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Original Article / Özgün Araştırma

Propofol Versus Thiopental for Rapid-Sequence Induction in Isolated Systolic Hypertensive Patients: A Factorial Randomized Double-Blind Clinical Trial

Hızlı Seri Anestezi İndüksiyonu Uygulanan İzole Sistolik Hipertansiyonlu Hastalarda Propofol ve Tiopentalin Karşılaştırılması: Faktöriyel Randomize Çift Kör Klinik Araştırma

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Abstract / Öz

Objective: We investigated the effects of four different anaesthesia induction protocols on the haemodynamic response to laryngoscopy and tracheal intubation during rapid-sequence induction (RSI) in systolic hypertensive patients.

Methods: One hundred and twenty hypertensive adult patients (systolic pressure >140 mmHg and diastolic pressure <90 mmHg), classified according to the American Association of Anesthesiologists as Class II and III were randomized into four groups. After pre-oxygenation for 3 minutes, induction and tracheal intubation were performed by blinded investigators, who also scored the intubation. Study groups composed of 30 patients each received lidocaine 1 mg kg^{-1}+thiopental 5 mg kg^{-1} or remifentanil 1 μg kg^{-1}+thiopental 5 mg kg^{-1} or lidocaine 1 mg kg^{-1}+propofol 2 mg kg^{-1} or remifentanil 1 μg kg^{-1}+propofol 2 mg kg^{-1}. Succinylcholine was the muscle relaxant. Haemodynamic data were obtained before (baseline) and after induction, at intubation, and at 1, 3, 5 and 10 minutes after intubation. A rise or drop in the arterial blood pressure and heart rate >20% were considered to be significant.

Results: Patients receiving remifentanil+propofol had a reduction in the systolic and mean blood pressure >20% when compared to patients receiving remifentanil and thiopental: systolic values were 125±27 mmHg in the remifentanil+propofol group versus 153±35 mmHg in the remifentanil+thiopental group 1 minute after intubation ($p<0.01$); the mean arterial pressure values were 87±18 mmHg in the remifentanil+propofol group versus 105±25 mmHg in the remifentanil+thiopental group 1 minute after intubation ($p<0.05$).

Conclusion: Propofol was not superior to thiopental for the attenuation of the response to laryngoscopy and intubation during RSI in systolic hypertensive patients, whereas propofol+remifentanil combination appears to be so in terms of the heart rate stability.

Keywords: Rapid sequence induction, isolated systolic hypertension, propofol, thiopental, remifentanil

Amaç: Bu çalışmada izole sistolik hipertansiyonu olan hastalarda hızlı - seri anestezi indüksiyonu sırasında dört farklı protokolde ilaç uygulamasının, laringoskopi ve entübasyonda hemodinamik cevap üzerine olan etkileri karşılaştırıldı.

Yöntemler: Çalışmaya, izole sistolik hipertansiyonu olan (sistolik kan basıncı >140 mmHg, diastolik kan basıncı <90 mmHg) ASA II-III grubu, 18-79 yaş arası 120 hasta dahil edildi. Hastalar randomize olarak 4 gruba ayrıldı. 3 dakikalık preoksijenasyonu takiben araştırmacılar tarafından indüksiyon ve endotrakeal entübasyon gerçekleştirildi ve entübasyon tüm hastalarda skorlandı. Çalışma grupları 30'ar hastadan oluşuyordu ve gruplara; lidokain 1 mg kg^{-1} + tiopental 5 mg kg^{-1}, veya remifentanil 1 μg kg^{-1} + tiopental 5 mg kg^{-1}, veya idokain 1 mg kg^{-1} + propofol 2 mg kg^{-1} veya remifentanil 1 μg kg^{-1} + propofol 2 mg kg^{-1} uygulandı. İndüksiyon öncesinde, entübasyon sırasında, entübasyonu takiben 1., 3., 5. ve 10. dakikalarda hastaların hemodinamik parametreleri kaydedildi. Arter kan basıncında ve kalp atım sayısında %20'den fazla artış veya düşüş anlamlı olarak kabul edildi.

