

Evaluation of intubating conditions with rocuronium 0.6 mg/kg using train of four stimulation in elective surgery

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ABSTRACT

Background and Aims: Train of four (TOF) stimulation has been recommended to be used with neuromuscular blocking agents. The incidence of excellent intubating conditions with rocuronium, when used with TOF, is lacking. This study aimed to estimate the proportion of patients having excellent intubating conditions with rocuronium 0.6 mg/kg using TOF at adductor pollicis longus at T1 and T0, time to achieve T1 or T0 and incidence of sore throat, immediate and 24 hours post-extubation. **Methods:** This prospective non-randomised study was carried out in 250 patients of either sex, of American Society of Anesthesiologists physical status I-II, undergoing surgery under general anaesthesia with tracheal intubation after rocuronium 0.6 mg/kg monitored by TOF. Patients were divided among T1 and T0 groups. Intubating conditions were assessed using the Copenhagen scale. Results were analysed using the Chi-square test and the Student's t-test. A *P* value of <0.05 was considered significant. **Results:** Intubating conditions were excellent in 84% patients (87.9% in group T0 and 80.1% in group T1, *P* = 0.216). The mean onset time was 142.98 ± 27.04 seconds in group T0 and 122.38 ± 30.76 seconds in group T1 (*p* < 0.01). The incidence of immediate (*p* = 0.02) and late (*p* = 0.01) sore throat was higher in the T1 group. **Conclusion:** The proportion of patients having excellent intubating conditions with rocuronium 0.6 mg/kg was higher at T0 but not statistically significant. It takes 20 seconds longer to achieve T0 as compared to T1 with a lesser incidence of immediate and late sore throat.

Key words: Neuromuscular monitoring, rocuronium, sore throat, train of four

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INTRODUCTION

Rocuronium is one of the most commonly used non-depolarising muscle relaxants for intubation of the trachea. Clinically acceptable conditions have been obtained with rocuronium 0.6 mg/kg in 90 seconds.^[1] However, there are not many studies to quantify the proportion of patients having excellent conditions and time required to achieve them. Also, a standard observable endpoint, that is, disappearance of either three (T1) or all twitches (T0) after a train of four (TOF) stimulus is lacking. The literature does not indicate which endpoint provides the best intubating conditions.

Therefore, this study was planned to estimate the proportion of patients having excellent intubating conditions with rocuronium 0.6 mg/kg when

intubation was guided by TOF stimulation in elective surgery.

METHODS

This prospective non-randomised study was carried out in a tertiary care centre after approval by the Institutional Ethics Committee from November

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2016 to March 2018 in adult patients aged 18–60 years, of either sex, with American Society of Anesthesiologists (ASA) physical status I-II, posted for elective surgery of more than 1 hour duration, under general anaesthesia with endotracheal intubation. Patients with history of neuromuscular disease, anticipated difficult airway and body mass index <20 and >30 were excluded from the study. The trial was registered prospectively with the Clinical Trials Registry of India (CTRI/2016/10/007419). Written informed consent was obtained from all patients for inclusion in the study and publication of data. The study was done in accordance with the principles of the Declaration of Helsinki.

After wheeling the patient to the operating room, routine monitors and bispectral index (BIS) were applied and an intravenous line was secured.

An induction protocol using premedication with midazolam, opioid analgesia, inducing agent and inhalational agent decided by the consultant anaesthesiologist was followed, to achieve a BIS of 40–50. Neuromuscular transmission was monitored by the Drager Trident monitor integrated with the Drager Primus anaesthesia workstation. The device was set up and skin electrodes were applied after preparation of the ulnar side just above the palmar crease. The black cable (negative terminal) of the monitor was attached to the distal electrode, while the red cable (positive terminal) was attached to the proximal electrode. The acceleromyograph sensor was attached to the thumb. A skin temperature probe was attached on the palm for continuous measurement. Before starting the actual stimulus, the mode was set on auto, which calculates the supramaximal current for the individual and standardises the twitch height.

After loss of consciousness, the neuromuscular block was monitored by TOF stimulation at adductor pollicis longus (APL). Four successive stimuli were delivered at 2 Hz (every 0.5 sec) with a pulse duration of 200 μ s. Each set of four stimuli was repeated every 10 seconds. The temperature of thenar eminence was maintained at >32°C. Rocuronium 0.6 mg/kg was administered over 5 seconds as a bolus. When one of the four twitches is present (T1), approximately 90% of receptors are occupied. The disappearance of all the four twitches (T0) indicates that 100% of receptors are occupied.

