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Risk factors of mortality among COVID-19 patients receiving non-invasive ventilation at Addis Ababa governmental COVID-19 treatment centers

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Abstract

Introduction: *during the global COVID-19 pandemic, non-invasive ventilation has become a widely utilized method for treating patients experiencing acute respiratory failure. Non-invasive pressure ventilation is frequently employed as a standard approach for managing acute respiratory failure resulting from COVID-19 pneumonia, as opposed to invasive ventilation methods. However, there is a lack of research on its effectiveness. Therefore, this study aimed to determine the risk of mortality among COVID-19 patients receiving non-invasive ventilation.* ***Methods:*** *a multi-centric retrospective cross-sectional study was conducted on the records of 402 patients at the Eka Kotebe COVID-19 Center, St. Peter COVID-19 Care Center, and Millennium COVID-19 Treatment Center. The systematic random selection technique was employed in order to select the study unit, and data was extracted from patient charts using a pretested method and validated before being entered into Epi-data Manager 4.6 versions. Descriptive, bivariate, and multivariable analyses were performed using binary logistic regression in SPSS 25. In the multivariate logistic regression, a predictor variable was considered to have a significant connection if its p-value was less than 0.05 at a 95% confidence level.* ***Results:*** *four hundred and two patient records were reviewed during the study period and showed the mean patient´s age was 62.6 years, with male predominance. It revealed that 11.7% [CI: 8.7-15.2] of COVID-19 patients who received non-invasive positive pressure ventilation died, as being critical for COVID-19 patients was a main cause of non-invasive initiation. Patients over the age of 60 were more likely to die among those who received non-invasive ventilation for COVID-19 [AOR = 5.4 95% CI 1.32, 23.1]. Conversely, patients without diabetes were less likely to die [AOR = 0.23 95% CI 0.11, 0.48]. Moreover, patients with a tidal volume greater than 500 ml were more likely to pass away [AOR =2.2 95% CI 1.11,4.43], as were those who were on non-invasive ventilation (NIV) for more than 8 days [AOR = 0.24 95% CI.08, 0.81].* ***Conclusion:*** *the significance of patients who were given non-invasive ventilators ended up dying. Age, diabetes, and high tidal volumes are linked to a higher risk of death. Non-invasive ventilation for over eight days showed a protective effect. Removing factors that caused NIV and ventilated COVID-19 patients' deaths may reduce mortality.*

Introduction

COVID-19 is a global public health calamity caused by coronavirus 2, which causes SARS-CoV-2 (severe acute respiratory syndrome). It predominantly affects the respiratory, gastrointestinal, hepatic, kidney, central nervous system, and endocrine systems of humans, livestock, and other wild animals [1]. The ongoing new coronavirus disease 2019 (COVID-19) pandemic has demonstrated that acute hypoxemic respiratory failure (AHRF) accounts for a large global need for non-invasive ventilation [2]. Non-invasive ventilation (NIV) plays a significant role in the treatment of respiratory failure caused by a variety of factors [3]. For severe acute respiratory syndrome coronavirus 2 coronavirus disease 2019 (COVID-19), non-invasive ventilation was not advised. Related acute respiratory failure [C-ARF] during the pandemic's earliest phase due to the aerosol-generating potential [4, 5] and the inconsistent reports of benefits from previous pandemic experiences [4,6-8]. According to reports, invasive mechanically ventilated COVID-19 patients did badly and had a death rate of greater than 50% [9].

Non-invasive ventilation with pressure outperforms in terms of lowering inspiratory effort and assisting patients with hypercapnia and respiratory acidosis, and it has also been demonstrated to minimize intubation rates [9]. However, NIV can increase the risk of negative outcomes for patients by delaying the adoption of invasive mechanical ventilation. For COVID-19 patients, early intubation was first advised, but it was also linked to a greater fatality rate. Since then, no definite suggestion regarding the best oxygenation or ventilation technique (invasive or non-invasive) to utilize for COVID-19 patients has been made, leaving numerous medical experts in a great deal of ambiguity and increased patient risk is linked to both early and late intubation [10,11]. Non-invasive ventilation ventilation has been proven to be effective in treating seriously ill patients with conditions like chronic obstructive pulmonary disease (COPD), cardiogenic pulmonary edema, obstructive sleep apnea (OSA), and hyper apneic respiratory failure. However, it is not as clear how helpful IV treatment is for managing patients with pneumonia, acute respiratory distress syndrome (ARDS), and COVID-19 specifically. Previous experience using near-infrared spectroscopy (NIRS) during viral pandemics like SARS, MERS, and H1N1 could provide valuable information on how to use it effectively during the COVID-19 pandemic [12]. Asymptomatic to severe ARDS, multi-organ system failure and mortality are all common clinical presentations of COVID-19. The idea that there can be several COVID-19 phenotypes that can explain the variance in clinical presentation needs more support. However, the variation in illness severity and presentation might make initial treatment difficult [13-16].

