29th TCTAP2024

No Antithrombotic Therapy After Transcatheter Aortic Valve Replacement: Insight from the OCEAN-TAVI Registry

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Disclosure

I have the following potentiel conflicts of interest to declare:

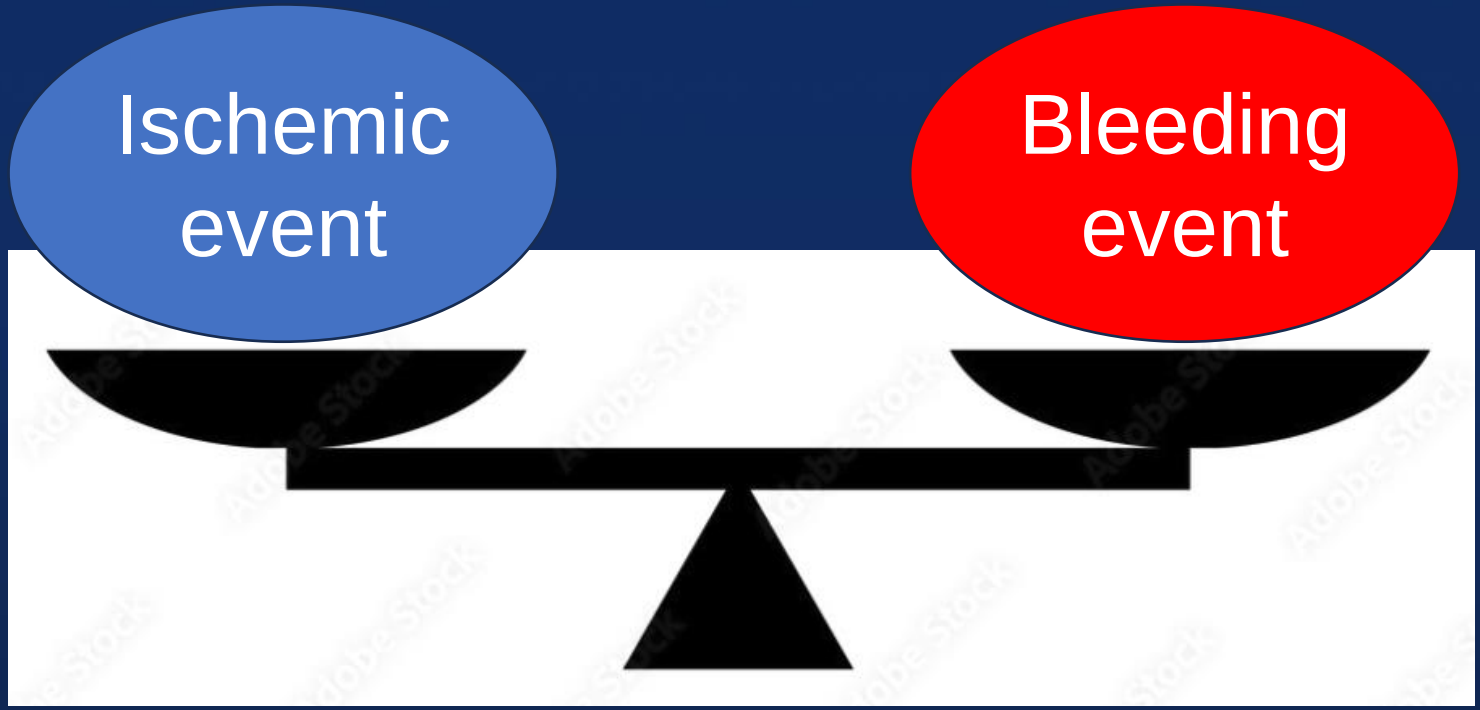
Proctor: Abbott, Edwards Lifesciences, Medtronic

