Effects of Dexmedetomidine on cerebral oxygen saturation in patients undergoing laparoscopic hysterectomy: a randomised ,parallel-group study

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Abstract

Abstract Background:This study is to investigate the relationship between the Trendelenburg position and regional cerebral oxygen saturation (rSO2) during laparoscopic hysterectomy and possible effects of Dexmedetomidine on cerebral hypoxia of patients undergoing this surgery. Methods: Randomized, prospective and single-blinded study. Patients aged 20 to 65 years are enrolled in this trial,25 in each group. Saline and Dexmedetomidine were infused into petients of Control group and Dexmedetomidine group respectively. Regional cerebral oxygen saturation (rSO2) and hemodynamic parameters were recorded before and after induction of anesthesia and once every 20 min in the Trendelenburg position and 10 min after supine position. We determined prospectively the association of the development of cerebral desaturation and the patient's position with clinical outcomes of the entire surgery. Results: There was no significant difference between these groups according to demographic characteristics. Right and left rSO2 values of patients in control group decreased at 20 min,40 min and 60 min in the Trendelenburg position, but they increased 10 min after changed to supine position.For Dexmedetomidine group,rSO2 were improved during the Trendelenburg position constantly. The relationship between rSO2 values and cognitive dysfunction was not significant. Conclusion:Dexmedetomidine provides higher rcSO2 values during the Trendelenburg position for laparoscopic hysterectomy. Trial registration: Chinese Clinical Trial Registry. No: ChiCTR1800019174. Prospective registration. Key words: NIRS,rSO2,Trendelenburg position, Dexmedetomidine

Background

Patients with gynecological diseases may undergo different types of surgery.In recent years, laparoscopic surgery is increasingly used for the treatment of gynecological diseases,particularly laparoscopic hysterectomy,but such laparoscopicabdominal surgery is at particular risk for perioperative cerebral hypoxia and ischemia consequently[1][2].In most cases, patients are put on Trendelenburg position and CO_2 pneumoperitoneum during laparoscopic surgery,which leads to the changes in CBF (Cerebral blood flow) and ICP(Intracranial Pressure)[3]. CBF is normally kept constant over a range of arterial blood pressures by autoregulatory mechanisms that ensure a steady supply of oxygenated blood to the brain[4].Cerebral autoregulation can be monitored in real-time by processing regional cerebral oxygen saturation (rSO_2) and therefore measurement of this signal—— NIRS (near-infrared spectroscopy) has attracted attention in many clinical fields especially anesthesiology[5-7] .This device uses red and infrared light emitted via optodes that are uni- or bilaterally, providing a continuous, venous weighted signal.

The rSO_2 signal is measured transcutaneously and non-invasively and has the ablity to estimate the balance between oxygen delivery and oxygen demand.As is known in the previous studies,decreasing of rSO_2 is a risk in laparoscopic hysterectomy,which affects the development of cerebral hypoxia. Dexmedetomidine[8][9], the potent α_2-adrenoceptor agonist,has sedative,analgesic, sympatholytic and anxiolytic properties,It has caught the attention of researchers and clinicians due to its cardioprotective,renoprotective, and neuroprotective properties during perioperative period.

This study was conducted to investigate the possible effects of Dexmedetomidine on regional cerebral oxygen saturation(rSO_2) in patients undergoing gynecological laparoscopic surgery.

Methods

This study protocol was approved by the Ethics Committee of the First People's Hospital of Lianyungang,China. Our study adheres to CONSORT guidelines and the CONSORT diagram is shown in Figure 1. Each patient had signed informed consent before participation in this study. The inclusion criteria were adult patients, aged 20 to 60 years, conforming to American Society of Anesthesiologists physical status classifications I and II, and scheduled for elective laparoscopic hysterectomy under general anesthesia at the First People's Hospitalof Lianyungang were recruited. Patients were excluded if they metany of the following criteria:pulmonary hypertension, portal hypertension, severe peripheral vascular disease, heart disease, respiratory diseases, mental illness, or emotional or mental retardation.

