Efficacy of dexmedetomidine *versus* remifentanil to blunt the hemodynamic response to laryngoscopy and orotracheal intubation: a randomized clinical trial

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Abstract

The study aims to compare the efficacy of dexmedetomidine (DEX) *vs*. remifentanil (REM) to blunt the hemodynamic response to laryngoscopy and orotracheal intubation. Enrolled in a double-blind clinical trial, 124 patients undergoing elective surgery under general anesthesia at Amirkabir Hospital (Arak, Iran), were assigned into four groups equally (31 patients in each group), DEX, REM, DEX-REM, and normal saline (NS), who received intravenous DEX (1 µg/kg), REM (1 µg/kg), their equal mixture (each 0.5 µg/kg, 1 minute before tracheal intubation), and NS, respectively. Then, blood pressure (BP), heart rate (HR), and arterial oxygen saturation (SaO_2) were measured on arrival to the operating room, 1 minute before laryngoscopy and tracheal intubation, immediately after intubation, and afterwards every 5 to 15 minutes, and finally the data were analyzed using SPSS 18.0. The groups were same regarding to age, sex and baseline hemodynamic variables including mean of BP ($P = 0.157$), HR ($P = 0.105$) and SaO_2 ($P = 0.366$). Tukey *post-hoc* test showed that there DEX, REM, and a DEX + REM groups was same regarding to MBP and HR, but these hemodynamic responses were higher in NS group than other groups at all time after laryngoscopy and intubation ($P < 0.05$). Moreover, repeated measure test showed a decreasing trend in MBP and HR in three intervention groups at all time after intubation ($P > 0.05$). A DEX/REM mixture had the lowest BP and three intervention groups had lower HR than the NS group. A mixture of the drugs used seems to lead to not only a prevented increase in HR and BP during laryngoscopy but also a decreased BP and HR. This study was registered in Iranian Registry Clinical Center with the registration No. IRCT2016092722254N1.

Key words: dexmedetomidine; intratracheal, intubation; laryngoscopy, remifentanil; tracheal intubation

doi: 10.4103/2045-9912.241065
How to cite this article: Modir H, Yazdi B, Moshiri E, Mohammadbeigi A, Afshari S. Efficacy of dexmedetomidine *versus* remifentanil to blunt the hemodynamic response to laryngoscopy and orotracheal intubation: a randomized clinical trial. Med Gas Res. 2018;8(3):85-90.
Funding: The study was supported by a grant from Arak University of Medical Sciences, Arak, Iran.

Introduction

Laryngoscopy and tracheal intubation (TI) during anesthesia induction boost catecholamine release by sympathetic stimulation, which may lead to increased blood pressure (BP), heart rate (HR), and arrhythmia, and cause myocardial ischemia and infarction in patients with risk factors, such as high BP and ischemic heart disease.[1,2] Local anesthetics, beta receptor blockers, and opiates are thus used to prevent cardiovascular changes during intubation1 and some studies have shown that fentanyl, sufentanil, alfentanil, and other opioids prevent the changes induced by interventions with anesthesia.[3-6]

Remifentanil (REM) is a highly commonly used analgesic drug to counter the complications of TI, with a low volume of distribution and rapid clearance, whose hemodynamic changes can occur in a short period of time.[7] While Clonidine, an alpha-2 receptor agonist, reduces the sympathetic nervous system response and inhibits harmful cardiovascular changes, dexmedetomidine (DEX) is also an alpha-2 agonist, lately widely used and more effective than clonidine, whose selectivity to the α1 and α2. Alpha 2 receptors is equal to 1600:1, *vs*. 200:1 for clonidine.[8,9] Besides, some studies have shown that DEX reduces hemodynamic changes during anesthesia and surgery,[7,10-14] while some have denied the effect of it on hemodynamic response to TI.[15] However, some studies have compared DEX with other drugs.[7,16-18]

The significance of hemodynamic changes after intubation, increasing BP, HR, and arrhythmia in many patients, reveals the need for further studies aimed at finding an effective drug to control and prevent these changes. Thereby, we decided to compare some common drugs used in the control changes and to determine the ones with better efficacy, in order to take a step towards improving the health of patients under intubation. Thus the study aims to compare the efficacy of controlling the increased BP and HR following orotracheal intubation (OI) using DEX *vs*. REM.

