Supplementary Online Content

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This supplementary material has been provided by the authors to give readers additional information about their work.

eTable 1. Study-specific inclusion and exclusion criteria

2.1 Enrollment Inclusion Criteria
Patient must meet all of the following criteria to be eligible for treatment in the study:
1. Patient is > 18 years of age.
2. Patients undergoing percutaneous intervention with stent deployment (or has w/in 3 calendar days).
3. Patients without known contraindication to dual antiplatelet therapy for at least 30 months after enrollment and stent implantation.
4. The patient has consented to participate and has authorized the collection and release of his medical information by signing the "Patient Informed Consent Form". The informed consent will be valid for the duration of the trial or until the patient withdraws.
2.2 Enrollment Exclusion Criteria
Patients will be excluded from the study if any of the following criteria are met:
1. Index procedure stent placement with stent diameter <2.25 mm or >4.0 mm.
2. Pregnant women.
3. Planned surgery necessitating discontinuation of antiplatelet therapy (>14 days) within the 30 months following enrollment.
4. Current medical condition with a life expectancy of less than 3 years.
5. Concurrent enrollment in another device or drug study where the primary endpoint has not yet been reached or the device/drug might affect major endpoint outcomes in either open label or randomized phases of the DAPT study. The patient may only be enrolled in the DAPT Study once.
6. Patients on long-term warfarin (or similar anticoagulant) therapy who are anticipated to still be on warfarin at the time of randomization.
7. Patients with hypersensitivity or allergies to one of the drugs or components indicated in the Instructions for Use for the device implanted.
8. Patients unable to give informed consent.
9. Patient treated with both DES and BMS during the index procedure.
2.3 Randomization Inclusion Criterion at 12 months
Patient must meet the following criterion to be eligible for randomization in the study:
1. Patient is "12 Month Clear", defined as patients who are treated with 12 months of DAPT post index procedure and who are event free (from all death, myocardial infarction, stroke, repeat coronary revascularization, stent thrombosis, and major bleeding – "severe" or "moderate" by GUSTO classification) during that time. During the open label portion of this study (time 0-12m post-index procedure), a patient is considered compliant with the thienopyridine therapy for the purposes of eligibility if they take between 80% and 120% of the prescribed drug in the 0-6 month and 6-12 month periods without an interruption of therapy longer than 14 days.

2.4 Randomization Exclusion Criteria at 12 months
Patients will be excluded from randomization if any of the following criteria are met:
1. Pregnant women.
2. Patient switched thienopyridine type or dose within 6 months prior to randomization.
NOTE: thienopyridine switching during the open label portion of this study is discouraged.
3. Percutaneous coronary intervention or cardiac surgery between 6 weeks post index procedure and randomization.
4. Planned surgery necessitating discontinuation of antiplatelet therapy (>14 days) within the 21 months following randomization.
5. Current medical condition with a life expectancy of less than 3 years.
6. Patients on warfarin or similar anticoagulant therapy.

eTable 2. Baseline characteristics of all randomized patients

Characteristic	Drug-Eluting Stents N=9961	Bare Metal Stents N=1687	P Value	Continued Thienopyridine N=5862	Placebo N=5786	P Value
Patients						
Age (years); Mean±SD (N)	61.7±10.2 (9961)	59.0±10.8 (1687)	<.001	61.4±10.3 (5862)	61.2±10.3 (5786)	0.38
Female	25.4% (2526/9961)	23.7% (399/1687)	0.14	75.2% (4405/5862)	74.6% (4318/5786)	0.52
Race-Non-White*	8.8% (857/9765)	7.4% (123/1665)	0.07	8.7% (500/5748)	8.5% (480/5682)	0.64
Weight (kg); Mean±SD (N)	91.5±19.6 (9940)	88.3±18.6 (1686)	<.001	91.0±19.6 (5850)	91.1±19.4 (5776)	0.78
BMI (Kg/m^2); Mean±SD (N)	30.5±5.8 (9874)	29.5±5.4 (1677)	<.001	30.4±5.7 (5810)	30.4±5.8 (5741)	0.82
Diabetes mellitus	30.6% (3037/9933)	21.2% (354/1668)	<.001	29.8% (1737/5839)	28.7% (1654/5762)	0.22
Hypertension	74.9% (7445/9940)	64.3% (1077/1674)	<.001	74.1% (4330/5840)	72.6% (4192/5774)	0.06
Cigarette smoker	24.7% (2432/9858)	43.8% (710/1620)	<.001	27.4% (1582/5777)	27.4% (1560/5701)	0.98
Stroke/TIA	3.3% (324/9937)	4.6% (77/1681)	0.01	3.4% (198/5845)	3.5% (203/5773)	0.72
Congestive heart failure	4.6% (461/9927)	3.7% (63/1681)	0.11	4.7% (273/5840)	4.4% (251/5768)	0.42
Peripheral arterial disease	5.8% (568/9794)	4.9% (81/1670)	0.14	5.5% (319/5768)	58% (330/5696)	0.55
Prior PCI	30.7% (3047/9923)	19.1% (321/1680)	<.001	28.6% (1668/5833)	29.5% (1700/5770)	0.31
Prior CABG	11.6% (1149/9942)	5.9% (100/1682)	<.001	10.6% (618/5851)	10.9% (631/5773)	0.53
Prior MI	21.6% (2118/9823)	20.4% (338/1653)	0.32	21.7% (1252/5777)	21.1% (1204/5699)	0.48
Indication for Index PCI						
ACS	26.0% (2588/9961)	58.6% (988/1687)	<.001	30.8% (1805/5862)	30.6% (1771/5786)	0.84
STEMI	10.5% (1045/9961)	37.6% (635/1687)	<.001	14.4% (845/5862)	14.4% (835/5786)	1.00
NSTEMI	15.5% (1543/9961)	20.9% (353/1687)	<.001	16.4% (960/5862)	16.2% (936/5786)	0.78
Unstable Angina**	16.7% (1663/9961)	9.4% (158/1687)	<.001	15.6% (915/5862)	15.7% (906/5786)	0.96
Stable Angina	37.7% (3752/9961)	23.5% (397/1687)	<.001	35.5% (2081/5862)	35.7% (2068/5786)	0.79

