Original Article

Comparative Analysis of Closed-Loop Ventilation Mode with Conventional Ventilation Modes in Intensive Care Unit Patients

Closed-Loop Ventilation with Conventional Ventilation Modes in ICU

Imran ul Haq[1], Sadia Imran[4], Usman ul Haq[2], Muhammad Fareed Azam[1], Verdah Sabih[1] and Muhammad Ali[3]

ABSTRACT

Objective: To compare the number of manual adjustments and workload between closed-loop ventilation mode IntelliVent®-ASV and conventional synchronized intermittent mandatory ventilation mode in traumatic brain injury.

Study Design: Randomized controlled trial study.

Place and Duration of Study: This study was conducted at the Intensive therapeutic care unit (ITC), POF Hospital, Wah Cantt. P. From November 2018 to April 2019.

Materials and Methods: Total of 100 patients with head injuries admitted in ITC, were selected through consecutive non-probability sampling and randomly allocated into two groups. group A receives closed-loop ventilation and group B synchronized intermittent mandatory ventilation. All ventilation parameters were recorded breath-by-breath and noted at 6 hours intervals and averaged over 48 hours. The number of manual adjustments assesses the workload for the healthcare team. Safety and efficacy were assessed by maintenance and fluctuations of $EtCO_2$ and mortality outcomes.

Results: Number of manual ventilator setting changes required was lower in IntelliVent®-ASV as compared to the conventional ventilation group (7.46 ± 1.54 versus 12.84± 1.59) which was statistically significant (p-value 0.000). Mean $EtCO_2$ reading among IntelliVent®-ASV Group and SIMV Group (35.58+2.12 Vs 33.26+1.48 respectively) shows that mean $EtCO_2$ was better with IntelliVent®-ASV (p-value 0.000). Frequency and percentage of mortality were lower in the IntelliVent®-ASV Group compared to the SIMV group, 4(8%) Vs 12 (24%), which was statistically significant (p-value 0.029)

Conclusion: IntelliVent®-ASV required less manual intervention thereby reducing the workload in ICU.

Key Words: Close loop IntelliVent®-ASV mode, conventional ventilation mode, $EtCO_2$.

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INTRODUCTION

Traumatic brain injury (TBI) is among the leading cause of morbidity and mortality in young patients. In Pakistan where the rate of head injuries is annually 81 per 100,000.[1] Direct brain injury and secondary brain injury disrupt the blood flow to the brain and additional lung pathology can augment this process[2].

[1.] Department of Anesthesia / Maxillofacial Surgery[2] / Surgery[3], Wah Medical College, Wah Cantt.
[1.] Department of Anesthesia, PIMS Islamabad.

Correspondence: Dr. Muhammad Fareed Azam, FCPS Anesthesia Wah Medical College, Wah Cantt.
Contact No: 03335232245
Email: dr.fareed.azam@gmail.com

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Hypoxemia and hyper/hypocapnia by altering the cerebral vessel auto-regulation lead to secondary brain insults, which alter the outcome. [3, 4] Hence, an appropriate mode of Ventilation in head injury patients can help decrease the mortality rate.

Different approaches to artificial ventilation have different specifications in brain injury patients.[5] Maintenance of $PaCO_2$ (partial pressure of CO_2) in arterial blood within its narrow therapeutic range. Traditionally the physicians attending the artificial ventilation (AV) have to regulate the partial pressure through adjustment of minute ventilation volume (MV) as per arterial capnographic data and readings of other blood gases. [6]

The workload on care providers requires continuous availability and monitoring of the ventilation while performing adjustments. Reducing the workload will reduce the chances of human error and save the human resource among healthcare providers. A closed-loop ventilation mode IntelliVent®-ASV adjusts itself automatically in both passive and spontaneous

breathing patients for settings of ventilation and oxygenation.[7]

