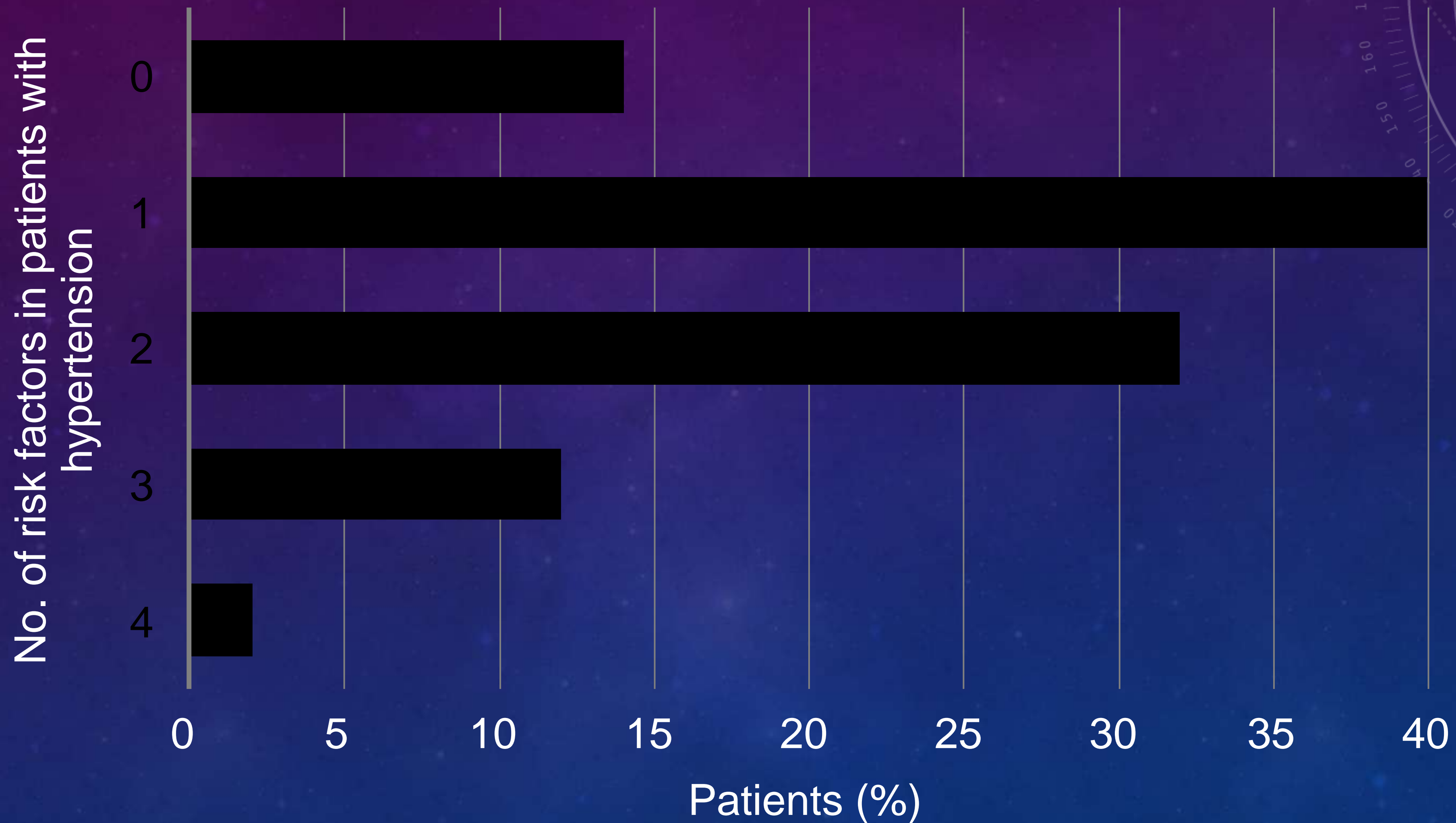
BITHÉRAPIE DANS LE TRAITEMENT DE L’HTA

PR. CHRAIBI SAID

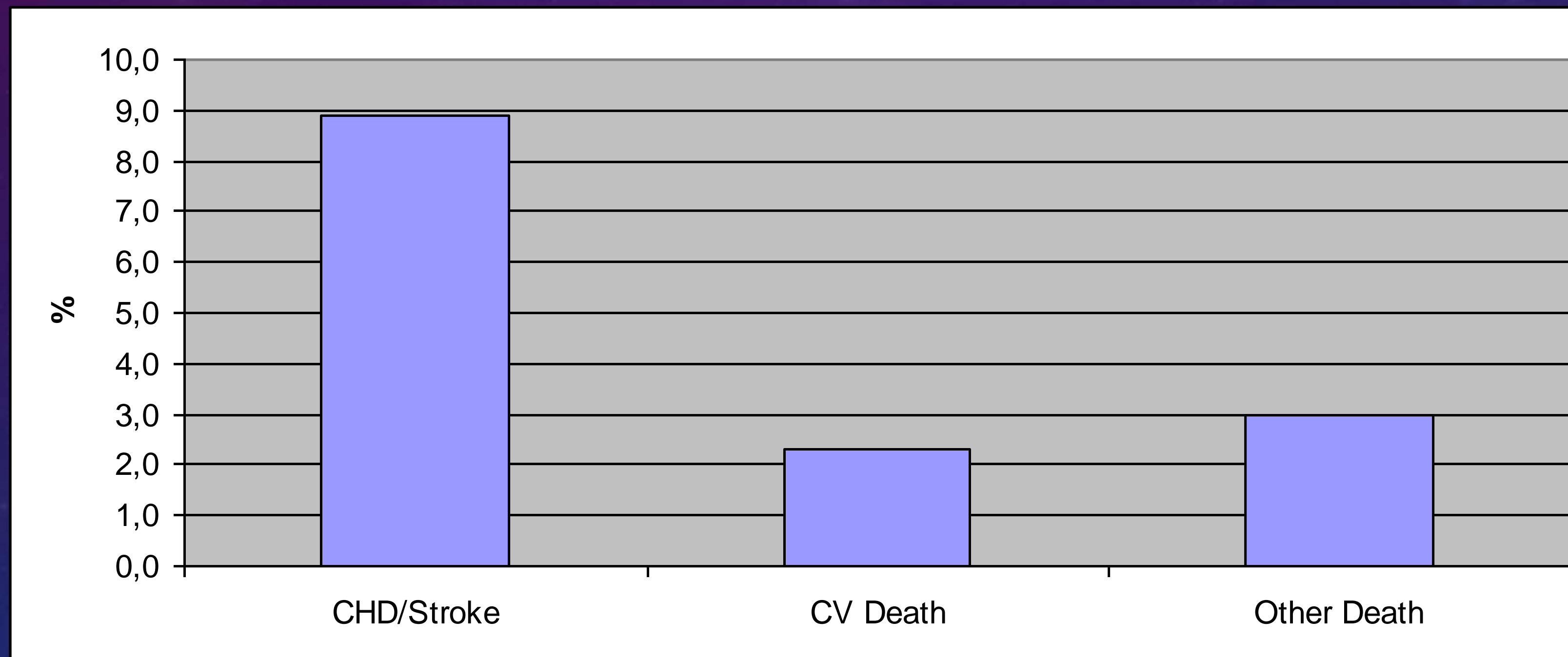
Casablanca le 14 décembre 2017

MOST PATIENTS WITH HYPERTENSION HAVE ADDITIONAL RISK FACTORS



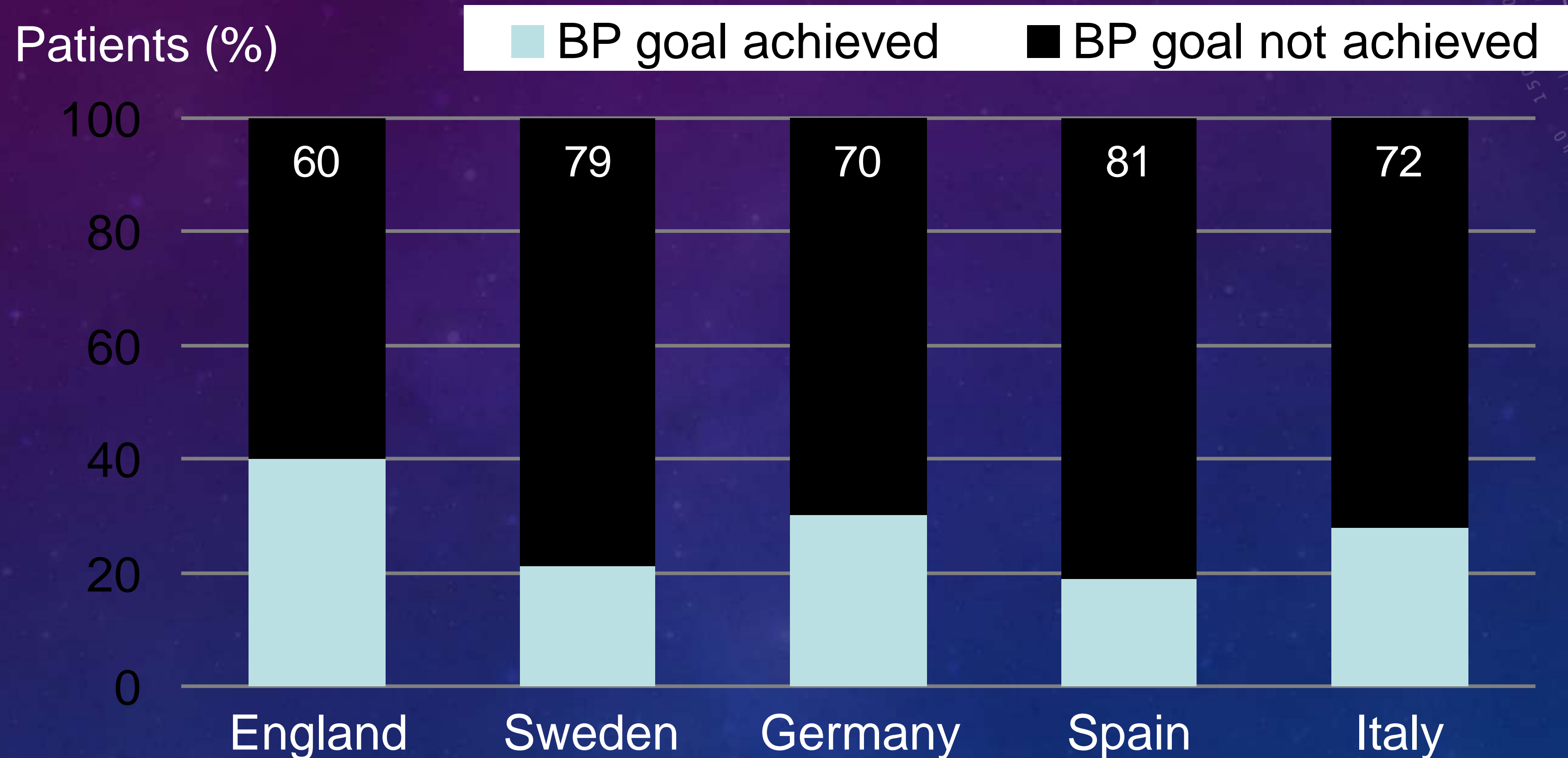
Mancia et al. J Hypertens 2004;22:51–7

L'INCIDENCE DES COMPLICATIONS CARDIOVASCULAIRES MAJEURES CHEZ LES HYPERTENDUS TRAITÉS À RISQUE ÉLEVÉ SELON ESH
SUIVI SUR 3 ANS DE 9 772 HYPERTENDUS TRAITÉS



