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If you believe that this document breaches copyright please contact librarypure@kcl.ac.uk providing details, and we will remove access to the work immediately and investigate your claim.
A 39-year-old male presented with an epicardial ICD system infection. He had separate shock leads placed in posterior epicardium and subcutaneously, and a transvenous pace-sense lead. A Tightrail sheath under direct visualisation successfully extracted the pericardial lead and avoided the need for sternotomy. This is the first description of an epicardial shock lead extracted with a rotating mechanical cutting tool.
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Title of Manuscript:

*First use of a rotating mechanical dilator sheath to extract an epicardial defibrillator lead from the pericardial space*

This manuscript, or part of it, has neither been published nor is currently under consideration by any other Journal.

I declare that:

*(Please tick the relevant statement below):*

- ✔️ my co-authors listed below have read the manuscript and approved its submission to Europace. Each author has signed to that effect below, or

- ❌ in the case of 5 or more authors, every author has read and approved the manuscript and has delegated me, as corresponding author, to sign this declaration on their behalf.

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Professor Gerhard Hindricks  
Editor-in-Chief  
EP Europace  

Dear Professor Hindricks,

Many thanks for writing back to us regarding our manuscript “First use of a rotating mechanical dilator sheath to extract an epicardial defibrillator lead from the pericardial space”. Following the very helpful feedback from your reviewers we have revised the manuscript and addressed their comments. Please find below a point-by-point response to all the comments of the initially submitted manuscript.

Response to reviewers

Response to reviewer comments

All responses are in this typeface and colour

Response to Reviewer 1

Reviewer #1: Original approach using state of the art technology.

Specific comments:

1) But the case report is "over descriptive" about patient history, and less about the technique. The authors should focus discussion on how the extraction tool should be properly used.

We thank the reviewer for this observation that there should be greater emphasis on the technique involved in using the rotating dilator sheath. We have removed the overly descriptive elements of the patient history. By making these changes, we have reduced the word count of the description of patient history by 57 words, leaving more space for the technical description (see lines 41-53): “A 39-year-old male presented with a device infection. A secondary prevention transvenous implantable cardioverter defibrillator (ICD) was implanted aged 14 years following ventricular fibrillation (VF).

Transvenous systems were complicated by high defibrillation thresholds (DFTs) and repeated extractions of failing leads. When his 4th system failed 20 years later, rather than a
further extraction, he had a subcutaneous-ICD (SICD) (Emblem; Boston Scientific, Marlborough, MA) implanted. This was complicated by persistent myopotential sensing, so a decision was made to implant a new system. After percutaneous puncture, an epicardial system with a single coil transvenous lead (Sprint Quatro; Medtronic, MN) was placed in the posterior pericardium and attached to the atrial epicardium, a single coil (Transvene; Medtronic MN) placed subcutaneously and parasternally, and a Capsurefix 5076 (Medtronic, MN) pace-sense lead placed via a subclavian puncture, were all tunnelled to a new generator (Evrea, Medtronic, MN) in a subrectus pocket”.

For the technical description on the use of the rotating mechanical sheath, we have amended the manuscript accordingly (see lines 79-87): “The lead was prepared with retraction of the screw mechanism and a lead locking device (LLD EZTM, Philips Healthcare, USA) stylet was deployed. Gentle manual traction was applied but the lead was adhered within the pericardial space. A rotating dilator sheath (13F 545-513 Tightrail; Spectranetics, CO) under direct visualisation was used to successfully extract the pericardial lead (Panel 1B; supplement for video). The outer sheath was not used as venous access did not need to be maintained and allowed greater flexibility of the tool. Mechanical extraction was undertaken to free the lead from the fibrous binding sites (Panel 1C). The patient had extraction of the two remaining ICD leads in the RV apex and CS, with some fragments remaining in the brachiocephalic vein, and successful implantation of a new transvenous ICD device (see supplement figure 1).

We have also made relevant changes to the short case description to make it less descriptive on the patient history and more focused on the technical use of the tool. See lines 11-18 of the short description: “The lead was prepared with retraction of the screw mechanism and a lead locking device (LLD EZTM, Philips Healthcare, USA) stylet was deployed. Gentle manual traction was applied but the lead was adhered within the pericardial space. A rotating dilator sheath (13F 545-513 Tightrail; Spectranetics, CO) under direct visualisation was used to successfully extract the pericardial lead (Panel A). The outer sheath was not used as venous access did not need to be maintained and allowed greater flexibility of the tool. Mechanical extraction was undertaken to free the lead from the fibrous binding sites (Panel B).”