Region			<.001			0.96
North American	89.5% (8918/9961)	60.9% (1028/1687)		85.5% (5011/5862)	85.3% (4935/5786)	
Europe	8.1% (807/9961)	35.8% (604/1687)		12.0% (706/5862)	12.2% (705/5786)	
Australia or New Zealand	2.4% (236/9961)	3.3% (55/1687)		2.5% (145/5862)	2.5% (146/5786)	
Any Risk Factor for Stent Thrombosis	50.9% (4799/9436)	69.0% (1137/1647)	<.001	53.5% (2978/5572)	53.7% (2958/5511)	0.82
Any Clinical	32.3% (3016/9346)	63.6% (1046/1645)	<.001	37.2% (2056/5531)	36.7% (2006/5460)	0.65
Enzyme positive ACS (STEMI or NSTEMI)	26.0% (2588/9961)	58.6% (988/1687)	<.001	30.8% (1805/5862)	30.6% (1771/5786)	0.84
Renal insufficiency/failure	4.2% (420/9932)	2.9% (48/1677)	0.01	4.3% (251/5839)	3.8% (217/5770)	0.14
LVEF < 30%	1.6% (146/9125)	3.8% (61/1590)	<.001	2.1% (111/5399)	1.8% (96/5316)	0.36
Any Lesion-Related	31.3% (3089/9873)	38.1% (641/1681)	<.001	32.4% (1880/5812)	32.2% (1850/5742)	0.89
> 2 vessels stented	0.5% (48/9961)	0.1% (1/1687)	0.01	0.3% (19/5862)	0.5% (30/5786)	0.12
> 2 lesions per vessel	1.9% (187/9959)	1.0% (17/1687)	0.01	1.7% (102/5861)	1.8% (102/5785)	0.94
Lesion length ≥ 30 mm	10.1% (1004/9947)	6.6% (111/1687)	<.001	9.5% (558/5854)	9.6% (557/5780)	0.85
Bifurcation sidebranch ≥ 2.5 mm	6.5% (647/9946)	4.3% (72/1687)	<.001	6.2% (363/5852)	6.2% (356/5781)	0.94
In-stent restenosis of a DES	3.2% (313/9916)	0.5% (9/1687)	<.001	2.7% (159/5839)	2.8% (163/5764)	0.74
Vein bypass graft stented	2.8% (280/9959)	2.5% (42/1687)	0.52	2.5% (149/5861)	3.0% (173/5785)	0.14
Unprotected left main stented	0.4% (42/9959)	0.1% (1/1687)	0.02	0.3% (19/5861)	0.4% (24/5785)	0.45
Thrombus-containing lesion	11.8% (1070/9091)	27.4% (462/1687)	<.001	14.5% (784/5416)	14.0% (748/5362)	0.44
Prior Brachytherapy	0.3% (26/9918)	0.1% (2/1679)	0.42	0.2% (14/5836)	0.2% (14/5761)	1.00
Thienopyridine at randomization			<.001			0.97
Clopidogrel	65.3% (6500/9961)	86.7% (1462/1687)		68.4% (4008/5862)	68.3% (3954/5786)	
Prasugrel	34.8% (3461/9961)	13.3% (225/1687)		31.6% (1854/5862)	31.7% (1832/5786)	