Subjects and Methods

After obtaining written consent, 124 patients were included in study. Inclusion criteria are as follows: patients with American Society of Anesthesiologists (ASA) status I–II,[19] Mallampati class I–II,[6,20] patients aged 15–65 years, who were undergoing elective surgery under general anesthesia and laryngoscopy and OI at Valiasr and Amirkabir hospitals, Arak, Iran were enrolled in a randomized, double-blinded trial, so that the patients and study analyst were not aware of the intervention group. This study follows the Consolidated Standards of Reporting Trials (CONSORT) guidelines. The flowchart is depicted in **Figure 1**.

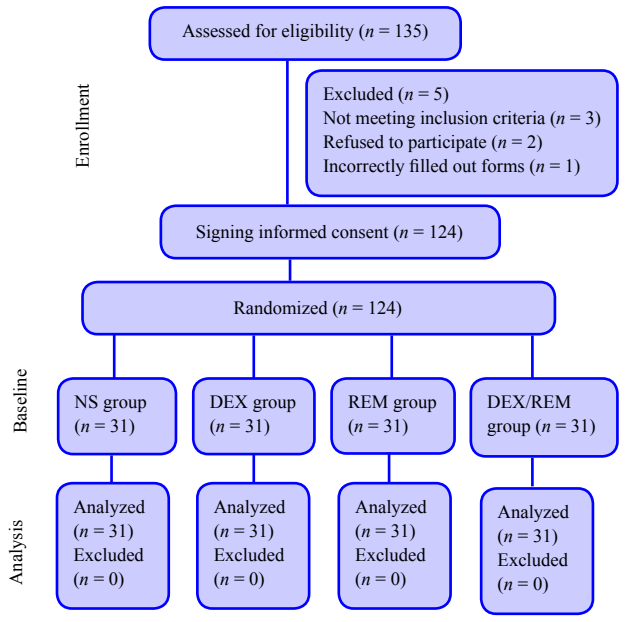

Figure 1: The flowchart of included patients through each stage of a randomized trial.
Note: NS: Normal saline; DEX: dexmedetomidine; REM: remifentanil.

Exclusion criteria are as follows: ASA greater than II, Mallampati class III–IV (patients with severe intubation difficulty), more than two intubation attempts, poor BP control, history of cardiovascular diseases, history of endocrine diseases (such as diabetes, hyperthyroidism or hypothyroidism), pregnancy, and addiction to opioids. Patients were assigned into four groups, including those who received normal saline (NS) (n = 31), DEX (n = 31), REM (n = 31), and DEX-REM combination (n = 31), and all patients were admitted one day before surgery while fasting for 8 hours. They were received electrocardiogram (EKG), pulse oximetry, and non-invasive blood pressure monitoring, on arrival to the operating room.

After initial assessment of vital signs, patients without any knowledge of which group they belong to received: intravenous DEX (1 mg/kg) (precedex, manufactured by Hospira, Inc., Lake Forest, IL, USA) diluted with 50 mL of NS for the DEX group over 10 minutes, 50 mL of NS injected to the those in the NS and REM groups at the same time at 10 minutes before the induction, then all were pre-oxygenated with oxygen 100% and anesthesia induction was performed with propofol (2 mg/kg, over 30 seconds), followed by atracurium (0.4 mg/kg) and intravenous midazolam (0.01 mg/kg). One minute before intubation, REM (GlaxoSmithKline Manufacturing S.P.A, Parma, Italy) 1 mg/kg was injected with 3 mL of NS in the REM group, which the volume (3 mL) was also used to match four groups at the same time in the NS and DEX groups. In the DEX-REM group, REM 0.5 μg/kg was injected with 3 mL of NS, 1 minute before TI and they received intravenous DEX (0.5 μg/kg) diluted with 50 mL of NS over 10 minutes. TI was applied *via* mouth by only one "anesthetist", while anesthesia was maintained with 1% isoflurane and (50/50) mixture of nitrous oxide/oxygen. Besides recording the data on arrival to the operating room, we measured systolic and diastolic blood pressure, mean blood pressure, as well as HR, and arterial oxygen saturation (SaO_2) 1 minute before laryngoscopy and TI, immediately after intubation and then every 5 to 15 minutes, and data were then recorded.

