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Original Research Article

Comparison of Haemodynamic Responses between Train-of-Four and Bispectral Index Guided Tracheal Intubation versus Clinical Assessment Guided Tracheal Intubation: A Prospective Randomised Study

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Abstract

Background and Aims: Laryngoscopy and tracheal intubation provoke transient but potentially hazardous sympathetic responses. Adequate neuromuscular blockade and depth of anaesthesia at the moment of intubation may attenuate this response. We compared haemodynamic changes and intubating conditions when the appropriate moment for tracheal intubation was determined by combined train-of-four (TOF) and bispectral index (BIS) monitoring versus conventional clinical assessment.

Methods: In this prospective, randomised, single-centre study, 68 adult patients of either sex, ASA physical status I–II, scheduled for elective laparoscopic cholecystectomy under general anaesthesia, were allocated by lottery to two groups of 34 each. In Group M (monitor-guided), the trachea was intubated when TOF count at the adductor pollicis was zero and BIS was ≤ 40. In Group C (clinical assessment), the trachea was intubated after clinical judgement of jaw-muscle relaxation and loss of the eyelash reflex. Heart rate (HR), systolic, diastolic and mean arterial pressures (SAP, DAP, MAP), peripheral oxygen saturation (SpO_2) and intubating conditions (Copenhagen score) were recorded at baseline (T0), after induction (T1), pre-intubation (T2), and 1 (T3), 3 (T4) and 5 (T5) minutes after intubation. Data were analysed with Student's t-test and the chi-square or Fisher's exact test, as appropriate.

Results: HR, SAP, DAP and MAP were significantly higher in Group C than in Group M at all post-intubation time points ($P < 0.05$). The peak HR after intubation was 107.5 ± 12.7 bpm in Group C versus 97.0 ± 3.0 bpm in Group M ($P < 0.0001$), and peak MAP was 112.0 ± 2.0 mmHg versus 100.0 ± 4.1 mmHg, respectively ($P < 0.0001$). Excellent intubating conditions (score 5) were achieved in all 34 patients in Group M, whereas all Group C patients had only moderate conditions (score 3–4; $P < 0.0001$).

Conclusion: Combined TOF and BIS monitoring to time tracheal intubation produces significantly better intubating conditions and attenuates the haemodynamic stress response compared with conventional clinical assessment.

Keywords: Bispectral Index; Haemodynamics; Laryngoscopy; Neuromuscular Monitoring; Tracheal Intubation; Train-Of-Four.

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Introduction

Laryngoscopy and endotracheal intubation during induction of general anaesthesia elicit strong nociceptive stimuli that often lead to reflex sympathetic stimulation. In otherwise healthy patients these cardiovascular changes are transient and well tolerated, but in those with coronary artery disease, systemic hypertension or intracranial pathology the resulting tachycardia and surge in arterial pressure may precipitate myocardial ischaemia, arrhythmia or secondary brain injury.[1,2] Numerous pharmacological strategies—including opioids, lignocaine, beta-blockers, calcium-channel blockers, alpha-2 agonists, gabapentinoids and topical airway anaesthesia—have been used to blunt this pressor response, but each adds expense, polypharmacy and potential haemodynamic instability of its own.[3] A simple, drug-free approach is therefore attractive. The magnitude of the circulatory response depends on the type and depth of anaesthesia, the patient's age and comorbidities, the duration of laryngoscopy, and—crucially—the adequacy of neuromuscular blockade at the moment of tube insertion.[4,5] Intubating before maximum block is reached forces the laryngoscopist to overcome residual muscle tone, prolonging laryngoscopy and amplifying the sympathetic response. Train-of-four (TOF) stimulation of the adductor pollicis provides an objective, bedside index of neuromuscular block: a TOF count of zero indicates near-complete paralysis of peripheral muscle and corresponds closely to optimum conditions at the larynx.[6] In routine practice, however, neuromuscular monitoring is rarely used; most anaesthetists begin laryngoscopy on the basis of clinical signs—loss of the eyelash reflex, jaw relaxation and a fixed post-administration interval based on the published onset time of the muscle relaxant.

Equally important is the hypnotic component of anaesthesia. The bispectral index (BIS), derived from processed electroencephalography, reflects the depth of the hypnotic state, and a BIS value of 40–60 is generally accepted as adequate surgical anaesthesia. Adding BIS to neuromuscular monitoring should, in principle, ensure that the patient is both adequately anaesthetised and adequately paralysed at the moment of laryngoscopy.

