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Dexmedetomidine versus propofol as a sedative on reduction of intubation rate in patients undergoing noninvasive ventilation in ICU patients

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Abstract
Background: Owing to numerous studies, applying sedation during non-invasive breathing technique should be taken into account to lower the percentage of non-invasive ventilation failure and to relax the patient. In order to enhance the effectiveness of non-invasive ventilation, this study will ascertain the efficacy and safety of dexmedetomidine and propofol when used as analgesia-based sedatives in patients.
Methods: Ninety adult patients of both sexes with a BMI of below thirty who experienced acute respiratory failure owing to a COPD flare-up or pneumonia with respiratory distress on non-invasive ventilation participated in this prospective randomly controlled clinical study. Patients were randomly assigned to undergo one of two treatments: Group D received dexmedetomidine (0.5 µg/kg/h as a continually IV infusion without an initial bolus, then calibrated each half an hour up until the maximum rate of 1 µg/kg/h, Group P: obtained propofol (rate of 5 µg/kg/min as a constant via IV infusion without a beginning bolus, then titrated by 1.5 µg/kg/min every half an hour up up to the greatest rate of 10.0 µg/kg/min) and Group C (Control group) didn't get any sedative or analgesia.
Results: SpO_2, PaO_2 and SaO_2 improved significantly in the two groups D and P with slight improvement in group C ($P < 0.05$). pH showed improvement in both group D and P with little improvement in Group C and significant difference between both groups and group C. PCO2 and HCO3 comparison between the three groups showed decrease in both group D and P with little decrease in group C. Heart rate (HR) and MAP (mean arterial pressure) were substantially distinct between D and P at their lowest levels at 1 hour after sedation, 6 hours, 12 hours, and 24 hours between the two groups, with a considerably greater MAP in the control group at these same time points. Sedation-agitation scale (SAS) and visual analogue scale (VAS) scores decreased substantially in the D and P groups followed dexmedetomidine or propofol administration. With no improvement in SAS and VAS score in control group. But difference between both D group and P group was significant during ongoing infusions via IV of dexmedetomidine or propofol at their lowest doses of effectiveness at 1 hour, six hours, twelve hours, & twenty-four hours.
Conclusions: In individuals going through non-invasive ventilation, dexmedetomidine is superior to propofol in terms of sedation and analgesia, yielding than improved outcomes in terms of a reduction in the rate of intubation, ICU immortality, and stay in the hospital.

Keywords: Dexmedetomidine, propofol, sedation, non-invasive, ventilation

Introduction

Without using an endotracheal tube, non-invasive ventilation (NIV) entails providing the patient positive pressure ventilation [1]. Continuous positive airway pressure (CPAP) and bi-level positive airway pressure (BIPAP) are the two primary methods of non-invasive ventilation [2]. Since the use of CPAP and bi-pap can prevent the need for intubation in patients with acute respiratory failure caused by chronic obstructive pulmonary disease (COPD) or acute cardiogenic pulmonary edema, non-invasive mechanical ventilation (NIV), also known as CPAP and bi-pap, has become frequently used in intensive care units (ICUs) [3] [4]

This form of ventilation delivers the same physiological advantages of lessened labor of breathing and enhanced gas exchange as invasive mechanical ventilation. Additionally, it prevents intubation's difficulties and the elevated risks of ventilator-associated pneumonia and sinusitis, particularly in patients with comorbidities or immunosuppressed individuals [5].

There are some drawbacks to using non-invasive ventilation, such as nasal bridge ulceration and discomfort from the mask, but overall there are fewer complications associated with using non-invasive ventilation compared to using invasive ventilation because artificial airways are not required [2].

Patients who received dexmedetomidine had a noticeably lower non-invasive ventilation failure rate, which minimized the need for intubation and facilitated the weaning from mechanical ventilation [6].

Severe hypoxemia and mostly unaltered lung mechanics are frequent in patients with ARDS and covid-19 pneumonia [7], Therefore, it is fair to expect that CPAP therapy will be beneficial for patients with covid-19 [7]. Non-invasive ventilation is a viable option for patients with COVID-19 who are experiencing acute hypoxemic respiratory failure outside of an intensive care unit and can be thought of as a useful way to increase oxygenation in individuals who are not responding to standard oxygen treatment [4].

According to several research, sedation during non-invasive ventilation should be taken into consideration to lower the rate of non-invasive ventilation failure and provide comfort for the patient [8]. Physiologic responses caused by stress that involve a rapid heartbeat shortness of breath, and hypertension ought to be lessened without hindering breathing or the hypoxic drive or cough reflex in an attempt to achieve sedation. It should also calm down anxiety, alleviate discomfort, and alleviate these physiological responses [9].

The findings of this study, which looked at the relationship between utilizing sedation during non-invasive ventilation and intubation rate and ICU length of stay, will aid in directing healthcare practitioners because non-invasive ventilation is regularly used in ICUs. Determining the effectiveness and safety of dexmedetomidine and propofol as analgesia-based sedatives in non-invasive ventilation patients was the study's primary goal in order to enhance the effectiveness of non-invasive ventilation.

Patients and Methods

Ninety patients treated in the intensive care units (ICU) of Tanta university hospitals enrolled in this prospective randomly controlled clinical study, Egypt between August 2021 and August 2022. It was performed on people over the age of 18 and under 65 of males and females with a BMI of under thirty who had a history of acute respiratory failure due to pneumonia or COPD exacerbation and respiratory distress, including: respiratory rate of over twenty-four breathes each minute; improved use of accessory respiratory muscle; acute respiratory acidosis showed levels of partial pressure of carbon dioxide in artery (PaCO2) were more than 45 mmHg; and pulse oxygen saturation (SpO2) was less than 80%. Special infection control precautions were done for patients with pneumonia due to COVID-19 [10, 11].

