

# PROCAMIO

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## Plan

- Lignes directrices nord-américaines et européennes
- Études antérieures
- Étude PROCAMIO

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### Lignes directrices de l'*American Heart Association (AHA)*

Adult Tachycardia

If IV antiarrhythmics are administered, procainamide (**Class IIa**, LOE B), amiodarone (**Class IIb**, LOE B), or sotalol (**Class IIIb**, LOE B) can be considered.

Neumar RW, Otto CW, Link MS, et al. Part 8: adult advanced cardiovascular life support: 2010 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation* 2010;122(Suppl. 3):S729-S767.

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### Lignes directrices de l'American Heart Association (AHA)

CLASS IIb (MODERATE)	Benefit >> Risk
Suggested phrases for writing recommendations:	
<ul style="list-style-type: none"> <li>Is reasonable</li> <li>Can be useful/effective/beneficial</li> <li>Comparative Effectiveness Phrases†                             <ul style="list-style-type: none"> <li>Treatment/strategy A is probably recommended/indicated in preference to treatment B</li> <li>It is reasonable to choose treatment A over treatment B</li> </ul> </li> </ul>	

CLASS IIb (WEAK)	Benefit ≈ Risk
Suggested phrases for writing recommendations:	
<ul style="list-style-type: none"> <li>May/might be reasonable</li> <li>May/might be considered</li> <li>Usefulness/effectiveness is unknown/unclear/uncertain or not well established</li> </ul>	

© Neumar RW, Otto CW, Link MS, et al. Part 8: adult advanced cardiovascular life support: 2010 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. Circulation 2010;122(Suppl. 3): S729-S767.

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### Lignes directrices de l'American Heart Association (AHA)

Side Effects	Precautions or Special Considerations
<ul style="list-style-type: none"> <li>Bradycardia, hypotension, torsades de pointes</li> </ul>	<ul style="list-style-type: none"> <li>Avoid in patients with QT prolongation and CHF</li> </ul>
<ul style="list-style-type: none"> <li>Bradycardia, hypotension, phlebitis</li> </ul>	

© Neumar RW, Otto CW, Link MS, et al. Part 8: adult advanced cardiovascular life support: 2010 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. Circulation 2010;122(Suppl. 3): S729-S767.

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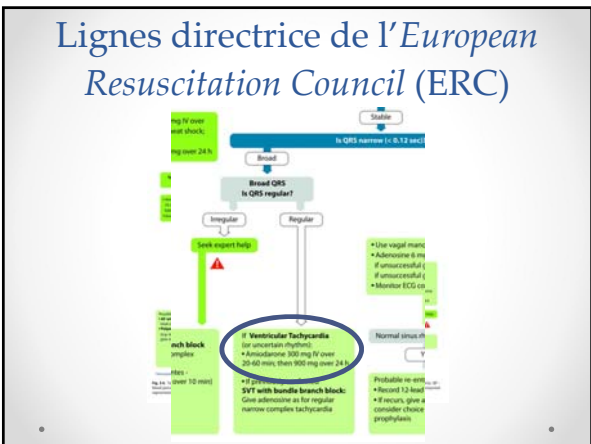
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Études antérieures

Emergency Med J. 2008 Jan 25;13(1):8-9.

**Intravenous amiodarone for the pharmacological termination of haemodynamically tolerated sustained ventricular tachycardia: is bolus dose amiodarone an appropriate first-line treatment?** Emerg Med J. 2008;25:15-18.

**Success rate of 29% for IV amiodarone**

**Abstract**  
Lam S.  
Daniel  
Thomasi  
Gary S.

**OBJECTIVE:** To determine the pharmacological termination rates within 20 min and 1 h and incidence of requiring emergency direct current cardioversion (DCCV) during this period.

**Methods:** A retrospective analysis of 100 patients with haemodynamically tolerated sustained ventricular tachycardia (VT) who were treated with intravenous amiodarone. The primary endpoint was the success rate of amiodarone in terminating VT within 20 min. Secondary endpoints included the success rate within 1 h and the incidence of requiring DCCV.

