AβYSS

Assessment of βeta blocker interruption one Year after an uncomplicated myocardial infarction on Safety and Symptomatic cardiac events requiring hospitalization

Johanne SILVAIN, Guillaume CAYLA, Emile FERRARI, Grégoire RANGE, Etienne PUYMIRAT, Nicolas DELARCHE, Paul GUEDENEY, Eric VICAUT, Gilles MONTALESCOT on behalf of the ABYSS investigators of the ACTION Study Group.

Pr Johanne SILVAIN - August 30th, 2024

In memoriam of Jean-Philippe Collet who actively participated in the trial as investigator and Steering Committee member

Disclosures

Pr Johanne SILVAIN declares the following financial relationship, all outside the scope of this trial.

Consulting Fees or Lecture Fees: Biotronik ; Sanofi Aventis, CSL Behring S.A.

Travel Support, Hospitality: Abbott Medical, Biotronik , Medtronic, Novo Nordisk.

Proctoring : Abbott Medical

Stockholder: 4P-Pharma

Background

- The historical benefit of treatment with β-blocker (βB) after a myocardial infarction (MI) is being questionned in our era of modern reperfusion strategies.

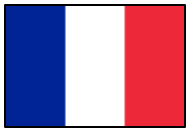
- The safety of the interruption of chronic βB treatment is unknown.

Hypothesis

- βB interruption among patients with a history of MI , preserved LVEF (>40%), would be clinically safe and improve patients' quality of life (QoL).

Methods

- Academic, multicenter, open label, randomized, non-inferiority trial conducted at 49 sites in France.



Study Organization

Academic Research Organization

- Pr Gilles MONTALESCOT (Scientific Director)
- Pr Johanne SILVAIN (Principal Investigator)
- Pr Eric VICAUT (Méthodologist-statistician)
- Abdourahmane DIALLO (Independent Statistician)
- Karine BROCHARD (Project Manager)
- Nathalie KINGUE ELESSA (Project Manager)

Steering Committee

- Pr Johanne SILVAIN (Paris, France)
- Pr Gilles MONTALESCOT (Paris, France)
- Pr Eric VICAUT (Paris, France)
- Pr Guillaume CAYLA (Nîmes, France)
- Pr Emile FERRARI (Nice, France)
- Dr Paul GUEDENEY (Paris, France)
- Dr Grégoire RANGE (Chartres, France)
- Pr Etienne PUYMIRAT (Paris, France)
- Dr Nicolas DELARCHE, (Pau, France)

Administrative Sponsor

Assistance Publique - Hôpitaux de Paris

- Marine CAMUS – Pôle Promotion
- Naouel BENAHMED – Pôle Vigilance
- Dr Priscilla ANDRIAMIANDRISOA – Pôle Vigilance

Funding

PHRC 2015 – French Ministry of Health & ACTION Group

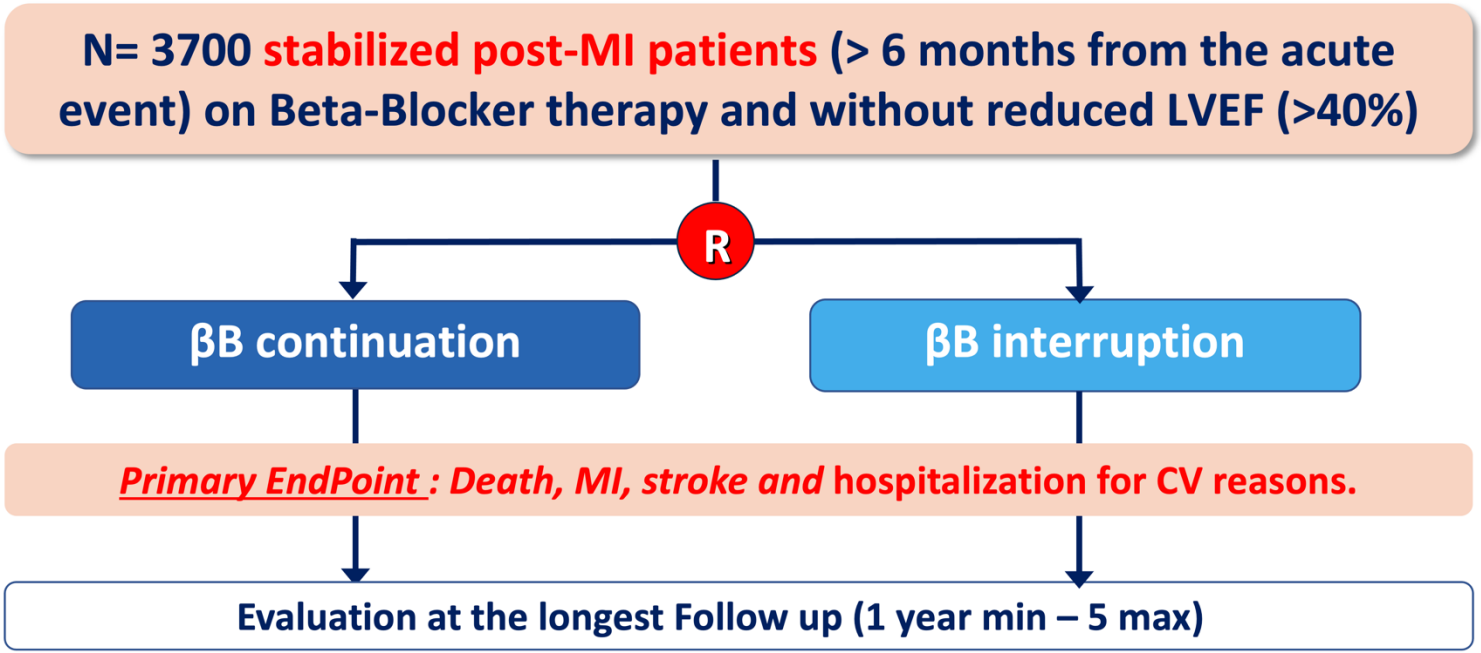
Data Safety Member Board

- Pr. Nicolas DANCHIN – Chair
- Pr. Jean-Marc DAVY
- Pr. Patrick MISMETTI

Clinical Events Committee

- Pr Michel SLAMA (Paris) – Chairman
- Dr Raphaëlle DUMAINE (Paris)
- Dr Laurent PAYOT (St Brieuc)
- Dr Karim AACHA (Paris)
- Dr Mohamad EL KASTY (Jossigny)

