



SASCI Opinion - Myval TAVI System

27 September 2024

This is an updated opinion issued on 22 Aug 2023 regarding the Myval TAVI System and in response to significant new evidence published in the Lancet earlier this year [Lancet 2024; 403: 2695–708].

We deem the following as important:

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

The literature on the Myval is limited but comprises case series with good outcomes. Myval has not been tested against surgery, but such a trial would no longer be ethically possible. Newer devices would therefore have to be tested in trials compared to industry standard valves.

The LANDMARK trial was published earlier this year in a very reputable medical journal (Lancet). The design and methods of the trial is of a high standard. The Myval system was compared in a randomised fashion to contemporary industry standard devices. At 30 days, the results were similar in the two groups with regards to a variety of outcomes and we agree with the authors' conclusion: the LANDMARK trial establishes the non-inferiority of Myval compared with contemporary THV for early safety and effectiveness composite endpoints at 30 days for the treatment of individuals with symptomatic severe native aortic stenosis. The results were reported at 30 days and further evaluation at longer follow up would be important.

From a technical point of view, reports from operators who have used the device are that it handles well, and the valve can be implanted with accuracy and good short-term results.

The valve comes in a wide range of sizes, including sizes that cover patient anatomy that would otherwise not be suitable for TAVI with other valves currently available in South Africa. Furthermore, the valve is currently offered at significantly lower cost relative to the other valves on the market in SA.

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

Yours sincerely,

Hellmuth Weich

Immediate Past President SASCI