Cardiorenal study; X Girerd 2010

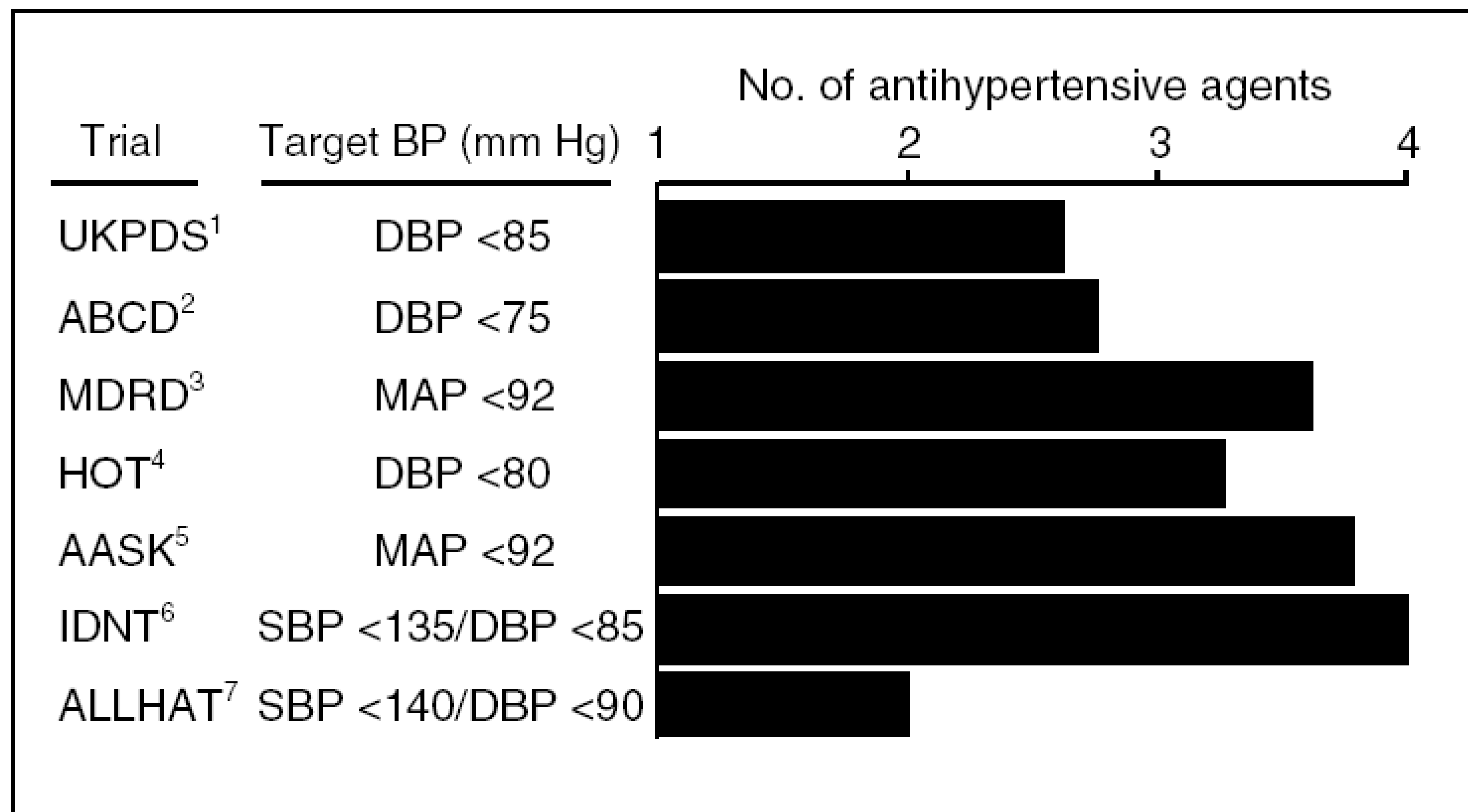
APPROXIMATELY 70% OF PATIENTS* IN EUROPE DO NOT REACH BP GOAL



*Treated for hypertension
BP goal is <140/90 mmHg

Wolf-Maier et al. Hypertension 2004;43:10–17

Associations thérapeutiques dans les grandes études

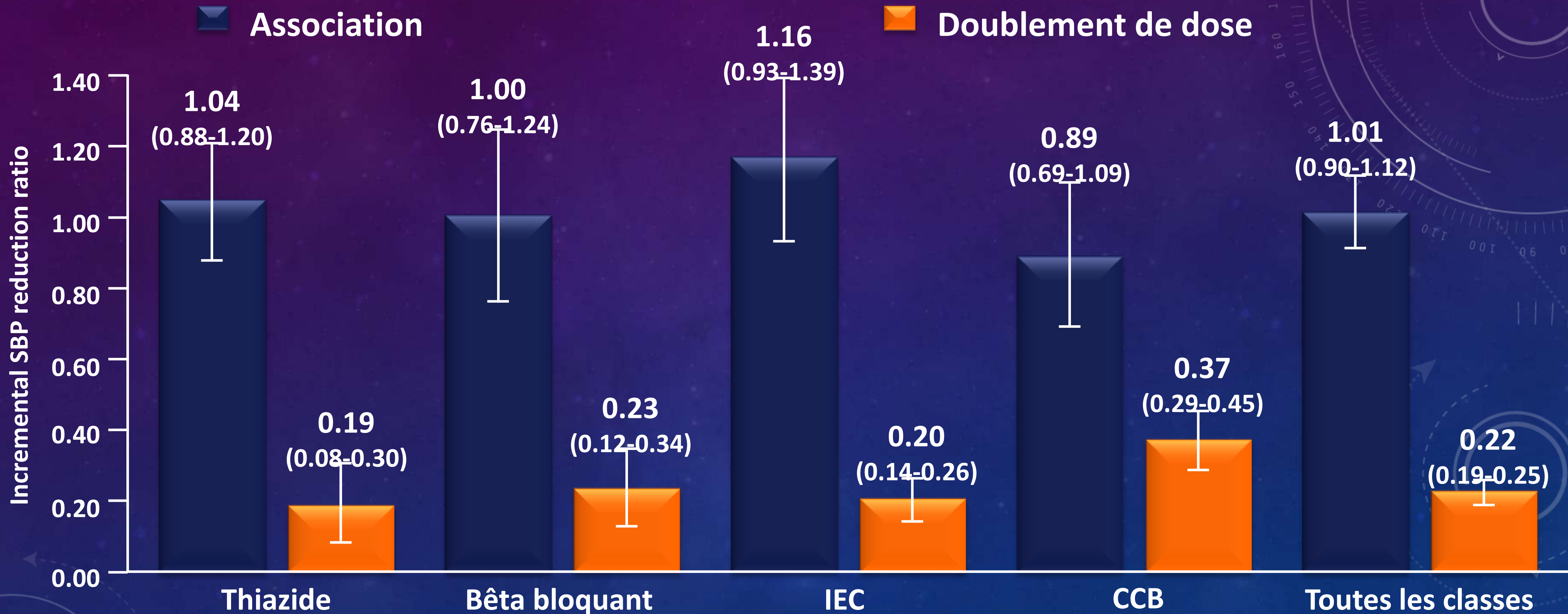


DESCRIPTION DES SCHÉMAS THÉRAPEUTIQUES POUR LES HYPERTENDUS
OBSERVATOIRE THALÈS-CÉGÈDIM ANNÉE 2010

	Hypertendus prévalents Dernière ordonnance 2010	
	Nbre	%
Ordonnances analysées	**10 114 490**	**100,0%**
Monothérapie	4 133 543	40,9%
Bithérapie faiblement dosée	287 027	2,8%
Bithérapie	3 409 428	33,7%
Fixe	1 791 449	17,7%
Libre	1 617 979	16,0%
Trithérapie	1 717 643	17,0%
Quadrithérapie et +	566 849	5,6%

Source : Thalès-Cégédim ; HAS

Association vs monothérapie réduction PA : Meta-analyse de 11,000 participants 42 essais



Association versus doublement de dose: p <0.05 pour les comparaisons

Wald DS, et al. *Am J Med.* 2009;122:290-300.

ADVANTAGES OF FIXED VERSUS FREE COMBINATIONS OF TWO ANTIHYPERTENSIVE DRUGS

	Fixed	Free
Simplicity of treatment	+	–
Compliance	+	–
Efficacy	+	+
Tolerability	+*	–
Price	+	–
Flexibility	–	+

*Lower doses generally used in fixed-dose combinations
+ = potential advantage

Les associations préférées IHS survey

	ISRA/IC	ISRA/D	IC/D	IC/BB	D/BB
Hypertension	87%	71%	16%	19%	10%
Hypertension et diabète	84%	39%	3%	0%	0%

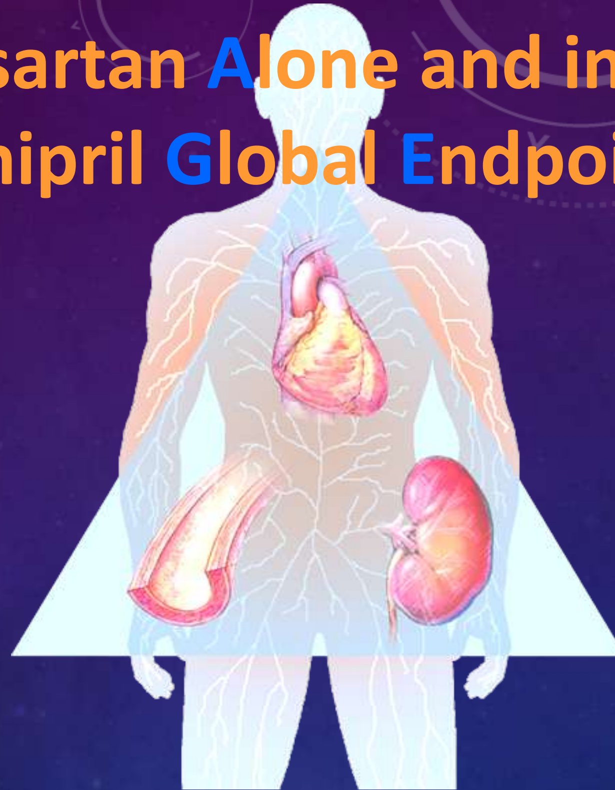
ISRA inhibiteur SRA
IC: inhibiteur calcique
D: diurétique
BB: bêta bloqueurs

Journal of Hypertension 2013, 31, 1043–1048

Les caractéristiques pharmacocinétiques de l'association

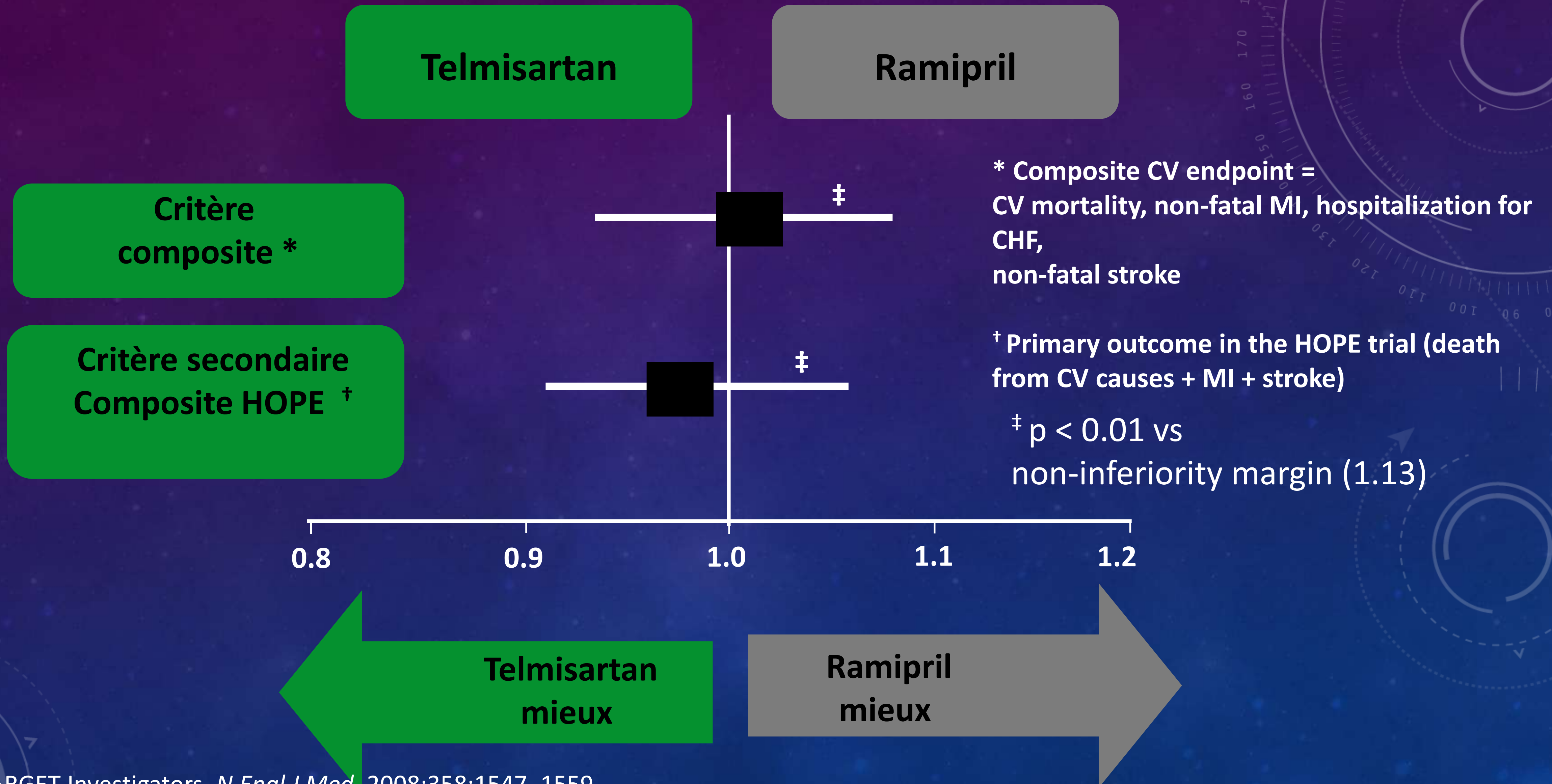
	TELMISARTAN	AMLODIPINE
Lipophilie = bonne diffusion tissulaire	+	+
Volume de distribution = bonne diffusion tissulaire	500 l	21l
Demi-vie	> 20 heures	35-50 heures
Affinité récepteur AT 1	élevée	
Dissociation du récepteur	lente	
Rapport vallée pic	> 90%	> 85%
Elimination rénale	Sécurité	Sécurité

ONgoing Telmisartan Alone and in combination with Ramipril Global Endpoint Trial



Etude de l'effet du Telmisartan en monothérapie et en association avec le Ramipril sur les événements cardiovasculaires

ONTARGET et prévention des événements cardiovasculaires



The ONTARGET Investigators. *N Engl J Med.* 2008;358:1547–1559.