Study Design



NCT03498066 - EUDRACT No: 2017-003903-23

Inclusion Criteria

1. Patients ≥ 18 years of age
2. Current treatment with βB
3. Prior acute MI ≥ 6 months before randomization

Exclusion Criteria

1. Recent ACS (<6 months)
2. Altered LVEF <40%
3. Other primary indication for βB
- Uncontrolled high blood pressure (HBP)
- Prior episode of heart failure in the past 2 years
- Persistent angina or ischemia
- Prior episode of ventricular or supraventricular arrhythmia in the past year

Outcomes

Primary end point : Death, MI, stroke, or hospitalization for cardiovascular (CV) reasons

Main secondary end point : Change in QoL as measured by the European Quality of Life–5 Dimensions (EQ5D) questionnaire

Other secondary end points :

- Death, MI, stroke
- Death, MI, stroke, or hospitalization for heart failure
- Blood pressure and heart rate control

Clinical endpoints were evaluated at 6 months, 12 months and every year until the longest follow-up (minimum, 1 year).

Silvain J. et al. Am Heart J. 2023 epub Jan 20

Analysis Plan and Power

- 80% power to test the non-inferiority hypothesis for a prespecified margin of **3% in absolute risk difference** assuming overall event rate of 12%

- Sample size 3700 participants

- **Non-inferiority study** based on concordance of conclusions made in both ITT and PP populations，two-sided test with alpha=0.05, log-binomial regression model using multiple imputation

Silvain J. et al. Am Heart J. 2023;258:168-176

Key Baseline Characteristics

	βB INTERRUPTION N = 1846	βB CONTINUATION N = 1852
Age — yr	63.5 ± 11.2	63.5 ± 10.9
Male sex — no. (%)	1530 (82.9)	1531 (82.6)
Hypertension — no. (%)	786 (42.6)	805 (43.4)
Diabetes — no. (%)	372 (20.1)	375 (20.2)
Past medical history		
ST-segment elevation MI — no. (%)	1168 (63.3)	1162 (62.7%)
Median duration between MI and randomization (IQR)— yr	2.9 (1.2—6.2)	2.8 (1.1—6.6)
Revascularization for the MI event — no. (%)	1755 (95.1)	1757 (94.8)
Health status at baseline		
Median LVEF at randomization (IQR) — %	60 (52—60)	60 (52—60)
Patients with LVEF between 40 to 50% — no. (%)	430 (23.3)	435 (23.5)
Residual angina — no. (%)	21 (1.1)	30 (1.6)
Median Heart Rate (IQR)— BPM	63 (57—71)	63 (57—71)
Median systolic blood pressure (IQR)— mm Hg	132 (121—144)	131 (121—144)
Median diastolic blood pressure (IQR) — mm Hg	77 (70—83)	77 (70—83)
LDL cholesterol - Median (IQR) - mg/dl	70 (56—91)	73 (56—95)

Follow up

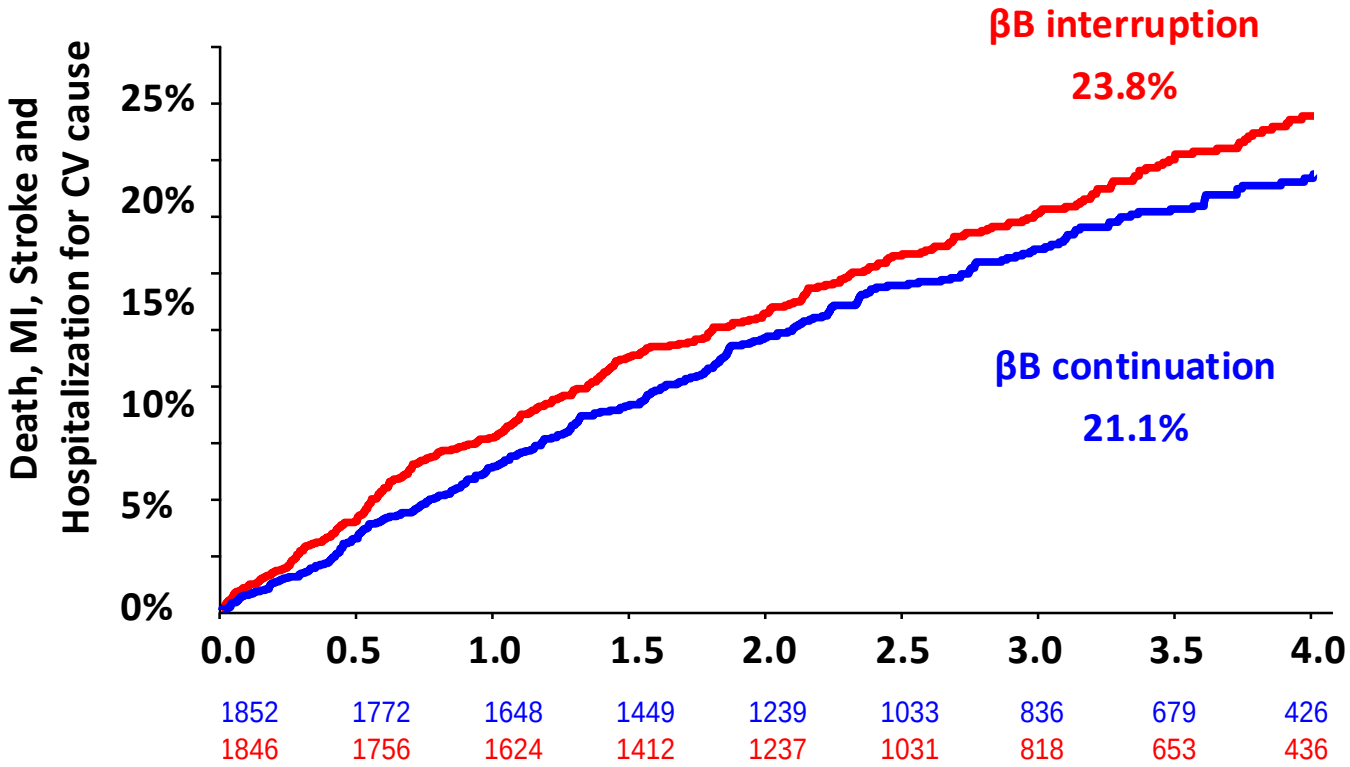
- Randomization between **August 28, 2018**, and **September 12, 2022**; scheduled recruitment continued during the coronavirus disease 2019 pandemic and lockdown in France.