The Ethics Committee of the Faculty of Medicine at Tanta University in Egypt granted clearance for the study with approval code number 34809/7/21.

Patients with an excessively high body mass index (BMI) (more than 30), severe dementia with a Glasgow Coma Scale (GCS) score of less than or equal to 12, drug and alcohol abusers, emergency endotracheal intubation, a definite intubation refusal, and patients or their families are excluded from treatment. Patients who suffer acute respiratory failure due to other conditions decline to participate. Patients with acute respiratory failure needing intubation from the beginning, such as those with increasing loss of consciousness or hemodynamic stability, patients with severe systemic diseases, such as those with poorly managed hypertension, pacemaker insertion, and patients with chest injuries.

The following treatments were randomly assigned to all qualified patients: Group P (30 patients) got propofol, Group C (30 patients) did not get any sedation or analgesia, and Group D (30 patients) received dexmedetomidine.

Dexmedetomidine was administered to group D at a rate of 0.5 g/kg/h as a continuous intravenous infusion without an initial bolus, and every half-hour thereafter (up to the maximal rate of 1 g/kg/h) was titrated to maintain a Sedation-Agitation Scale (SAS) score of between 3 and 4.

In group P, propofol was administered continuously through intravenous infusion without a starting bolus at a rate of 5 mg/kg/min. The rate was subsequently increased by 1.5 mg/kg/min every half-hour (up to the maximal rate of 10.0 mg/kg/min) to maintain an SAS score between 3 and 4.

Patients in group C, Control, received neither sedation nor analgesia.

After a period of ten minutes when any dexmedetomidine tartrate or propofol dose was raised, an infusion of midazolam with a dose from 0.01 to 0.02 mg/kg would be infused as necessitated when the patient displayed a sign of agitation (SAS score of no less than 5), as well as the injection of fentanyl with a dose from 0.5 to 1 μg/kg would be infused as necessitated when a patient exhibited distress (Visual Analogue Scale, VAS score of no less than 5 of 10 cm).

Non-invasive ventilation

With the aid of a Philips ventilator (BiPAP Vision, Respironics Inc., USA), non-invasive respiration was carried out. The ventilator can be employed with a nose mask or a nose-mouth mask to provide constant positive airway pressure (CPAP), spontaneous (S), and spontaneous/timed (S/T) ventilation.

Following were measured: demographic data, respiratory function assessment: respiratory rate, SpO_2 and arterial blood gases (PH, PCO_2, HCO_3, PaO_2, SaO_2), were monitored at base line, every10 minutes in 1st 1 hour and recorded every 30 minutes during the next six hours and every 6 hours to the end of the pharmaceutical infusion for the trial, Hemodynamic assessment: heart rate (HR), blood pressure, both (HR) and non-invasive blood pressure were tracked at baseline, every 10 minutes in the first hour, recorded on a thirty-minute basis during the next six hours, and every six hours to the end of the study's medication infusion. The level of sedation was calculated using an SAS score, with an SAS score of 0. The blood gases analysis were performed at non-invasive ventilation initiation and 1, 6, 12, and 24 hours after the drugs had been given. The bedside nurse recorded the information on the form when the patient was unable to complete the VAS based on the patient's self-reported pain score, doses of midazolam and fentanyl, intubation rate, length of stay in the ICU, time to endotracheal intubations, and ICU mortality estimated as a percentage of the dead cases to the total cases in each group. SAS is a type of non-invasive ventilation that is valid and trustworthy to evaluate agitation and sedation in ICU patients. And can be done bedside by the health care provider [12] and Faces pain rating scale: After obtaining

instructions on how to apply the tools and with little urging, it is simple to understand and operate them, which justifies its usage in a therapeutic context. Furthermore, it is trustworthy and legal [13].

Sample size calculation

Applying the Epi-Info statistical tool developed by the World Health Organization and the Centers for Disease Control and Prevention, Atlanta, Georgia, USA, version 2002, the sample size and power analysis were computed. The following criteria were used to calculate sample size: 95% confidence interval -80% research power - 15% expected to result in the favorably treated group as opposed to 50% in the least favorably treated group. -For each research group, the sample size determined by the aforementioned criteria was N>26. To account for lost data, the sample size was expanded to 30.

Statistical analysis

The IBM Inc., Armonk, NY, USA-based SPSS version 25 was used for the statistical analysis. In order to determine whether parametric or nonparametric statistical testing should be utilized, the distribution of quantitative data was tested using the Shapiro-Wilks normality test and histograms. The three groups' parametric variables were compared using the F (NOVA) test, with the post hoc (Tukey) test used to compare each pair of groups separately. Parametric variables were represented as mean and standard deviation (SD). Using the Kruskal-Wallis test (H), non-parametric variables were reported as median and range. Categorical variables were statistically analyzed using the Chi-square test and presented as frequency and percentage. Statistical significance was defined as a two-tailed P value ≤ 0.05.

Results

From August 2021 to August 2022, there were 201 patients treated with non-invasive ventilation, nonetheless, ninety participants participated in our investigation whereas a total of 111 patients were eliminated based on the aforementioned inclusion and exclusion criteria (Figure 1).