2) Since there is an increased number of epicardial implantations performed in younger population, the potential value of this technique should be highlighted.

We thank the reviewer for this highlighting important context. We have amended the manuscript to emphasise this (see lines 105-106): “This is particularly important in the paediatric and younger adult population who often have epicardial leads implanted.”

3) What are the alternatives, thoracoscopy, other?
We have clarified in the penultimate paragraph what alternatives are available to the subxiphoid approach employed in this case (see lines 90-92): “Direct visualisation with a thoracoscope allowed removal of this lead using a Tightrail sheath without complication in this high-risk and complex case, whilst avoiding a more invasive sternotomy, mini-thoractotomy or thorascopy.”

4) Finally, after percutaneous puncture,

This line has now been removed to address the over descriptive nature of the patient history as per point one of the reviewer.

5) Please add the location of the puncture (subxiphoid).

We thank the reviewer for this, we have edited the manuscript to make it clearer that the initial epicardial shock lead was inserted via a subxiphoid puncture. See lines 49-53: “After percutaneous subxiphoid puncture, an epicardial system with a single coil transvenous lead (Sprint Quatro; Medtronic, MN) was placed in the posterior pericardium and attached to the atrial epicardium, a single coil (Transvene; Medtronic MN) placed subcutaneously and parasternally, and a Capsurefix 5076 (Medtronic, MN) pace-sense lead placed via a subclavian puncture, all tunnelled to a new generator (Evrea, Medtronic, MN) in a subrectus pocket.”

Response to Reviewer 2

Reviewer #2:
Thank you for interesting case report on using transvenous extraction tools for epicardial shock coil removal.

1. It should be stressed in the paper that this use is off label and should only be performed in hybrid theatre with sternotomy immediately available.

We thank the reviewer for this important observation. We have amended the manuscript to reflect this. See lines 92-93: “As this was a complex case with an off-label use of the Tightrail sheath, its use should be limited to high-risk settings, such as the hybrid operating theatre with cardiothoracic support.”

2. Considering the case it seems strange that only one transvenous lead was infected and the others not. This is not according to guidelines and should be mentioned in the paper. In general, the purpose should always be a full removal of all present materials in case of infection. Why was decided not to extract the other leads in this young patient? What was the clinical result afterwards? (days and months) and what options were chosen to place a new system or was this not placed?
We thank the reviewer for this observation. To clarify, all the transvenous material attached to the subrectus generator was infected on the PET-CT, however the remaining leads were not infected. The clinical decision was to perform a staged extraction of all material before reimplanting a secondary prevention ICD. To clarify this, the following changes have been made to the manuscript (see lines 55-69): “Two years later, positron emission tomography (PET)/computed tomography (CT) (PET-CT) imaging confirmed infection of the abdominal generator with extension to the proximal portions of the pericardial shock lead and transvenous lead (Panel 1A). A decision was made to perform a staged extraction, with initial removal of the infected material and further extraction of the remaining transvenous material later.”; and see lines 85-97: “Subsequently, the patient had extraction of the two remaining ICD leads in the RV apex and CS, and successful implantation of a new transvenous ICD device (see supplement figure 1).”

With respect to the figures, to clarify which material was identified as infected, there was colour coding on the figure attached to the long case description (see Panel 1A). We have also added a new supplementary figure to show the final x-ray of all extracted material with the new transvenous ICD device the patient was left with. For ease, these have been added below.

**Figure showing panel 1A**

![Figure showing panel 1A](image)

**Supplementary figure 1**

*Figure: Panel A – Plain AP radiograph prior to lead extraction for infected material identified on PET-CT. Purple arrows are of infected device material as identified by imaging. 1) subcutaneous parsiternal single coil, 2) endocardial RV apex/sense lead, 3) Abdominal ICD generator, 4) single coil pericardial shock lead. Green arrows are non-infected material 5) single coil in RV, 6) single coil in CS, 7) SVC coil. Panel B – Still image from peri-procedural fluoroscopy demonstrating removal of pericardial coil. 8) rotating dilator sheath. Panel C - Extracted pericardial ICD lead with evidence of dense fibrosis on the shock coil.*
Many thanks for considering this revised manuscript for publication. We believe we have addressed all your reviewer’s comments and look forward to hearing from you.

