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Results from a national observational survey of UK cardiologists on antibiotic envelope use during cardiac electronic device implantation

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ABSTRACT

Objective The aim of this study was to conduct a survey of cardiac device implanting physicians to report utilisation trends, barriers and attitudes around the use of antibiotic envelope utilisation in the UK.

Design An online survey devised by an implanting physician focus group, which included a mixture of multiple-choice and open text questions, was sent via email to UK-based physicians.

Participants 500 implanting physicians across 159 sites in the UK, identified from the National Institute for Cardiovascular Outcomes Research Database.

Results Responses were received from 117 participants (79% of whom were consultant cardiologists). The TYRX absorbable antibiotic envelope was most commonly used for device upgrades, compared with de novo pacemakers, cardiac resynchronisation therapy-pacemakers or -defibrillators (CRT-P/CRT-D) implants and generator replacements. A limited number (13%) of respondents used the PADIT (Prevention Of Arrhythmia Device Infection Trial) score to guide their use of TYRX while 31% of respondents were unaware of the score. Several risk factors (early pocket re-intervention, previous device infection and procedural duration) were reported as the most important factors in consideration of TYRX use; however, these are not included in the PADIT score. Key barriers to adoption included cost-effectiveness and lack of compelling clinical data and guidelines. Technical concerns were reported by 27% of respondents, translating into reduced utilisation in clinical practice.

Conclusion This survey provides a snapshot of antibiotic envelope utilisation across device implanters in the UK. The PADIT score does not reflect the key decision-making factors reported by our surveyed cohort. There remains significant variation in patient selection and practical techniques as well as uncertainty surrounding the clinical evidence and cost-effectiveness of the TYRX envelope.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study used a mixture of multiple-choice, open-ended, quantitative and qualitative questions enabling analysis of both statistical trends and the underlying experiences of implanting physicians.
⇒ This study was an anonymous voluntary survey; hence, it is subject to non-response bias and response bias with skewed opinions potentially reflecting quite strongly in the study.
⇒ Data around the number of cardiac implantable electronic device implantations are self-reported by participants and may not accurately portray real-life statistics.

INTRODUCTION

Cardiac implantable electronic device (CIED)-related complications are becoming more prominent, as the number of CIED implants is increasing annually.[1] Infections of CIEDs are a major complication as they are difficult to diagnose and have an associated mortality of ~4%.[2 3] The incidence of CIED-related infections has increased faster than the rate of total CIED implantations per year.[3] Potential contributors include the growing use of CIEDs in patients with multiple comorbidities as well as a rise in the numbers of complex device implants.[3] Management of CIED-related infections often requires prolonged hospital stays, intravenous antibiotic use and often, the complete removal of the CIED.[2] This does not only incur a significant mortality and morbidity burden but also a huge financial burden on healthcare systems.[4] Despite the utilisation of prophylactic preoperative antibiotics and sterile surgical techniques, CIED-related infections have become a notable concern, complicating around 4.4% of device implantations.[3] Cardiac resynchronisation therapy (CRT) devices have been noted to have higher incidences of infections of up to 9.5% compared with pacemakers (0.5%–1%) and ICD (implantable cardioverter defibrillator) implants (1.7%).[5] With the increasing complexity of implanted devices and increasing comorbidities of recipients, this number is expected to rise each

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year.[6] Given the complexity and economic burden of treating CIED infections, using an effective prophylactic agent in appropriately selected patient might be most effective.[7]

Preventative methods such as antibiotic-eluting CIED envelopes have been proposed as a promising strategy.[8] The absorbable TYRX antibacterial envelope has been shown to be an effective novel strategy in preventing CIED-related infection.[9] The TYRX (Medtronic, Minneapolis, Minnesota, USA) envelope consists of a polypropylene mesh that elutes minocycline and rifampicin providing prophylactic antibiotic cover against infection lasting a minimum of 7 days.[10] The WRAP-IT (The Worldwide Randomized Antibiotic Envelope Infection Prevention) trial showed that participants randomised to have the TYRX envelope in their CIED implant had 61% fewer deep incisional pocket infections when compared with the control group.[11] A meta-analysis showed that the utilisation of TYRX was associated with a 74% relative risk reduction in major CIED-related infections in high-risk patients compared with control.[12]