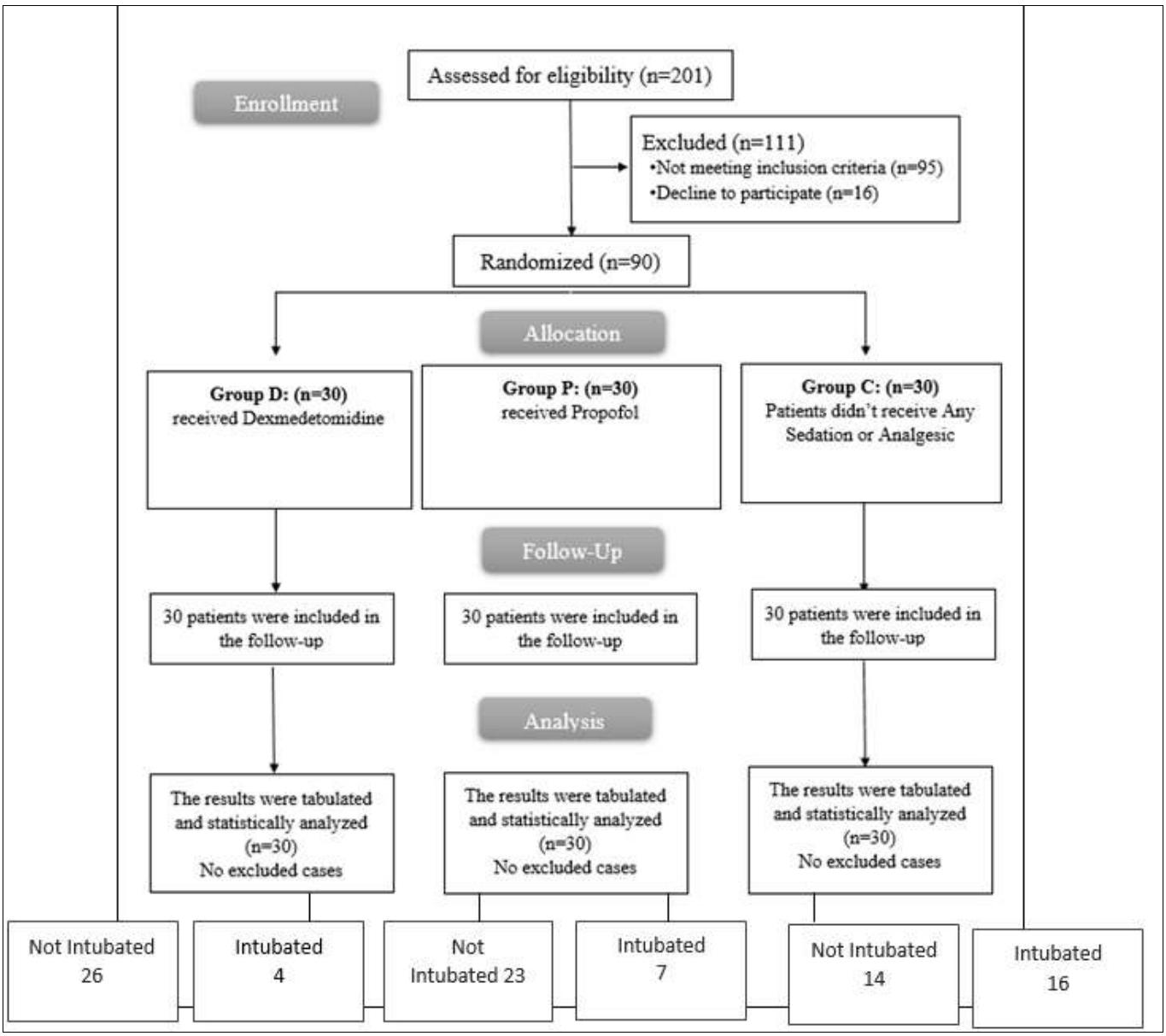


Figure 1: Patient enrolment and intubation flow diagram

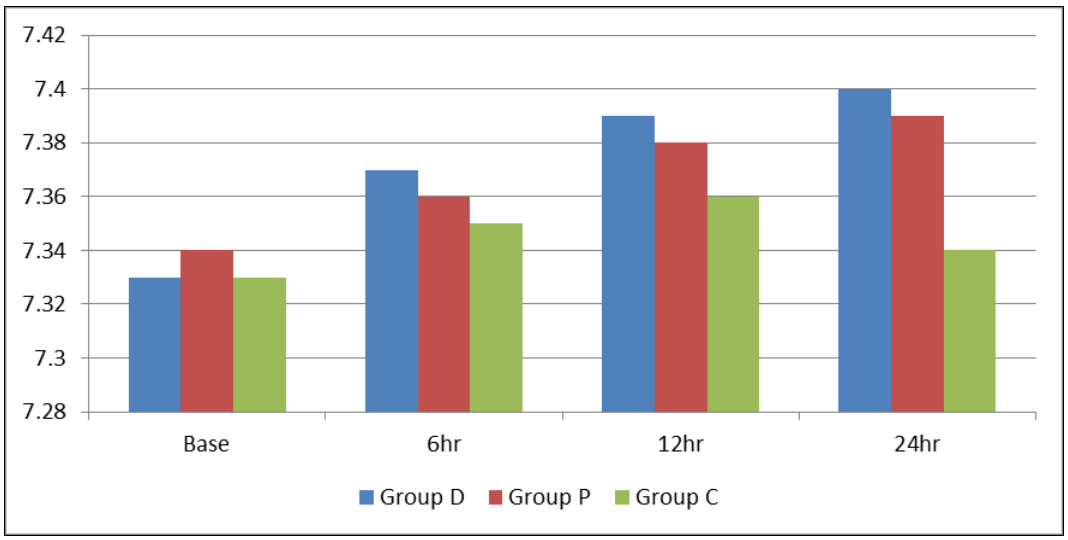
The demographic data (age, sex, BMI, type of respiratory failure, comorbidities, medical therapy and special habits) were insignificantly different between both groups (table1)