Previous work has compared TOF-guided intubation with clinical assessment alone and consistently shown better intubating conditions and a blunted haemodynamic response with monitoring.[6,7] However, data combining objective monitoring of both depth of anaesthesia (BIS) and neuromuscular block (TOF) to time tracheal intubation remain limited. We hypothesised that timing tracheal intubation by the combined criterion of TOF count = 0 at the adductor pollicis and BIS $\leq$ 40 would produce significantly better intubating conditions and a smaller increase in heart rate and arterial pressure than would conventional clinical assessment.

The primary objective of this study was to compare changes in heart rate and mean arterial pressure after tracheal intubation between the two strategies. Secondary objectives were the comparison of systolic and diastolic arterial pressure, peripheral oxygen saturation and intubating conditions.

Materials and Methods

Study design and setting: This prospective, randomised, single-centre study was conducted in the operating theatre of the Department of Anaesthesiology, Bankura Sammilani Medical College and Hospital, Bankura, West Bengal, between November 2020 and May 2022.

The protocol was approved by the Institutional Ethics Committee and registered with the West Bengal University of Health Sciences. Written informed consent in the participant's own language (English, Hindi or Bengali) was obtained from every participant after a full explanation of the study procedure and the expected risks.

Participants: Adult patients of either sex, aged 20–70 years, ASA physical status I or II, scheduled for elective laparoscopic cholecystectomy under general anaesthesia with tracheal intubation, with a modified Mallampati grade I or II airway, were eligible. Exclusion criteria were: refusal to participate; anticipated difficult airway; known hypersensitivity to any study drug; labile blood pressure; severe renal, endocrine or cardiac disease, including conduction defects; chronic therapy with beta-blockers; morbid obesity; chronic alcohol or substance use; pregnancy or lactation; and oesophageal intubation occurring during the procedure.

Sample size: Assuming a clinically relevant difference in heart rate of 10 beats per minute between groups, an SD of 14 beats per minute, a two-sided α of 0.05 and a power of 80%, the calculated sample size was 31 per group using the formula $n = (Z_\alpha + Z_\beta)^2 \times (SD)^2 / d^2$. To allow for dropouts, 34 patients per group (68 in total) were enrolled.

Randomisation and allocation: Eligible participants were allocated by simple lottery in a 1:1 ratio to one of two groups (n = 34 each):

Group M (monitor-guided): the trachea was intubated when the train-of-four count at the adductor pollicis muscle reached zero AND the bispectral index was $\leq$ 40.

Group C (clinical assessment): the trachea was intubated when the attending anaesthetist judged jaw relaxation to be adequate and the eyelash reflex was lost.

Pre-operative assessment and preparation: A standard pre-anaesthetic evaluation, including a complete history, physical examination, airway assessment, and routine investigations (haemogram, fasting blood glucose, blood urea, serum creatinine, liver function tests, coagulation profile, electrocardiogram and chest radiograph), was performed in every patient. Patients were fasted overnight and premedicated with oral alprazolam 0.25 mg and ranitidine 150 mg on the morning of surgery.

Anaesthetic technique: On arrival in the operating theatre, an 18-gauge intravenous cannula was secured and Ringer's lactate was started at 6 mL $kg^{-1} h^{-1}$. Standard monitoring (electrocardiography, non-invasive arterial pressure, pulse oximetry, capnography) was applied. The TOF-Watch (or equivalent peripheral nerve stimulator) was attached over the ulnar nerve at the wrist and BIS sensors over the forehead. After pre-oxygenation with 100% oxygen for three minutes, anaesthesia was induced with intravenous fentanyl 2 µg kg^{-1}, followed by propofol 2 mg kg^{-1} titrated to loss of the eyelash reflex. Vecuronium 0.1 mg kg^{-1} was then administered to facilitate tracheal intubation. In Group M, supramaximal TOF stimulation of the ulnar nerve was delivered every 10 s and BIS was monitored continuously. Laryngoscopy with a Macintosh blade and tracheal intubation with an appropriately sized cuffed endotracheal tube were performed when the TOF count was zero and the BIS value was ≤ 40.

In Group C, the same induction and neuromuscular blocking drugs were administered. Laryngoscopy and intubation were performed when the attending anaesthetist clinically judged the patient to have adequate jaw relaxation and a lost eyelash reflex, without reference to the TOF or BIS monitors.