Speaker honorarium: Edwards Lifesciences, Medtronic,

What is the optical anti-platelet regimen after TAVI

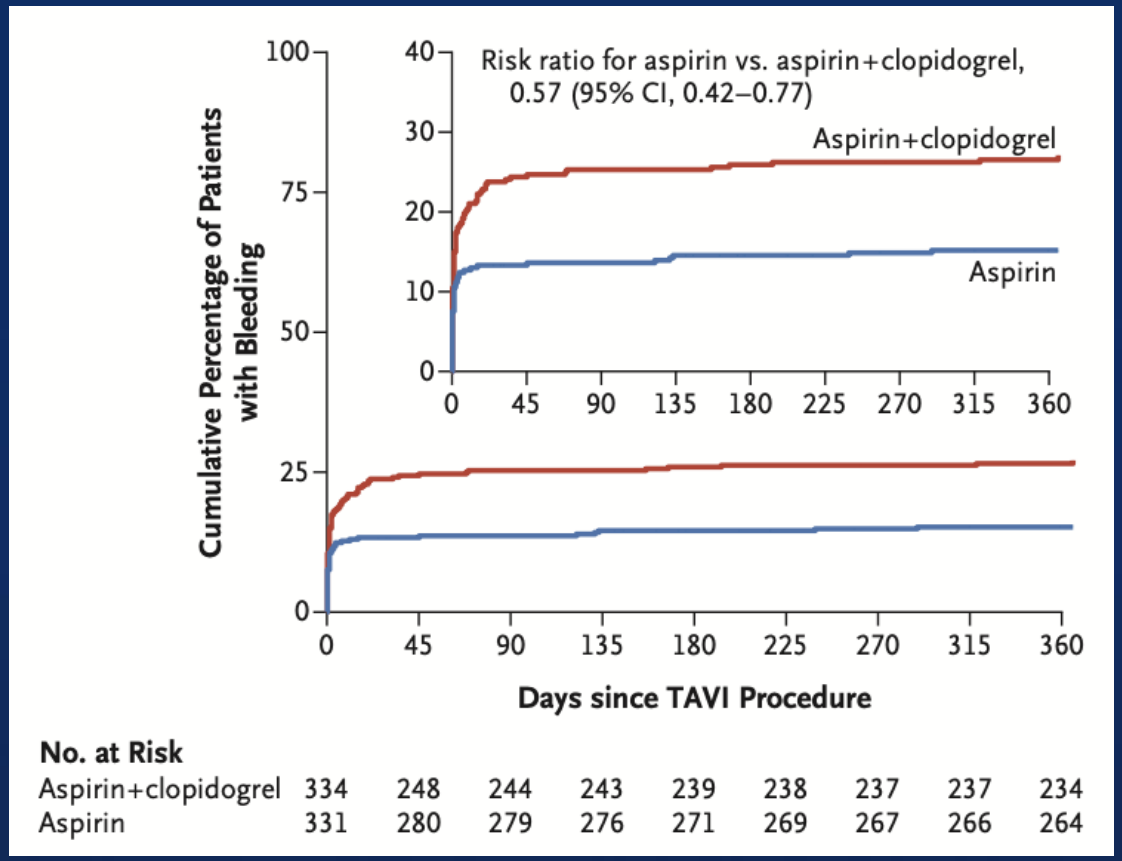
Balances between bleeding and ischemic event

