Auto titrating versus fixed EPAP intelligent volume-assured pressure support (iVAPS) Ventilation in Patients with COPD and Hypercapnic Respiratory Failure

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Abstract

Intelligent volume-assured pressure support (iVAPS) is new noninvasive ventilation (NIV) modes can automatically adjust pressure support to deliver effective ventilation.

The objectives are to compare treatment efficacy and level of satisfaction between auto-titrating expiratory positive airway pressure (Auto EPAP) and fixed (Fixed-EPAP) during (iVAPS) treatment in stable hypercapnic chronic obstructive pulmonary disease (COPD) patients.

Patients & methods:

In this prospective single-blinded, randomized study, 50 patients with chronic stable hypercapnic (COPD) who met the study criteria; patients were randomized into group I treated with Auto-EPAP and group II who received Fixed EPAP during iVAPS treatment for 5 consecutive days. Patient's characteristics, Arterial blood gases, and lung function test were recorded. Numeric rating scale (NRS), dyspnea and comfort scale were obtained. The patients were evaluated and followed up after initiating therapy for 5 consecutive days. Outcome measures were recorded at baseline (T0) and after three (T1) and five (T2) days of each consecutive period. All parameters were collected and statistically analyzed.

Results:

No significant differences were found regarding age, sex, and BMI. It was noted that daytime PaCO2 decreased significantly over the follow-up period in group I patients treated with (Auto-EPAP) as compared with (Fixed EPAP). Regarding patient comfort and dyspnea during iVAPS treatment, dyspnea sensation was significantly lower with Auto –EPAP (7.9±1.8 (T0) vs. 3.5±1.1 (T2), p-=0.001) and Fixed – EPAP (7.7±1.9 (T0) vs. 3.4±1.6 (T2), p=0.001), but no significance was reached between both groups. However, Auto EPAP demonstrated significant improvement in comfort when compared with Fixed-EPAP modality. However, the overall satisfaction in patients receiving Auto EPAP modality was significantly increased. Mean tidal volume tended to be higher in Auto EPAP **(698±213 ml**) compared with (**628±178 ml) in fixed EPAP (P =0.001*).** The air leak was significantly lower in auto adjusting mode (2.5 ± 1.3 vs.3.7 ± 2.2 L/ min) in fixed EPAP modality.

Conclusion: This new auto-titrating NIV mode may provide additional benefit in decreasing PaCO2 more efficiently and improve patient s comfort and satisfaction.

Introduction

Chronic obstructive pulmonary disease (COPD) is a progressive and debilitating respiratory condition; it is the only leading cause of death that is still increasing. COPD patients who develop hypercapnic respiratory failure have a particularly poor prognosis [1].

The pathophysiological processes underlying chronic hypercapnic respiratory insufficiency in COPD are not completely understood, the possible mechanisms may be contributed to derangements in ventilatory mechanics, muscle function, and gas exchange [2].

Nocturnal non-invasive ventilation (NIV) became an important treatment modality in COPD patients with chronic hypercapnic respiratory failure, based on heterogeneity in the underlying pathophysiology and on data regarding symptoms. Still, however, its relevance for quality of life and life expectancy has been a topic of debate[3].

Currently, volume-targeted (VT) modes of non-invasive ventilation (NIV) devices are new hybrid modes incorporating features of both volume and pressure ventilation. Some VT mode target a preset tidal volume, known as average volume assured pressure support (AVAPS) device, and others preset alveolar ventilation such as intelligent VAPS (iVAPS) device mode to maintain airway patency[4].

Intelligent volume-assured pressure support (iVAPS), uses an automated algorithm to adjust inspiratory pressure support (PS) within a predetermined range, to maintain appropriate target ventilation. It offers an alternative to standard pressure preset (NIV) modes and may improve patient comfort and compliance. Besides, they might have clinical benefits such as reduced air leak and improved sleep quality [5].

The purpose of this study was to compare auto titrating (Auto EPAP) versus fixed EPAP during intelligent volume-assured pressure support (iVAPS) treatment in patients with COPD and chronic hypercapnia in terms of (1) treatment efficacy, and (2) patient satisfaction.

Patients & Methods

This prospective single-blinded, randomized study was conducted over one year from November 2018 to November 2019 at Assiut University Hospital. The study was conducted in accordance with the Declaration of Helsinki. The study was approved by the Faculty of Medicine Ethics Committee, Assiut University. All the patients provided written informed consent before being enrolled in the study.

