


## RESEARCH ARTICLE

# Rocuronium 0.3 or 0.9 mg/kg comparing onset time, duration of action, and intubating conditions in patients 80 years and older: A randomized study

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## Abstract

**Background:** Limited data exist about the optimal dose of rocuronium for intubation in elderly patients. We hypothesized that rocuronium 0.9 mg/kg would lead to a shorter onset time than 0.3 mg/kg in patients above 80 years.

**Methods:** Thirty-four patients were randomized to either rocuronium 0.3 or 0.9 mg/kg. The primary outcome was onset time defined as time to train-of-four (TOF) count of 0. Other outcomes included duration of action (time to TOF ratio >0.9), proportion of excellent intubating conditions using the Fuchs-Buder scale and tracheal intubating conditions using the Intubating Difficulty Scale (IDS).

**Results:** Rocuronium 0.9 mg/kg resulted in shorter onset time compared to rocuronium 0.3 mg/kg; 108 s (SD 40) vs. 228 s (SD 140) (difference: 119 s [95% CI: 41–196],  $p = .005$ ), respectively. However, in 66% of the patients receiving rocuronium 0.3 mg/kg a TOF count of 0 was not obtained. Duration of action was longer after rocuronium 0.9 mg/kg: 118 min (SD 43) vs. 46 min (SD 13) (difference: 72 min [95% CI: 49–95]  $p < .0001$ ), and a greater proportion of excellent intubating conditions (Fuchs-Buder) was obtained; 11/16 (69%) vs 4/18 (22%) ( $p = .006$ ). No difference was found regarding IDS score.

**Conclusion:** Rocuronium 0.9 mg/kg resulted in a shorter onset time compared to rocuronium 0.3 mg/kg in patients above 80 years of age. In 66% of the patients receiving rocuronium 0.3 mg/kg a TOF count of 0 was not obtained.

## Editorial Comment

Rocuronium dose and effect may be influenced by patient extreme age. This study assessed onset and duration of effect time of two distinct dosing levels in cases older than 80 years. The chosen higher dose had quicker onset, and the lower dose mixed effects for reaching full blockade according to neuromuscular function assessment.

Trial registry number: NCT04512313.

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## 1 | INTRODUCTION

Tracheal intubation during anesthesia can be facilitated by the administration of the neuromuscular blocking agent (NMBA) rocuronium.<sup>1</sup> However, in elderly patients both onset time and duration of action of rocuronium may be influenced by changes in pharmacodynamics and pharmacokinetics due to the age-related reduction in cardiac output, liver function, and renal function.<sup>2</sup> In patients above 80 years of age a dose of rocuronium 0.6 mg/kg has an onset time of approximately 135 s and a clinical duration of action of approximately 81 min which is significantly longer compared to young adults.<sup>3</sup>

Rocuronium's onset time and duration of action is dose-dependent.<sup>4,5</sup> In adults a dose of rocuronium 0.3 mg/kg (1 × effective dose [ED] 95) has a short duration of action but a long onset time,<sup>6</sup> whereas a dose of 0.9 mg/kg has a long duration of action but a short onset time.<sup>5,6</sup> In the elderly patients, however, there are few data to guide the dosage of rocuronium. These data are needed to identify the optimal dose of rocuronium to both facilitate tracheal intubation but also to prevent a long duration of action since this patient population is at high risk of residual neuromuscular blockade<sup>7,8</sup> and postoperative respiratory complications.<sup>9,10</sup> A higher dose, such as rocuronium 0.9 mg/kg would be expected to decrease onset time but also to increase the duration of action. As an alternative, a smaller dose of rocuronium, that is, 0.3 mg/kg may have a shorter duration of action but maybe at the expense of a prolonged onset time. A dose of 0.3 mg/kg could even be insufficient to obtain a TOF count of 0. Hence, it is unknown to what extent either increasing or reducing the dose of rocuronium influences onset time, duration of action, and tracheal intubating conditions in the elderly. Therefore, we aimed to assess both a smaller dose (0.3 mg/kg) and a higher dose (0.9 mg/kg) in patients above 80 years of age to determine onset time, duration of action, and effect on intubating conditions. We hypothesized that rocuronium 0.9 mg/kg would be associated with a shorter onset time compared to 0.3 mg/kg in patients above 80 years of age.

