EPICARDIAL CATHETER ABLATION FOR VENTRICULAR TACHYCARDIA ON UNINTERRUPTED WARFARIN: A SAFE APPROACH FOR THOSE WITH A STRONG INDICATION FOR PERI-PROCEDURAL ANTICOAGULATION?

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ABSTRACT

Background: Current guidelines for epicardial catheter ablation for ventricular tachycardia (VT) advocate that epicardial access is avoided in anticoagulated patients and should be performed prioronse to heparinisation. Recent studies have shown that epicardial access may be safe in heparinised patients. However, no data exist for patients on oral anticoagulants. We investigated the safety of obtaining epicardial access on uninterrupted warfarin.

Methods: A prospective registry of patients undergoing epicardial VT ablation over two years was analysed. Consecutive patients in whom epicardial access was attempted were included. All patients were heparinised prior to epicardial access with a target activated clotting time (ACT) of 300-350 seconds. Patients who had procedures performed on uninterrupted warfarin (in addition to heparin) were compared to those not taking an oral anticoagulant.

Results: 46 patients were included of which 13 were taking warfarin. There was no significant difference in clinical and procedural characteristics (except INR and AF) between the two groups. Epicardial access was achieved in all patients. There were no deaths and no patients required surgery. A higher proportion of patients in the warfarin group had a drop in haemoglobin of >2g/dL compared to the no-warfarin group (38.5% versus 27.3%,p=0.74) and delayed pericardial drain removal (7.8% versus 3.03%,p=0.47). There was no difference in overall procedural complication rate. No patients required warfarin reversal or blood transfusion.

Conclusion: Epicardial access can be achieved safely and effectively in patients' anticoagulated with warfarin and heparinised with therapeutic ACT. This may be an attractive option for patients with a high stroke risk.

INTRODUCTION

Catheter ablation of ventricular tachycardia (VT) is increasingly used as a therapeutic option in patients with sustained VT.[1,2] This is typically performed endocardially initially,[2,3] with an epicardial approach conventionally used on a subsequent occasion when an endocardial substrate has not been identified at the index procedure[4], although a combined approach is being undertaken increasingly during the index procedure.[5] Epicardial access might be obtained at the outset in cases where an epicardial substrate is more likely e.g. arrhythmogenic right ventricular cardiomyopathy, dilated cardiomyopathy and cardiac sarcoidosis.[6]

Percutaneous epicardial access has become an established technique allowing access to the epicardial surface for mapping and ablation.[7,8] Epicardial ablation is a relatively safe approach with a major complication rate around 4 - 8% in tertiary centres.[9] Consensus guidelines recommend that epicardial access is avoided in anticoagulated patients and should be performed prior to systemic heparinisation.[2] Recent studies have shown that epicardial access may be safe in heparinised patients.[10] However, there are no data supporting the safety of epicardial ablation in patients on oral anticoagulants. This is at odds with modern ablation for atrial fibrillation where benefits to periprocedural uninterrupted anticoagulation are demonstrable.[11,12]

In this study we report our experience of obtaining epicardial access on uninterrupted warfarin. We compared patients who underwent epicardial VT ablation (post systemic heparinisation) while on uninterrupted warfarin to those who were not taking an oral anticoagulant in a case-control study to determine the risks and benefits of both approaches.

METHODS

Study design:

Retrospective, case-control study of patients undergoing epicardial catheter ablation for VT. Consecutive patients in whom epicardial access was attempted after heparinisation were included in the study. Patients on warfarin were compared in a case-control study to those not on any oral-anticoagulant. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the institution's human research committee. All patients were recruited at a single centre (The Barts Heart Centre, St Bartholomew's Hospital). Prior to the procedure, all patients gave written informed consent.