- **Inclusion criteria:** COPD patients aged 40–75 years with stable chronic hypercapnia at rest (partial pressure of carbon dioxide [paCO2] <50 mmHg) [6], naive to NIV, ability to provide written informed consent.
- **Exclusion criteria:** patients with unstable hemodynamic and respiratory conditions (e.g., recent acute heart failure, respiratory exacerbation or infection with worsening symptoms within the last month, malignancies, non-compliance with NIV (average usage of <4 h/night), Pre-existing conditions: severe bullous lung disease, pneumothorax or pneumomediastinum, pulmonary embolism), Sleep- disordered breathing (overlap syndrome, obesity hypoventilation).

Patients characteristics including (age, sex, body mass index [BMI]) smoking habit (current smoker, never smoker, ex-smoker); year of COPD diagnosis were recorded.

Spirometry (VMax 6150, SensorMedics, Yorba Linda, CA) at the time of the study were performed. Lung function parameters (FEV1, FVC, FEV1/FVC) were obtained from all patients. Also, predicted lung volumes and voluntary respiratory muscle strength values) MIP and MEP) were recorded as recommended [7,8].

Arterial blood gas (ABG) (Model 850, Chiron Diagnostics, Medfield, MA) (pH, PaCO2, PaO2, PaO2/FiO2) were performed on room air for all patients. The sample was taken during the initial assessment appointment (after study consent) to ensure that patients were clinically stable before the study.

Randomization and Treatment Settings

During an in-hospital stay of several days, eligible patients were commenced for treatment with Auto-EPAP (Group I) and (Fixed-EPAP) (Group II) during (iVAPS) **[(Astral 150, ResMed Corp. iVPAPs device algorithms**] treatment for 5 consecutive days. Randomization was performed (1:1) by a laboratory scientist not involved with the study using the technique of shuffled sealed envelopes containing equal numbers of each treatment arm (Figure1).

Using iVAPS with Auto-EPAP, settings were instructed to keep the range 'open', so the algorithm could be tested across the full range: Maximum pressure: 25–35 cmH2O, PS maximum: 15–25 cmH2O, PS minimum: 5 cmH2O, EPAP max: 15 cmH2O, EPAP minimum: 5 cmH2O, Rise time: 300 ms, AVAPS rate: 2 cmH2O/min. In both modes, the target tidal volume was set 6-8 ml/kg of the patient's ideal body weight.

NIV- iVAPS was delivered via either a nasal or oronasal mask, and the mask was carefully adjusted as part of routine clinical care.

Additional oxygen at a fixed inspiratory fraction (FiO2) was added when required with the scope to maintain the oxygen saturation (SaO2) level above 90%. (Supplementary material)

Measurements:

- Physiological variables including Exhaled VT, respiratory rate (RR), heart rate, and arterial blood gas (ABG) were recorded at baseline (T0) and then after 3 (T1) and 5 (T2) days of each consecutive period.
- Subjective assessment of dyspnea was determined using a numerical rating scale [9]. NRS consists of a scale numbered (0–10), 0='Not breathless at all' and 10= 'Breathlessness as bad as you can imagine'. A higher score represents greater symptom severity.
- Patient's comfort [10] was assessed at the end of each test period. All patients were asked to grade the comfort of the device (1-10) using the following scale: 1= severe discomfort; and 10= very good level of comfort.
- The overall Patient satisfaction level was assessed in the morning. All subjects have completed a visual analog satisfaction (VAS) questionnaire. Patients scored satisfaction (0–10) of their experience from the previous night. Questions included: (1) How well did you sleep last night? (2) How rested do you feel this morning? (3) How often did you wake during the night? (4) How uncomfortable was your iVAPS pressure? (5) Overall, how satisfied were you with your quality of sleep last night?
- The patient's compliance to iVAPS was recorded using the Encore Pro SmartCard located within the machine and included (number of hours/night of use).