The New England
Journal of Medicine

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VOLUME 342 JANUARY 20, 2000 NUMBER 3

EFFECTS OF AN ANGIOTENSIN-CONVERTING–ENZYME INHIBITOR, RAMIPRIL, ON CARDIOVASCULAR EVENTS IN HIGH-RISK PATIENTS

THE HEART OUTCOMES PREVENTION EVALUATION STUDY INVESTIGATORS*

HOPE : RAMIPRIL VERSUS PLACEBO

Evènements cardiovasculaires

–22%
***P*<0.001**

Mortalité cardiovasculaire

–26%
***P*<0.001**

Infarctus du myocarde

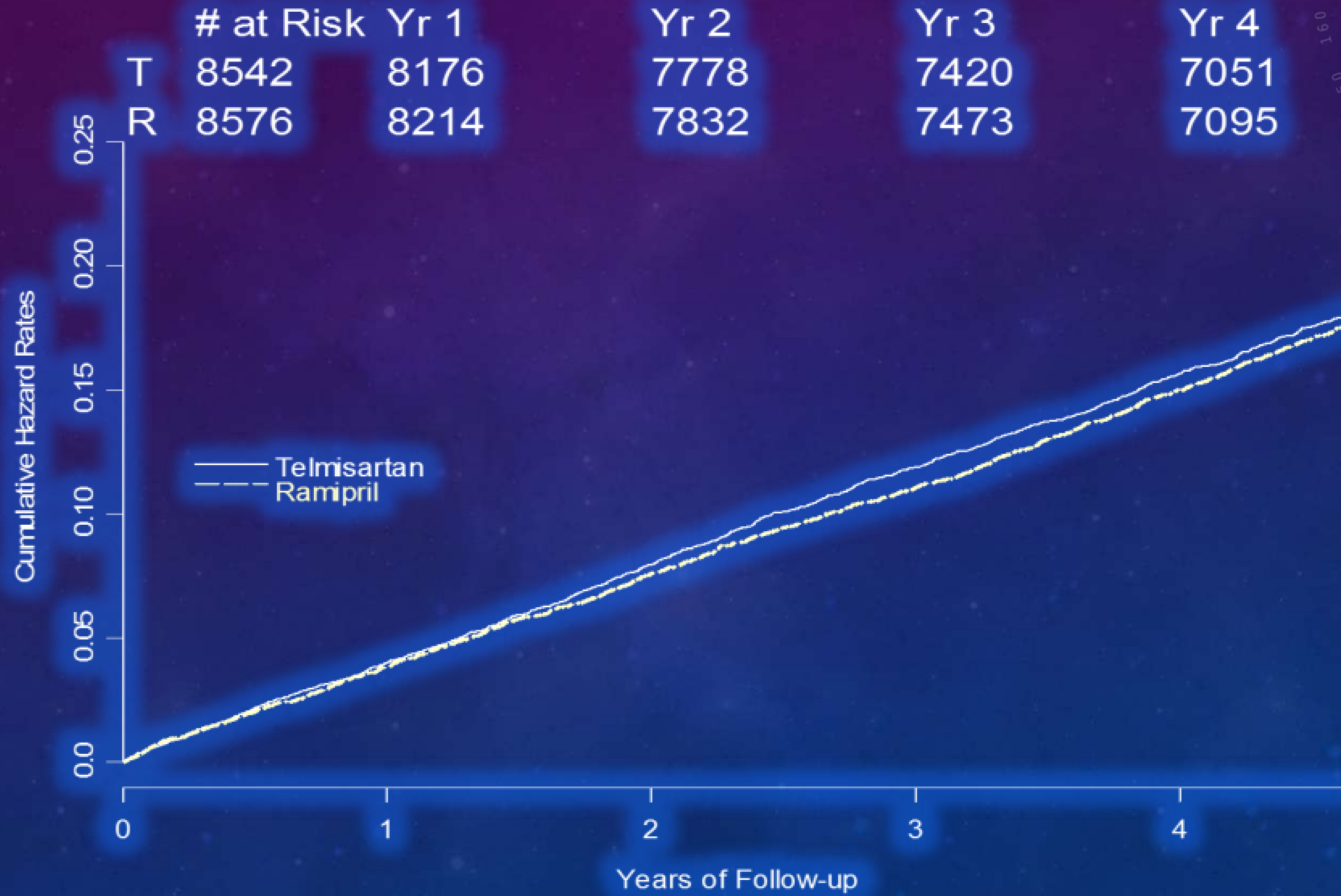
–20%
***P*<0.001**

AVC

–32% *P*<0.001

Yusuf S et al. N Engl J Med 2000

NOMBRE D’ÉVÉNEMENTS TELMISARTAN VS RAMIPRIL



ETUDE PROSPECTIVE RANDOMISÉE EN DOUBLE AVEUGLE COMPARANT LA CHLORTHALIDONE , L'AMLODIPINE , LISINOPRIL , ET UN ALPHA BLOQUANT SUR 6 ANS.

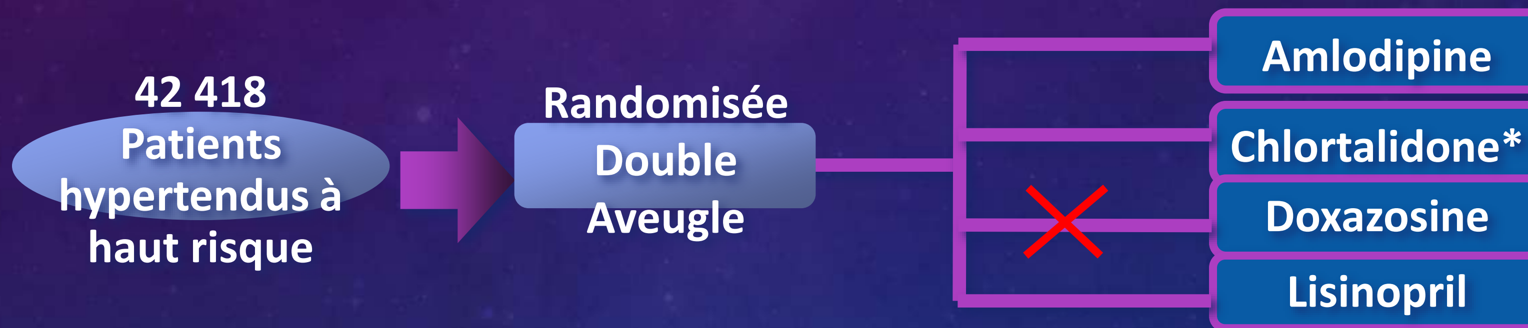
- 42 418 PATIENT
- PLUS DE 55ANS
- AU MOINS UN FRCVX
- 623 CENTRES

PROFIL DES PATIENTS

- 36% de diabétiques
- 47% de femmes
- 47% ayant une maladie cardiovx

ALLHAT

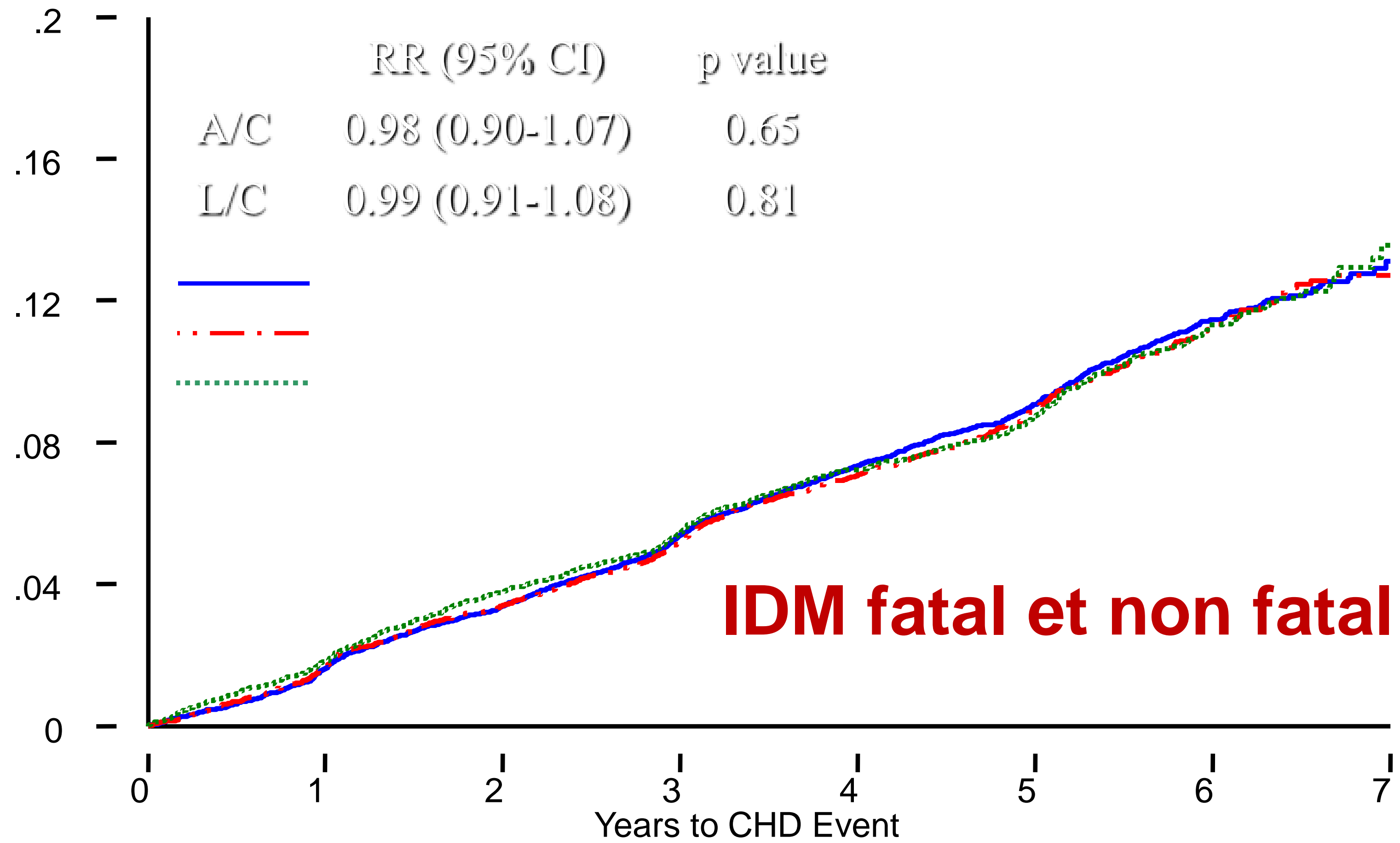
- Suivi : 4-8 ans (moyenne : 6 ans)
- I.Coronaire fatale + IDM non fatal



Ref : Hypertension. 2001; 37:19-27

*La chlortalidone n'est pas commercialisée en France

ALLHAT



ALLHAT

	RR (95% CI)	p value
A/C	0.93 (0.82-1.06)	0.28
L/C	1.15 (1.02-1.30)	0.02

Taux cumulés d'AVC

Chlortalidone
Amlodipine
Lisinopril

Les AVC

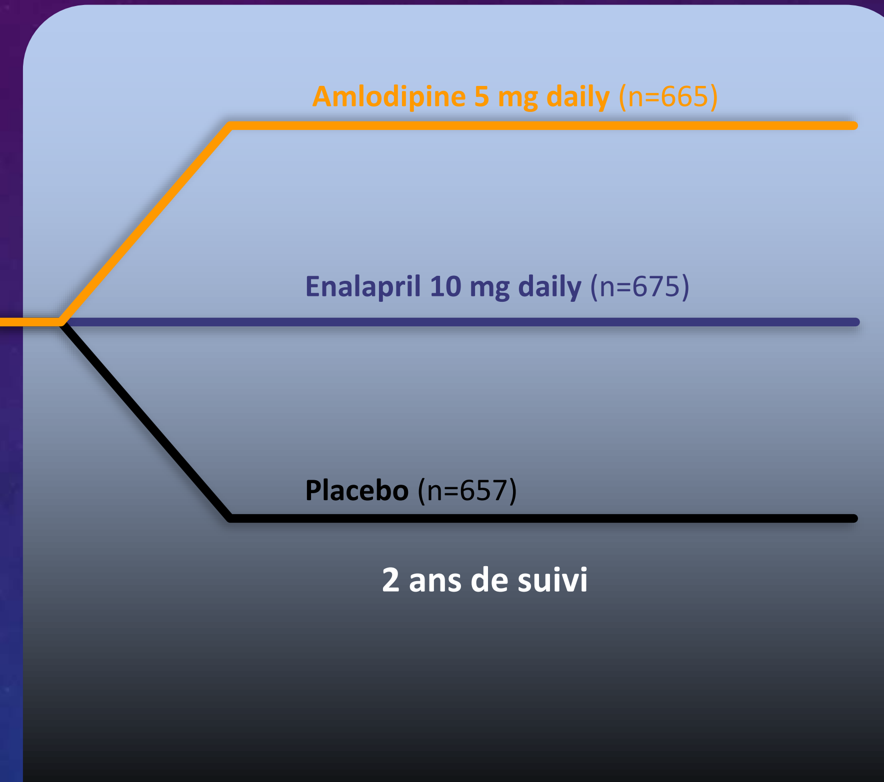
Nu								
Chlor	15,255	14,515	13,934	13,309	11,570	6,385	3,217	567
Amlo	9,048	8,617	8,271	7,949	6,937	3,845	1,813	506
Lisin	9,054	8,543	8,172	7,784	6,765	3,891	1,828	949