The safety and efficacy of IntelliVent®-ASV is confirmed through studies and they report its feasibility in ICU.[5] These studies have made agreement regarding the reduction of workload for the ICUs by using closed-loop ventilation modes.[8] IntelliVent®-ASV manages the settings on automatic mode, however, it also introduces new settings of targets for ventilation and oxygenation. When compared to pressure support mode, the requirement of manual ventilator setting was decreased for spontaneously breathing patients in ICU, from 13±11 to 4±3 in 48 hours duration.[9] Using the sensors of pulse oximetry and capnometry that are integrated into the ventilator, INTELLiVENT- ASV® is able to implement an algorithm that adjusts the minute ventilation volume (MV), positive end-expiratory pressure levels (PEEP), and oxygen fraction.

The algorithm is set as per the clinical condition of the patient for target setting and maintenance of end-tidal carbon dioxide pressure at the end of the exhaled breath (EtCO2) and oxyhemoglobin saturation in arterial blood (SpO2) range. In IntelliVent a narrow range of EtCO2 is maintained by the brain injury algorithm with adjustment of MV and thereby levels of targeted SpO_2 are reached with adjustment of fraction of oxygen. IntelliVent-ASV® increases or decreases MV when the value of $EtCO_2$ is outside the set range.[6]

Hence, IntelliVent-ASV was found effective for providing optimal respiration in patients in the post-cardiac surgery phase.[2] This efficacy was also proved in patients suffering from acute respiratory failure and weaning from artificial ventilation.[10,11,12]. It is able to deliver individualized ventilation to decrease workload and reduce weaning duration over short periods of time.[13-16]

Currently, we lack papers that are focused on the IntelliVent®-ASV mode in acute brain injury patients. The aim of our prospective randomized controlled study was to compare the number of manual ventilator settings required with IntelliVent®-ASV versus conventional ventilation mode i.e. Synchronized Intermittent Mandatory Ventilation (SIMV) in ITC patients with severe TBI thereby decreasing workload on ICU caregivers.

The secondary outcome was to evaluate the efficacy and safety of the IntelliVent-ASV mode in the form of maintaining the target range of PaCO2 and efficiency for a higher ventilation variability improving thus oxygenation in these patients, the incidence of mortality and the acceptance of care givers team.

MATERIALS AND METHODS

This randomized, controlled, study was conducted in the Intensive therapeutic care (ITC) unit, at POF Hospital, Wah Cantt. A total of 100 Patients with head injuries admitted in ITC, from November 2018 to April 2019, with expected duration of mechanical ventilation for more than 48 hours were selected through consecutive non-probability sampling and randomly allocated into two groups. Even-numbered patients were allocated automated closed-loop IntelliVent®-ASV mode and odd-numbered patients were given conventional SIMV mode named as group A and Group B respectively.

Inclusion Criteria: Eligible participants were adults aged 18 or over, intubated and mechanically ventilated for less than 24 hours before inclusion with an expected duration of mechanical ventilation of at least 48 hours.

Exclusion Criteria: Exclusion criteria were patients with GCS of 3/15 with a head injury, broncho-pleural fistula, ventilation drive disorder such as Cheynes Stocke's breathing, chronic or acute dyshemoglobinemia, patient with "Do Not Resuscitate" order before inclusion. Informed consent was taken from all the patient's attendants falling in the inclusion criteria.

Each patient was individually assessed and evaluated according to the departmental protocols and ABGs. All ventilation parameters were recorded breath-by-breath. SpO2 was measured with a finger probe i.e., pulse plethysmography. The EtCO2 was measured by a mainstream capnograph connected to the ventilatory circuit. The EtCO2 was measured throughout ventilation. All ventilation parameters were noted at 6 hours intervals and averaged over 48 hours. The data was entered in the Performa.