Study patients:

All patients undergoing catheter ablation for VT in whom epicardial access was attempted after heparinisation (with or without uninterrupted warfarin) were included in this study. Consecutive patients from April 2013 to April 2015 were included. Patients who underwent epicardial ablation while on uninterrupted warfarin (Warfarin Group) were compared to those who were not taking an oral anticoagulant (No-warfarin group). Patients in whom epicardial access was attempted prior to heparinisation were excluded from the study. No patient underwent epicardial ablation on a NOAC during the study period.

Catheter ablation procedure:

All procedures were carried out under intravenous moderate sedation. Patients were heparinised (after obtaining vascular access) with a target activated clotting time (ACT) of 300 – 350 seconds. Anticoagulation was not reversed in patients on uninterrupted warfarin.

7F and 8F sheaths were placed in the right femoral vein (unless there was a specific contraindication) and a 4F sheath in the right femoral artery, allowing continuous arterial pressure monitoring. Electroanatomical mapping of the left

ventricle was performed anterogradely following puncture of the inter-atrial septum. When retrograde access was sought in addition, an 8F sheath substituted the 4F arterial sheath. Carto 3 was used in all cases.

Epicardial access was obtained in fully heparinised patients (with or without warfarin) via a percutaneous sub-xiphoid approach using the technique described by Sosa et al.[7] In brief, either an 18G epidural Tuohy needle, or a similar introducer needle, was advanced under local anaesthesia towards the cardiac silhouette in an anteroposterior or left anterior oblique projection, aiming for the inferior border of the heart (either anteriorly or posteriorly). The needle was advanced until a 'give' was felt as the needle punctured the parietal pericardium, a small injection of contrast (<2mls) confirmed that the needle tip was within the pericardial space. A 0.032 inch guide wire was then advanced and either a short 8F sheath or a 9F steerable sheath (Agilis, St Jude Medical Inc, NM, USA) was used to secure access and aid catheter manipulation. Epicardial mapping and ablation was performed using a Smart Touch radiofrequency ablation catheter. During mapping, a continuous flow of 2 mL/min was used and during ablation the flow was increased to 10-30 mL/min. Fluid was periodically aspirated from a side port of the sheath to prevent accumulation of pericardial fluid during the procedure. Where necessary, coronary angiography was performed to define the proximity of the proposed ablation site to epicardial coronary arteries. Heparin reversal with protamine was not performed prior to obtaining pericardial access to facilitate further endocardial mapping and ablation if required after epicardial mapping.[10]

Post-procedure, the catheters were removed and the pericardial sheath exchanged for a pigtail catheter. The catheter was aspirated to dryness and absence of residual pericardial fluid confirmed on a transthoracic echocardiogram. Hydrocortisone (100mg) was administered into the pericardial space via the pericardial drain, which was clamped for 15 minutes before being left on free

drainage overnight. An echocardiogram was repeated 12hrs post-procedure and if the absence of a pericardial effusion was confirmed then a further bolus of hydrocortisone (100 mg) was administered and the pericardial drain removed.

Follow up:

Patients were typically discharged from hospital on the second day post ablation (i.e. approximately 48 hours post procedure). Patients were followed up in clinic at three months following their ablation regarding study endpoints with an ICD check in those with a device in situ. Additional review of medical notes and electronic health records was carried out to obtain a complete dataset.

Study end points:

The primary end point of the study was a composite of major and minor procedural complications. Major complications were (a) death from any cause (b) > 2g/dL drop in haemoglobin (c) need for surgical intervention (d) coronary artery damage (e) abdominal visceral laceration. Minor complications included (a) inadvertent RV puncture (b) delayed (>24hr post procedure) pericardial drain removal due to on-going fluid accumulation.

Secondary endpoints included acute procedural success and freedom from arrhythmia at 3-month follow-up. Acute ablation success was defined as an identifiable epicardial target and non-inducibility was not sought in all patients.

Statistical analyses:

Data were analysed on an intention-to-treat basis. All analyses were carried out using SAS version 9.3, statistical software. Continuous data were presented as mean ± standard deviation or median (range) if not normally -distributed. Categorical data were reported as a percentage. Continuous data were compared using unpaired t-test (if normally-distributed) and Mann-Whitney U test if not normally-distributed.