It should be noted that all the patients' records were obtained through the SAADAT monitoring system (SAADAT Co., Tehran, Iran). Moreover, the information recorder was not aware of the classifications of patients and the type of ongoing intervention.

Finally, the data obtained were analyzed by SPSS 18.0 software (SPSS, Chicago, IL, USA) at a 0.05 level. Descriptive statistics were used to explore the patient's characteristics. One-way analysis of variance (ANOVA) was used to compare age and hemodynamic responses among four groups. The Tukey *post hoc* test used for one to one comparision between groups. The trend analysis of BP and HR in each group was performed with repeated measures ANOVA.

Results

Characteristics of the patients intravenously receiving DEX and/or REM and undergoing elective surgery under general anesthesia

This trial enrolled 124 patients assigned into four groups receiving: NS, DEX, REM, and a DEX/REM mixture. The mean age of participated patients was 35.66 ± 10.96 years old and ranged between 18 to 65 years old. From all 124 studied patients, 54% (67 patients) were male and 46% (57 patients) were female.

Baseline measurements of the patients intravenously receiving DEX and/or REM and undergoing elective surgery under general anesthesia

Table 1 shows that the groups was same regarding to age (P = 0.069), sex (P = 0.768) and baseline hemodynamic variables including mean of BP (P = 0.157), HR (P = 0.105) and SaO_2 (P = 0.366). Therefore, the randomization adequacy was approved and no statistically significant difference was found in baseline among four groups (P > 0.05).

Hemodynamic comparison of the patients intravenously receiving DEX and/or REM and undergoing elective surgery under general anesthesia

Based on results in **Table 2**, no significant difference was found in MBP before laryngoscopy and intubation in all groups (P = 0.124). However, a significant difference was observed among four groups in MBP at all time after laryngoscopy and intubation including immediately, 1, 5, 10, and 15 minutes after laryngoscopy and intubation (P < 0.001). The Tukey *post hoc* test showed that there was no significant difference among DEX, REM, and a DEX-REM groups, but the MBP in NS group was statistically higher other intervention groups at all time after laryngoscopy and intubation (P < 0.05). The repeated measure ANOVA showed that there was an increasing trend in MBP of NS group (P = 0.034), while it was decreasing in all three intervention groups (P < 0.05; **Figure 2**).

As shown in **Table 3**, there was a significant difference in the mean of HR at all time of study since before laryngoscopy and intubation to 15 minutes after laryngoscopy and intubation (P < 0.05). The all three intervention groups including DEX,

Table 1: Comparison the sex distribution, mean of age and baseline hemodynamic measurements of the patients intravenous received DEX and/or REM undergoing elective surgery under general anesthesia

Item	DEX-REM	DEX	REM	NS	*P*-value
Age (year)	33.65±7.218	37.23±12.953	32.68±7.296	39.10±13.816	0.069
Mean of blood pressure (mmHg)	93.52±3.511	93.26±4.131	92.26±4.726	91.16±5.367	0.157
Heart rate (*n*/min)	81.71±6.246	84.00±8.914	86.42±7.451	83.58±6.966	0.105
Arterial oxygen saturation (%)	95.39±0.558	95.71±0.902	95.52±1.288	95.81±1.167	0.366
Male gender (*n*(%))	15(48.4)	16(51.6)	17(54.8)	19(61.3)	0.768

Note: Data were expressed as the mean ± SD, except male gender, and analyzed by one-way analysis of variance in age and hemodynamic responses, and repeated measures analysis of variance in blood pressure and heart rate. NS: Normal saline; DEX: dexmedetomidine; REM: remifentanil.

Table 2: Effect of dexmedetomidine *vs.* remifentanil on the mean blood pressure (mmHg) of patients undergoing elective surgery under general anesthesia before and after laryngoscopy and intubation at all time of surgery

Time	DEX-REM	DEX	REM	NS	*P*-value
Before laryngoscopy and intubation	90.42±3.45	91.87±4.12	90.16±4.44	92.39±5.14	0.124
Immediately after laryngoscopy and intubation	88.74±3.91	89.42±3.65	87.29±6.58	98.03±3.09	<0.001
1 min after laryngoscopy and intubation	84.58±5.43	87.48±4.23	86.71±6.33	98.48±4.23	<0.001
5 min after laryngoscopy and intubation	83.26±5.51	86.84±3.95	86.84±6.11	97.45±3.86	<0.001
10 min after laryngoscopy and intubation	83.87±5.07	85.90±3.56	88.29±6.01	95.39±4.04	<0.001
15 min after laryngoscopy and intubation	84.68±4.53	87.45±2.94	89.26±5.88	95.55±3.97	<0.001

Note: Data were expressed as the mean ± SD, and analyzed by one-way analysis of variance followed by Tukey *post hoc* test. NS: Normal saline; DEX: dexmedetomidine; REM: remifentanil; min: minute(s).