CAMELOT

CAMELOT A ÉVALUÉ LES EFFETS DE L'AMLODIPINE OU DE L'ÉNALAPRIL SUR LES ÉVÉNEMENTS CV CHEZ LES PATIENTS NORMOTENDUS AVEC UNE MALADIE CORONARIENNE

1,997 patients avec une maladie coronarienne

- 2 semaines de run-in avec placebo
- Valeur moyenne initiale de la PA 129/78 mm Hg

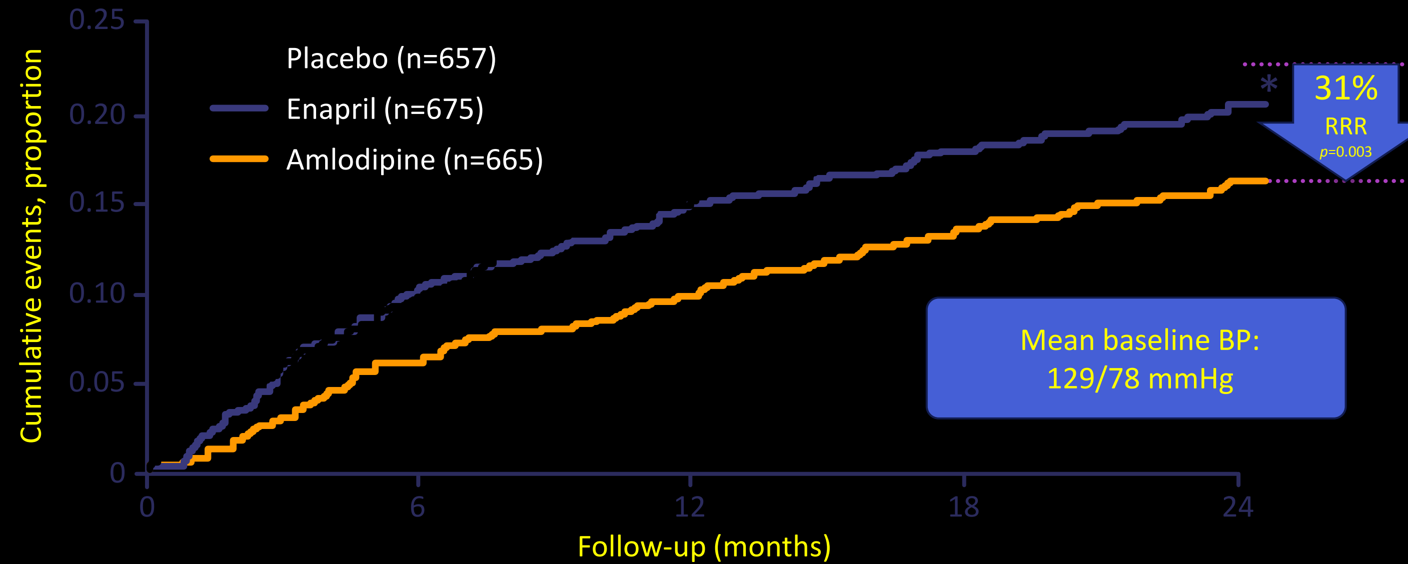


- A la fin de la deuxième semaine, si la dose initiale a été tolérée, le participant double la dose quotidienne de médicament
- Critère principal: incidence des événements cardiovasculaires
- Critères secondaires: incidence des événements indésirables

Nissen SE et al. *JAMA.* 2004;292(18):2217-25.

DANS CAMELOT, L'AMLODIPINE A RÉDUIT SIGNIFICATIVEMENT LE TAUX D'ÉVÉNEMENTS CARDIOVASCULAIRES DE 31% CHEZ LES PATIENTS NORMOTENDUS AVEC UNE MALADIE CORONARIENNE

CAMELOT: Incidence des événements cardiovasculaires



No. at Risk

Placebo	655	588	558	525	488
Enalapril	673	608	672	553	529
Amlodipine	663	623	599	574	535

* Relative risk reduction with enalapril vs. placebo: 15% (*p*=0.16)
RRR = relative risk reduction

Nissen SE et al. *JAMA.* 2004;292(18):2217-25.

Inhibiteur Calcique et Antagoniste des récepteurs AT1

Inhibiteur calcique
- Vasodilatation artérielle
- Système sympathique +++
- Réduction ischémie myocardique
- Oedèmes

ARA 2
- Blocage SRA
- Béneféces rein

PA

ARA 2
- Vasodialatation mixte
- Système sympathique --
- Attenuation des oedèmes
- Absence effet direct ischémie

Synergie

d'action

Bénéfices complémentaires

Inhibiteur calcique
- Activation SRA
- Pas de bénéfices rénaux

Mistry et al. *Expert Opin Pharmacother.* 2006;7:575–581; Sica. *Drugs.* 2002;62:443–462; Quan et al. *Am J Cardiovasc Drugs.* 2006;6:103–113.

TEAMSTA PROGRAMME

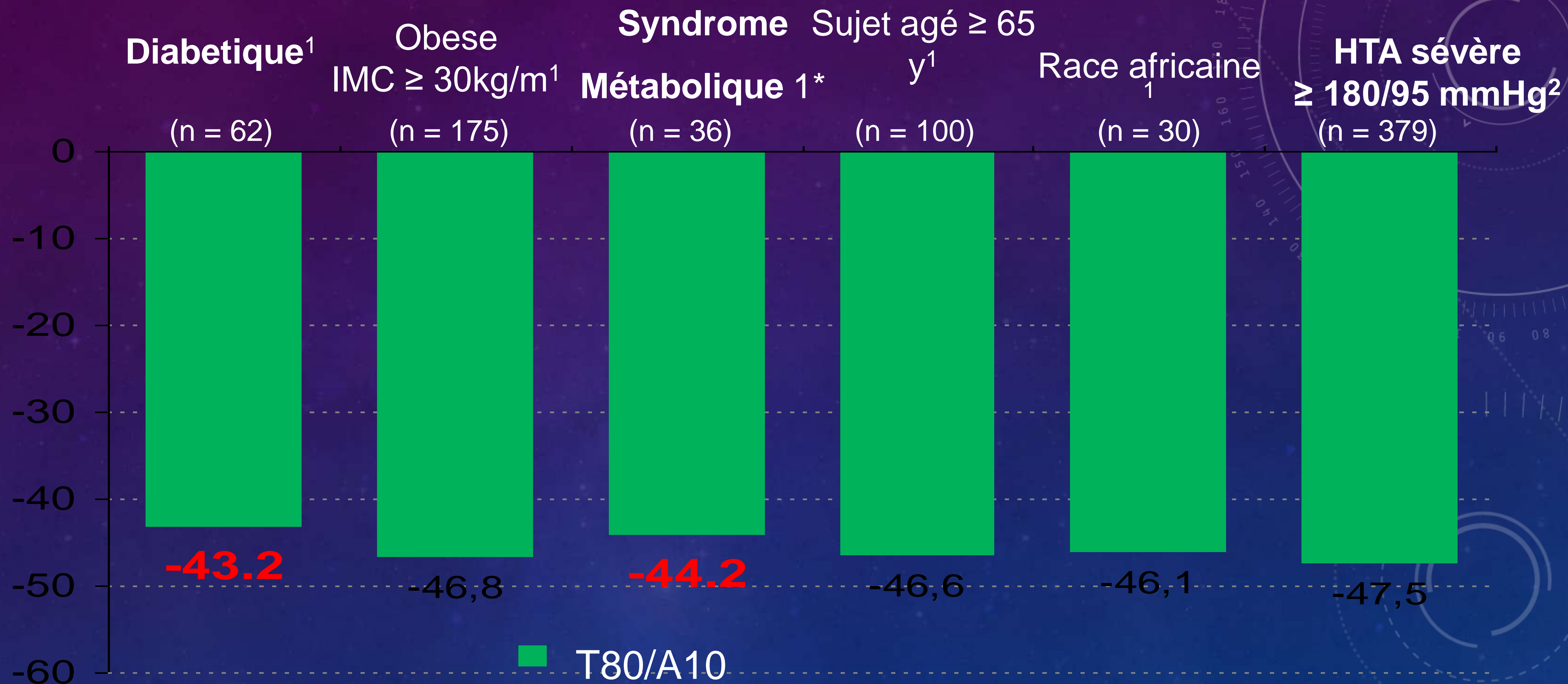
TElmisartan plus AMlodipine STudy-A

Programme des études TEAMSTA ®

Etudes	Objectifs
Phase III	
• 4x4 factorial design[1,2,3]	Combinations of T20–80 mg and A2.5–10 mg vs respective monotherapies in patients with stage 1 or 2 hypertension
• TEAMSTA-5[4]	T40–80/A5 single-pill combinations vs A5–A10 monotherapy in hypertensive patients not sufficiently controlled with A5 (DBP ≥ 90 mmHg)
• TEAMSTA-5 follow-up[5]	6-month follow-up of TEAMSTA-5 (long-term safety and efficacy)
• TEAMSTA-10[6]	T40–80/A10 single-pill combinations vs A10 monotherapy in hypertensive patients not sufficiently controlled with A10 (DBP ≥ 90 mmHg)
• TEAMSTA-10 follow-up[7]	6-month follow-up of TEAMSTA-10 (long term safety and efficacy)
Phase IIIb/IV	
• TEAMSTA severe[8]	T80/A10 single-pill combination vs T80 and A10 monotherapy in patients with severe hypertension (SBP ≥ 180 mmHg and DBP ≥ 95 mmHg)
• TEAMSTA diabetes[9,10]	T80/A10 single-pill combination vs A10 monotherapy in hypertensive diabetics
• TEAMSTA switch	Switch of RAS-I non-responders to telmisartan/amlodipine single-pill combinations
• TEAMSTA protect	Telmisartan/amlodipine vs olmesartan / HCTZ on endothelial dysfunction beyond BP

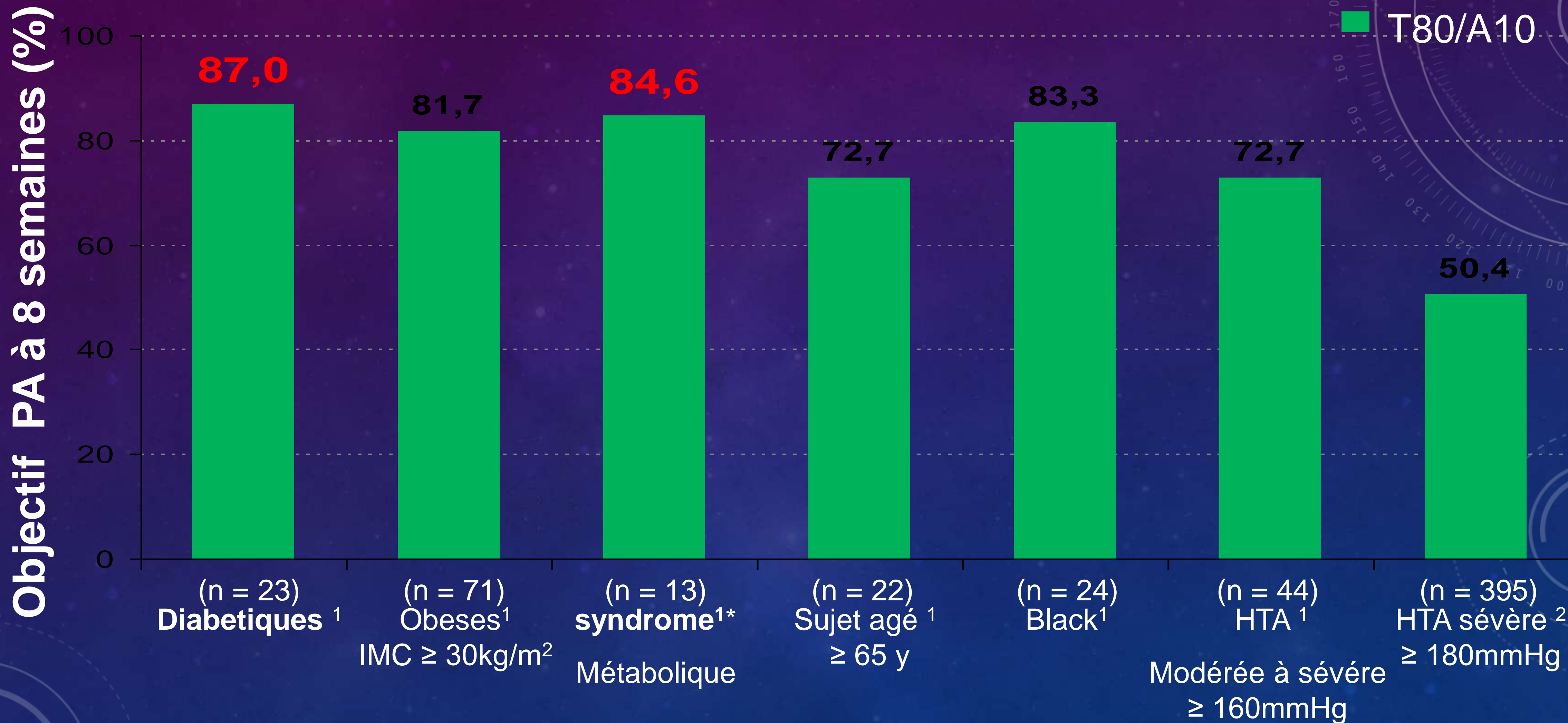
1. Littlejohn TW III, et al. *J Clin Hypertens.* 2009:11:207–213. 2. Littlejohn TW III, et al. *Postgrad Med.* 2009;121:5–14. 3.Guthrie et al. Curr Med Res Opin 2011 Sep 12. [Epub ahead of print]; 4. Neldam S et al. J Clin Hypertens (Greenwich) 2011 Jul;13(7):459-66; 5. Neldam S et al. J Hypertens 2010, 28 Suppl A, e475; Abstract PP.27.95; 6. Neldam S et al presentation ESH 2009(P911); 7. Neldam S et al. J Hypertens 2010, 28 Suppl A, e474; Abstract PP.27.90; 8. Neutel JM, et al. *J Clin Hypertens.* 2010 (ESH abstract & presentation); Neutel JM, et al. ASH 2010 abstract & poster presentation (LB-PO-10 r); 9. Sharma et al J Hypertens 2011, 29 Suppl A, e99; Abstract 7A.00; 10. Sharma et al J Hypertens 2011, 29 Suppl A, e279; Abstract PP.15.424