- Patients were followed for a **median of 3.0 years** (interquartile range, 2.0 to 4.0) up to 5 years (minimum one year).

- **Low rate of cross over (5.7%)** from one strategy to the other (209 patients) and was more frequent in the interruption group (158 patients [**8.6%**]) than in the continuation group (51 patients [**2.8%**]).

Primary Results

Primary Outcome

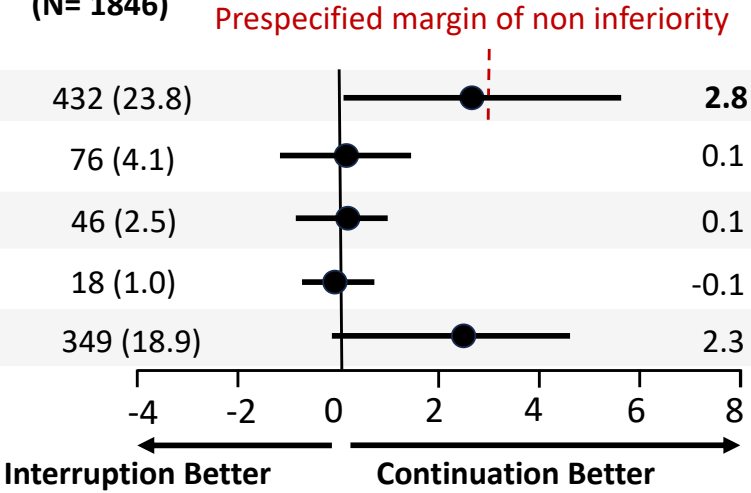


ITT
HR 1.16
(95% CI) 1.01 to 1.33
p = 0.44 for non-inferiority

Per Protocol
HR 1.06
(95% CI) 0.92 to 1.22
p = 0.09 for non-inferiority

Primary Outcome Components

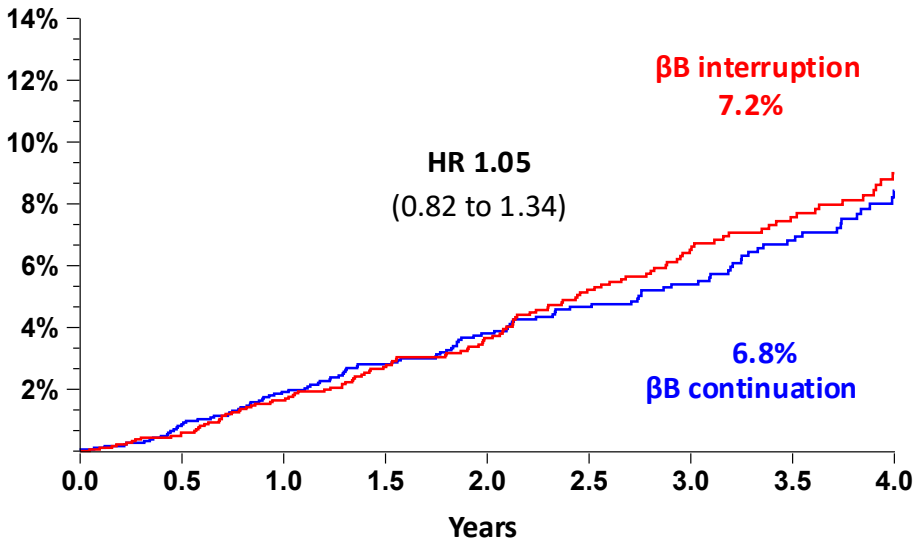
End Points	Beta-Blocker Continuation (N=1852)	Beta-Blocker Interruption (N= 1846)	Risk Difference (95% CI) (percentage points)
Primary Endpoint	384 (21.1)	432 (23.8)	**2.8 (<1 to 5.5)**
Death	74 (4.0)	76 (4.1)	0.1 (-1.2 to 1.4)
Myocardial Infarction	44 (2.4)	46 (2.5)	0.1 (-0.9 to 1.1)
Stroke	19 (1.0)	18 (1.0)	-0.1 (-0.7 to 0.6)
Hospitalisation for cardiovascular reason	307 (16.6)	349 (18.9)	2.3 (-0.1 to 4.8)



Interruption of βB treatment was **NOT non-inferior** to a strategy of βB continuation