Statistical analysis

Statistical package for the social sciences (SPSS), version 20 (produced by IBM SPSS Statistics for Windows, version 20; IBM Corp., Armonk, New York, USA) software was used for the collected data. Values were presented in mean and standard deviation using the Mann–Whitney U-test for comparison between the two study groups. The qualitative data were compared between the two groups using the $\chi 2$-test and the quantitative data were compared using Student's t-test. Changes in gasometrical parameters over time among the two groups were analyzed using the one-way analysis of variance test. A P-value of less than 0.05 was considered significant.

Results

A total of 50 stable hypercapnic COPD patients were included in this study. After randomization, 25 patients were assigned to (Auto-EPAP) group I and 25 patients with fixed EPAP (group II) during iVAPS treatment

Patients' characteristics and baseline lung function and arterial blood gases are presented in Table (1).

In both groups, It was noted that daytime $PaCO_2$ decreased significantly over the follow-up period in group I patients treated with (Auto-EPAP) as compared with (Fixed EPAP) (table 2). Other parameters of gas exchange improved in both groups, without significant differences.

As shown in Table (3), patient comfort and subjective dyspnea assessment comparing Auto EPAP and fixed EPAP during iVAPS treatment. A significant decrease in dyspnea sensation with Auto –EPAP (7.9±1.8 (T0) vs. 3.5±1.1 (T2), p-=0.001) and Fixed – EPAP (7.7±1.9 (T0) vs. 3.4±1.6 (T2), p=0.001), but this improvement was not significant. However, Auto EPAP demonstrated significant improvement in comfort when compared with Fixed-EPAP modality. However, the overall level of satisfaction in patients receiving Auto EPAP was significantly increased.

Treatment compliance was assessed from cumulative use (data not shown, P = 0.433) or mean night-time use (347 ± 145 and 350 ± 144 min for Auto adjusting and fixed EPAP modality, respectively, P = 0.256) over the study periods and was similar for the two groups. Table (4) showed the ventilatory pattern response recorded during the 5-days period. Mean tidal volume tended to be higher in Auto EPAP **(698±213 ml**) compared with (**628±178 ml) in fixed EPAP modality (P =0.001*).** Air leak was observed to be lower in auto adjusting mode 2.5 ± 1.3 vs. 3.7 ± 2.2 L per minute in fixed EPAP.

Discussion

Intelligent volume-assured pressure support (iVAPS) is a hybrid mode of servoventilation, providing constant automatic adjustment of pressure support (PS) to achieve target ventilation determined by the patient's requirements. Hence, the purpose of this study was to compare auto titrating (Auto EPAP) versus fixed EPAP during intelligent volume-assured pressure support (iVAPS) treatment in patients with COPD and chronic hypercapnia regards treatment efficacy, and level of patients satisfaction.

The current study noted a higher amount of PaCO2 levels decreases within a shorter period of time in patients treated with auto-titrating (iVAPS) mode. This response with automatic mode is more pronounced within the first day of usage, and significantly greater reductions in PaCO2 levels take place during follow up period. In agreement with our results, Gursel et al. investigate the efficiency of AVAPS-AE mode in hypercapnic respiratory failure. The authors found 10 mmHg reduction in PaCO2 levels had been achieved within a short time period in autotitrating group [11].The more efficient PaCO2 reduction in Auto titrating mode may be attributed to the higher tidal volume that was achieved. Recently, two further studies reported that this ventilation mode effective and safe in patients with chronic obstructive pulmonary disease (COPD) and hypercapnic respiratory failure [12, 13].

Actually, target tidal volume of the two groups was set similarly 6–8 ml/ideal kg of the patient; but, the actual tidal volume was significantly higher in auto titrating group. Our findings were supported with several studies [11,12]. This might be explained by better elimination of upper airway resistance and improved lung mechanics. Therefore, auto-adjusting iVAPS has an important role in treating of hypercapnia in COPD patients.

In our study on COPD patients, it appears noteworthy that Auto EPAP modality was associated with better patient comfort and satisfaction. The major theoretical advantage of the VT mode is providing automatic adjustment of pressure support to achieve target alveolar ventilation. This allows the ventilator to maintain a given tidal volume in an environment of deteriorating respiratory compliance. Its application was thought to be more tolerable and effective in hypercapnic COPD patients; as the result of dynamic changes in airway resistance and lung mechanics thus potentially suggesting a more favorable physiological benefit if used for a longer period. As compared with the previous conventional PS modes, iVAPS has been shown to provide better comfort and satisfaction and a more efficient decrease of PCO2 [14,15,16]. Such improvements in adherence and comfort could have an impact on long term outcomes in COPD patients.

