the suture needle tip or cautery during a device upgrade procedure. All lead repairs and revisions were confirmed to be successful by testing at the time of the procedure. There was no association between device type and the likelihood of LRP vs LRV as an attempted strategy ($\chi^2 = 2.25$, $P = 0.53$). The right arterial lead (34%), followed by the left ventricular lead (30%), was the most frequently repaired lead in the group undergoing repair. Of all the leads, the right ventricular lead was the most likely to undergo a revision rather than a repair (66.7% vs 24%, $P < 0.01$), according to the preference of the operating physician. The procedure duration was not

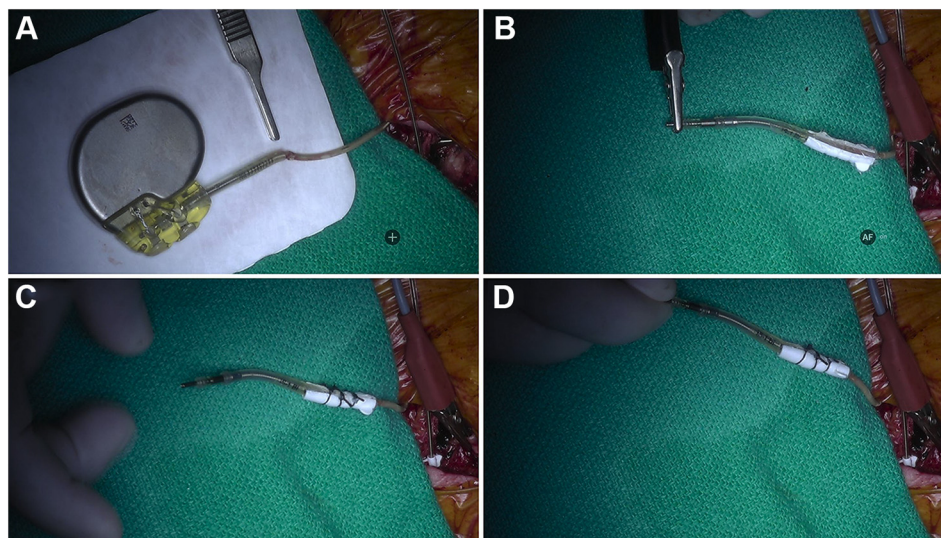


Figure 1. Illustration of the process of lead repair on a Medtronic device (Medtronic, Minneapolis, MN). (A) Identification of the visible insulation defect. (B) Application of a silicone adhesive-coated suture (anchoring) sleeve to the site of the insulation break. (C) Suture (silk) ties over the anchoring sleeve. (D) Manipulation of the repaired lead back into the pocket.

statistically different for the LRV vs LRP group (90.0 ± 43.7 minutes vs 72.3 ± 24.6 minutes, $P = 0.27$).

The mean duration of follow-up from the time of the index procedure to the time of abstraction was 1.15 ± 0.78 years. The complication rate in the study cohort was 5.3%, with no statistically significant difference between the LRV and LRP groups [3 (8%) in the LRV group vs 1 (5%) in the LRP group, $P = 0.61$]. Three complications were noted in the LRV group, 2 of which were lead dislodgement post-procedure requiring repositioning, and one of which was a case of lead endocarditis 7 years post-lead replacement. In the LRP group, one complication was detected and was a recurrence in lead dysfunction requiring lead revision after 8 years. One death was identified in each group, not related to the device or a device-related procedure (Table 2).

Discussion

Lead repair of insulation defects with silicone adhesive and an anchoring sleeve was associated with similar rates of early

and late complications and all-cause mortality, compared with lead replacement. Lead repair may be a safe alternative to lead revision in the management of visible lead insulation defects.

Lead repair, compared with lead revision, has been shown to be associated with a shorter procedure time and hospital stay, as well as lower rates of procedural complications.⁴ The results of our study add to the existing literature on the safety of the lead-repair strategy and suggest that financially, it is a lower-cost alternative. When both strategies are deemed feasible, lead repair may be more cost effective and economical and should be considered at the time of inspection.

