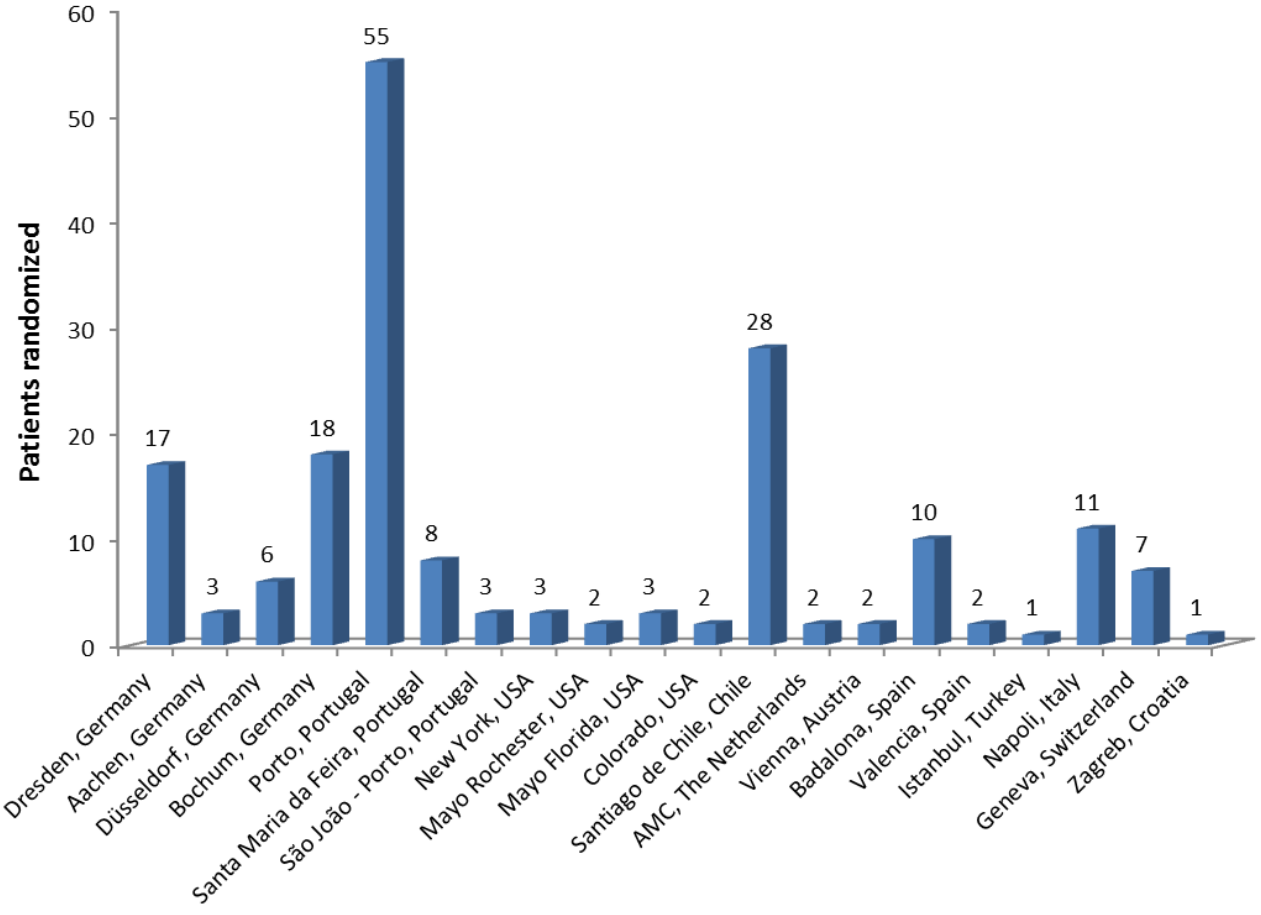
News Letter 3

Dresden, April 21, 2015

Dear National Coordinators and Local Investigators of PROBESE,
Dear Friends,

Good news first: The Data and Safety Monitoring Board (DSMB), under chairmanship of Prof. Daniel Sessler, analyzed our trial after inclusion of 120 patients and recommended the continuation of PROBESE. By today, we all have randomized 184 patients out of 748 finally needed, and the number of centers actively recruiting is largely growing up. Thank you for your hard work!



Monitoring and completeness of data

We are aware that data collection and documentation represent much work. Therefore, we very much appreciate your effort in screening and randomizing patients. In order to achieve our main goal, an updated and complete database is necessary. Following a recommendation of the DSMB, we will monitor data completeness and plausibility yet during the inclusion period. The staff of the Clinical Trial Network of the European Society of Anaesthesiology will conduct such monitoring directly at the electronic platform. Also, on-site visits may take place upon request of the DSMB.

Please be aware that following another recommendation of the DSMB we now have deadlines for **complete online data entry** (eCRF), as follows:

- Preoperative visit: two weeks after surgery
- Intraoperative visit: two weeks after surgery
- Postoperative visit (until day 5): three weeks after surgery
- Discharge: two weeks after discharge
- Follow up 90 days: two weeks thereafter

Early discharge and follow up

If a patient is discharged earlier than postoperative day 5, the patient needs to be visited only on the days of hospital stay, not longer. The patient is formally *lost to follow up* during the non-hospital days, which must be explained in the CRF in the corresponding data fields. In case of early discharge, please enter the set of data into the two CRF sheets, the postop day 1-5 visit and the day of discharge visit.

Next steps for centers that obtained final IRB approval:

You can start screening and enrolling patients as soon as you received the login data for the website based electronic data entry and randomization system (REDCap™). However, before we can send you the login data, we need the following documents and information:

- Copy of the final IRB approval (adequate quality)
- Completed Call-for-Centers form
- Copy of the Information-for-Patients and Informed-Consent forms, if another language than English or German has been used
- Confirmation of adequate translation as requested by the trial coordinator

- Names, email addresses and individual investigator role (**either** intraoperative treatment including randomization, **or** postoperative follow- up). Please remember that outcome assessors must be blinded to patient group assignment

Please do not hesitate to contact us if you need support.

Yours sincerely,

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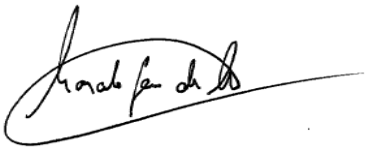

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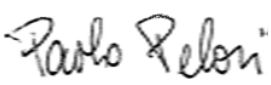

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