The study was double-blind, parallel-arm placebo-controlled and performed randomly in the Anesthesia Department of First People Hospital of Lianyungang in Jiangsu,China.According to Intervention mode which was applied, patients were allocated into two groups,normal saline group(Con Group) and Dexmedetomidine group(Dex Group).Randomization was done by pulling out the envelope in which it was written the group division.Patients underwent at least 12-hour preoperative fasting once they were enrolled in the study. All patients were monitored with noninvasive blood pressure measurement, electrocardiography, and pulseoximetry after entering the operating room. For invasive arterial blood pressure measurement, a 20-gauge catheter was introduced via radial artery puncturewith 2% lidocaine. Invasive hemodynamic monitoring was performed out before anesthesia induction. For continuous monitoring of the regional cerebral oxygen saturation (rSO_2), two NIRS sensors was attached to patient's forehead which was cleansed with alcohol and a monitor was connected to sensors ,therefore,the values of rSO_2 could be shown on the monitor .

The patients of Dex Group are infused with Dexmedetomidine hydrochloride 0.5μg/kg one time before the anesthesia induction,and the infusion time is 10 minutes,then change to maintain the infusion as 0.5μg/kg.h.The patients of Control group are infused with equal amount of physiology saline.Anesthesia was induced with a regimen of 2- to 3-μg/kg fentanyl followed by 1.5～2.5mg/kg propofol. Tracheal intubation was facilitated with 0.15-mg/kg cisatracurium. Moreover, anesthesia was maintained with intravenous propofol(4~12 mg/kg.h) and remifentanil(0.1~0.2ug/kg.min).

Before the anesthesia induction,we collected the following patient data: mean arterial pressure (MAP), basal values of rSO_2, peripheral blood oxygen saturation(SpO_2),heart rate (HR),systolic blood pressure(SBP)and diastolic blood pressure(DBP).Basal value of rSO_2 in awake patient just before Dexmedetomidine hydrochloride orphysiology saline was infused and anesthesia was taken as initial point for assessment of rSO_2 changes in different time points of the procedure.Values on the NIRS monitor were recorded as T0 after entering into operating room immediately, T1 2 minutes after anesthesia induction ,T2 20 minutes after anesthesia induction,T3 40 minutes after anesthesia induction,then as left and right (LSO_2-RSO_2) once every 20 minutes until the patient was returned to a supine position,T7 at the end of surgery—10 mins after patients were set up in neutral supine position and CO_2 was blown out.During the whole perioperative period rSO_2,MAP, HR, SpO_2 and $ETCO_2$ were noted.

Statistical analyses were performed with SPSS version 20 software (IBM Corporation, Armonk, NY). Continuous datas were expressed as means and standard deviations and were analyzed with the independent sample t-test and one-way ANOVA. A comparison of the two groups was performed with repetitive measurement deviation analysis. P <0.05 was considered statistically significant.

Results

A total of 62 patients were enrolled in our clinical study, twelve patients were excluded due to not meeting the inclusion criteria or other reasons(Figure 1)Basic demographic characteristics of patients are presented in Table1.The two groups were similar with respect to age, weight, height, ASA physical status ,phypreoperative hemoglobin and hematocrit values (Table 1).

The patients' hemodynamic parameters are shown in Table 2 and 3. The ANOVA statistics indicated that intraoperative MAP values increased in both the Control and Dex groups after induction of anesthesia.What' more,significant difference was shown in these two groups at times T1 and T2. According to Table 3, intraoperative HR values decreased gradually over time after anesthesia induction,but the difference between the two groups was not significant. No difference was noted between groups in BIS data throughout the entire intraoperative period (Figure 2).

rSO_2 data are presented in Figure 3A and B .Our investigation indicated that intraoperative rSO2 values at times T2, T3, T4, T5 and T6 were significantly lower when compared with baseline values in control group, whereas return of rSO_2 values was observed in the time point of supine. An increase of rSO_2 value was found at timeT1 during the anesthesia induction ,however there was no significant change between sides in both groups,the left side (P=0.371),the right side (P=0.875).The occurrence of cerebral oxygen desaturation were detected more frequently in patients assigned to receive placebo during the study period,especially in time points of T3,T4,T5 and T6 (P=0.000,0.000,0.000 and 0.001).During the same period in Dexmedetomidine group, regional cerebral saturation was kept above a safety threshold (<20% decline in rSO_2 from baseline). The t-test statistics illustrate that cerebral desaturation is more likely in the control group.

