British Journal of Anaesthesia **103 (6):** 867–73 (2009)
doi:10.1093/bja/aep290 Advance Access publication November 3, 2009

BJA

PAEDIATRICS

Prospective randomized controlled multi-centre trial of cuffed or uncuffed endotracheal tubes in small children[#]

M. Weiss[1]*[†], A. Dullenkopf[1], J. E. Fischer[2], C. Keller[3], A. C. Gerber[1†] and the European Paediatric Endotracheal Intubation Study Group[‡]

[1]Department of Anaesthesia, University Children's Hospital Zurich, Steinwiessstrasse 75, CH 8032 Zurich, Switzerland. [2]Mannheim Institute of Public Health, University of Heidelberg, Germany. [3]Department of Anaesthesia, Schulthess Clinic, Zurich, Switzerland

**Corresponding author. E-mail: markus.weiss@kispi.uzh.ch*

Background. The use of cuffed tracheal tubes (TTs) in small children is still controversial. The aim of this study was to compare post-extubation morbidity and TT exchange rates when using cuffed *vs* uncuffed tubes in small children.

Methods. Patients aged from birth to 5 yr requiring general anaesthesia with TT intubation were included in 24 European paediatric anaesthesia centres. Patients were prospectively randomized into a cuffed TT group (Microcuff® PET) and an uncuffed TT group (Mallinckrodt®, Portex®, Rüsch®, Sheridan®). Endpoints were incidence of post-extubation stridor and the number of TT exchanges to find an appropriate-sized tube. For cuffed TTs, minimal cuff pressure required to seal the airway was noted; maximal cuff pressure was limited at 20 cm H_2O with a pressure release valve. Data are mean (SD).

Results. A total of 2246 children were studied (1119/1127 cuffed/uncuffed). The age was 1.93 (1.48) yr in the cuffed and 1.87 (1.45) yr in the uncuffed groups. Post-extubation stridor was noted in 4.4% of patients with cuffed and in 4.7% with uncuffed TTs ($P=0.543$). TT exchange rate was 2.1% in the cuffed and 30.8% in the uncuffed groups ($P<0.0001$). Minimal cuff pressure required to seal the trachea was 10.6 (4.3) cm H_2O.

Conclusions. The use of cuffed TTs in small children provides a reliably sealed airway at cuff pressures of $\leq$20 cm H_2O, reduces the need for TT exchanges, and does not increase the risk for post-extubation stridor compared with uncuffed TTs.

Br J Anaesth 2009; **103**: 867–73

Keywords: anaesthesia, paediatric; complications, stridor; equipment, cuffs tracheal; equipment, tubes tracheal

Accepted for publication: September 1, 2009

In traditional paediatric airway management, the general use of cuffed tubes in children aged below 8–10 yr has been considered inappropriate.

Fear of airway mucosa injury mainly based on case reports and scruples, to ignore standard textbook advice, have prevented widespread use of cuffed paediatric tubes until today,[1 2] despite contradictory findings albeit in older children in single-centre studies.[3–6]

Oversized outer tube diameters, inadequately designed cuffs, wrongly positioned or missing depth marks, and cuff overinflation have been identified to cause airway damage in children managed with a cuffed tube.[7–12]

[†]*Declaration of interest*. M.W. and A.G. are involved in the development and evaluation of new cuffed paediatric tracheal tubes in co-operation with Microcuff GmbH, Weinheim, Germany, Covidien, Athlone, Ireland, and Kimberly Clark, Health Care, Atlanta, GA, USA.

[‡]Members of the European Paediatric Endotracheal Intubation Study Group are listed in the Appendix.

[#]This article is accompanied by Editorial I.

A new cuffed tracheal tube (TT) (Microcuff® PET; Kimberly Clark, Health Care, Atlanta, GA, USA) with an anatomically designed high volume–low pressure tube cuff,[13–15] with a recommendation chart for tube size selection has recently become available for paediatric anaesthesia.[16]

The aim of the present study was to compare post-extubation airway morbidity, measured as post-extubation stridor, after the use of these cuffed TTs in combination with a cuff pressure release valve[17 18] and uncuffed TTs in children from birth up to 5 yr. In addition, this study assessed the intubation attempts and ventilation indices with the use of cuffed TTs compared with the uncuffed.

