1 2	Prevention and treatment of pericardial tamponade in the electrophysiology laboratory - an European Heart Rhythm Association Survey
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## 1 Abstract:

### 2 Background

- 3 Pericardial tamponade (PT) is the most frequent severe complication during EP procedures and requires immediate,
- 4 coordinated and effective treatment. However, multiple aspects of PT treatment are not standardized or under
- 5 ongoing debate.

### 6 Methods

- 7 An online questionnaire consisting of 26 multiple-choice questions was sent out to the European Heart Rhythm
- 8 (EHRA) Research Network and also distributed via social media outputs. The EHRA survey was conducted between
- 9 May and June 2023.

### 10 Results

A total of 213 replies were received from European (87%), and non-European countries. 90% of all participants 11 perform interventions in dedicated EP labs equipped with different ablation platforms. In case of PT most participants use X-ray as the main imagaing modality guiding pericardial puncture, predominantly aiming for an 12 13 anterior puncture site. Sheaths of different sizes are introduced into the pericardial space (84.3%), followed by a 14 15 pigtail catheter. Application of protamine is an established but variable step in the majority (84.6%). NOAC antidotes are not used by 73.3% of participants, while 15.2% routinely apply them. Retransfusion of aspirated blood 16 is performed by 72.1% ((before protamin administration (18.2%), after protamin administration (13.5%), if 17 pericaridal effusion cannot be controlled (40.4%)). 72.4% retransfuse without blood filter systems. The decision for 18 19 surgical intervention is mostly taken if bleeding continues despite all interventional measures.

# 20 Conclusions

The current survey demonstrates that the management of PT is heterogeneous among centers. Findings of this
 survey may help to guide operators in their treatment and decisions in the setting of PT.

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### 24 Introduction:

Catheter ablation is an established treatment option for various types of arrhythmias and in general has a high success rate and an excellent safety profile (1). However, despite increasing experience, improved ablation strategies and technologies complications can occur and can be potentially life threatening (2-14). Pericardial

tamponade (PT) is the most frequent severe complication during EP procedures and requires immediate, 1

- 2 coordinated and effective treatment. However, the treatment of PT is not standardized and various aspects are
- 3 debated (15). Therefore, we conducted a survey evaluating the infrastructure, safety precautions and treatment
- 4 strategies in the setting of PT in European and non-European electrophysiology (EP) centers.
- 5

#### 6 Methods:

- An online questionnaire consisting of 26 multiple-choice questions was sent to the European Heart Rhythm (EHRA) 7
- 8 Research Network and was also distributed via social media platforms. The exact questionnaire is provided as
- 9 Supplementary Data. The EHRA survey was conducted between May and June 2023.
- 10

#### 11 **Results**:

#### 12 **Baseline data**

13 We received a total of 213 replies. The majority of respondends were from European (87%), and 13% from non -European countries (Figure 1). A total of 68% of all participants practice at academic institutions and 32% at non-14 academic hospitals. The number of ablation procedures per year varied from up to 500 EP-procedures in 45% of 15 participants, 501-1000 procedures in 27%, 1001-1500 procedures in 14% and finally more than 1500 procedures in 16 the remaining 15%. While 92% of all participating EPs report to perform diagnostic EP-procedures, 95% perform ablations of supraventricular tachycardias, 92% of atrial fibrillation, 94% of atrial flutter and 91% of ventricular tachycardia (VT). Of note, a total of 58% of responders perform epicardial VT ablation and 62% offer interventional occlusion of the left atrial appendage (**Figure 2**). 17 18 19 20

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## 22

23 Reflecting the spectrum and load of EP procedures, 90.2% of all participants perform their interventions in 24 dedicated EP labs. With 91%, 3D-mapping in combination with irrigated contact force enabled radiofrequency (RF) 25 catheters is the most frequently available ablation modality followed by a cryoballon technology (79.5%).

26 Conventional RF ablation is applied in (71.4%), and non-contact force guided RF ablation with 3D mapping in

About two thirds (65.8%) of all responders have institutional cardiac surgery on site. A total of 88.2% of the wnloaded from https://academic.oup.com participants report to have echocardiography permanently available inside the EP-lab. Moreover, 94.6% answered to have a pre-prepared epicardial puncture set inside the lab which contains all items being necessary for While 72.7% participants report to have no restrictions for patient's body mass index (BMI), 8.2% answered to have BMI limits for all procedures and another 19.1% have BMI restrictions for left atrial and left ventricular ablation procedures only. BMI limits ranged between 35-55 kg/m<sup>2</sup>. Regarding age, 85.2% have no age limits, while 3.7% have age limits for all procedures and 11.1% for left atrial and left ventricular interventions only (ranging from 75-85 years). INP limits for patients on vitamin K antagonists were reported by 22.7% with INP limits ranging from 2.4

Another 7.1% are also equipped with other ablation platforms.

emergency epicardial puncture and drainage.