Table 3: Effect of dexmedetomidine *vs.* remifentanil on the mean of heart rate (*n*/min) of patients undergoing elective surgery under general anesthesia before and after laryngoscopy and intubation at all time of surgery

Time	DEX-REM	DEX	REM	NS	*P*-value
Before laryngoscopy and intubation	79.42±6.12	81.26±8.47	85.10±7.39	83.10±7.90	0.024
Immediately after laryngoscopy and intubation	77.58±5.07	75.74±9.50	76.84±7.92	98.94±9.18	<0.001
1 min after laryngoscopy and intubation	77.45±4.96	72.81±8.80	73.10±7.86	105.32±10.08	<0.001
5 min after laryngoscopy and intubation	76.77±4.99	71.06±8.43	69.97±8.65	109.29±10.71	<0.001
10 min after laryngoscopy and intubation	78.23±4.44	75.26±7.69	73.26±7.45	100.39±9.45	<0.001
15 min after laryngoscopy and intubation	77.13±4.20	74.16±7.28	72.55±6.09	94.58±7.07	<0.001

Note: Data were expressed as the mean ± SD, and analyzed by one-way analysis of variance followed by Tukey *post hoc* test. NS: Normal saline; DEX: dexmedetomidine; REM: remifentanil; min: minute(s).

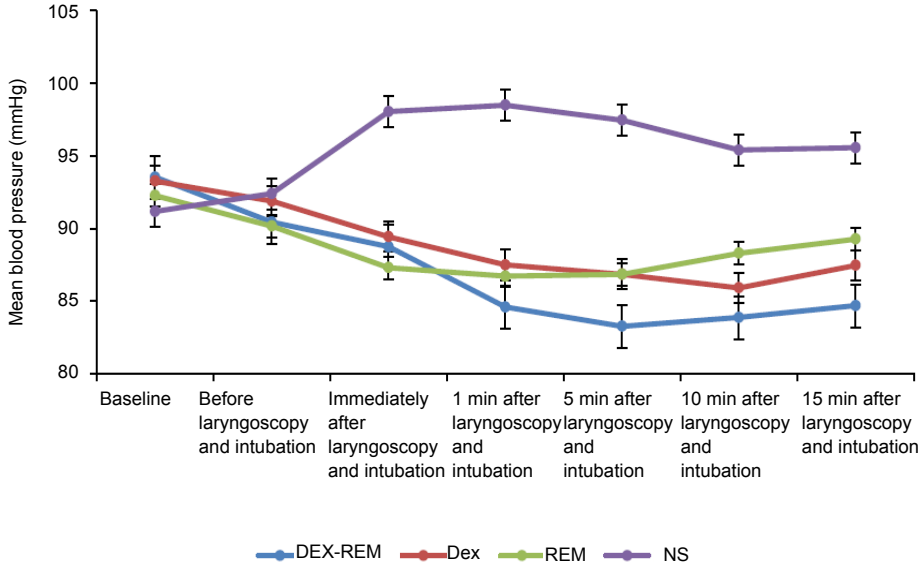

Figure 2: The trend of mean blood pressure at the time of arrival, immediately before and after laryngoscopy, 1, 5, 10 and 15 min after laryngoscopy and intubation of patients undergoing elective surgery under general anesthesia.
Note: Data are expressed as mean and analyzed by one-way analysis of variance followed by Tukey *post hoc* test. NS: Normal saline; DEX: dexmedetomidine; REM: remifentanil; min: minute(s).