The number of manual adjustments assesses the workload on the health giver team. Safety and efficacy were assessed by the achievement of previously defined ranges of non-optimal and optimal ventilation among patients of these two groups. Data were analyzed using SPSS Version 25. T-test was employed to compare the two groups and $p \leq 0.05$ was considered statistically significant. User acceptance was assessed by a survey once a day at the end of the day shifts for the critical care nurse and physician in charge of the subject using a Likert Scale (categorical linear scale) ranging from 0 (very easy) to 10 (very difficult).

RESULTS

The age range in this study was from 18 to 60 years with a mean age of 36.74 ± 10.01 years in Group A and 35.8 ± 10.82 years in Group B. In group A 28(56%) were male and 22(44%) were female, and in group B 30(60%) were male and 20(40%) were female

The mean GCS score for each group is given in table-1.

Table No. 1: Mean±SD of patients' GCS Scores in both groups.

GCS	Group-A Mean±SD (n=50)	Group-B Mean±SD (n=50)
Score	5.66 ± 1.17	5.5± 1.18

The diagnosis of the patients enrolled in the study is given in Table 2.

Table No. 2: Frequency & percentage of Diagnosis among both the groups

	Group-A (n=50) Frequency (%age)	Group-B (n=50) Frequency (%age)	Total (n=50) Frequency (%age)
Contusion	8 (16%)	10 (20%)	18 (18%)
Contusion+IVB	0 (0%)	2 (4%)	2 (4%)
Contusion+SDH	1 (2%)	0 (0%)	1 (1%)
DAI	13 (26%)	11 (22%)	24 (24%)
Hypoxic	4 (8%)	5 (10%)	9 (9%)
ICB	4 (8%)	3 (6%)	7 (7%)
IVB	6 (12%)	7 (14%)	13 (13%)
SDH	2 (4%)	0 (0%)	2 (2%)
IVB + SDH	12 (24%)	12 (24%)	24 (24%)

The difference between the numbers of manual adjustments is given in Table 3.

Table No. 3: Mean±SD of Manual Adjustments in both groups.

Work Load	Group-A Mean±SD (n=50)	Group-B Mean±SD (n=50)	p-value
Number of Manual Adjustments	7.46 ± 1.54	12.84± 1.59	0.000

Mean $EtCO_2$ reading among Group-A and Group-B were 35.58+2.12 and 33.26+1.48 respectively, which shows that mean $EtCO_2$ was better within group-A (p-value 0.000)

The frequency and percentage of mortality among the two groups were different with lesser mortality in Group-A, which was also statistically significant.

Table No. 4: Frequency and percentage of mortality among two groups.

Mortality	Group-A	Group-B	Total	p-value
Yes	4 (8%)	12 (24%)	16 (16%)	0.029
No	46 (92%)	38 (76%)	84 (84%)	
Total	50	50	100	

Nurses working in ITC and attending physicians gave their opinion which was in favor of close loop INTELLiVENT®-ASV mode, being easier to use when compared to conventional SIMV mode ventilation. Results reported by nurses were 0 (0-1) versus 1 (0-2) (P<0.001) while results recorded for physicians were 0 (0-1) versus 2 (0-4) (P<0.01), for INTELLiVENT®-ASV and conventional SIMV mode respectively.

DISCUSSION

IntelliVent®-ASV used in this study makes automatic adjustments as per clinical condition and respiratory mechanics.

The reduction in the workload may be extremely valuable in highly busy ICUs.[17] The results of our study also confirm that the number of manual adjustments required with closed loop IntelliVent®-ASV were significantly less than required with conventional SIMV mode, that was 7.46 ± 1.54 manual adjustments Vs 12.84± 1.59 respectively (p-value of 0.001). The results of our study are in line with Arnold JM. et al [19], who reported decreased number of manual settings with IntelliVent®-ASV as compared to conventional ventilation mode. The number of manual ventilator setting changes per 24-hour period per subject was 5 versus 10 manual settings per subject per day (P<0.001) in INTELLiVENT®-ASV Vs. conventional ventilation modes (volume assist control and pressure support) respectively in post-cardiac surgery and spontaneous breathing patients in ICU. A number of previously done studies also confirm this advantage with INTELLiVENT®-ASV.[5,9,11,19,20.]

