Effect of Aspirin Dose on Hemocompatibility Related Outcomes with a Magnetically Levitated Left Ventricular Assist Device:

An Analysis from the MOMENTUM 3 study

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Relevant Financial Relationship Disclosure Statement

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Omar Saeed

I will not discuss off label use and/or investigational use of the following drugs/devices:

The following relevant financial relationships exist related to this presentation:

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D.C. and P.S were employees of Abbott during the conduct of this study.
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Introduction

- Aspirin (ASA) is considered a cornerstone antithrombotic therapy during LVAD support
- In the setting of shear related platelet dysregulation and Acquire Von Willebrand Syndrome (AVWS), it remains uncertain if ASA therapy is beneficial or confers a bleeding risk
- Hemocompatibility-related adverse events (HRAEs) vary between devices and the optimal dose of ASA remains unknown during Heart Mate 3

Methods

- A post-hoc analysis of the MOMENTUM 3 trial to assess the association of Usual (325 mg) or Low (81 mg) dose ASA and HRAEs during HM3

- Eligibility Criteria
  - Not on >1 anti-platelet agent
  - On Usual or Low dose ASA on POD 7
  - No HRAE ≤7 days after HM3 implantation

- INR was maintained at 2-3

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Methods

- Comparison group assignment:
  - Usual (325 mg) vs. Low (81 mg) dose ASA on Day 7 after HM3 implantation

- Data were available at baseline, at HM 3 implant, post implant day 1, day 7, discharge, 1 month, 3 months, 6 months and then every 6 months until the 2-year follow-up

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Methods

- Primary Endpoint
  - Survival free from a HRAE at 2 years after HM3 implantation between patients on Usual or Low-dose ASA
  - HRAEs included:
    - Gastrointestinal or non-surgical bleeding
    - Stroke (hemorrhagic or ischemic)
    - Thromboembolic events including suspected or confirmed pump thrombosis
    - Arterial thromboembolism with or without end-organ involvement

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Methods

- Secondary Endpoint
  - Survival free from hemorrhagic or thrombotic events analyzed separately between patients on Usual or Low-dose ASA at 2 years

- Sensitivity Analyses
  - ≥325mg vs. <325mg
  - >81mg vs. ≤81mg
  - Included patients on DAPT

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Methods

- Survival free from HRAEs was calculated by Kaplan Meier methods
- Analyses were landmarked at day 7 and censoring was done for heart transplantation or withdrawal
- Multivariable Cox proportional regression was used to calculate adjusted hazard ratios (aHR)
- P-values <0.05 were considered statistically significant