Many thanks,

Yours sincerely,

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Professor Gerhard Hindricks  
Editor-in-Chief  
EP Europace

Dear Professor Hindricks,

We would be grateful if you would kindly consider the following case report entitled, “First use of a rotating mechanical dilator sheath to extract an epicardial defibrillator lead from the pericardial space”, for publication in EP Europace.

In the manuscript, we report the case of a 39-year-old male who presented with an epicardial ICD system infection. After multiple revisions of his original transvenous system and a subsequent S-ICD, he eventually had a shock lead placed in posterior pericardium and attached to the atrial epicardium, a further shock lead subcutaneously parasternally placed, and a transvenous pace-sense lead. The patient subsequently had an infection of this epicardial system, and an extraction was performed. A Tightrail sheath under direct visualisation successfully extracted the pericardial lead and avoided the need for sternotomy.

This is the first description of an epicardial shock lead extracted with a rotating mechanical cutting tool. This case highlights the utility of specialised extraction tools for removal of leads in the pericardial space preventing the need for sternotomy and avoiding myocardial or coronary artery injury.

We feel this case report would be of interest to the readers of EP Europace. The manuscript is original, and no portion is under consideration for publication elsewhere or has been previously published. All authors are responsible for the contents and have read and approved the manuscript for submission.

Many thanks,

Yours sincerely,

Dr Vishal Mehta MBBS MRCP (corresponding author)  
King’s College London  
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St Thomas’ Hospital  
Westminster Bridge Road  
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Click here to access/download Supplementary file Supplement Figure 1.pdf
Short Summary:
A 39-year-old male with an implantable cardioverter-defibrillator (ICD) was referred for device extraction. Transvenous systems were complicated by high failed defibrillation thresholds (DFTs) and failing leads. After a fourth system failure, he had a subcutaneous-ICD (SICD) (Emblem; Boston Scientific, Marlborough, MA), which was complicated by myopotential sensing. Finally, an epicardial system with a single coil (Sprint Quatro; Medtronic, MN) placed in the posterior pericardium, a single coil (Transvene; Medtronic MN) placed subcutaneously, and a Capsurefix 5076 (Medtronic, MN) pace-sense lead were all tunnelled to a subrectus generator.

Two years later PET-CT confirmed system infection. Explant of infected material occurred in a hybrid theatre. A subxiphoid incision was performed for direct visualisation of the pericardial space. The proximal portion of the pericardial lead was visualised using a Convergent introducer sheath (Atricure, West Chester, OH) and thoracoscope, however the tip was not visualised. Extraction with manual traction failed. A rotating dilator sheath (13F 545-513 Tightrail; Spectranetics, CO) under direct visualisation successfully extracted the pericardial lead (panel A; supplement). There were dense fibrous adhesions around the distal coil (panel B).

We describe the first epicardial shock lead extracted with a rotating mechanical cutting tool aided by direct visualisation, thereby avoiding sternotomy.
A 39-year-old male with an implantable cardioverter-defibrillator (ICD) was referred for device extraction. Transvenous systems were complicated by high failed defibrillation thresholds (DFTs) and failing leads. After a fourth system failure, he had a subcutaneous ICD (SICD) (Emblem; Boston Scientific, Marlborough, MA), which was complicated by myopotential sensing. Finally, multiple system failures resulted in the implant of an epicardial system with a single coil (Sprint Quatro; Medtronic, MN) placed in the posterior pericardium, a single coil (Transvene; Medtronic MN) placed subcutaneously, and a Capsurefix 5076 (Medtronic, MN) pace-sense lead were all tunnelled to a subrectus generator.