Preprocedural considerations

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age limits for all procedures and 11.1% for left atrial and left ventricular interventions only (ranging from 75-85 years). INR limits for patients on vitamin K-antagonists were reported by 32.7%, with INR-limits ranging from 2-4. The remaining participants did not report INR restrictions for any EP procedures. 20.9% of responders do not interupt NOAC therapy, 15.5% stop it the day before, 18.2% the evening before, and 41.8% at the day of the procedure. 3.6% report other strategies. Procedural aspects and safety considerations 1.8% of participants monitor blood pressure invasively during diagnostic EP-procedures, 9% during ablation of atrial flutter or atrial tachycardia, 13.6% during ablation of atrial fibrillation and 13.6% for interventional closure of the left atrial appendage. In VT ablation procedures, blood pressure is monitored invasively by 84.5%. Another 13.6% report to uniquely use non-invase blood pressure monitoring for all procedures. Transseptal puncture is guided by fluoroscopy only in 48.9% of respondents. Transesopageal echocardiography (TOE) as an additional imaging mode is used by 27.5% and intracardiac echocardiography (ICE) by 24.8% of the 

(44.6%). Of note, pulsed field ablation (PFA) is already widely spread and applied by 29.5% of all participants.

(TOE) as an additional imaging mode is used by 27.5% and intracardiac echocardiography (ICE) by 24.8% of the  $\frac{8}{22}$ participants. 48.9% purely rely on fluoroscopy and 6.4% report to use other guiding modalities for transseptal puncture (Figure 3). Diagnostic catheters are positioned within the coronary sinus by the majoritiy of participants (86.1%). 23.1% also place a diagnostic catheter at the His bundle region for transseptal puncture, and 8.3% use a

pigtail catheter or wire inside the aorta. The remaining 9.3% report to use no diagnostic catheter for guidance of
 transseptal punctures.

Additional modalities used for TSP are pressure control (50.1%), contrast staining of the fossa ovalis before
 advancing the transseptal needle (29.4%), introduction of a guidewire into the left atrium or the left superior
 pulmonary vein once transseptal puncture is performed (55.9%) and/or contrast injection after transseptal access
 (49%), respectively (Figure 3).

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## 8 Treatment of pericardial tamponade

9 For pericardiocentesis of a PT most participants report to use X-ray as the main imgaing modality to guide pericardial puncture. The most frequently used views are anterior-posterior (AP, 58.7%) and left anterior oblique (45.2%). 14.2% also perform the puncture in a right anterior oblique angulation (14.4%). In addition to X-ray, echocardiography is used by 61.5%. A minority of responders does not use any imaging modality and 5.8% report to use other modalities. Pericardial puncture can be targeted on the anterior and the posterior site. An anterior access is preferred by most (67.3%). Once epicardial access is gained, most physicians (84.3%) introduce sheaths of different sizes into the pericardial space (5F 9.8%, 6F 35.3%, 7F 14.7%, 8F 21.6%, other sizes 2.9%), followed by a pigtail catheter (5F 23.5%, 6F 50%, 7F 19.6%, other sizes 6.7%).

use other modalities. Pericardial puncture can be targeted on the anterior and the posterior site. An anterior access is preferred by most (67.3%). Once epicardial access is gained, most physicians (84.3%) introduce sheaths of different sizes into the pericardial space (5F 9.8%, 6F 35.3%, 7F 14.7%, 8F 21.6%, other sizes 2.9%), followed by a pigtail catheter (5F 23.5%, 6F 50%, 7F 19.6%, other sizes 6.7%).
The majority of respondents (84.6%) applies protamine in case of a PT. Timing of protamine injection varies with injection immediately upon diagnosis of PT in 42.7%, after complete drainage of PT in 35.4%, and after successful access to the pericardium in 17.7%. Some (4.2%) report other strategies regarding protamine application (Figure 4). The protamine dose is adjusted according tothe last measured ACT level in 43.3%, and 37.1% apply protaminin a 1:1 ratio to previous heparin administration. Among the remaining participants, 3000 I.E. and 5000 I.E. are given as an institutional standard in 4.1% and 9.3%, respectively.
NOAC antidotes are routinely administered by 15.2% of respondenst, while73.3% of them never use antidotes.