Bulgular: Remifentanil + propofol uygulanan hastalar, remifentanil + tiopental uygulanan hastalarla karşılaştırıldığında sistolik ve ortalama kan basıncında %20'den fazla düşüş olduğu gözlendi: entübasyondan 1 dakika sonra sistolik kan basıncı değerleri propofol + remifentanil grubunda 125±27 mmHg iken tiopental + remifentanil grubunda 153±35 mmHg ($p<0,01$); ortalama arter basınç ölçümleri propofol + remifentanil grubunda 87±18 mmHg iken tiopental + remifentanil grubunda 105±25 mmHg ($p<0,05$) olarak saptandı.

Sonuç: İzole sistolik hipertansiyonlu hastalarda hızlı seri anestezi indüksiyonu sırasında propofol'ün tiopentale göre bir üstünlüğü yoktu. Bununla beraber propofol + remifentanil kombinasyonu, kalp hızının stabilize edilmesi açısından daha üstün gözükmekteydi.

Anahtar Kelimeler: Hızlı seri indüksiyon, izole sistolik hipertansiyon, propofol, tiopental, remifentanil

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Introduction

Laryngoscopy and tracheal intubation provoke upper airway reflexes and cause stimulation of the sympathetic nervous system, with an undesirable increase in the blood pressure and heart rate (1). High-blood pressure, tachycardia or arrhythmias at induction may cause myocardial ischemia, which may lead to serious complications in patients with underlying cerebrovascular disease (2).

The induction phase is the most stressful moment of general anaesthesia (3), and the haemodynamic response is explicitly evoked in rapid-sequence induction (RSI) (4), a process whereby pharmacologic agents, specifically an induction agent and a neuromuscular blocking agent are administered in a rapid succession to facilitate endotracheal intubation (5). This increase in the haemodynamic response is more prominent in hypertensive patients, particularly during RSI (6).

Isolated systolic hypertension (ISH) defined as systolic blood pressure (SBP) >140 mmHg and diastolic blood pressure (DBP) ≤90 mmHg predominates after the age of 50 years, owing to the tendency of SBP to rise and DBP to drop (7, 8). Several clinical studies evaluated the impact of RSI on hypertensive patients (SBP >140 mmHg and DBP >90 mmHg), but not on patients with ISH. Since high pulse pressure is known to be responsible for cardiac complications (9), ISH is likely to cause fatal/non-fatal stroke or ischemic heart disease during anaesthesia induction. Therefore, in RSI, stabilization of the pulse pressure as much as possible seems to be vital in patients with ISH.

This prospective, randomized study is designed to evaluate whether propofol is superior to thiopental for attenuation of the exaggerated haemodynamic response to laryngoscopy and endotracheal intubation during RSI.

Methods

This was a randomized double-blind study conducted in Turkey with 120 patients aged between 30 and 79 years with imbalanced randomization. After obtaining approval from the institutional review board and informed consent, 120 American Association of Anesthesiologists (ASA) physical status II–III patients with ISH who were presenting for elective surgery, were randomly allocated into four groups by the sealed envelope technique. Patients were diagnosed as ISH according to the National Heart, Lung, and Blood Institute definitions in the preoperative assessment (10) and were applied hypertension treatment for at least for 6 weeks either with antihypertensive drugs or salt-restricted diet. Systolic or diastolic heart failure, neuromuscular disease, electrocardiographic evidence of heart block and anticipated difficult airway were the exclusion criteria. Patients who were taking antihypertensives received their regular antihypertensive therapy. None of the patients took premedication on the day of surgery.