Two years later PET-CT confirmed system infection. Explant of infected material occurred in a hybrid theatre. A subxiphoid incision was performed for direct visualisation of the pericardial space. The proximal portion of the pericardial lead was visualised using a Convergent introducer sheath (Atricure, West Chester, OH) and thoracoscope, however the tip was not visualised. Extraction with manual traction failed. The lead was prepared with retraction of the screw mechanism and a lead locking device (LLD EZ™, Philips Healthcare, USA) stylet was deployed. Gentle manual traction was applied but the lead was adhered within the pericardial space. A rotating dilator sheath (13F 545-513 Tightrail; Spectranetics, CO) under direct visualisation was used to successfully extract the pericardial lead (Panel 1B; supplement for video). The outer sheath was not used as venous access did not need to be maintained and allowed greater flexibility of the tool. Mechanical extraction was undertaken to free the lead from the fibrous binding sites (Panel 1C). The lead was prepared with retraction of the screw mechanism and a lead locking device (LLD EZ™, Philips Healthcare, USA) stylet was deployed. Gentle manual traction was applied but the lead was adhered within the pericardial space. A rotating dilator sheath (13F 545-513 Tightrail; Spectranetics, CO) under direct visualisation was used to successfully extract the pericardial lead (Panel 1B; supplement for video). The outer sheath was not used as venous access did not need to be maintained and allowed greater...
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We describe the first epicardial shock lead extracted with a rotating mechanical cutting tool aided by direct visualisation, thereby avoiding sternotomy.
Epicardial Lead

Rotating Dilator Sheath

Dense fibrous adhesions around the explanted epicardial lead
Title: First use of a rotating mechanical dilator sheath to extract an epicardial defibrillator lead from the pericardial space

Short title: Epicardial defibrillator lead extraction with rotating dilator sheath

Authors:

Dr Vishal S Mehta MBBS \textsuperscript{1,2} – corresponding author
Dr Mark K Elliott MBBS \textsuperscript{1,2}
Dr William Regan MBChB \textsuperscript{3}
Dr Jonathan M Behar PhD \textsuperscript{1}
Professor Eric Rosenthal MD \textsuperscript{3}
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Conflicts of Interest:

M. Elliott and V. Mehta have received fellowship funding from Abbott, outside of the submitted work.
M.Elliott has received project funding from Rosetrees Trust, outside of submitted work. C.A. Rinaldi
receives research funding and/or consultation fees from Abbott, Medtronic, Boston Scientific and
MicroPort, outside of the submitted work.

Acknowledgements:
Funding: The work was supported by the Wellcome/EPSRC Centre for Medical Engineering [WT203148/Z/16/Z].

Keywords
Transvenous lead extraction; mechanical sheath; epicardial; Tightrail

Long summary:
A 39-year-old male presented with a device infection. A secondary prevention transvenous implantable cardioverter defibrillator (ICD) was implanted aged 14 years following ventricular fibrillation (VF). Investigations showed exercise-induced ventricular tachycardia and a family history suggestive of a SCN5A channelopathy.

Transvenous systems were complicated by high defibrillation thresholds (DFTs) and repeated extractions of failing leads. When his 4th system – a dual coil in the RV and single coil in the coronary sinus (Riata; St Jude Medical, Sylmar, CA) – failed 20 years later, rather than a further extraction, he had a subcutaneous-ICD (SICD) (Emblem; Boston Scientific, Marlborough, MA) implanted. This was complicated by persistent myopotential sensing and inappropriate shocks despite 4 revisions over a 3-year period. A decision was made to implant a new system. Finally, after percutaneous puncture, an epicardial system with a single coil transvenous lead (Sprint Quatro; Medtronic, MN) was placed in the posterior pericardium and attached to the atrial epicardium, a single coil (Transvene; Medtronic MN) placed subcutaneously and parasternally, and a Capsurefix 5076 (Medtronic, MN) pace-sense lead placed via a subclavian puncture, were all tunnelled to a new generator (Evrea, Medtronic, MN) in a subrectus pocket.
Two years later, positron emission tomography (PET)/computed tomography (CT) (PET-CT) imaging confirmed infection of the abdominal generator with extension to the proximal portions of the pericardial shock lead and transvenous lead (Panel 1A).