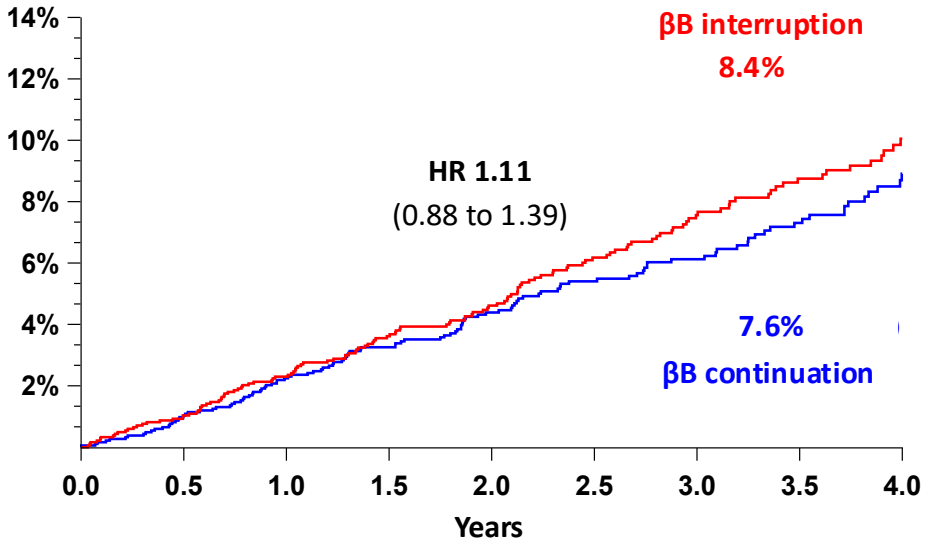
Secondary Outcomes

Death, MI, Stroke



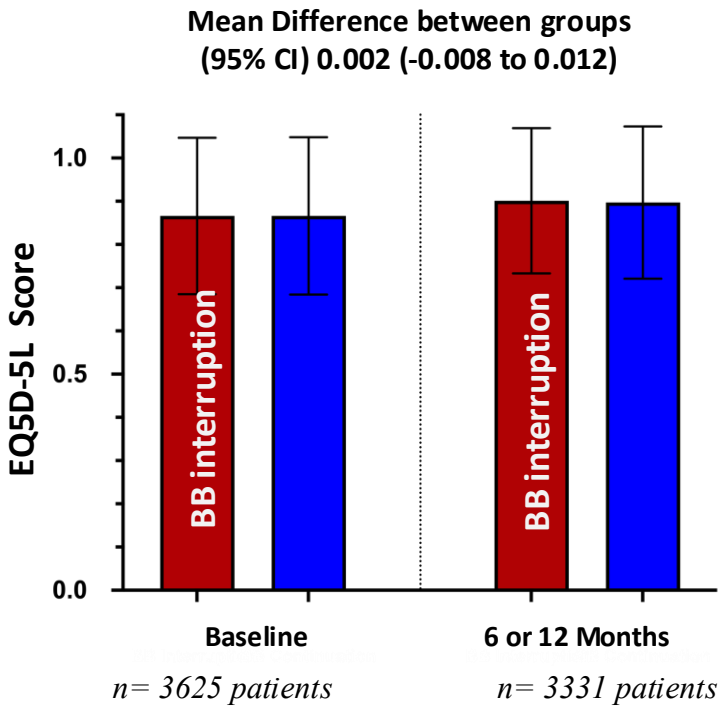
1852	1817	1724	1541	1344	1127	909	723	429
1846	1821	1729	1545	1360	1141	899	715	441

Death, MI, Stroke and Hospitalization for Heart Failure



1852	1814	1718	1533	1334	1117	902	720	429
1846	1813	1717	1530	1344	1125	888	706	440

Quality of Life



No improvement of Quality of Life

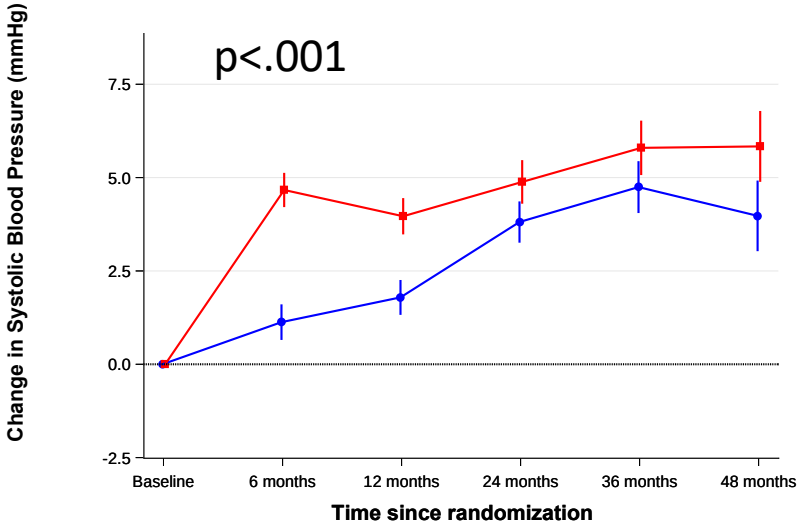
Hospitalization

End points — no. (%)	βB interruption N = 1846	βB continuation N = 1852
Hospitalization for cardiovascular reason	**349 (18.9%)**	**=307 (16.6%)**
Coronary-related reasons	**263 (14.2)**	**221 (11.9)**
Angina/ischemia	67 (3.6)	55 (3.0)
Angiography	146 (7.9)	117 (6.3)
Percutaneous coronary intervention	90 (4.9)	84 (4.5)
Coronary artery bypass graft surgery	4 (0.2)	4 (0.2)

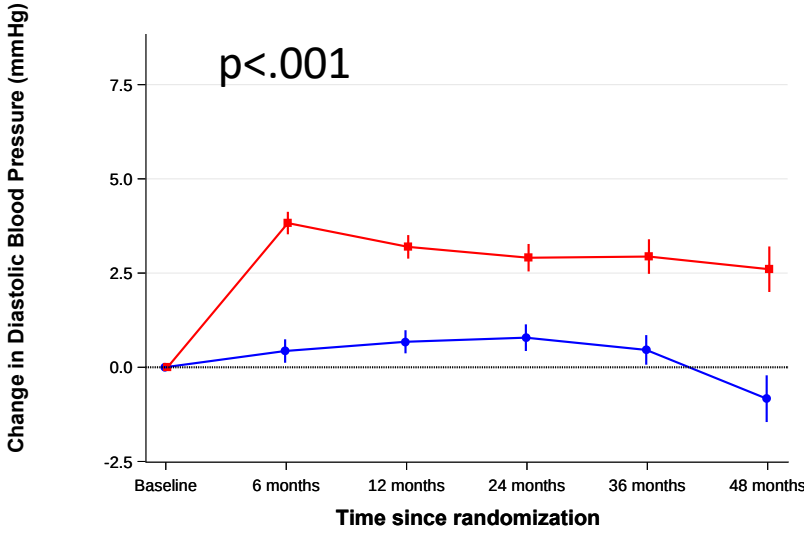
Higher rate of coronary-related reasons

Secondary Results

Effect of βB interruption on Blood Pressure



No. with Data						
ß-blocker continuation	1813	1323	1414	1072	727	413
ß-blocker interruption	1810	1413	1441	1067	719	408