Methods

The study was planned and organized as a prospective, randomized, controlled multi-centre trial by the Department of Anaesthesia, University Children's Hospital Zurich, Switzerland. The study protocol was approved by an International Study Review Board. Local ethics committee approval was given by each study centre and written parental informed consent was obtained for all patients.

The study procedure was instructed on-site in each study centre by the main investigator. An instructional CD was also provided.

Study sites were provided with sealed, opaque, consecutively numbered envelopes that contained the randomization code. The envelopes were opened immediately before induction of anaesthesia.

Cuffed TTs were sent by the manufacturer. The cuff pressure manometers, pressure release valves, and, if needed, airway pressure gauges were directly sent from the University Children's Hospital Zurich to the study centres.

Patients aged from birth to <5 yr in 24 European paediatric anaesthesia centres requiring general anaesthesia with tracheal intubation were recruited. Patient's inclusion and exclusion criteria are summarized in Table 1. Baseline patient characteristics, history, and type of procedure were noted.

In the author's institution, a stridor rate of about 2% was observed before this study.[19] A conservative estimate based on the literature would suggest a baseline rate of post-extubation stridor using uncuffed tubes of 2.5%.[3 20–25] An unacceptable deterioration using cuffed TTs would amount to an increase in post-extubation stridor incidence rate to a total of 4%.

A study observing similar rates in both groups should be sized to have a power of 90% at a type I error rate of 5% to detect a difference of 1.5%. Using the sample size estimation software PASS (NCSS Statistical Software, Kaysville, UT, USA), the sample size was estimated at 3928 individuals including adjustments for interim analysis and clustering according to the O'Brian and Fleming[26] stopping rule.

The management of anaesthesia was according to the guidelines and standards of the local anaesthesia departments. Cuffed TT sizes (Microcuff® PET) were selected as follows: ID 3.0 mm for birth (>3 kg body weight) to <8 months; ID 3.5 mm for 8 to <18 months; ID 4.0 mm for 18 to <36 months; and ID 4.5 mm for 36 to <60 months.[16]

Table 1 Inclusion and exclusion criteria

Inclusion criteria
Children aged from birth (weighing ≥3 kg) to <5 yr
Children requiring oro-tracheal or naso-tracheal intubation with a Magill shaped TT or preformed (RAE) TT as a part of their anaesthetic care and planed controlled ventilation during the surgical/interventional/diagnostic procedure
Tracheal intubation performed using direct laryngoscopy
Extubation after the procedure in the operating theatre
Procedure performed in the supine position
Patients for elective and emergency surgery, interventions, or both if there is no risk for regurgitation or pulmonary aspiration
ASA physical status I and II
Written parental consent
Exclusion criteria
No parental written consent obtained
Known airway anomalies (airway stenosis, including Down's syndrome)
Known or suspected difficult intubation
Known need for abnormal tube size
Children at risk for regurgitation
Surgery of the larynx and/or of the trachea, neck, and/or upper oesophagus
Pulmonary diseases (concurrent pneumonia or bronchial infection, asthma requiring inhalation medication, pulmonary malformations)
ASA physical status >II
Fibreoptic intubation or alternative intubation technique
Planned postoperative ventilation in the ICU
Weight and/or height percentiles <3%/>97%

Uncuffed TT sizes were selected according to local institutional guidelines. Each study centre used their usual uncuffed paediatric TTs (Mallinckrodt®, Portex®, Rüsch®, Sheridan®) for the uncuffed group.

