SASCI
South African Society of Cardiovascular Intervention

SASCI Opinion on Navitor TAVI System

1 November 2024

Please Note:

- SASCI is not mandated or equipped to approve medical devices.
- Some SASCI Exco members are proctors for various devices and may have potential conflict of interest.
- SASCI is restricted to comment on the scientific data in support of the device and the technical aspects/handling of the device.

SASCI Statement:

Patients with severe symptomatic aortic stenosis (AS) have traditionally been treated with surgical aortic valve replacement (SAVR). Transcatheter aortic valve implantation is a percutaneous option that has been shown to be at least as effective as SAVR in numerous sub-groups of patients with severe AS.

SASCI supports the introduction of applicable new technology in South Africa, provided that the SASCI/SCTSSA Joint Consensus Statement and Guideline 2022 is followed and adhered to. https://www.sasci.co.za/uploads/files/DOI-10-5830-CVJA-2022-049.pdf

Physicians (MDT) performing TAVR should only have access to this technology following an extensive training program involving certification by international or local proctors. Abbott (and Baroque Medical) have formulated a strict training program for this technology.

The following is noted regarding the Navitor TAVI System:

- The Navitor has similar indications to existing TAVIs in the market.
- There is no direct comparison of Navitor to surgery as this would be unethical.
- The Navitor received FDA approval for use in higher risk patients based on non-randomised data.
- Safety and clinical endpoints have been met in various published clinical trials, following the evolution of technology over years of clinical experience and reported in literature.
- Pacemaker rates are high but may be lower with newer implantation techniques, although this has not been shown.
- Transcatheter aortic valve replacement with the Portico and Navitor valve appears safe and effective, with low mortality and clinical outcomes in high-risk patients with severe AS.
- The literature review between 2012 and 2024 supports the recommendations.

For these reasons, we believe it has a place in our market.

Yours sincerely,

Jean Vorster, Vice-President SASCI