A ventilator-induced lung injury may result from ventilation with large tidal volumes and higher driving pressures, according to investigations on mechanically ventilated patients with ARDS. In spontaneously breathing patients, we may expect similar consequences if patients are breathing with large driving pressures and large tidal volumes without being appropriately monitored. Based on this concept, the traditional term ventilator-induced lung injury has been modified by some authors into ventilation-induced lung injury, to underline the fact that it is not the ventilator itself injuring the lung, but rather the unprotected ventilation [17]. The use of non-invasive respiratory support (NIRS) (i.e. High-flow nasal cannula (HFNC), Continuous Positive Airway Pressure (CPAP), and NIV) as a viable treatment strategy has sparked controversy due to the considerable mortality rate and longer ventilator days associated with invasive mechanical ventilation (IMV) in patients with severe COVID-19. The relevance of NIRS in reducing intubation in patients with moderate respiratory diseases and the possible positive impacts on patient outcome and resource consumption are at the heart of this discussion. The use of NIRS may delay intubation and lung-protective breathing in patients with more advanced disease, worsening respiratory mechanics through self-inflicted lung injury. This is still a valid problem [18-22].

Methods

Study design and population: a multi-centric retrospective cross-sectional study in Addis Ababa looked at 402 confirmed COVID-19 patients who received NIV ventilator support between Sep 2020 and Oct 2021. The patients' records were extracted from 4 COVID centers, treating a total of 6210 COVID-19 cases. The study included all COVID-19 patients admitted to governmental COVID-19 treatment centers in Addis Ababa who received NIV as initial ventilator support. Patient charts that were incomplete and deaths within two hours of NIV initiation were not included in the analysis.

Sample size determination and sampling technique: to determine the necessary sample size, we used the single population proportion formula with a 5% margin of error, 95% confidence level, and 0.5 proportion of NIV usage and eventually, we got 423 sample sizes. We used proportional sample size allocation to select the final sample from each treatment facility, including the Ekakotebe COVID-19 Center, St. Peter COVID-19 Care Center, and Millennium COVID-19 Treatment Center. To determine the necessary sample size, we used a single population (Figure 1). The systematic random selection technique was used and a strict random sampling process to select patient charts for our study. The sampling interval [K] was determined by dividing the study population of each site by the corresponding sample size, resulting in a value of six [6]. We assessed every sixth chart after the first chart was chosen by lottery.

Operational definition

The average number of positive end-expiratory pressure (PEEP): the average number of PEEP taken from three consecutive day records.

Average number tidal volume: average number of tidal volume taken from three consecutive day records.

Mortality: patient died while he/she was under treatment for NIV.

SPO_2/FiO_2 ratio: = mild SPO_2/FiO_2 ratio 235-314, moderate SPO_2/FiO_2 ratio 150-234 and severe - SPO_2/FiO_2 ratio < 150) [23].

Data collection tools and quality assure: data were gathered using a pretested and structured extraction checklist, developed from patient registration follow-up and based on prior research [7,17-20]. Sociodemographic factors, clinical and laboratory tests, comorbidities, NIV kinds, and outcome variables are all included. The tool was first validated by subject-matter experts. Furthermore, Cornbrash's alpha (=0.86) was used to do the reliability testing. Four data collectors and one supervisor, who were M.Sc. [master of nursing in science] holders, received training on the fundamentals of the checklist and data collection tool to enable them to extract data from patient files.

Data processing and analysis: data was entered into Epi Data 4.4.2.2, checked for accuracy, and exported to SPSS 25 for analysis. Bivariate analysis was used to determine the association between independent variables and mortality on NIV. Variables with p-value ≤0.25 were selected for a multivariable model, an adjusted odds ratio with a 95% confidence interval was used to evaluate the association, with statistical significance at p-value=0.05.