Table 1: Contrasts the three groups under study with regard to of demographic details

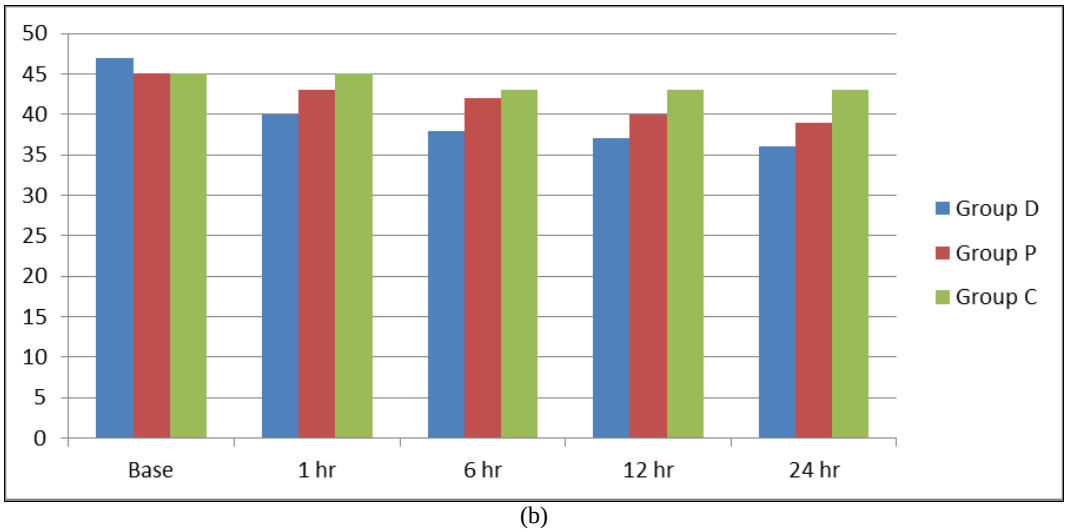
		Group D (number=thirty)	Group P (number=thirty)	Group C (number=thirty)	P-value
Age in years	Mean ± SD	54.10 ± 10.35	51.83 ± 10.90	52.80 ± 11.44	0.722
Sex	Male	12(40%)	17(56.67%)	11(36.67%)	0.247
	Female	18(60%)	13(43.33%)	19(63.33%)	
BMI (kg/m^2)	Mean ± SD	24.38± 3.65	25.58± 2.33	24.52± 3.59	0.301
Type of respiratory failure	Type I	10 (33.3%)	14(46.7%)	16(53.3%)	0.284
	Type II	20 (66.7%)	16(53.3%)	14(46.7%)	
Comorbidities	Diabetic	11(36.6%)	6(20.0%)	8(26.6%)	0.332
	Hypertensive	5(16.6%)	7(23.3%)	9(30%)	
	Renal	3(10.0%)	2(6.6%)	0(0%)	
Medical therapy	Insulin	5(16.6%)	3(10%)	4(13.3%)	0.421
	AHD	5(16.6%)	7(23.3%)	9(30%)	
	Dialysis	1(3.3%)	0(0%)	0(0%)	
Special habits	Smoking	23(76.6%)	20(66.6%)	19(63.3%)	0.302

BMI stands for body mass index, SD for standard deviation, F for one-way ANOVA, and p is the p-value for comparing the three groups under study. Group P: Propofol, Group C: Control, Group D: Dexmedetomidine

pH and PaO_2 comparison between the three groups showed improvement in both group D and P with little improvement in Group C with insignificant difference between both groups D and P and significant difference between both groups and group C in pH. PCO2 and HCO3 comparison between the three groups showed decrease in both group D and P with little decrease in group C with insignificant difference between both groups D and P and significant difference between both groups and group C. (Fig.2).



(a)



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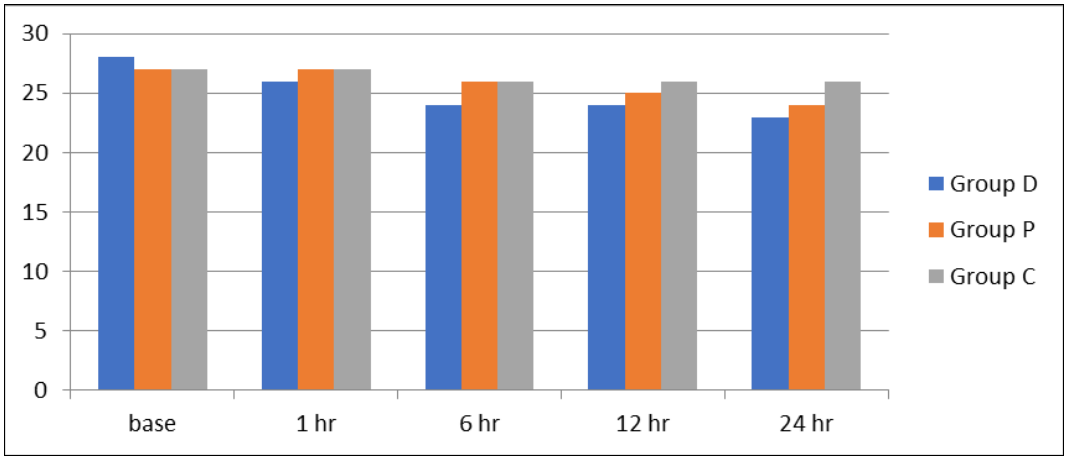