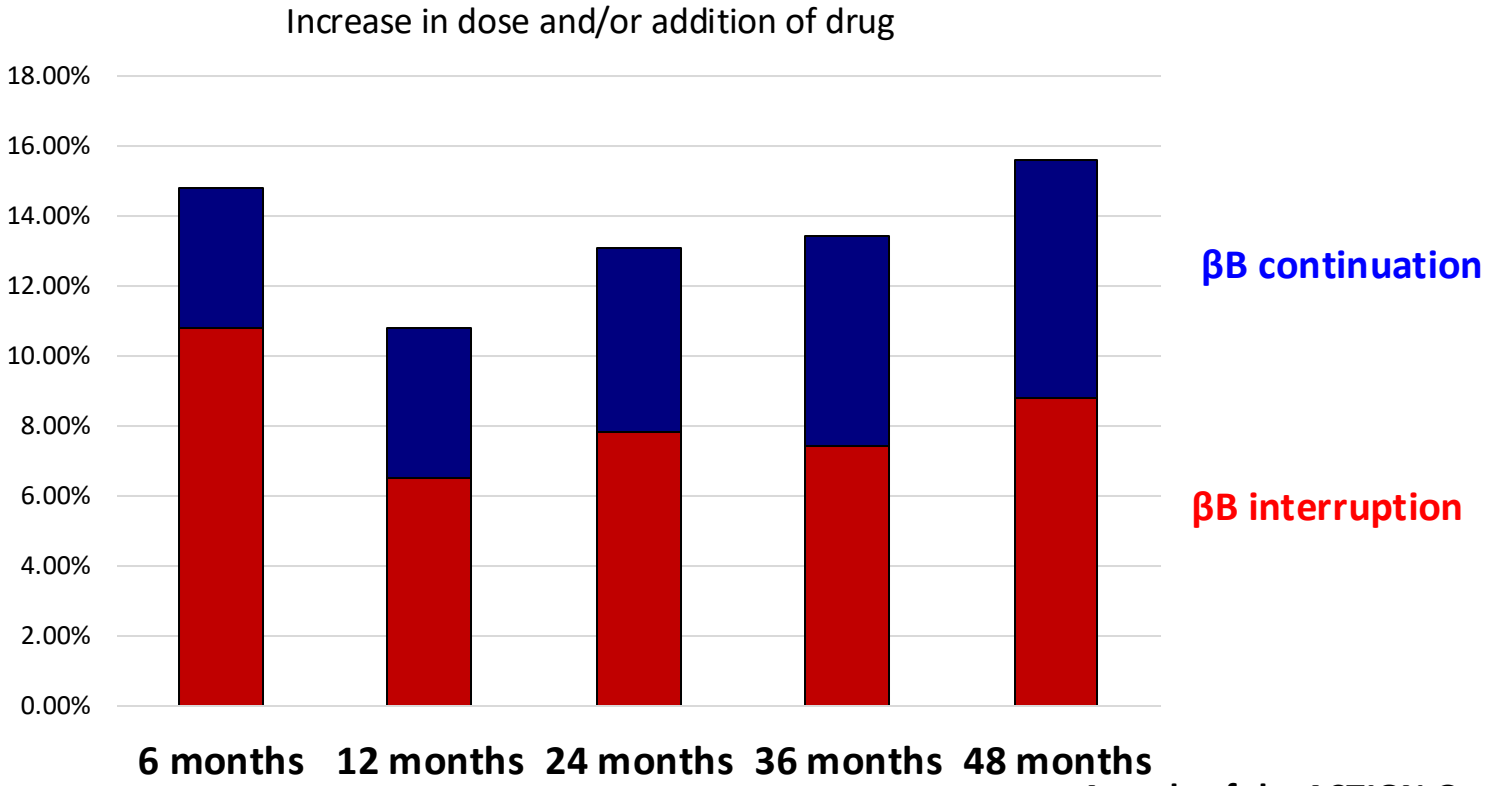
No. with Data						
ß-blocker continuation	1814	1321	1413	1072	726	412
ß-blocker interruption	1810	1413	1440	1068	719	408

βB interruption group at 6 months resulted in an increase of :

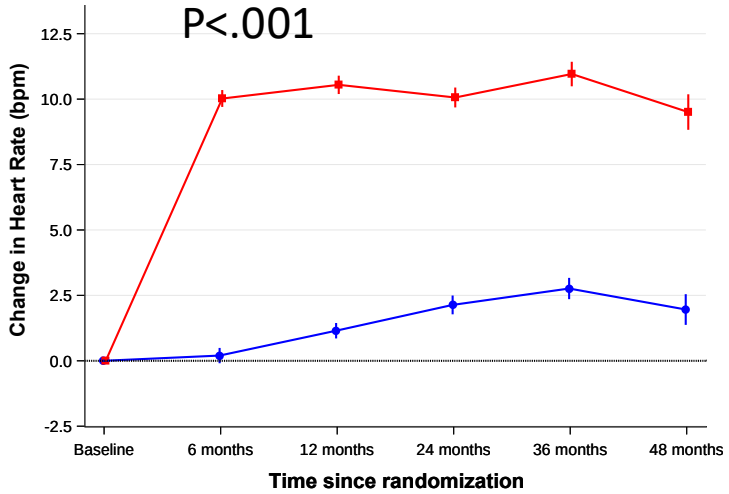
+ 3.7 mmHg Systolic Blood Pressure [2.6, 4.8 mmHg]; p<.001

+ 3.9 mmHg Diastolic Blood Pressure [3.0, 4.0 mmHg]; p<.001

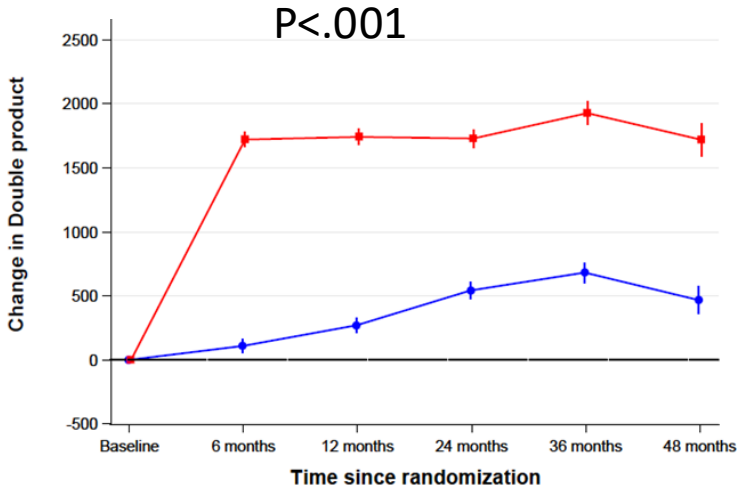
Any increase of antihypertensive therapy



Effect of βB interruption on Heart Rate control



No. with Data						
ß-blocker continuation	1815	1312	1402	1040	708	394
ß-blocker interruption	1808	1409	1415	1046	679	394



No. with Data						
ß-blocker continuation	1789	1280	1369	1019	689	387
ß-blocker interruption	1791	1379	1391	1026	673	382