Trachea was intubated at the discretion of the consultant anaesthesiologist when either all four

twitches or three twitches disappeared (T0 or T1, respectively). All neuromuscular parameters were defined according to “good clinical research practice (GCRP) in pharmacodynamic studies of neuromuscular blocking agents”.^[2]

Onset time was noted and defined as the time from the start of injection of rocuronium to achieving T1 or T0. The anaesthesiologist intubating the trachea was blinded to the endpoint of TOF achieved. Intubating conditions were recorded as excellent, good or poor.^[2] Anaesthesia was maintained with volatile inhalational agents to target a BIS of 40–60. At the end of surgery, the volatile agent was switched off, residual neuromuscular block was reversed and the trachea was extubated. A note was made of anaesthetic agents administered.

Postoperative sore throat was enquired immediately after extubation and at 24 h after surgery.

For analysis, patients were divided into two groups: those whose trachea was intubated at T1 and those at T0.

The primary objective of the study was to estimate the proportion of patients having excellent intubating conditions with rocuronium 0.6 mg/kg when intubation was guided by TOF stimulation in elective surgery. The secondary objectives studied were time to achieve T1 or T0 after administration of rocuronium (onset time), intubating conditions, influence of anaesthetic agents on intubating conditions, and incidence of sore throat immediate and 24 hours post-extubation between T1 and T0 groups. Intubating conditions were analysed with respect to onset time.

Sample size was calculated on the basis of a previous study by Patel *et al.*^[3] where excellent intubating conditions were reported in 83.33% of patients. With a confidence interval of 95% and a margin of error of 5%, we were required to include at least 214 patients. Assuming difficult intubation or device malfunction in 10% of patients, we decided to include 250 patients.

Data were tabulated and analysed statistically using Statistical Package for Social Sciences version 20.0. Quantitative variables (mean time taken for intubation) were expressed as mean \pm standard deviation (SD) and evaluated using Student's t-test. The qualitative variables (intubating conditions and post-operative sore throat) were expressed as frequencies/percentages

and compared using Chi-square test. Receiver operating characteristic (ROC) curve analysis was carried out for intubating conditions with respect to onset time. A *P* value <0.05 was assumed to be statistically significant.

RESULTS

A total of 258 patients fulfilling inclusion criteria were recruited for the study. Four patients refused to consent and in four patients there was equipment malfunction. A total of 250 cases were therefore tabulated and analysed.

Patients in our study were predominantly female and of ASA grade I. Age and ASA status were comparable between the groups [Table 1].

Mean onset time was 132.60 ± 30.71 seconds. It was 142.98 ± 27.04 seconds in group T0 and 122.38 ± 30.76 seconds in group T1 ($p < 0.05$). The intubating conditions were excellent in 84% of patients (87.9% in group T0 and 80.1% in group T1), but the difference was not statistically significant ($P = 0.22$; Table 2).

Gender, choice of intravenous induction agent and inhalational agents, use of nitrous oxide, dose of midazolam, fentanyl and onset time were analysed for presumed effect on the intubating conditions. However, none of them had a clinical or statistical relation with respect to intubating conditions [Table 3].

Table 1: Patient characteristics			
Groups	Group T0 (n=124)	Group T1 (n=126)	P
Age (years)	37.54±12.34	35.78±11.41	0.242
Gender			
Female	87 (70.16%)	88 (69.8%)	0.533
Male	37 (29.8%)	38 (30.1%)	
ASA			
I	83 (66.9%)	89 (70.6%)	0.310
II	41 (33.06%)	37 (29.36%)	

T0: Intubation at TOF count 0; T1: Intubation at TOF count 1; ASA: American Society of Anesthesiologists. Data are expressed as number(frequency) or as mean±standard deviation

No significant differences were found between groups with respect to Cormack-Lehane grade and number of attempts taken to intubate [Table 4]. However, incidence of immediate and late sore throat was higher in the T1 group [Table 5].

ROC analysis of onset time versus intubating conditions revealed that conditions would be poor if intubation is attempted at ≤ 60 seconds (sensitivity 100% and positive likelihood ratio 1), while excellent conditions can be obtained if intubation is attempted at 180 seconds (sensitivity 100% and positive likelihood ratio 1; Figure 1).