## 2 | METHODS

The study was approved by The Scientific Ethics Committee (February 27, 2020 – protocol number H-19079175), Danish Medicines Agency (EudraCT 2019–004343-76) and Danish Data Protection Agency (Videnscenter for Dataanmeldelser, November 6, 2018 – VD-2018-427). The study was registered at [Clinicaltrials.gov](https://clinicaltrials.gov) (NCT04512313, date of registration: August 13, 2020) prior to enrollment of patients. Written informed consent was obtained from all patients and the trial was conducted in accordance with the Declaration of Helsinki. REDCap was used for data management. This manuscript adheres to the applicable CONSORT guidelines. We included patients from the Department of Anesthesia, Centre of Head and Orthopedics, Rigshospitalet, University of Copenhagen, Denmark and Department of Anesthesia, Juliane Marie Center, Rigshospitalet, University of Copenhagen, Denmark. The study was conducted according to the International Conference on Harmonization (ICH)/ Good

Clinical Practice (GCP) guidelines.<sup>11</sup> An independent inspector from the GCP unit of Copenhagen University Hospitals, Denmark supervised the trial. Inclusion criteria comprised age above 80 years, tracheal intubation with use of rocuronium, total intravenous anesthesia, elective surgery with an anticipated duration of at least 60 min, and an American Society of Anesthesiologists (ASA) physical health class I to III. Exclusion criteria comprised patient in prone position, allergy to rocuronium, indication for rapid sequence induction and neuromuscular disease that would interfere with neuromuscular monitoring.

A concealed computer-generated randomization list was used for allocating patients to either the rocuronium 0.3 mg/kg group or to the rocuronium 0.9 mg/kg group.

### 2.1 | Anesthesia

Opposite of the neuromuscular monitor an intravenous catheter was inserted into a vein of the forearm. The patients were monitored with non-invasive blood pressure, electrocardiogram, core temperature, and pulse oximetry. Patients received fentanyl 2 µg/kg and propofol 1–2 mg/kg for induction of anesthesia after preoxygenation. After calibration and obtainment of a stable neuromuscular signal for 2 min, either rocuronium 0.3 mg/kg or rocuronium 0.9 mg/kg was injected over 5 s according to allocation. Ideal body weight was used for doses of rocuronium. This was calculated in kg as height (cm) minus 105 for women and height (cm) minus 100 for men or actual body weight (the lowest). Tracheal intubation was performed when Train-of-four (TOF) count monitored with acceleromyography was 0. In case a TOF count of 0 was not obtained tracheal intubation was performed 5 min after administration of rocuronium. The anesthetist assessed intubating conditions employing the Fuchs Buder scale<sup>12</sup> and the intubating difficulty score (IDS)<sup>13</sup> (Tables 3 and 4). Use of a stylet or a videolaryngoscope was also recorded. After tracheal intubation, the anesthetic breathing circuit was connected to the tube, and mechanical ventilation was initiated targeting normocapnia. Anesthesia was maintained with an infusion of propofol of approximately 5 mg/kg/h and remifentanyl 0.25–0.5 µg/kg/min. From induction of anesthesia until tracheal intubation administration of ephedrine was recorded. A core temperature above 35°C and a peripheral skin temperature above 32°C, was secured by the use of an upper body forced air warming system. Upon full recovery from neuromuscular block (TOF ratio >0.9) patients were extubated. If spontaneous recovery had not occurred reversal was performed with either sugammadex (2–4 mg/kg) or neostigmine (30–50 µg/kg). Postoperative standard treatment of pain comprised opioids, NSAIDs, and paracetamol.