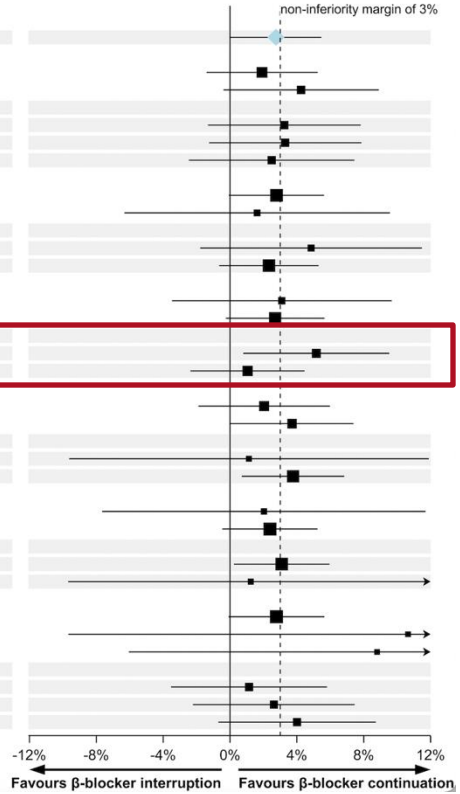
βB interruption group at 6 months resulted in an increase of :

+ 9.8 bpm Resting Heart Rate [9.1, 10.6 bpm] , P<.001

+1616 Double Product (SBP x HR)[1484, 1749], P<.001

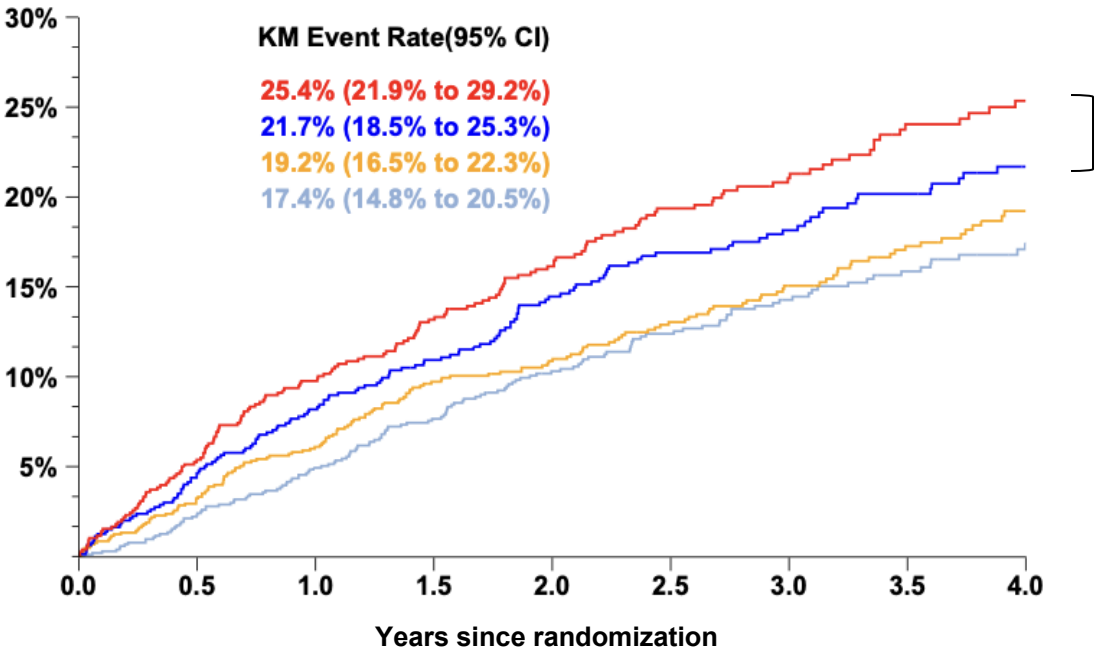
Prespecified Subgroup

Subgroup	β-blocker interruption events/total (%)	β-blocker continuation events/total (%)	Risk difference (95% CI)
Overall	432/1812 (23.8)	384/1821 (21.1)	2.8 (0.0 to 5.5)
Last MI before randomization			
STEMI	250/1148 (21.8)	227/1143 (19.9)	1.9 (-1.4 to 5.2)
NSTEMI	182/664 (27.4)	157/678 (23.2)	4.3 (-0.4 to 8.9)
Time between last MI and randomization, tertiles			
T1, <1.6 years	131/588 (22.3)	118/620 (19.0)	3.2 (-1.3 to 7.8)
T2, 1.6 to <4.9 years	140/630 (22.2)	109/576 (18.9)	3.3 (-1.3 to 7.9)
T3, ≥4.9 years	160/589 (27.2)	152/616 (24.7)	2.5 (-2.5 to 7.4)
Age group			
<75 years	337/1532 (22.0)	300/1561 (19.2)	2.8 (-0.1 to 5.6)
≥75 years	95/280 (33.9)	84/260 (32.3)	1.6 (-6.3 to 9.6)
Sex			
Female	79/307 (25.7)	66/316 (20.9)	4.8 (-1.8 to 11.5)
Male	353/1505 (23.5)	318/1505 (21.1)	2.3 (-0.6 to 5.3)
Diabetes mellitus			
Yes	110/361 (30.5)	101/369 (27.4)	3.1 (-3.5 to 9.7)
No	322/1451 (22.2)	283/1452 (19.5)	2.7 (-0.3 to 5.7)
Hypertension			
Yes	223/770 (29.0)	188/790 (23.8)	5.2 (0.8 to 9.5)
No	209/1042 (20.1)	196/1031 (19.0)	1.0 (-2.4 to 4.5)
Multivessel Disease			
Yes	253/941 (26.9)	240/966 (24.8)	2.0 (-1.9 to 6.0)
No	179/871 (20.6)	144/855 (16.8)	3.7 (0.0 to 7.4)
Renal Insufficiency			
Yes	22/105 (21.0)	22/111 (19.8)	1.1 (-9.6 to 11.9)
No	365/1450 (25.2)	314/1467 (21.4)	3.8 (0.7 to 6.8)
Ejection Fraction			
FE <50 %	51/170 (30.0)	47/168 (28.0)	2.0 (-7.7 to 11.7)
FE ≥50 %	367/1603 (22.9)	331/1614 (20.5)	2.4 (-0.5 to 5.2)
Revascularization type			
Complete	361/1572 (23.0)	316/1590 (19.9)	3.1 (0.2 to 5.9)
Incomplete	50/150 (33.3)	43/134 (32.1)	1.2 (-9.7 to 12.2)
Revascularization			
PCI	383/1631 (23.5)	329/1589 (20.7)	2.8 (-0.1 to 5.6)
Fibrinolysis	7/26 (26.9)	7/43 (16.3)	10.6 (-9.7 to 31.0)
CABG	20/62 (32.3)	19/81 (23.5)	8.8 (-6.1 to 23.7)
Heart rate, tertiles			
T1, <60 beats/min	137/612 (22.4)	126/593 (21.2)	1.1 (-3.5 to 5.8)
T2, 60 to <68 beats/min	129/551 (23.4)	121/582 (20.8)	2.6 (-2.2 to 7.5)
T3, ≥68 beats/min	153/613 (25.0)	128/611 (20.9)	4.0 (-0.7 to 8.7)