**Results:** The success rate of amiodarone in terminating VT within 20 min was 29%. The success rate within 1 h was 45%. The incidence of requiring DCCV was 15%.

**Conclusion:** Intravenous amiodarone is an appropriate first-line treatment for the acute termination of tolerated sustained ventricular tachycardia.

**Keywords:** Amiodarone, ventricular tachycardia, pharmacological termination.

**Introduction:** Sustained ventricular tachycardia (VT) is a common arrhythmia that can be life-threatening if not promptly terminated. The first-line treatment for tolerated sustained VT is pharmacological. Amiodarone is a class III antiarrhythmic drug that has been shown to be effective in terminating VT. However, the success rate of amiodarone in terminating VT is variable. A retrospective analysis of 100 patients with tolerated sustained VT who were treated with intravenous amiodarone was conducted to determine the success rate of amiodarone in terminating VT within 20 min and 1 h and the incidence of requiring emergency direct current cardioversion (DCCV) during this period.

**Methods:** A retrospective analysis of 100 patients with tolerated sustained VT who were treated with intravenous amiodarone was conducted. The primary endpoint was the success rate of amiodarone in terminating VT within 20 min. Secondary endpoints included the success rate within 1 h and the incidence of requiring DCCV.

**Results:** The success rate of amiodarone in terminating VT within 20 min was 29%. The success rate within 1 h was 45%. The incidence of requiring DCCV was 15%.

**Conclusion:** Intravenous amiodarone is an appropriate first-line treatment for the acute termination of tolerated sustained ventricular tachycardia.

**Keywords:** Amiodarone, ventricular tachycardia, pharmacological termination.

**Introduction:** Sustained ventricular tachycardia (VT) is a common arrhythmia that can be life-threatening if not promptly terminated. The first-line treatment for tolerated sustained VT is pharmacological. Amiodarone is a class III antiarrhythmic drug that has been shown to be effective in terminating VT. However, the success rate of amiodarone in terminating VT is variable. A retrospective analysis of 100 patients with tolerated sustained VT who were treated with intravenous amiodarone was conducted to determine the success rate of amiodarone in terminating VT within 20 min and 1 h and the incidence of requiring emergency direct current cardioversion (DCCV) during this period.

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Études antérieures

Circulation Journal  
Official Journal of the Japanese Circulation Society  
http://www.j-circ.or.jp

**ORIGINAL ARTICLE**  
Arrhythmia/Electrophysiology

**Termination rate of 76% with IV procainamide**

**Abstract**  
Gorgeles AP, van den Dool A, Hofis A, Mulleneers R, Smeets JL, Vos MA, Wellens HJ. Comparison of procainamide and lidocaine in terminating sustained monomorphic ventricular tachycardia. Am J Cardiol. 1996;78:43-46.

**OBJECTIVE:** To compare the efficacy of procainamide and lidocaine in terminating sustained monomorphic ventricular tachycardia (VT).

**Methods:** A retrospective analysis of 100 patients with tolerated sustained VT who were treated with intravenous procainamide or lidocaine was conducted. The primary endpoint was the success rate of procainamide or lidocaine in terminating VT within 20 min. Secondary endpoints included the success rate within 1 h and the incidence of requiring DCCV.

**Results:** The success rate of procainamide or lidocaine in terminating VT within 20 min was 76%. The success rate within 1 h was 95%. The incidence of requiring DCCV was 5%.

**Conclusion:** Intravenous procainamide or lidocaine is an appropriate first-line treatment for the acute termination of tolerated sustained ventricular tachycardia.

**Keywords:** Procainamide, lidocaine, ventricular tachycardia, pharmacological termination.

**Introduction:** Sustained ventricular tachycardia (VT) is a common arrhythmia that can be life-threatening if not promptly terminated. The first-line treatment for tolerated sustained VT is pharmacological. Procainamide and lidocaine are class I antiarrhythmic drugs that have been shown to be effective in terminating VT. However, the success rate of procainamide or lidocaine in terminating VT is variable. A retrospective analysis of 100 patients with tolerated sustained VT who were treated with intravenous procainamide or lidocaine was conducted to determine the success rate of procainamide or lidocaine in terminating VT within 20 min and 1 h and the incidence of requiring emergency direct current cardioversion (DCCV) during this period.