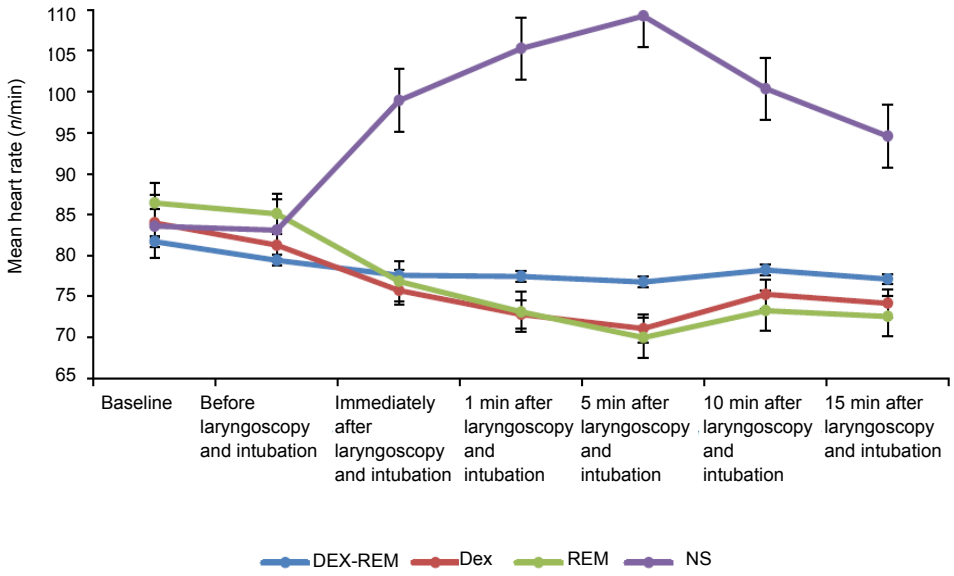

Figure 3: The trend of mean heart rate at the time of arrival, immediately before and after laryngoscopy, 1, 5, 10 and 15 min after laryngoscopy and intubation of patients undergoing elective surgery under general anesthesia.
Note: Data are expressed as mean and analyzed by one-way analysis of variance followed by Tukey *post hoc* test. NS: Normal saline; DEX: dexmedetomidine; REM: remifentanil; min: minute(s).

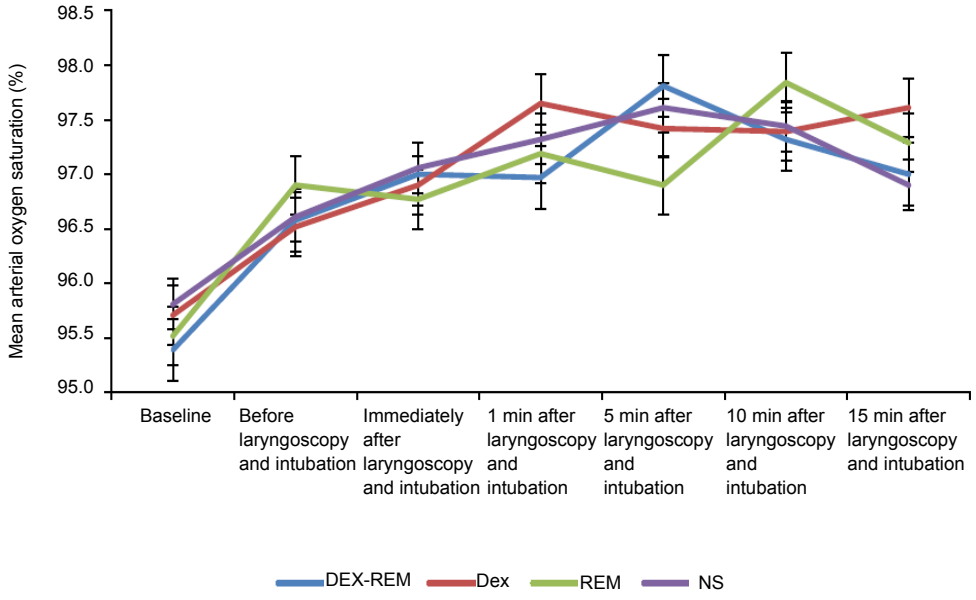

Figure 4: The trend of mean arterial oxygen saturation at the time of arrival, immediately before and after laryngoscopy, 1, 5, 10 and 15 min after laryngoscopy and intubation of patients undergoing elective surgery under general anesthesia.
Note: Data are expressed as mean and analyzed by one-way analysis of variance followed by Tukey *post hoc* test. NS: Normal saline; DEX: dexmedetomidine; REM: remifentanil; min: minute(s).