### 2.2 | Neuromuscular monitoring

Neuromuscular monitoring was performed according to Good Clinical Research Practice (GCRP) for pharmacodynamic neuromuscular studies.<sup>12</sup> Neuromuscular function was monitored with the TOF-Watch SX connected to a computer for collection of neuromuscular data (Version 2.5 INT 2007; Organon). The skin was cleaned with an abrasive and two ECG

electrodes (Ambu® BlueSensor N) were placed along the ulnar nerve on the distal forearm. We placed the acceleration transducer on the thumb with a hand adaptor. The TOF Watch SX was started upon loss of eyelash reflex. Two TOF nerve stimulations were given followed by tetanic stimulation with 50 Hz for 5 s. Calibration was performed with the CAL button (CAL 2 modus) and neuromuscular function was monitored by TOF stimulation (2 Hz for 1.5 s) every 15 s. Neuromuscular data were pseudo-anonymized and stored on a drive.

### 2.3 | Follow up

Seven days postoperatively we scrutinized the medical record and interviewed the patients about specific adverse events that we considered relevant for the trial. These included abnormal ECG, injection site edema, bronchospasm, residual muscle weakness, double vision, and bronchospasm.

### 2.4 | Blinding

Before the surgery, study medicine was prepared in the medicine room under double control by the investigator who also performed the randomization. The computer program Research Electronic Data Capture

(REDCap)<sup>14</sup> which only the investigator preparing the intervention medicine had access to generated the allocation sequence. The study medicine was labeled “study drug rocuronium 0.3 or 0.9 mg/kg” and drawn up in 10 ml syringes of equal volume. Tracheal intubation was performed by an attending anesthetist blinded toward allocation as the neuromuscular monitoring equipment was covered so anesthesia personnel were not able to see the TOF response during intubation. Surgical personnel were blinded. The investigator monitoring neuromuscular function was not blinded and notified the attending anesthesiologist when tracheal intubation could be done. Patients were blinded toward allocation during hospitalization and at the 7-day follow-up.

### 2.5 | Endpoints

The primary outcome was onset time, defined as the time from the end of rocuronium injection to train-of-four (TOF) count of 0 monitored by acceleromyography. Secondary outcomes were duration of action defined as time from end of rocuronium injection to reappearance of TOF ratio >0.9, intubating conditions at a TOF count of 0 scored according to Fuchs-Buder<sup>12</sup> and IDS score,<sup>13</sup> use of a video laryngoscope, use of stylet, time used for intubation (from lifting the laryngoscope when the TOF count was 0 until successful intubation, identified by capnography) and administration of ephedrine from induction of anesthesia until tracheal