Tracheal intubation was performed under direct laryngoscopy by the oral or nasal route, without or with the use of bougies or stylets. TT insertion depth was managed according to institutional guidelines in uncuffed TTs and according to the depth marking in cuffed TTs. If there was resistance to passing the tube through the larynx, a tube one size smaller (−0.5 mm ID) was selected. Air leak pressure after intubation was tested with the patient supine and the head in the neutral position. An audible air leak at the patient's mouth had to be present at ≤20 cm H_2O positive inflation pressure in uncuffed TTs and in cuffed TTs with the cuff fully deflated in accordance with the recommendations of Motoyama and colleagues,[27] Koka and colleagues,[25] Stocks,[28] and Lee and colleagues.[29] If there was no air leak present at 20 cm H_2O inflation pressure, the tube was judged to be too large and had to be exchanged for the next smaller size (−0.5 mm ID).[27 28] A cuffed TT size ID 3.0 mm was exchanged to an uncuffed TT size ID 3.0 mm. When changing an uncuffed TT to the next smaller size which resulted in excessive air leak, a throat pack or cuffed TT was used.

After assuring that no oversized tubes were inserted in either group, adequacy of sealing was tested by mechanical ventilation of the patients. TTs with excessive air

Fig 1 Test assembly used in the cuffed group: cuffed paediatric TT (Microcuff® PET) attached to a cuff pressure manometer with pressure release valve (arrow) limiting cuff pressure at 20 cm H_2O.

leak, not allowing adequate ventilation, were exchanged to the next larger size (+0.5 mm ID).

For cuffed TTs, the cuff was inflated with the cuff pressure manometer. Cuff pressure was limited to 20 cm H_2O with a pressure release valve (Fig. 1).[30] When in the uncuffed group a smaller tube was too small and a larger one too large, a throat pack could be used or the patient was switched to a cuffed TT.

Minimal sealing pressure was assessed under steady-state ventilation conditions and maintained during the procedure. This was performed by slowly reducing the cuff pressure until an audible leak appeared at the patient's mouth and then the pressure was increased until leak disappearance. Minimal cuff pressure required to seal the airway and quality of sealing were recorded. Further intubation time, anaesthetic technique, course of intubation, leak pressure, peak inspiratory pressure, use of throat package, and number of TT exchanges to find the appropriate-sized tube were also recorded. The final TT inserted (cuffed or uncuffed) was noted.

Intraoperatively, the presence of plateau-type end-tidal capnography, oxygenation, accidental endobronchial intubation, or extubation and the need for secondary TT exchange (excessive leakage) were recorded.

Patients' tracheas were extubated awake or asleep. Immediately before extubation, the cuff was fully deflated and then the TT was removed from the patient's trachea. Duration of intubation, occurrence of laryngospasm, post-extubation stridor, defined as any new high pitched inspiratory sound, within 1 h after extubation, were recorded by an independent assessor in the child free of pain, secretions, and residual airway obstruction. Medications applied to treat post-extubation stridor and the need for ICU admission or re-intubation were noted.

Data management and statistical analysis

Completed data forms were copied at the local centre and the original data forms sent to the organizers and checked. If required, the investigators were contacted by e-mail to complete the data forms. Data forms were electronically scanned and stored (Kaiser Data, Wollerau, Switzerland). Statistical calculations were performed by the Mannheim Institute of Public Health, University of Heidelberg, Germany.

Baseline characteristics and outcomes across the groups (initial cuffed *vs* initial uncuffed and final cuffed *vs* final uncuffed TTs) were compared using Student's *t*-test for normally distributed data, Mann–Whitney *U*-test for non-normally distributed data, and χ^2 analysis for nominal data. Risk ratio was assessed to analyse the impact of a new treatment (e.g. cuffed tubes) on an outcome (e.g. stridor) and was calculated as the risk in the treatment group (cuffed tubes group) divided by the risk in the control group (uncuffed tubes group). A risk ratio of 1 indicated the same risk for the outcome in both groups with no association between the risk factor and the outcome. A risk ratio of <1 was interpreted as a less likely occurrence of the outcome in the experimental group than in the control group, suggesting that the factor may be protective. Finally, a risk ratio >1 was identified as a more likely occurrence of the outcome in the experimental group than in the control group, suggesting that the factor may be disadvantageous. All analyses have been calculated using SAS (Version 8.2, SAS Inc., Cary, NC, USA) or SPSS (Version 16, SPSS Inc., Chicago, IL, USA).