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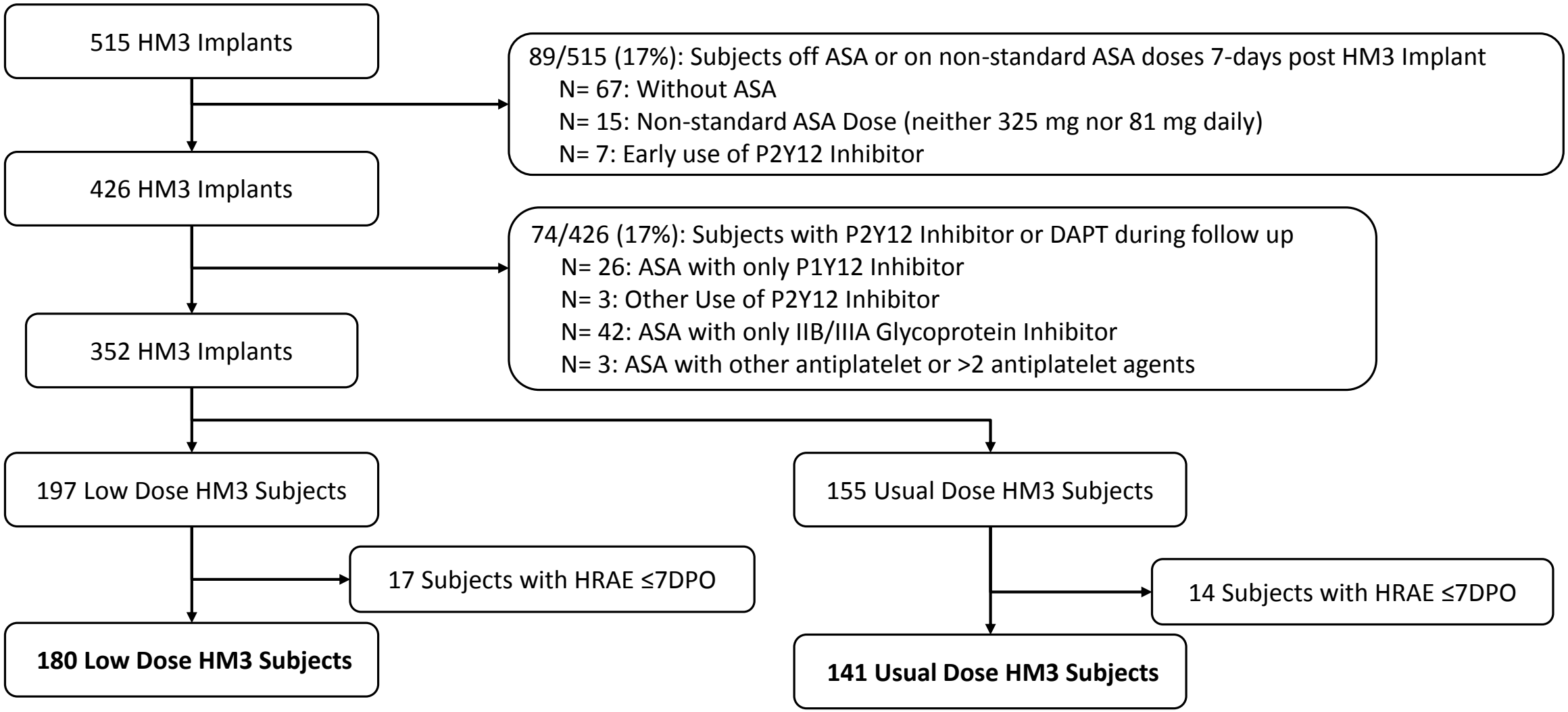
CONSORT Diagram



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Baseline Characteristics

	Low Dose Aspirin 81 mg/day n=180	Usual Dose Aspirin 325 mg/day N=141	P-Value
Age (Mean)	**60.3 ± 12.1 (180)**	**57.3 ± 12.7 (141)**	**0.04**
Age (Median [Q1 Q3])	64 [53.5, 69]	59 [49, 67]	
Men	78.3% (141/180)	82.3% (116/141)	0.38
Race - White	65.6% (118/180)	64.5% (91/141)	0.85
Ischemic Cause of Heart Failure	37.2% (67/180)	34.0% (48/141)	0.56
Intravenous Inotropic Agents	83.9% (151/180)	84.4% (119/141)	0.90
Intra-Aortic Balloon Pump	12.2% (22/180)	14.2% (20/141)	0.60
Serum Creatinine (mg/dl)	1.32 ± 0.42 (180)	1.35 ± 0.42 (141)	0.59
Serum Sodium (mmol/l)	135.4 ± 4.4 (180)	135.3 ± 3.9 (141)	0.88
Mean Arterial Pressure (mmHg)	79.4 ± 11.3 (138)	78.3 ± 9.7 (99)	0.45
INTERMACS Profiles			
1-2	34.4% (62/180)	31.9% (45/141)	0.63
3-7	65.6% (118/180)	68.1% (96/141)	
Intent Goal of Pump Support			
BTT/BTC	**32.8% (59/180)**	**44.7% (63/141)**	**0.03**
DT	**67.2% (121/180)**	**55.3% (78/141)**	
Diabetes	40.6% (73/180)	49.6% (70/141)	0.10
History of Bleeding	0.0% (0/180)	0.7% (1/141)	0.44
History of Stroke	10.0% (18/180)	9.9% (14/141)	0.98
History of Atrial Fibrillation	42.8% (77/180)	44.0% (62/141)	0.83
Baseline Platelet Count ($10^3/\mu l$)	206.9 ± 64.3 (180)	205.3 ± 62.1 (141)	0.83