No. of treated lesions; Mean±SD (N)	1.3±0.6 (9961)	1.2±0.4 (1687)	<.001	1.3±0.5 (5862)	1.3±0.5 (5786)	0.29
No. of treated vessels; Mean±SD (N)	1.1±0.3 (9944)	1.0±0.2 (1687)	<.001	1.1±0.3 (5854)	1.1±0.3 (5777)	0.34
No. of stents; Mean±SD (N)	1.5±0.8 (9961)	1.3±0.6 (1687)	<.001	1.5±0.7 (5862)	1.4±0.7 (5786)	0.25
Minimum stent diameter			<.001			0.85
< 3 mm	46.5% (4634/9961)	24.1% (407/1687)		43.4% (2542/5862)	43.2% (2499/5786)	
≥ 3 mm	53.5% (5327/9961)	75.8% (1280/1687)		56.6% (3320/5862)	56.8% (3287/5786)	
Total stent length – mm; Mean±SD (N)	27.6±16.9 (9961)	23.9±13.1 (1687)	<.001	27.2±16.3 (5862)	26.9±16.6 (5786)	0.41
Lesion(s) ††						
Treated vessel						
Left main	0.9% (110/12993)	0.1% (1/1966)	<.001	0.7% (55/7561)	0.8% (56/7398)	0.85
Left anterior descending	40.8% (5301/12993)	31.2% (614/1966)	<.001	40.0% (3023/7561)	39.1% (2892/7398)	0.27
Right coronary artery	32.4% (4210/12993)	45.2% (889/1966)	<.001	34.3% (2590/7561)	33.9% (2509/7398)	0.67
Circumflex	22.9% (2979/12993)	21.0% (413/1966)	0.06	22.2% (1679/7561)	23.2% (1713/7398)	0.17
Venous graft	2.5% (327/12993)	2.5% (49/1966)	1.00	2.4% (178/7561)	2.7% (198/7398)	0.21
Arterial graft	0.5% (66/12993)	0.0% (0/1966)	<.001	0.5% (36/7561)	0.4% (30/7398)	0.54
Modified ACC–AHA lesion class B2 or C‡	43.3% (5397/12472)	47.7% (890/1866)	<.001	44.0% (3194/7260)	43.7% (3093/7078)	0.72

Abbreviations: ACC, American College of Cardiology; ACS, acute coronary syndrome; AHA, American Heart Association; BMI, body mass index; CABG, coronary artery bypass graft; DES, drug-eluting stent; LAD, left anterior descending; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NSTEMI, non-ST elevation MI; PCI, percutaneous coronary intervention; STEMI, ST-elevation MI; TIA, transient ischemic attack.

*Race was self-reported.

**This category included unstable angina without reported elevation of cardiac enzymes.

††A total of 13007 lesions were treated in DES-treated patients, 1966 in BMS-treated patients, 7569 in the continued thienopyridine group, and 7404 in the placebo group.