UNE RÉDUCTION SIGNIFICATIVE CHEZ LES HYPERTENDUS À RISQUE CV



Journal of clinical hypertension 2012;14:206-215

UN TAUX DE CONTRÔLE ÉLEVÉ (< 140/90 MMHG) CHEZ LES HYPERTENDUS À RISQUE CV



Journal of clinical hypertension 2012;14:206-215

ORIGINAL PAPER

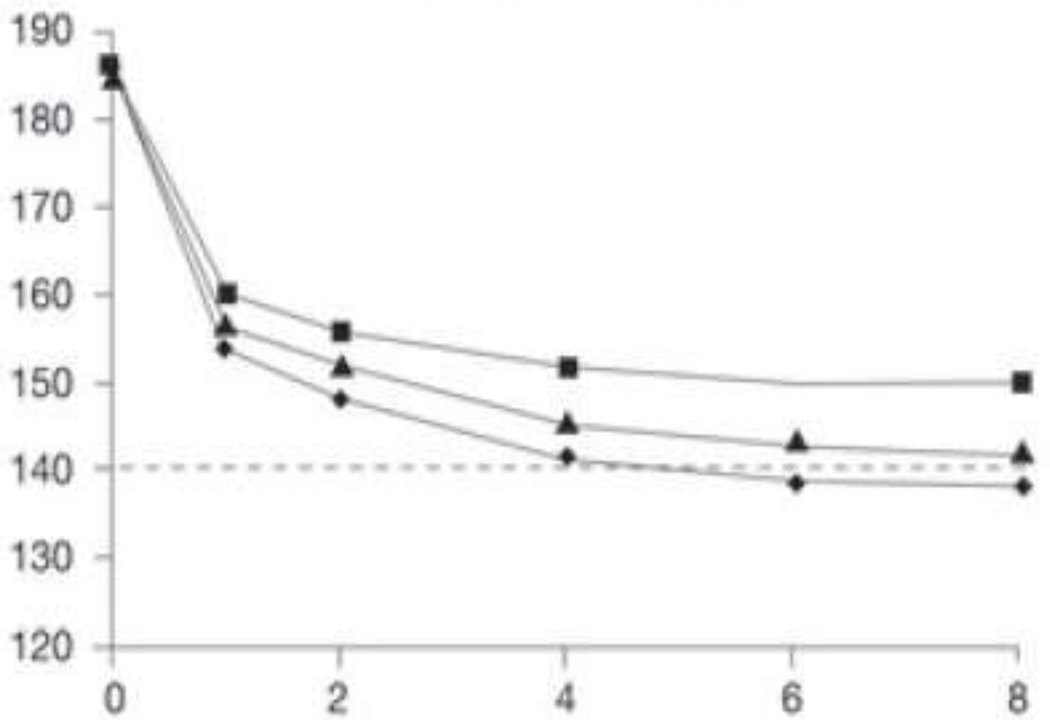
Single-Pill Combination of Telmisartan/Amlodipine in Patients With Severe Hypertension: Results From the TEAMSTA Severe HTN Study

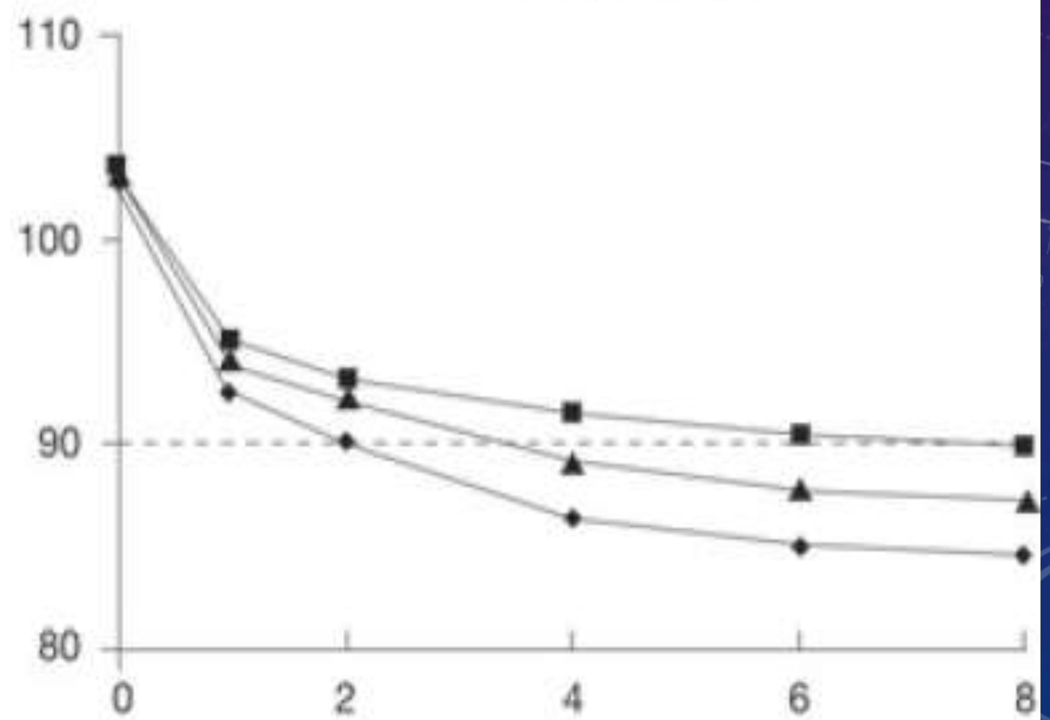
Joel M. Neutel, MD;[1] Giusepe Mancia, MD;[2] Henry R. Black, MD;[3] Bjorn Dahlöf, MD;[4] Holly Defeo, RN;[5] Ludwin Ley, MD;[6] Richard Vinisko, MS;[5] and on behalf of the TEAMSTA Severe HTN Study Investigators*

From the Orange County Research Center, Tustin, CA;[1] University of Milano-Bicocca, San Gerardo Hospital, Milan, Italy;[2] New York University School of Medicine, New York, NY;[3] Sahlgrenska University Hospital/Östra, Gothenburg, Sweden;[4] Boehringer Ingelheim Pharmaceuticals Inc, Ridgefield, CT;[5] and Boehringer Ingelheim GmbH & Co KG, Ingelheim, Germany[6]

PAS / PAD > 180 / 95 mm Hg

Journal of clinical hypertension 2012;14:206-215



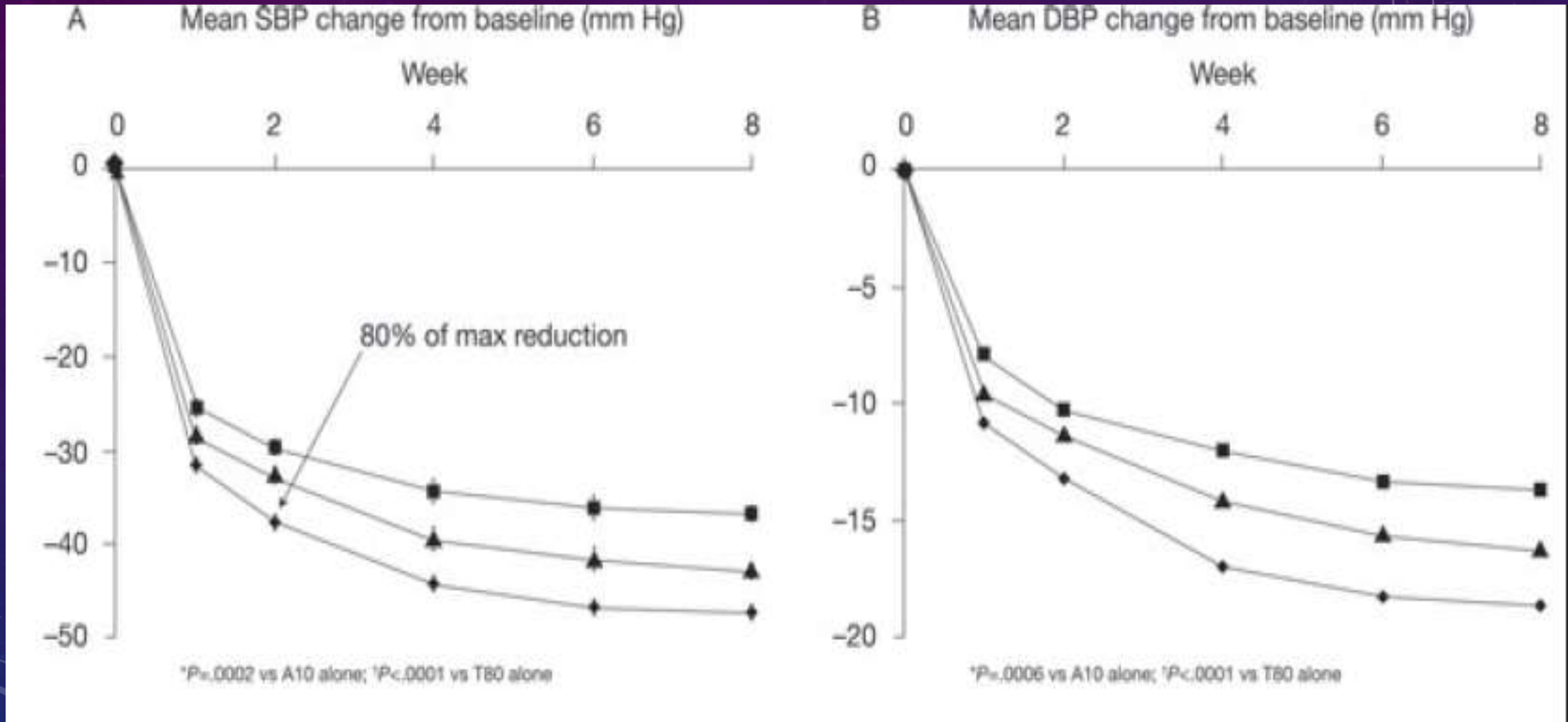


T80 (n=189) A10 (n=195) T80/A10 (n=379)