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PROCAMIO

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European Heart Journal  
ISSN 1744-4871

**CLINICAL RESEARCH**  
Arrhythmia/Electrophysiology

**Randomized comparison of intravenous procainamide vs. intravenous amiodarone for the acute treatment of tolerated wide QRS tachycardia: the PROCAMIO study**

**Mercedes Ortiz<sup>1,2</sup>, Alfonso Martín<sup>1</sup>, Fernando Arribas<sup>1</sup>, Blanca Coll-Vinent<sup>4</sup>, Carmen del Arco<sup>5</sup>, Rafael Peinado<sup>6</sup> and Jesús Almendral<sup>1,2,3</sup>, on Behalf of the PROCAMIO Study Investigators**

<sup>1</sup>Department of Cardiology, Hospital General Universitario Gregorio Marañón, Madrid, Spain; <sup>2</sup>Emergency Department, Hospital Universitario Carlos III, Madrid, Spain; <sup>3</sup>Department of Cardiology, Hospital Universitario de Galdakao, Galdakao, Spain; <sup>4</sup>Emergency Department, Hospital Clínico, Barcelona, Spain; <sup>5</sup>Emergency Department, Hospital Universitario de La Princesa, Madrid, Spain; and <sup>6</sup>Department of Cardiology, Hospital Universitario La Paz, Madrid, Spain

Received 20 November 2015; revised 7 April 2016; accepted 20 April 2016

**OBJECTIVE:** To compare the efficacy of intravenous procainamide vs. intravenous amiodarone for the acute treatment of tolerated wide QRS tachycardia.

**Methods:** A randomized controlled trial comparing intravenous procainamide vs. intravenous amiodarone for the acute treatment of tolerated wide QRS tachycardia. The primary endpoint was the success rate of procainamide or amiodarone in terminating wide QRS tachycardia within 20 min. Secondary endpoints included the success rate within 1 h and the incidence of requiring DCCV.

**Results:** The success rate of procainamide or amiodarone in terminating wide QRS tachycardia within 20 min was 76%. The success rate within 1 h was 95%. The incidence of requiring DCCV was 5%.

**Conclusion:** Intravenous procainamide or amiodarone is an appropriate first-line treatment for the acute termination of tolerated wide QRS tachycardia.

**Keywords:** Procainamide, amiodarone, wide QRS tachycardia, pharmacological termination.

**Introduction:** Sustained wide QRS tachycardia (WT) is a common arrhythmia that can be life-threatening if not promptly terminated. The first-line treatment for tolerated WT is pharmacological. Procainamide and amiodarone are antiarrhythmic drugs that have been shown to be effective in terminating WT. However, the success rate of procainamide or amiodarone in terminating WT is variable. A randomized controlled trial comparing intravenous procainamide vs. intravenous amiodarone for the acute treatment of tolerated wide QRS tachycardia was conducted to determine the success rate of procainamide or amiodarone in terminating WT within 20 min and 1 h and the incidence of requiring emergency direct current cardioversion (DCCV) during this period.

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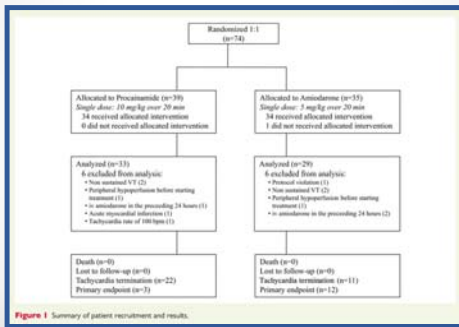
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# PROCAMIO

- Amiodarone 5 mg/kg vs Procainamide 10 mg/kg sur 20 min pour le traitement des tachycardies à QRS large stables.
- Période d'étude 40 min + Période d'observation 24h
- Multicentrique, Prospective, Randomisée

