Letters to the Editor

In-hospital outcomes after PCI and TAVI versus combined aortic valve replacement and coronary surgery

Acerca de los resultados hospitalarios tras ICP y TAVI frente a la sustitución quirúrgica de la válvula aórtica y cirugía coronaria combinadas

To the Editor,

We have read with interest the study by McInerney et al.[1] published in *Revista Española de Cardiología* and offer some comments that we believe may be of interest to readers.

We note that none of the authors of the article are cardiovascular surgeons. Surgeons could have contributed their experience to the interpretation of the analysis of administrative databases which, as is well known, are subject to highly significant biases in the analysis of clinical indicators.[2,3] For example, the article reported an incidence of postoperative atrial fibrillation of 2.8%. This value is 5 to 10 times lower than the value known until now[4] and is the lowest ever published. However, it seems that the authors overlooked this anomaly, which can only be understood by reference to coding errors and would have been noticed by authors familiar with postoperative complications.

Likewise, we believe that errors were made in patient selection. The authors claim to have excluded patients undergoing mitral or tricuspid surgery from the surgical group. However, after assessing the selection codes in the appendix, they did not exclude other associated procedures, such as thoracic aortic surgery, septal defects, or any type of mitral or tricuspid repairs. We performed our own analysis of the minimum data set (MDS) using stricter exclusion criteria and found that both the number of patients in the surgical arm (n = 3446) and their mortality (4.7%) decreased by more than 30%.

Furthermore, the authors decided to exclude all events related to transcatheter aortic valve implantation (TAVI) and percutaneous coronary intervention (PCI) during the same hospital admission, as it was impossible to determine if these were planned or rescue procedures. We performed an MDS query with similar codes for TAVI and detected 187 TAVI and PCI events during the same hospital admission (representing almost 20% of the percutaneous arm referred to in the article), with mortality of 8.6% (n = 16). We suggest that the elimination of these patients may involve serious bias and that, in any case, such bias is greater than if they had been included while taking into account that the indication for PCI may be difficult to determine with certainty.

The selection of patients undergoing TAVI with PCI in the previous 6 months is also questionable for the following reasons: *a)* it is difficult to univocally identify different events concerning the same patient in the MDS; *b)* the implementation of ICD-10[5] has led to some hospitals having very deficient MDS data; c) it is arbitrary to exclude patients treated with PCI in the same or a subsequent care episode; and *d)* it is impossible to determine whether the previous TAVI and PCI procedures were performed for the same clinical syndrome or for a different one.

Regarding the propensity score analysis, it should be emphasized that the characteristics of the matched surgical cohort differed from those of the original cohort (eg, older age, more women, chronic kidney disease, chronic obstructive pulmonary disease, heart failure, etc). It is highly likely that, between 2016 and 2019, any patient with this profile would have been a candidate for TAVI, because the surgical risk would have been high or prohibitive. If the local multidisciplinary teams had decided to opt for surgery, it would have probably been due to the technical impossibility of using a percutaneous approach. Thus, we wonder what useful conclusion for daily clinical practice can be drawn from such a comparison.

In the matched-groups comparison, 10 of the 15 adjustment variables had a standardized mean difference at least 0.1, indicating that the matching was suboptimal. The fact that the estimated propensity score distribution (see figure 2B[1]) was similar does not imply that the measured baseline covariates were balanced between the 2 groups, nor does it imply that the propensity score model was correctly specified. The area under the curve of the propensity score model is also of little consequence, as it is well known that the area under the curve does not give any indication of whether an important confounding variable has been omitted from the propensity score estimation model.[6]

In summary, we believe that the findings of this study should be interpreted with extreme caution. We understand that the analysis of databases that include a surgical group may give rise to selection biases and flaws in the interpretation of the results. The participation of surgeons in the analysis of these data may help to ameliorate such problems. Furthermore, we believe that the comparison of clinical indicators should be based on clinical registries. In this regard, the Spanish Society of Cardiovascular and Endovascular Surgery has set up the Spanish Registry of Cardiac Surgery, which can analyze more than 1200 process and outcome indicators at the patient level. We encourage other scientific societies to implement this initiative so that future comparative studies can be performed without the need to resort to administrative databases.

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AUTHORS' CONTRIBUTIONS

All authors contributed equally to the writing of this letter.