National Institute for Health and Care Excellence currently has not made clear recommendations due to withdrawal of the evidence submission to appraise the use of TYRX.[13] European Society of Cardiology guidelines state that antibiotic-eluting envelopes may be considered in reintervention CIED procedures or for patients at high risk of CIED infections.[14] A European Heart Rhythm Association consensus statement supports the use of antibiotic envelopes in high-risk scenarios, including those defined in the WRAP-IT study population.[15] A list of CIED infection risk factors is provided, but a lack of guidelines and clear indications on when to use TYRX envelopes leaves the decision at the discretion of the implanting physician.[14]

Implanting physicians may use scoring systems, such as PADIT, to help identify patients at high risk of device infections at the time of CIED implant.[16] The PADIT risk score takes into consideration the patient's age, medical history and the type of procedure the patient will undergo to estimate a risk of hospitalisation relating to device infection.[16] Physicians can use this to aid their decision making; however, the scoring system provides only a framework to predict infection risk and does not advise or provide cut-offs for the implementation of preventive techniques.

The aim of this study was to conduct a survey of CIED implanting physicians to report utilisation trends, barriers and attitudes around the use of antibiotic envelope utilisation in the UK.

METHODS

Survey design

A literature review was conducted to identify relevant publications and national/international guidelines to assess indications, efficacy and barriers around the use of TYRX. The survey was designed to consist of multiple choice, ranking and free text questions to explore the respondents' view around the use of TYRX. For the multiple-choice questions, multiple answers were able to be selected. Additionally, respondents had an optional section to disclose self-reported CIED implantation and TYRX use numbers. The survey was aimed at both junior and consultant implanting physicians. A focus group of physicians evaluated the proposed survey and provided feedback.

Survey platform and distribution

The questions were exported as a self-administered online survey using Qualtrics. Participants' responses were anonymously recorded. The survey was sent via email to implanting physicians based on the National Institute for Cardiovascular Outcomes Research database by cross-checking National Health Service (NHS) outlook email addresses. Survey invites were sent across to a diverse group of implanting physicians, including those who work in tertiary centres and district general hospitals. Responses were collected from October 2023 to December 2023. The survey was sent to 500 physicians across 159 sites across the UK with one reminder for completion sent 2 weeks from initial dissemination. A copy of the survey (online supplemental material 1) and list of hospitals from which physicians were contacted (online supplemental material 2) can be found in the supplementary appendix.

Data collection and analysis

Anonymous data were collected directly on Qualtrics. On completion of the survey time, all responses were exported as a CSV file. Table, graphs and data analysis were conducted on Microsoft Excel.

Patient and public involvement

Both patients and the public were not involved in the design, conduct or reporting or dissemination of our research.

RESULTS

The survey was sent to 500 implanting physicians from 159 sites in the UK and was completed in the time frame by 117 clinicians (response rate of 23.4%, 117/500). 79% of respondents were consultant cardiologists and 21% were cardiology registrars. All responses were included in the analysis. Our cohort included a wide spectrum of annual implant numbers, including high-volume implanting physicians (200+ CIED implants annually) as well as lower-volume implanters (20–60 CIED implants annually). On average, the cohort performed 68 de novo device implants, 10 upgrades and 32 generator changes annually (table 1).

Use of antibiotic cardiac device envelope

TYRX was rarely used for de novo anti-bradycardia pacemakers (6% of procedures from only 50% of operators) but more frequently used for device upgrades (52% of

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Table 1 Summary of respondents' implant numbers and TYRX usage per year (n=75)

	Total number of implanters	Average number of procedures	Number of TYRX users	Average number of TYRX used
De novo pacemaker	70	67.7	35	3.8
De novo CRT-P	67	21.5	36	2.8
De novo CRT-D/ICD	63	20.9	43	3.5
Upgrade procedures	62	10.1	47	6.2
Generator replacement	70	32.8	54	7.3

CRT-D, cardiac resynchronisation therapy-defibrillator; CRT-P, cardiac resynchronisation therapy-pacemaker; ICD, implantable cardioverter defibrillator.

procedures from 76% of operators) (figure 1). De novo implantations of larger devices (CRT-P/CRT-D) had greater utilisation of TYRX than simple pacemakers (CRT-P 15% of implants and CRT-D 18%).