## Randomisation



## Population

**Table 1 Patient baseline characteristics**

Characteristics	Procainamide (n = 33)	Amiodarone (n = 29)	P
Age (years)	42 ± 16	49 ± 11	0.08
Emergency room	36 (79)	24 (83)	0.7
Structural heart disease	26 (79)	23 (79)	0.96
Coronary artery disease	19 (60)	15 (52)	0.62
Dilated cardiomyopathy	4 (18)	4 (14)	0.84
Amyloidogenic right ventricular cardiomyopathy	1 (3)	1 (3)	0.94
Other	4 (12)	3 (10)	0.83
LVEF	0.40 ± 0.13 (n = 29)	0.37 ± 0.13 (n = 24)	0.37
SBP at admission (mmHg)	115 ± 14	116 ± 18	0.85
Heart rate (beats/min)	179 ± 25	176 ± 22	0.75
QRS (ms)	153 ± 24	163 ± 32	0.13
QRS morphology			0.37
Right bundle branch block	24 (73)	18 (62)	
Left bundle branch block	9 (27)	11 (38)	
Proximal (mmHg)	4.4 ± 0.4 (n = 38)	4.4 ± 0.7 (n = 26)	0.23
Creatinine (mg/dL)	1.3 ± 0.5 (n = 29)	1.4 ± 0.4 (n = 26)	0.29
Litacaine during transport to hospital	0	0	—
Admission at emergency room	4 (12)	6	0.05
Previous oral pharmacological treatment	0	0	0.02
<b>Amiodarone</b>	0	20	0.02
β-blockers	11 (33)	12 (41)	0.52
ACE-inhibitors/ARBs	14 (42)	14 (48)	0.89
Calcium channel blockers	2 (6)	3 (10)	0.89
Other class I or II antiarrhythmic drugs	0	0	—

Values are n (%) and mean ± SD.  
LVEF, left ventricular ejection fraction; SBP, systolic blood pressure.

## Résultats – Issue primaire

- Incidence des événements cardiaques majeurs (MACE) 40 minutes suivant le début de la perfusion.
- Procainamide 9% vs Amiodarone 41%
  - Statistiquement significatif (P 0.006)
  - NNH 3
  - Indice de fragilité : 3 patients

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## MACE – Population générale

**Table 2** Safety and efficacy of study drugs in the entire population

	All patients (n = 42)	Procainamide (n = 33)	Amiodarone (n = 29)	P
Major cardiac adverse events during study period	15 (24)	3 (9)	12 (41)	0.006
Total adverse events during study period	22 (53)	8 (24)	14 (48)	0.054
Time to adverse event (min)	17 ± 9	17 ± 12	16 ± 7	0.7
Tachycardia termination during study period	33 (53)	22 (67)	11 (38)	0.026
Time to tachycardia termination (min)	14 ± 9	14 ± 10	16 ± 5	0.3
Total adverse events during the observation period	15 (24)	6 (18)	9 (31)	0.24

Values are n (N) and mean ± SD.

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## MACE – Population générale

**Table 4** Cardiac adverse events during the study period (40 min)

Adverse event	Procainamide	Amiodarone
Major cardiac adverse events during study period		
Acute pulmonary oedema requiring DCCV	0	2
Severe hypotension requiring cessation of infusion	1	1
Severe hypotension requiring immediate DCCV	2	6*
Peripheral hypoperfusion and/or dyspnoea with severe hypotension requiring immediate DCCV	0	3
Other adverse events during study period		
Hypotension that did not require cessation of infusion or DCCV	5	2
Adverse events during observation period		
Acute pulmonary oedema with peripheral hypoperfusion	1	1
Dyspnoea with peripheral hypoperfusion	1	0
Hypotension	3	5
Sinus bradycardia	1	0
Arrhythmic storm and cardiogenic shock	0	1
Neurothorax	0	1
Acute myocardial infarction 4 h after drug administration	0	1

DCCV, direct current cardioversion.  
\*DCCV was cancelled in one patient due to spontaneous reversion to sinus rhythm.

