Author's response to reviews

Title: Complications after endovascular stent-grafting of thoracic aortic diseases

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Version: 2 Date: 8 September 2006

Author's response to reviews: see over
Here are the answers to the Reviewers suggestions and concerns:

**Reviewer #1:**
The Authors reported their experience in the endovascular treatment of thoracic aorta. They achieved very good results in terms of mortality and morbidity, even inferior to those reported in most of the larger series from Literature. Methods, materials and techniques are clearly explained in the manuscript. Results are very well described and analyzed in details in the discussion, However:
1. The Authors reported that 4 patients underwent extra-anatomical carotid-carotid bypass before stent-graft deployment. They routinely perform an angio CT scan of the intracranial vessel, but how the preoperative evaluation of the supraortic vessels is carried out? It could be useful to better clarify this issue. Are the supraortic vessels studied preoperatively in all patients or only when a hybrid procedure has to be performed? Which kind of imaging modalities is used?
   **Answer:** every patient who presented with thoracic aortic disease (especially aortic arch one) was evaluated with duplex-ultrasonography and/or CT-angiography of the epiaortic trunks and intracranial vessels in order to achieve more information about the Willis circle.
2. The Authors described four cases of hybrid aortic arch replacement with a carotid-carotid bypass followed by thoracic stent grafting. Differently from a hybrid thoracoabdominal procedure, a hybrid aortic arch procedure can be performed simultaneously without increasing mortality and morbidity. Why a staged operation has been preferred? Which criteria has been used in choosing the sequence of the surgical revascularization?
   **Answer:** No. All the procedures involving the aortic arch was performed simultaneously. Timing was: extra-anatomic bypass first, and subsequently (during the same intervention), endovascular stent-grafting.
3. The Authors report a 33% rate of left subclavian artery overstenting with only one case of preventive surgical revascularization, that means 6% of the cases. Consequently, it seems that the Authors don’t care particularly about the LSA. However, this is an important issue, as emerged from the most recent Literature, also in order to reduce the incidence of paraplegia when a long segment of the thoracic aorta has to be excluded. Which are your indications to a preventive revascularization of the LSA? Only the presence of a predominant left vertebral artery, as in the case described in the manuscript?
   **Answer:** Definitely. The Reviewer can see the following article about the personal experience of the Author on this topic with special consideration on our indication for LSA revascularization:
4. In their experience the Authors described four cases of simultaneous endovascular exclusion of thoracic and abdominal aortic aneurysm. Concomitant localization of aneurismatic disease at different levels of thoracic and abdominal aorta is a well known condition, which opens many questions, mostly in terms of indication to treatment and selection of sequence and technique of repair. The Authors may probably better explain their indications to treatment and criteria used in selecting between a simultaneous and a staged operation.
   **Answer:** The Reviewer can see the following article about the personal experience of the Author on this topic with special consideration on our indication for simultaneous or stage procedure:
Endovascular repair for concomitant multilevel aortic disease.

5. The Authors reported a 21.6% prevalence of preoperative renal failure and a perioperative renal failure rate of 13%. Nevertheless they did not discuss any possible correlation between these two data. It is important to specify if the perioperative renal failure cases were observed in patients with a chronic renal failure or in asymptomatic patients, for the obvious clinical consequences. Moreover the Authors described their strategy in preventing contrast nephropaty based on the use of non-ionic contrast agents associated with hydration and administration of diuretics. What about the role of N-acetylcysteine, which has been demonstrated on recent reviews, to be effective when used on high dose whereas diuretics are suggested to be suspended in presence of contrast exposure?

**Answer:** In our experience, 8 patients suffered from preoperative chronic renal failure (8/47, 17%): in the postoperative course, 3 patients only developed acute renal failure but only 1 occurred on a preoperative chronic insufficiency. Patients with known preoperative chronic failure received N-acetylcysteine, Mannitol and/or dopamine and, selectivity, fenoldopam.

Unfortunately, statistical analysis was never performed at our Institute on this topic to determine the real benefit of this kind of renal protection protocol.

**Minor Essential Revisions**

Abstract
**Answer:** corrected

2. Page 2, methods, lines 8-9 (All complications occurring during hospitalisation were recorded): as in the paper the Authors considered not only in-hospital but also early and long term complications, they have to be mentioned also here in the abstract.
**Answer:** corrected

3. Page 2, methods, line 5 (5 patients (10%) with thoraco-abdominal aortic aneurysms were excluded from the analyses): if you consider 5 more patients you have 5/57 that gives 9%.
**Answer:** no, because we did not consider these 5 patients for the final analyses

4. Page 2, methods, line 7 [mean EuroSCORE was 9±13 (range 3-19, median 15)]: the euroSCORE has been just mentioned in the abstract without a more detailed explanation in the paper. Moreover, how could you obtain a mean of 9 with a median of 15, and a SD of 13 with a range of 3-19?
**Answer:** corrected

5. Page 2, methods, line 6 (fifteen patients): 15 out of 52 corresponds to 29% rather than 32%.
**Answer:** no, because it’s 15/47

6. Page 2, results, line 3 (range, 45-285; median 90): the two terms have to be inverted as median goes before range. Furthermore, from a statistical point of view, all the variables have to be expressed in the same way (e.g. mean±SD or median and range).
**Answer:** corrected