The result of all these benefits is that with IntelliVent®-ASV, variability of SpO2 (pulse oximetry), PMAX (peak inspiratory pressure), PINSP (inspiratory pressure created by the ventilator), and PEEP (positive end-expiratory pressure) was statistically higher compared to conventional mode. $EtCO_2$ fluctuations can be ranked among the main cause of secondary brain injury causing disease progression. Anan'ev E.P. and co-researchers reported in 2017 that there was no significant difference between the values of EtCO2 and PaCO2 while using the IntelliVent modes and P-CMV.[6] The study reported PaCO2 levels of 36 (35—37) mm Hg and 36 (34—38) mm Hg in the IntelliVent mode and the P-CMV mode respectively (p=0.35). The levels of EtCO2 were 33 (32—37) mm Hg in IntelliVent mode and 34.5 (31—39) mm Hg in P-CMV ventilation mode (p=0.39). Although there were no significant differences reported between PaCO2 and EtCO2 in either mode the spread of the parameters during artificial ventilation (AV) was significantly less using the IntelliVent ventilation. In another study, IntelliVent®-ASV was able to provide more variable ventilation both in terms of PEEP and PINSP. Importantly, this variability was driven by the patient's physiological variability including change of spontaneous breathing activity, neural drive, modification of respiratory mechanics, change of carbon dioxide production etc.[10] Same improvement was found in oxygenation in a cross-over study where comparison of IntelliVent®-ASV was made to pressure support. [11]

In our study, the mean $EtCO_2$ reading was significantly better with IntelliVent-ASV® (p-value 0.000) compared to conventional SIMV. This proves the efficacy of IntelliVent mode over the conventional mode in terms of maintaining $EtCO_2$ and hence preventing any secondary brain injury or a cascade of inflammatory reactions that would have deteriorated the TBI. The spread of the parameters' during AV was also less using IntelliVent ventilation in our study.

This longer time period spent in this optimal zone is also considered safe and protective both against hypoxia as well as hyperoxia. This is thus expected that potential injuries that may be associated with hypoxia or hyperoxia can be decreased with IntelliVent®-ASV.

A study published in June 2016 reported that although the number of mortalities was less in IntelliVent®-ASV during ICU stay, this data was statistically non-significant. Nevertheless, it was stated important for future studies, to either confirm or invalidate these results.[10] Our study also reported number of mortalities less in IntelliVent®-ASV, 4(8%) Vs 12(24%) in group A and Group B respectively. It was statistically significant in our study so it opens the door for further work in this regard.

The caregivers have previously reported both types of ventilation modes as easy to use, however, consistently easier to use was reported INTELLiVENT®-ASV compared to conventional ventilation.[18] In our study opinion was also in favor of INTELLiVENT®-ASV, being easier to use when compared to conventional SIMV mode ventilation. This ease of use is probably due to the automatic adaptation of INTELLiVENT®-ASV settings as per the patient's conditions, decreased requirement of manual changes, and automatic switching between passive to spontaneous breathing mode or vice versa.

CONCLUSION

This study concluded that this closed-loop ventilation required less manual intervention thereby reducing the workload in ICU. It proved to be effective and safe while delivering ventilation in terms of better EtCO2 and less mortality. Moreover, IntelliVent®-ASV is easier to use for caregivers as compared to conventional ventilation modes.

Author's Contribution:

Concept & Design of Study:	Imran ul Haq
Drafting:	Sadia Imran, Usman ul Haq,
Data Analysis:	Muhammad Fareed Azam, Verdah Sabih, Muhammad Ali
Revisiting Critically:	Sadia Imran, Usman ul Haq
Final Approval of version:	Sadia Imran, Imran ul Haq

Conflict of Interest: The study has no conflict of interest to declare by any author.

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