CONFLICTS OF INTEREST

M. Carnero Alcazar has received consulting fees from Edwards Lifesciences, Abbott Vascular, and AtriCure. The other authors declare no conflicts of interest.

APPENDIX. AUTHORS' INSTITUTION

Spanish Society of Cardiovascular and Endovascular Surgery: Manuel Carnero Alcázar (secretary), José López Menéndez (spokesperson) and Jorge Rodríguez-Roda Stuart (president).

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[◇] Appendix shows the institution to which the authors belong and their positions.

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In-hospital outcomes after PCI and TAVI versus combined aortic valve replacement and coronary surgery. Response

Acerca de los resultados hospitalarios tras ICP y TAVI frente a la sustitución quirúrgica de la válvula aórtica y cirugía coronaria combinadas. Respuesta

To the Editor,

We appreciate the interest expressed by Carnero et al. in our article on hospital outcomes in patients with aortic stenosis and concomitant coronary artery disease.[1] Previous studies have validated the usefulness of the Minimum Data Set (MDS) for analyzing clinical process outcomes in Spain, including research by Carnero et al.[2] We recognize that some postprocedural complications may have been underestimated due to undercoding the MDS, a limitation that was acknowledged in our article. However, the results concerning more serious complications, such as in-hospital mortality, are not affected by this limitation.

It was noted that the results could be biased by the nonexclusion of surgical procedures involving the thoracic aorta, septal defects, and mitral/tricuspid repairs. According to our data, an analysis excluding such procedures would result in a population of 4388 patients with surgical aortic valve replacement (SAVR) and coronary artery bypass grafting (CABG), with an associated crude mortality rate of 6.98%, which is higher than that of the transcatheter aortic valve implantation (TAVI) and percutaneous coronary intervention (PCI) group (3%; $P = .001$). The propensity score analysis corresponding to these exclusions showed that for 774 matched patients, mortality in the TAVI + ICP group was lower than that in the SAVR + CABG group (mean treatment effect, 3.3% vs 7.2%; odds ratio [OR] = 0.44; 95% confidence interval [95%CI], 0.26-0.74; $P < .001$).

Carnero et al. consider that the exclusion of patients undergoing TAVI and PCI in the same episode may involve bias. However, the validity of our study is limited to the comparison of the results in patients—with the characteristics described—who underwent TAVI after having undergone PCI in the previous 6 months vs those who underwent SAVR + CABG in the same episode. Therefore, these results are not applicable to patients who underwent TAVI and PCI in the same episode, which is a therapeutic strategy that has also been used in a minority of previous registries (< 10%).[3]

Other observations refer to the fact that the authors consider it "difficult" to univocally identify different events concerning the same patient in the MDS; nevertheless, our identification methodology has demonstrated its robustness through extensive use in numerous previous publications.[4] The original letter noted the possible deficiency of MDS data after the implementation of ICD-10; however, the validity of the MDS to analyze clinical processes has also been demonstrated, as we mentioned at the beginning of this letter.[2] Lastly, the authors consider it "impossible" to determine whether the previous TAVI and PCI procedures were performed for the same clinical syndrome or for a different one; nonetheless, our article does not refer to any syndrome, but to procedures related to severe aortic stenosis (SAVS and TAVI) and concomitant coronary artery disease requiring revascularization (CABG and PCI).

Finally, regarding comments on the propensity score analysis, it should be noted that we have verified that our model does not present problems of linearity (the quadratic terms of the continuous variables are not significant) or collinearity (the mean variance inflation factor is 1.03). In addition, we have specified a new model with perfect matching in our study population (480 pairs) as well as another model that included the additional exclusions indicated by Carnero et al. (462 pairs). In both cases, we found that in-hospital mortality was lower in the post-TAVI + PCI group than in the SAVR + CABG group (mean treatment effect, 2.5 vs 7.5%; OR = 0.34; 95%CI, 0.16-0.67; $P < .001$; and 2.4 vs 6.7%; OR = 0.34; 95%CI, 0.15-0.70; $P = .002$).

We agree with the authors of the letter that the study results should be interpreted within the context described based on MBDS coding. However, until results from audited prospective clinical registries and randomized trials are available, this type of analysis contributes additional information to the scarce evidence available and may assist in hypothesis generation for future studies.

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