Utilisation of risk-stratification scoring systems

The PADIT risk stratification score was routinely used by 13% of respondents for all implantations, but a larger proportion (35%) use it when they deem there to be clinical uncertainty (figure 2a). 31% of device implanters surveyed were not aware of the PADIT scoring system. A further 14% were aware of the scoring system but did not use it due to its perceived limitations. Three respondents (2.5%) reported using an alternative scoring system called the BLISTER (Blood results, Long procedure time, Immunosuppressed, Sixty years old (or younger), Type of procedure, Early re-intervention, Repeat procedure) score.

The use of PADIT by survey implanters did not affect TYRX utilisation with similar numbers seen between operators that use PADIT scoring system to those that did (figure 2b).

Understanding decision making around TYRX use

The most frequent factors reported leading to TYRX utilisation were: (1) early pocket re-intervention (75% of respondents), (2) previous device infection (73%), (3) procedures with long duration (>2 hours) (58%), (4) upgrade of device (43%) and (5) chronic steroid use of >5 mg (42%) (figure 3a).

Previous device infection was ranked most frequently as the most important factor leading to decision making for TYRX utilisation (48% ranked this highest) (figure 3b). The PADIT risk stratification system was only ranked as the most important factor by 10% of respondents. Other commonly selected highly ranked factors included early pocket intervention (21%), fevers and raised inflammatory markers (15%).

Barriers to antibiotic envelope utilisation

The main reported deterrent for using TYRX was a concern around cost-effectiveness (70%) (figure 4). Other barriers included concerns around guidelines and evidence (32% and 22%, respectively) and also operative concerns including difficulty placing the device in the pocket (27%). Respondents reporting technical barriers (operative barriers, difficulty wrapping the device in TYRX and difficulty placing TYRX covered device into pocket) used TYRX less frequently than respondents who did not report these barriers across all implant types (figure 5).

The largest difference was for upgrade and generator procedures, where those implanters expressing technical barriers had ~20% lower TYRX utilisation.

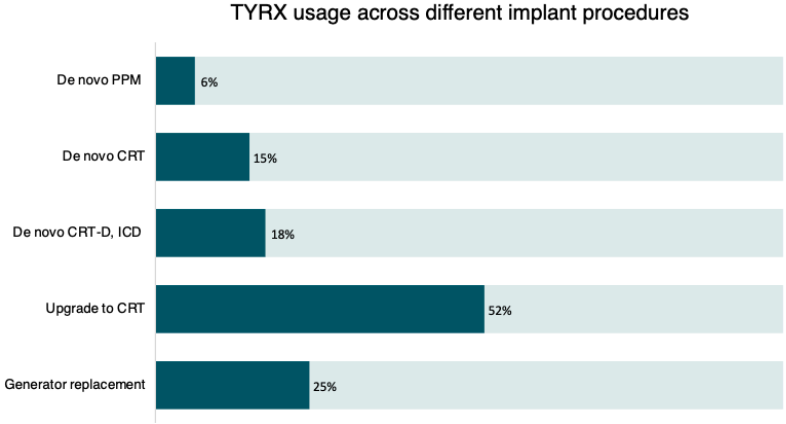


Figure 1 Percentage of TYRX usage in implant procedures among TYRX users. CRT, cardiac resynchronisation therapy; PPM, permanent pacemaker; CRT-D, cardiac resynchronisation therapy-defibrillator; ICD = implantable cardioverter defibrillator.