7. Page 2, results, line 5 (LSA was over-stented in 17 cases): 17 out of 52 corresponds to 33% instead of 36%.
**Answer:** no, because it’s 17/47

8. Page 2, results, line 6 (major complication included...): there is a mismatch in the listed complications between the abstract and the manuscript (page 10): 9 cases of pneumonia are listed in the abstract and 8 in the paper; 4 cases of arrhythmia are missing in the abstract whereas one case of colic ischemia is missing in the paper. In addition, in this context could be useful to report the overall complication rate instead of the complete list of all complications.
**Answer:** corrected, but we preferred to specify all the single type of complication; we believe it should be more useful

9. Page 2, conclusion, line 2 (was lower than previous reported to results of either electively and emergency performed conventional repair): was lower than either electively and emergency conventional repair, previously reported.
Answer: corrected

Manuscript
Answer: corrected
2. Page 5, second paragraph, line 1 (fifteen patients): 15 out of 52 corresponds to 29% instead of 32%.
Answer: no, because it's 15/47
Answer: corrected
4. Page 5, third paragraph, line 4-5: the unit of measure is missing after the mean dissecting aneurysm and the mean ulcer diameter.
Answer: corrected
5. Page 6, second paragraph, line 10-11 (multiple system trauma patients): polytraumatized patient.
Answer: corrected
6. Page 7, second paragraph, line 1: the type of endograft used is missing in five patients since 24 TAG plus 12 TX1-TX2 plus 11 Talent/valiant account for 47 patients.
Answer: no, because we considered 47 patients for the final analysis
7. Page 7, third paragraph, line 3-4 (A clinical neurological investigation was carried out if any neurological complications, with additional diagnostics used as required): a clinical neurological investigation was carried out in case of neurological complications, with additional diagnostics imaging if required.
Answer: corrected
8. Page 7, third paragraph, line 3-4 (All complications occurring while the patient remained in the hospital were recorded): as not only in-hospital but also early and long term complications were reported, this has to be specified.
Answer: corrected
9. Page 9, first paragraph, line 3-9: all the variables have to be expressed in the same way (e.g., mean±SD or median and range).
Answer: corrected
10. Page 9, first paragraph, line 6 (The overall amount of contrast administered averaged): the average total amount of contrast was.
Answer: corrected
11. Page 9, mortality, line 2 (In the elective group cause of death was massive hemorrhagic shock following secondary rupture): in the elective group a cause of death was an hemorrhagic shock due to a secondary rupture.
Answer: corrected
12. Page 9, mortality, line 1-2: the Authors reported 3 deaths, one in the elective and two in the emergency group. If this is correct, the overall mortality rate is 5.7%, with a 2.7% mortality in the elective group.
Answer: no, because it's 2/15 (emergency) and 1/32 (elective), respectively
13. Page 10, endoleaks, line 3 (embolization of at the origin): embolization at the origin
Answer: corrected
14. Page 10, endoleaks, line 5 (1 type 1b endoleaks): 1 type 1b endoleak.
Answer: corrected
15. Page 10, overstented supra-aortic arteries, line 1 (LSA was fully covered in 17 patients): 17 out of 52 corresponds to 33% rather than 15%.
Answer: corrected
16. Page 10, overstented supra-aortic arteries, line 11-12 (Retrograde reflux leaks from the subclavian artery into the aorta occurred in 1 case): retrograde reflux from the left subclavian artery occurred in 2 cases, as reported in the endoleaks section, one early and the other lately.
Answer: corrected
17. Page 10, other complications: the case of colic ischemia, mentioned in the results section of the
abstract, is not reported here.

Answer: corrected

19. Page 12, discussion, line 9 (had a lower than reported procedure related mortality): had a procedure related mortality lower than reported.

Answer: corrected

20. Page 12, discussion, line 16 (could help in select): could help in selecting.

Answer: corrected

21. Page 14, second paragraph, line 8: the Authors report a 21.6% prevalence of preoperative renal failure. Nevertheless, the preoperative chronic renal failure rate reported in the table 1 (Demographic data and co-morbidities) is 17%.

Answer: corrected

Discretionary Revisions
1. In the abstract, the background could be improved giving, for example, a more detailed introduction to the problem that Authors are going to consider.
2. To report all the rates in the same way, with or without decimals, may be more correct.
3. With an angio CT scan of the intracranial vessels is “tricky” to evaluate the patency of the anterior spinal artery (page 6, line 1)

Reviewer #2
This is an interesting retrospective analysis about endovascular treatment of descending thoracic aortic disease in 52 patients. The outcome is favourable compared to open surgery. The authors states, that cerebrospinal fluid drainage or other adjunctive therapy to prevent spinal cord ischemia was not routinely used. In which patients was it used and what kind of adjunctive therapy does they mean?

Answer: we never used spinal drainage

On page 14 the implant of a cuff at the endoleak site is described. What kind of cuff was used and how was the implantation performed. This findings are part of the results and should be attached to the chapter “Endoleaks”.

Answer: we never had type 1a endoleak; we only observed type 1b (distal attachment site), and then additional SG was deployed to seal the leakage

There are some grammatical and sentence structure errors in the manuscript (e.g. p.5, last line: coronarographic, p.6, line 17 laparatomy, p.7 line 1,2,11,12, etc.

Answer: corrected

Regards,

Varese, September 7th, 2006

on behalf of other Authors:
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