Ethical declaration: the study was approved by the Institutional review board at Saint Paul's Hospital Millennium Medical College. A cooperation letter was obtained from the research directorate to the clinical director of all four COVID Centers, and ethical approval code PM14/4099 was granted for the study. Data collection was carried out with permission from the clinical director and record room officers of each center. The study was conducted in accordance with the Declaration of Helsinki and its amendments. Informed consent was waived due to the retrospective nature of the study and the use of anonymous clinical data.

Results

Socio-demographic characteristics: an overall of 402 patient records were reviewed during the study period, with a response rate of 95%. The study finding revealed that 250 subjects were male [50.5%] and it showed mortality of COVID-19 patients who were supported with non-invasive positive pressure were more common in older (41- 60 years) and >60 years compared to younger ones with female preponderance [female/male = 1.35: 1]. The mean age of the study subjects was found to be 62.6 at 95% CI [61.41,63.83] and SD 12.3 years. The majority of deaths [5.5%] occurred between the ages of [21-23], and regarding of history of smoking, most of them were nonsmokers (Table 1).

Clinical and ventilator parameter of COVID-19 patients: regarding the ventilator parameter 314 (78.1%) cause of non-invasive ventilation (NIV) initiation (commencement] was critical COVID-19 (Figure 2). This study also revealed the mean oxygen saturation/fraction of inspired oxygen (SPO_2/FiO_2) ratio of patients before starting the non-invasive respiratory support was found in severe respiratory failure [95%] according to the Kigali criteria and the most common method of Non-invasive ventilation support for COVID-19 patients was Bi-PAP 344 [85.57%]. Moreover, the study findings revealed that most of the patients

252 [62.68%] were kept on non-invasive positive pressure ventilation for four to seven [4-7] days (Table 2).

Comorbidity: three-hundred and sixteen (316) patients had coexisting medical illnesses, of which 12 (2.9%) had three or more comorbidities and 101 (25.12%) patients had two comorbidities. Diabetes was the commonest comorbidity among others that had been recognized among 41.04% of the study participants, followed by hypertension (37.8%), asthma (11.2%), and COPD (8.2%), and comorbidity classification according to sexual difference females have three or two comorbidities when compeer with male (Table 3).

The magnitude of mortality in NIV: based on the study found, 11.7% at 95% CI (8.7-15.2) of COVID-19 patients had ventilated were NIV died, and of those 344 [85.6%] were ventilated using bi-level positive airway pressure while only 58 [4.45%] of study participants were ventilated by continuous airway pressure (Table 2).

Factors associated with mortality: in bivariate analysis, a variable such as sex, age, cause of initiation, method of ventilation, diabetes mellitus, hypertension, asthma, white blood cell, temperature, tidal volume, and length of stay on NIV was found to be candidate variables for multivariable analysis with a p-value of less than 0.25. Then, multivariable analysis was run by including these variables for confounder adjustment after performing model fitness and other assumption tests. Finally, diabetes mellitus, age greater than 60 years, tidal volume >500ml, and length of stay on NIV>8 showed a statistically significant association with the presence of new-onset diabetes mellitus among COVID-19 patients at a 95% confidence level had significant association with the death on non-invasive ventilation at 95% CI (Table 4). The study findings revealed that patients with diabetes were 3.96 times more likely to die [(AOR=3.96, 95% CI (2.34-78.6)), p=0.001] than those with no diabetes. The odds of mortality were among COVID-19 patients who got an average tidal volume of more than 500ml were 2.23 more likely to die [(AOR = 2.23, 95% CI 1.106, 4.522) p=0.026] than those who had an average tidal volume of less than 500ml. Likewise, patients aged >60 years old were [(AOR=5.4, 95% CI 1.32, 23.26), P=0.024] at an increased risk of mortality on non-invasive positive pressure ventilation compared to their counterparts. Lastly, the odds of mortality on non-invasive positive ventilation were .025 times less likely among those who stay on NIV for greater than eight days [(AOR=0.25, 95% CI .075,0.805), p=0.02*] when compared with patients who stay on NIV for more than <8 days (Table 4).