Results

Four thousand and eight hundred study envelopes were sent to the study centres. A manufacturing change in the TT shaft material resulted in increased risk of kinking of the TT. This required temporary recall of the Microcuff® PET tube. Because the rectification of this problem required several months, the study was stopped ahead of schedule.

A total of 2406 completed data forms were returned from the study centres. One hundred and sixty data forms (106 in the cuffed group/54 in the uncuffed group) had to be excluded because the age group or the TT size with regard to age group was not correctly selected. Finally, 2246 children from 24 study centres were investigated (1119/1127 cuffed/uncuffed tubes). Five patients (one in the cuffed group/four in the uncuffed group) remained intubated after operation and were not included in the assessment of post-intubation morbidity. Numbers of patients investigated per centre ranged from 7 to 188; median 83 patients.

Children's age was 1.93 (1.48) yr in the initially cuffed (n=1119) and 1.87 (1.45) yr in the initially uncuffed (n=1127) study groups. Patient characteristics, history, and type of procedure are presented in Tables 2 and 3. Induction and intubation data are given in Table 4.

Post-intubation stridor was noted in 4.4% in the final cuffed group and in 4.7% in the final uncuffed group (P=0.543, risk ratio 0.936) (Tables 5 and 6). Exclusion of patients with one or several tube exchanges did not significantly alter post-extubation morbidity among the two groups (Table 5).

TT exchange rate was 2.1% in the cuffed and 30.8% in the uncuffed study groups (P<0.0001, risk ratio 0.068). The reasons for tube exchange in the two groups are shown in Table 7. Minimal cuff pressure to seal the trachea in the cuffed group was 10.6 (4.3) cm H_2O.

Intraoperatively, capnography was reliable in 98.6% (cuffed TTs) and in 95.6% (uncuffed TTs) (P<0.0001, risk ratio 1.03) (Table 8).

Table 2 Patient characteristics (n=2246) in the two groups who finally had cuffed or uncuffed tubes

	Cuffed tubes	Uncuffed tubes
Patients investigated	1197	1049
Age of patients (yr) [mean (range)]	1.94 (0–4.99)	1.85 (0–4.98)
Weight of patients (kg) [mean (SD)]	11.4 (4.7)	11.2 (4.6)
Gender (female/male)	33.1%/66.9%	35.0%/65.0%
ASA (I/II)	66.2%/33.8%	33.4%/66.6%
Prior croup	23 (2.0%)	27 (2.6%)
Actual or recent respiratory tract infection (<4 weeks)	159 (13.6%)	131 (12.9%)

Table 3 Type of procedure (per patient more than one intervention possible) in the two groups who finally had cuffed or uncuffed tubes

	Cuffed tubes (n=1197)	Uncuffed tubes (n=1049)
Interventions	1246	1081
Head surgery	143	108
ENT	171	161
Cleft	73	87
Thoracic	17	13
Abdominal	310	263
Laparoscopy	26	12
Urology	284	223
Limb	92	79
Cardiac catheterization	16	14
Gastroenterology	13	15
Radiology	28	35
Others	73	71

Table 4 Induction and tracheal intubation data in the two groups who finally had cuffed or uncuffed tubes

	Cuffed tubes (n=1197)	Uncuffed tubes (n=1049)
Intubation route (oral/nasal)	95.4%/4.6%	91.6%/8.4%
Tube brand used (Magill/preformed curved)	77.8%/22.2%	77.9%/22.1%
Muscle paralysis used	61.9%	57.6%
Bougie/stylet used	5.7%	12.9%
Local anaesthesia spray used	4.5%	5.4%
Induction (i.v./inhalation)	34.5%/65.5%	34.2%/65.8%
Systemic steroids used (PONV)	17.0%	16.8%
Systemic NSAID used (Pain)	35.2%	40.2%
Oro-gastric suctioning used	53.8%	50.6%
Difficulties with intubation	2.3%	2.5%
Patients with >1 intubation attempts	5.7%	8.4%
Patients with >1 tube insertion attempts	3.4%	9.0%

Discussion

The main finding of the present study was that the Microcuff® PET used according to the proposed recommendation for tube size selection with cuff pressure limited to ≤20 cm H_2O can be safely used in small children, since the incidence of post-extubation stridor was not increased when compared with uncuffed TTs. Furthermore, minimal tube exchange rate, a reliable, sealed airway, and improved capnography trace were the main benefits of cuffed TTs.