43% of the population had hypertension at baseline

Primary Endpoint in Hypertensive (HBP) patients



adjHR 1.18
95%CI 1.01 to 1.36
P=0.03

adjHR 1.05
95%CI 0.86 to 1.28
P=.64

No. at Risk

No HBP β-blocker continuation	1047	1013	947	837	711	591	482	388	235
No HBP β-blocker interruption	1060	1019	948	831	725	604	491	392	243
HBP β-blocker continuation	805	759	701	612	528	442	354	291	191
HBP β-blocker interruption	786	737	676	581	512	427	327	261	193

A study of the ACTION Group
www.action-groupe.org

Limitations of the trial

- **Prospective randomized open blinded end-point (PROBE)** study design

  => all events were adjudicated in a blinded fashion.

- **Hospitalization for Cardio-Vascular reason** is a soft endpoint but important in the life of patients.

- **The 3% absolute risk margin of non-inferiority** can be discussed

Key Messages

- ABYSS did not demonstrate the safety of **βB interruption in MI patients with preserved LVEF ,** a strategy that led to a higher rate of hospitalizations <u>especially in hypertensive patients.</u>

- **βB interruption** <u>did not improve patient's quality of life</u> and **increased Blood Pressure, resting Heart Rate**

Thanks to all 259 investigators !