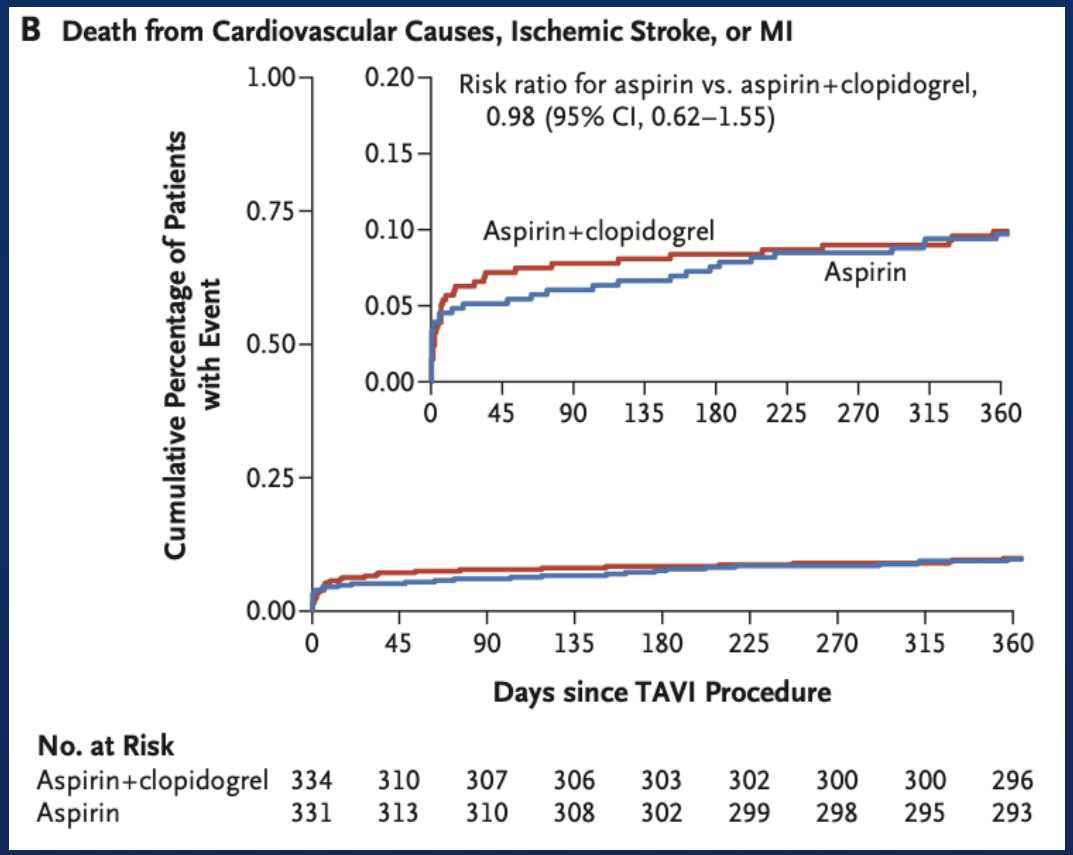
DAPT or SAPT???



Aspirin with or without Clopidogrel after Transcatheter Aortic-Valve Implantation

POPular TAVI trial (Cohort A)





Among patients undergoing TAVI who did not have an indication for oral anticoagulation, the incidence of bleeding and the composite of bleeding or thromboembolic events at 1 year were significantly less frequent with aspirin than with aspirin plus clopidogrel administered for 3 months.

Brouwer J, et al. N Engl J Med. 2020 Oct 8;383(15):1447-1457.