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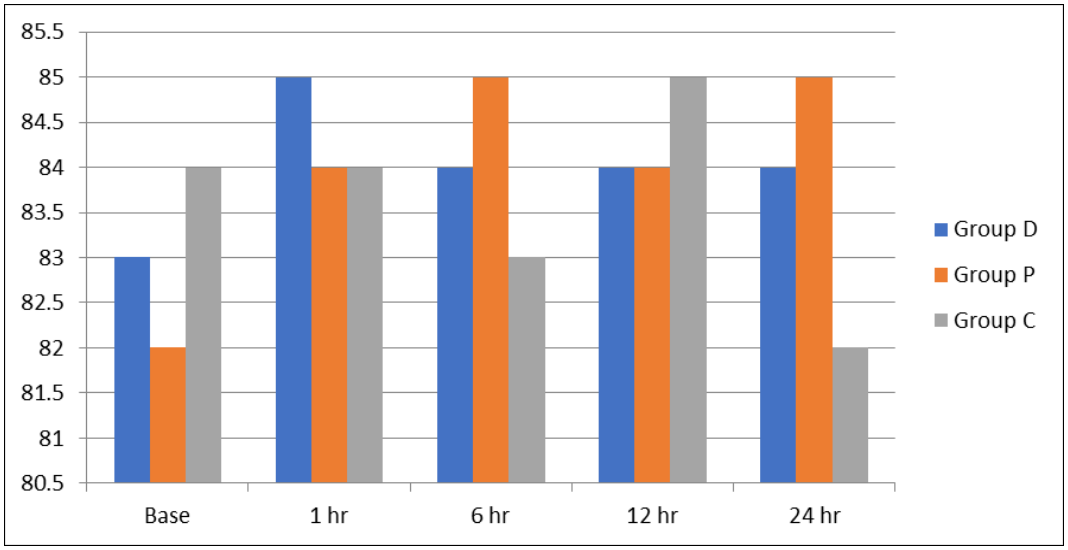
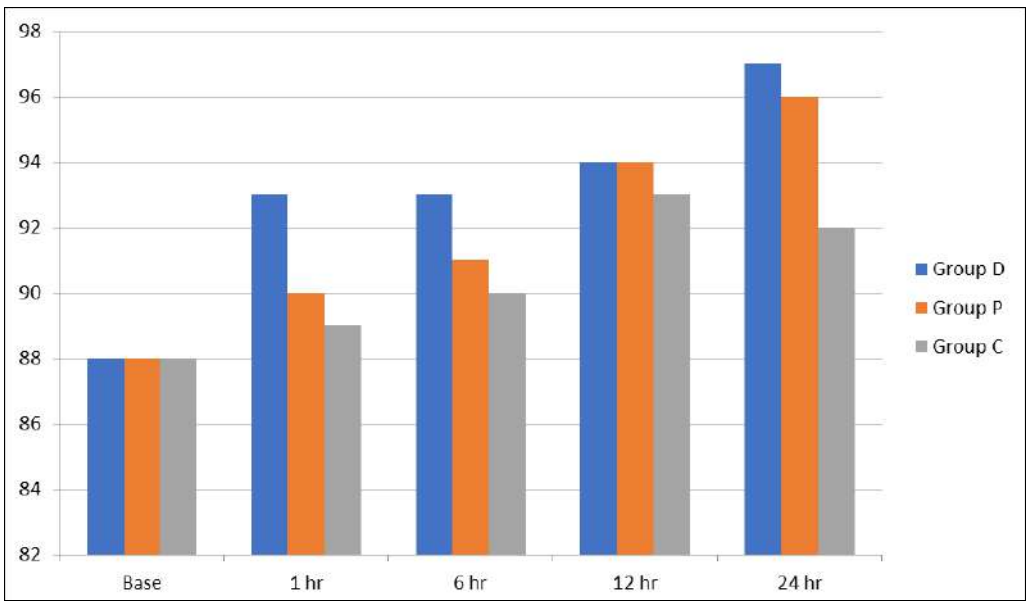


(d)

Fig 2: pH (A), PCO_2 (B), HCO_3 (C), and PaO_2 (D) of the studied patients

With just a minor rise in group C ($p< 0.05$), SaO2 dramatically enhanced in groups D and P. After the injection of dexmedetomidine or propofol, SAS and VAS scores dramatically fell in both the D and P groups. Lacking a change in the control group's SAS or VAS score. At baseline, there was not a significant disparity in the three groups' SAS and VAS scores, but at one hour, six hours, twelve hours, and twenty-four hours post an ongoing IV infusion of dexmedetomidine or propofol at its lowest effective dose, there was a substantial distinction between the D group and the P group (Fig.3)