Lead insulation defects are the leading cause of lead failure.⁴ Abrasions to the outer insulation can occur in the pocket, due to friction with other device components or damage during device manipulation or upgrade.⁵⁻⁷ Distal abrasions to the lead system, within the vascular space, are also well documented. In the case of crush syndrome, friction between the lead and adjacent bone structures, namely the clavicle and first rib, results in insulation breaks.⁵ Lead repair using a medical adhesive requires that the insulation defect be

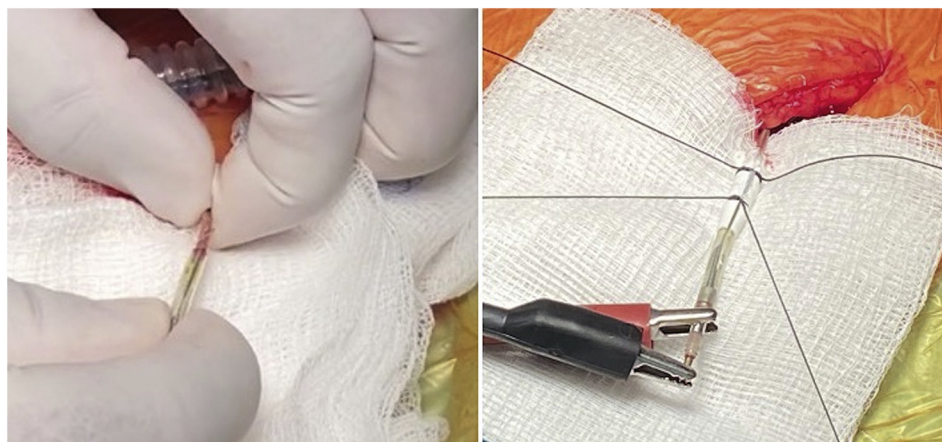



Figure 2. A picture of an insulation defect noted on a lead which subsequently underwent repair with silicone adhesive. The defect can be seen in Video 1  (view video online).

Table 1. Study participants' baseline characteristics

Characteristic	Overall (n = 57)	Lead-repair strategy (n = 21)	Lead-revision strategy (n = 36)
Age, y, mean (SD)	75.5 (11.8)	75.1 (13.2)	75.8 (11.0)
Sex, female	18 (32.5)	6 (29)	12 (34)
Procedure duration, min, mean ± SD	84.5 ± 39.2	72.3 ± 24.6	90.0 ± 43.7
Device			
ICD	14 (24.6)	5 (24)	9 (25)
CRT-D	19 (33.3)	10 (48)	9 (25)
PPM	11 (19.3)	2 (9)	9 (25)
CRT-P	13 (22.8)	4 (19)	9 (25)
Lead involved			
RV	29 (50)	5 (24)	24 (66.7)
RA	14 (25)	8 (38)	6 (16.7)
DF	7 (12.5)	2 (9)	5 (13.8)
LV	7 (12.5)	6 (29)	1 (2.8)

Values are n (%), unless otherwise indicated.

CRT-D, cardiac resynchronization therapy defibrillator; CRT-P, cardiac resynchronization therapy pacemaker; ICD, implantable cardioverter-defibrillator; DF, defibrillator lead; PPM, permanent pacemaker; LV, left ventricular; RA, right arterial; RV, right ventricular; SD, standard deviation.

clearly visible and delineable in order to appropriately apply the repair strategy to a target region on the lead. This situation precludes the applicability of lead repair in insulation defects that are electrically detected but not visible at the time of inspection, owing to the defects being either distal within the venous system or simply not visible to the operator. Visible insulation defects constitute a breach in the integrity of the lead, even in the absence of electrical dysfunction. They have the potential to progress and ultimately be manifested as failure of lead function. These defects should therefore be addressed at the time of inspection, as exposing a patient to a repeat procedure would further increase their risk of complications (including infection).