2021 ESC/EACTS Guidelines for the management of valvular heart disease

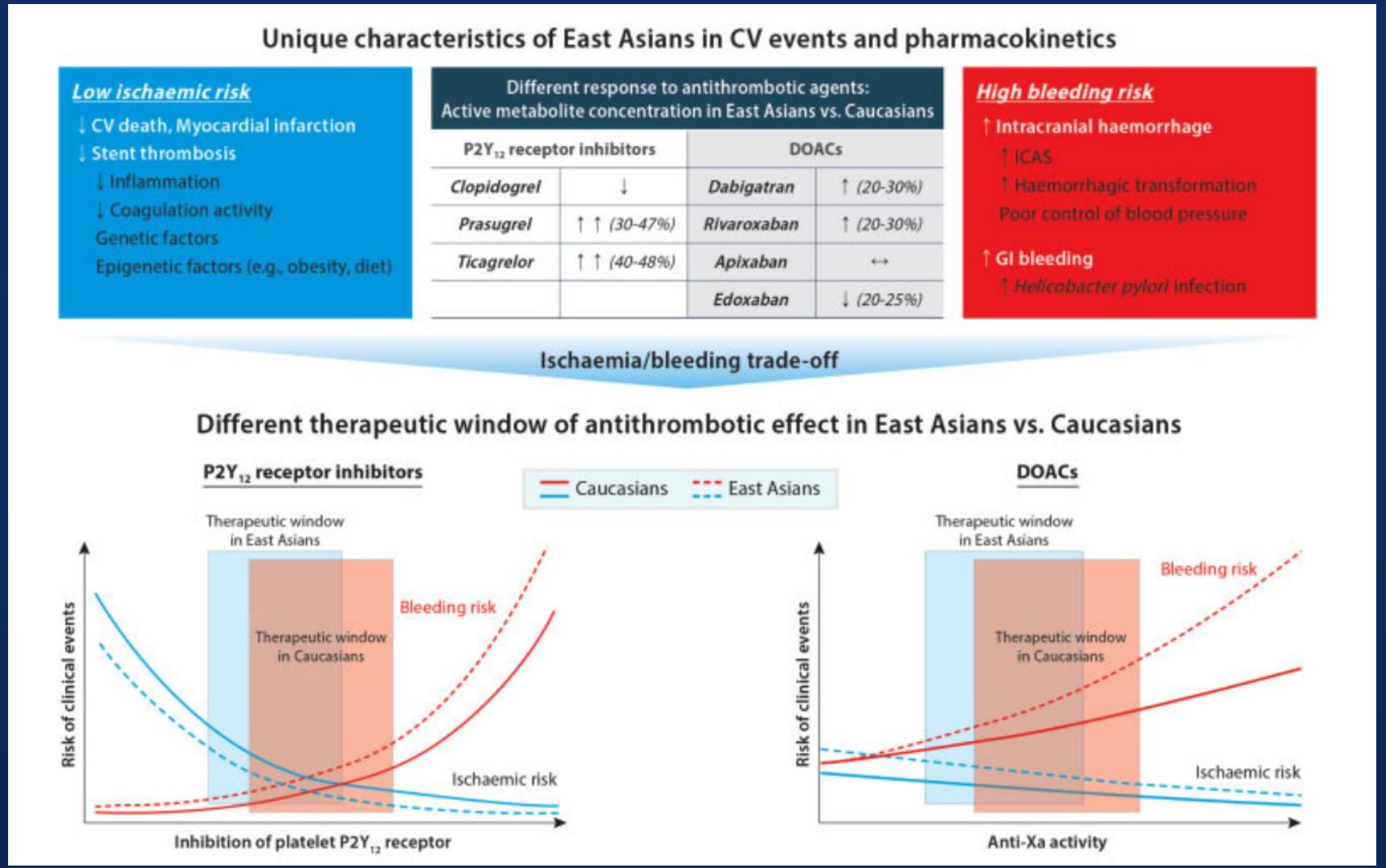
ASA monotherapy is recommended.

Transcatheter aortic valve implantation		
OAC is recommended lifelong for TAVI patients who have other indications for OAC.[501] [f]	I	B
Lifelong SAPT is recommended after TAVI in patients with no baseline indication for OAC.[495,496,521]	I	A
Routine use OAC is not recommended after TAVI in patients with no baseline indication for OAC.[497]	III	B

European Heart Journal (2022) **43**, 561–632

The East Asian Paradox: An Updated Position Statement on the Challenges to the Current Antithrombotic Strategy in Patients with Cardiovascular Disease