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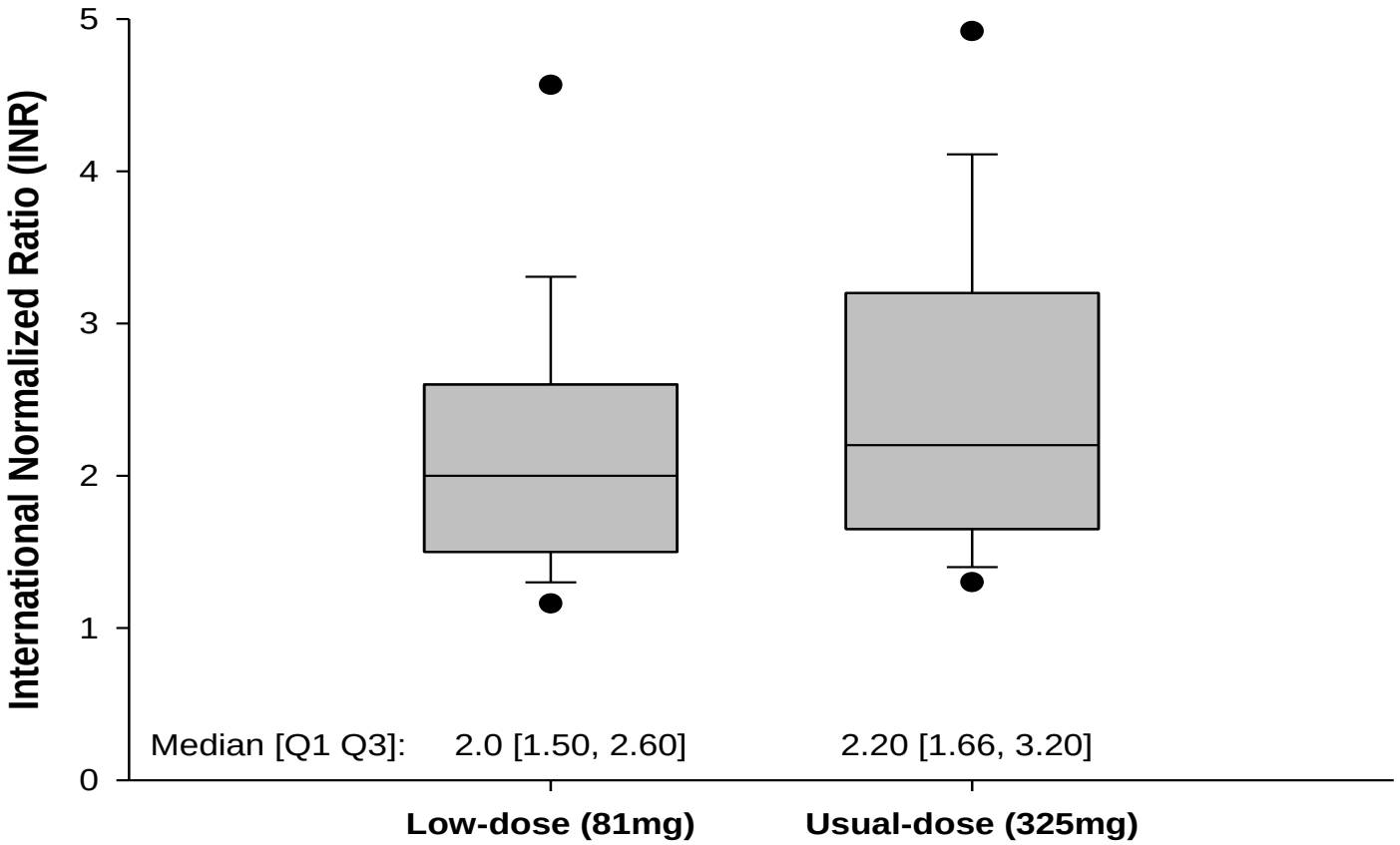
Similar INR between ASA Groups at HRAEs