All intubations were performed by an anaesthetist with at least three years of clinical experience who was blinded to the timing criterion used in the alternate arm. Anaesthesia was maintained with isoflurane 0.8–1.2% in a 50:50 mixture of oxygen and nitrous oxide, with incremental doses of vecuronium guided by clinical need and surgical stimulation. At the end of surgery, residual neuromuscular block was reversed with neostigmine 0.05 mg kg^{-1} and glycopyrrolate 0.01 mg kg^{-1}, and the trachea was extubated after the patient fulfilled standard extubation criteria.

Outcome Measures: The primary outcomes were heart rate (HR) and mean arterial pressure (MAP). Secondary outcomes were systolic arterial pressure (SAP), diastolic arterial pressure (DAP), peripheral oxygen saturation (SpO_2), and intubating conditions. All variables were recorded at six time points:

- T0 – baseline, before induction;
- T1 – immediately after induction of anaesthesia;
- T2 – immediately before laryngoscopy;
- T3 – 1 minute after tracheal intubation;
- T4 – 3 minutes after tracheal intubation;
- T5 – 5 minutes after tracheal intubation.

Intubating conditions were graded on the Copenhagen scoring scale based on jaw relaxation, vocal cord position and the patient's response (coughing or bucking) to intubation and cuff inflation. A composite score of 5–6 was classed as good, 3–4 as moderate and 0–2 as poor.

Statistical Analysis: Data were entered in a Microsoft Excel spreadsheet and analysed with SPSS version 27.0 (IBM Corp., Armonk, NY, USA) and GraphPad Prism version 5. Continuous variables are presented as mean ± standard deviation (SD) and categorical variables as frequencies and percentages. Continuous variables were compared between groups by the unpaired Student's t-test; categorical variables were compared by the chi-square test or Fisher's exact test, as appropriate. A two-tailed P value < 0.05 was considered statistically significant.

Results

A total of 68 patients completed the study, 34 in each group; there were no dropouts.

The two groups were comparable for sex distribution (17 male and 17 female in each group; P = 1.000), age (52.9 ± 12.5 years in Group M versus 51.5 ± 5.3 years in Group C; P = 0.556) and ASA physical status. Mean body weight was slightly higher in Group M (68.5 ± 1.5 kg) than in Group C (66.0 ± 4.1 kg; P = 0.001), and mean height was slightly lower (147.5 ± 7.6 cm versus 155.0 ± 5.1 cm; P < 0.001).

All 68 patients were operated for chronic cholecystitis and underwent laparoscopic cholecystectomy. The mean duration of surgery was somewhat longer in Group M (62.5 ± 7.6 min) than in Group C (55.0 ± 5.1 min; P < 0.001) (Table 1).

Table 1: Demographic and operative characteristics of the two groups.

Variable	Group M (n = 34)	Group C (n = 34)	Statistic	P value
Age (years), mean ± SD	52.9 ± 12.5	51.5 ± 5.3	t-test	0.556
Sex (M / F)	17 / 17	17 / 17	$\chi^2 = 0.00$	1.000
Weight (kg), mean ± SD	68.5 ± 1.5	66.0 ± 4.1	t-test	0.001
Height (cm), mean ± SD	147.5 ± 7.6	155.0 ± 5.1	t-test	< 0.001
Duration of surgery (min)	62.5 ± 7.6	55.0 ± 5.1	t-test	< 0.001
Diagnosis: chronic cholecystitis	34 (100%)	34 (100%)	—	—
Procedure: laparoscopic cholecystectomy	34 (100%)	34 (100%)	—	—

Heart rate: Although the mean heart rate was significantly lower in Group M at baseline than in Group C (71.0 ± 7.1 versus 88.0 ± 2.0 bpm; P < 0.0001), the response to laryngoscopy and intubation was markedly more pronounced in Group C. At 1 minute after intubation (T3), the mean heart rate rose to 102.5 ± 7.6 bpm in Group C compared with 91.0 ± 5.1 bpm in Group M (P < 0.0001), and at 3 minutes (T4) it peaked at 107.5 ± 12.7 bpm versus 97.0 ± 3.0 bpm, respectively (P < 0.0001). By 5 minutes after intubation (T5) the difference was no longer significant (107.5 ± 17.8 versus 102.0 ± 8.1 bpm; P = 0.105), suggesting that the tachycardic response in Group C was beginning to subside (Table 2).