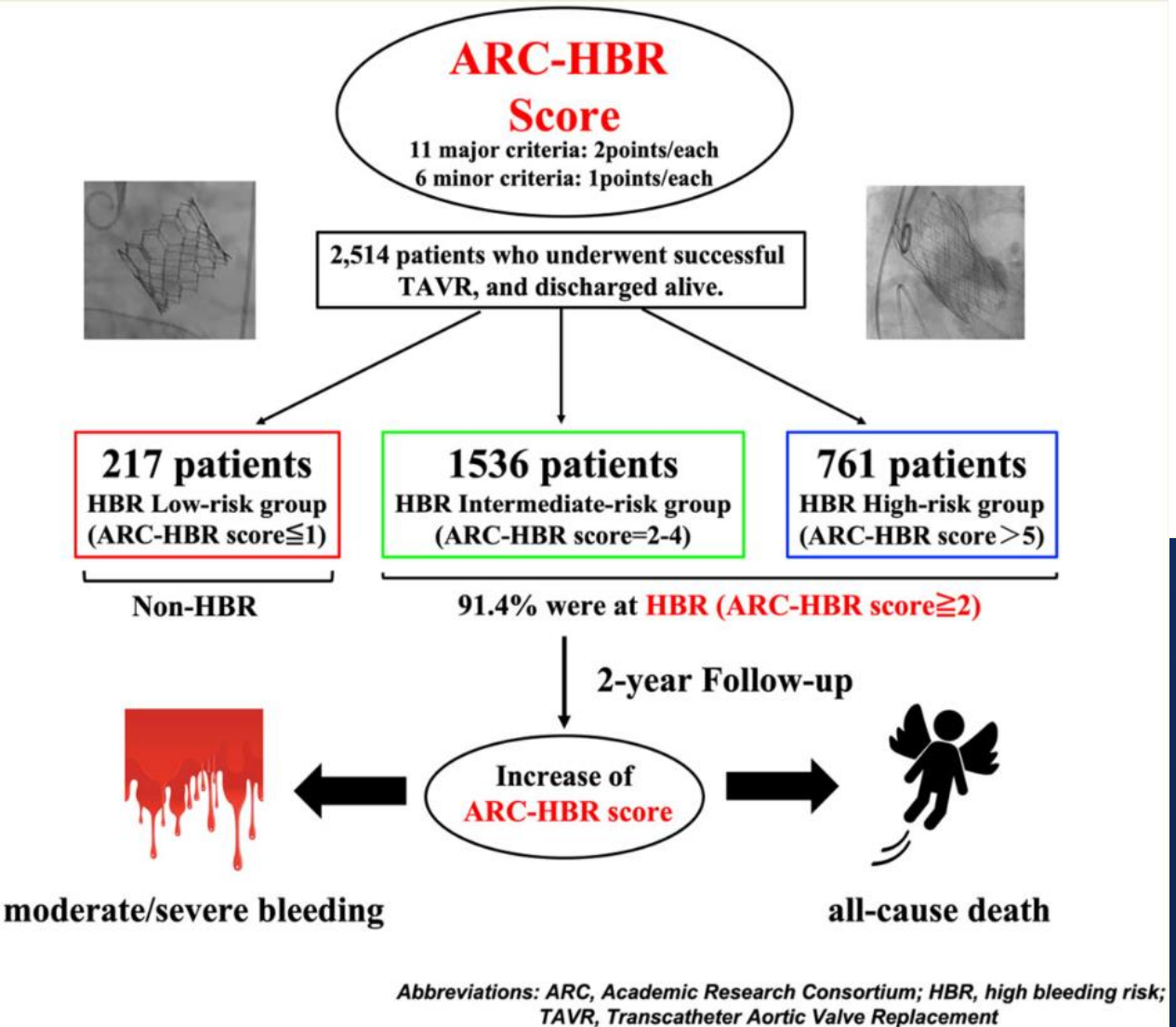
EAST Asian paradox: Low ischemic event, High bleeding event.



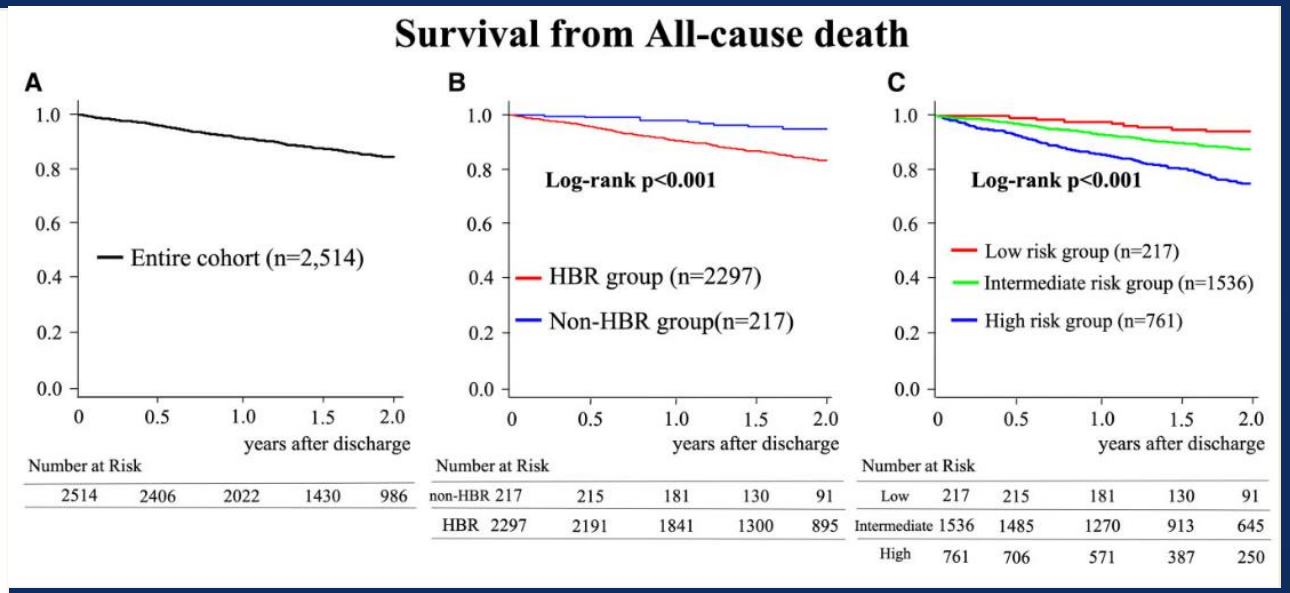
Thromb Haemost 2021;121:422–432.