To date, only single-centre experience with cuffed TTs has been published.[3–6] Because of the many limitations associated with these studies (e.g. limited numbers, non-randomized design, not including infants or young children), it has so far not been possible to draw valid conclusions in the longstanding debate relating to the use of cuffed *vs* uncuffed TTs in paediatric anaesthesia. Since a modern cuffed TT designed for small children has recently become commercially available, a large prospective, randomized, multi-centre trial was required to further investigate this issue in small children.

The study was terminated prematurely due to reasons beyond our control. An improved version of the Microcuff PET became available only 1 yr after the study stopped. Despite not being able to recruit the number indicated by the initial power calculation, the study still managed to include more than 2000 patients, demonstrating similar incidences of post-extubation stridor with longer intubation times in the cuffed group.

The most central finding of the present study was that the incidence of post-extubation stridor was not affected by the use of cuffed TTs. In this study, an anatomically designed cuffed TT with controlled and limited cuff pressure was used and the tube size selected strictly according to size recommendations. The incidence of post-extubation stridor in both patient groups is consistent with the findings of Ashtekar and Wardhaugh[31] and should alleviate the fear of many paediatric anaesthetists that cuffed TTs may cause increased post-extubation stridor rates in small children. However, it is important to note that cuffed TTs with oversized outer tube diameters, wrongly designed cuffs, and cuffs used without cuff pressure control can cause airway damage.[7–10]

Table 5 Primary outcomes: post-extubation morbidity and therapy. *$P<0.05$; **$P<0.01$

	Cuffed tubes final after exchanges ($n=1197$)	Uncuffed tubes final after exchanges ($n=1049$)	Cuffed tubes initial without exchange ($n=1095$)	Uncuffed tubes initial without exchange ($n=780$)
Duration of tracheal intubation (min) [mean (SD)]	107.5 (79.9)	99.0 (72.8)**	103.0 (76.6)	93.8 (71.7)**
Extubation (awake/asleep)	49.0%/51.0%	46.7%/51.4%	48.2%/51.8%	43.6%/56.4%
Laryngospasm	4.5%	3.5%	4.6%	3.4%
Time from extubation to assessment (min) [mean (SD)]	30.4 (27.6)	27.6 (24.4)*	30.6 (27.7)	26.4 (23.3)*
Inspiratory stridor: all	4.4%	4.7%	4.3%	4.4%
Inspiratory stridor: with signs of severe dyspnoea	0.33%	0.29%	0.37%	0.26%
Epinephrine nebulizer (% patients with stridor/% all patients)	18.9/0.84	30.6/1.44	15.1/0.73	22.4/1.40
NSAID (% patients with stridor/% all patients)	30.2/1.38	36.7/1.72	30.2/1.47	30.6/2.1
Systemic steroids (% patients with stridor/% all patients)	20.8/0.92	22.4/1.05	15.1/0.73	18.4/1.15
Unplanned ICU-admission (% patients with stridor/% all patients)	5.6/0.25	2.1/0.10	5.7/0.27	2.04/1.13
Need for re-intubation (% patients with stridor /% all patients)	3.8/0.18	2.1/0.10	3.8/0.18	2.04/1.13