Table 2: Heart rate (beats per minute) at each time point.

Time point	Group M (n = 34)	Group C (n = 34)	P value
T0 (baseline)	71.0 ± 7.1	88.0 ± 2.0	< 0.0001
T1 (post-induction)	74.0 ± 6.1	83.5 ± 1.5	< 0.0001
T2 (pre-intubation)	79.0 ± 7.1	83.5 ± 1.5	0.0006
T3 (1 min post)	91.0 ± 5.1	102.5 ± 7.6	< 0.0001
T4 (3 min post)	97.0 ± 3.0	107.5 ± 12.7	< 0.0001
T5 (5 min post)	102.0 ± 8.1	107.5 ± 17.8	0.1053

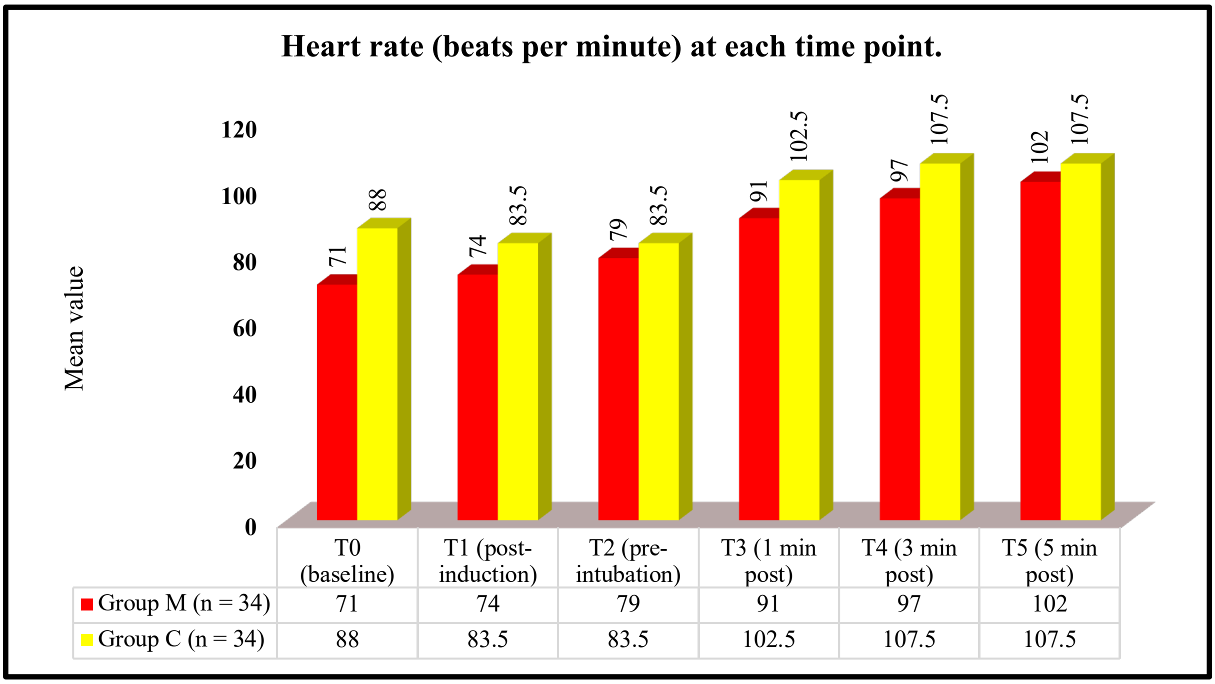

Figure 2: Heart rate (beats per minute) at each time point.

Arterial blood pressure: Systolic, diastolic and mean arterial pressures were significantly lower in Group M than in Group C at every time point from T0 to T5 (P < 0.05 for all).

The peak post-intubation values were observed at T4. The mean SAP at T4 was 149.0 ± 9.1 mmHg in Group C versus 131.0 ± 1.0 mmHg in Group M (P < 0.0001), and the mean MAP was 112.0 ± 2.0 mmHg versus 100.0 ± 4.1 mmHg, respectively (P < 0.0001). Compared with baseline, Group C showed a marked rise in MAP after intubation, peaking at +10 mmHg above its baseline at T4, whereas Group M demonstrated only a modest rise (peak MAP +7 mmHg above its baseline) and returned promptly toward baseline by T5 (Table 3).

