PROCAMIO

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Plan

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

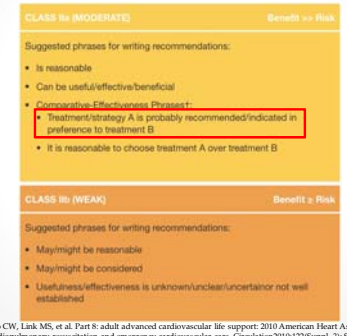
Lignes directrices de l'*American Heart Association* (AHA)

Adult Tachycardia

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

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



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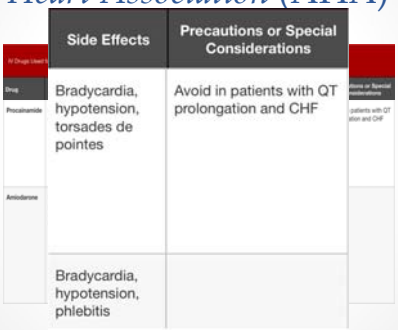

Drug	Side Effects	Precautions or Special Considerations
Procainamide	Bradycardia, hypotension, torsades de pointes	Avoid in patients with QT prolongation and CHF
Amiodarone	Bradycardia, hypotension, phlebitis	

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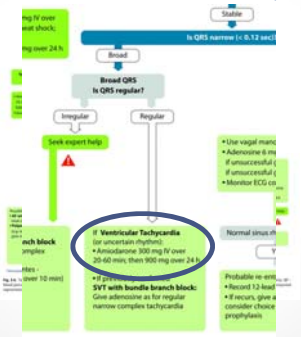
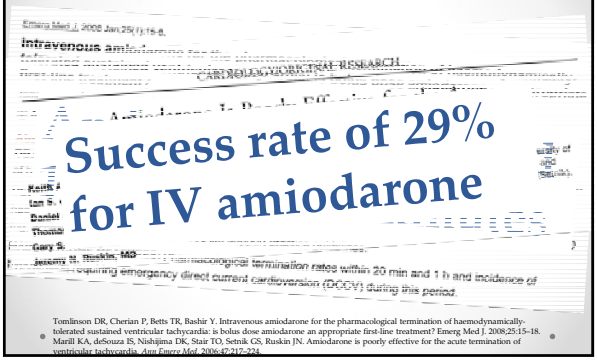
Lignes directrice de l'*European Resuscitation Council* (ERC)

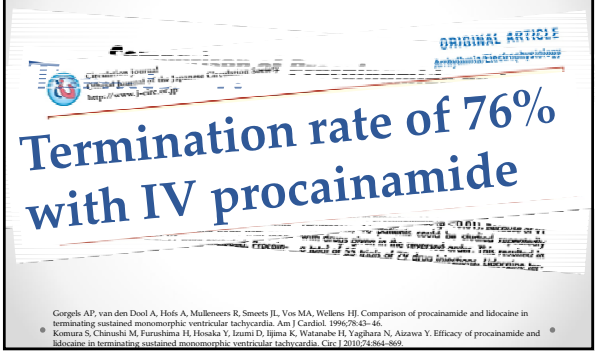


Études antérieures



Tomlinson DR, Cherian P, Betts TR, Bashir Y. 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.
Marill KA, deSouza IS, Nishijima DK, Stair TO, Setnik GS, Ruskin JN. Amiodarone is poorly effective for the acute termination of ventricular tachycardia. *Ann Emerg Med*. 2006;47:217–224.

Études antérieures



Gorgels AP, van den Dool A, Hofs 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.
Komura S, Chinushi M, Furushima H, Hosaka Y, Izumi D, Iijima K, Watanabe H, Yagihara N, Aizawa Y. Efficacy of procainamide and lidocaine in terminating sustained monomorphic ventricular tachycardia. Circ J 2010;74:864–869.

