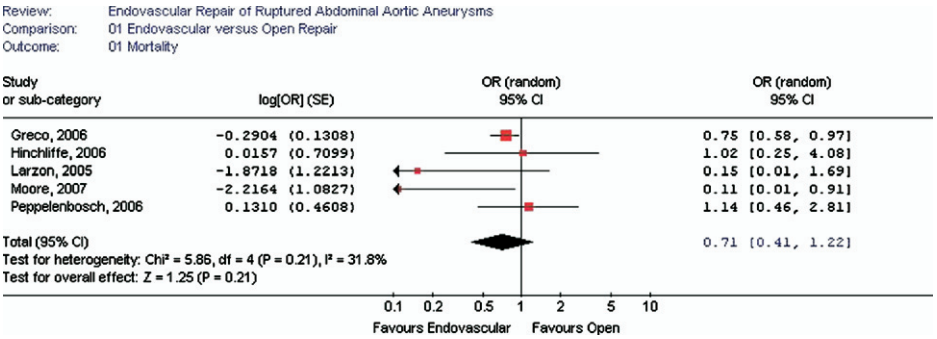

Fig. Forest plot of adjusted odds ratios of included studies.

Larzon et al,[6] an exact method was used to estimate multivariate logistic regression analysis of mortality in relation to circulatory shock, age >76 years, loss of consciousness, hemoglobin <90 g/L, creatinine >190 μmol/L, and electrocardiographically documented ischemia. In the randomized controlled trial by Hinchliffe et al,[7] patient characteristics in the two treatment arms were similar. Pooled analysis of the adjusted ORs from the four observational studies and the OR from the randomized controlled trial (representing 6097 patients: 389 in the endovascular repair group and 5708 in the open repair group) demonstrated a statistically nonsignificant 29% reduction in mortality with endovascular relative to open repair in a random-effects model (OR, 0.71; 95% confidence interval, 0.41 to 1.22; $P = .21$) (Fig). There was neither between-study heterogeneity of results analyzed by means of standard χ^2 tests ($P = .21$) nor evidence of significant publication bias assessed mathematically using an adjusted rank-correlation test ($P = .33$).

Despite the conclusions by Mastracci et al,[1] the present meta-analysis pooling adjusted ORs failed to demonstrate statistically significant benefit of endovascular over open repair for mortality in ruptured abdominal aortic aneurysms.

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Reply

Thank you for the opportunity to respond to the letter from Dr Takagi and colleagues. Dr Takagi and colleagues write that we "concluded that mortality in patients undergoing endovascular repair of ruptured abdominal aortic aneurysms was lower than that in historical reports of unselected patients undergoing open repair." Though this is an accurate report of the data, it does not accurately represent our conclusions, which take into account the strength of the evidence and the possibility that other confounding factors – most importantly, patient selection – might have led to the observed findings.[1] In the discussion, we wrote "it is not possible to conclude that the results in patients treated with REVAR are better than those for open surgery" and in the abstract "Mortality in people who underwent REVAR is lower than that in historical reports of unselected people undergoing open repair. Further investigation is needed to determine whether the difference in mortality is attributable to patient selection alone or to this new approach to treatment." Clear inferences about relative efficacy cannot be drawn from our work, and we said as much.

We made an a priori decision to analyze the data in the manner reported: that is, to include only the treatment arms. We hypothesized (correctly, as it turned out) that the composition of comparison groups would be highly variable between studies.

Dr Takagi and colleagues briefly report an alternative approach to the problem of summarizing data from observational studies. They included only studies which reported adjusted odds ratios for mortality comparing REVAR with open surgery. Likely because of the brevity of the current format, they do not report the composition of the group undergoing open repair in the case of the observational studies, which we regard as critical. The factors controlled for in statistical analysis differ between the four observational studies, and do not include the presence of circulatory shock in one of the four. These adjusted odds ratios have been combined with the unadjusted odds ratio from the single randomized controlled trial in this area. Though there are obvious limitations to this approach (as there are to our own), it is not unreasonable, and we would encourage Takagi and colleagues to present a complete version of their research synthesis for peer review and publication. As presented here, our interpretation of their data (a statistically nonsignificant benefit from endovascular technique: odds ratio 0.71; 95% confidence interval, 0.41 to 1.22; $P = .21$) does not change our conclusions. As we wrote of our own findings, "this work offers support for this technique in patients in centers

where adequate expertise and resources are available without incurring delay." Our further recommendations for future work, that a large multicenter randomized controlled trial be performed and that centers performing endovascular repair of ruptured aneurysms contribute to a central registry, are also unchanged.