Recommended treatment goal <140/90 mm Hg

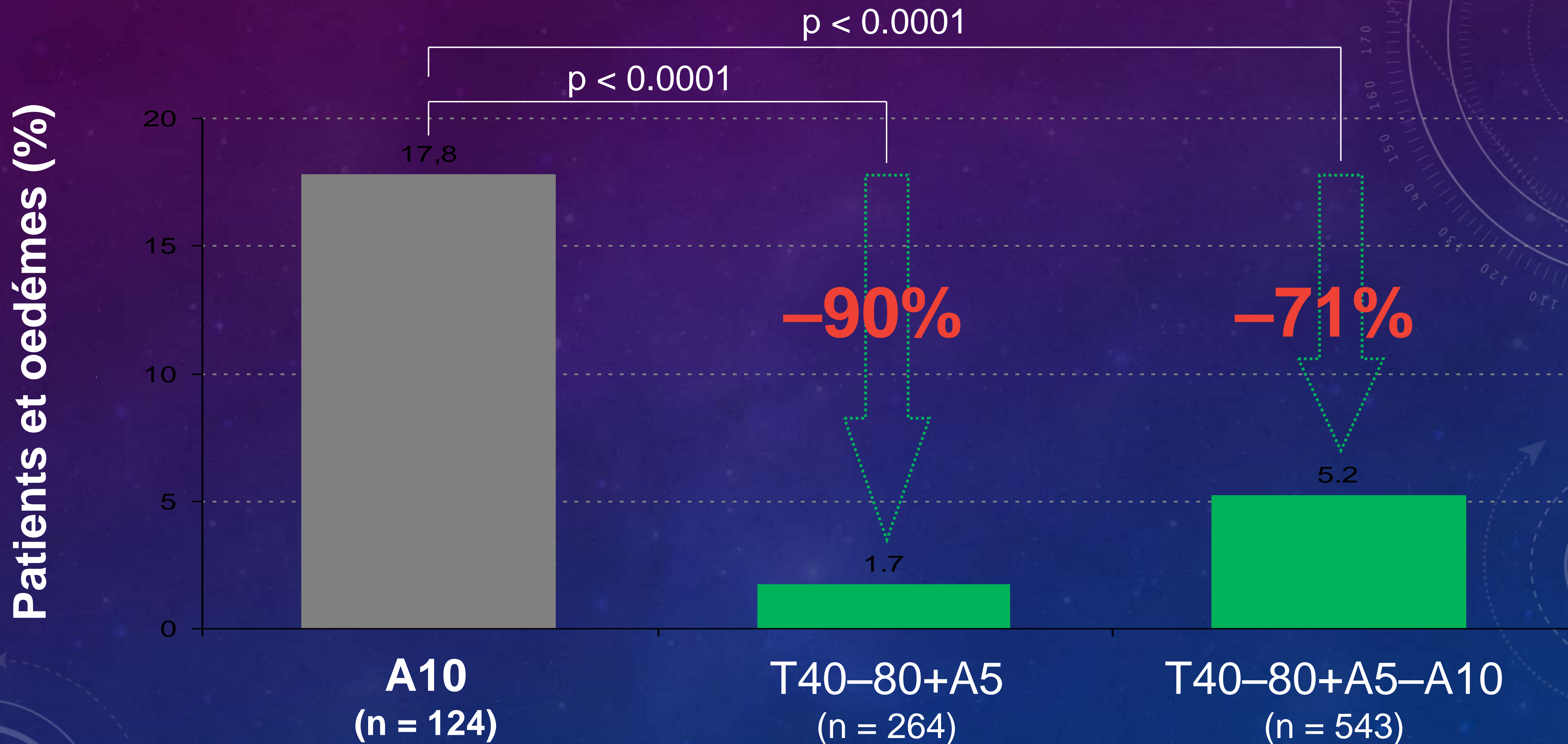
Journal of clinical hypertension 2012;14:206-215

80% effet maximum observé à 2 semaines



Journal of clinical hypertension 2012;14:206-215

BONNE TOLÉRANCE VIS À VIS DES OEDÉMES DES MEMBRES INFÉRIEURS



Littlejohn et al. *J Clin Hypertens.* 2009;11:207–213.

QUELLE CIBLE THÉRAPEUTIQUE CHEZ L'HYPERTENDU ?

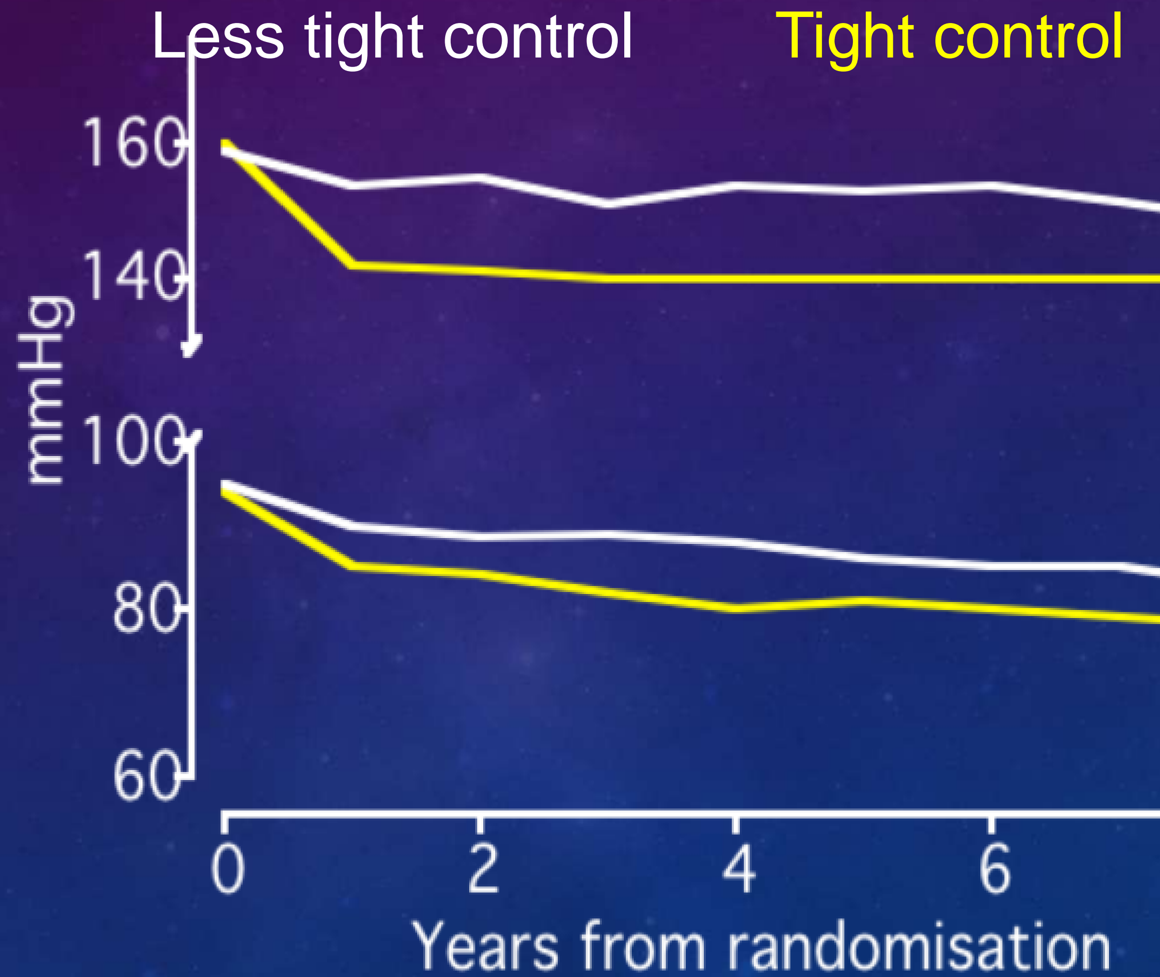
2007

< 130/80 mmHg si HTA + haut risque CVx

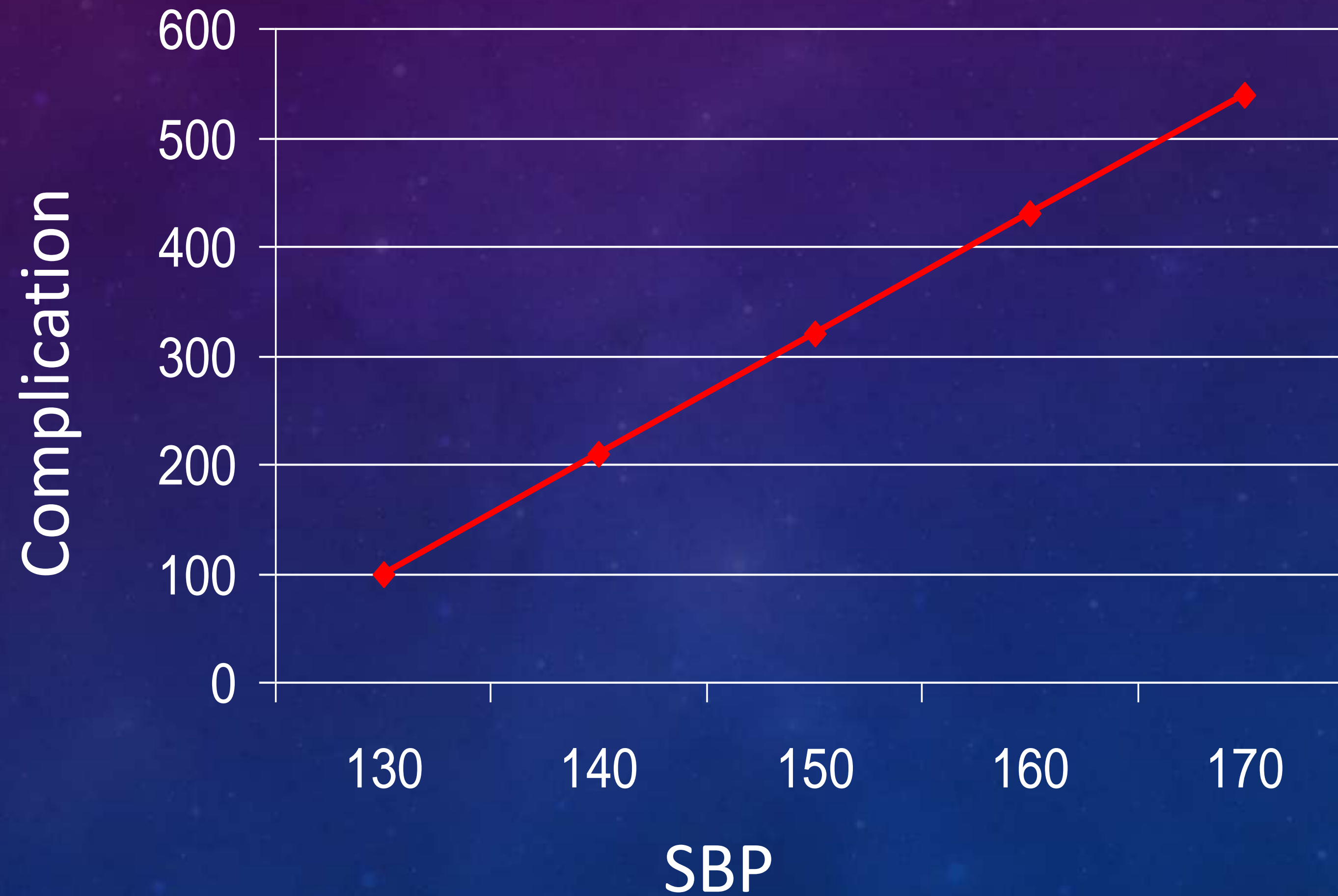
< 125/75 mmHg si nephropathie associée

Eur Heart J 2007, 28 : 88-36

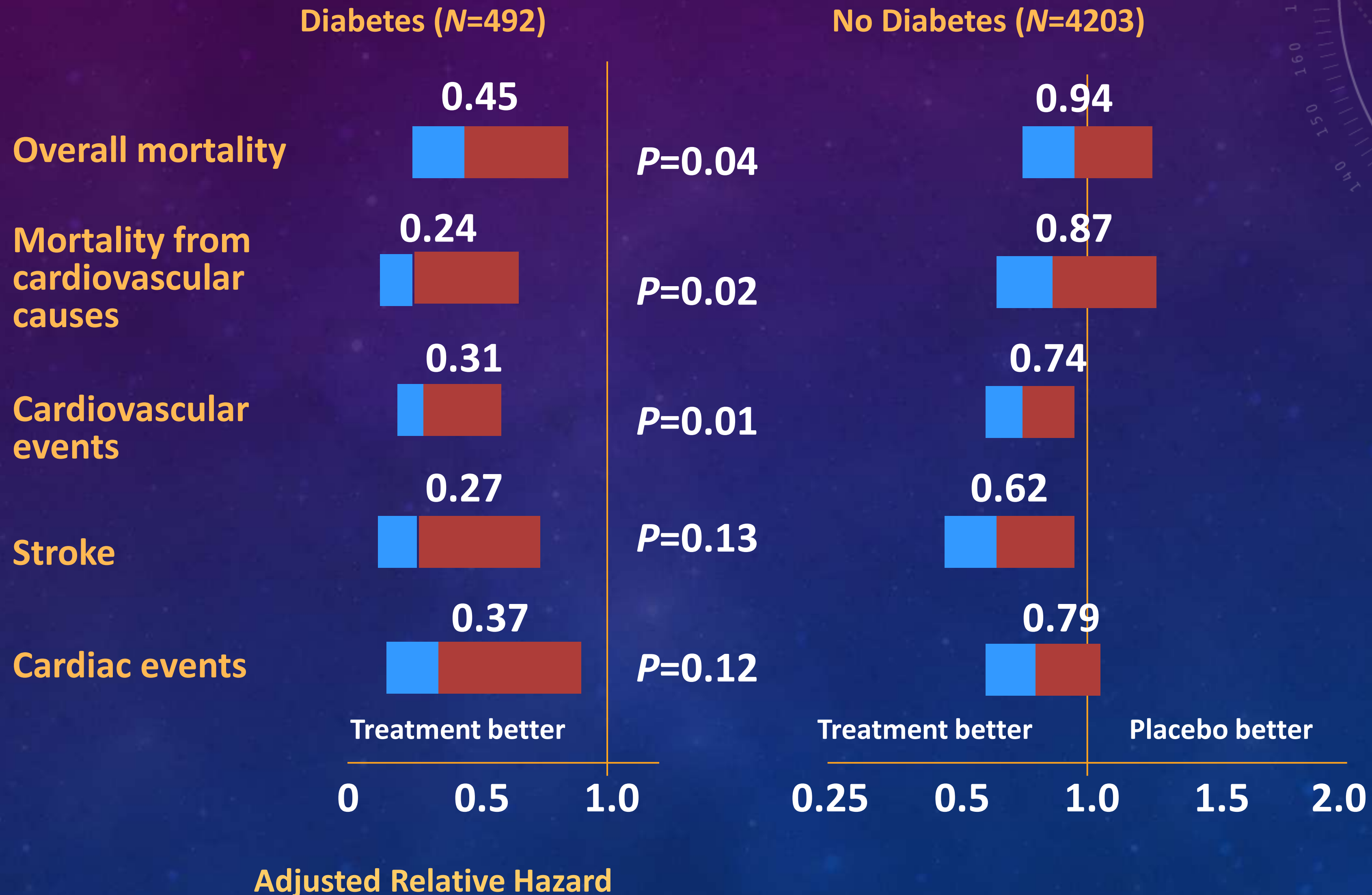
UKPDS - BLOOD PRESSURE
TIGHT VS LESS TIGHT CONTROL



UKPDS - LOWER BLOOD PRESSURE = LOWER RISK !