NOAC antidotes are routinely administered by 15.2% of respondenst, while73.3% of them never use antidotes.
 Another 11.4% only apply NOAC antidotes in certain situations such as unresponsiveness of bleeding to protamine
 administration. Additional application of clotting factors is not considered by 91.7% of centers. However, 8.3%
 would apply prothrombin complex, fresh frozen plasma or tranexame acid as necessary.

Auto-transfusion of aspirated blood is reported to be done by 76% of all participants. Some start autotransfusionbefore protamin administration (18.2%), others after protamin administration (13.5%), and others only

if pericaridal effusion cannot be controlled (40.4%). Another 1.9% report to have other strategies regarding re - or 1

2 autotransfusion. For auto-transfusion, 72.4% of participants do not use a blood filter, 15.8% use a blood filter, and

3 another 11.8% autotransfuse via a cell safer only (Figure 5). While 90.4% do not have a maximal limit of

retransfused blood, 6.4% have defined limits (maximum of 1-2l), and 3.2% have different strategies. 4

5 The decision for surgical intervention is mostly taken if bleeding continues despite all interventional measures. 6 Accordingly, 55.7% of the participants answered to decide for surgical backup and intervention if the bleeding continues for more than 60-80 min. Another 25.4% consider surgical assistance if the amount of aspirated blood 7 8 9 10

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continues for more than 60-80 min. Another 25.4% consider surgical assistance if the amount of aspirated blood exceeds a predefined limit, ranging from 1000 ml to 3000 ml among centers. Another 18.9% consider other measures such as no reduction of aspirated blood per minute, hemodynamic instability, or suspicision of a left atrial/ventricular defect. **Postinterventional aspects**After successful epicardial puncture, drainage and stabilization of the patient most respondents (48.5%) keep the pigtail catheter until there is no evidence of further bleeding after re-initiation of an indicated anticoagulation. Another 7.9% remove the pigtail as soon as the bleeding has stopped, and 43.6% report other strategies such as keeping the pigtail for two up to 72 hours, and including repeat echocardiography showing complete drainage of 13 14 15 keeping the pigtail for two up to 72 hours, and including repeat echocardiography showing complete drainage of 16 effusion without further aspiration. 17

Specific medications applied after PT drainage are nonsteroidal antiinflammatory drugs (NSAID) in 48.6% of 18 19 participants for a mean of 10 days, colchicine in 47.2% for a mean of 19 days, cortisone in 8.3% as a single shot in 20 the majority, and/or antibiotics in 31.9% for a mean of 2 days.

21 If indicated, anticoagulation therapy is re-initiated within 0-72 hours after pigtail removal.

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#### 23 Onsite cardiac surgery versus no onsite cardiac surgery

- While many aspects between centers with and without onsite cardiac surgey are comparable, there are also major 24
- 25 differences. The mean total number of procedures in participant's centers with onsite cardiac surgery is higher with
- 26 850±595 versus 634±569. Operators at centers without cardic surgery less frequently report to perform epicardal

- 1 VT ablation (37% versus 72%) and protamine is more often regularly applied in case of percicardial tamponade (81%)
- 2 versus 70%).
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#### 4 Discussion:

Downloaded from https://academic.oup.com/europace/advance-article/doi/10.1093/europace/euad378/7504798 by guest on 5 Despite technological advancements and procedural expertise PT remains a frequent and potentially lifethreatening complication in the EP-lab. However, in experienced centers and when managed by experienced 6 operators PT can be effectively treated. There are no general recommendations on how to prevent and how to 7 8 treat PT. The current survey found that:

- 1. Most centers have no restrictions regarding age and BMI even for complex left atrial/ventricular 9 10 procedures.
- 11 2. Transseptal puncture is mostly performed fluoroscopically and frequently facilitated by diagnostic catheters 12 and/or additional imaging modalities such as TOE or ICE.
- 13 3. In case of PT pericardial puncture is mainly guided by fluorosopy and echocardiography and most 14 responders aim for an anterior puncture site, followed by introduction of a sheath and a pigtail catheter.
- 15 4. Protamine is applied by a majority of participants immediately when PT is diagnosed or after complete 16 drainage of pericardial effusion. NOAC antidotes are only administered by a minority of respondents.
- 17 5. A majority does directly autotransfuse aspirated blood without a blood filter and with no maximal limit for blood retransfusion. 18
- 19 6. Surgical intervention is mainly considered if bleeding continues despite all interventional measures.
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#### 21 EP-infrastructure and equipment

22 While two thirds of all responders report to have institutional cardiac surgery, almost all state to have echocardiography permanently available inside the EP-lab and prepared epicardial puncture sets. Although 🔓 23 institutional cardiac surgery might extent the window for interventional measures to treat PT, echocardiography 24 permanently on hand and prepared puncture sets allow for straight forward and time-efficient diagnosis and  $\frac{8}{24}$ 25 26 emergency treatment without unnecessary loss of time.

