

Anticoagulation and the risk of complications in ventricular tachycardia and premature ventricular complex ablation

5

Short title: Anticoagulation complications and VT ablation

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65

67 **Abstract**

68

69 *Background*

70 Many patients undergoing ventricular tachycardia (VT) or premature ventricular
71 complex (PVC) ablation receive anti-thrombotic medications. Their
72 uninterrupted use has the potential to affect complication rates.

73 We assessed the incidence of complications in a large cohort of patients
74 undergoing these procedures, according to anti-thrombotic medication use.

75

76 *Methods*

77 From June 2014 to June 2016, 201 VT and PVC ablations were performed at a
78 single center. We allocated patients to three groups: A - anticoagulation group
79 (INR \geq 1.5 or NOAC or full dose LMW heparin on day of procedure); B -
80 antithrombotic group (antiplatelet therapy and/or prophylactic LMW heparin on
81 day of procedure); C - no anti-thrombotics group. We assessed peri-procedural
82 complication rates in each group. Multivariable analysis was performed.

83

84 *Results*

85 Group A (47 patients) had an 8.5% procedural complication rate: one stroke, one
86 pseudoaneurysm, one femoral artery occlusion and one access site hematoma.

87 In this group, 37 patients had femoral arterial and 18 had epicardial access.

88 In Group B (46 patients) the complication rate was 6.5%: two cardiac
89 tamponades and one pericardial effusion without compromise.

90 Group C (108 patients) had a 5.6% complication rate: three cardiac tamponades
91 (with one peri-procedural death and one concomitant gastric vessel injury), one

92 pericardial effusion without compromise, one stomach perforation and two
93 access site hematomas.
94 Multivariable analysis did not show any significant predictors of complications,
95 though age approached significance.

96

97 *Conclusions*

98 Complication rates were not significantly different between groups. These
99 findings suggest that VT and PVC ablation can be performed safely in patients
100 with uninterrupted anti-thrombotic medications.

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105 **Keywords:** ventricular tachycardia; ablation; anticoagulation; PVC; ventricular
106 ectopic; complications

107

108 **Introduction**

109

110 An increasing number of patients receiving anticoagulants and antiplatelet agents
111 require ventricular tachycardia (VT) or premature ventricular complex (PVC)
112 ablation. The risks of interrupting anticoagulation must be balanced against
113 potential bleeding risks associated with continuation.

114 Until recently, patients receiving anticoagulant therapy with either a vitamin K
115 antagonist (VKA), e.g. warfarin, or a non-vitamin K anticoagulant (NOAC) would
116 typically stop these prior to VT or PVC ablation in an attempt to minimize risks of
117 bleeding. The change in practice in relation to anticoagulation for patients
118 undergoing atrial fibrillation (AF) ablation, whereby these agents are continued
119 uninterrupted through the procedure¹⁻⁴, has been accompanied by similar changes
120 in the setting of VT and PVC ablation, with increasing numbers of these procedures
121 now also being performed with uninterrupted anticoagulant therapy. In addition,
122 approximately half of VT ablations are performed on patients with ischemic heart
123 disease (IHD), many of whom are receiving single or dual antiplatelet therapy.

124 Adequate antithrombotic therapy during the procedure is important to minimize
125 the risks of both overt and subclinical thromboemboli⁵. The most recent EHRA
126 position document on antithrombotic management for electrophysiology
127 procedures suggests continuing VKAs uninterrupted for endocardial left ventricular
128 (LV) ablations, but discontinuing 3-5 days prior to anticipated epicardial access,
129 with bridging therapeutic doses of heparin. It advises discontinuation of NOAC
130 therapy \geq 24 hours prior to LV ablation⁶. However, there is no advice on the safety

131 of continuing dual antiplatelet therapy.
132 To investigate the safety of performing VT or PVC ablation without interruption of
133 anticoagulant and/or antiplatelet therapy, we assessed the incidence of
134 complications in a contemporaneous cohort of patients undergoing these
135 procedures.