RÉDUCTION DU RISQUE – HYPERTENSION CIBLE=130/80 MM HG

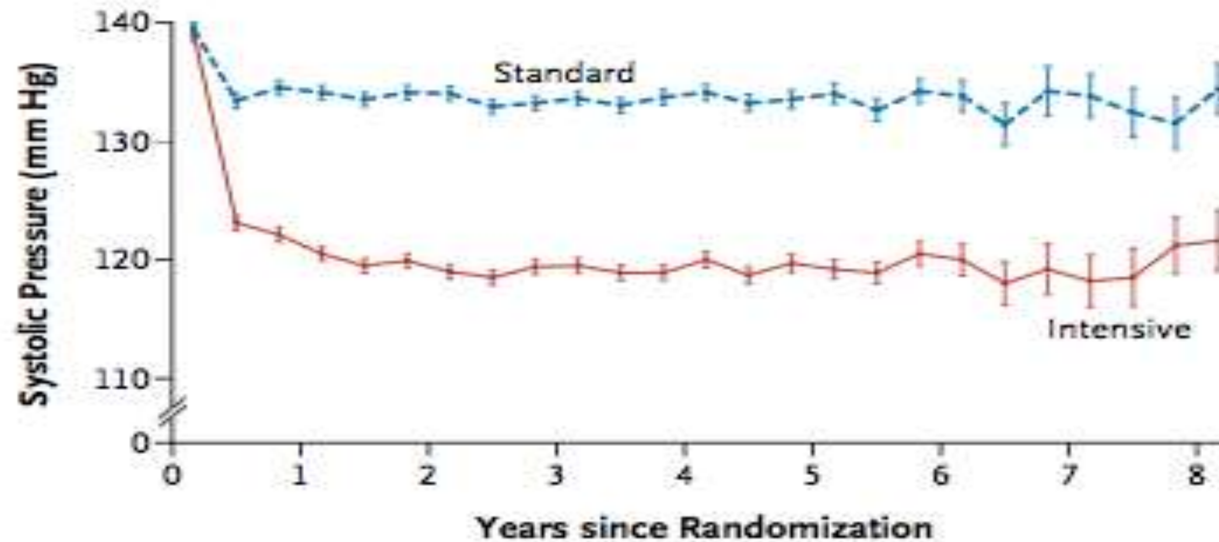


Tuomilehto J, *et al*, *NEJM* 1999;340(9):677-684.

ESC 2013 / JNC 8

Guideline	Population	Goal BP, mm Hg
2014 Hypertension guideline	General ≥60 y	<150/90
	General <60 y	<140/90
	Diabetes	<140/90
	CKD	<140/90
ESH/ESC 2013[37]	General nonelderly	<140/90
	General elderly <80 y	<150/90
	General ≥80 y	<150/90
	Diabetes	<140/85
	CKD no proteinuria	<140/90
	CKD + proteinuria	<130/90

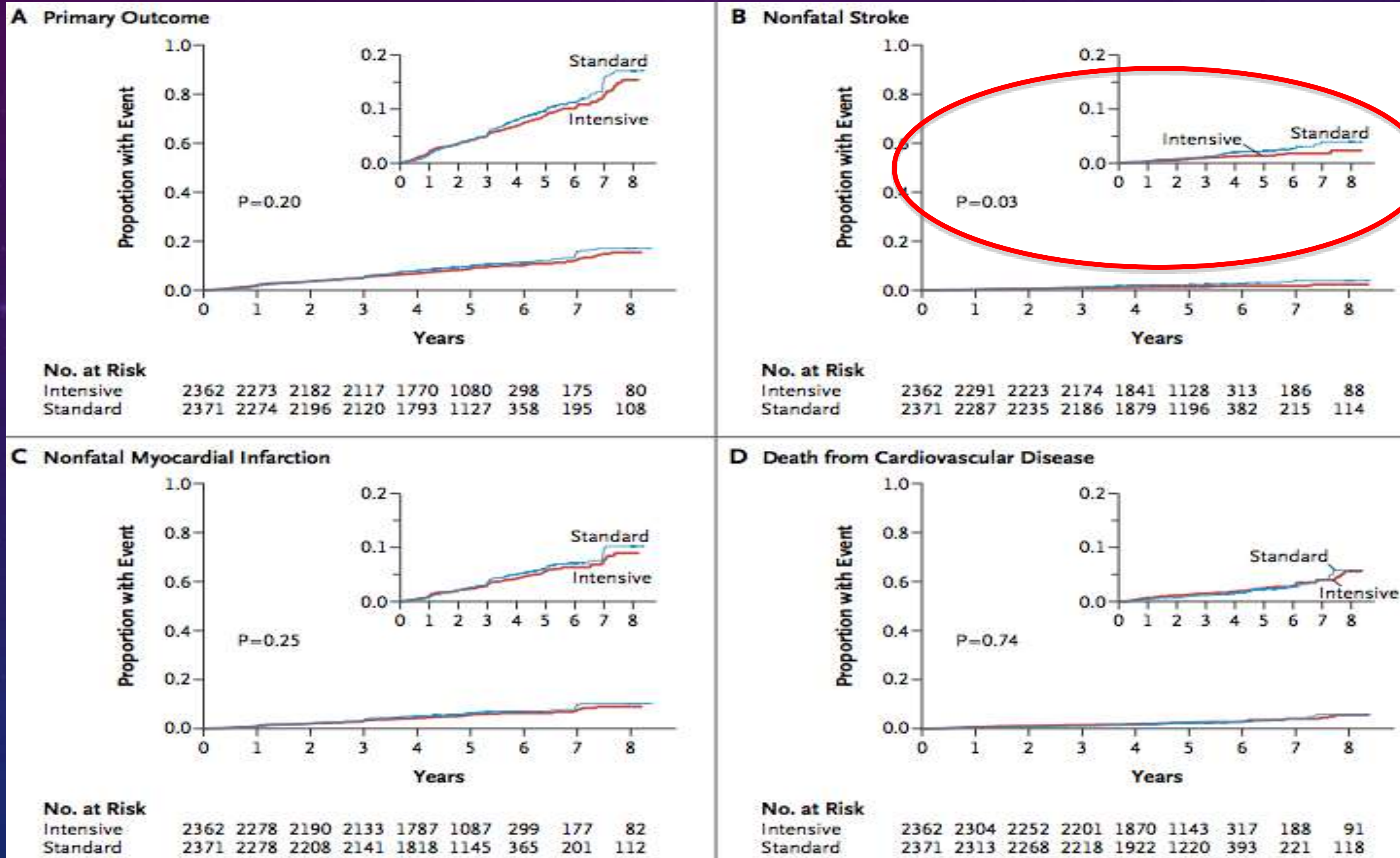
EFFECTS OF INTENSIVE BLOOD-PRESSURE CONTROL IN TYPE 2 DIABETES MELLITUS THE ACCORD STUDY GROUP*



Mean No. of Medications Prescribed								
Intensive	3.2	3.4	3.4	3.5	3.5	3.5	3.4	3.4
Standard	1.9	2.1	2.1	2.2	2.2	2.3	2.3	2.3
No. of Patients								
Intensive	2174	2071	1973	1792	1150	445	156	156
Standard	2208	2136	2077	1860	1241	504	203	201

N Engl J Med 2010

EFFECTS OF INTENSIVE BLOOD-PRESSURE CONTROL IN TYPE 2 DIABETES MELLITUSTHE ACCORD STUDY GROUP*



N Engl J Med 2010

APRÈS ….

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Randomized Trial of Intensive versus Standard Blood-Pressure Control

The SPRINT Research Group*

published on November 9, 2015, at NEJM.org.

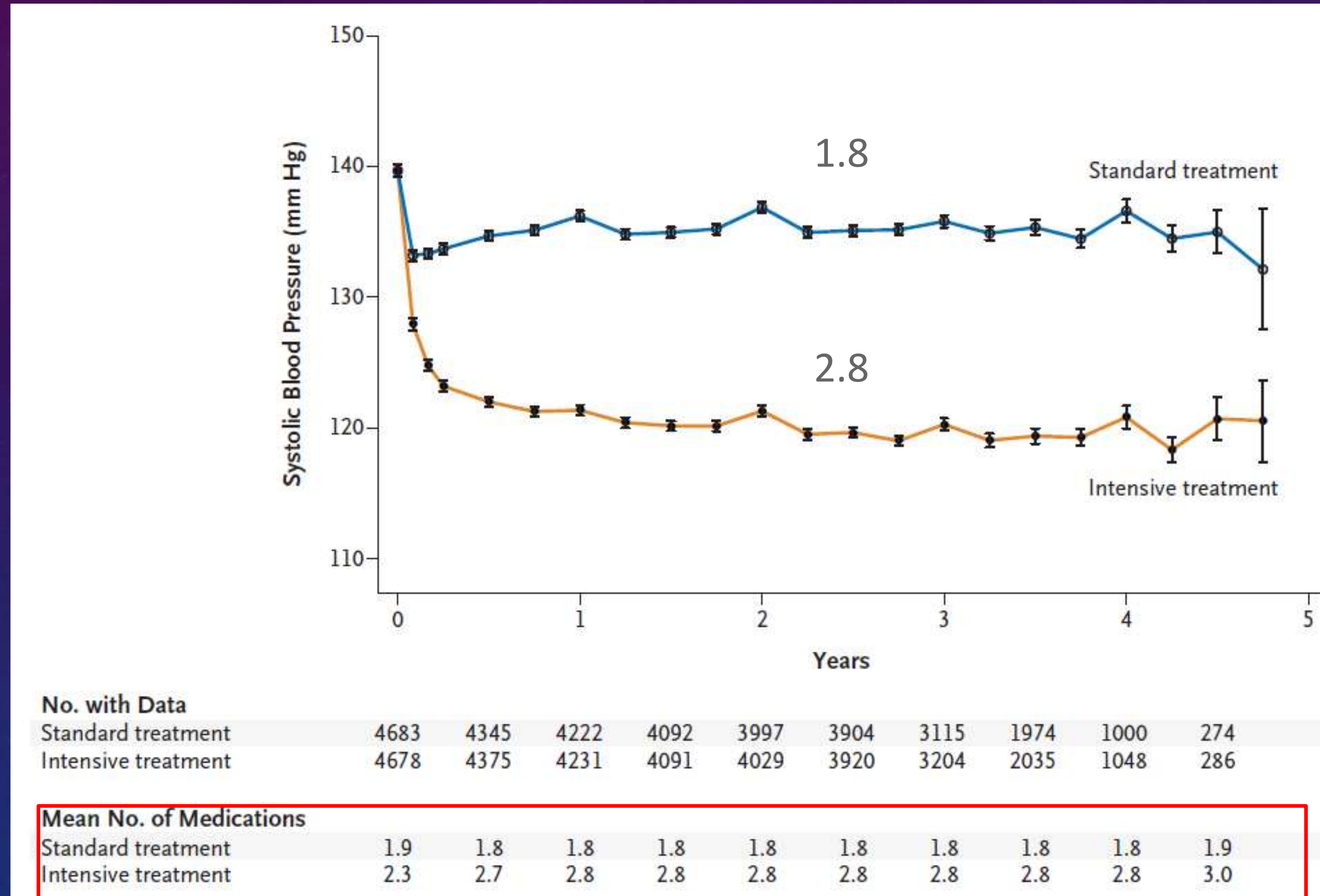
PARTICIPANTS

Participants were required to meet all the following criteria: an age of at least 50 years, a systolic blood pressure of 130 to 180 mm Hg, and an increased risk of cardiovascular events.

Characteristic	Intensive Treatment (N=4678)	Standard Treatment (N=4683)
Framingham 10-yr cardiovascular disease risk score — %	20.1±10.9	20.1±10.8
Body-mass index‖	29.9±5.8	29.8±5.7
Antihypertensive agents — no./patient	1.8±1.0	1.8±1.0
Not using antihypertensive agents — no. (%)	432 (9.2)	450 (9.6)
Age — yr		
Overall	67.9±9.4	67.9±9.5
Among those ≥75 yr of age	79.8±3.9	79.9±4.1

published on November 9, 2015, at NEJM.org.