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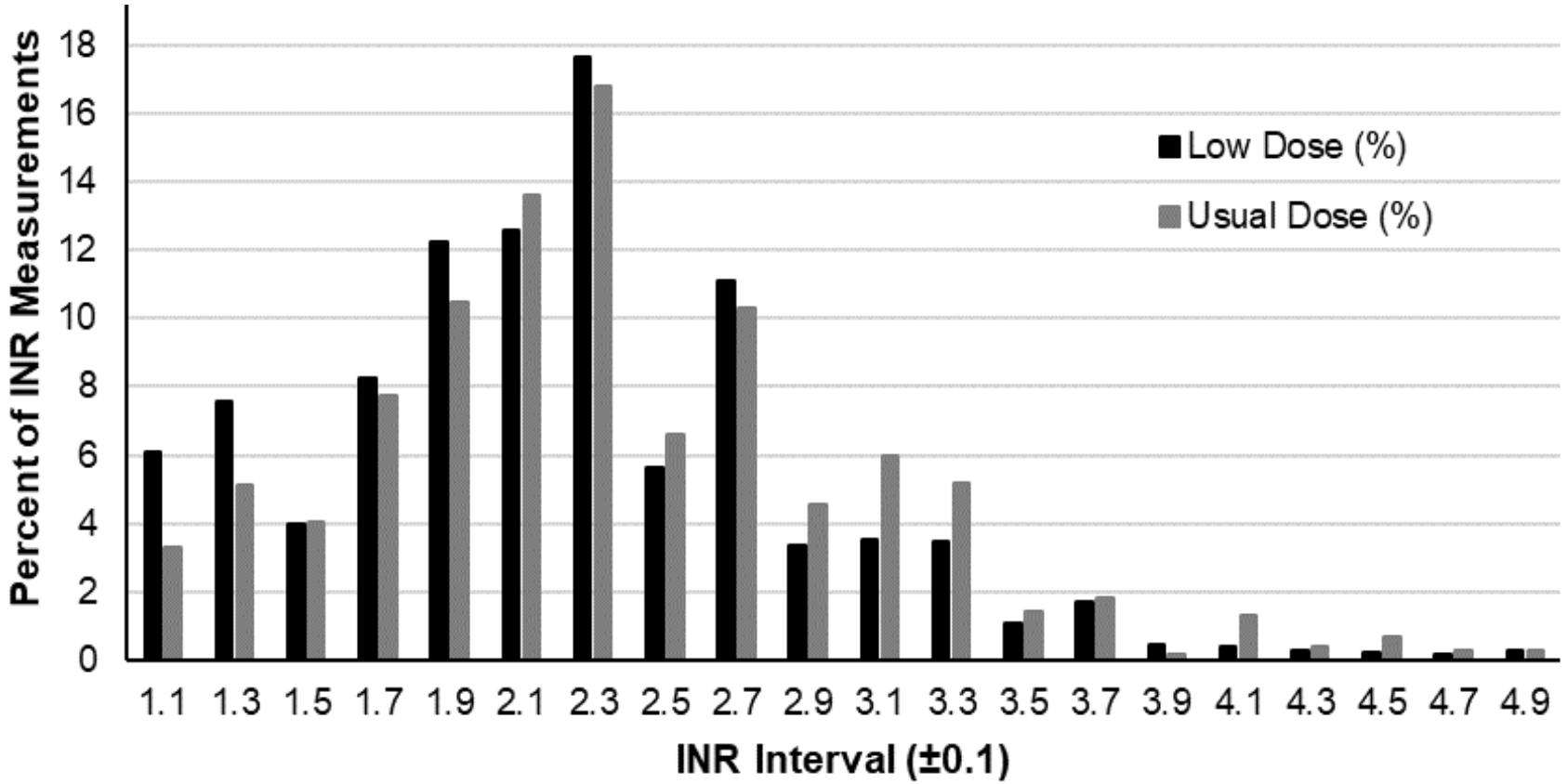
Similar INR between ASA Groups during Follow up