Discussion

Cerebral oxygen metabolism of patients undergoing laparoscopichy sterectomy may be affected by the changes in the CBF and ICP which is proven to be associated with certain perioperative complications[10][11]. The change of cerebral saturation could be monitored continuously by measuring near-infrared spectroscopy (NIRS) transcutaneously which can process regional cerebral oxygen (rSO_2) signals[13].However , NIRS ,which is probably prone to reflect the cerebral saturation, has not been applied previously as a routine method to observe changes in rSO_2 in this patient population. The incidence of cerebral desaturation in patients undergoing laparoscopic hysterectomy can be determined prospectively by NIRS technology[14]. Studies suggested that rSO_2 values decreased after Trendelenburg position and there were significant increases of rSO_2 values at 20, 40, 60 and 80 min after Trendelenburg position was put on during the intraoperative period. Previous studies[15-17] have suggested that the decline of rSO_2 could result from the prevention of venous return which leads to decreased cerebral perfusion pressure (CPP) when the patient's head was not straightened. The main reason may be that the elevation of diaphragm after carbon dioxide pneumoperitoneum causes the increase of thoracic pressure, and then oppresses the vena cava and vertebral vein, which makes the resistance of venous return higher. Rosenthal et al.reported [18] that the pneumoperitoneum pressure of pigs was 16 mmHg and ICP was 150% higher than control group in Trendelenburg position. On the other hand, elevated concentration of blood carbon dioxide, cerebral vasodilation and increased CBF could be casued by CO_2 pneumoperitoneum. There is a linear correlation between CBF and arterial carbon dioxide ($PaCO_2$) in a certain range (20-80 mmHg). Carbon dioxide could be considered as one of the factors that can cause increased ICP in pneumoperitoneum, however, its effect is far less than that of unphysiological factors. Increased $ETCO_2$ was found in this study, but majority of the values still remains within a certain range of variation (35-45mmHg). Rosenthal et al. [19] studied the changes of ICP in porcine pneumoperitoneum under different ventilation volume and the results showed that low ventilation increased $PaCO_2$, ICP and MAP significantly, while high one did not play the same role significantly and he suggested that in order to maintain cerebral perfusion pressure (CPP), the compensatory increase of MAP was observed ,which was shown in both Control and Dexmedetomidine groups of our study.Therefore, the main reason for the increase of ICP in this trial is the cerebral venous obstruction due to head-down position and increased intra-abdominal pressure (IAP) caused by pneumoperitoneum instead of the elevation of blood carbon dioxide. The rise of resistance of intracranial venous return occured immediately when the pneumoperitoneum and Trendelenburg position were put on, and no obvious change was observed with the prolongation of the time of

pneumoperitoneum[20-22]. These above described changes may result in reduction of cerebral perfusion pressure and disturb cerebral oxygenation.

Our results revealed that the significantly higher rSO_2 values were obtained by continuous infusion of Dexmedetomidine in perioperative period. It is interesting to note that in this group, rSO_2 values at almost all time points, were kept above a safety threshold (<20% decline from basal value). The highly selective α_2-adrenoceptor agonist, Dexmedetomidine, has anxiolytic, sedative, and modest analgesia operties, and are increasingly used for patients undergoing surgery [23-25]. The neuroprotective effect of

Dexmedetomidine was first studied by Hoffman et al [26]. It was reported that in the rat model of incomplete cerebral ischemia, Dexmedetomidine pretreatment could significantly reduce serum concentration of catecholamine and improve the neurological and pathological results in a dose-dependent manner. Altimidazole, an α2 receptor blocker, can eliminate this effect, suggesting that the cerebral protective effect of Dexmedetomidine is generated by α_2 receptor. During cerebral ischemia reperfusion, Dexmedetomidine can reduce the content of malondialdehyde (MDA) in brain tissue, reduce the level of nitric oxide (NO) and tumor necrosis factor (TNF-α), increase the activity of superoxide dismutase (SOD) and catalase (CAT), thus reduce nerve injury . Dexmedetomidine could also treat brain injury caused by subarachnoid hemorrhage by inhibiting the release of catecholamine in brain tissue and alleviating vasospasm. Our results are consistent with the above described studies and indicated that less frequent occurrence of cerebral desaturation is observed in Dexmedetomidine group. Dexmedetomidine could be used as a measurement to treat disturbed cerebral oxygenation for patients undergoing laparoscopichy sterectomy.