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## MACE – Cardiopathies structurelles

**Table 5** Safety and efficacy of study drugs in patients with structural heart disease

	All patients (n = 49)	Procainamide (n = 26)	Amiodarone (n = 23)	P
Major cardiac adverse events during study period	13 (26)	3 (11)	10 (43)	0.017
Total adverse events during study period	19 (38)	8 (31)	11 (48)	0.22
Time to adverse event (min)	17 ± 10	19 ± 13	16 ± 7	0.6
Tachycardia termination during study period	26 (53)	17 (65)	9 (39)	0.069
Time to tachycardia termination (min)	15 ± 10	15 ± 11	16 ± 5	0.9
Total adverse events during the observation period	13 (26)	6 (23)	7 (30)	0.56

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## Résultats - Issues secondaires

- Efficacité de la cardioversion chimique pour cesser les tachycardies à QRS large
- Procainamide 67% vs Amiodarone 38%
  - Statistiquement significatif (P 0.026)
  - NNT 3
  - Indice de fragilité: 1 patient

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## Résultats - Cardioversion chimique

**Table 2** Safety and efficacy of study drugs in the entire population

	All patients (n = 62)	Procainamide (n = 33)	Amiodarone (n = 29)	P
Major cardiac adverse events during study period	15 (24)	3 (9)	12 (41)	0.006
Total adverse events during study period	22 (35)	8 (24)	14 (48)	0.052
Time to adverse event (min)	17 ± 8	17 ± 13	16 ± 7	0.2
Tachycardia termination during study period	33 (53)	22 (67)	11 (38)	0.034
Time to tachycardia termination (min)	14 ± 9	14 ± 10	16 ± 5	0.3
Total adverse events during the observation period	15 (24)	6 (18)	9 (31)	0.24

Values are n (%) and mean ± SD.

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## Indice de fragilité

### Fragility Index

Control Events: 11

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Intervention Events: 22

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Control Total: 29

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Intervention Total: 33

The Fragility Index of this trial was found to be 1 event(s).

This would increase the p-value to 0.072925897783305.

Events	Non-Events	p-value
11	18	0.04053988
12	17	0.0729259

What is the Fragility Index (FI)?

CALCULATE >

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## Résultats - Issues secondaires

**Table 2 Safety and efficacy of study drugs in the entire population**

	All patients (n = 62)	Procainamide (n = 33)	Amiodarone (n = 29)	P
Major cardiac adverse events during study period	15 (24)	3 (9)	12 (41)	0.006
Total adverse events during study period	22 (35)	8 (24)	14 (48)	0.052
Time to adverse event (min)	17 ± 9	17 ± 12	16 ± 7	0.7
Tachycardia termination during study period	33 (53)	22 (67)	11 (38)	0.026
Time to tachycardia termination (min)	14 ± 9	14 ± 10	16 ± 5	0.3
Total adverse events during the observation period	15 (24)	6 (18)	9 (31)	0.24

Values are n (%), and mean ± SD.

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## Limitations

- Nombre insuffisant de patients
  - 74/302
- Indice de fragilité bas
- Étude non à l'aveugle
- Doses utilisées et nombre accru d'événements indésirables avec l'amiodarone

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## Doses utilisées

- Europe: 300 mg sur 20 à 60 minutes.
- Amérique du Nord: 150 mg sur 10 minutes
- Dosages non rapportés dans les résultats de l'étude.
  - Procainamides
    - 70 kg = 35 mg/min sur 20 min.
    - 100 kg = 50 mg/min sur 20 min.
  - Amiodarone
    - 70 kg = 350 mg sur 20 min.
    - 100 kg = 500 mg sur 20 min.

**Antiarrhythmic Infusions for Stable Wide-QRS Tachycardia**

**Procainamide IV Dose:**  
20-50 mg/min until arrhythmia suppressed, hypotension ensues, QRS duration increases >50%, or maximum dose 17 mg/kg given. Maintenance infusion: 1-4 mg/min. Avoid if prolonged QT or CHF.

**Amiodarone IV Dose:**  
First dose: 150 mg over 10 minutes. Repeat as needed if VT recurs. Follow by maintenance infusion of 1 mg/min for first 6 hours.

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## PROCAMIO

- Meilleure **efficacité** et **profil d'innocuité** de la **procainamide**
- Population générale ET population avec **cardiopathie structurale**
- **Toujours** être prêt pour une cardioversion électrique

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Merci

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