Table 3: A Systolic, diastolic and mean arterial pressures at each time point. Systolic arterial pressure (mmHg)

Time point	Group M (n = 34)	Group C (n = 34)	P value
T0	125.0 ± 15.2	136.0 ± 4.1	< 0.0001
T1	124.0 ± 12.2	136.0 ± 4.1	< 0.0001
T2	116.0 ± 18.3	131.0 ± 11.2	< 0.0001
T3	120.0 ± 22.3	145.0 ± 5.1	< 0.0001
T4	131.0 ± 1.0	149.0 ± 9.1	< 0.0001
T5	135.0 ± 3.0	132.0 ± 6.1	0.0125

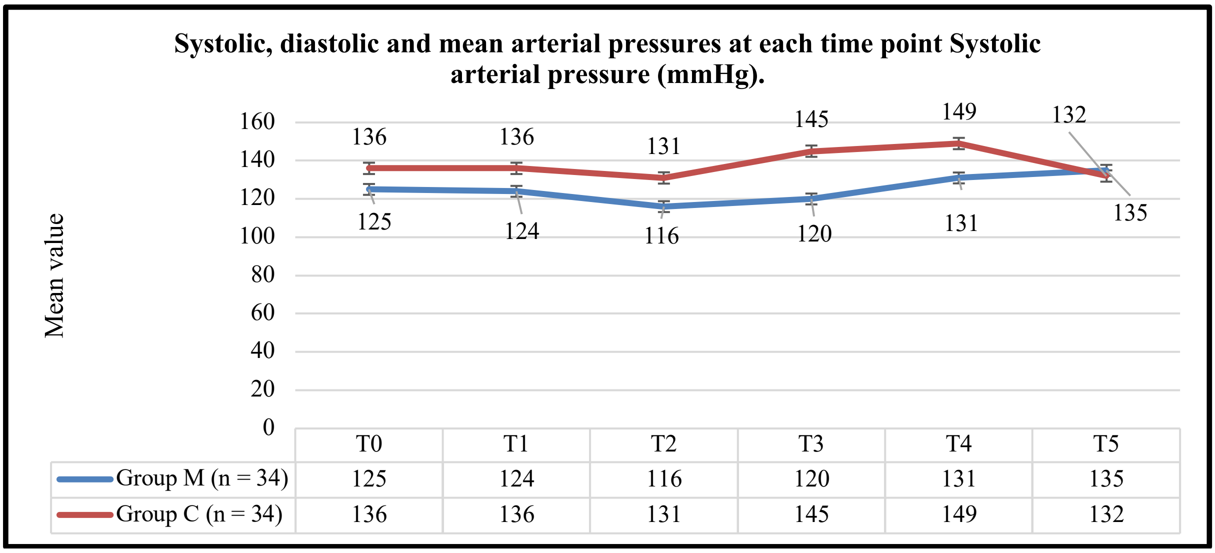

Figure 3 A: Systolic, diastolic and mean arterial pressures at each time point. Systolic arterial pressure (mmHg)

Table 3 B: Systolic, diastolic and mean arterial pressures at each time point. Diastolic arterial pressure (mmHg)

Time point	Group M (n = 34)	Group C (n = 34)	P value
T0	77.0 ± 1.0	85.0 ± 1.0	< 0.0001
T1	77.0 ± 5.1	87.0 ± 1.0	< 0.0001
T2	80.0 ± 6.1	88.0 ± 0.0	< 0.0001
T3	82.0 ± 4.1	91.0 ± 1.0	< 0.0001
T4	85.0 ± 5.1	94.0 ± 2.0	< 0.0001
T5	81.0 ± 5.1	90.0 ± 0.0	< 0.0001