Routine monitoring consisting of electrocardiography, pulse oximeter and noninvasive blood pressure measurement was set. The investigators (AA, ZA) performing and scoring the intubation were also blinded to the induction agents given, by using a surgical blanket between the patients' arms and themselves. After pre-oxygenation for 3 minutes, Group TL (n=30) received lidocaine 1 mg kg^{-1} in 30 seconds and thiopental 5 mg kg^{-1} subsequently for induction of anaesthesia. Similarly, Group TR (n=30) received remifentanil 1 μg kg^{-1} and thiopental 5 mg kg^{-1}, Group PL (n=30) received lidocaine 1 mg kg^{-1} and propofol 2 mg kg^{-1} and Group PR (n=30) received remifentanil 1 μg kg^{-1} and propofol 2 mg kg^{-1}. Succinylcholine was the neuromuscular blocker in all groups, and tracheal intubation was performed at the end of 60 seconds. Cricoid pressure was not applied. Haemodynamic data consisting of heart rate (HR); peripheral oxygen saturation (SpO_2) (%), systolic arterial pressure (SAP), diastolic arterial pressure (DAP) and mean arterial blood pressure (MAP) (mmHg), were recorded at baseline, before induction, at intubation and at the 1st, 3rd, 5th and 10th minutes after intubation, respectively. Intubation scores were noted for all the patients. Jaw relaxation, the ease of laryngoscopy, resistance to blade, vocal cords positioning, coughing and movement of the limbs were evaluated and graded. The grading was labelled as excellent (2 points), good (1 point) or poor (0 points), and the total intubation score was noted (Table 1). Excellent intubation was described as equal or higher than 12 points in the total intubation score (11).

Table 1. Assessment of intubation conditions

Variables	Excellent (2)	Good (1)	Poor (0)
Laryngoscopy	Easy	Fair	Difficult
Jaw relaxation	Relaxed	Not fully relaxed	Poor relaxation
Resistance to blade	None	Slight	Active
Vocal cords position movement	Abducted None	Intermediate Moving	Closed Closing
Reaction to insertion of tracheal tube and/or cuff inflation			
Movement of the limbs	None	Slight	Vigorous
Coughing	None	Diaphragm movement	Sustained (>10 seconds)

Table 2. Patient characteristics

	Group TL n=30	Group TR n=30	Group PL n=30	Group PR n=30	p
Age	54±12	58±13	54±14	55±11	x
Height (cm)	167±8	166±9	165±8	166±10	x
Weight (kg)	78±12	78±13	74±11	82±10	x
Sex (F/%)	18/60	16/53	20/66	17/56	x
Use of antihypertensive drugs (N/%)	14/46	17/56	18/60	15/50	x
Mallampati score					
I	14	13	13	13	
II	12	12	15	9	
III	3	5	2	6	
IV	1	-	-	2	x
Cormack–Lehanne score					
I	20	18	17	20	
II	8	11	11	6	
III	2	1	2	3	
IV	-	-	-	1	x
Upper-lip bite test					
Class I	22	17	15	17	
Class II	4	10	12	12	
Class III	4	3	3	1	x
Maximum mouth opening (cm)	4.5±0.8	4.6±1.4	4.2±0.6	4.4±0.7	x
Head extension (°)	102.2±8.6	103.2±13.6	101.9±9.1	104.7±10.1	x
Sternomental distance (cm)	14.1±2.5	14±2.1	14.4±2.9	14.5±2.5	x
Thyromental distance (cm)	7.8±1.3	8±1.2	7.9±1	7.9±1.3	x

Data are expressed as mean±SD or number of patients. (x: p>0.05)

Isoflurane 1.5% and N_2O 50% in oxygen inhalation was used for anaesthesia maintenance in the patients. The haemodynamic alterations were managed by modifying the inhaled concentration of the anaesthetic agents and rate of fluid administration. None of the patients required vasoactive drug support. All the preoperative medications were noted.