The current study demonstrated lower levels of air leak in Auto EPAP despite higher pulmonary volumes and EPAP levels. A study by McArdle et al. studied patients with chronic hypoventilation using iVAPS with AutoEPAP or FixedEPAP over two separate nights of attended PSG. They found that the leak was similar in the two groups. However, there was less frequent sleep technologist and mask adjustment for leak intervention [17].In contrast, a study by Gursel et al. found higher air leaks reached by AVAPS-AE. The reason may be due to using a single limb machine that had an intentional leak. Thus, a further investigation is required to observe if higher air leaks may change patient–ventilator synchrony [11].

The strengths of this study include its randomized design, using the random assignment technique, patients unaware of the device mode being used. Though, the risk of bias is not achieved. Also, we studied patients already using NIV, in whom previous EPAP settings were available, hence minimizing the need for manual titration. All COPD were subjected to lung function test, muscle strength and arterial blood gas information; instead of relying on the referring clinician diagnosis and patient history.

There was some limitation in our study, Firstly; the small number of patients. Secondly; this randomized study was evaluated for a short duration of time (5 days crossover) in stable hypercapnic COPD patients; however long-term outcomes are not addressed. Hence, future study is needed to assess the efficacy of Auto-EPAP iVAPS treatment on exacerbation rate, hospital admission, quality of life. Third; VT devices have sophisticated algorithms and a wide range of technical features in its usage; unfortunately, we did not study ventilator variables as automatic adjustment of triggering and cycling thresholds that may have an important role in device effectiveness.

Conclusion

iVAPS is clearly an interesting adjunct to the tools made available to clinicians in the field of hypercapnic ventilatory failure, this study is to compare clinical or subjective benefit in terms of using auto-titrating or fixed EPAP during iVAPS perceived in a sample of patients with stable hypercapnic COPD. Auto-titrating iVAPS has been shown to provide higher pulmonary volumes and a more efficient decrease of PCO2 resulting in improved patient comfort and satisfaction.Further investigations are needed to address long-term outcomes of auto titrating iVAPS treatment on COPD exacerbation or hospital admissions and quality of life.

Abbreviations

iVAPS= Intelligent volume-assured pressure support; NIV= Noninvasive ventilation; Auto EPAP= auto-titrating expiratory positive airway pressure; COPD =chronic obstructive pulmonary disease ; NRS= Numeric rating scale ; VT = volume-targeted ; BMI= body mass index ; PaCO2 = partial arterial carbon dioxide pressure; PaO2 = partial arterial oxygen pressure; FEV1 = forced expiratory volume in 1 s; FVC = forced vital capacity; RV = residue volume; TLC = total lung capacity; MIP and MEP = maximal inspiratory and expiratory pressure.

Declarations

Ethical approval and consent to participate

The research received ethical approval from the Ethics Committee of the Faculty of Medicine. The data were confidential. All procedures in the current study were performed according to the ethical standards of the institutional research committee.

Consent for publication

Not applicable.

Institutional review board statement

This study was approved by the Faculty of Medicine Ethics and Scientific Research Committees.

Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Declaration of Competing Interest

The authors have no conflicts of interest to declare.

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Authors' contributions

Doaa Magdy was responsible for the idea and the design of the study. Ahmed Metwally collected the data and shared in writing the methods used in the study. Doaa Magdy was involved in writing and revising the article for valuable intellectual content. Ahmed Metwally revised the manuscript for the final submission.

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Tables

Table (1): Patients' characteristics, baseline lung function test and blood gases of the study group (n=50):