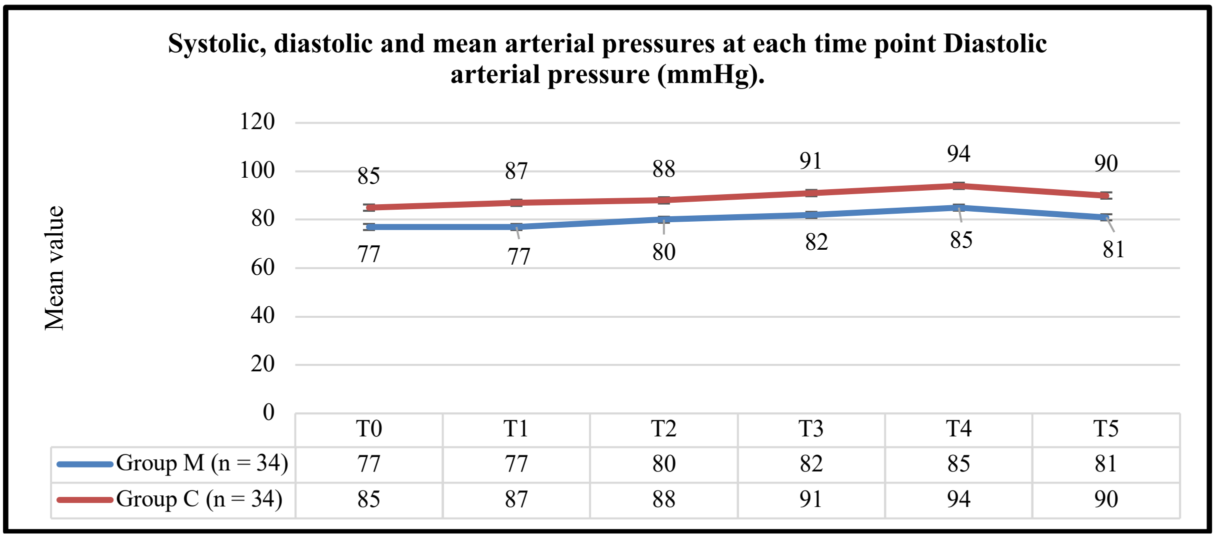

Figure 3 B: Systolic, diastolic and mean arterial pressures at each time point. Diastolic arterial pressure (mmHg)

Table 3 C: Systolic, diastolic and mean arterial pressures at each time point. Mean arterial pressure (mmHg)

Time point	Group M (n = 34)	Group C (n = 34)	P value
T0	94.5 ± 2.5	102.0 ± 2.0	< 0.0001
T1	92.0 ± 2.0	103.5 ± 0.5	< 0.0001
T2	92.0 ± 2.0	102.5 ± 3.6	< 0.0001
T3	101.5 ± 2.5	108.5 ± 2.5	< 0.0001
T4	100.0 ± 4.1	112.0 ± 2.0	< 0.0001
T5	98.5 ± 2.5	104.0 ± 2.0	< 0.0001

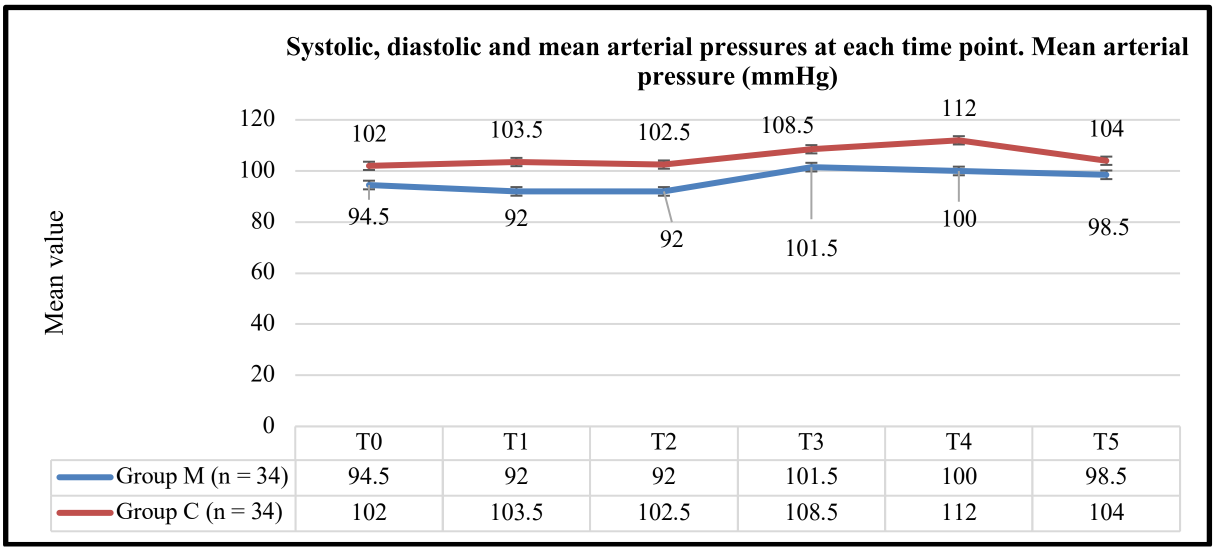

Figure 3.C Systolic, diastolic and mean arterial pressures at each time point. Mean arterial pressure (mmHg)

Peripheral oxygen saturation: Peripheral oxygen saturation remained within the clinically acceptable range (≥ 96%) throughout the procedure in both groups.