DISCUSSION

Neuromuscular blockers (NMBs) are widely used in anaesthesia practice for endotracheal intubation. The degree of neuromuscular block is usually evaluated by clinical criteria or presumed by the time elapsed after administration. The recommendation for application of neuromuscular monitoring to patients receiving NMBs is based on two important issues: first, on the variable individual response to muscle relaxants and second because of the narrow therapeutic window. Adequate muscle relaxation for intubation corresponds to a narrow range of 90 to 95% receptor occupancy.^[2] Inadequate muscle relaxation during intubation can lead to difficulty in securing the airway or multiple attempts leading to laryngeal morbidities such as oedema, postoperative hoarseness (4–42%) and vocal cord injury.^[4]

As diaphragm and laryngeal muscles are not accessible clinically, it is appropriate to choose a site that has a similar response. As it is difficult to quantify the relaxation of the laryngeal muscles, surrogates such as APL, orbicularis oculi, corrugator supercilii and flexor hallucis brevis have been utilised, though APL is the preferred site.^[5,6] Even though cessation of response of orbicularis oculi occurs earlier than corrugator supercilii, it does not guarantee satisfactory intubating

Table 2: Time taken for intubation and intubating conditions				
	Group T0 (n=124)	Group T1 (n=126)	Total	P
Time taken for intubation Mean±SD				
Seconds	142.98±27.04	122.38±30.76	132.60±30.71	<0.01*
Intubating conditions				
Excellent	109 (87.9%)	101 (80.1%)	210 (84%)	0.216
Good	14 (11.2%)	22 (17.4%)	36 (14.4%)	
Poor	1 (0.8%)	3 (2.38%)	4 (1.6%)	
n	124	126	250	

T0: Intubation at TOF count 0; T1: Intubation at TOF count 1; *significant *P* value; SD: Standard deviation; n: Number of patients. Data are expressed as number(frequency) or as mean±standard deviation

Table 3: Factors affecting intubating conditions

Factors	Excellent n(%)	Not Excellent n(%)	P
Gender			
Female	147 (84%)	28 (16%)	1.000
Male	63 (84%)	12 (16%)	
Group			
T0	109 (87.9%)	15 (12.1%)	0.095
T1	101 (80.2%)	25 (19.8%)	
IV induction agents			
Propofol	158 (86.8%)	24 (13.2%)	0.054
Thiopentone	52 (76.5%)	16 (23.5%)	
Nitrous oxide			
Yes	145 (85.8%)	24 (14.2%)	0.262
No	65 (80.2%)	16 (19.8%)	
Inhalation			
Sevoflurane	148 (87.1%)	22 (12.9%)	0.130
Isoflurane	28 (73.7%)	10 (26.3%)	
None	34 (80.9%)	8 (19.1%)	
Variable	Condition	Area under ROC curve	P
Midazolam dose	Excellent	210	0.534
	Not excellent	40	
Fentanyl dose	Excellent	210	0.562
	Not excellent	40	
Onset Time	Excellent	210	0.540
	Not excellent	40	

IV: Intravenous; ROC: Receiver operating characteristic; n: Number of patients

Table 4: Cormack-Lehane grading and number of attempts of intubation

	Group T0 (n=124)	Group T1 (n=126)	n (%)	P
Cormack- Lehane grade				
1	83 (66.9%)	87 (69%)	170 (68%)	0.768
2	40 (32.2%)	37 (29.3%)	77 (30.8%)	
3	1 (0.8%)	2 (1.5%)	3 (1.2%)	
Number of attempts of intubation				
One	118 (95.1%)	117 (92.8%)	235 (94%)	0.596
Two	6 (4.8%)	9 (7.2%)	15 (6%)	
n	124	126	250	

T0: Intubation at TOF count 0; T1: Intubation at TOF count 1; n: Number of patients

Table 5: Immediate and late sore throat

Sore throat	Group T0 (n=124)	Group T1 (n=126)	n(%)	P
Immediate				
Yes	8 (6.5%)	21 (16.6%)	29 (11.6%)	0.02*
No	116 (93.5%)	105 (83.3%)	221 (88.4%)	
Late				
Yes	0 (0.00%)	7 (5.6%)	7 (2.8%)	0.01*
No	124 (100%)	119 (94.4%)	243 (97.2%)	
n	124	126	250	

T0: Intubation at TOF count 0; T1: Intubation at TOF count 1; *significant P value; n: Number of patients. Data are expressed as number(frequency)

conditions. Corrugator supercilii can predict the presence of excellent tracheal intubating conditions and allow intubation earlier than that of APL.^[5] Though

excellent intubating conditions were observed most frequently with neuromuscular block assessment at APL, it delays the intubation time.^[7,8] We chose APL to assess the onset of action as the response of APL is close to that of laryngeal muscles.