A bias toward using a repair strategy may have been expected in older patients, given its less-invasive nature; however, such a bias was not observed within our cohort. A repair strategy was more likely to be pursued for lower-risk leads (eg, the right arterial lead) as well as in settings of high-risk revisions (eg, the left ventricular lead). Such a strategy may also be favoured in cases of venous occlusion, when deemed safe. Although no venous occlusions were identified in our study population, the literature suggests a prevalence of ~12% in referred patients.⁸

Insulation defects have been shown to be associated with a higher rate of endocarditis, thought to result mechanically from lead-surface irregularities serving as a harbour and nucleation point for pathogens.⁵ Lead repair may therefore be theoretically associated with higher rates of lead endocarditis,

given that residual irregularities are maintained by the silicone glue and sleeve. In our study, we did not detect any cases of endocarditis or pocket infection in the lead-repair group. This lack of such cases may be due to the small sample size and relatively low rate of lead endocarditis, as reported in the literature. A single case of endocarditis within the lead-revision group was detected, 7 years post-index procedure.

Limitations

This is a single-academic centre retrospective study, subject to the limitations inherent to the observational design. All the devices and components within this study were from a single manufacturer (Medtronic, Minneapolis, MN), and all insulators were made of silicone. Thus, the generalizability of the study finding to alternative devices and other insulation polymers is limited. Ascertainment of long-term durability is limited by the mean follow-up duration (1.15 ± 0.78 years). Finally, structural details (eg, size and shape) of the insulation defects were not specified in procedure notes, precluding identification of any association of such with the management strategy chosen.

Conclusion

The results of this study suggest that a lead-repair strategy with a medical adhesive and an anchoring sleeve for the management of visible lead insulation defects is associated with a similar rate of early and late complications, compared with a lead-revision strategy, and may be a viable and safe alternative.

Table 2. Complication rates and all-cause mortality for the lead-repair strategy vs lead-revision strategy groups

Complications/mortality	Lead-repair strategy (n = 21)	Lead-revision strategy (n = 36)	P
Early complications (< 30 d)			
Pocket infection	0	0	NS
Pocket hematoma	0	0	NS
Lead dislodgement/repositioning	0	2	0.27
Cardiac perforation	0	0	NS
Pneumothorax	0	0	NS
Late complications (> 30 d)			
Recurrent lead dysfunction	1	0	0.19
Endocarditis	0	1	0.41
Total	1	3	0.62
All-cause mortality	1	1	0.70

NS, nonsignificant.

Funding Sources

The authors have no sources of funding to declare.

Disclosures

The authors have no conflicts of interest to disclose.

References

1. Haqqani HM, Mond HG. The implantable cardioverter-defibrillator lead: principles, progress, and promises. *Pacing Clin Electrophysiol* 2009;32:1336-53.
2. Kołodzińska A, Kutarski A. Lead insulation failure, a serious complication: risk factors and management. *Kardiol Pol* 2015;73:585-91.
3. Lau EW. External insulation breach near the tip of a single ventricular pacing lead. *J Innov Card Rhythm Manag* 2012;3:668-71.
4. Mahapatra S, Homoud MK, Wang PJ, Mark Estes NA III, Link MS. Durability of repaired sensing leads equivalent to that of new leads in implantable cardioverter defibrillator patients with sensing abnormalities. *Pacing Clin Electrophysiol* 2003;26:2225-9.
5. Kołodzińska A, Kutarski A, Grabowski M, et al. Abrasions of the outer silicone insulation of endocardial leads in their intracardiac part: a new mechanism of lead-dependent endocarditis. *Europace* 2012;14:903-10.
6. Kusumoto FM, Schoenfeld MH, Wilkoff BL, et al. 2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. *Heart Rhythm* 2017;14:e503-51.
7. Aquilina O. A brief history of cardiac pacing. *Images Paediatr Cardiol* 2006;8:17-81.
8. Li X, Ze F, Wang L, et al. Prevalence of venous occlusion in patients referred for lead extraction: implications for tool selection. *Europace* 2014;12:1795-9.

Supplementary Material

To access the supplementary material accompanying this article, visit *CJC Open* at <https://www.cjopen.ca/> and at <https://doi.org/10.1016/j.cjco.2021.07.019>