The between-group differences, although occasionally reaching statistical significance (for example, 99.0 ± 1.0% in Group C versus 97.0 ± 1.0% in Group M at T3; $P < 0.0001$), were within ± 2% and of no clinical importance. No patient in either group experienced clinically significant desaturation ($SpO_2 < 92\%$).

Intubating conditions: Intubating conditions were strikingly different between the two groups. All 34 patients in Group M (100%) achieved a Copenhagen score of 5, indicating good intubating conditions.

In Group C, by contrast, 17 patients (50%) had a score of 4 and 17 patients (50%) a score of 3, all in the moderate category; no Group C patient achieved a score of 5. The mean Copenhagen score was 5.00 ± 0.00 in Group M and 3.50 ± 0.51 in Group C ($P < 0.0001$) (Table 4).

Table 4. Distribution of intubating conditions (Copenhagen score).

Copenhagen score (category)	Group M (n = 34)	Group C (n = 34)	P value
Score 5 (Good)	34 (100%)	0 (0%)	< 0.0001
Score 4 (Moderate)	0 (0%)	17 (50%)	
Score 3 (Moderate)	0 (0%)	17 (50%)	
Mean score ± SD	5.00 ± 0.00	3.50 ± 0.51	< 0.0001

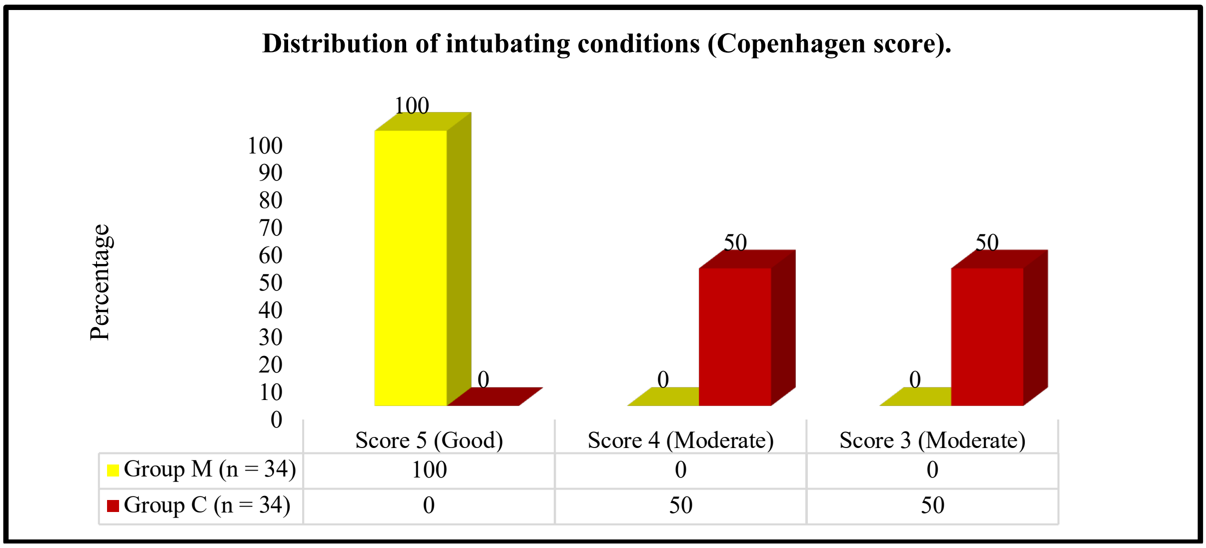

Figure 4: Distribution of intubating conditions (Copenhagen score).