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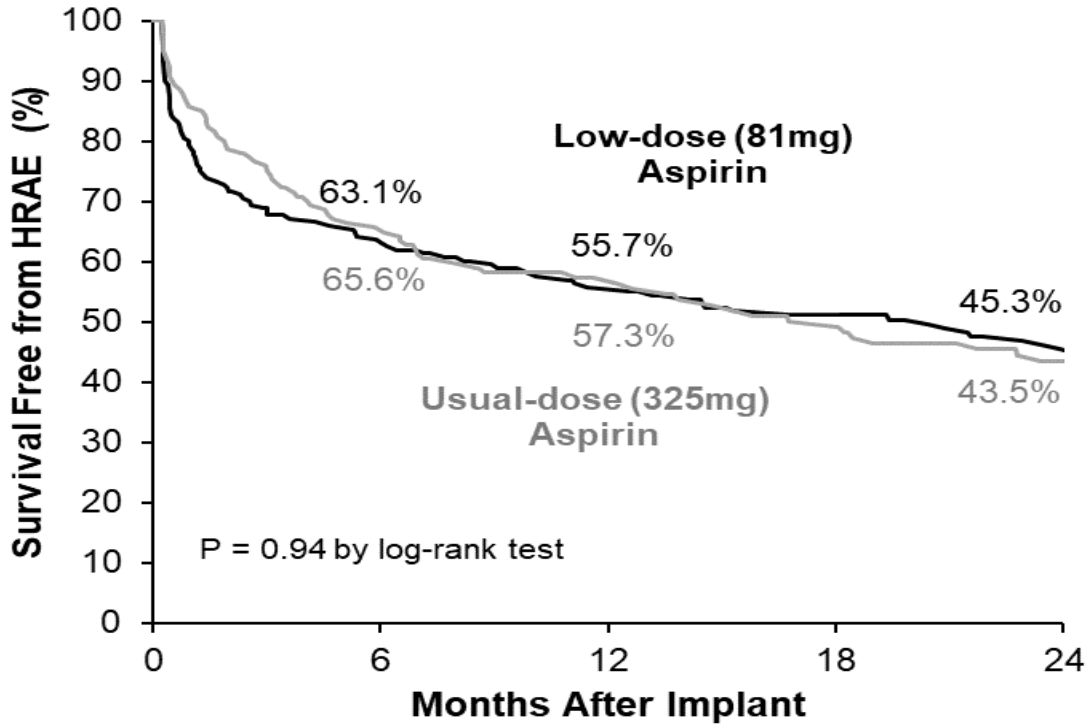
Survival Free from HRAEs



No. at Risk:					
Low-dose (81mg)	180	109	87	75	62
Usual-dose (325mg)	141	89	65	54	38

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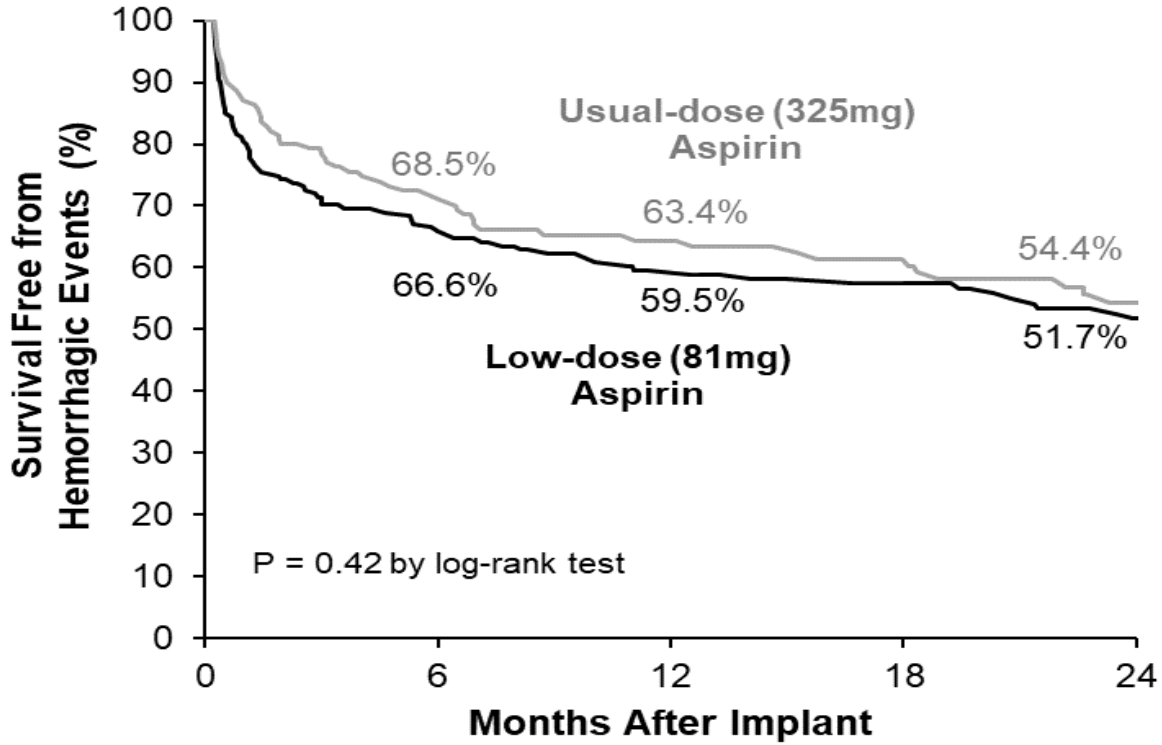
Survival Free from Hemorrhagic Events