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138

139 **Methods**

140

141 This study included 201 consecutive VT and PVC ablations performed at St
142 Bartholomew's Hospital, London between June 2014 and June 2016. We divided
143 patients to three groups: A – anticoagulation group (those taking warfarin with
144 international normalized ratio (INR) ≥ 1.5 on day of procedure, or patient received
145 NOAC or full dose LMW heparin on day of procedure); B – antithrombotic group
146 (antiplatelet therapy with aspirin and/or an adenosine diphosphate (ADP) receptor
147 antagonist (usually clopidogrel) and/or prophylactic LMWH on day of procedure);
148 and group C – no antithrombotics group (patients not receiving any antithrombotic
149 agents). The INR on the day of procedure was ascertained by either laboratory
150 result, or documented point of care testing. NOAC use on day of procedure was
151 confirmed either by review of the prescription chart, or documentation in the
152 patient's notes or procedure report. Antiplatelet use was determined by review of
153 prescription charts and medical records.

154 Peri-procedural major complications in each group were defined as those resulting
155 from the procedure and occurring prior to discharge from hospital, together with
156 one or more of: i. causing long-term harm, ii. delaying discharge, iii. requiring
157 procedural/surgical intervention. These were assessed by review of patients'
158 medical records and procedure reports. Patient information was anonymized.

159

160 *Antithrombotic therapy*

161 For patients receiving antiplatelet agents (aspirin or clopidogrel), these were
162 continued uninterrupted through the procedure. Warfarin or NOAC therapy was
163 given prior to and following the procedure according to a number of factors,
164 including indication for anticoagulant, procedural urgency, international normalized
165 ratio (INR) stability, and cardiologist preference..

166

167 *Catheter ablation procedure*

168 Vascular access was guided by ultrasound from late 2015 onwards. For procedures
169 involving catheterization of the left heart, intravenous heparin was administered to
170 achieve an activated clotting time (ACT) of 300-350 seconds.

171 The majority (89%) of procedures were performed under conscious sedation with
172 midazolam and diamorphine, with the remainder under general anesthesia.

173 Procedures were performed using fluoroscopic guidance and 3D electroanatomic
174 mapping with CARTO 3 Smart Touch (Biosense Webster, Diamond Bar, USA).

175 Transesophageal echocardiography was used to exclude left heart thrombus, and to
176 guide trans-septal puncture in cases performed under general anesthesia. In the

177 vast majority of procedures, ablation was performed with 3.5 mm saline-irrigated
178 tip ablation catheters (Smart Touch or Smart Touch SF catheters, Biosense
179 Webster); non-irrigated 4mm tip ablation catheters were rarely used. Ablation with
180 irrigated tip catheters was performed in power control mode, between 25-45 W
181 dependent on the site of ablation.

182 Epicardial access was obtained via the subxiphoid approach, in the manner
183 described by Sosa⁷. This was obtained following endocardial LV mapping, and
184 therefore after heparinisation, and in the presence of ACT>250, based on previous
185 work within the unit demonstrating safety of this approach⁸.

186 Coronary angiography was performed in patients in whom epicardial ablation was
187 planned in the basal to mid-ventricular regions, to avoid inadvertent radiofrequency
188 energy damage to epicardial vessels. Proximity of the phrenic nerve was excluded
189 via pacing prior to epicardial ablation of the lateral LV.

190 Following left ventricular endocardial ablation, if the patient was not already
191 receiving an antiplatelet or anticoagulant agent, aspirin 300mg daily was
192 commenced and continued for at least six weeks.

193

194 *Statistics*

195 Univariable and multivariable analyses were performed with binary logistic
196 regression using Stata/IC 14.2 (StataCorp, Texas, USA). Predictors with p<0.1 in
197 univariable analysis were entered into the multivariable model, as well as
198 antithrombotic groups, given the focus of the study and mechanistic plausibility.

199 Between-group comparison of procedural complication rates was also assessed
200 with Fisher's exact test. A p-value of less than 0.05 was considered significant.

201

202

203

204 **Results**

205

206 *Patient characteristics and co-morbidities*

207 Demographic and co-morbidity data for each group are shown in Table 1. There
208 were significant differences between groups for all variables, except prevalence of
209 hypertension. Of particular note were the younger average age of Group C, the male
210 preponderance of Groups A and B, the higher prevalence of IHD in Group B, and the
211 lower average LVEF in Groups A and B. These differences to some extent reflect the
212 proportions of patients in each group undergoing VT vs PVC ablation (discussed
213 below).