To avoid a sternotomy, the infected leads were explanted in a hybrid operating theatre using a minimally invasive approach alongside the cardiothoracic team. A subxiphoid incision was performed and the generator removed. The parasternal coil and endocardial pacing lead were removed by manual traction. Blunt dissection enabled direct visualisation of the pericardial space and the pericardial lead was inspected using a Convergent introducer sheath (Atricure, West Chester, OH) and thoracoscope. The tip was not visualised due to adhesions within the pericardial space. Manual traction alone failed to remove the lead. A rotating dilator sheath (13F 545-513 Tightrail; Spectranetics, CO) under direct visualisation was used to successfully extract the pericardial lead (Panel 1B; supplement for video) with evidence of dense fibrous adhesions around the distal coil (Panel 1C). There was no evidence of peri- or myocardial trauma. Staphylococcus epidermidis and cutibacterium acnes were grown from enrichment culture of the extracted material.

This is the first description of an epicardial shock lead extracted with a rotating mechanical cutting tool. Direct visualisation with a thoracoscope allowed removal of this lead using a Tightrail sheath without complication in this high-risk and complex case, whilst avoiding sternotomy. Although the ICD lead had only been in situ in the pericardium for 2 years, dense adhesions prevented removal with manual traction, demonstrating the risk of encapsulation even with shorter lead dwell periods1. This case highlights the utility of specialised extraction tools for removal of leads in the pericardial space, thereby preventing the need for sternotomy and avoiding myocardial or coronary artery injury.
For videos see supplementary material

References

Figure: Panel A – Plain AP radiograph prior to lead extraction for infected material identified on PET-CT. Purple arrows are of infected device material as identified by imaging. 1) subcutaneous parasternal single coil, 2) endocardial RV pace/sense lead, 3) Abdominal ICD generator, 4) single coil pericardial shock lead. Green arrows are non-infected material 5) single coil in RV, 6) single coil in CS, 7) SVC coil. Panel B – Still image from peri-procedural fluoroscopy demonstrating removal of pericardial coil. 8) rotating dilator sheath. Panel C - Extracted pericardial ICD lead with evidence of dense fibrosis on the shock coil.
Title: First use of a rotating mechanical dilator sheath to extract an epicardial defibrillator lead from the pericardial space

Short title: Epicardial defibrillator lead extraction with rotating dilator sheath

Authors:

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Dr Mark K Elliott MBBS 1,2
Dr William Regan MBChB 3
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Professor Eric Rosenthal MD 3
Professor Christopher A Rinaldi MD, FHRS 1,2

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To avoid a sternotomy, the infected leads were explanted in a hybrid operating theatre using a minimally invasive approach alongside the cardiothoracic team. A subxiphoid incision was performed and the generator removed. The parasternal coil and endocardial pacing lead were removed by manual traction. Blunt dissection enabled direct visualisation of the pericardial space and the pericardial lead was inspected using a Convergent introducer sheath (Atricure, West Chester, OH) and thoracoscope. The tip was not visualised due to adhesions within the pericardial space. Manual traction alone failed to remove the lead. A rotating dilator sheath (13F 545-513 Tightrail; Spectranetics, CO) under direct visualisation was used to successfully extract the pericardial lead (Panel 1B; supplement for video) with evidence of dense fibrous adhesions around the distal coil (Panel 1C). There was no evidence of peri- or myocardial trauma. Staphylococcus epidermidis and cutibacterium acnes were grown from enrichment culture of the extracted material. The patient had extraction of the two remaining ICD leads in the RV apex and CS, with some fragments remaining in the brachiocephalic vein, and successful implantation of a new transvenous ICD device (see supplement figure 1).

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cardiothoracic support. Although the ICD lead had only been in situ in the pericardium for 2 years, dense adhesions prevented removal with manual traction, demonstrating the risk of encapsulation even with shorter lead dwell periods\(^1\). This is particularly important in the paediatric and younger adult population who are more likely to have epicardial leads\(^2\).

This case highlights the utility of specialised extraction tools for removal of leads in the pericardial space, thereby preventing the need for sternotomy and avoiding myocardial or coronary artery injury.

For videos see supplementary material

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A 39-year-old male presented with an epicardial ICD system infection. He had separate shock leads placed in posterior epicardium and subcutaneously, and a transvenous pace-sense lead. A Tightrail sheath under direct visualisation successfully extracted the pericardial lead and avoided the need for sternotomy. This is the first description of an epicardial shock lead extracted with a rotating mechanical cutting tool.