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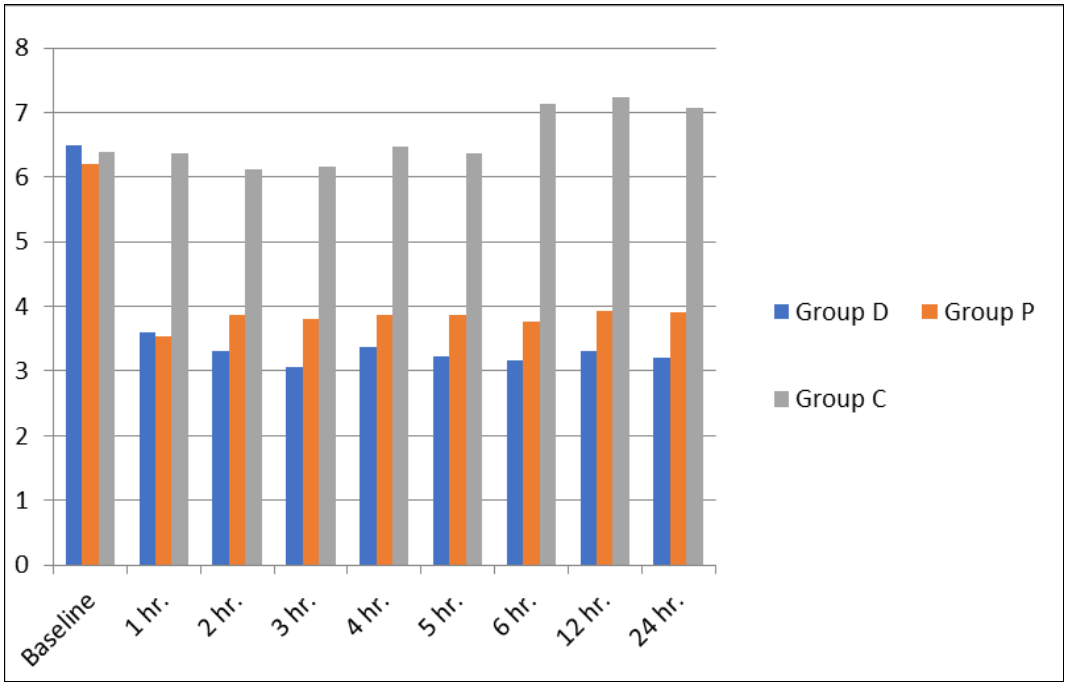

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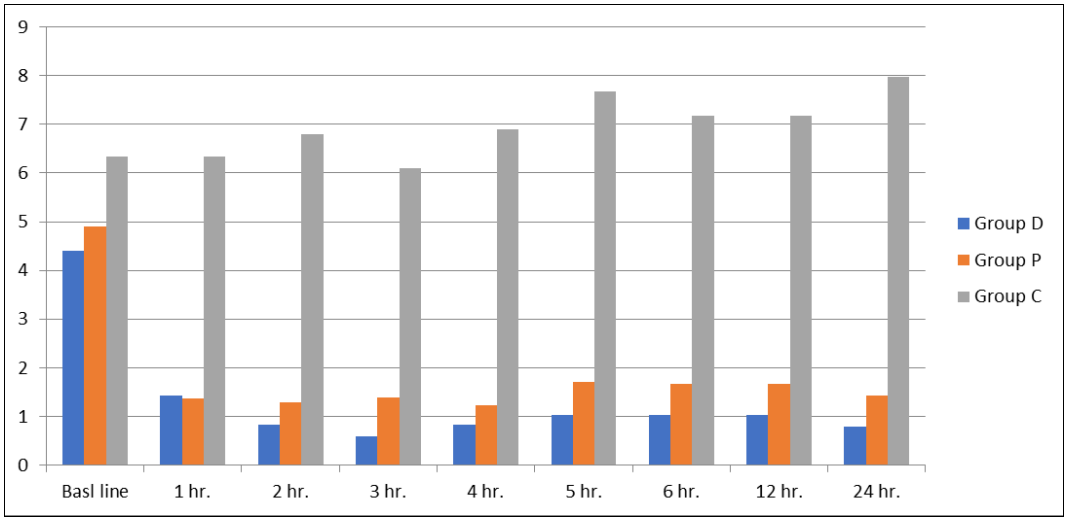
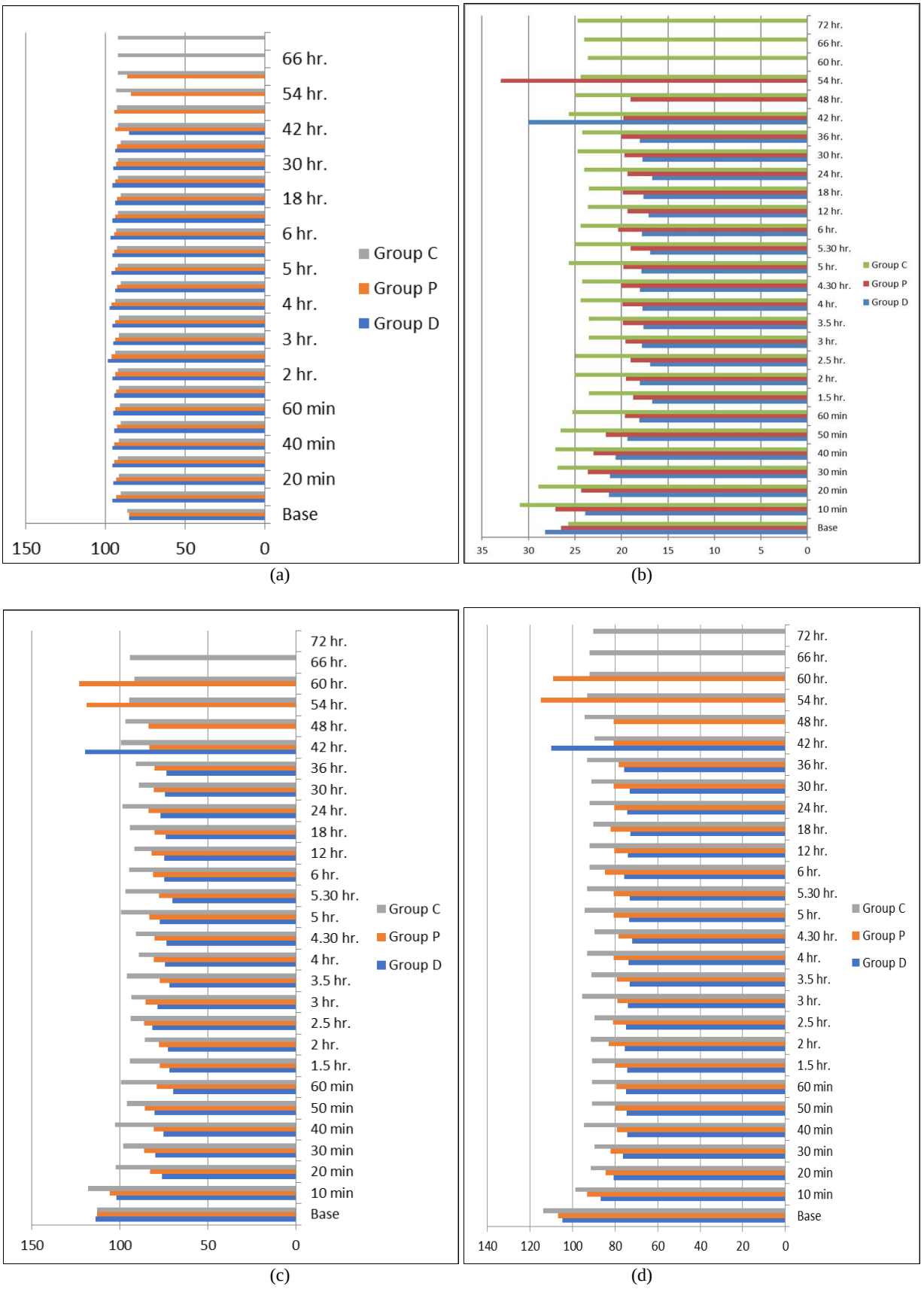