Table 6 Stridor rates per age group. NS, not significant

Age groups	Cuffed tubes (final) (n)	Stridor (n)	Uncuffed tubes (final) (n)	Stridor (n)
All (A–D)	1197	53 (4.4%)	1049	49 (4.7%)^{NS}
A: 0 to <8 months	326	9 (2.8%)	298	14 (4.7%)^{NS}
B: 8 to <18 months	247	15 (6.1%)	234	8 (3.4%)^{NS}
C: 18 to <36 months	311	15 (4.8%)	266	17 (6.4%)^{NS}
D: 36 to <60 months	313	14 (4.8%)	251	10 (4.0%)^{NS}

Table 7 Reasons for tube exchange and incidence; data expressed as number of incidents or as indicated. **$P=0.01$; ***$P<0.001$; ****$P<0.0001$

	Cuffed tubes initial ($n=1119$)	Uncuffed tubes initial ($n=1127$)
Tube passage		
Resistance to pass into the trachea	7	46***
Leakage (n tested)	1112	1081
>20 cm H_2O inflation pressure for air leak	10	112***
Sealing (n tested)	1102	969
Peak inspiratory pressure used (cm H_2O) [mean (SD)]	17.3 (3.4)	16.3 (3.2)***
No audible air leak	1018	398
Acceptable air leak	78	383
Excessive air leak	6	188
Minimal cuff pressure for sealing cm H_2O [mean (SD)]	10.6 (4.3)	—
Tube exchange		
Tube exchange	24 (2.1%)	347 (30.8%)****
Reason for tube exchange		
Resistance to pass the tube	7	46***
No air leak at 20 cm H_2O	10	112***
Excessive air leak at IPPV	6	188***
Others (too long preformed tube)	1	1
Patients with more than one tube exchange	5	87***
Total number of tube exchanges	29	434***
Throat pack used	2.7%	10.0%**

In this context, it should also be pointed out that data regarding post-extubation stridor are difficult to compare between different studies. The time of assessment varies from immediately after extubation to discharge from the recovery room.[3 20–25 32 33] Residual airway obstruction due to anaesthetics, pain, and secretions must also be accounted for. In the present study, clear and stringent definitions for stridor and its assessment were followed. This fact may explain why the incidences of stridor in our study (4.4% and 4.7%, respectively) were higher than the value used for the initial power calculation (2.5%). However, a similar incidence of post-extubation stridor in younger children can be found in other studies.[25] Publications reporting lower stridor frequencies usually also include children in the 6–16 yr age range where the risk of stridor is much less.[3 6] The fact that the majority of participating centres did not have any previous experience with the use of cuffed TTs and the multi-centric nature of the study also support the general applicability of the study findings.

Cuffed tubes were selected with a smaller diameter, and the cuff was inflated as required to fill the individual gap between the tube and the tracheal wall. This principle resulted in 15 times reduced need for TT changes and considerable less use of throat packaging. In fact, the chance to find an appropriate TT at the first attempt was 97.9% for cuffed and only 69.5% for uncuffed TTs. Particularly, in prehospital, emergency, and intensive care settings, and also for less experienced anaesthetists, a paediatric TT which fits almost 100% at first attempt provides a considerable benefit.

Table 8 Intraoperative incidence of the secondary outcomes. ****$P<0.0001$

	Cuffed tubes ($n=1197$)	Uncuffed tubes ($n=1049$)
Reliable capnography	98.6%	95.6%****
Oxygenation problems	1.0%	1.1%
Accidental endobronchial intubation	1.5%	2.5%
Accidental extubation	0.6%	0.4%
Secondary tube exchange required	0.5%	1.0%

Reassuringly, the cuff inflation pressure (10.6 cm H_2O) needed to accomplish an adequate tracheal seal was substantially less than with other paediatric TT cuffs reported[34] and below the 25 cm H_2O threshold that has been shown to cause increased airway morbidity with uncuffed tubes.[32] The better tracheal seal caused by the TT cuff was also found to result in significantly enhanced conditions regarding the ability to record an adequate capnography trace, something that occasionally can be very difficult if uncuffed TTs are used. As mentioned above, these positive effects of using a cuffed TT could be accomplished without increasing the risk for post-extubation stridor. It must be pointed out that the excellent findings obtained with the Microcuff PET in this study cannot be generalized without further studies to all cuffed paediatric tubes available.[7 9 10]

In conclusion, when using appropriately designed cuffed TTs with a clear concept for cuff pressure control and tube size selection, cuffed tubes have a much higher chance of fitting at first attempt than uncuffed tubes. Cuffed TTs are not *per se* associated with higher airway morbidity in small children, objectified here as post-extubation stridor, and thus they can be used safely in this age group.