EFFICACY ON SBP IN THE INTENSIVE TREATMENT GROUP IS OBTAINED WITH THE ADDITION OF 1 ANTIHYPERTENSIVE DRUG ON THE DRUG LIST

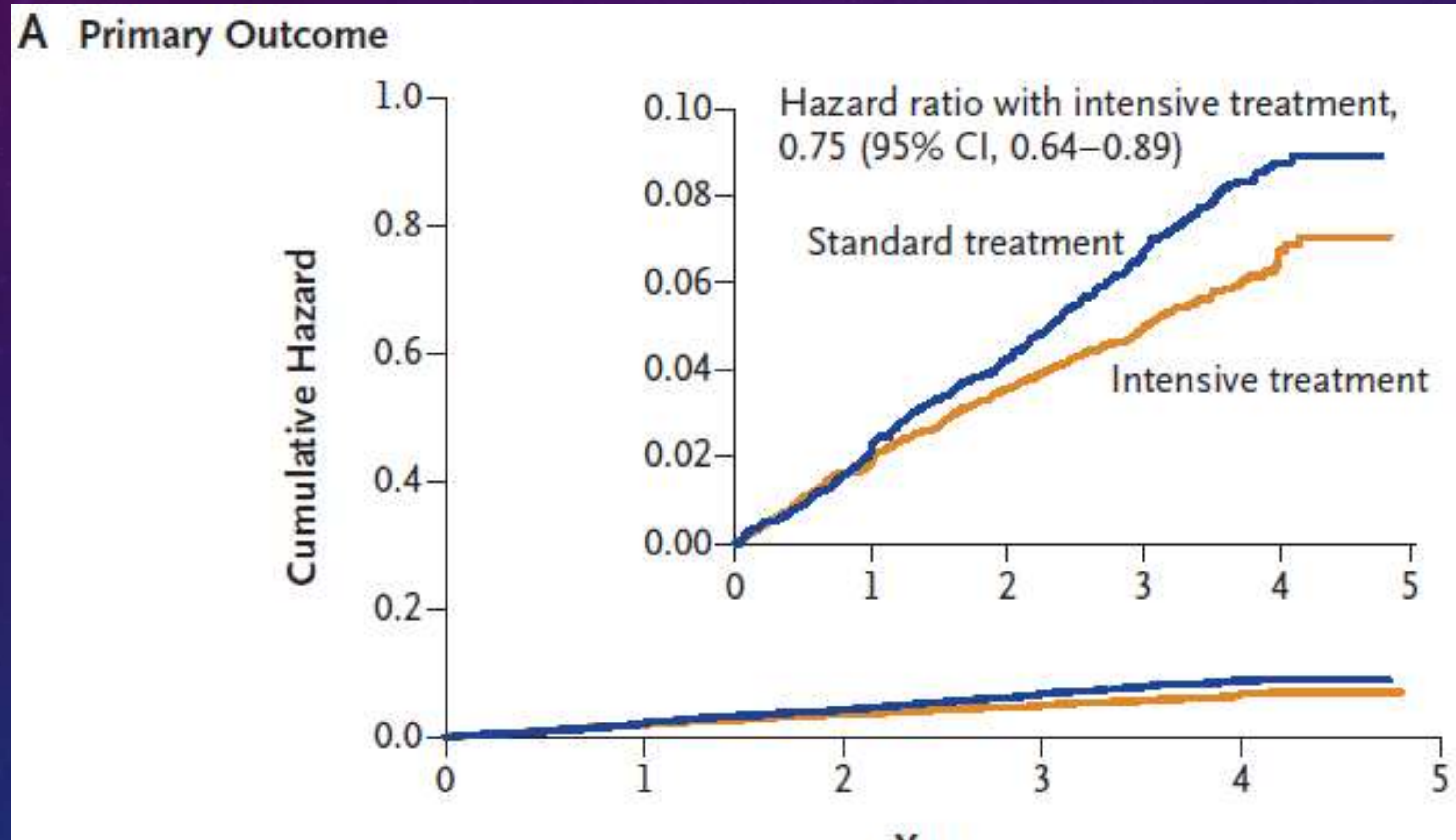


No. with Data										
Standard treatment	4683	4345	4222	4092	3997	3904	3115	1974	1000	274
Intensive treatment	4678	4375	4231	4091	4029	3920	3204	2035	1048	286

Mean No. of Medications										
Standard treatment	1.9	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9
Intensive treatment	2.3	2.7	2.8	2.8	2.8	2.8	2.8	2.8	2.8	3.0

The SPRINT Research Group* published on November 9, 2015, at NEJM.org.

CARDIOVASCULAR PREVENTION IS DEMONSTRATED AFTER 1 YEAR IN FAVOR OF INTENSIVE TREATMENT



The SPRINT Research Group* published on November 9, 2015, at NEJM.org.

SPRINT , EMPAREG ET LES MÉTA ANALYSES

A meta-analysis of 73,913 patients with DM reported that an SBP <130 mm Hg reduced stroke by 39%. However, there was no significant risk reduction for MI (23). Two meta-analyses addressing target BP in adults with DM restricted the analysis to RCTs that randomized patients to different BP levels (4, 7). Target BP of 133/76 mm Hg provided significant benefit compared with that of 140/81 mm Hg for major cardiovascular events, MI, stroke, albuminuria, and retinopathy progression (4). Several meta-analyses of RCTs included all trials with a difference in BP (24, 25), but 2 restricted their analyses to trials in which participants were randomized to different BP target levels (4, 7).

SPRINT demonstrated cardiovascular benefit from intensive treatment of BP to a goal of <120 mm Hg as compared with <140 mm Hg but did not include patients with DM. However, the results of ACCORD and SPRINT were generally consistent (26). In addition, a SPRINT substudy demonstrated that patients with prediabetes derived a benefit similar to that of patients with normoglycemia (8). Previous trials have shown similar quantitative benefits from lowering BP in persons with and without DM (9).

Hypertension

Whelton PK, et al.
2017 High Blood Pressure Clinical Practice Guideline

2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

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Kenneth A. Jamerson, MD#
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Jackson T. Wright, Jr, MD, PhD, FAHA##

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Categories of BP in Adults*

BP Category	SBP		DBP
Normal	<120 mm Hg	and	<80 mm Hg
Elevated	120–129 mm Hg	and	<80 mm Hg
Hypertension			
Stage 1	130–139 mm Hg	or	80–89 mm Hg
Stage 2	≥140 mm Hg	or	≥90 mm Hg

*Individuals with SBP and DBP in 2 categories should be designated to the higher BP category.

BP indicates blood pressure (based on an average of ≥2 careful readings obtained on ≥2 occasions, as detailed in Section 4); DBP, diastolic blood pressure; and SBP systolic blood pressure.

Whelton PK, et al.
2017 High Blood Pressure Clinical Practice Guideline

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A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

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Recommendations for BP Goal for Patients With Hypertension

References that support recommendations are summarized in Online Data Supplement 26 and Systematic Review Report.

COR	LOE	Recommendations
I	SBP: B-R^{SR} DBP: C-EO	1. For adults with confirmed hypertension and known CVD or 10-year ASCVD event risk of 10% or higher (see Section 8.1.2), a BP target of less than 130/80 mm Hg is recommended (1-5).
IIb	SBP: B-NR DBP: C-EO	2. For adults with confirmed hypertension, without additional markers of increased CVD risk, a BP target of less than 130/80 mm Hg may be reasonable (6-9).

QUELLE PLACE DE LA BITHÉRAPIE DANS LES RECOMMANDATIONS ?

NICE

Step	
Step 1	**A** (for patients aged <55 years) or **C*** (for patients aged ≥55 years and all black people of African or Caribbean descent)
Step 2	**A + C***
Step 3	**A + C + D**
Step 4	**Resistant hypertension** **A + C + D + further diuretic†** (or α blocker or β blocker if further diuretic treatment is not tolerated or is contraindicated or ineffective) Consider seeking specialist advice

Key

A = Angiotensin converting enzyme inhibitor or angiotensin II receptor blocker

C = Calcium channel blocker

D = Thiazide-like diuretic

* Calcium channel blocker preferred, but consider thiazide-like diuretics in people with oedema or high risk of heart failure

† Consider low dose spironolactone or higher doses of thiazide-like diuretic

BMJ 2011;343:d4891

Initiation du traitement par des associations à doses fixes

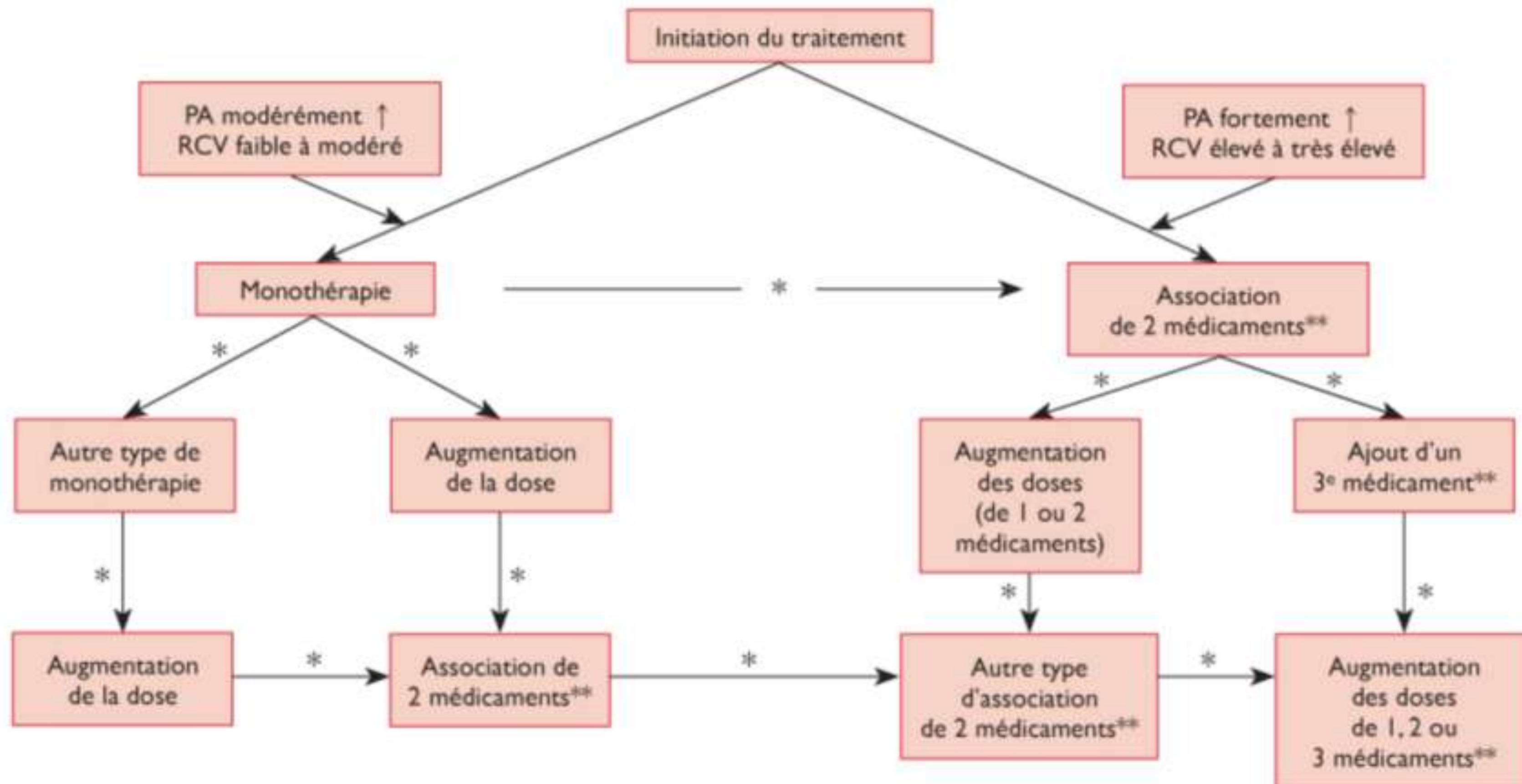

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Table 6. Categories of BP in Adults*

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Normal	<120 mm Hg	and	<80 mm Hg
Elevated	120–129 mm Hg	and	<80 mm Hg
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*Individuals with SBP and DBP in 2 categories should be designated to the higher BP category.
BP indicates blood pressure (based on an average of ≥2 careful readings obtained on ≥2 occasions, as detailed in Section 4); DBP, diastolic blood pressure; and SBP systolic blood pressure.

Recommendations for Choice of Initial Monotherapy Versus Initial Combination Drug Therapy*

COR	LOE	Recommendation
I	C-EO	1. Initiation of antihypertensive drug therapy with 2 first-line agents of different classes, either as separate agents or in a fixed-dose combination, is recommended in adults with stage 2 hypertension and an average BP more than 20/10 mm Hg above their BP target.
IIa	C-EO	2. Initiation of antihypertensive drug therapy with a single antihypertensive drug is reasonable in adults with stage 1 hypertension and BP goal <130/80 mm Hg with dosage titration and sequential addition of other agents to achieve the BP target.

CONCLUSION

- L'HTA est fréquemment associée à un niveau de risque CVx élevé
- La cible thérapeutique de l' HTA est de 130/80 mmhg
- Le taux de contrôle de l'HTA chez les patients à haut risque est encore faible
- Souvent nécessité de deux médicaments ou plus pour contrôler l'HTA
- Beaucoup de progrès ont été fait dans le traitement de l'HTA pour réduire le niveau de risque CVx