Statystical analysis

A preliminary estimate of sample size of 30 patients per group was calculated upon an expected 25% difference in MAP based on a previous study (6) with Type I error of 0.05 and Type II error of 0.20. Data were expressed as the mean±SD and number of patients. Patients' characteristics were compared with one-way analysis of variance (ANOVA) with post hoc analysis and χ^2. The total intubation condition score was analysed with the Kruskal–Wallis one-way ANOVA, and data were presented as the mean±SD. All haemodynamic data were analysed with ANOVA for repeated measurements and a paired Student t-test with Bonferroni post hoc test. The number of patients exhibiting hypotension (patients exhibiting more than 20% decrease in baseline SAP, DAP and MAP) at anaesthesia induction, hypertension at endotracheal intubation and at 1, 3, 5 and 10 minutes after the endotracheal intubation (patients exhibiting more than 20% increase in baseline SAP, DAP and MAP) were further analysed between groups by χ^2. The statistical analysis was computed by the Statistical Package for the Social Sciences version 16.0 software (SPSS Inc.; Chicago, IL, USA). A p-value of less than 0.05 was considered to be statistically significant.

Results

A total of 120 patients comprising 49 men and 71 women were studied. None of the patients were excluded from the study. Demographic data are shown in Table 2. There were no significant differences between groups in terms of demographic data and intubation scores.

The arterial blood pressure and HR changes are shown in charts. HR values (Figure 1) at baseline were similar in all

groups. SAP values (Figure 2) in Group PR were higher than Group TL at baseline (p<0.05), but they were similar at induction. DAP (Figure 3) and MAP values (Figure 4) at baseline and at induction were similar in all groups.

