International Platform of Registered Systematic Review and Meta-analysis Protocols

INPLASY PROTOCOL

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None declared.

Outcomes following early catheter ablation for ventricular tachycardia in adult patients with structural heart disease and implantable cardioverter-defibrillator: protocol for an updated systematic review and meta-analysis of randomized studies

Shalganov, TN[1]; Stoyanov, MK[2]; Traykov, VB[3].

Review question / Objective: **Does early catheter ablation for scar-related monomorphic ventricular tachycardia improve outcomes (defined as any appropriate ICD therapy, appropriate ICD shocks, all-cause mortality, VT storm, cardiovascular mortality, cardiovascular hospitalizations, complications) in adult patients with ischemic or nonischemic cardiomyopathy and implantable cardioverter-defibrillator?**
Condition being studied: **Ventricular tachycardia in patients with structural heart disease is usually an arrhythmia using the myocardial scar as a substrate for reentry. It poses a risk of syncope and sudden cardiac death, especially in patients with reduced ejection fraction. Most antiarrhythmic drugs are of little value and their use is restricted in patients with LV systolic dysfunction. Catheter ablation is a viable option for the treatment of ventricular tachycardia. In patients with previous myocardial infarction the arrhythmogenic scar is located most frequently subendocardially and is readily accessible using endocardial approach, while in non-ischemic cardiomyopathy the scar is frequently located in the midmyocardial or subepicardial layers. This is the reason endocardial catheter ablation to be less effective in those patients and to more often necessitate epicardial approach.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 June 2022 and was last updated on 26 June 2022 (registration number INPLASY202260080).

INTRODUCTION

Review question / Objective: **Does early catheter ablation for scar-related monomorphic ventricular tachycardia improve outcomes (defined as any appropriate ICD therapy, appropriate ICD shocks, all-cause mortality, VT storm, cardiovascular mortality, cardiovascular hospitalizations, complications) in adult patients with ischemic or nonischemic**

cardiomyopathy and implantable cardioverter-defibrillator?

Rationale: Sustained ventricular tachycardia (VT) in patients with structural heart disease is regarded as life-threatening condition, especially if left ventricular (LV) ejection fraction is reduced. Ischemic and non-ischemic cardiomyopathy are the most common conditions associated with VT. Implantable cardioverter-defibrillators (ICD) are usually considered first line treatment in patients with structural heart disease and VT, but this therapy does not prevent VT recurrences and has known drawbacks. Several studies and few meta-analyses of patients with previous myocardial infarction and severe/moderate left ventricular systolic dysfunction have shown that endocardial catheter ablation can reduce VT recurrences, ICD therapy/shocks, and VT storm in this patient population. However, data on patients with non-ischemic cardiomyopathy have shown relatively disappointing results of ablation. Very recently several new studies with mixed population (ischemic and nonischemic aetiology) and endoepicardial approach have been published thus adding a large pool of patients. This added approach and diverse aetiologies might influence the hard outcomes, including all-cause and cardiovascular mortality.

Condition being studied: Ventricular tachycardia in patients with structural heart disease is usually an arrhythmia using the myocardial scar as a substrate for reentry. It poses a risk of syncope and sudden cardiac death, especially in patients with reduced ejection fraction. Most antiarrhythmic drugs are of little value and their use is restricted in patients with LV systolic dysfunction. Catheter ablation is a viable option for the treatment of ventricular tachycardia. In patients with previous myocardial infarction the arrhythmogenic scar is located most frequently subendocardially and is readily accessible using endocardial approach, while in non-ischemic cardiomyopathy the scar is frequently located in the midmyocardial or subepicardial layers. This is the reason endocardial catheter ablation to be less effective in those patients and to more often necessitate epicardial approach.

METHODS

Search strategy: Search will be conducted in PUBMED, DOAJ, and Cochrane Library for parallel group randomized human trials. Search string will be used with the keywords “ablation” AND “ventricular tachycardia”. Search will not be restricted by language or time period.
PUBMED: Search in “Title/Abstract”
PUBMED filters: “clinical trial”
All retrieved results will be saved with the abstracts for subsequent review by the authors.
DOAJ: Search in “Title”, Search in “Abstract”
DOAJ filters: “medicine”
All retrieved results will be saved with the abstracts for subsequent review by the authors.
Cochrane Library: Search in “Title Abstract Keyword (with word variations)”
Cochrane filters: “trials”
All retrieved results will be saved with the abstracts for subsequent review by the authors.
All 3 lists of results will be combined in a single list.
Every title shall be checked for duplicate results and the duplicates will be removed from further review.
The remaining titles and abstracts will be reviewed by the authors independently for appropriateness. All publications will be removed that are obviously irrelevant to the study question, have not relevant population, or intervention, or control arm, or outcomes, or are retrospective, or are not suitable for review (i.e., case reports, reviews, letters, editorials, opinions). Available meta-analyses will also be removed, but not before being checked for publications missed by the searches.
The remaining titles will be reviewed in full text by the authors independently. All publications will be removed if they are irrelevant to the study question, have not relevant population, or intervention, or control arm, or outcomes, or are