Table 4: Effect of dexmedetomidine *vs.* remifentanil on mean arterial oxygen saturation (%) of patients undergoing elective surgery under general anesthesia

	DEX-REM	DEX	REM	NS	*P*-value
Before laryngoscopy and intubation	96.58±0.886	96.52±0.72	96.90±0.54	96.61±0.80	0.188
Immediately after laryngoscopy and intubation	97.00±0.68	96.90±0.83	96.77±0.92	97.06±0.77	0.518
1 min after laryngoscopy and intubation	96.97±1.17	97.65±0.79	97.19±0.95	97.32±0.75	0.134
10 min after laryngoscopy and intubation	97.81±0.83	97.42±2.26	96.90±3.65	97.61±0.76	0.419
15 min after laryngoscopy and intubation	97.32±0.79	97.39±1.05	97.84±0.69	97.44±1.40	0.326
25 min after laryngoscopy and intubation	97.00±2.37	97.61±0.84	97.29±1.24	96.90±3.61	0.612

Note: Data were expressed as the mean ± SD, and analyzed by one-way analysis of variance followed by Tukey *post hoc* test. NS: Normal saline; DEX: dexmedetomidine; REM: remifentanil; min: minute(s).

REM, and a DEX/REM mixture caused a decrease in HR. The lowest HR was observed in the DEX group immediately, 1 and 5 minutes and those in the REM group at 10 and 15 minutes after laryngoscopy and intubation. However, no significant difference was found among three intervention groups ($P > 0.05$). The repeated measure of analysis of variance showed that there was an increasing trend in mean of HR in NS group ($P = 0.034$), while all three intervention groups caused decreas-

ing trend in HR ($P < 0.05$; **Figure 3**).

Given the results, no significant differences were seen in SaO_2 among different groups in measured minutes ($P > 0.05$; **Table 4**). In addition, the overall trend of SaO_2 in all study groups was increasing and significant ($P < 0.05$; **Figure 4**).

Discussion

The present study aims to compare the efficacy of DEX and REM on the hemodynamic response to laryngoscopy and OI. Among four groups of NS, DEX and REM and DEX/REM mixture in the study, no significant difference was found in mean blood pressure, mean heart rate and SaO_2 on arrival to the operating room, before and after laryngoscopy and intubation ($P > 0.05$). Immediately, 1, 5, 10, and 15 minutes after laryngoscopy and intubation ($P = 0.001$), this difference was found statistically in the groups. BP: The highest in the NS group *vs*. the lowest in the DEX-REM group; significant differences were also found in HR among the groups ($P = 0.001$): the highest in the NS group, while the lowest BP was observed in DEX group immediately, 1 and 5 minutes after laryngoscopy and intubation, *vs*. that in REM group at 10 and 15 minutes. Given the results, no significant difference was found in SaO_2 among all groups at the measured times ($P > 0.05$). Our results showed the lowest BP in the DEX-REM group and the lowest HR in the DEX group, respectively, immediately, 1, and 5 minutes after laryngoscopy and intubation, and same HR in the REM group at 10 and 15 minutes. In all intervention groups, the drugs, though, reduced HR, as compared with the NS group, no significant difference was found among them.

Aimed at comparing the effects of fentanyl and REM on hemodynamic response to endotracheal intubation and myoclonus in elderly patients (> 65 years, 65 cases) with etomidate induction, a study was finally concluded that the REM group (*vs*. the control and fentanyl groups) showed a significant increase in all hemodynamic variables, after intubation,[21] possibly due to the anesthetics studied, while, the elderly were targeted in their study. However, our REM group patients had lower HR and BP, as compared with the NS group. Lee et al.[7] aimed to compare the efficacy of DEX and REM to blunt hemodynamic response to laryngoscopy and TI, orotracheal intubation conducted a study on hemodynamic responses after orotracheal intubation in three groups of 30 patients, including normal saline-treated as control group, DEX, and REM groups. Another study by Moshiri et al.[17] showed that the reduction of heart rate in dexmedetomidine group was lower than Propofol. Moreover, hemodynamic responses were same in electroconvulsive therapy in another study.[16]