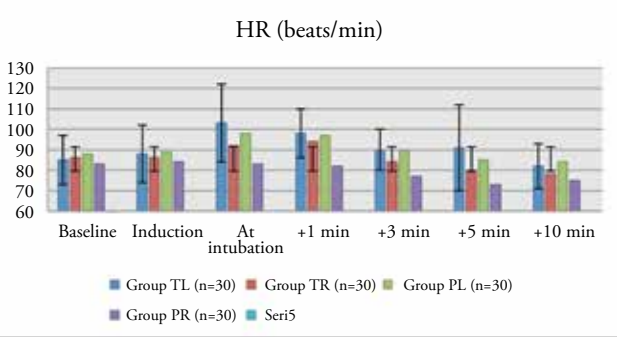

Figure 1. Data are expressed as mean±SD. HR: heart rate

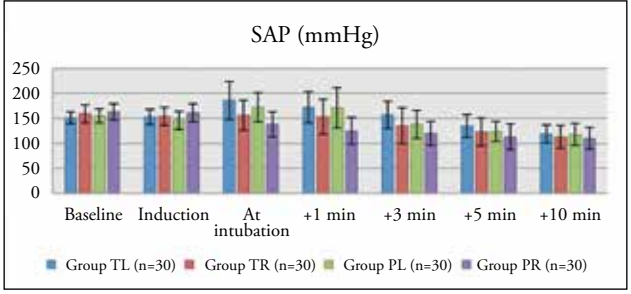

Figure 2. Data are expressed as mean±SD. SAP: systolic arterial pressure

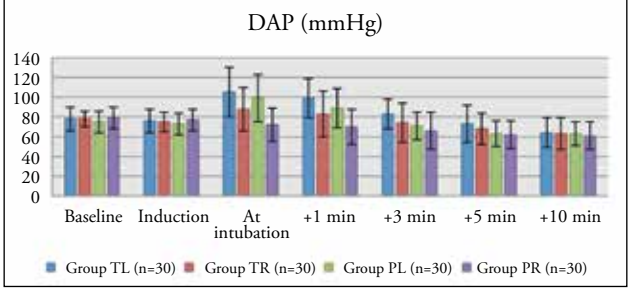

Figure 3. Data are expressed as mean±SD. DAP: diastolic arterial pressure

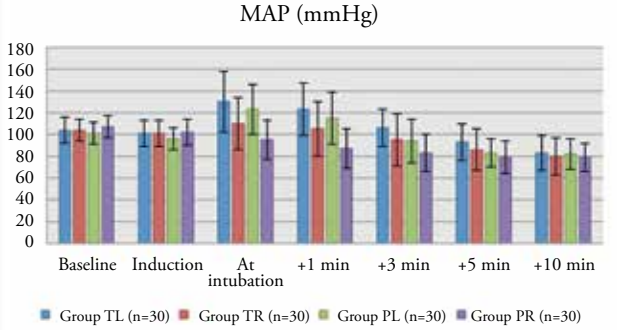

Figure 4. Data are expressed as mean±SD. MAP: mean arterial pressure

Heart rate values were comparable between groups. The mean HR value in Group PR was lower than Group TL (p<0.01) and Group PL (p<0.05) at intubation, 1 minute and 5 minutes after intubation (Figure 1). When the HR values were compared to baseline levels, there was an increase in Group TL (p<0.01), Group PL (p<0.01) and Group TR (p<0.05) 1 minute after intubation. At intubation, there was an increase only in Group TL (p<0.01) and Group PL (p<0.01).

The analysis of data within groups revealed that 1 minute after intubation, the mean SAP value in Group PR was significantly lower, when compared to other groups (p<0.01). The mean SAP values in Group TR (p<0.05) and Group PR (p<0.01) were lower than Group TL, 3 minutes after intubation. When the SAP values were compared to the baseline levels; there was an increase in Group TL (p<0.01) and Group PL (p<0.01), at intubation and 1 minute after intubation.

At intubation, the mean DAP of Group PR was lower than Group TR (p<0.01). Although there was no difference between these two groups in SAP and MAP at intubation, the mean values of SAP (p<0.01) and MAP (p<0.05) were lower in Group PR, 1 minute after intubation.

In all groups, SpO_2 increased after pre-oxygenation compared with baseline values. No severe desaturation was observed during the study period (SpO_2<90%).

Discussion

The aim of this study was to compare the two induction agents, propofol and thiopental, with which lidocaine or remifentanil were combined either as an attenuating agent in RSI, in patients with ISH.

Hypertension is a common clinical condition and a complex disease with multiple components that should be diagnosed and re-evaluated preoperatively (12). In our study, whether the patient was under antihypertensive medication was taken into consideration; however, the drug types of the patients were not enrolled. Nevertheless, it was not evaluated whether the patients took their individual antihypertensive medication or not right before surgery. Thus, the effect of antihypertensive medication on haemodynamic response during RSI in patients with ISH could not be evaluated. Evaluating the same-type or different-type antihypertensive drugs' effects on RSI of anaesthesia in this group of patients needs further investigation.

It is also known that high SBP leads to left ventricular hypertrophy, which increases the preoperative morbidity (13, 14). Thus, stabilization of the pulse pressure in this group of patients during RSI may become more of an issue in patients with lower cardiac reserves, rather than healthy adults. In 2417 CABG patients, Aronson et al. (15) found ISH to be associated with a 40% increase in the likelihood of cardiovascular morbidity perioperatively. In addition, ISH leads to higher pulse pressures than systolic+diastolic hypertension together. The pulse pressure is related with the stiffness of

the big arteries and also the reflection of the velocity of the pressure to the arterial system. When arteries are stiffened by atherosclerosis or accumulation of calcium, increases in returning rates of the peripherally originating 'reflected pressure waves' occur, and this increase leads to rises in peak systolic pressures (8). While SBP is constant, increases in pulse pressure develop a greater risk for coronary ischemia (9, 16).

Thiopental and propofol are the most common hypnotic agents used for RSI. According to a previous study, the induction doses of propofol 2 mg kg^{-1} and thiopental 5 mg kg^{-1} were judged to be equipotent in our study. Pharyngeal and laryngeal reactivity during laryngoscopy have shown to be depressed more with propofol when compared to an equipotent dose of thiopental (17). The addition of lidocaine or remifentanil during induction of anaesthesia must have undoubtedly changed the sole effects of the two hypnotics in our study, without leading to a statistically significant difference between groups in terms of intubation scores.