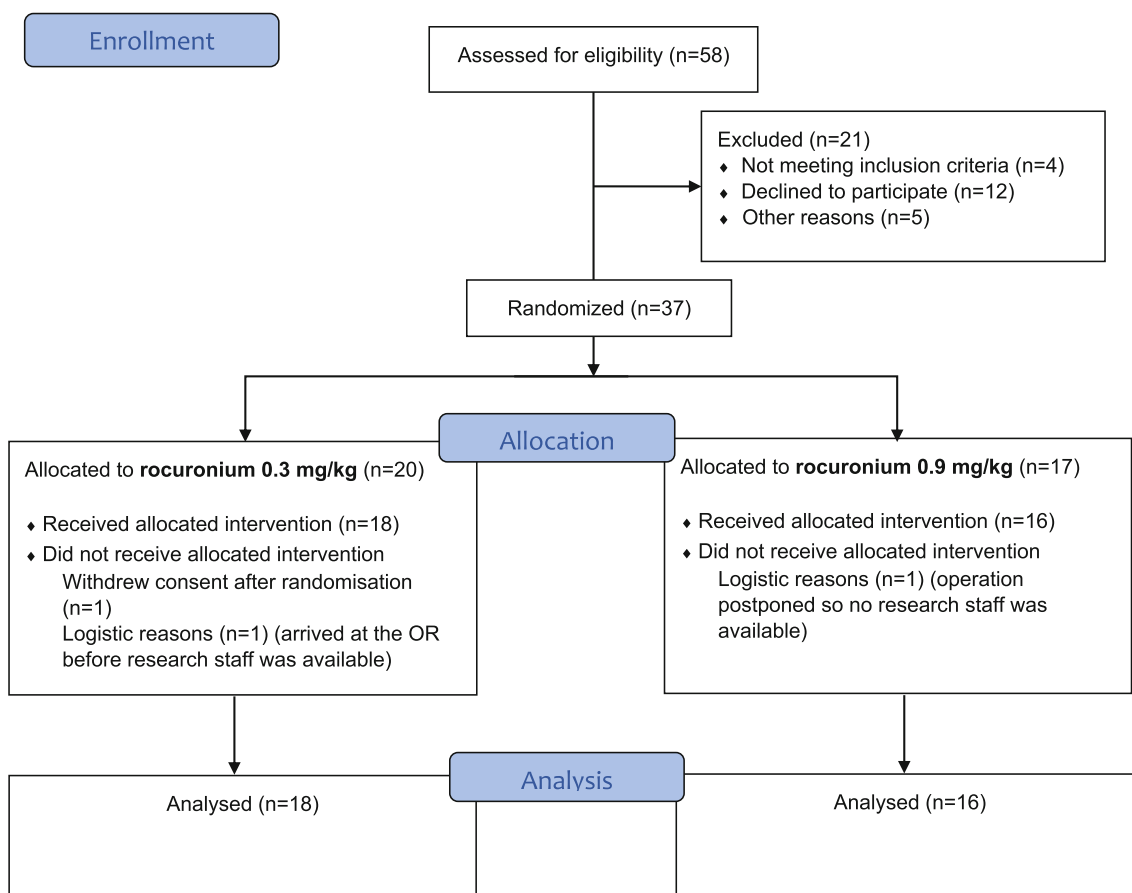


FIGURE 1 Flow diagram

intubation. After performing the intubation, the anesthesiologist was interviewed by an investigator who filled out a score for each variable regarding intubation conditions. Excellent intubating conditions were defined as a score of 6 according to the Fuchs-Buder scale.

## 2.6 | Statistical analysis

We used SAS Studio 3.8 software (SAS Institute Inc.). Patient characteristics and outcomes were reported as mean with standard

**TABLE 1** Baseline characteristics of patients above 80 years of age randomized to either rocuronium 0.3 or 0.9 mg/kg ( $n = 37$ )

	Rocuronium 0.3 mg/kg	Rocuronium 0.9 mg/kg
<i>n</i>	20	17
Age years (IQR)	83 (81.5–84)	85 (84–86)
Sex M/F	10/10	4/13
BMI kg/m <sup>2</sup>	25.4 (2.7)	25.1 (6.0)
ASA II/III	9/11	10/7
Daily medicine		
Diuretics	7 (35%)	8 (47%)
Magnesium	1 (5%)	1 (6%)
Comorbidity		
Renal disease	0	1 (6%)
Diabetes	3 (15%)	1 (6%)
Hypertension	12 (60%)	11 (65%)
Heart disease	4 (20%)	6 (35%)

Note: Continuous data presented as mean and standard deviation (SD). Abbreviation: IQR, inter quartile range.

**TABLE 2** Intraoperative data including onset time and duration of action for rocuronium 0.3 and 0.9 mg/kg in patients above 80 years of age

	Rocuronium 0.3 mg/kg	Rocuronium 0.9 mg/kg	Difference with 95% CI	<i>p</i> value
<i>n</i>	18	16		
NMB reached TOF 0	6 (33%)	16 (100%)	66% (45%–88%)	<.001
Onset time (s)	227 (140) <i>n</i> = 6	108 (40) <i>n</i> = 16	119 (41–196)	.005
Duration of action (min)	46 (13) <i>n</i> = 16	118 (43) <i>n</i> = 11	72 (49–95)	<.0001
Time used for intubation, (s) <sup>a</sup>	89 (66)	68 (21)	21 (–56 to 14)	.23
Duration of anesthesia, (min)	205 (75)	209 (84)	–	–
Duration of surgery, (min)	121 (55)	126 (61)	–	–
Type of surgery				
Orthopedic	9	7	–	–
Plastic/breast	7	6	–	–
Gynecology	1	1	–	–
Other	1	2	–	–
Use of inhalational anesthesia	0	2 (12%)	–	–