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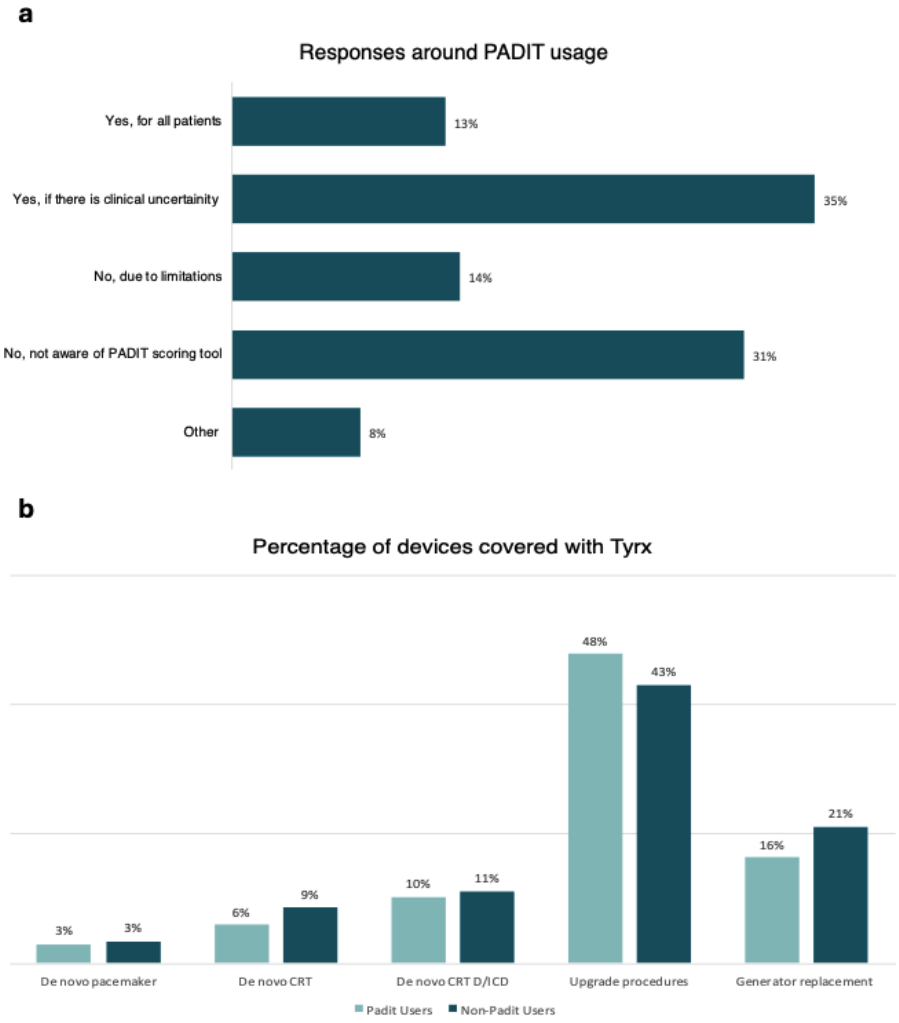


Figure 2 (a) Response around the use of PADIT score (n=117). (b) TYRX usage across reported PADIT users and non-PADIT users. CRT, cardiac resynchronisation therapy; CRT-D, cardiac resynchronisation therapy-defibrillator; ICD, implantable cardioverter defibrillator; PADIT, Prevention Of Arrhythmia Device Infection Trial.

Techniques for using the TYRX envelope

For bradycardia pacemakers, the majority of respondents reported using a medium-sized envelope to either wrap the device only (30%) or to wrap both device and the leads (33%) prior to placing into the pocket (figure 6A). 26% of respondents used a large-sized envelope to wrap both the device and leads. 9% of respondents reported cutting the envelope into pieces and placing it within the pocket before then placing the pacemaker device into it. Almost 75% of participants always invert the TYRX envelope prior to use with pacemakers.

The method of using TYRX in CRT-D/ICD implantations differed with the majority of respondents selecting to use the large envelope to wrap both leads (45%) and device or device only (24%) (figure 6B). 15% of participants selected using a medium-sized device to cover the device only, while only 8% selected to cut the envelope and place it into the pocket prior to implantation. Similarly, almost 75% of participants always invert the envelope prior to use with ICD/CRT-D.

DISCUSSION

This survey provides a contemporary overview around TYRX use among implanting physicians in the UK. Around half of our respondents would use TYRX if needed for a de novo PPM implant and an even greater proportion of implanters would use TYRX for complex procedures and device reinterventions. This survey further highlights contrasting opinions among our respondents as to how to assess and stratify use of TYRX based on risk stratification, how to use absorbable envelopes and barriers to their utilisation.

Risk stratification for the use of TYRX

Risk scoring systems do not encapsulate a number of key factors which device operators consider to be important. Many of these factors are strongly associated with CIED infection risk, which may explain why a number of respondents (14%) report that while they are aware of scores such as PADIT, they do not use it because of the perceived limitations.