	Group I Auto EPAP Modality (n=25)	Group II (Fixed EPAP) Modality (n = 25)	P-value
Age (years)	**58.2±3.3**	**56.3±5.6**	**0.231**
Sex (Male%)	**12(48%)**	15 (60%)	**0.034**
BMI ((kg/m2)	**27.4±4.1**	***27.9±3.4***	**0.543**
Years of COPD diagnosis	8.3±4.2	8.2±5.7	**0.342**
Arterial blood gases			
PH	7.37±0.03	7.37±0.02	0.345
Pa Co_2 (mm Hg)	62.7±6.6	63.3±6.5	0.321
Pa O_2 (mm Hg)	73.1±9.2	72.8±10.4	0.361
Pa O_2/Fi O_2	262.2±38.3	264.5±34.1	0.251
Pulmonary function			
FVC actual	1.62±0.68	1.43±0.84	0.073
FVC % predicted	64.2±15.1	65.6±16.3	0.177
FEV_1 actual	0.89±0.21	0.87±0.24	0.076
FEV_1% predicted	47.2±9.5	46.8±7.4	0.235
FEV_1/FVC	49.1±13.4	48.6±11.2	0.663
RV, L	3.78±0.29	3.58±0.34	0.342
TLC ,L	5.45±0.15	5.54±0.63	0.321
MIP %pred	42.4±16.3	39.9 ±20.8	0.54
MEP %pred	68.0±38.4	69.1±46.7	0.43

Values are mean (standard deviation) BMI = body mass index; PaCO2 = partial arterial carbon dioxide pressure; PaO2 = partial arterial oxygen pressure; FEV1 = forced expiratory volume in 1 s;FVC = forced vital capacity; RV = residue volume; TLC = total lung capacity; MIP and MEP = maximal inspiratory and expiratory pressure; *=Significant.

Table (2): The time course of the study outcomes using Auto- EPAP and fixed EPAP) during iVAPS treatment in COPD patients.

	Group I Auto EPAP Modality (n=25)				Group II (Fixed EPAP) Modality 5n = 2)				P**
	T0	T1	T2	P*	T0	T1	T2	P*	
RR (bpm)	16.4±3.4	15.4±4.6	16.6±4.6	0.231	16.3±5.6	15.7±5.4	16.5±4.5	0.132	0.231
HR (beat/min)	102±3	99.3±4	97.2±5	0.65	100±8.1	96.2±3	97.7±4	0.23	0.34
PH	7.37±0.03	7.37±0.02	7.38±0.01	0.231	7.37±0.02	7.37±0.02	7.38±0.02	0.453	0.543
Pa Co_2 (mm Hg)	62.5±6.1	52.3±4.1	52.2±3.1	0.001*	63.3±6.1	59.1±7.1	55.2±6.2	0.001*	0.001*
Pa O_2 (mm Hg)	70.4±12.6	74.7±5.9	76.3±8.5	0.012	72.3±13.4	73.2±9.3	76.6±10.9	0.043	0.321
Pa O_2/Fi O_2	268.4±40	278.3±36	278.3±34	0.231	264.1±34	275.3±37	279.3±40	0.432	0.546

Data presented as mean (standard deviation);RR= Respiratory rate; bpm= breaths per minute; HR= heart rate; PaCO2, partial arterial carbon dioxide tension; PaO2, partial arterial oxygen tension; SaO2, arterial oxygen saturation; T0 = baseline assessment; t(T1)= after 3 day of intervention; and (T2) after 5 days;*Significant

Table (3): Dyspnea and Comfort Score during the Study Period

	Group I Auto EPAP Modality (n=25)				Group II Fixed EPAP Modality (n=25)				P**
	T0	T1	T2	P*	T0	T1	T2	P*	
Dyspnea score	7.9±1.8	4.2±1.3	3.5±1.1	0.001*	7.7±1.9	4.3±1.7	3.4±1.6	0.001*	0.231
Comfort score	6.3±2.1	3.9±2.1	3.4±1.8	0.001*	6.4±1.09	4.9±1.5	3.7±1.6	0.001*	0.002*
Level of satisfaction	6.2±1.9	6.4±1.9	7.9±2.01	0.001*	6.18±1.3	6.2±1.6	7.2±1.9	0.001*	0.002*

Data presented as mean (standard deviation)

Table (4): Ventilatory pattern response recorded during both modalities

Pressure	Auto EPAP (n = 25)	Fixed EPAP (n=25)	p-value
Mean EPAP, cmH2O	10.3±2.1	7.9±3.1	0.002*
Mean IPAP, cmH2O	18.2±3.1	17.1±3.2	0.342
Mean pressure support, cmH2O	9.2±2.1	10.5±1.8	0.002*
Leak, L/minute	2.5±1.3	3.7±2.2	0.001*
95th centile leak, L/minute	16.2±2.1	23.7±3.2	0.001*
Mean respiratory rate, bpm	16.2±4.2	16.3±4.3	0.435
Mean tidal volume, ml	698±213	628±178	0.001*

Data are shown as mean ± standard deviation; EPAP= expiratory positive airway pressure; iVAPS, intelligent volume-assured positive airway pressure support; bpm= breaths per

minute; mL= milliliters; *Significant..