Categorical data were compared using chi-square test. A p-value of less than 0.05 was considered significant.

RESULTS

Study patients:

46 consecutive patients undergoing VT ablation with epicardial access being performed post heparinisation were included in the study. 13 of these were on uninterrupted warfarin at the time of the procedure (Warfarin group), whereas 33 were not on any oral anticoagulants (No-warfarin group). Within the limitations of the current study design, the two groups were appropriately matched with regard to clinical and procedural characteristics other than for AF (92.3 versus 9.1%, $p < 0.0001$) and INR (2.30 ± 0.70 versus 1.04 ± 0.07, $p < 0.0001$). In the warfarin group, the CHA2DS2-VASc ranged from 2 – 4 (mean ± SD, 2.5 ± 0.7) and the majority (92.3%) of patients were anticoagulated for stroke risk prevention on the background of atrial fibrillation. No patient had a history of previous cardiac surgery. The clinical characteristics of the two groups are shown in Table 1.

Procedural data:

The vast majority of procedures were performed as emergent or emergency cases. All procedures were performed by a consultant electrophysiologist, assisted by a junior trainee. The number of operators for each procedure ranged from two to four. All patients received intravenous unfractionated heparin for endocardial mapping prior to pericardial access, with a target activated clotting time (ACT) of 300-350 seconds. Those on warfarin had a mean INR of 2.30 ± 0.70. Successful epicardial access was achieved in all (n= 46, 100%) patients. No patients in the warfarin group required reversal of anticoagulation.

The treated VT in both groups was non-ischaemic the vast majority of patients (69.2% in warfarin group and 66.7% in the no-warfarin group). Coronary

angiogram was performed prior to ablation in 60% of patients in the warfarin group and 63.6% in the no-warfarin group. The proportion of patients who had multiple targets for ablation was similar across both groups (30.7% and 27.2% in the warfarin and no-warfarin groups respectively). The vast majority of patients in both groups (>50%) had no inducible clinical VT as an ablation end-point. Those in whom non-inducibility was not sought as an ablation end point was due to poorly tolerated ventricular arrhythmias (n = 10), induction of ventricular fibrillation (n = 3), lengthy procedure (n = 3) and other (n = 3). An even spread was noted across both groups. There was no significant difference in the procedural data between the two groups – Table 2.

Study endpoints:

Primary endpoint – Complications

There were no deaths in this patient cohort and no patient required surgical intervention. None of the patients suffered coronary artery damage or abdominal visceral laceration. A higher proportion of patients in the warfarin group had a drop of haemoglobin of >2g/dL and delayed pericardial drain removal (>24 hours post-procedure) compared to the no-warfarin group (n = 5, 38.5% versus n = 9, 27.3%, p = 0.74 and n = 1, 7.8% versus n = 1, 3.03%, p = 0.47). However, none of these patients required blood transfusion.

There was no significant difference in the overall procedural complication rate (warfarin versus no-warfarin group), including death/surgical intervention (0 versus 0), coronary artery damage (0 versus 0), RV puncture (30.8% versus 15.2%, p = 0.23), >2g/dL drop in Hb (38.5% versus 27.3%, p = 0.74) and delayed pericardial drain removal (7.8% versus 3.03%, p = 0.47) – Figure 1.

Secondary endpoint – Procedural Success

Acute ablation success (defined as an identifiable epicardial target and termination of arrhythmia) was similar in both groups (warfarin versus no-warfarin 69.2% versus 72.7%, p = 0.81). Non-inducibility of VT was not sought in all cases. At 3-month follow-up post procedure, 72.7% patients in the warfarin group and 58.6% patients in the no-warfarin group reported resolution of symptoms or cessation of ICD therapies – Figure 2. A small proportion of patients required a repeat procedure after their 3-month follow-up review (8.3% in warfarin group versus 22.6% in no-warfarin group, p = 0.26). In patients who required re-do procedures there was recurrence of clinical VT in all except one.