(c)

Fig 3: SaO_2 (A), SAS (B), and VAS (C) of the studied patients

Following persistent infusions via IV of dexmedetomidine and propofol, RR dropped to its normal levels in groups D and P with no discernible difference between either group, whereas RR slowly improved in the control group. With a marginal enhancement in group C, SpO2 substantially rose in groups D and P and fell in group C (p<0.05). Whereas HR and MAP matched in all three groups at baseline, HR raised during continuous infusions via IV of dexmedetomidine and propofol in groups D and P compared with baseline, but not in group C. The distinction in between-group comparisons was noteworthy between D and P at its' lower limit at 1 hour after sedation, 6 hours, 12 hours, and 24 hours between the two groups, with a substantial rise in MAP in the control group at 1 hour after sedation (figure.4).



(a) (b)

(c) (d)

Figure(4): Respiratory rate (A), SpO_2 (B), and heart rate (C), and mean arterial pressure (D) of the studied patients.

The necessity for midazolam and fentanyl infusions varied considerably across group D and group P which showed more doses needed for group P which indicate better sedation and analgesia of dexmedetomidine than propofol (table.2)

Table 2: Contrast between group D & P regarding no of doses of midazolam and fentanyl

No. Doses Midazolam	Group D	Group P	P
Mean ± SD.	0.23 ± 0.43	0.90 ± 1.03	<0.001*
No. Doses Fentanyl	Group D (n = 30)		Group P (n = 30)
Mean ± SD.	0.23 ± 0.43		0.90 ± 1.03

In regards to the number of patients who necessitate intubation and the length of the ICU stay, there is no discernible difference between groups D and P. Nevertheless, there is a substantial distinction between the two groups and group C, demonstrating the positive impacts of dexmedetomidine and propofol on lowering the need for intubation, contributing to the success of non-invasive ventilation, and shortening ICU stays in contrast to the control group.

Mortality of cases was recorded as follows: From the 4 intubated cases in D group. 3 cases died representing 10% of the whole group cases, From the 7 intubated cases in group P 5 cases died which representing 16% of the whole group cases, From the 16 cases intubated in group C 10 cases died representing 33% of the whole group cases. This illustrates how dexmedetomidine and propofol collaborate in order in reducing ICU mortality.

There was no discernible difference in the three groups' time to intubation when compared which means that both drugs had no significant effects on this parameter.

There was no discernible difference between the three groups when the three groups' ventilation types were juxtaposed. (table.3)

Comparison of the groups' rates of intubation, length of ICU stays, ICU mortality, ETI, and non-invasive ventilation types is shown in Table 3.

		Group D (number = thirty)		Group P (number = thirty)		Group C (number = thirty)		P-value
		No.	%	No.	%	No.	%	
Intubated	Not intubated	26	86.7	23	76.7	14	46.7	0.002*
	Intubated	4	13.3	7	23.3	16	53.3	
	P value between groups	p1=0.317, p2=0.001*, p3=0.017*						
Length of ICU Stay	Mean ± SD.	2.80 ± 0.81		3.13 ± 0.97		5.10 ± 0.84		<0.001*
	P value between groups	p1=0.310, p2<0.001*, p3<0.001*						
ICU Mortality		3	10	5	16	10	33	0.002*
Ventilation	CPAP	10 (33.3%)		14 (46.7%)		16 (53.3%)		0.284
	S/T	20 (66.7%)		16 (53.3%)		14 (46.7%)		
		Group D (n = 4)		Group P (n = 7)		Group C (n = 16)		P value
Time To ETI	Mean ± SD.	36 ± 12.72		58.3 ± 12.24		31.2 ± 11.52		0.059

Discussion

In our study both drugs showed hemodynamic stability with better results for dexmedetomidine over propofol and reduced respiratory rate with improved blood gases profile in both groups, length of stay in ICU reduced from 5.1 days in control group to 3.1 days in propofol group and 2.8 days in dexmedetomidine group, our study also demonstrated how both medications contributed to the effectiveness of non-invasive breathing and the decline in the intubation frequency.