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Regarding "Informed consent for AAA repair: Assessing variations in surgeon opinion through a national survey"

Berman et al[1] are to be commended for seeking "to define national surgeon opinion regarding the content of informed consent discussions" for AAA repair, but leave out an important aspect. Although they cite the two randomized trials demonstrating no benefit from repair of AAA smaller than 5.5 cm in diameter and note that the legal definition of informed consent "includes discussion of the risks, benefits, and alternatives to an intervention", they neglect to ask in their survey whether the surgeon discussed the trial results with patients who have AAA smaller than 5.5 cm. If patients with AAA substantially below this threshold are told that they "need" AAA repair and subsequently suffer an adverse outcome, preoperative review of the surgical risks without discussion of whether repair was indicated may not be considered sufficient.

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Reply

We agree that discussion of whether repair is indicated is an essential component of informed consent not only for patients with smaller aneurysms but for all patients considering AAA repair. This falls under the category of discussion of "alternatives to intervention", the alternative in this case being no intervention at all. In our survey, 97% of respondents stated that it was essential to discuss outcomes related to nonintervention during informed consent. (We did not discuss these findings due to space limitations.) We did not ask specifically about informed consent practices with patients with aneurysms <5.5 cm, but we believe that it is important in all cases to present the data and help each individual patient arrive at the treatment decision that is best for them rather than telling anyone that they "need" an aneurysm repair.

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Regarding "Endovascular vs open repair of acute abdominal aortic aneurysms–A systematic review and meta-analysis"

The recent meta-analysis comparing endovascular with open repair of acute (ruptured or symptomatic intact) abdominal aortic aneurysms (AAAs) supports a considerable benefit of endovascular aneurysm repair (EVAR) procedures.[1] Compared with open repair, EVAR was associated with a significant 38% reduction in mortality (pooled odds ratio, 0.624; 95% confidence interval [CI], 0.518 to 0.752; $P < .0001$), a shorter intensive care unit (pooled effect size estimate, −0.70 days; 95% CI, −1.05 to −0.35 days; $P < .0001$), and hospital stay (pooled effect size estimate, −0.33 days; 95% CI, −0.50 to −0.16 days; $P = .0001$), as well as a significant reduction in blood loss (pooled effect size estimate, −1.88 lt; 95% CI, −2.49 to −1.27 lt; $P < .0001$) and procedure time (pooled effect size estimate, −0.65 hours; 95% CI, −0.95 to −0.36 hours; $P = .0001$).[1]

In two of the five parameters examined in the meta-analysis, there was evidence of both heterogeneity and bias, that is, in intensive care unit stay (heterogeneity: Cochran Q test, 46.57; $P < .0001$; bias: Egger test, −3.98; $P = .0085$), and operative blood loss (heterogeneity: Cochran Q test, 51.91; $P < .0001$; bias: Egger test, −4.94; $P = .0032$).[1] In another two parameters, there was evidence of either heterogeneity or bias, ie, in mortality (heterogeneity: Cochran Q test, 15.449; $P = .750$; bias: Egger test, −0.649; $P = .017$) and procedure duration (heterogeneity: Cochran Q test, 30.82; $P = .0012$; bias: Egger test, −0.34; $P = .82$).[1] The only parameter showing neither significant heterogeneity nor bias was the length of postoperative stay.[1]

Additionally, in all the trials evaluated in the meta-analysis, the inclusion criteria for study entry were: (1) adequate hemodynamic stability for patients to undergo a preoperative CT scan, (2) AAA anatomical suitability for EVAR (eg, appropriate proximal neck length), and/or (3) the presence of sufficient personnel for the performance of EVAR. When these inclusion criteria were not met, the patient was either excluded from the study or an emergency open AAA repair was performed.

Another drawback that questions the validity of the results of this meta-analysis is that only one of the 23 studies included was a randomized controlled trial between EVAR and open repair for ruptured AAAs;[2] however, this study also had several exclusion criteria.[2]

Based on the specificity of the selection/inclusion criteria, as well as the reported heterogeneity and associated bias of the reported results, it may be premature for any definite conclusions to be drawn. EVAR may be a reasonable option for symptomatic (but intact) AAAs; however, in true emergency AAAs (as in the case of ruptured AAAs), patients may not be hemodynamically stable for a preoperative evaluation CT scan of the AAA anatomy to be performed. There may also be ethical limitations in designing appropriate randomized controlled trials to provide definitive