No. at Risk:					
Low-dose (81mg)	180	109	87	76	62
Usual-dose (325mg)	141	92	68	57	40

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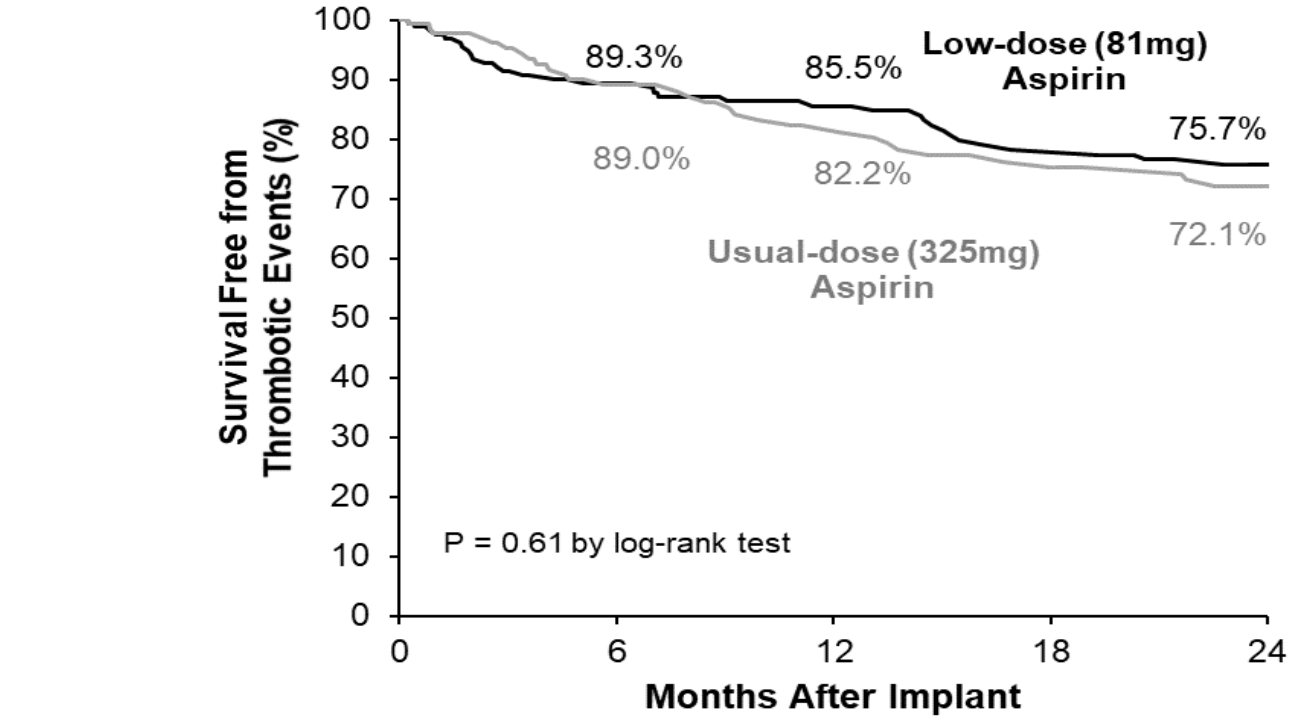
Survival Free from Thrombotic Events



No. at Risk:					
Low-dose (81mg)	180	121	107	96	87
Usual-dose (325mg)	141	98	83	74	67