An increase of rSO_2 is observed at time T2 when the anesthesia induction was done. Both propofol and volatile anesthetics [27][28]may be protective against injury due to cerebral ischemia.

There are some limitations to present this study. First, NIRS devices measure saturation in a regional cortex which is a mix of venous, arterial and capillary compartments. Therefore, the values may not only show changes in oxygen supply but also decreases in brain blood volumes/compartments. Secondly, NIRS measures saturation continuously ,which means the values we recorded can not reflect the effect of cerebral desaturation exactly. Furthermore, the exact safety threshold we choose for the definition of cerebral desaturation is not generally accepted.

In our study, interventions should be used once a 25% decline of rSO_2 value compared with baseline is observed during the surgery. Cerebral perfusion due to the gravitational effects can be tolerated if mean blood pressure (MAP) remains within the autoregulation range.

Conclusions

In conclusion, our study suggested that the changes of cerebral saturation can be detected by NIRS technology, which means that the information of the supply and demand for cerebral oxygenation can be provided in the intraoperative period and may play a role in preventing disorders related to postoperative cerebral function. Our trial suggested that venous infusion of Dexmedetomidine during the entire surgical procedure could provide higher rSO_2 values significantly and be used as a treatment for the disturbed brain oxygen saturation. We believe that, by the selection of the non-invasive NIRS technique for monitoring brain oxygen saturation and by choosing most appropriate inventions for the population of specific patient, the incidence of negative cerebral complications can be successfully reduced.

Abbreviations

ASA: American Society of Anesthesiologists;

BIS: Bispectral index;

BMI: Body mass index;

NIRS:Near-infrared spectroscopy

rSO_2：Regional cerebral oxygen saturation

SpO_2：Pulse Oxygen Saturation

MAP：Mean arterial pressure

Declarations

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Availability of data and materials

The datasets generated and analyzed during the current study are not publicly available due institutional restrictions but are available from the corresponding author on reasonable request.

Authors’ contributions

YQQ initiated the study, performed statistically processing, contributed to the writing of the manuscript, QHT and ZZB developed the study design, contributed to data collection and proofread the manuscript, Bing Wang and ZXB advised the study design, is responsible for the anesthesia SOPs and proof read the manuscript, DFY operated most of the patients is responsible for the postoperative care of the patients and contributed to data collection, ZMX contributed to data collection and writing of the manuscript, CZ contributed to data collection and wrote the manuscript. All authors contributed substantially to this work and all of them revised and agreed to the final version of the manuscript with full access to all data.

Ethics approval and consent to participate

The analysis and publication of the data were approved by Ethics Committee of the First People's Hospital of Lianyungang, China. Approval date: July 15, 2018. The informed consent of this study was signed by each parent and we obtained the written consent from all the participants (approval number KY-20180713-5) .

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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Tables

Table 1

Characteristic	NS Group	DEX Group	P
Sex			
Age(y)	43±11(22-65)	40±12(20-65)	0.305
Height(cm)	161±5(150-173)	162±4(154-170)	0.506
Weight(kg)	60.64±7.79(48-77)	64.40±11.85(42-85)	0.200
[a]BMI（kg/m^2）	23.68±3.23(19.05-28.98)	24.48±4.39(15.62-34.05)	0.510
[b]ASA group			
I	8(32%)	10(40%)	
II	17(68%)	15(60%)	
Hemoglobin(g/L)	121±11(96-147)	118±17(85-145)	0.358
Hematocrit	37±4(24-46)	37±5(28-45)	0.932

Data are mean, standard deviation, range, number and percent.