DISCUSSION

In the present study we report our experience of obtaining epicardial access in patients on uninterrupted warfarin. The main findings of the study indicate that the risk of obtaining epicardial access do not seem to be significant in patients anticoagulated with warfarin and heparinised with a therapeutic ACT. We found no significant impact on the rate of bleeding complications or any difference in the overall complication rate of epicardial VT ablation between the warfarin and no-warfarin group.

Although catheter ablation for VT is an established technique, there is wide variation in success rates due to the high complexity of VT substrate and procedure related complications.[13-15] High recurrence rates post ablation are common and 15-20% of patients require epicardial ablation for arrhythmia termination and resolution of symptoms.[16-18] In our cohort of patients nearly 59% were symptom free at three months follow-up post epicardial ablation and recurrence of VT requiring a further procedure was low (8.3% in warfarin and 22.6% in no-warfarin group). These data are comparable to those of previously-published trials, albeit with a shorter follow-up period.[19,20] Hence, epicardial ablation was effective in this cohort of patients and the

procedural success did not appear to be affected by the patients' anticoagulation status.

Obtaining access to the pericardial space and epicardial surface of the heart comes with its own risks including significant pericardial bleeding and damage to adjacent structures including the liver.[4,17] To prevent these complications, current guidelines suggest that pericardial access should be avoided in anticoagulated patients.[2] This approach poses procedural dilemmas as epicardial targets are often sought after endocardial mapping (which requires systemic heparinisation). Pericardial access would therefore need to be obtained from the outset prior to systemic anticoagulation or at a second procedure. Alternatively heparin and/or warfarin could be reversed before obtaining pericardial access. However, reversal of heparin precludes further endocardial mapping and ablation. Furthermore, discontinuation of warfarin prior to the procedure or reversal of warfarin intra-procedurally has significant implications for periprocedural management and potential adverse events. Data from AF ablation suggests optimal management is to continue warfarin without interruption.[11,12] The ideal approach, if it were not shown to unduly increase risk, would involve combining endocardial and epicardial mapping in the same procedure and hence achieving pericardial access in heparinised patients without discontinuing oral anticoagulants (if any).

Previous published data in a small cohort of patients have shown that pericardial access is feasible in heparinised patients.[10] The present study shows for the first time that epicardial ablation can be performed safely and effectively in patients on warfarin and peri-procedural systemic heparinisation. We found that the overall complication rate was low and consistent with previously published data.[9] There were no deaths in this patient cohort and no patient required surgical intervention. Moreover, none of the patients suffered coronary artery damage or abdominal visceral laceration. More patients on uninterrupted warfarin had a drop of

haemoglobin > 2g/dL and more had delayed pericardial drain removal (7.8% versus 3.03%). These small differences did not reach significance given the small numbers and it would require a much larger study to show whether this difference is real. Importantly, none of these patients had other major bleeding complications or required a blood transfusion. Whilst this is encouraging, it provides no data on the impact of oral anticoagulation on the severity of a major bleeding event should it occur. However, in the event of bleeding, rapid and complete reversal of warfarin is feasible using synthetic clotting factor concentrates.[21]

On the other hand, the benefits of performing epicardial ablation on uninterrupted warfarin (in addition to systemic heparinisation) are manifold. It is a very attractive approach for patients at high risk of thromboembolic phenomena in whom warfarin would ideally not be discontinued. Discontinuation of warfarin would require more frequent INR measurements when warfarin is re-started post procedure. The dosing can be complex and lead to under or over anticoagulation.

It seems that it is feasible to continue uninterrupted warfarin for VT ablation, and that should epicardial access be desired after heparinisation and endocardial mapping/ablation, then it can be safely obtained without the need to reverse either heparin or warfarin. Obtaining epicardial access with peri-procedural heparinisation allows the operator to combine endocardial and epicardial mapping in the same procedure. This approach avoids obtaining access at the outset and therefore negates the additional risk of epicardial puncture if endocardial ablation has been successful.