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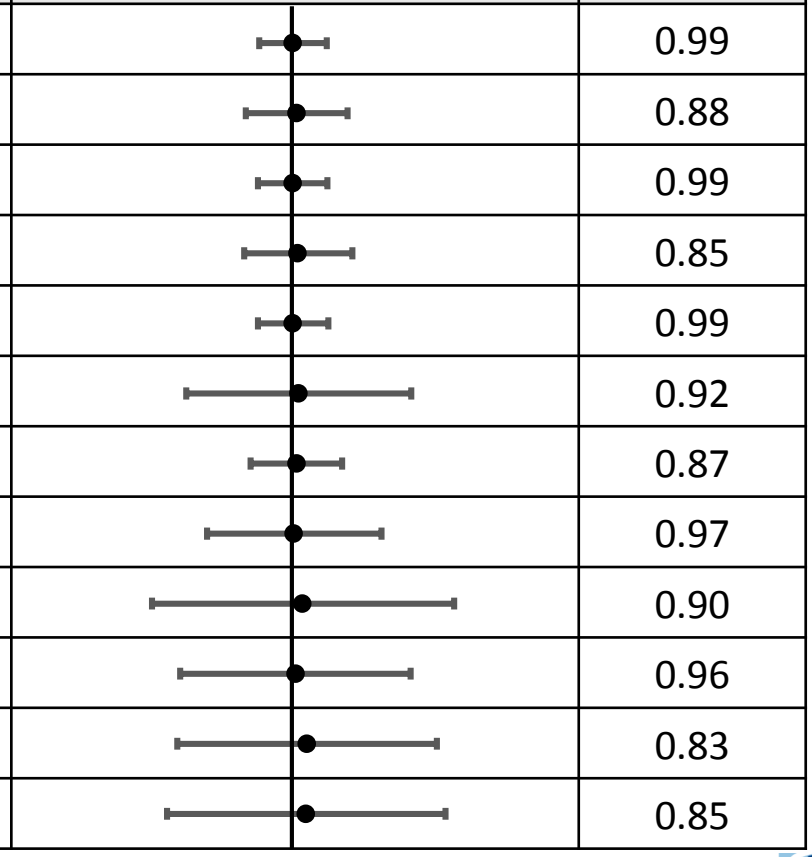
Adjusted Hazard Ratios of Adverse Events

	Adjusted Hazard Ratio [95% CI] *	Favors Usual-dose ← → Favors Low-dose	P-value
HRAE	1.00 [0.72, 1.40]		0.99
- Thrombotic Events	1.04 [0.63, 1.72]		0.88
- Hemorrhagic Events	1.00 [0.71, 1.41]		0.99
Mortality	1.05 [0.62, 1.80]		0.85
Overall Bleeding	1.00 [0.71, 1.42]		0.99
- Requiring Surgery	1.06 [0.35, 3.22]		0.92
- GI Bleeding	1.04 [0.66, 1.63]		0.87
Stroke	1.01 [0.43, 2.40]		0.97
- Ischemic	1.10 [0.25, 4.91]		0.90
-Hemorrhagic	1.03 [0.33, 3.20]		0.96
- Disabling	1.15 [0.32, 4.14]		0.83
- Non-Disabling	1.14 [0.29, 4.52]		0.85



*Adjusted Hazard Ratio Co-variates: Age, Intended Goal of Support (BTT/DT), Gender

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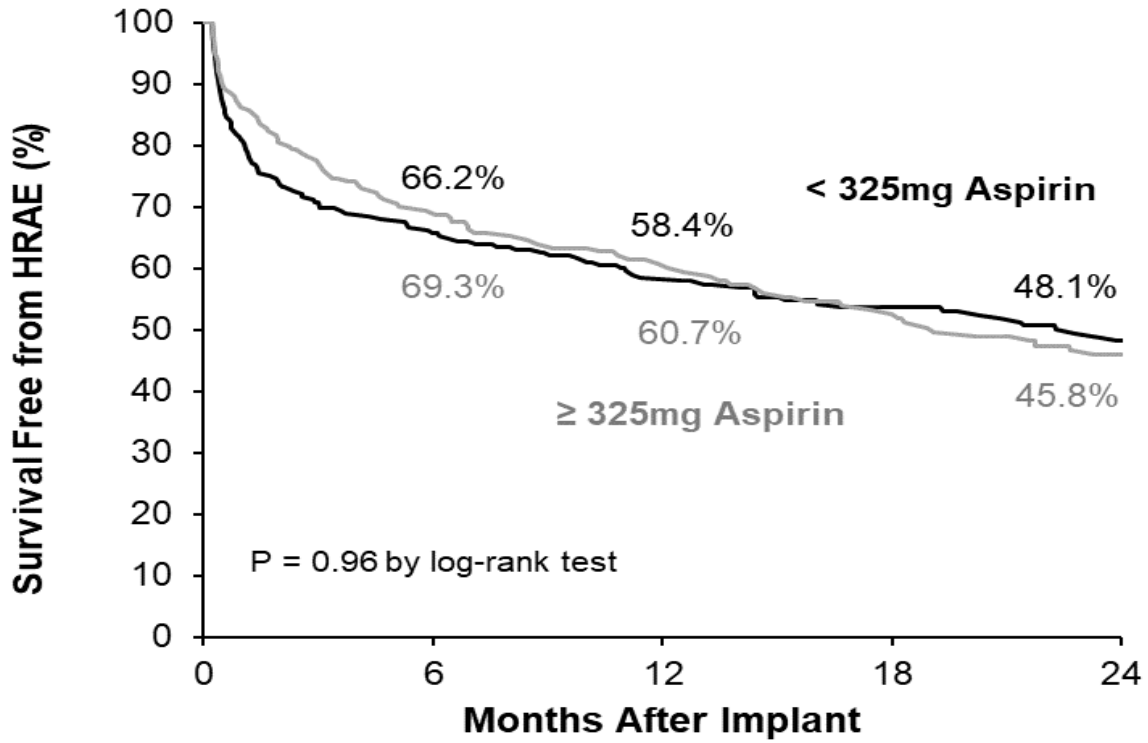
Sensitivity Analysis: ≥325mg vs. <325mg