Note: Continuous data presented as mean and standard deviation (SD). In seven patients the duration of action was not determined due to administration of a reversal agent, administration of supplemental doses of rocuronium and monitoring difficulties.

<sup>a</sup>From taking the laryngoscope until tracheal intubation verified by capnography.

deviations (SD), median with interquartile ranges (IQR) or count with frequencies. A *t* test was used for comparison of parametric data, non-parametric data were compared with Mann–Whitney Test, and proportions were compared with chi-square or Fisher's exact test. Ninety-five percent confidence intervals were used for quantifying differences. A  $p < .05$  was considered statistically significant.

The sample size calculation was based on our primary hypothesis. From a previously conducted study<sup>15</sup> we estimated a standard deviation of 20 s for onset time. A difference of 30 s between the two groups who received 0.3 or 0.9 mg/kg rocuronium was determined to be clinically relevant. Based on a sample size analysis we calculated that 17 patients in each group would allow us to detect this difference with a power of 90% and 5% risk of type 1 error.

## 3 | RESULTS

A total of 58 patients were eligible of which four patients did not meet the inclusion criteria, 12 declined to participate and five patients were excluded due to other reasons (Figure 1). A total of 37 patients were included between December 17, 2020, and May 21, 2021, in the study. Two patients, one in each group, did not receive the study medicine due to logistic reasons after randomization and one patient in Group Rocuronium 0.3 mg/kg withdrew consent after randomization. Accordingly, data from 34 patients were analyzed (Table 1).

In Group Rocuronium 0.3 mg/kg six patients (33.3%) reached a TOF count of 0 compared to 16 patients (100%) in Group Rocuronium 0.9 mg/kg ( $p < .001$ ) difference 66% (95% CI 45%–88%).

Rocuronium 0.9 mg/kg resulted in significantly shorter onset time compared to rocuronium 0.3 mg/kg; mean 108 s (SD 40) vs. 227 s (SD 140) ( $p = .005$ ), respectively, difference 119 s (95% CI 41–196).

**TABLE 3** Tracheal intubating conditions assessed after administration of either rocuronium 0.3 mg/kg or rocuronium 0.9 mg/kg in patients above 80 years of age

	Rocuronium 0.3 mg/kg	Rocuronium 0.9 mg/kg	Difference (%) with 95% CI	<i>p</i> value <sup>a</sup>
<i>n</i>	18	16		
Excellent intubating conditions (Fuchs-Buder)	4 (22%)	11 (69%)	47 (17–77)	.006
Administration of ephedrine during induction, before TOF count 0	11 (55%)	6 (35%)	17 (–14 to 48)	.23
Use of video laryngoscope	8 (44%)	6 (38%)	6 (–26 to 40)	.68
Use of stylet	9 (50%)	6 (38%)	12 (–20 to 46)	.46
Intubating difficulty score (IDS)	2 (1–3)	1 (0–2)	–	.18 <sup>b</sup>
IDS > 0	4 (22%)	6 (38%)	15 (–16 to 45)	.33
Time from administration of rocuronium until successful intubation (s)	385 (121)	188 (54)	196 (129–263)	<.0001 <sup>c</sup>

Note: Data presented as count and frequencies (%) or mean and standard deviation (SD). IDS presented as median and interquartile range (IQR). Abbreviation: CI, confidence interval.

<sup>a</sup>Chi-square test.

<sup>b</sup>Mann–Whitney's rank-sum test.

<sup>c</sup>t test.