*P <0 .05 statistically significant.

a BMI= body mass index,

b ASA PS = American Society of Anesthesiologists physical status,

Table 2

[a]HR	NS Group	DEX Group	P
[b]T0	72±14(45-114)	77±15(55-112)	0.213
[c]T1	64±13(49-114)	67±15(48-120)	0.575
[d]T2	60±9(46-91)	66±13(47-113)	0.129
[e]T3	59±10(46-86)	59±10(47-80)	0.956
[f]T4	59±10(45-95)	59±9(44-85)	1.000
[g]T5	59±7(48-80)	57±8(42-76)	0.451
[h]T6	59±8(49-73)	58±10(44-75)	0.938
[i]T7	68±10(54-96)	62±9(50-78)	0.037*

Data are mean and standard deviation.

a HR = heart rate,

b T0 = baseline measurement,

c T1 = induction measurement,

d T2 = measurement 20 min after induction,

e T3 = measurement 40 min after induction,

f T4 = measurement 60 min after induction,

g T5 = measurement 80 min after induction, h T6 = measurement 100 min after induction,

g T7 = measurement 10 min after supine.

 P <0.05 statistically significant.

Table 3

[a]MAP	NS Group	DEX Group	*P
[b]T0	84±11	86±11	0.083
[c]T1	81±8	86±10	0.036*
[d]T2	100±13	90±12	0.005*
[e]T3	99±8	95±10	0.154
[f]T4	92±10	97±9	0.064
[g]T5	96±10	95±6	0.720
[h]T6	96±7	97±9	0.981
[i]T7	94±7	90±6	0.122

Data are mean and standard deviation.

a MAP =mean arterial pressure,

b T0 = baseline measurement,

c T1 = induction measurement,

d T2 = measurement 20 min after induction,

e T3 = measurement 40 min after induction,

f T4 = measurement 60 min after induction,

g T5 = measurement 80 min after induction,

h T6 = measurement 100 min after induction,

g T7 = measurement 10 min after supine.

 P <0.05 statistically significant.