STUDY LIMITATIONS

These data are limited to a small cohort of patients in a single centre. The two groups were approximately matched, albeit a trend towards greater age and co-morbidity in the anticoagulated group. Whilst the warfarinised group was older and frailer, with

the oldest patient being 88yrs. We recognize that as yet the safety and efficacy of VT ablation in the elderly and frail patients in general remains unclear. Given the limitations of clinical practice and the low event rate for bleeding complications, it is unlikely that a randomised trial will be performed in this area. Large multicentre studies are required to confirm these findings and establish the safety of peri-procedural anticoagulation during epicardial VT ablation. Nevertheless, these data give no signal of increased risk with this strategy. All oral anticoagulation was performed with warfarin, the safety of newer anticoagulants in this setting remains unknown.

CONCLUSIONS

This study suggests that epicardial access can be achieved without significant increased risk in patients on uninterrupted warfarin in addition to systemic heparinisation (with therapeutic INR and ACT). Although the risk and benefit of this approach remains incompletely defined, these data may be reassuring for physicians considering uninterrupted warfarin in patients with a strong indication for peri-procedural anticoagulation. Larger multicentre studies are required to confirm these findings and to test the safety of newer oral anticoagulants in this setting.

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TABLES

Table 1: Clinical Characteristics

n = 46	NO WARFARIN	WARFARIN	*P* value
Sex [F/M. %]	18.2	8.33	0.39
Age [years]	53.3±16.6	63.4±11.1	0.06
Background heart disease			
Normal heart [%]	18.2	0	0.1
Ischemic heart disease [%]	33.3	30.8	0.88
Dilated cardiomyopathy [%]	33.3	53.8	0.19
Others [n, %]	15.2	15.4	0.98
Hypertension [%]	37.5	61.5	0.14
Diabetes mellitus [%]	25	30.8	0.68
Dyslipidemia [%]	37.5	53.8	0.31
CKD [%]	6.1	15.3	0.32
COAD [%]	6.1	7.7	0.85
AF [%]	9.1	92.3	<0.0001
CVA/TIA [%]	0	0	
Medication			
Beta blocker [%]	82.1	100	0.1
Calcium antagonist [%]	6.1	0	0.36
Class Ic-AA [%]	12.1	15.4	0.76
Amiodarone [%]	15.2	23.1	0.52
ACEI/AT2 blocker [%]	59.4	76.9	0.26
INR at procedure			
range	0.9 - 1.2	1.9 - 3.9	<0.0001
mean±SD	1.04±0.07	2.30±0.70	<0.0001
Proportion with INR ≥ 2.0	0/33	12/13 (92%)	<0.0001

Table 1: Clinical Characteristics. The clinical characteristics of the warfarin (n = 13) and no-warfarin (n = 33) group are shown in this table. Data are reported as percentage or mean ± SD. AA: anti-arrhythmic, ACEI: Angiotensin Converting Enzyme Inhibitor, AT2: Angiotensin 2 receptor antagonist, INR: International

normalised ratio. * Normal heart refers to absence of any structural abnormality on transthoracic echocardiogram and/or cardiac MRI.

Table 2: Procedural Characteristics

n = 46	NO WARFARIN	WARFARIN	*P* value
Elective procedure [%]	39.4	23.1	0.29
Catheters used [n]	2.1	2	0.76
Procedure time [min]	229±68	241±87	0.62
Fluoroscopy time [min]	28±18	31±23	0.64
Radiation dose [cGy·cm2]	3564±3283	5516±5214	0.13
INR at procedure	1.04±0.07	2.30±0.70	<0.0001
Treated VT characteristics			
Ischaemic [%]	33.3	30.8	0.88
Coronary angiogram [%]	63.6	60	0.82
>1 target [%]	27.2	30.7	0.78
Non-inducibility as end-point [%]	57.6	61.5	0.80

Table 2: Procedural characteristics. The procedural characteristics of the warfarin (n = 13) and no-warfarin (n = 33) group are shown in this table. Data are reported as percentage or mean ± SD. INR: International normalised ratio.