**TABLE 4** Tracheal intubating conditions (Fuchs-Buder) assessed after administration of either rocuronium 0.3 mg/kg or rocuronium 0.9 mg/kg in patients above 80 years of age

	Rocuronium 0.3 mg/kg	Rocuronium 0.9 mg/kg	<i>p</i> -value <sup>a</sup>
<i>n</i>	18	16	
Vocal cords position			
1 Abducted	15 (75%)	13 (76%)	.70
2 Intermediate	2 (10%)	3 (18%)	
3 Closed	0	1 (5%)	
Vocal cords movement			
1 None	15 (75%)	15 (88%)	.58
2 Moving	3 (15%)	1 (6%)	
3 Closing	0	0	
Reaction to intubation: movement			
1 None	9 (45%)	16 (94%)	.004
2 Slight	9 (45)	0	
3 Vigorous	0	0	
Reaction to intubation: coughing			
1 None	5 (25%)	13 (76%)	.004
2 Slight	12 (60%)	1 (6%)	
3 Sustained	1 (5%)	2 (12%)	
Laryngoscopy: jaw relaxation			
1 Relaxed	18 (90%)	15 (88%)	.50
2 Not fully	0	1 (6%)	
3 Poor	0	0	
Laryngoscopy: resistance to laryngoscope			
1 None	17 (85%)	15 (88%)	.90
2 Slight	1 (5%)	1 (6%)	
3 Reactive	0	0	

Note: Data presented as count and frequencies (%).

<sup>a</sup>Chi-square.

Also, duration of action was significantly longer with a mean value of 118 min (SD 43) vs. 46 min (SD 13), respectively (Table 2). In Group Rocuronium 0.9 mg/kg we found a greater proportion of excellent intubating conditions (Fuchs-Buder) compared to Group Rocuronium 0.3 mg/kg; 11/16 (69%) vs 4/18 (22%) difference 47% (95% CI: 17–77) ( $p = .006$ ), respectively (Table 3).

No difference in IDS score was found comparing Group Rocuronium 0.9 mg/kg with Group Rocuronium 0.3 mg/kg; median 1 (IQR: 0–2) vs. median 2 (IQR: 1–3) ( $p = .18$ ). An IDS > 0 was seen in 38% and 22% of patients, ( $p = .33$ ), respectively. Finally, no difference was found in use of video laryngoscope or use of a stylet (Table 4).

In seven patients the duration of action of rocuronium could not be determined. Four patients (all in Group Rocuronium 0.9 mg/kg) had a reversal agent administered before a TOF ratio >0.9 was reached. Two patients (one in each group) had supplemental doses of rocuronium administered due to request from the surgeon and in one patient in Group Rocuronium 0.3 mg/kg monitoring difficulties prevented detection of time to TOF ratio >0.9. No difference was found in the occurrence of administration of ephedrine during induction ( $p = .23$ ). In Group Rocuronium 0.9 mg/kg two patients were administered sevoflurane after induction of anesthesia.

There was one case of serious adverse events in the Rocuronium 0.9 mg/kg which involved readmission to hospital due to constipation and hyponatremia. This serious adverse event was not thought to be related to the study drug. We did not identify any adverse events from the pre-defined list.

## 4 | DISCUSSION

We found that rocuronium 0.9 mg/kg had a shorter onset time (mean 108 s) than rocuronium 0.3 mg/kg (mean 228 s) in elderly patients. However, in 66% receiving rocuronium 0.3 mg/kg a TOF count of 0 was not obtained. Also, rocuronium 0.9 mg/kg resulted in a longer duration of action (mean 118 min vs 46 min, respectively) and a larger proportion of excellent intubating conditions. Compared to a dose of 0.6 mg/kg in the elderly, 0.9 mg/kg reduced onset time by approximately 30 s whereas the duration of action was almost 40 min longer.<sup>3</sup>