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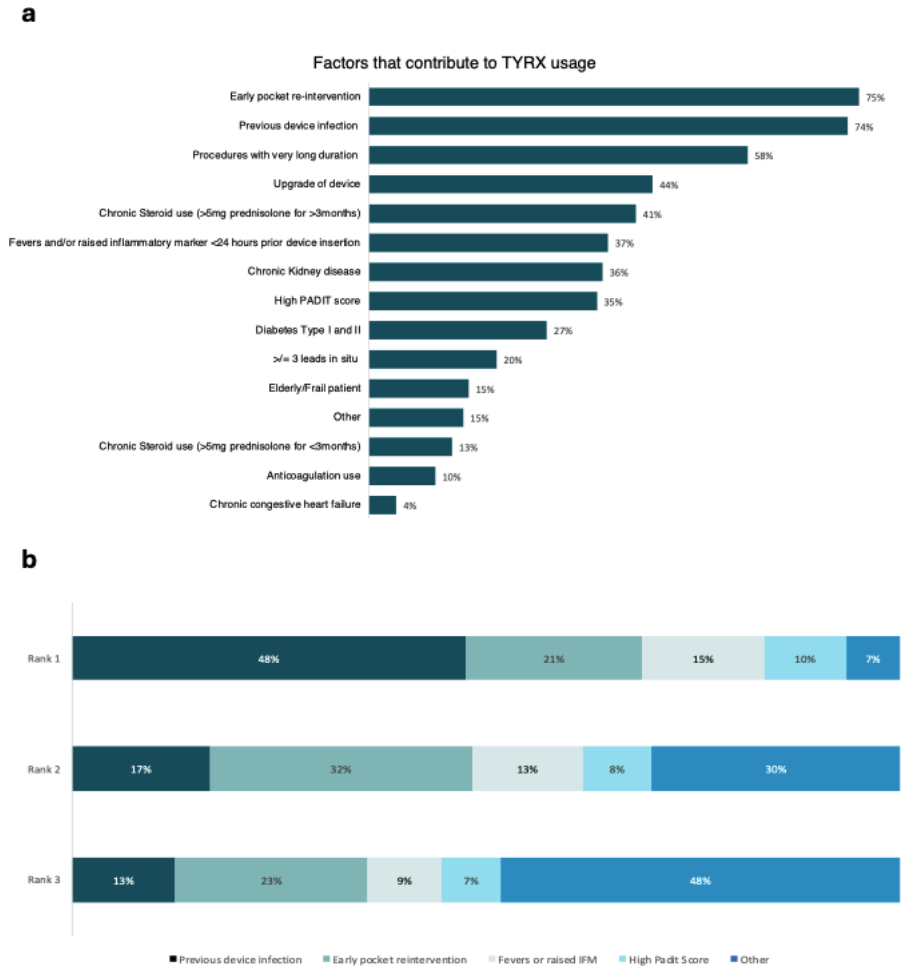


Figure 3 (a) Selected risk factors for the use of TYRX (n=117). (b) Ranking of importance (with Rank 1 being most influential) of risk factors to determine TYRX use. PADIT, Prevention Of Arrhythmia Device Infection Trial; IFM, inflammatory markers.

In contrast, though, around half of the respondents reported not using PADIT due to lack of awareness of scoring systems or their perceived limitations. The PADIT scoring system, for example, was first established following the Prevention of Arrhythmia Device Infection Trial, which aimed to collect data around independent predictors of device infection.[17] Further research, aimed at validating the PADIT score, identified that an increase in one point on the PADIT score was associated with a 28% increase in infection risk.[16] Despite this predictive value of the PADIT score, around half of the respondents of this survey reported not using PADIT due to a lack of awareness or perceived limitations of it.

Some participants reported using the BLISTER score, which is a similar scoring system to predict the infection risk of a cardiac device procedure. The BLISTER

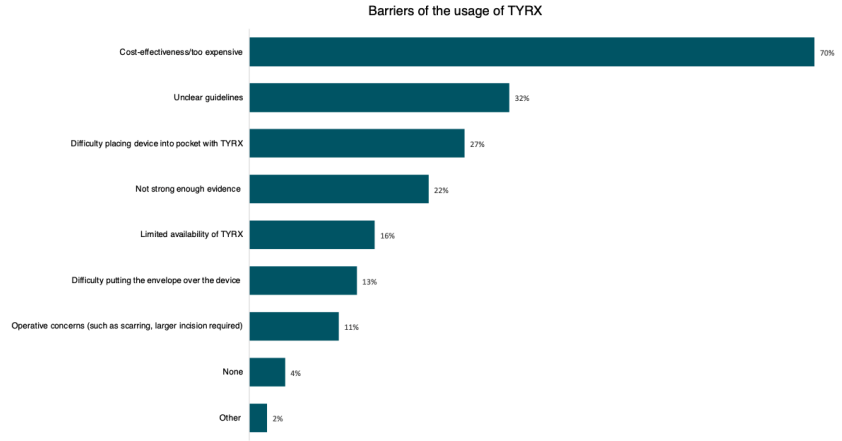


Figure 4 Barriers and deterrents around the usage of TYRX as selected by implanting physicians (n=90).