No. at Risk:					
< 325mg	232	148	112	94	78
≥ 325mg	174	117	91	74	54

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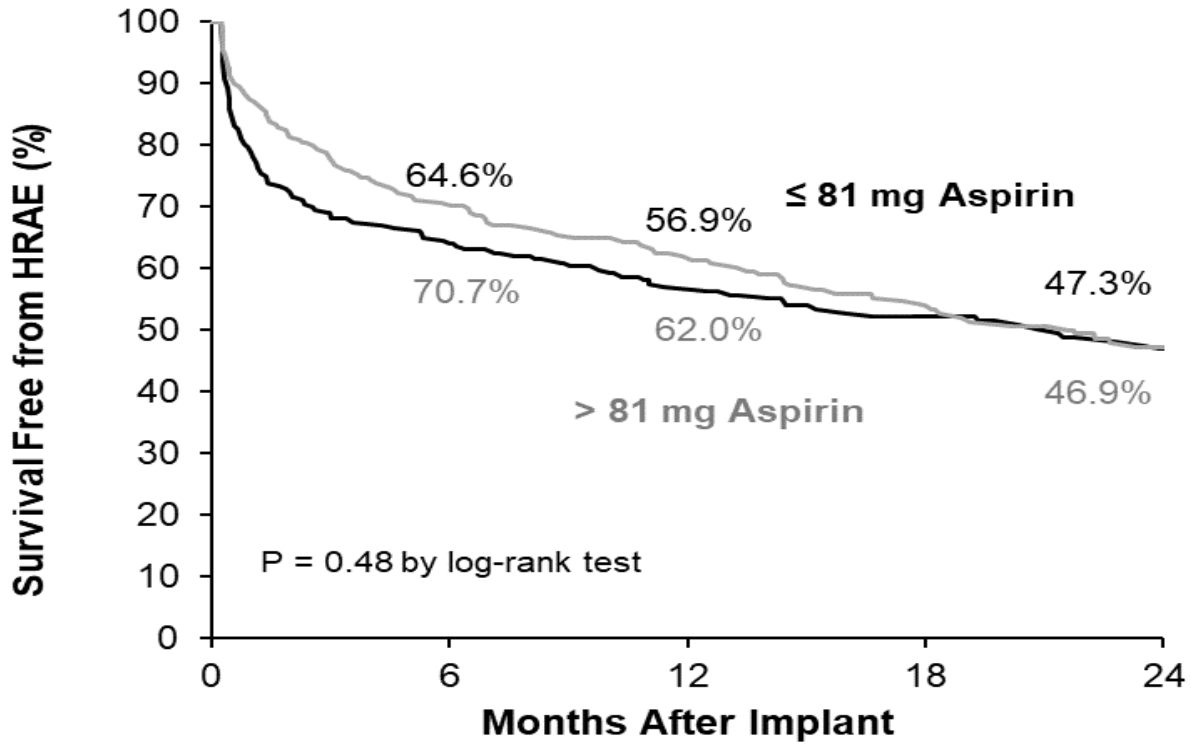
Sensitivity Analysis: >81mg vs. ≤81mg



No. at Risk:					
≤ 81 mg Aspirin	207	128	98	84	71
> 81 mg Aspirin	199	137	105	84	61

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Conclusions

- Survival free of HRAEs, as well as specific bleeding or thrombotic events, was similar between Usual (325 mg daily) and Low (81 mg daily) dose ASA during HM3 support

- Whether ASA can be avoided during HM3 support remains undetermined and will be further investigated in the ARIES trial

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Thank You!!

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