Figures

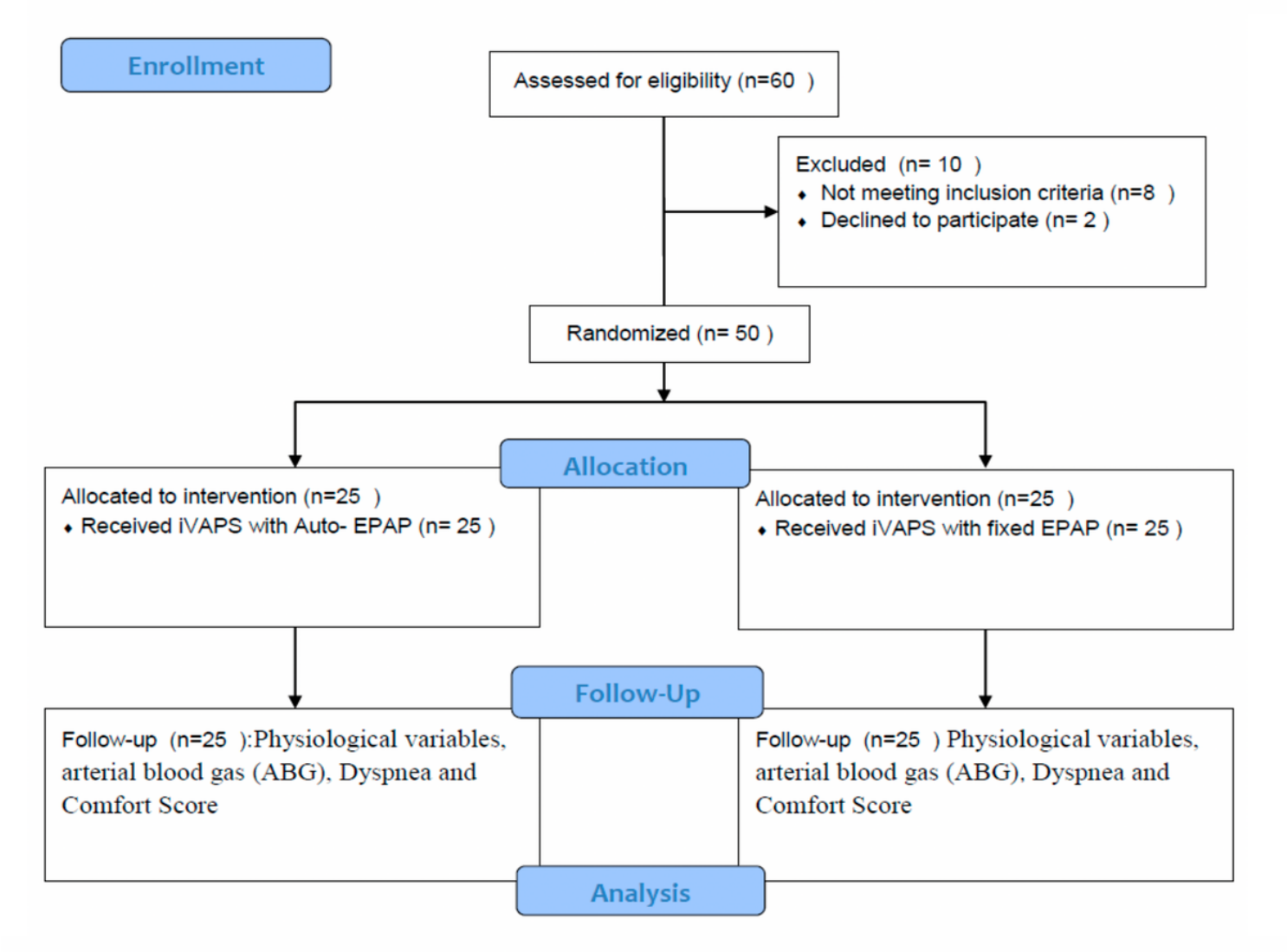

Figure 1

Flow diagram chart

Supplementary Files

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