Carotid Stent Cell Design: Lack of Benefit or Lack of Evidence?

To the Editor:

We would like to congratulate Schillinger and colleagues for their recent retrospective analysis on 1684 patients who underwent carotid stenting with either a closed- or open-cell stent design. The authors concluded that current data do not support the superiority of a specific carotid stent cell design. Although we thank Schillinger and colleagues for the significant effort spent in collecting and analyzing the published data, we must highlight that many relevant methodological issues beyond those discussed by authors should be taken into much greater account, because they may explain the apparent lack of benefit of a specific carotid stent cell design over the other.

First, it is tempting and highly attractive to speculate that closed-cell design stents may provide more effective plaque coverage and reduce the risk for embolization of particles compared with open-cell design stents. If so, then it would be intuitive to assume this effect to be negligible during the procedure where cerebral protection devices are expected to minimize the impact of stent design on the distal embolization process, whereas their predictable effects may become apparent only on removal of the cerebral protection devices. Neurological events which occur during the procedure may actually be an important confounder in this analysis. The authors should be commended for showing outcomes occurred intraprocedurally and from sheath removal to 30 days, separately. However, landmark analysis evaluating neurological prognosis in patients who are free from neurological complications at the end of the procedure would be much more appropriate to assess this hypothesis.

Second, assuming a subacute (ie, from day 1 up to 30 days) cumulative event rate, in terms of the composite of death, stroke or transient ischemic attack (TIA), in the range of 1% in patients treated with open-cell stent design, as reported by the authors, almost 9500 patients would be required to show a 50% relative decrease in patients receiving a closed-cell stent design with a type I and II error set at 5% and 20%, respectively. In other terms, the analysis recently reported by Schillinger and colleagues is largely underpowered (actual power is in the range of 50%) and as such mainly inconclusive. Indeed, the rate of death, stroke and TIA in the subacute phase went from 1% in the open-cell design stents down to 0.3% in the closed-cell design stent, whereas the composite of death or stroke went from 0.8% to 0.1%, respectively. The same trend was consistently reported in both asymptomatic and symptomatic patients, which again calls for larger properly powered studies focusing on the influence of stent design on events occurring after completion of the carotid stenting procedure.

Third, the authors used the propensity-score matching procedure to compare patients treated with open- versus closed-cell stent design in order to adjust for the presence of multiple and important imbalances between groups. However, they failed to show key parameters related to the statistical process which are of utmost importance to judge the appropriateness of the matching procedure, such as: median and interquartile range of the propensity score for the use of one-cell stent design over the other in both groups, the overall c-statistic for the whole multivariable model to evaluate its discrimination capacity, and the goodness-of-fit for the model. Thus, we encourage authors to make this information available to the readers.

In summary, we feel that the recently reported lack of benefit of closed-cell stent design over the open-cell stent design lacks good evidence, because of methodological and type II error issues. Properly designed study models as well as randomized controlled studies to assess the benefit of one type of stent cell design over the other should be encouraged.

Disclosures

None.

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