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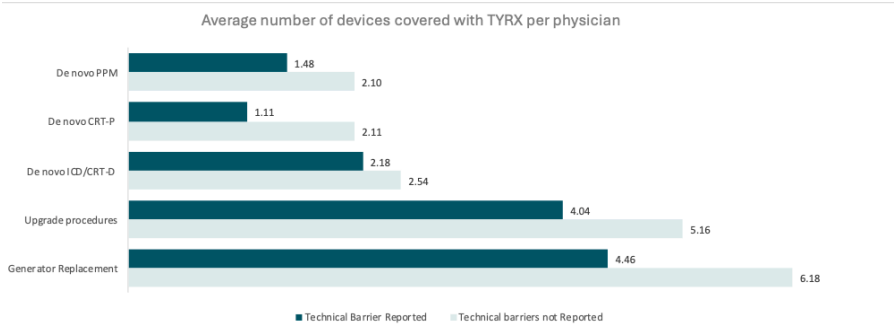


Figure 5 Comparison of TYRX usage between respondents that did and did not select skill-based barriers. CRT-P, cardiac resynchronisation therapy-pacemaker; CRT-D, cardiac resynchronisation therapy-defibrillator; ICD, implantable cardioverter defibrillator; PPM, permanent pacemaker.

score includes 'duration of procedure over 120 min' and 're-intervention within 2 years', which is not taken into consideration in the PADIT score (table 2).[18] A recent study comparing the two scoring systems suggested that the BLISTER score might be superior at predicting infection risk compared with the PADIT scoring system in both standard and high-risk cohorts.[18] The BLISTER score may provide a potential solution to help clinicians make more accurate decisions about infection risk of a given procedure and evaluate the need to use TYRX.[18]

Another factor that was not considered in this survey or by risk stratifications score is the presence of risk factors that affect mortality in patients admitted with CIED-related infections. Coagulopathies and malnutrition were identified as predictors of mortality in patients with CIED infections. Hence, future studies should explore whether

