basis of their underlying malignancy. Unfortunately, our study does not provide definitive answers to the above-mentioned questions, but confirms that survival was low in the overall cohort, and that CAS was performed with low peri-procedural risk but with high restenoses rates. We continue to indicate carotid revascularization after a careful discussion of our institutional results, the risks of stroke or stroke-related disability, the patients overall prognosis, and the anatomical characteristics of the lesion. In general, patients with no evidence of recurrent cancer and who are symptomatic and have suitable anatomy are treated by either CAS or open surgery, depending on factors such as presence of concomitant radical neck dissection, tracheostomy, or skin damage. For asymptomatic patients, we recognize that the indication of revascularization remains controversial and that one should carefully analyze the patient's life expectancy and anatomical risk for the procedure. However, carotid revascularization continues to have a role in selective patients with significant progression of the carotid lesion and no evidence of recurrent metastatic disease or limited life expectancy.

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Regarding "Evaluation of the Endurant stent graft under instructions for use vs off label conditions for endovascular aortic aneurysm repair"

We read the article by Torsello et al with interest.[1] While the use of endovascular aneurysm repair (EVAR) has revolutionized the management of infrarenal abdominal aortic aneurysm (AAA) its use has only been shown feasible in 40% to 60% of AAA. Advances in technology, imaging, graft design, and operator experience has lead to an extension of their use beyond initial manufacturer's guidelines. The device studied in this article is licensed to a 10-mm neck extending or rather shortening the previous benchmark of 15 mm. Nevertheless, the ability to place the graft at operation outside this use is shown to be associated with increased type I endoleak. Numbers did not reach significance as the primary endpoint frequency was low and study group small.

We have previously shown that use of EVAR outside IFU was associated with a worse outcome that translated into patient mortality in symptomatic AAA.[2] Recently we conducted a review of the EUROSTAR database of over 7500[3] cases to determine the long-term outcome of elective infrarenal endografts inserted outside the manufacturers' IFUs. We found a significant association between the "off label" use of endografts and the incidence of type 1 endoleak, which is in agreement with the authors. However, our data also showed that grafts placed outside IFU were associated with increased all-cause mortality and type I endoleak was associated with increased aneurysm related mortality at long-term follow-up. The grafts in our study, however, were older generation and did not include the Endurant. These datasets support the authors comments that use of EVAR outside IFU can be done but short-term results that may appear satisfactory are in fact significantly worse in long-term follow-up.

We suggest that use of devices outside license or recommended usage should be undertaken only in the centers with robust data collection, or better still, in clinical trials. EVAR is an excellent prophylactic treatment for infrarenal AAA when undertaken correctly, however, it appears less effective if outside IFU and increases the risk for long-term failure. Long-term follow-up of EVAR has shown the early advantages of infrarenal EVARs over open surgery disappear with time.[4] The consequence of using "off-label" stent grafts may have resulted in steadily increased numbers of ruptured aneurysms. This has prompted us to resort to a more liberal use of fenestrated stent grafts, given the excellent early results with the latter.

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Reply

We read with interest the comment of Cross et al and we thank them for the attention paid to our article.

We completely agree with the authors that the use of endografts outside the manufacturers' instructions for use (IFU) was responsible of a higher risk of type I endoleak[1]; our population study did not have the right power to obtain a statistical significance, but we explained this bias in the text. Furthermore, our follow-up was too short to give rough conclusions.[2]

Then, we agree with the authors that the applicability of endovascular aneurysm repair outside IFU should be reserved for those centers with great experience in aortic endovascular procedures.

In other reports, we suggested the use of alternative procedures (fenestrated stent grafts, chimney technique) in selected patients with a long life expectancy and with stable lesions, even if these advanced endovascular techniques have still not resolved problems. In fact, the

rate of secondary procedures in the long-term period in patients treated with fenestrated stent grafts is not negligible,[3] and the chimney technique shows satisfying results in series with a small number of patients with a short-term follow-up.[4]

The Endurant stent graft is a new-generation device and we are expecting better long-term results in terms of migration, module disconnection, and fatigue of the materials than those offered by the first- and second-generation devices.[5] So, we confirm the cautious application in selected patients of endovascular aneurysm repair outside the Endurant-specific IFU.[2]

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Carotid artery stenting may be contraindicated in female patients with symptomatic carotid artery stenosis

Carotid artery stenting (CAS) has reported inferior outcomes compared with carotid endarterectomy (CEA) for the management of symptomatic carotid artery stenosis.[1] The 2011 guidelines by the American Heart Association/American Stroke Association (AHA/ASA) and several other associations recommended CAS as an "alternative to CEA for symptomatic patients" (class I; level of evidence B).[2] The AHA/ASA Guidelines used the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) to support this recommendation.[3]

CREST recently reported a subgroup analysis on the influence of sex on outcomes after CAS compared with CEA.[4] Although symptomatic men showed similar periprocedural stroke rates whether undergoing CAS or CEA (3.3% vs 2.4%, respectively; hazard ratio [HR], 1.39; 95% confidence interval [CI], 0.78-2.48; $P = .26$), women assigned to CAS had >2.5-fold higher periprocedural stroke rates compared with those undergoing CEA (5.5% vs 2.2%, respectively; HR, 2.63; 95% CI, 1.23-5.65; $P = .013$). Similar results were reported for periprocedural death rates. As the authors commented, "women might be at higher risk of periprocedural stroke and death because of technical difficulties related to the fact that they have smaller internal carotid arteries than men; women, on average, have 40% smaller internal carotid arteries than men."[4]

Another recent report compared the outcomes of CAS vs CEA in women vs men using the Nationwide Inpatient Sample (n = 54,658 procedures) during 2004 and 2005.[5] Although females had similar rates of perioperative stroke with males undergoing CEA (1.0% vs 1.0%, respectively; $P = .9$) or CAS (2.7% vs 2.0%, respectively; $P = .2$), symptomatic women had higher perioperative stroke rates compared with either asymptomatic females (3.8% vs 0.9%, respectively; $P < .001$) or symptomatic men (3.8% vs 2.3%, respectively; $P = .03$).[5] The conclusion reached was that "CEA may be the preferred treatment in female patients who warrant intervention for cerebrovascular disease, unless compelling reasons exist to perform CAS."[5]

Maneuvering CAS guidewires and catheters in the smaller female carotid arteries with "unstable" plaques may produce more microemboli than in males; these microemboli may account for the increased periprocedural stroke rates in symptomatic female patients undergoing CAS.[4,5]

The inferior results of CAS compared with CEA for symptomatic female patients,[4,5] therefore, indicate that CAS is not an acceptable "alternative" to CEA in this group of patients.

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