214

215 **Table 1**

216

217 *Antithrombotic use*

218 Table 2 shows the use of antithrombotic agents for patients in Groups A and B. For
219 patients in Group A receiving warfarin, the mean INR on the day of procedure was
220 2.5 (range 1.6 to 4.3). The INR was 1.5-1.9 in 7 patients, 2.0-3.5 in 38 patients, and
221 greater than 3.5 in only two patients.

222

223 **Table 2**

224

225 *Procedural data*

226 The largest number of procedures were performed for patients in Group C, and
227 interestingly there was a fairly even split in the proportion of VT vs PVC ablations in
228 this group despite the lower prevalence of IHD. Group A had the largest proportion
229 of VT ablations (Table 3).

230 As expected, most patients in each group had femoral venous access. The
231 proportion of femoral artery and trans-septal access was lower in Group C than
232 Groups A and B, likely reflecting the greater proportion of PVC ablations in Group C.
233 The highest proportion of epicardial access was in Group A, in keeping with the
234 percentage of VT ablations for this group.

235 Thirty-seven patients in group A had femoral arterial access, i.e. whilst
236 therapeutically-anticoagulated. Of these, 24/37 were on warfarin (mean INR 2.5 at
237 time of procedure), 12/37 received a NOAC, and 1/37 received LMW heparin on the
238 day of the procedure.

239 Eighteen patients in Group A had epicardial access. Of these, 16/18 were on
240 warfarin (mean INR 2.5), and 2/18 received a NOAC on the day of the procedure.

241 The proportion of procedures in each group in which LV ablation was performed
242 was as follows: Group A - 81%; Group B - 79%; Group C - 48%.

243

244 **Table 3**

245

246 *Complications*

247 There were 47 patients in Group A, with four suffering complications, giving a
248 procedural complication rate of 8.5% (Figure 1). Femoral artery pseudoaneurysm
249 occurred in a 62 year old male undergoing VT ablation; this required surgical repair.
250 An 80 year old female undergoing PVC ablation suffered femoral artery occlusion
251 which was managed medically. She had received rivaroxaban on the day of the
252 procedure. A 69 year old female undergoing VT ablation suffered a vascular access
253 site hematoma which was managed conservatively. She was taking warfarin, with
254 INR 2.9 on the day of the procedure. A 72 year old male undergoing VT ablation
255 suffered an ischemic stroke 10 hours after the procedure. This was confirmed on a
256 computed tomography (CT) scan. A transesophageal echocardiogram prior to the
257 procedure had excluded intracardiac thrombus. He had been receiving warfarin,
258 though as the INR was 1.4 he received full dose enoxaparin both the day before and
259 on the day of the procedure.

260

261 **Figure 1**

262

263 Of the 46 patients in Group B, three suffered complications, with a procedural
264 complication rate of 6.5%. All were receiving aspirin monotherapy. Two of the
265 patients suffered pericardial effusion with tamponade: the first was a 79 year old
266 male undergoing VT ablation who required surgical closure of the perforation. The
267 second patient was a 71 year old male who developed tamponade on the ward

268 following PVC ablation; this was drained percutaneously. The third patient was an
269 80 year old male undergoing VT ablation who developed an effusion during the
270 procedure without hemodynamic compromise. An attempt to drain the effusion
271 was unsuccessful, and he remained in hospital for observation for 5 days.
272
273 There were 108 patients in Group C. Six suffered complications, giving rise to a
274 procedural complication rate of 5.6%.
275 A 49 year old male undergoing VT ablation with an epicardial approach suffered
276 cardiac tamponade which was drained percutaneously. He also developed a
277 hematoma lateral to the stomach, with moderate hemoperitoneum.
278 A 93 year old male undergoing VT ablation suffered cardiac tamponade requiring
279 drainage, as well as a left groin hematoma related to femoral artery access.
280 A 79 year old male suffered cardiac tamponade during VT ablation, and was
281 transferred to the intensive treatment unit, where he died the following day.
282 A 39 year old male undergoing VT ablation suffered a probable gastric puncture
283 during attempted epicardial access. The patient remained nil by mouth for 3 days
284 and there were no sequelae.
285 A 32 year old male undergoing VT ablation suffered a groin hematoma which was
286 managed conservatively but which delayed discharge.
287 And finally, a 58 year old male undergoing VT ablation via epicardial approach
288 suffered a respiratory arrest with hypotension. An echocardiogram demonstrated a
289 small amount of pericardial fluid but no features of tamponade, and the patient

290 improved with reversal of sedation. The effusion was subsequently drained and
291 delayed discharge home.