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#### 1 Procedural aspects and safety considerations

2 Transseptal mispuncture is one of the main reasons for PT. Different techniques can be applied and finally the 3 mode of transseptal puncture is influenced by individualized strategies and by personal experience. However, the 4 ultimate demand is to perform transseptal punctures as controlled and as safe as possible. To facilitate transseptal 🚊 puncture, many centers use catheters at different anatomical positions to improve understanding of the individual 5 anatomy. A catheter inside the coronary sinus will provide a rough visualization of the mitral valve and left atrial 6 dimensions. In addition, a synchronous movement of the transseptal sheath and transseptal needle assembly 7 positioned at the fossa ovalis with the coronary sinus catheter indicates adequate septal contact and position. 8 9 Some participants use an additional catheter at the His bundle region or a pigtail catheter or wire inside the aorta 🗟 10 to mark the aortic root to prevent inadvertent aortic puncture (16,17). Mostly, transseptal puncture is guided by fluoroscopy only, but other imaging modalities might be added such as transesophageal or intracardiac 🙍 11 12 echocardiography. Both echo modalities will not only help to guide the transseptal sheath and needle to the fossa ovalis but will also facilitate to specifically target anterior or posterior puncture sites within the fossa ovalis 🖗 13 depending on the ablation system used (e.g. cryoballoon ablation posterior and inferior, in PFA ablation rather 14 midseptal and inferior) or the intended ablation strategy (e.g. pulmonary vein isolation or antegrade left ventricular 15 access). Transseptal puncture with pressure control is applied by most operators. Verification of successful left 16 atrial access before advancing the transseptal sheath by either introducing a guidewire into the left atrium or a pulmonary vein or by injection of contrast medium avoids advancement of the sheath in case of inadvertent pericardial puncture.
Treatment of pericardial tamponade
There are different ways to get epicardial access but two thirds of all responders prefer an anterior epicardial puncture site which has been shown to be safer than a posterior one (18). In an analysis by Mathew et al. a 17 18 19

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22 puncture site which has been shown to be safer than a posterior one (18). In an analysis by Mathew et al. a 23 24 posterior epicaridal access was strongly associated with a higher rate of severe puncture -related complications and 🖣 a higher necessity for later surgical repair (18). Fluorscopy in different views and additonal echocardiography as 😤 25 answered by three out of four EPs are the leading imaging modalities to guide the puncture. Almost all participants 26 27 introduce a sheath into the pericardial space as soon as access is etablished. A sheath has two major procedural 28 advantages. First, it can be used for direct aspiration of blood and the bigger the size the more volume can be 29 mobilized. Second, blood inside the pigtail catheter, which is introduced by a majority of participating EPs, can clot 30 and in worst case the pigtail has to be exchanged. This is facilitated over the sheath as a continuous and safe access

to the pericardial space. Of note, in tall or obesed patients it might be beneficial to use a longer or even a
transseptal sheath.

Hemostasis and anticoagulation play a major role in the acute treatment of PT. Protamine administration in order
to antagonize previously applied heparin in left atrial/left ventricular procedures is an essential step. Especially in
centers without institutional cardiac surgery backup, early application of protamine is the strategy of choice.
However, the administration of protamine also bears a risk for clot formation inside the pericardial space which can
complicate the situation by impeding further and complete drainage of the pericardial effusion. This is probaby the
reason why about one third of responders decide to first aspirate all blood from the pericardium before protamine
is administered. In about 80% the dose of protamine depends on previously measured ACT levels or of the total
dose of applied heparin.
Additional application of clotting factors or DOAC antidotes is not performed by the majority of responders. While
clotting factors such as PPSB, prothrombin complex or fresh frozen plasma are only considered by 8.3%, NOAC

Additional application of clotting factors or DOAC antidotes is not performed by the majority of responders. While clotting factors such as PPSB, prothrombin complex or fresh frozen plasma are only considered by 8.3%, NOAC antidotes are routinely applied by only 15.2%. The decision to administer NOAC antidotes might be influenced by costs but also by the fact that PT even in patients under NOAC therapy might be safely and effectively managed without antidotes.