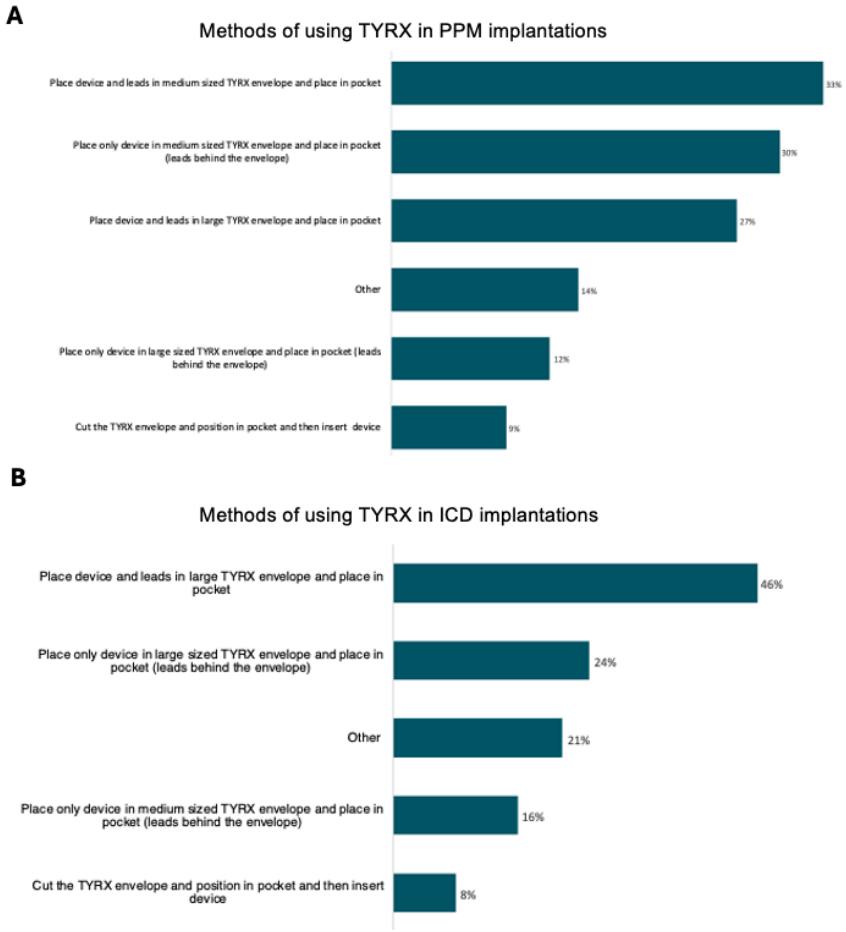


Figure 6 Methods of using TYRX in pacemakers (A) or CRT/ICD (B) implant procedures. CRT, cardiac resynchronisation therapy; ICD, implantable cardioverter defibrillator.

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Table 2 Components of PADIT and BLISTER scores

PADIT	BLISTER
Prior procedures on same pocket	Number of previous procedures
Age	Age
Depressed renal function	eGFR (<30)
Immunocompromised state	Immunosuppression
Type of procedure	Re-intervention within 2 years
	Type of procedure
	Procedure duration >120 min
	CRP within 24 hours of procedure (≥50)

BLISTER, Blood results, Long procedure time, Immunosuppressed, Sixty years old (or younger), Type of procedure, Early re-intervention, Repeat procedure; PADIT, Prevention Of Arrhythmia Device Infection Trial.

the use of TYRX has also beneficial outcomes in patients who develop CIED-related infections despite prevention methods.

Previous device infection was frequently selected as the most important factor among our participant cohort when making decisions about using antibiotic envelopes. However, it is not considered in either scoring system. Validity tests support the survey respondents' approach with an increased predictive value of 'previous device infection' as a risk factor for future device infection when used alongside the PADIT score (HR 5.66, p<0.0001).[16]

Our survey reinforces the importance of developing a robust risk-stratifying scoring system to allow implanting physicians to make appropriate decisions regarding patient selection for CIED infection prevention measures.

Barriers

Cost effectiveness

70% of respondents perceived cost-effectiveness as a deterrent for the use of antibiotic envelopes. This appears to be a perceived barrier as several cost-effective analyses have shown the benefits of TYRX use within the NHS. A UK-based cost-effectiveness analysis has shown that TYRX reduces device-related infection risk compared with standard of care, especially in patients with an ICD or CRT-D.[19] The model demonstrated that in a 12-month time horizon, TYRX was able to reach a cost-effectiveness threshold between £20 000 and £30 000 per QALY gained compared with standard of care.[19] Another retrospective cost analysis model has shown that TYRX is cost-effective in patients with heart failure.[20] Cost analysis demonstrated that a CIED infection admission can cost on average £61 585 with specifically cardiac-related costs amounting up to £49 541.25.[20] The use of TYRX can cost-save up to £624 per patient, and with approximately 295 new ICD/CRT implantations per million people, this could potentially save the NHS around £9 700 000.[20]

Technical implant considerations

Up to 27% of respondents reported technical concerns, including difficulty placing the envelope into a pocket, difficulty placing the envelope over device and other operative concerns including the potential of increased scarring and need for larger incisions and pockets. This translated into reduced use of TYRX in clinical practice for those respondents.

The WRAP-IT trial did not comment on any specific techniques for insertion of the TYRX envelope, and the results from this survey suggest substantial variation in operators' practice. A large number of respondents reported inverting the envelope prior to use (ie, turning the envelope inside out) despite this being off-label use. A possible rationale for this practice is the perception that by facing the inner layer of envelope outwards, the envelope is easier to handle and place into a device pocket. This is not recommended by the manufacturers' instruction for use and may impact the elution profile of the antibiotic. Future product solutions aimed at lowering the risk of device infection may benefit from additional guidance regarding best practice techniques (driven by the relevant evidence base) as well as addressing ergonomic considerations, which may mitigate any technical barriers to widespread use and adoption.