retrospective, or are single-armed, or are not suitable for review, and the authors independently confirmed that these are not suitable for further review. All titles that are not rejected unanimously will be reviewed again for appropriateness and the final decision will be taken after discussion and consensus.
The remaining full text publications will be included in the review and meta-analysis.

Participant or population: >= 18-year-old patients with structural heart disease and an ICD implanted for VT or planned to be implanted, regardless of anti-arrhythmic drug treatment status.

Intervention: Early catheter ablation for scar-related VT, regardless of the access (endocardial or endo-epicardial) and approach (substrate ablation of abnormal potentials within the scar or electrophysiologically guided ablation).

Comparator: No ablation or deferred ablation.

Study designs to be included: Parallel-group randomized human clinical trials.

Eligibility criteria: Inclusion criteria: published randomized studies on patients >= 18-year-old with structural heart disease and an ICD implanted or planned to be implanted for VT; follow-up >= 12 months; >= 3 of the outcomes available (see outcomes). Exclusion criteria: studies on patients with hypertrophic cardiomyopathy, myocarditis, Chagas disease, congenital heart diseases, surgical ablation, stereotactic radioablation.

Information sources: PUBMED, Cochrane Library, DOAJ.

Main outcome(s): Any appropriate ICD therapy, appropriate ICD shocks, all-cause mortality, VT storm.

Additional outcome(s): Cardiovascular mortality, cardiovascular hospitalisations, complications. Change in quality of life will be analyzed if data are available.

Data management: Full text studies (see Search strategy) that seem appropriate for the review will be reviewed independently by all authors. All titles that are not approved/rejected unanimously will be reviewed again for appropriateness and the final decision will be taken after discussion and consensus. Data will be extracted by TS and MS and verified by VT. Data for the systematic review will include: first author, year of publication, sample size, comparator, ablation procedure design, access to the heart, use of navigation system, procedural end-point, primary outcome, secondary outcomes, inclusion criteria, age, sex, LV ejection fraction, hypertension, diabetes mellitus, use of amiodarone, use of beta-blockers, length of follow-up, cross-over to ablation arm. Data on the dichotomous outcomes will be extracted from the full texts and any supplementary files available by the first author (TS) and verified and approved by the other authors (MS and VT), and will be recorded in Excel tables for import in the statistical program. RevMan 5.4 and R package Metafor for jamovi will be used for writing the review and making the statistics.

Quality assessment / Risk of bias analysis: Quality assessment will be done using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group tool. Risk of bias assessment will be done using the revised Cochrane Risk-of-Bias tool (RoB 2) for randomized trials in categories: selection (random sequence generation and allocation concealment), performance (blinding of participants and personnel), attrition (missing outcome data), detection (measurement of the outcome), reporting (selection of the reported result).

Strategy of data synthesis: Dichotomous outcomes will be assessed using study-level data. We will conduct a random-effect meta-analysis using the inverse-variance DerSimonian-Laird model estimator. Measure of effect will be reported as odds ratio (OR) and 95% confidence intervals (CI). An outcome less frequently present in the ablation arm will have a OR <1.

Statistical heterogeneity between studies will be assessed with the Cochrane Q statistic and the I^2 statistic. Publication bias evaluation will be performed using rank correlation and regression tests.

Subgroup analysis: Subgroup analysis may be undertaken for LVEF >35%, if possible.

Sensitivity analysis: Leave-one-out approach will be used, excluding the study with the highest weight.

Language: No restriction.

Country(ies) involved: Bulgaria.

Keywords: Systematic review; ventricular tachycardia; catheter ablation; implantable cardioverter-defibrillator; all-cause mortality.

Dissemination plans: Publication.

Other relevant information: The institutional affiliation of Milko Stoyanov is National Heart Hospital, Sofia, Bulgaria. The institutional affiliation of Vassil Traykov is Acibadem City Clinic Tokuda hospital, Sofia, Bulgaria. Milko Stoyanov and Tchavdar Shalgano read and approved the protocol of the review and meta-analysis.

Contributions of each author:

Author 1 - Tchavdar Shalganov - Conceived and designed the review, wrote the protocol of the review.

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