Especially, elderly patients are susceptible to residual neuromuscular blockade (NMB)<sup>8</sup> and it may therefore be tempting to administer a reduced dose of muscle relaxant. However, an important finding from the present study was that administration of rocuronium 0.3 mg/kg (corresponding to ED95<sup>16</sup>) only one third reached a TOF count of 0. In addition, excellent tracheal intubating conditions were only found in approximately 20% of the patients, suggesting that a dose of 0.3 mg/kg may be insufficient for facilitating tracheal intubation in elderly patients. On the contrary, administration of 0.9 mg/kg provided excellent intubating conditions in almost 70% of the patients. Also, a dose of 0.9 mg/kg administered in elderly had an onset time close to what was found after 0.6 mg/kg in younger adults (90 s).<sup>3</sup> The larger dose, however, resulted in a mean duration of action of almost 2 h.

The strengths of our study were the randomized blinded design and monitoring of the neuromuscular blockade according to research guidelines.<sup>13</sup> However, there were some limitations. We were only able to detect a TOF count of 0 in six patients after administration of 0.3 mg/kg. This influenced the time to tracheal intubation in Group Rocuronium 0.3 mg/kg since it was decided that the anesthesiologist should only wait up to 5 min for the NMB to reach a TOF count of 0. In addition, this more shallow level of NMB in the Group Rocuronium 0.3 mg/kg probably also influenced intubating conditions.

Another limitation was that intubating conditions were assessed by the Fuchs-Buder scale and the IDS score which are based on direct laryngoscopy only. However, the IDS score has previously been used in studies of assessment of intubating conditions comparing videolaryngoscopes with direct laryngoscopy.<sup>17</sup> Finally, duration of action in Group Rocuronium 0.9 mg/kg may have been prolonged by the administration of sevoflurane in two patients.<sup>18</sup>

There is no standardized assessment or consensus on how to evaluate intubating conditions.<sup>19</sup> We used both the Fuchs-Buder score<sup>12</sup> and the IDS score<sup>13</sup> to identify most possible details of tracheal intubating conditions. The effect of NMBAs on the laryngeal muscles are assessed especially by the Fuchs-Buder score<sup>12</sup> whereas the IDS score<sup>13</sup> also assesses for example the number of attempts, the technique employed, and Cormack Lehane grade. This may explain why we were only able to detect a difference in intubating conditions using the Fuchs-Buder score.

A relatively large proportion of patients in both groups were given ephedrine before a TOF count of 0 was reached. This may have influenced the onset time, since administration of ephedrine increases cardiac output.<sup>20,21</sup>

When difficulties in tracheal intubation for example due to limited neck movement are expected or encountered<sup>17</sup> or in the presence of poor dental status daily clinical practice at our institution is to use a videolaryngoscope and therefore this was also allowed in our protocol. However, employment of a videolaryngoscope does not necessarily provide easier advancement of the tube into the trachea, which may be impaired by coughing which occurred more often in group Rocuronium 0.3 mg/kg.

We calculated that a sample of 34 was needed in this study but complete data were only available in 22 patients. Nevertheless, we found statistically significant differences in both duration of action of rocuronium and tracheal intubation conditions. It seems that a dose of rocuronium 0.3 mg/kg compared to 0.9 mg/kg was too low to facilitate tracheal intubation in patients above 80 years of age with only 22% of the patients assessed as having excellent intubation conditions. In another recent study of patients above 80 years of age rocuronium 0.6 mg/kg provided excellent intubation conditions in 28% of the patients.<sup>22</sup> A dose of rocuronium 0.9 mg/kg which provided excellent intubation conditions in 69% of the patients, therefore, seems better to facilitate tracheal intubation, but this is at the expense of a prolonged duration of action and must be confirmed in a study comparing rocuronium 0.6 mg/kg with 0.9 mg/kg.

In conclusion, rocuronium 0.9 mg/kg resulted in a shorter onset time and better tracheal intubating conditions compared to a dose of

0.3 mg/kg in patients above 80 years of age undergoing general anesthesia. However, this was at the expense of a longer duration of action. Also, rocuronium 0.3 mg/kg seems inefficient to obtain a TOF count of 0.

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## CONFLICT OF INTEREST

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