

TAVI *versus* Surgery: What is the Truth?

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KEYWORDS

TAVI-Aortic valve replacement.

INTRODUCTION

When the TAVI procedures appeared about 15 years ago the surgery had already 50 years of experience. The aortic valve replacement was codified with a lot of publications of the series. The results of AVR are today well known and established with excellent results. An evolution was made at the beginning of this century, becoming more “biological” than “mechanical”. In another handsome concerns have recently been provided against this evolution particularly between 60 and 70 years.

For 10 years we got many publications about TAVI procedures with major papers comparing TAVI with Surgery. But when we read those papers we don't understand how it can be published with such conclusions. We have selected 4 major papers: two in NEJM, one in JAMA and one in Lancet journal [1-4]. The major problems regarding those papers was the selection of the patients and the associated procedures performed which encountered worse results. Therefore the comparison was not validly despite a propensity score was used.

FIRST PAPER

The five year comparison between TAVI and Surgery [1].

A major bias in the selected patients existed because the

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surgery cohort included 27 % of redo procedures after coronary artery bypass grafting (CABG)! The redo procedures after CABG are an ideal indication for TAVI procedure, because the operative risk of death or complications is high in such procedures after the surgery. Therefore the comparison is not possible.

Despite the adverse selections of surgical patients the results showed more rehospitalizations, more strokes, and more deaths more paravalvular leak, more pace makers at 5 years in TAVI group. Nevertheless the conclusion was: non inferiority for the TAVI group. What could be the results of the same study without the 27 % of redo procedures? The other major problem of this paper consisted in the support by Edwards which provide the TAVI device: there was a major conflict of interest.

SECOND PAPER

The Partner 3 study (Mack et al) .The AVR surgery group included about 30 % of associates procedures whose about 13 % of CABG and less than 7 % of associate procedures in the TAVI group. Therefore again, the comparison between the 2 groups was not possible! For example a patient who is operated on for a single AVR is absolutely different than a patient operated on for AVR associated with CABG. In other hand the conclusions of this paper

WAS the opposite of the results at five years provided in the first paper (in term of complications rehospitalization and deaths).

THIRD PAPER

The authors studied the patient at low risk in a large retrospective study, using a propensity score. But again, there was a high difference in the 2 groups. The surgery group included about 16 % of the CABG associated (3) like in the second paper. In the fourth paper (4) the severe paravalvular leak rate amounted to 3 to 9 %. Those leaks could encountered major complications (cardiac failure-death) during the follow-up. After standard AVR the severe paravalvular leaks rate is close to 0 %! Therefore, even in some older patients TAVI procedures can have worse evolution during the first year following the procedure. But worst repercussion provided by this

complication is underestimated in most publications about TAVI procedures.

TO CONCLUDE

We cannot make any conclusions with those 4 major papers which, however provides the main actual guidelines. Nevertheless, many conclusions have been already made all around the world. The major bias was the sponsoring of this paper by the industry encountering major scientific bias as shown in this letter. A comparison between a TAVI group and isolated AVR is needed for the low or moderate risk patients (a redo procedure after CABG and associate procedures must be excluded).

All these papers made a comparison between apples and strawberries! It's time to compare two apple varieties to make accurate conclusions without the sponsoring by the apple's suppliers!

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