It has been postulated that laryngeal muscles being resistant to the effects of NMBs,^[8] require at least twice the ED95 dose (ED95 is defined as the dose of a muscle relaxant required to decrease the height of single twitch by 95%. ED95 of rocuronium is 0.3 mg/kg).^[9] GCRP guidelines state that either single twitch or TOF can be used as a guide for intubation, TOF is preferable because it is more sensitive to lesser degree of receptor occupancy than single twitch.^[2] For this reason, a reversal strategy based on quantitative TOF monitoring has been found better than no TOF monitoring.^[10] Observation of evoked TOF responses after a dose of non-depolarising muscle relaxant allows prediction of onset time of paralysis of laryngeal muscles in individual patients. When the neuromuscular monitor has been used, the endpoint for laryngeal intubation varies and has not been standardised. Even the GCRP recommends either a 0.1 Hz single twitch or a TOF stimulus.^[2] But the endpoint for intubation using TOF has not been defined.

In the absence of availability of neuromuscular transmission monitors, timed intubation has been practised. However, patient factors^[2] such as age, gender,^[11] medical condition (ASA status), body weight affect the pharmacokinetics and pharmacodynamics of the drug.

This observational study shows that 84% of patients will have excellent intubating conditions with rocuronium 0.6 mg/kg using TOF at the APL. If intubation is performed at T0 instead of T1, 8% more patients will have excellent intubating conditions. This would require an additional 20 seconds, a statistically significant difference.

The proportion of patients having excellent conditions after rocuronium 0.6 mg/kg varies widely in the literature from 80 to 94%,^[3,12-14] when monitored clinically or using neuromuscular monitoring. The pack insert of rocuronium bromide lists a different proportion based on the manufacturer. While Esmeron® (Mercke Sharp & Dohme, Australia) describes acceptable conditions (Excellent + Good) in 99% of patients at 60 seconds,^a Zemuron® (Merck and Co., Inc., USA) lists 96% at 60 seconds.^b Khurshid