In a prospective preliminary study, in 2007 Constantin *et al.* [8] revealed that remifentanil was continuously infused to achieve conscious sedation (scoring 2-3 on the Ramsay scale) and that this prevented intubation in 9 out of 13 patients (69%), resulting in a decrease in respiratory rate and an improvement in arterial blood gases after 1 hour. Throughout the trial period, no patient displayed hemodynamic abnormalities or a decrease in respiratory drive. Additionally, an improvement in blood gas readings and a reduction in respiratory rate were seen during analog-sedation with remifentanil.

The outcomes of our research concurred with those of Constantin *et al.* [8], our results showed success rate of about 86% in group D, 76% in group P, In addition, both dexmedetomidine and propofol infusion maintained vascular stability and reduced respiratory rate and improved the outcomes of non-invasive ventilation but the limitation in the study of Constantin *et al.* [8] was the small sample size (n=13).

The outcomes of our research concurred with those of Akada *et al.* [14] was the first time dexmedetomidine was administered as a sedative during non-invasive ventilation, and the scientists indicated that after an hour of infusion, gas exchange and respiratory rate had gotten better. This study showed success rate of 100% for dexmedetomidine infusion but the sample size was small n =10.

It's well known that propofol has no analgesic effects [15] supported by a study made by Wang and Meng, in 2021 [9] When butorphanol and propofol were contrasted in patients getting noninvasive ventilation, it became obvious that both groups saw a considerable reduction in the noninvasive ventilation intolerance score, SAS score, and VAS. Between the groups, there was not a substantial disparity in SAS score and VAS, but there was noteworthy variance among both groups in the quantity of fentanyl administration to attain the necessary degree of analgesia involving higher doses of fentanyl needed to treat patients on propofol the infusion than butorphanol, which is supported by our study, number of patients required fentanyl doses in propofol group was 14 versus 7 patients required fentanyl doses in dexmedetomidine group which reflect the analgesic effect of dexmedetomidine which is advantage over propofol.

In 2019, a study was made by Baptiste Deletomb *et al.*[16] showed that In contrast with placebo, dexmedetomidine enhanced the length of NIV: 280 min (118-450) (median, 25-75th quartiles) against 120 min (68-287) Dexmedetomidine had been associated to a lower RASS score, as follows: -0.8 (-1.0; 0.0) as opposed to 0.0 (-0.5; 0.0) (p< 0.01),

Dexmedetomidine administration without bolus dose is very

important to avoid its adverse effects especially bradycardia and hypotension. A study was made in 2011 by Hoy and Keating [17]. Showed that If administered as a bolus loading dosage, drowsiness with dexmedetomidine was connected to a considerably (p<0.005) greater incidence of hypotension and bradycardia and a considerably lower frequency of hypertension than sedation with placebo.

Another study made by Vennl and Grounds [18] in 2001 comparing both propofol and dexmedetomidine regarding sedation, analgesia and hemodynamics. Dexmedetomidine was infused as a loading dosage of 2.5 g kg 1 h over a period of ten minutes, followed by a maintenance dose of 0.2 to 2.5 g kg 1 h into a peripheral or central vein. After a loading dose infusion of up to 1 mg kg over 10 min, if necessary, propofol was administered undiluted as an infusion of 1-3 mg kg per hour.

For both the propofol and dexmedetomidine groups, the percentage of time spent at what many would consider an ideal depth of sedation (i.e. RSS 2±4) was similar: 49.1% (43.7) for the propofol group and 46.3% (33.1) for the dexmedetomidine group. Sedation over the entire study period, the median RSS was 5 (4±5) and 5 (4±6) (P=0.68) for the respective groups.

However, patients receiving propofol infusions needed considerably more alfentanil [2.5 (2.2±2.9) mg h1] than patients getting dexmedetomidine [0.8 (0.65±1.2) mg h1] for intraoperative analgesia.

When compared to the propofol group, patients receiving dexmedetomidine had substantially lower HR (P=0.034). At baseline and throughout the research period, the two groups' arterial and central venous pressures were comparable (P=0.60 and 0.21, respectively). There were no adverse cardiovascular events in either group, and no patients needed inotropes. There were no variations in arterial pressures between the groups for this time period after the sedation was stopped (P=0.60), and no rebound phenomenon was seen. This difference may be due to the difference in the used doses from ours and different scale of sedation.

In comparison with our study, difference between sedative effect of dexmedetomidine and propofol is significant but at its lower limit with dexmedetomidine more perfect in sedating patients than propofol infusion with less doses of midazolam needed, the results of our study regarding analgesia is the same with this study revealing less need of opioid for dexmedetomidine when compared with propofol, regarding hemodynamics we had the same results with HR but MAP difference was significant at its lower limit in our study with lower mean arterial blood pressure in dexmedetomidine group.

One drawback is that it was single-center research, and other studies may have had outcomes that differed. The low social and educational level of our patients made them non-cooperative and agitated when using this renders the success of non-invasive ventilation a significant task. Adverse effects and complications of using dexmedetomidine and propofol during NIV were mentioned in many other studies [6, 9, 19], but in our study they were minor and minimal, so we didn't include them in the outcomes of our study. Clinical studies are needed with multicenter cooperation and on larger scale to validate our findings. Furthermore, studies regarding the most effective concentrations of the used drugs are required.

Conclusion

Over propofol, dexmedetomidine is preferable in both sedation & analgesia for patients with non-invasive ventilation, hence better results in reduction in rate of intubation, ICU mortality and a hospitalization.

Nil in terms of donations and sponsorship

No conflicts of interest

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