292

293 In summary, with regard to complications attributable to bleeding, the incidence of
294 vascular access-related hematoma in Groups A, B, and C was 2.1%, 0%, and 1.9%,
295 respectively. And while there were no pericardial effusions, tamponades or
296 abdominal visceral injuries in Group A, the respective rates in Group B, were 2.2%,
297 4.3% and 0%, and in Group C, 0.9%, 2.8% and 1.9% (Figure 1).

298

299 *Survival to discharge*

300 Overall, 97% of patients survived to hospital discharge. Of the seven patients who
301 did not survive, two were in Group A, one was in Group B, and four were in Group C.
302 There was one procedure-related death (see above).

303

304 *Predictors of complications*

305 In univariable analysis using logistic regression, only age was significant with $\alpha=0.1$
306 (Table 4). In multivariable logistic regression analysis, age and Group were
307 included given the latter's clinical significance and relevance to the study. Age
308 reached near significance (odds ratio 1.04, 95% confidence interval 1.00-1.09,
309 $p=0.054$). Comparing complication rates between groups, with Group C as the
310 reference group, there were no significant differences (A vs C $p=0.822$, B vs C $p=$
311 0.573). Between-group comparison of complication rates with Fisher's Exact test
312 also found no significant difference ($p=0.804$).

313

314 **Table 4**

315

316

317

318 **Discussion**

319

320 *Focus of the study*

321 This study has compared procedural complication rates according to antithrombotic
322 drug regimens for patients undergoing VT and PVC ablations. It is the first study to
323 provide detailed data on the use of contemporary antithrombotic agents, including
324 NOACs and antiplatelets in the setting of VT/PVC ablation. The paucity of data in
325 this setting, together with the increase in these procedures and recognition of
326 subclinical adverse effects⁵ makes it important to have evidence to guide decision-
327 making in this high-risk group of patients.

328 We chose to analyze VT and PVC ablation procedure data together due to the
329 frequent use of arterial, and to a lesser extent, trans-septal access in both settings.
330 For example, femoral arterial access was used in almost 50% of PVC ablation cases
331 (data not shown).

332

333 *Use of anticoagulants and antiplatelet agents*

334 The majority of patients in Group A received anticoagulant monotherapy, and in
335 Group B received antiplatelet monotherapy. Following the publication of trials

336 comparing strategies of uninterrupted anticoagulation and a 'bridging' strategy with
337 LMW heparin, trans-septal puncture for atrial fibrillation ablation is now routinely
338 performed without interruption of warfarin⁴, and more recently the same approach
339 with NOACs has also been reported³. In addition, femoral arterial access is often
340 obtained in patients receiving single or dual antiplatelet therapy who are
341 undergoing percutaneous coronary intervention (PCI). And the most recent
342 ESC/EACTS guidelines advocate performing PCI without interruption of
343 anticoagulation, though preferably via the radial route⁹.

344 In our study, 37/130 (28%) patients who had femoral arterial access were in Group
345 A, i.e. in the presence of an INR>1.5 or NOAC therapy. Reassuringly, only 1 of the
346 complications in Group A could be associated with the propensity to bleeding
347 induced by anticoagulant therapy, with 2 complications related to thrombosis
348 despite therapeutic anticoagulation. Thus, the incidence of hematomas was similar
349 between Groups A, B and C. There were no retroperitoneal bleeds seen. The use of
350 vascular ultrasound became routine at our center towards the end of 2015, i.e. over
351 half-way through our study timeframe, so further reductions in vascular
352 complications may be possible¹⁰.