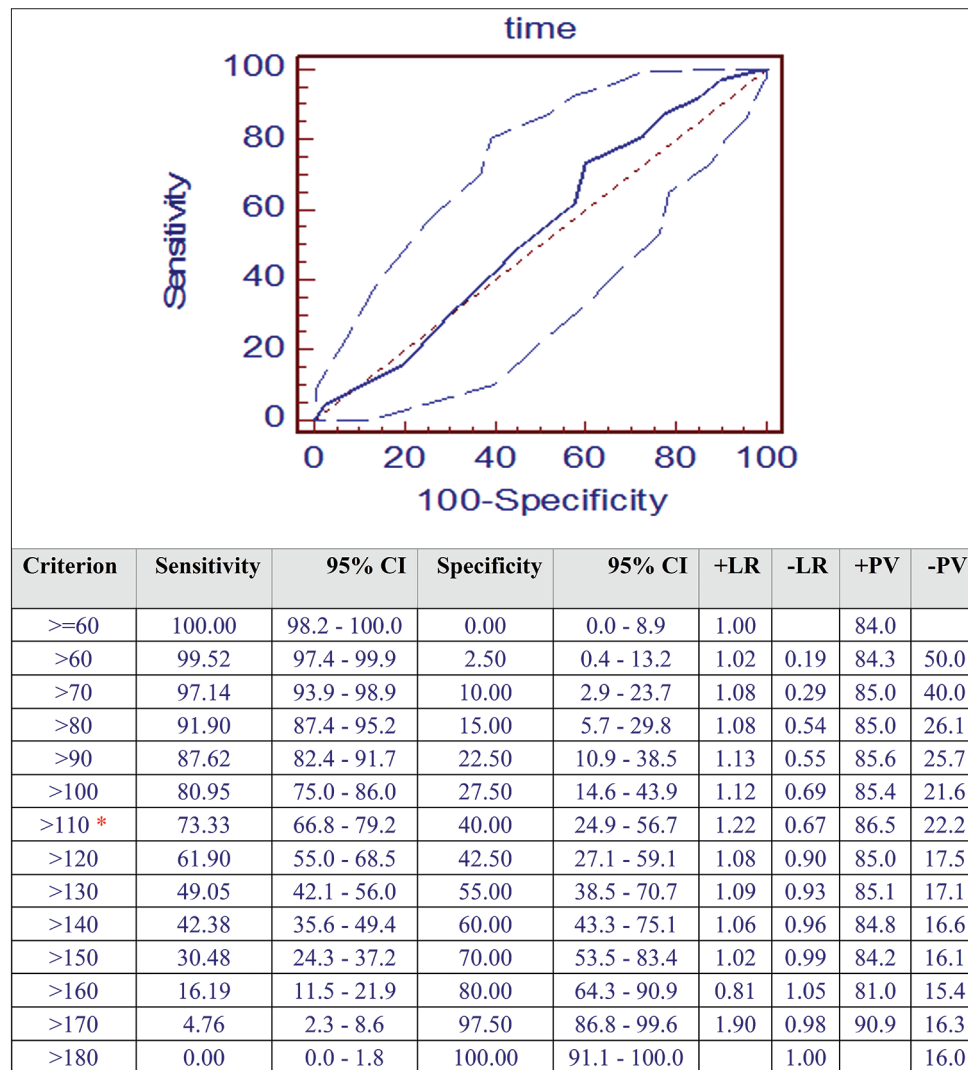


Figure 1: Receiver operating characteristic (ROC) curve of onset time versus intubating conditions. CI: Confidence interval; LR: Likelihood ratio; PV: Predictive value

et al.^[15] reported excellent intubating conditions at T1 in 53% of patients with rocuronium 0.6 mg/kg using TOF at adductor pollicis. They assessed the intubating conditions using the Cooper scale.^[1] Zhou *et al.*^[16] reported that only 46.6% of patients had excellent intubating conditions at 60 seconds using a similar dose.

Traditional teaching has been to attempt intubation at 180 seconds after 0.6 mg/kg rocuronium. We obtained a mean onset time of 132.60 ± 30.71 seconds when guided by TOF at APL. On extrapolation of the ROC curve of onset time with respect to excellent conditions, a positive likelihood ratio of 1 was obtained for excellent conditions at onset time of ≥ 180 seconds.

However, the onset time in literature ranges from 75 to 163 seconds.^[1,3,14,16,17] Esmeron® describes

the time of onset as 126 seconds,^a while that of Zemuron® is 108 seconds.^b Zhou *et al.*^[16] reported an onset time of 141 ± 65 seconds at T1 which was more than our study (122 ± 31 seconds) with the use of Rocunium® (Neon Laboratories Limited, India). A study, however, reported an onset time of 75 seconds at T0.^[3] The faster onset time could be due to orbicularis oculi stimulation in that study compared to APL stimulation in our study. Another study reported an onset time of 163 ± 56 seconds at T0 as compared to (143 ± 27 seconds) in our study with the use of Rocunium® (Neon Laboratories Limited, India).^[14] These variations can be due to differences in the muscle mass related to age, gender, race, manufacturer, site of twitch measurement and/or endpoint for the start of laryngoscopy [clinical, T1 or T0 and scoring systems used (Kreig/Cooper/Copenhagen)].^[11] Our study results were comparable

with Fuchs-Buder *et al.*^[18] who reported an onset time of 148 seconds with rocuronium 0.6 mg/kg at T0.

We found no difference with the use of propofol and thiopentone or other agents, however, some researchers have reported clinically excellent conditions in 60% of patients with thiopentone at 60 seconds as compared to 40% with propofol.^[19] Skinner *et al.*^[13] reported better intubating conditions with propofol (acceptable in 94% of patients) as compared to 75% with etomidate.

We could not find any study in literature which compared the proportion of patients with excellent conditions between T0 and T1 groups or differences in time taken. Poor intubating conditions may lead to trauma and postoperative hoarseness.^[4] Mencke *et al.*^[20] reported an incidence of 23% with neuromuscular monitoring. Only four patients (0.1%) complained of sore throat 24 hours postoperatively that too in the T1 group in our study. Nevertheless, tracheal intubation usually produces short-term hoarseness which usually lasts for three to seven days following surgery and rarely produces prolonged hoarseness.^[21] Ours is probably the first study which evaluated the late persistence of sore throat after short-term intubation.

Nonetheless, our study was limited by lack of comparison of intubating conditions and onset time in different age groups, comparison of TOF with single twitch and randomisation.

CONCLUSION

To conclude, the proportion of patients having excellent intubating conditions with rocuronium 0.6 mg/kg is higher at T0 (though not statistically significant), but it takes 20 seconds longer as compared to T1 with a lesser incidence of immediate and late sore throat. Excellent conditions for intubation can be obtained after 180 seconds of administration of rocuronium in a dose of 0.6 mg/kg.

- a) *Esmeron product information:* <https://secure.healthlinks.net.au/content/msd/pi.cfm?product=mkpesmer>, accessed on 28thfeb 2017.
- b) *Zemuron product information:* https://www.merck.com/product/usa/pi_circulars/z/zemuron/zemuron_pi.pdf, accessed on 28thfeb 2017.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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