Discussion

This prospective randomised study demonstrates that timing tracheal intubation by combined neuromuscular and hypnotic depth monitoring (TOF count = 0 at the adductor pollicis and BIS ≤ 40) produces significantly better intubating conditions and significantly smaller increases in heart rate and arterial pressure compared with conventional clinical assessment in adult patients undergoing elective laparoscopic cholecystectomy. The findings hold for systolic, diastolic and mean arterial pressures and persisted through the first three minutes after intubation—the period of greatest haemodynamic vulnerability. Our results are in close agreement with those of Nandi et al., who randomised 68 patients undergoing laparoscopic cholecystectomy to clinical-judgement-guided versus TOF-guided intubation and found significantly higher heart rate and mean arterial pressure in the clinically guided group, together with excellent or good intubating conditions in all TOF-guided patients but only 70% of clinically guided patients.[7] Witkowska et al. similarly reported better cardiovascular stability and intubation conditions when intubation was timed by the disappearance of the TOF response.[8] By adding BIS monitoring to TOF, the present study reinforces the principle that both arms of anaesthesia—neuromuscular block and hypnotic depth—must be adequate at the moment of laryngoscopy. Earlier work by Karwacki et al. demonstrated that BIS-guided titration reduces opioid and hypnotic requirements during total intravenous anaesthesia,[9] and Guignard et al. showed that BIS rises in parallel with the pressor response after intubation, so that BIS itself can serve as a marker of the cardiovascular response to noxious stimulation.[10]

The mechanism underlying the benefit observed in Group M is straightforward. Complete paralysis of the adductor pollicis approximates the time at which laryngeal adductors—which recover faster than peripheral muscles—are also fully blocked,[11] enabling the laryngoscopist to displace the tongue and tube the trachea with minimal resistance and minimal direct stimulation of laryngeal afferents. Adequate hypnotic depth (BIS ≤ 40) blunts central processing of the residual nociceptive afferents that do reach the brainstem. Together, the two interventions reduce the magnitude of reflex sympathetic outflow that drives the tachycardia and pressor response. Excellent intubating conditions occurred in 100% of Group M patients versus 0% of Group C patients. This is a clinically substantial benefit. Suboptimal intubating conditions are associated with vocal cord injury, post-operative hoarseness, sore throat and traumatic laryngoscopy, and they prolong the haemodynamically vulnerable phase of induction. Our findings echo those of Debaene et al., Plaud et al. and Haller et al., all of whom showed that intubating conditions are improved when neuromuscular monitoring rather than clinical judgement is used to time tube insertion.[12–14] In a recent large series, Kumar et al. reported excellent intubating conditions in 87.9% of patients when intubation was performed at TOF count zero, supporting the choice of T0 (rather than T1) as the target.[15] Heart rate at T5 (5 minutes after intubation) was the only time point at which the between-group difference lost statistical significance. This is consistent with the well-documented transient nature of the intubation pressor response, which typically resolves within 3–5 minutes in healthy patients.[16] In high-risk patients—those with coronary artery disease, hypertension or raised intracranial pressure—even a transient response of this magnitude can be deleterious, so the absolute benefit of monitor-guided intubation is expected to be greater than the relative benefit observed here in young, ASA I–II patients. Two unexpected demographic findings deserve comment. Mean body weight was slightly higher in Group M and mean height was slightly lower, both reaching statistical significance, although the absolute differences were small (2.5 kg and 7.5 cm) and unlikely to be clinically important. The mean duration of surgery was also longer in Group M (62.5 versus 55 minutes), which is consistent with previous reports that monitor-guided intubation lengthens the interval between muscle relaxant administration and laryngoscopy by 1–3 minutes;[7,8] this small time penalty is the price paid for ensuring optimal conditions, and is clearly justified by the haemodynamic and intubation benefits. The peripheral oxygen saturation data show only minor between-group differences without clinical significance. SpO_2 remained ≥ 96% in every patient at every time point, confirming that the additional 1–3 minutes spent waiting for the TOF count to reach zero in Group M did not jeopardise oxygenation after standard pre-oxygenation.

Conclusion

Timing tracheal intubation by combined train-of-four and bispectral index monitoring—waiting until the TOF count at the adductor pollicis is zero and the BIS is ≤ 40—produces significantly better intubating conditions and significantly smaller increases in heart rate and arterial pressure than conventional clinical assessment in adult patients undergoing elective laparoscopic cholecystectomy. We recommend objective monitoring of both neuromuscular block and depth of anaesthesia at the time of intubation, especially in patients with cardiovascular comorbidity in whom the haemodynamic stress response of laryngoscopy is most likely to cause harm.

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Author contributions: AB conceived the study, performed all data collection, statistical analysis and drafted the manuscript.

Data availability: De-identified individual participant data are available from the corresponding author on reasonable request.

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