Figures

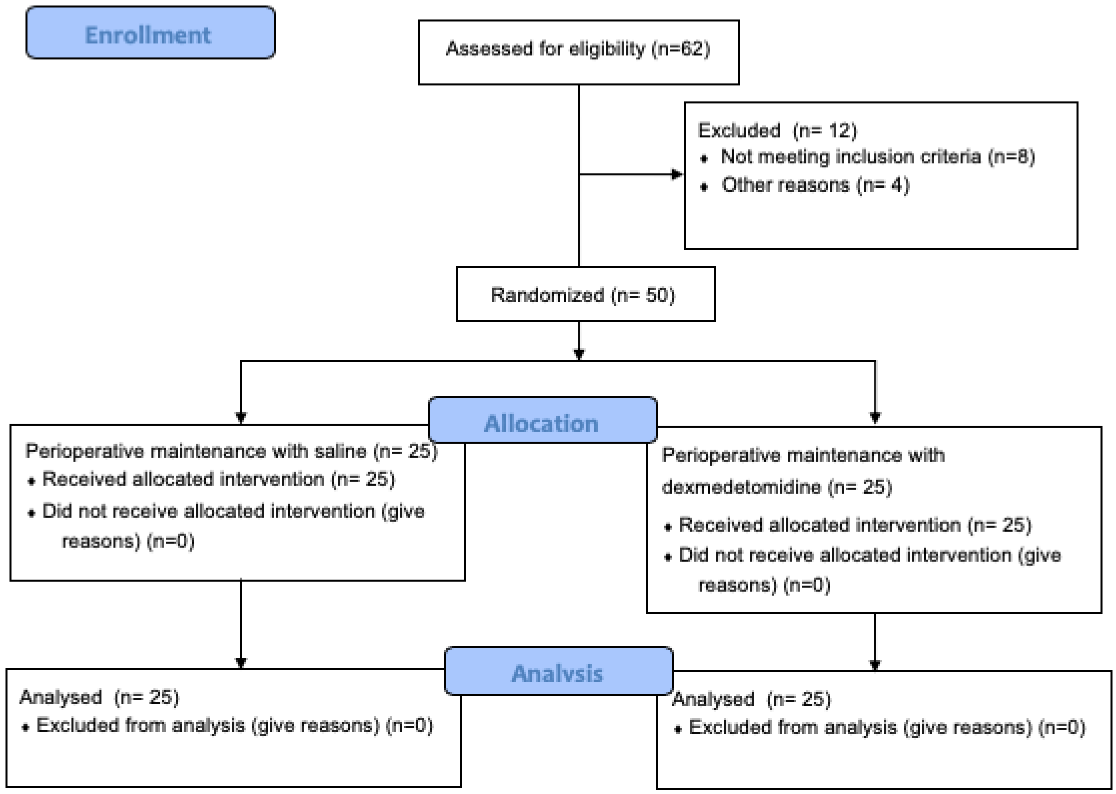


Figure 1

CONSORT diagram

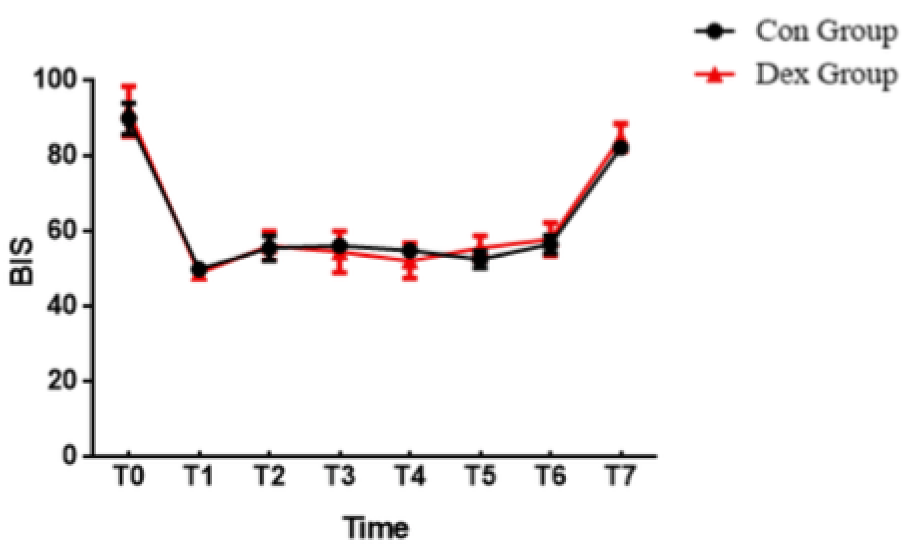
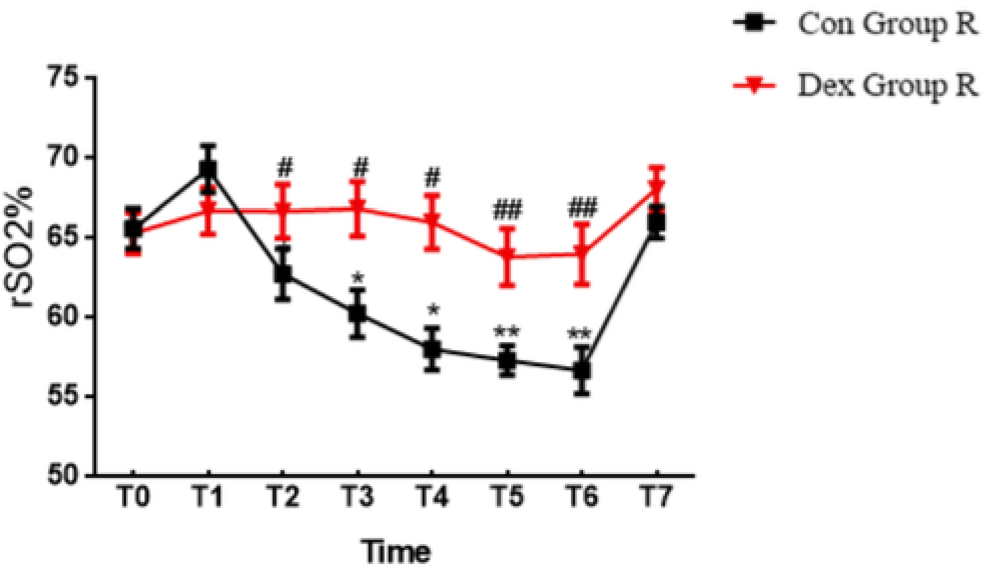


Figure 2

Trend of bispectral index (BIS) changes during laparoscopic hysterectomy in Control and Dexmedetomidine group. T0- measurement before induction, T1- measurement 2 minutes after induction T2- measurement 20 minutes after induction, T3-measurement 40 minutes after induction T4-

measurement 60 minutes after induction, T5- measurement 80 minutes after induction, T6- measurement 100 minutes after induction, T7- measurement 10 minutes after supine. No significant difference was observed during perioperative period.