Discussion

The rate of mortality in COVID-19 patients who need ventilator support (invasive and/or non-invasive) is higher than in those who do not need ventilator support [12]. According to this study, [(11.7%, 95% (CI 8.7-15.2)] of COVID-19 patients who were ventilated with non-invasive positive pressure died. This finding is consistent with the findings of an Italian study on the effectiveness and safety of non-invasive positive pressure ventilation, which found that 12% of patients died in hospitals without intubation [24]. Other studies conducted in Germany (44.8%) and Cameroon (52.8%) reported a higher prevalence of mortality on non-invasive ventilation than the current study result [16]. The difference in the availability of advanced NIV delivery equipment trained human power to manage the use of this mode of management, and management protocol differences in NIV use could be the reason. This finding contradicted the findings of a study conducted in France showing that death of the patient [4%] of 49 patients with CPAP was initiated [25]. This result is incomparable to this study; the possible reason is maybe due to the small sample size in their case. Further, it is also not consistent with a study done on Non-invasive positive pressure ventilation versus endotracheal intubation in the treatment of COVID-19 patients requiring ventilator support that reported mortality of COVID-19 patients on NIV was 69% [95%CI, 59-78%] [5].

This study reported mortality of COVID-19 patients who were supported with non-invasive positive pressure was more common in older [41- 60 years] and >60 years compared to younger ones with female preponderance [female/male = 1.35: 1]. This study resembles a study conducted at Cairo University Hospital a retrospective observational study on COVID-19 patients admitted to ICU, that showed mortality among non-invasive ventilated COVID-19 patients is more likely in older patients than in younger patients overall mortality age between 1-39 [10%) whereas age above 70 (43%) [18]. This study also revealed that bi-level positive airway pressure was the commonest type of non-invasive positive pressure ventilator used to ventilate patients while only 58b(4.45%) of the study, participants were ventilated by continuous airway pressure. This finding was in agreement with a study conducted in Milano and Peru, which found that the majority of patients were supported by Bi-PAP and less by CPAP [26,27]. The study findings revealed that Patients with diabetes were 3.96 times more likely to die [(AOR=3.96, 95% CI (2.34-78.6)), p=0.001] than those with no diabetes. This study is consistence with a study in Italy that showed diabetic mellitus is a risk factor for death, [(AOR 3.67, 95% CI(1.45-7.69) p=0.001] times when compared with those non-diabetics [28], being diabetic was found to be an important risk factor for death in those patients managed by non-invasive positive ventilation, this could be because diabetes mellitus, especially if uncontrolled, has been linked to a weakened immune system, reducing the body's ability to fight infections, including viral infections like COVID-19. Furthermore, diabetics are more likely to have and/or develop another chronic illness than non-diabetics. As a result, every diabetic patient is at risk of developing symptomatic infection and complications from any infectious condition, which could worsen their disease prognosis [29,30].

The average tidal volume and length of stay on NIV are associated with death. According to this study, patients who take a tidal volume of more than 500ml are 69% more likely to die than those who take a tidal volume of less than or equal to 500ml. This finding is consistent with an Italian study that found a high mortality rate among non-invasive positive pressure ventilated patients with high tidal volume, harmful trans-pulmonary pressures, and delayed initiation of IMV [31]. Likewise, patients aged >60 years old were [(AOR=5.4, 95% CI 1.32, 23.26), P=0.024] at an increased risk of mortality on non-invasive positive pressure ventilation compared to their counterparts. This finding is almost consistent with different findings like a meta-analysis published in 2020 and a study conducted in America also identified mortality was more likely among COVID-19 patients who ventilated with non-invasive ventilation and aged >60 years old [32-34]. This result is comparable with a Study done in south India that showed an increase in age-associated mortality among COVID-19 patients those who were ventilated with non-invasive ventilation [(AOR =1.06, 95% CI 1.03-1.08),0.001)[35' p=0.001) [35].

Finally, the odds of mortality on non-invasive positive ventilation were 0.25 times lower in patients who stayed on NIV for more than eight days [(AOR= 0.25, 95 % CI 0.075, 0.805), p=0.02*] compared to patients who stayed on NIV for less than eight days. This finding is comparable to a study conducted in Milan, Italy, which found that the median (IQR) duration of CPAP treatment was 6 [3-10] days, and death of NIV was 22.9% [36-38]. It is consistent. According to a study conducted in south India, the duration of stay on the NIV reduced the mortality of COVID-19 patients [OR, 0.91, 95 % CI, 0.86 to 0.96] [39]. The possibility that staying on NIV for a long period causes a decrease in patient mortality is that those patients who stayed on NIV for a long period may have received endotracheal intubation for advanced support, but this finding only assessed the outcome of patients who were not intubated.