Academic Research Consortium High Bleeding Risk Criteria associated with 2-year bleeding events and mortality after transcatheter aortic valve replacement discharge: a Japanese Multicentre Prospective OCEAN-TAVI Registry Study

Most of the Japanese TAVI cohort was classified in HBR!



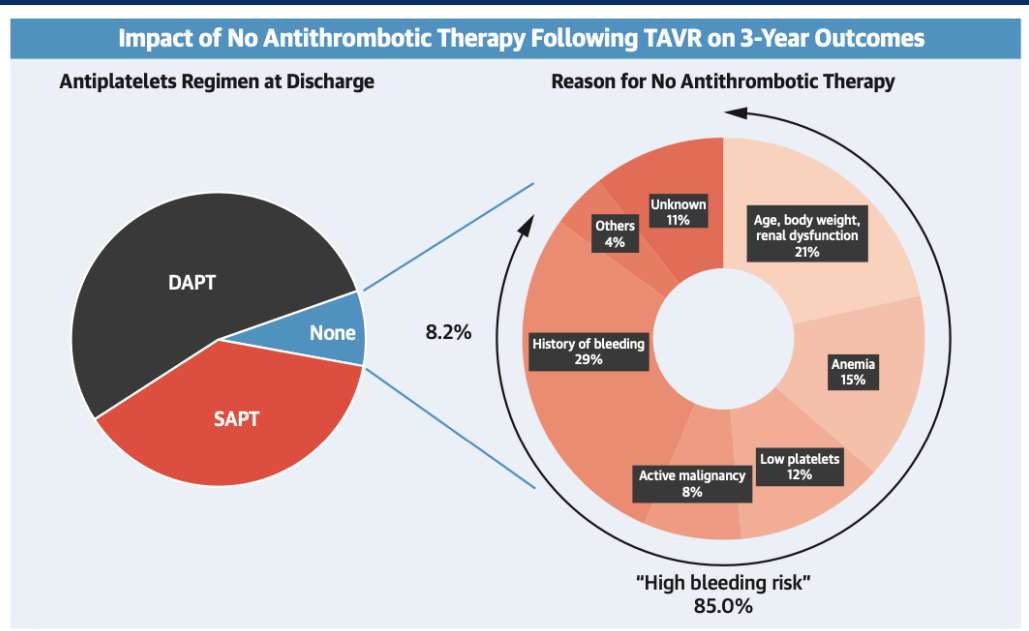
Abbreviations: ARC, Academic Research Consortium; HBR, high bleeding risk; TAVR, Transcatheter Aortic Valve Replacement

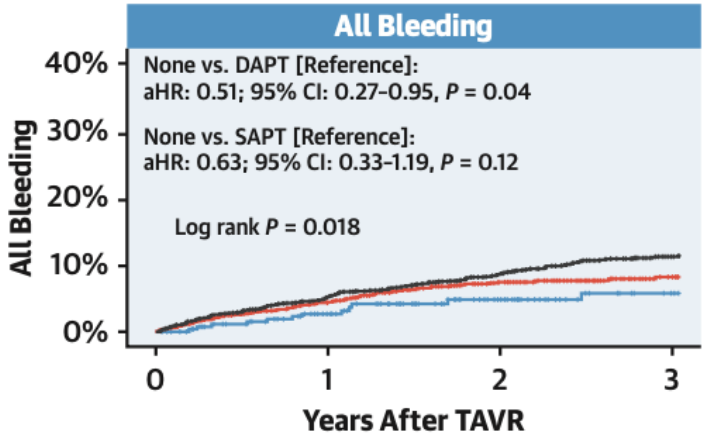


More than 90% of patients undergoing TAVI are classified in the HBR group, and the mortality rate increases with increasing BR.