Supporting clinical data and guidelines

Other key deterrents for the use of TYRX specifically included concerns around guidelines and the strength of evidence supporting its use in clinical practice, largely supported so far by a single randomised-controlled trial and subsequent meta-analysis of its data along with only smaller observational studies.[11 12 21] The WRAP-IT trial randomised 6983 patients to standard-of-care infection reduction strategies only or standard-of-care and use of the TYRX antibiotic envelope.[11] The trial showed a reduction of infection rates in those receiving the TYRX envelope; however, the application of this data to clinical practice may be limited due to the exclusion of patients at highest risk of device infection.[11] Exclusion criteria included patients with previous device infections, immunosuppression including chronic steroid use in excess of 20 mg/day and clinical signs of infection at the time of device insertion, and our survey suggests that these are all relevant clinical situations in which operators would want to use TYRX.[11] This is potentially a key driver of the concerns reported by survey participants around the strength of evidence supporting the use of TYRX in clinical practice. Another recent prospective study showed the protective effect of TYRX among both high and low infection risk device implantations.[21] The REINFORCE study demonstrated a significant reduction in the incidence of device-infection related clinical events among both low scoring PADIT (scores 0–4) populations (TYRX 0.0% vs control 1.7%, p=0.029) and high scoring PADIT (score ≥7) populations (TYRX 1.5% vs control 5.6%, p=0.022).[21] This highlights the need for future randomised-controlled trials to include both low and high-infection risk patients

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to evaluate the effectiveness of TYRX in clinically relevant situations.

Global perception around TYRX use

While this survey provides a snapshot of UK-based implanters' perception regarding the use of cardiac antibiotic envelopes, the general attitudes expressed in this survey appear to resonate with implanters across the globe.[22 23] A European international survey showed that use of PADIT was limited in European implanters, with 25% of respondents using the scoring system alongside patient profiles to determine infection risks and only 1% using PADIT alone.[22] The majority of European respondents (similarly to our cohort) chose previous device infection, revision/upgrade and procedures with long durations as relevant risk factors in determining CIED infection risk.[22] However, risk factors such as diabetes and chronic kidney disease were selected by significantly more European respondents (88% and 92%, respectively) compared with our UK-based cohort (27% and 36%, respectively).[22] Another survey based on US-based implanters showed that use of TYRX was primarily influenced by infection concerns, patients with comorbidities and previous history of CIED infections.[23] Specific risk factors were not explored further.

Utilisation of antibiotic envelopes may have increased since the publication of the landmark WRAP-IT study. A world-wide survey published shortly after the publication of WRAP-IT reported 37% of implanters would use TYRX.[24] The percentage of implanters that would use TYRX in our study is higher, potentially reflecting temporal changes following wider dissemination of the WRAP-IT results, although this difference may also have been impacted by constraints of different healthcare economies.[24] Within the UK, individual NHS hospitals must make their own funding decisions based on local decision-making frameworks as outlined in the NHS Constitution for the reimbursement of TYRX.[13] There is no universal reimbursement policy at present across NHS hospitals, and as such, decisions with regards to TYRX use in different regions of the UK are likely to vary and may reflect constraints from local health resource allocation priorities.

Limitations

This was a voluntary survey sent electronically to implanters across the UK. The results of our survey are subject to non-response bias. The results reflect only those implanters who chose to respond to our survey (23%) and it is possible, therefore, that the results do not capture the entire spectrum of current practice of antibiotic envelope utilisation among those implanters who were initially contacted. As an anonymous survey with voluntary participation, response bias may mean responders might either have been skewed to those with significant concerns or reservations around TYRX utilisation or equally, those who have adopted it readily into their implanting practice. Additionally, the absence of geographical data from our respondents makes it difficult to ascertain if particular regions/trusts were over-represented or under-represented. Extrapolation of these results to the overall cohort of UK implanters is as such limited. Reported data were not verified (eg, the number of procedures using TYRX in each category) and may represent a source of bias; however, this is a limitation inherent to observational survey design.

Conclusions

This survey of antibiotic envelope utilisation across device implanters provides an overall picture of the utilisation of TYRX across the UK. The survey highlights the variation in approaches to risk-stratification for those patients at high risk of device infection and key barriers to widespread adoption.

Contributors DK and NK conceived the study and supervised the project. AR led the writing and contributed to the questionnaire design. All authors contributed to the study's data collection. AR and MJS-S analysed the data. All authors contributed to drafting and revising the manuscript and approved the final version. NK is the guarantor of this work and affirms that the manuscript is an honest, accurate and transparent account of the study being reported, and that no important aspects have been omitted.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants but was not approved. Ethical approval was not required as no patients were involved in this study. This was a voluntary survey, and all physician participants gave consent to participate. According to the Health Research Authority guidelines as participants were not randomised, the study protocol did not demand deviation from standard care and findings are not generalisable, research ethic committee approval was not required. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Data are available upon request.

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