eTable 3. GUSTO and BARC Definitions

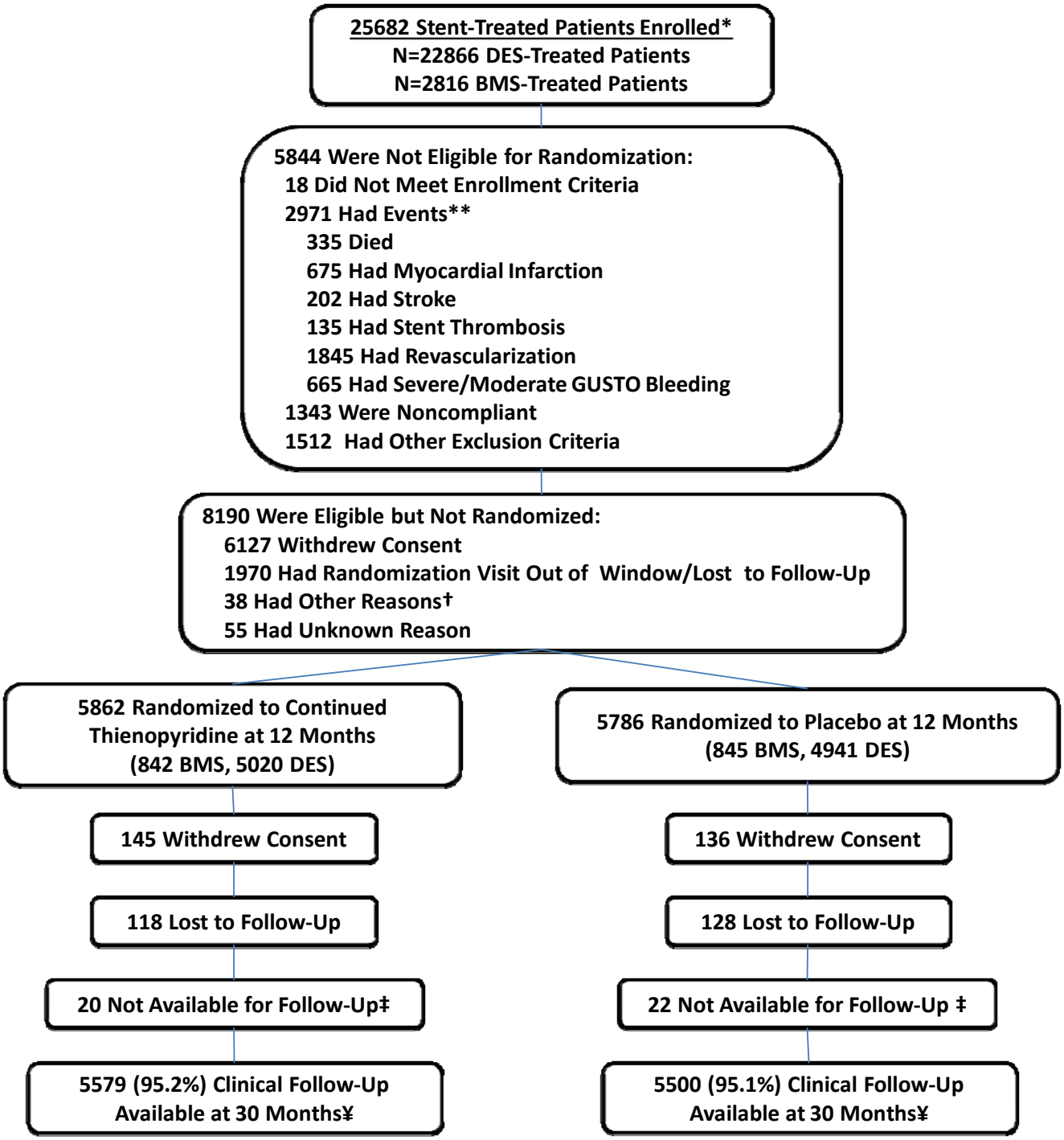
GUSTO:

- Severe or life-threatening
  - Intracerebral hemorrhage
  - Resulting in substantial hemodynamic compromise requiring treatment
- Moderate
  - Requiring blood transfusion but not resulting in hemodynamic compromise

BARC:

- Type 2: any overt, actionable sign of hemorrhage (eg, more bleeding than would be expected for a clinical circumstance, including bleeding found by imaging alone) that does not fit the criteria for type 3, 4, or 5 but does meet at least one of the following criteria: (1) requiring nonsurgical, medical intervention by a healthcare professional, (2) leading to hospitalization or increased level of care, or (3) prompting evaluation
- Type 3
  - Type 3a
    - Overt bleeding plus hemoglobin drop of 3 to <5 g/dL[*] (provided hemoglobin drop is related to bleed)
    - Any transfusion with overt bleeding
  - Type 3b
    - Overt bleeding plus hemoglobin drop ≥5 g/dL[*] (provided hemoglobin drop is related to bleed)
    - Cardiac tamponade
    - Bleeding requiring surgical intervention for control (excluding dental/nasal/skin/hemorrhoid)
    - Bleeding requiring intravenous vasoactive agents
  - Type 3c
    - Intracranial hemorrhage (does not include microbleeds or hemorrhagic transformation, does include intraspinal)
    - Subcategories confirmed by autopsy or imaging or lumbar puncture
    - Intraocular bleed compromising vision
- Type 4: CABG-related bleeding
  - Perioperative intracranial bleeding within 48 h
  - Reoperation after closure of sternotomy for the purpose of controlling bleeding
  - Transfusion of ≥5 U whole blood or packed red blood cells within a 48-h period[†]
  - Chest tube output ≥2L within a 24-h period
- Type 5: fatal bleeding
  - Type 5a
    - Probable fatal bleeding; no autopsy or imaging confirmation but clinically suspicious
  - Type 5b
    - Definite fatal bleeding; overt bleeding or autopsy or imaging confirmation

eFigure. Enrollment, randomization, and follow-up among randomized patients



*Screening for eligibility data are not available to report.
**Subjects may have >1 event.
† Site terminated participation, randomization target met prior to subject follow-up, or subject not recognized to be eligible by site
‡Subjects move, were incarcerated, or were prematurely exited from the study.
¥ Although the number of patients with available data on clinical follow-up at 30 months is reported in each group, the efficacy end points were analyzed with the last available follow-up information in the intention-to-treat population, which included all patients who underwent randomization.

eAppendix. DAPT Investigators by Country

Listed are investigators randomizing at least one DES patient.

ABBOTT XIENCE V USA STUDY
Co-Principal Investigators:
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United States

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BOSTON SCIENTIFIC LIBERTE POST-APPROVAL STUDY

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