No Antithrombotic Therapy After Transcatheter Aortic Valve Replacement Insight From the OCEAN-TAVI Registry

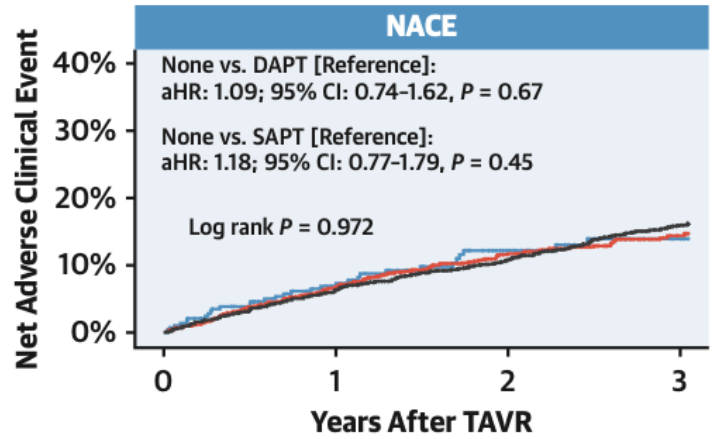
ASA or No ASA; That is the question





No. at Risk:

None	293	234	137	79
SAPT	1,354	1,069	620	300
DAPT	1,928	1,576	1,103	722



No. at Risk:

None	293	229	130	73
SAPT	1,354	1,063	614	297
DAPT	1,928	1,571	1,095	707

NACE; cardiovascular death, stroke, myocardial infarction, and life- threatening or major bleeding

Compared with SAPT/DAPT, the non-antithrombotic strategy was not associated with an increased risk of NACEs and potentially reduced the risk of bleeding events. The non-antithrombotic strategy may be an acceptable alternative to SAPT/DAPT in selected patients with TAVR.

Kobari Y, Hayashida K, and OCEAN group. J Am Coll Cardiol Intv 2023;16:79–91

Non-antithrombotic Therapy After Transcatheter Aortic Valve Implantation (NAPT) Trial

Quite simple study

Study design;

Prospective, randomized controlled, open- label blinded endpoint (PROBE) multicenter trial conducted in Japan, testing the non-inferiority of non-antithrombotic therapy compared with aspirin monotherapy in patients who underwent TAVI and had no indications for long-term OAC.

Inclusion Criteria

1. Patients who underwent TAVI with a transfemoral approach for aortic valve stenosis
2. Patients aged 20 years or older at the time consent is obtained
3. Patients who fully understand the main point of the study and consent in writing to participate in the study

Exclusion criteria

Never enroll the patients with TAVI complication

Never enroll the patients who need anti-platelet therapy and OAC

Never enroll the patients with Dialysis and post AVR

Never enroll the patients who are not candidate for TAVR

End-points

Primary endpoint

Composite endpoint comprised of all-cause mortality, myocardial infarction, stroke, and bleeding from randomization until the end of the study (follow-up for at least 1 year for up to 3 years)

Key secondary endpoints

Bleeding events from randomization until the end of the study
- Total incidence of Type 1, Type 2, Type 3, and Type 4 bleeding defined by VARC 3 Cardiovascular adverse events from randomization until the end of the study