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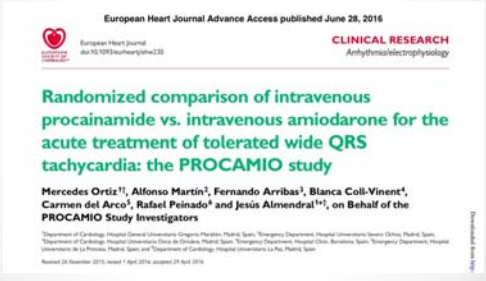
European Heart Journal Advance Access published June 28, 2016

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[†], Alfonso Martín[2], Fernando Arribas[3], Blanca Coll-Vinent[4], Carmen del Arco[5], Rafael Peinado[6] and Jesús Almendral[1*], on Behalf of the PROCAMIO Study Investigators

Ortiz M, Martín A, Arribas F, et al. Randomized comparison of intravenous procainamide vs. intravenous amiodarone for the acute treatment of tolerated wide QRS tachycardia: the PROCAMIO study. Eur Heart J. 2016;

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

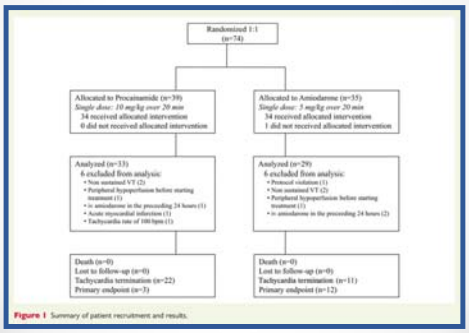

Figure 1 Summary of patient recruitment and results.

Population

Table 1 Patient baseline characteristics

Characteristics	Procainamide (n = 33)	Amiodarone (n = 29)	P
Age (years)	62 ± 16	69 ± 12	0.08
Emergency room	26 (79)	24 (83)	0.7
Structural heart disease	26 (79)	23 (79)	0.94
Coronary artery disease	15 (45)	15 (52)	0.62
Dilated cardiomyopathy	6 (18)	4 (14)	0.64
Arrhythmogenic 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 ± 0.15 (n = 24)	0.37
SBP at admission (mmHg)	113 ± 16	116 ± 19	0.85
Heart rate (beats/min)	179 ± 31	176 ± 32	0.75
QRS (ms)	153 ± 26	160 ± 32	0.13
QRS morphology			0.37
Right bundle branch block	24 (73)	18 (62)	
Left bundle branch block	9 (27)	11 (38)	
Potassium (mmol/L)	4.4 ± 0.6 (n = 28)	4.6 ± 0.7 (n = 26)	0.23
Creatinine (mg/dL)	1.3 ± 0.5 (n = 29)	1.4 ± 0.6 (n = 26)	0.29
Lidocaine during transport to hospital	0	0	—
Adenosine at emergency room	4 (12)	0	0.05
Previous oral pharmacological treatment			
Amiodarone	8	5(17)	0.02
β-Blockers	11 (33)	10 (34)	0.92
ACE-inhibitors/ARBs	16 (48)	14 (48)	0.89
Calcium channel blockers	2 (6)	2 (7)	0.89
Other class I or III 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%**
  - o Statistiquement significatif (P 0.006)
  - o NNH **3**
  - o Indice de fragilité : 3 patients

MACE – Population générale

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.

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
Neumothorax	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.

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

Résultats - Issues secondaires

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

Résultats - Cardioversion chimique

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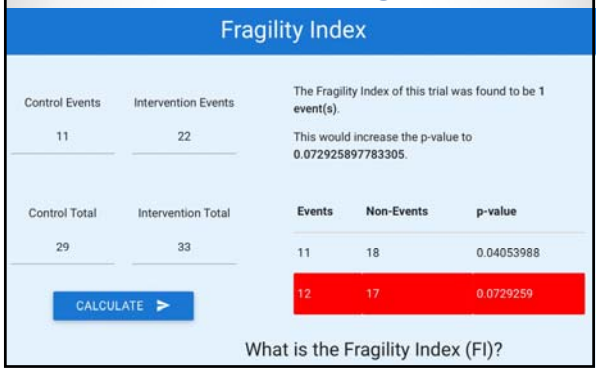
Indice de fragilité



Résultats - Issues secondaires

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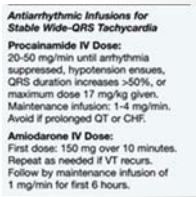
Limitations

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

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.
  - o Procainamides
    - 70 kg = 35 mg/min sur 20 min.
    - 100 kg = 50 mg/min sur 20 min.
  - o 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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- Meilleure **efficacité** et **profil d'innocuité** de la **procainamide**
- Population générale ET population avec **cardiopathie structurelle**
- **Toujours** être prêt pour une cardioversion électrique

Merci