Although the use of lidocaine is still controversial, administration of this agent 1-1.5 mg kg^{-1} intravenously 3 minutes before intubation is assumed to be beneficial in improving intubating conditions (18). In our study, we used lidocaine 1 mg kg^{-1}. The use of renifentanil 2 or 3 minutes before intubation suppresses the haemodynamic response and provides a haemodynamically stable intubation. Mild bradycardia and a decrease of 15%-20% in the arterial blood pressure may be observed with remifentanil (19). In our study, the mean HR did not exceed the baseline value neither at intubation nor in the following 10 minutes after intubation in Group PR. This difference can be attributed to propofol to interact with remifentanil more than thiopental does. There are clinical studies showing that propofol suppresses the pharyngeal and laryngeal activity better than thiopental during laryngoscopy in equipotent doses (17, 20-22). Mertens et al. (23) investigated the pharmacodynamics of remifentanil and its interaction with propofol. They reported that propofol reduces the amount of remifentanil to suppress the response to laryngoscopy and intubation. Pharyngeal and laryngeal reflexes are better depressed by propofol than by other intravenous induction agents; therefore, propofol might create more favourable conditions for intubation. For this reason, propofol is increasingly being used as the induction agent of choice for RSI in patients with haemodynamic stability. The main problem with propofol is hypotension and bradycardia. Although the mechanism is unclear, propofol increases the endothelial production and release of nitric oxide (NO) and causes hypotension (24). It is also known that this hypotensive effect of propofol is more prominent in ASA high-class patients (25, 26).

Many drugs (α-2 agonists, β-blockers, opioids, nicardipine, lidocaine, calcium antagonists, nitro-glycerine and magnesium-sulphate) (27) have been used to attenuate the haemodynamic response to endotracheal intubation. In the similar study of Alanoglu et al. (6), remifentanil and succinylcholine combination satisfactorily attenuated the haemodynamic response, with thiopental as the induction agent. In a randomized clinical study including 75 ASA I-II normotensive patients, Kim et al. (28) compared the haemodynamic effects of remifentanil, lidocaine, nicardipine and nitroglycerine during intubation. They found that remifentanil was better than all other three agents for attenuating the haemodynamic response to laryngoscopy and intubation. Dogru et al. (29) found 2.5 μ g kg^{-1} intramuscular dexmedethomidine 45–60 minutes prior to anaesthesia induction alleviates but does not prevent completely the haemodynamic response to intubation. Kim et al. (4) found that remifentanil, but not lidocaine suppresses the haemodynamic response to laryngoscopy and intubation during RSI, in their clinical trial including 48 ASA I-II normotensive male patients. On the contrary, there are clinical studies showing that addition of lidocaine at induction of anaesthesia improves intubating conditions.

Conclusion

Regardless of the anaesthetic agents or the techniques, the main goal for any RSI should be trying to prevent the sympathetic nervous system over-stimulation with either appropriate depth of aesthesia or smooth laryngoscopy, without leading hypoxemia or hypercapnia (30). Despite the 'everyday use', thiopental has been replaced by propofol in all areas of anaesthesia, propofol was not shown to be superior to thiopental in our study for attenuation of the hypertensive response to laryngoscopy and intubation, whereas propofol+remifentanil combination appears to be more beneficial in terms of heart rate stability in patients with ISH during RSI.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Ankara University School of Medicine (20.04.2009/150-4683).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – Z.A.; Design – Z.A., N.A.A., A.A.Y.; Supervision – Z.A., A.A.Y.; Resources – N.A.A., Ç.V.; Materials – N.A.A.; Data Collection and/or Processing – N.A.A., Ç.V.; Analiz ve/veya Yorum / Analysis and/or Interpretation – Z.A., A.A.Y., N.A.A., Ç.V.; Literature Search – N.A.A., Ç.V.; Writing Manuscript – N.A.A.; Critical Review – Z.A.

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