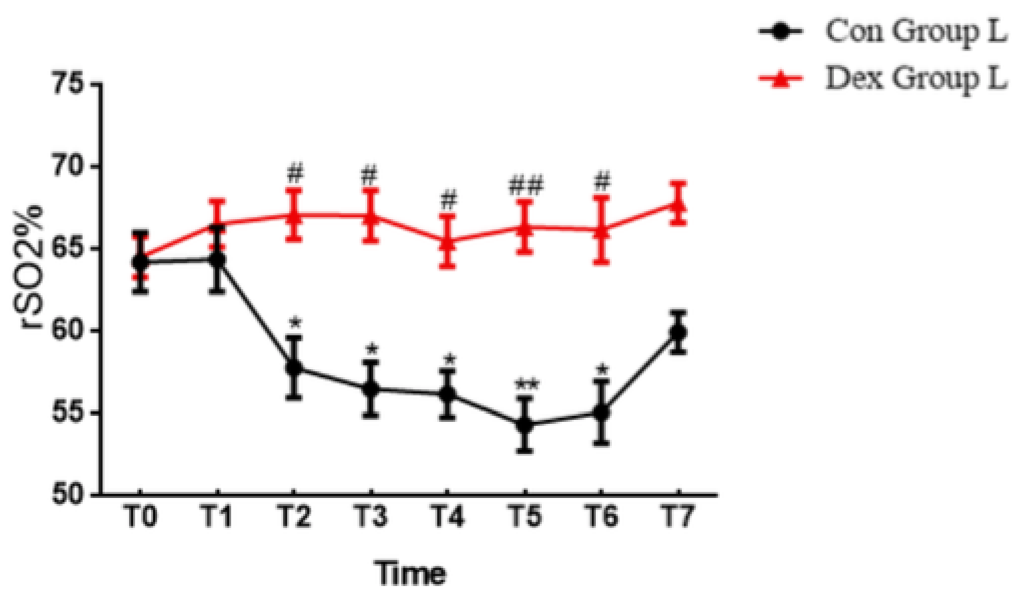


Figure 3

3A: Trend of left regional cerebral oxygen saturation (rSO2) changes during laparoscopic hysterectomy in Control and Dexmedetomidine group. T0- measurement before induction, T1- measurement 2 minutes after induction, T2- measurement 20 minutes after induction, T3-measurement 40 minutes after induction, T4- measurement 60 minutes after induction, T5- measurement 80 minutes after induction, T6- measurement 100 minutes after induction, T7- measurement 10 minutes after supine. Statistically significant increase of rSO2 values was noted two minutes after anesthesia induction in both groups.

After anesthesia induction rSO2 values gradually decreased in Con group. Decreasing of rSO2 was most intense at T5.10 minutes after supine position rSO2 values were slightly recovering and turning back near to basal rSO2 values in Con group, but values were statically higher in the VIMA group even after surgery and anesthesia Statistically higher values were noted in the Dex group in all time points during the surgery *$p < 0.05$, **$p < 0.01$ and ***$p < 0.001$ as significant difference to morphine group #$p < 0.05$, ##$p < 0.01$ and ###$p < 0.01$ as significant difference to respect Control treated with Dexmedetomidine. 3B: Trend of right regional cerebral oxygen saturation (rSO2) changes during laparoscopic hysterectomy in Control and Dexmedetomidine group. T0- measurement before induction, T1- measurement 2 minutes after induction T2- measurement 20 minutes after induction, T3-measurement 40 minutes after induction T4- measurement 60 minutes after induction T5- measurement 80 minutes after induction T6- measurement 100 minutes after induction T7- measurement 10 minutes after supine. Statistically significant increase of rSO2 values was noted two minutes after anesthesia induction in both groups. After anesthesia induction rSO2 values gradually decreased in Con group. Decreasing of rSO2 was most intense at T6.10 minutes after supine position rSO2 values were slightly recovering and turning back near to basal rSO2 values in Con group.Statistically higher values were noted in the Dex group in all time points during the surgery *$p < 0.05$, **$p < 0.01$ and ***$p < 0.001$ as significant difference to morphine group #$p < 0.05$, ##$p < 0.01$ and ###$p < 0.01$ as significant difference to respect Control treated with Dexmedetomidine.

Supplementary Files

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