FIGURE LEGENDS

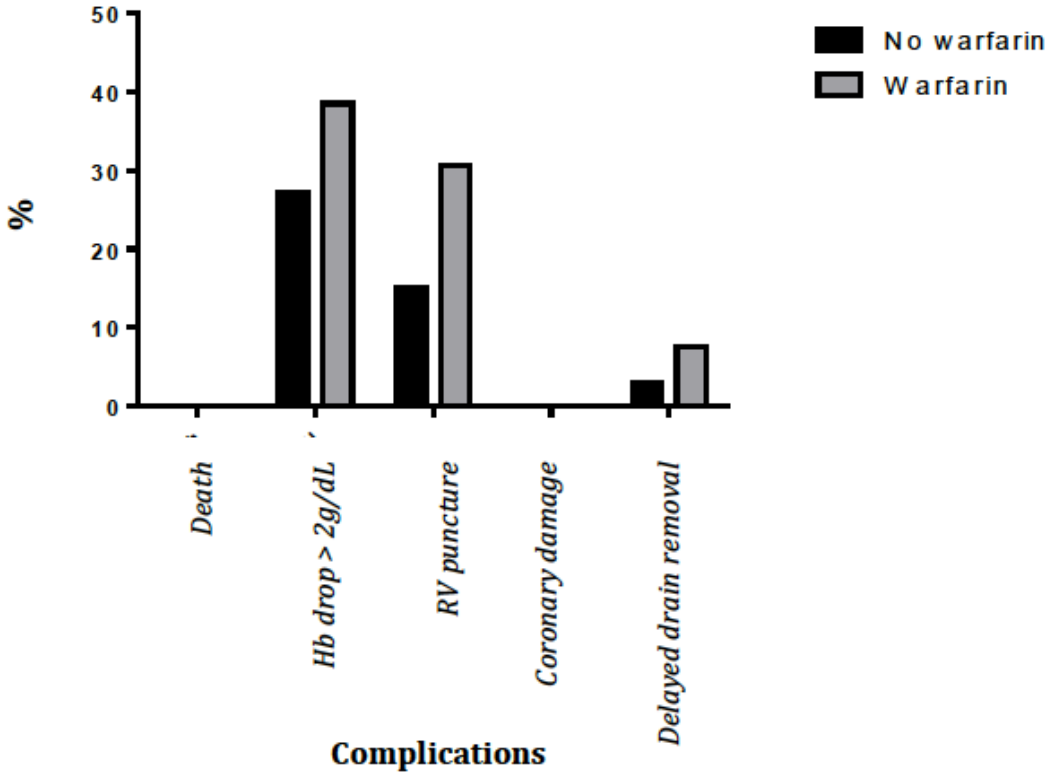
Figure 1: Procedural Complications

Box-plot showing complications in the warfarin (n=13) and no-warfarin (n=33) group. There was no significant difference in the complication rates between the warfarin and no-warfarin group: Hb drop>2g/dL (38.5% versus 27.3%, p = 0.74), RV puncture (30.8% versus 15.2%, p = 0.23), delayed pericardial drain removal (7.8% versus 3.03%, p = 0.47). There were no reported deaths or coronary artery damage in both groups.

Figure 2: Procedural Success and Success at 3-months

Box-plot showing immediate procedural success (24hrs post ablation) and success at 3 months follow up in the warfarin (n = 13) and no-warfarin (n = 33) group. Both acute and long-term ablation success was similar in both groups (warfarin versus non-warfarin 69.2% versus 72.7%, p = 0.81 and 72.7% versus 58.6%, p =0.37).

Figure 1: Procedural Complications



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