Pr Johanne SILVAIN	Dr. Alexandre LAFONT	Dr. Géraud SOUTEYRAND	Dr. Frédéric HELIOT	Dr Alexandre GAUTIER	Dr. Franscico CAMPELO-PARADA	
Dr. Olivier BARTHELEMY	Dr. Damien LOGEART	Dr. Pascal GOUBE	Pr. Florence LECLERCQ	Dr. Jean-Michel JULIARD	Dr. Eve CARIOU	
Dr. Marc Ornel BATONGA YANGA	Dr. Céline LUC	Dr. Yann ROSAMEL	Dr. Pierre ROBERT	Dr Olivier MILLERON	Pr. Didier CARRIE	
Dr. Nesrine BOUZIRI	Dr. Stéphane MANZO-SILBERMAN	Dr. Thibaut POMMIER	Pr. Emile FERRARI	Dr Neila SAYAH	Dr. Thomas CHOLLET	
Dr. Nassim BRAIK	Dr. Elise PAVEN	Pr. Yves COTTIN	Dr. Etienne FOURRIER	Pr. Philippe-Gabriel STEG	Pr. Meyer ELBAZ	
Dr. Alexandre CECCALDI	Dr. Georgios SIDERIS	Pr. Luc LORGIS	Dr. Julie KRAEMER	Dr. Zaven TERZIAN	Dr. Olivier LAIREZ	
Dr. Remi CHOUSSAT	Pr. Franck BOCCARA	Dr. Simon ELHADAD	Dr. Mohamed LABBAOUI	Pr. Pascal LIM	Dr. Clémence LAPERCHE	
Pr. Jean-Philippe COLLET	Dr. Yann ANCEDY	Dr. Remy COHEN	Dr. Nassim REDJIMI	Dr. David AOUATE	Pr. Jérome RONCALLI	
Dr. Arnaud FERRANTE	Dr. Marion CHAUVET-DROIT	Dr. Arnaud FERRANTE	Dr. Benjamin SARTRE	Dr. Paul-Matthieu CHIARONI	Dr. Clément SERVOZ	
Dr. Paul GUEDENEY	Dr. Stephane EDERHY	Dr. Jean-Louis GEORGES	Dr. Jules BATEAU	Dr. Damien FARD	Dr. Fabrice IVANES	
Pr. Nadjib HAMMOUDI	Pr. Alain FURBER	Dr. Nicolas BARON	Pr. Guillaume CAYLA	Dr. Raphaelle HUGUET	Pr. Denis ANGOULVANT	
Pr. Gérard HELFT	Dr. Wissam ABI-KHALIL	Dr. Elodie BLICQ	Dr. Annick ASTIE - DARDAILLON	Dr. Valentin LANDON	Dr. Thibaud GENET	
Dr. Florent HUANG	Dr. Thomas BENARD	Dr. Clément CHARBONNEL	Dr. Luc CORNILLET	Dr. Fatima DJELAILI	Dr. Carl SEMAAN	
Pr. Richard ISNARD	Dr. Loic BIERE	Dr. Raphaële CONVERS-DOMART	Pr. Benoît LATTUCA	Dr. Aurélien DE POMMEREAU	Dr. Gilles BAYET	
Pr. Mathieu KERNEIS	Dr. Audrey CAMARZANA	Dr. Géraldine GIBAULT GENTY	Dr. Bertrand LEDERMANN	Dr. Anne BELLEMAIN-APPAIX	Dr Ghislaine DU FAITRE	
Pr. Claude LE FEUVRE	Dr. Stéphane DELEPINE	Dr. Grégoire LEFEVRE	Dr. Clément LONJON	Dr. Nathaniel BITTON	Dr. Clément LONJON	
Dr. Lise LEGRAND	Dr. Gabriel GARCIA	Dr. Bernard LIVAREK	Dr. Pierre ROBERT	Dr. Jean-Noel LABEQUE	Dr. François JOURDA	
Dr. Stefan MANKIKIAN	Dr. Sylvain GRALL	Dr. Tahar TALEB BENDIAB	Dr. Christelle ROBERT	Pr. François SCHIELE	Dr. Vincent HUMEAU	
Pr. Gilles MONTALESCOT	Pr. Fabrice PRUNIER	Dr. Grégoire RANGE	Dr. Laurent SCHMUTZ	Dr. Matthieu BESUTTI	Dr. Brahim MAALEM BEN MESSAOUD	
Dr. Francoise POUSSET	Dr. François BRESOLES	Dr. Franck ALBERT	Dr. Camille SOULLIER	Dr. Marion CHATOT	Dr. Malek MOALLA	
Dr. Niki PROCOPI	Dr. Michel PANSIERI	Dr. Sandrine BAYLE	Dr. Christophe CAUSSIN	Dr. Benoît GUILLON	Dr. Stéphane MOUROT	
Dr. Androula PROCOPI	Dr. Stéphane ANDRIEU	Dr. Reda BENSAID	Dr. Nicolas AMABILE	Dr. Thibaut PETRONI	Dr. Olivier RESSENCOURT	Dr. Flora KOCHLY
Dr. Pierre SABOURET	Dr. Karim MOUSSA	Dr. Madalina DASOVEANU	Dr. Christelle DIAKOV	Dr. Romain ANDRE	Dr. Maxime FAYARD	Dr. Nathan MEWTON
Dr. Tomy SALLOUM	Dr. Mathieu PANKERT	Dr. Thibault DEMICHELI	Dr Alain DIBIE	Dr. Marion BEROUS	Dr. Jean Luc PHILIP	Dr. Cyril PRIEUR
Dr. Thomas WALLET	Dr Marine QUILLOT	Dr. Teodora DUTOIU	Dr Jean-Luc MONIN	Pr. Didier BRUERE	Dr. Marc GORALSKI	Dr. Jean LITALIEN
Dr. Michel ZEITOUNI	Pr. Farzin BEYGUI	Dr. Hervé GORKA	Dr Dounia SELHANE	Dr. Axel DE LABRIOLLE	Dr. Kamel REHAL	Dr. Sandrine GOUGNOT
Pr. Olivier VARENNE	Dr. Mathieu BIGNON	Dr. Radwane HAKIM	Dr. Nicolas DELARCHE	Dr. Laurent DELORME	Dr. Jean-Charles AISENFARB	Dr. Geoffray RAMBAUD
Dr. Alexandre LAFONT	Dr. Katrien BLANCHART	Dr. Laurent ROUSSEL	Dr. Pierre POUSTIS	Dr. Ziad HOUCHAYMI	Dr. Thierry FOURME	Dr. Timothée BESSEYRE DES HORTS
Dr. Fabien PICARD	Dr. Clément BRIET	Dr. Pierre SOCIE	Pr. Luc CHRISTIAENS	Dr. Jean-Philippe LABARRE	Dr. Angela ACHEAMPONG	Dr. Laure BATIAS
Dr. Malika SAADI	Dr. Adrien LEMAITRE	Dr. Christophe THUAIRE	Dr. Elisa LARRIEU ARDILOUZE	Dr. Javier MOLINA	Dr. Romain BOSLE	Dr. Antoine BOUVAREL
Dr. Maximilien SOCHALA	Dr. Idir REBOUH	Pr. Gilles LEMESLE	Dr. Jean Michel QUEDILLAC	Pr. Thomas CUISSET	Dr. Benjamin FAURIE	Dr. Vincent DESCOTES GENON
Pr. Etienne PUYMIRAT	Dr. Vincent ROULE	Pr. Christophe BAUTERS	Dr. Emmanuelle FILIPPI	Dr. Guillaume BONNET	Dr. Agathe GUILLARD-COADON	Dr Arnaud FLUTTAZ
Dr. Julia CAUDRON	Pr. Pascal MOTREFF	Dr. Cédric DELHAYE	Dr. Marie HAUGUEL	Dr. Pierre DEHARO	Dr. Pierre GAUTIER PIGNONBLANC	Dr. Florence GOOD
Dr. Antoine FAYOL	Dr. Aimé AMONCHOT	Dr. Pascal DELSART	Pr. Gregory DUCROCQ	Dr. Jean Charles SPYCHAJ	Dr. Damien GUIJARRO	Dr. Laurent DESPRETS
Dr. Victoria TEA	Dr. Andrea CIANCI	Pr. Nicolas LAMBLIN	Dr. Jérémie ABTAN	Dr. Romain CADOR	Dr. Léa MARGERIT	Dr. Flore BARBIER
Pr. Jean-Guillaume DILLINGER	Dr. Bernard CITRON	Dr. Thibault PAMART	Dr Vincent ALGALARRONDO	Dr. Yoann MOEUF	Dr. Jacques MONSEGU	Dr. Audrey CAMARZANA
Dr. Florence BEAUVAIS	Dr. Nicolas COMBARET	Dr. Sina POROUCHANI	Dr Audrey CAILLIAU	Dr. David ATTIAS	Dr. Jérôme WINTZER	Dr. Youna GOURRONC
Dr. Léa CACOUB	Dr Benjamin DUBAND	Dr. Guillaume SCHURTZ	Dr Arthur DARMON	Dr. Thibault LHERMUSIER	Dr. Thomas BOCHATON	Dr. Camille LE DOEUFF
Dr. Alain COHEN-SOLAL	Dr. Thomas MOUYEN	Dr. Arnaud SUDRE	Pr. Laurent FELDMAN	Dr. Stéphanie BLANCO	Dr. Nathalie GENOT	Dr. Thomas MOINEREAU
Pr. Patrick HENRY	Dr. Clément RIOCREUX	Pr Eric VAN BELLE	Dr. Quentin FISCHER	Dr. Frederic BOUISSET	Dr. Ahmad HAYEK	Dr. Camille PERAULT

ESC Congress 2024

London & Online

A study of the ACTION Group

www.action-groupe.org

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Beta-Blocker Interruption or Continuation after Myocardial Infarction

J. Silvain, G. Cayla, E. Ferrari, G. Range, E. Puymirat, N. Delarche, P. Guedeney, T. Cuisset, F. Ivanes, T. Lhermusier, T. Petroni, G. Lemesle, F. Bresoles, J.-N. Labeque, T. Pommier, J.-G. Dillinger, F. Leclercq, F. Boccara, P. Lim, T. Besseyre des Horts, T. Fourme, F. Jourda, A. Furber, B. Lattuca, N. Redjimi, C. Thuaire, P. Deharo, N. Procopi, R. Dumaine, M. Slama, L. Payot, M. El Kasty, K. Aacha, A. Diallo, E. Vicaut, and G. Montalescot, for the ABYSS Investigators of the ACTION Study Group*