Acknowledgements

We would like to thank Mr A. Meile (Medconnect, Lachen, Switzerland) and his secretary Mrs Erna Heinson for preparing, packaging, and delivery of the randomization envelopes to all study centres.

Funding

The study was supported by Microcuff GmbH, Weinheim, Germany, by providing the cuffed tracheal tubes, cuff pressure manometers, and release valves for no charge. Also it was supported by the Swiss Society for Anaesthesia and Resuscitation (SGAR) by a study grant.

Appendix

European Paediatric Endotracheal Intubation Study Group

M. Bernath, Lausanne, Switzerland; C. Best, Glasgow, UK; S. Bew, Leeds, UK; J. Bihlmayer, Augsburg, Germany; M. Bloch, Aberdeen, UK; V. Boels, Stockholm, Sweden; P. Bolton, Glasgow, UK; K. Boos, Hanover, Germany; P. Brooks, London, UK; J. Brown, Leeds, UK; D. Crass, Augsburg, Germany; D. Csomor, Bratislava, Slovakia; M. Dolci, Lausanne, Switzerland; T. Engelhardt, Aberdeen, UK; S. Eschertzhuber, Innsbruck, Austria; H. Forst, Augsburg, Germany; B. Frank, Regensburg, Germany; A. Frotzler, Zurich; O. Gabriel, Prague, Czech Republic; L. Gajdosiva, Kosice, Slovakia; S. Galton, London, UK; F. Gerheuser, Augsburg, Germany; J. Giest, Berlin (Helios), Germany; R. Greif, Berne, Switzerland; M. Grochova, Kosice, Slovakia; W. Habre, Geneva, Switzerland; M. Hadrawa, Augsburg, Germany; B. Hartmann, Aarau, Switzerland; W. Heindl, Loerrach, Germany; G. Henze, Zurich, Switzerland; O. Hilfiker, Aarau, Switzerland; S. Hivey, Glasgow, UK; C. Hoehne, Berlin (Virchow), Germany; H. Hollnberger, Regensburg, Germany; T. Hüttl, Munich, Germany; B. Kalnasova, Kosice, Slovakia; T. Kirwan, London, UK; B. Komanova, Kosice, Slovakia; J. Korcek, Kosice, Slovakia; S. Krohn, Hanover, Germany; M. Kulkarni, London, UK; **P.A. Lonnqvist, Stockholm, Sweden; A. Machotta, Berlin (Virchow), Germany; **G. Meakin, Manchester, UK; V. Mixa, Prague, Czech Republic; N. Morton, Glasgow, UK; **T. Nicolai, Munich, Germany; M. Oberhauser, St Gallen, Switzerland; M. Pellegrini, Geneva, Switzerland; T. Pirotte, Brussels, Belgium; B. Podhoransky, Bratislava, Slovakia; H.J. Rapp, Mannheim, Germany; M. Rolfs, Stockholm, Sweden; W. Roth, Innsbruck, Austria; B. Salgo, Zurich, Switzerland; H. Schepperle, Loerrach, Germany; J. Schimpf, Augsburg, Germany; A. Schmitz, Zurich, Switzerland; V. Sollmann, Augsburg, Germany; St Seiler, Berne, Switzerland; J. Strauss, Berlin (Helios), Germany; F. Stucki, Berne, Switzerland; E. Thil, Mannheim, Germany; **F. Veyckemans, Brussels, Belgium; L. Wichert, Berlin Virchow, Germany; A. Willker, Augsburg, Germany; G. Wilson, Aberdeen, UK.

**Member of the International Study Review Board.

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