



Newsletter 8

Dresden, May 2, 2016

Dear National Coordinators and Local Principal Investigators of PROBESE,
Dear friends,

After the extension of our PROBESE study, the trial is running even better. Thanks the invaluable work of all centers, also those that joined the consortium this year, the enrolment rate is stably high, and 930 patients have been randomized so far. In other words, PROBESE is already the largest randomized controlled trial on intraoperative mechanical ventilation ever, and this is **your** achievement! The numbers of patients included per center are depicted on the next page.

Interim analysis

The first interim analysis will be conducted after 956 randomized patients, which we expect to achieve within 2 weeks.

Data completion

In view of the upcoming interim analysis, we kindly ask you to complete data entry of your already randomized patients in REDCap™.

Important information about mechanical ventilation settings and recruitment maneuvers

We would like to draw your attention to the importance of following the mechanical ventilation protocol, especially with regard to the setting of tidal volume. Provided there is no contraindication, tidal volume should be kept at 7 ml/kg of predicted body weight. During the continuous online monitoring we noticed that tidal volumes exceed this value in some patients, possibly due to errors in the computation of predicted body weight. Therefore, we improved the eCRF to automatically display the predicted body weight and respective tidal volume when a patient is randomized.

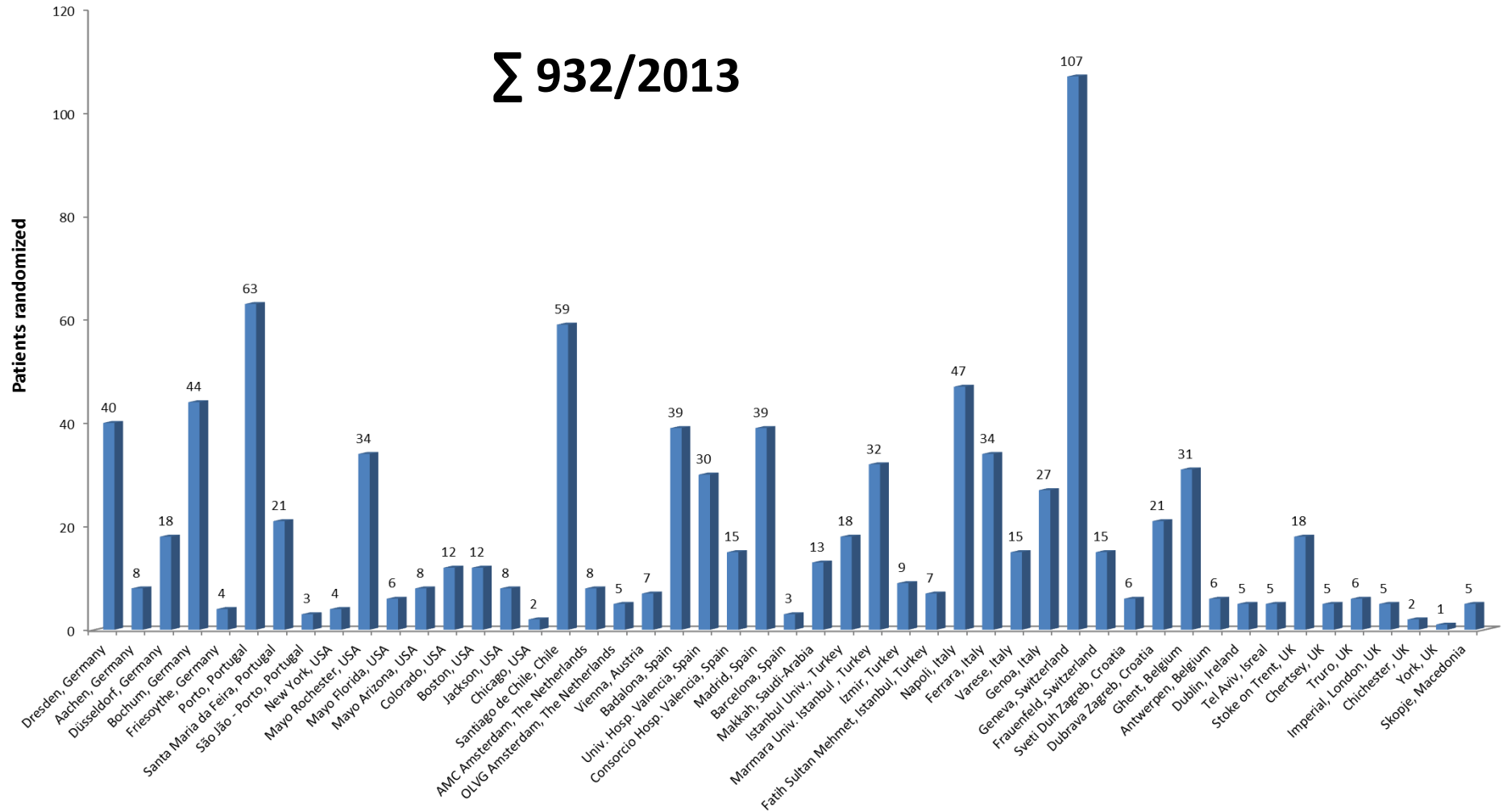
Provided there is no contraindication, respiratory rates during recruitment maneuvers should be set at 6 cycles/min. Also, during recruitment maneuvers, the PEEP should be increased incrementally from 12 until 20 cmH₂O if the tidal volume cannot be further increased and the inspiratory plateau pressure is lower than 40 cmH₂O.



Protective Ventilation with Higher versus Lower PEEP during General Anesthesia for Surgery in OBESSE Patients

The PROBESE Randomized Controlled Trial

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Please do not hesitate to contact us if you need further information.

Yours sincerely,

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