353 In our center, for patients who required an LV endo- and epicardial approach, we
354 performed the latter in the presence of heparin anticoagulation, i.e. without
355 reversal⁸. Of the 43 procedures requiring epicardial access in our study, 18 (42%)
356 were performed in Group A, i.e. in the presence of oral/subcutaneous, and heparin
357 anticoagulation. Reassuringly, there were no pericardial effusions, tamponades or
358 abdominal visceral injuries in Group A. In Group B, three patients who suffered

359 pericardial effusions or tamponades did not have epicardial access. In Group C, of
360 the 18 patients undergoing epicardial access, bleeding and/or abdominal vascular
361 complications occurred in three; heparin anticoagulation was present in two of
362 these. This small excess is noteworthy, and without obvious explanation.
363 Procedure-related mortality was very low, and almost all patients survived to
364 hospital discharge.

365

366 *Overall complication rates*

367 Previous trials and studies of VT ablation have reported complication rates between
368 4% and 11%, with the most common being cardiac perforation and tamponade,
369 major bleeding, stroke, stroke/transient ischemic attack, and lower limb vascular
370 problems¹¹⁻¹⁶. The complication rates for each group in our study were similar to
371 these. Other than the study by Peichl et al who utilized LMW heparin bridging at the
372 time of procedure¹⁴, the other studies did not report their approach to
373 antithrombotic therapy.

374 It is worth noting that although the procedural complication rates for Groups A, B,
375 and C were 8.5%, 6.5%, and 5.6% respectively, two of the six patients in Group C
376 had more than one complication, such that the complication rate per patient was
377 slightly higher in this group. Interestingly, the cardiac tamponade rate in Group C
378 was higher than Group A, and the only death in the study occurred in this group.
379 Although overall Groups A and B had a higher proportion of VT ablations and co-
380 morbidities than Group C (and Group A had more epicardial procedures), the
381 complications in Group C all occurred in patients undergoing VT ablations (and two

382 complications occurred in a 93 year old patient), such that within Group C, they
383 could be considered to be some of the higher risk procedures.

384

385

386 *Multivariable analysis*

387 Multivariable analysis showed that age was the only near-significant variable
388 ($p=0.054$), with odds of 1.04, equivalent to a 24% increase in odds for each 5 year
389 increment. This is both plausible, and in keeping with the findings of Peichl et al¹⁴.
390 They also found a higher complication rate in patients with structural heart disease
391 compared to idiopathic VT, though did not specify whether the latter included PVC
392 ablation, i.e. for non-sustained VT.

393 Interestingly, we found no significant differences in the risk of complications
394 between the different groups, with both univariable and multivariable analyses,
395 supporting the notion that therapeutic anticoagulation at the time of procedure is
396 safe within the studied INR range (1.6 to 4.3). Thus, although Group A's
397 complication rate was 8.5% compared to 5.6% in Group C, patients in Group A were
398 older, had more co-morbidities, and a lower average LVEF than Group C. In
399 addition, Group A had more VT ablations, and greater use of femoral arterial and
400 epicardial access.

401

402 *Study limitations*

403 This was a retrospective observational study from a single center with associated
404 selection biases. Despite a reasonably-sized cohort, there were limited data on the

405 use of dual or triple antithrombotic therapy. Finally, there was relative
406 heterogeneity between groups limiting the generalizability of the findings.

407

408

409

410 **Conclusion**

411

412 This is the first study to compare complication rates in patients undergoing VT and
413 PVC ablation, according to whether they received anticoagulation, antiplatelet
414 agents or neither. Our cohort included 201 patients undergoing these procedures in
415 a contemporary setting. Complication rates were similar to those previously
416 published, and small differences in these rates between groups were not significant.
417 Interestingly, there were no trends to bleeding-related complications in the
418 anticoagulation group. These results therefore support a strategy of continuing
419 anticoagulation uninterrupted for VT and PVC ablation, with the caveat that
420 prudence be practiced for patients receiving two or three antithrombotic agents,
421 and for those with INRs > 3.5.

422

423

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427 **Author contributions**

428 Concept/design: MD and JDL; Data collection, analysis and interpretation: DC, EV
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430 RJH, FK, PDL, RJS, SS; Approval of article: JDL, MD, DC, EV, AG, AC, MJE, RJH, FK, PDL,
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- 505

506 **Figure 1** Procedural complications in each group. Complications for Groups A,
507 B, and C, with subtypes for pericardial and vascular complications. Pseudoan. –
508 pseudoaneurysm, Art. occlusion – femoral arterial occlusion.