Finally, the systolic and diastolic BPs was clearly less in patients in two recent groups than those in the NS group, while HR was higher in the DEX and REM groups than that in the NS group.[7] In the present study, BP was lower in the intervention groups than in the NS group, while the least in the DEX-REM group. Three intervention groups showed lower HR than the NS group, which is not consistent with the by Lee et al's study.[7] A study by Mireskandari et al.[22] aimed to compare the effects of fentanyl, sufentanil, alfentanil, and REM on cardiovascular reactions to TI in children (1–6 years, 80 cases) undergoing elective surgery under general anesthesia, showed no significant difference inmean arterial pressure, systolic and diastolic BPs, and HR among the groups,[22] whose results are not consistent with ours, which the intervention groups had lower BP than the NS group, while the least in the DEX-REM group and had lower HR than the NS group. The different results can be attributed to different target groups: children in their trial *vs*. adults in ours.

Moreover, Yarkan et al.[11] aimed to evaluate the effects of DEX on hemodynamic response to TI in hypertensive patients (19–70 years, 60 cases in three groups) by comparing esmolol *vs*. sufentanil, eventually concluded that the administration of DEX before anesthesia induction can blunt the response in hypertensive patients. Unlike the NS group, DEX in our study reduced HR and BP. The Menda et al.'s double-blind trial[12] on 30 patients in two groups receiving placebo and DEX showed that DEX can be useful to attenuate the response in CABG patients receiving beta-blockade, whose results were consistent with ours in which DEX was associated with a decrease in BP and HR, as compared with the NS group. Another study[13] assessed the DEX effect on hemodynamic response during tracheal intubationon 50 patients undergoing elective surgery and showed that the need for thiopental and sevoflurane was decreased by 39% and 92%, respectively, during intubation and surgery in DEX group compared to placebo.[13] The results of this study about the efficacy of hemodynamic parameters were consistent with ours.

Our results showed the lowest BP in the group receiving DEX/REM mixture, and the lowest HR was observed in the DEX group immediately, 1 and 5 minutes, and in the REM group at 10 and 15 minutes after laryngoscopy and intubation, while the administered drugs lowered HR in the three groups than in the NS group. Given our results, the administration of DEX and fentanyl and their mixture based on our dose regimen may well not only prevent HBP resulting from stimulation during laryngoscopy and TI but can also relatively reduce it. It was found that this goal could be better achieved using a mixture of REM and DEX, thereby, the mixture is recommended to prevent HBP, if been considered. Given our results, the intervention drugs, whether used individually or in combination, are recommended to control HR during laryngoscopy and TI, and the choice of appropriate drugs depends on the patient's condition and the anesthesiologist's preference.

Acknowledgment

We would like to thank all the people who participated in this study, the Research and Technology of Arak University of Medical Sciences, and the Clinical Research Development Center of Valiasr Hospital, Arak.

Author contributions

HM performed the conception or designed the interpretation of data for the work; and revised the final approval of the article. BY performd the conception or designed the work and revised the final approval of the article. EM performed the acquisition and analyzed the data for the work and drafted the article. AM performed the conception or designed the work analysis, or interpretered the data for the work; and revised the final approval of the article. SA collected the data, analyzed the data for the work and drafted the article. All authors approved the final version of the manuscript for publication.

Conflicts of interest

There is no conflict of interest.

Financial support

The study was supported by a grant from Arak University of Medical

Sciences, Arak, Iran.

Institutional review board statement

The work is part of a thesis in General Medicine, with the Code of Ethics: IR.ARAKMU.REC.1394.274 and the clinical trial code number: IRCT2016092722254N1 in Iranian Registry Clinical Center.

Declaration of patient consent

The authors certify that they have obtained patient consent forms. In the form, patients have given their consent for their images andother clinical information to be reported in the journal. The patients understand that their names and initials not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Reporting statement

This study follows the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Biostatistics statement

The statistical methods of this study were reviewed by the biostatistician of the Arak University of Medical Sciences, Arak, Iran.

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Data sharing statement

Datasets analyzed during the current study are available from the corresponding author on reasonable request.

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Peer review

Externally peer reviewed.

Open access statement

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Received: 2018-05-30
Accepted: 2018-08-03

C-Editor: Yang LJ, Zhao M; S-Editor: Yu J; L-Editor: Wang L; T-Editor: Jia Y