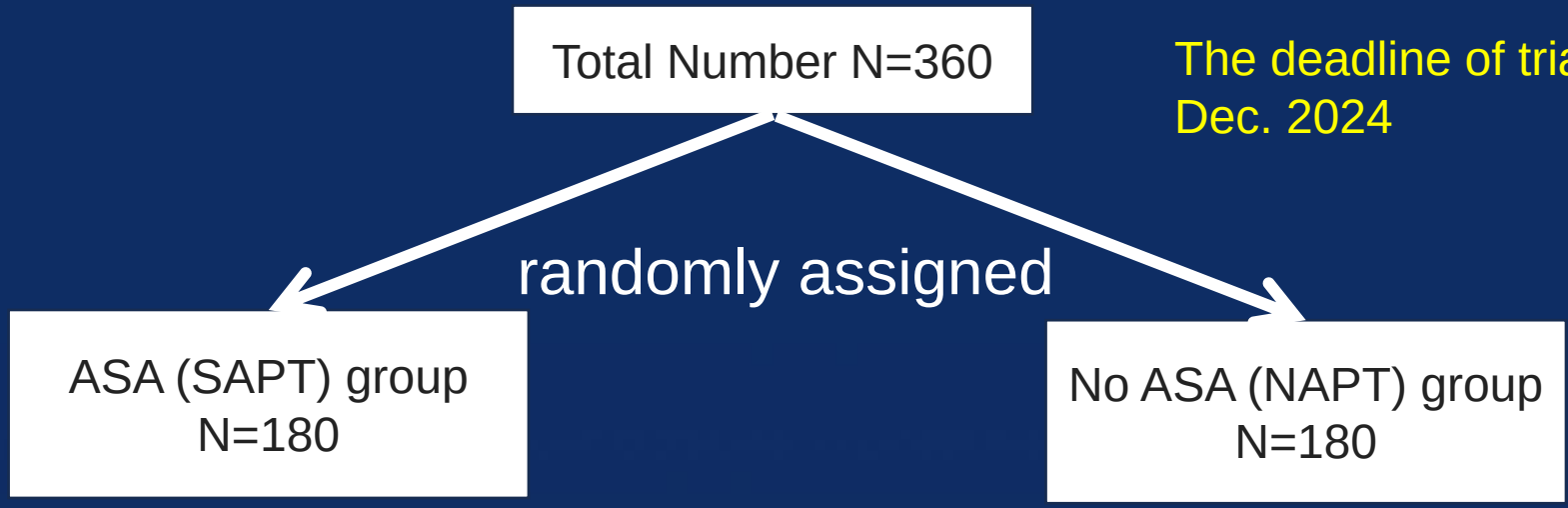
Other secondary endpoints

Bleeding events from randomization until the end of the study
- Incidence by Type for Type 1, Type 2, Type 3, and Type 4 bleeding as defined by VARC 3
- Incidence by Type for Type 1, Type 2, Type 3, Type 4, and Type 5 bleeding as defined by the BARC

Incidence of all-cause mortality from randomization until the end of the study Incidence of cardiovascular death from randomization until the end of the study Incidence of myocardial infarction from randomization until the end of the study Incidence of stroke from randomization until the end of the study
Incidence of transient ischemic attack from randomization until the end of the study Incidence of systemic embolism other than cerebral infarction from randomization until the end of the study
Incidence of hospitalization due to heart failure from randomization until the end of the study
Incidence of all hospitalizations from randomization until the end of the study Change in the mean aortic valve pressure gradient and effective orifice area at 6 months and 1 year on TTE

Exploratory endpoints
Incidence of HALT and RLM on computed tomography imaging analysis 1 year after TAVI
Change in the score conversion value based on KCCQ-12 implemented at randomization and at 1 year

Target sample size



The deadline of trial enrollment
Dec. 2024

Power Calculation;

ASA group *

Adverse events (composite of death, myocardial infarction, stroke, and bleeding) @1year: approximately 23%

10% Thromboembolic events resulting in death, stroke, and myocardial infarction

15% Bleeding events

NAPT group

Adverse events in the non-antithrombotic group @ 1year: approximately 18%

10% Thromboembolic events resulting in death, stroke, and myocardial infarction

8% Bleeding events,

If the hazard ratio margin of non-inferiority is set at 1.3 (a difference of 6% in incidence), the number of events required for a non- inferiority validation by the Schoenfeld method is 109 cases, corresponding to a required sample size of 302 cases. The significance level was set at one-sided 2.5% and the power was set at 80%. Considering 20% of dropouts from follow-up surveys, the target sample size is set at a total of 360 cases for both groups.

* The incidence of bleeding events in the aspirin group is estimated to be about 1.8 times the relative risk.

Conclusion

The NAPT trial will determine the non-inferiority of a non-antithrombotic therapy compared with aspirin monotherapy after TAVI.