costs but also by the fact that PT even in patients under NOAC therapy might be safely and effectively managed without antidotes.
Autotransfusion of aspirated blood is an important but disputatious aspect in PT management. Potential advantages are immediate use, easy implementation, low costs, avoidance of volume and blood loss and thus mostly no need for donor blood transfusion. Accordingly, 74% of all participants perform retransfusion of aspirated blood is directly and without a mechanical blood filter. About 16% use a blood filter and blood and almost three thirds do it directly and without a mechanical blood filter. About 16% use a blood filter and 12% would retransfuse via a cell safer. However, the use of latter is time-consuming to prepare and therefore often not practicable in the emergency situation. Of note, 90% report to not have a fixed volume limit and would retransfuse aspirated blood as long as neccessary and reasonable.
Involvement of surgical backup and repair is also a controversial point. Centers having an institutional cardiac our provide the decision for surgical backup and repair to not provide the tables as the more locus of the action for surgical backup and repair to a provide the tables as tables.

Involvement of surgical backup and repair is also a controversial point. Centers having an institutional cardiac surgery may have more leeway since the decision for surgical repair can be taken anytime if the patient's condition demands. However, if there is no institutional cardiac surgery but rather external cardiac surgical cooperation partners, the decision for potential surgical repair mightl be taken at earlier stages of the treatment cascade. The important aspect is to have cardiac surgical backup which is permanently available or on demand. The point in time to decide for surgical intervention is certainly very individual. In our survey 56% stated to involve surgeons if the bleeding continues for more than 60-80 min, while another 25% would do if the total amount of aspirated blood would exceed an amount of up to 3000 ml.

## 1 Postinterventional aspects

2 Keeping the pigtail catheter in place for several hours after successful treatment of PT is double edged (19). First, 3 further drainage from the pericardium might be neccessary in case of ongoing or recurring bleeding. At the other hand, pericarditis might develop if the pigtial catheter is kept and patients normally complain about thoracic 🖇 4 5 discomfort. In the survey almost 50% of respondents state to keep the pigtail catheter until there is no evidence of further bleeding after re-initiation of an indicated anticoagulation. There are different types of medical strategies 💈 6 7 following pericardial puncture and drainage aiming mainly for pain relief and prevention of pericarditis including 8 NSAIDs and colchicine applied by almost 50% of responders each. Also antibiotics are applied by more than 30% of 9 responders, but mostly for only 2 days.

10 The decision for reinitiation of an indicated oral anticoagulation after pigtail removal has to be carefully taken. At 11 one hand, left atrial thrombus formation and potential ischemic stroke needs to be prevented, at the other hand 12 there would be the risk of ongoing or recurrent bleeding. With 0-72 hours, there is a broad window within which 13 anticoagulation is reinitiated by respondents.

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# 15 Onsite cardiac surgery versus no onsite cardiac surgery

Having onsite cardiac surgery may not only affect the spectrum of EP procedures that is performed but also the 16 mode of treatment in case of a PT. While many parameters of our analysis given by the participants are 17 comparable, there are also differences: in centers with onsite cardiac surgery the mean no. of performed 18 19 procedures is higher. Although epicardial VT ablation is frequently offered at centers with onsite cardiac surgery, 20 the number of participants reporting on epicardal VT ablation without having onsite cardiac surgery is considerably high with 37%. This finding is of interest when considering the ongoing debate on whether a procedure with a rather high incidence of major complications such as severe PT should be offered and performed at such centers. Moreover, protamine is less often applied by participants at onsite cardiac surgery centers. In centers without 21 22 23 24 cardiac surgery usually all efforts are taken to stop the bleeding as soon as possible and thus protamine might be 25 applied at earlier stages of the treatment cascade.

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# 1 Limitations:

- 2 Analyzed data is based on per physician and not per center level, thus overestimating large EP centers perspectives
- 3 cannot be ruled out. The voluntary nature of the survey favors selection bias, and raises questions whether these
- 4 results represent a realistic reflection of the current practice. The survey included a limited number of 26 questions
- 5 only. Therefore, further details such as incidences of PT or the need for surgical intervention cannot be provided.
- 6

# 7 Conclusions:

- 8 The current survey demonstrates that the management of cardiac tamponade differs between EP -centers. Findings
- 9 of this survey may help to guide operators in their treatment and decision in the setting of PT.

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# 23 Data availability statement:

24 All relevant data are within the manuscript and its Supporting Information files.

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16		

- 1 Figures:
- 2 Figure 1:

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- 3 Imaging modalities for transseptal puncture
- 4
- 5

# 1 Figure 4:

# 2 Application of protamine