Limitations: first, the lack of differentiation between non-invasive positive ventilation and NIV, in many manuscripts, both CPAP, bi-level positive airway pressure (BIPAP), and NIV were included under the definition of "non-invasive ventilation", and the clinical outcomes [such as mortality] were often intended both for CPAP and NIV. Next, some crucial factors that might have been predictors of mortality may have been overlooked since the chart examination was retrospective. Furthermore, the use of ventilator settings and interfaces, ideal body weight [IBW], obesity, and other relevant data that might have had an impact on mortality were not obtained in this investigation due to unavailability. Finally, this research was restricted to government-run COVID-19 treatment facilities.

Conclusion

In COVID-19 patients ventilated using NIV, the majority of who were ventilated using bi-level positive airway pressure, a considerably greater frequency of mortality was seen. Increased mortality was linked to older age, diabetes, and tidal volumes greater than 500 ml. In COVID-19 NIV ventilated patients, a reduction of risk against death was found to exist for NIV stays longer than eight days. Eliminating such elements that have hastened the death of NIV, ventilated COVID-19 will potentially reduce the mortality of patients.

What is known about this topic

- *Non-invasive ventilation is a common treatment for COVID-19 patients with respiratory failure;*
- *Mortality rates among COVID-19 patients receiving non-invasive ventilation vary depending on various factors;*
- *Identifying risk factors for mortality in this patient population can help improve treatment outcomes.*

What this study adds

- *This study provides specific risk factors for mortality among COVID-19 patients receiving non-invasive ventilation in Addis Abeba, Ethiopia;*
- *The findings of this study can inform clinical decision-making and resource allocation at governmental COVID-19 treatment centers in the region;*
- *Understanding the risk factors for mortality in this patient population can help tailor interventions to improve outcomes.*

Competing interests

The authors declare no competing interests.

Authors' contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis, and interpretation, or in all these areas; took part in drafting, revising, or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted, and agree to be accountable for all aspects of the work. All the authors have read and agreed to the final manuscript.

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Tables and figures

Table 1: socio-demographic characteristics of COVID-19 patients who received non-invasive ventilation at governmental COVID-19 treatment centers of Addis Ababa, Ethiopia 2021

Table 2: clinical and ventilator parameters of COVID-19 patients who received non-invasive ventilation at governmental COVID-19 treatment centers of Addis Ababa, Ethiopia 2021

Table 3: comorbidity of COVID-19 patients who received non-invasive ventilation at governmental COVID-19 treatment centers of Addis Ababa, Ethiopia 2021

Table 4: bivariate and multivariate logistic regression factors associated with mortality of COVID-19 patients receiving non-invasive ventilation at governmental COVID-19 treatment centers in Addis Ababa, Ethiopia, in 2022

Figure 1: shows the flow chart of the study of the study subjects, at governmental COVID-19 treatment centers in Addis Ababa, Ethiopia, in 2022

Figure 2: show the common cause of initiation of non-invasive ventilation method at governmental COVID-19 treatment centers of Addis Ababa, Ethiopia 2021

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Table 1: socio-demographic characteristics of COVID-19 patients who received non-invasive ventilation at governmental COVID-19 treatment centers of Addis Ababa, Ethiopia 2021

Variable	**Category**	**Outcome status**	
		Dead	**Not dead**
Age	≤40	5(1.2)	10(2.48)
	41-60	22(5.5)	131(32.6)
	>60	20(5)	214(53.2)
Sex	Male	20(5)	203(50.5)
	Female	27(6.7)	152(37.8)
History of smoking	Yes	5(1.2)	67(16,6)
	No	42(10.44)	288(71.6)

Table 2: clinical and ventilator parameters of COVID-19 patients who received non-invasive ventilation at governmental COVID-19 treatment centers of Addis Ababa, Ethiopia 2021			
Variable	**Category**	**Outcome status**	
		Dead	**Not dead**
Method of NIV	CPAP	12	46
	Bi-PAP	35	309
Diabetic Mellitus	Yes	30	135
	No	17	220
Cause of initiation	Critical COVID-19	40	274
	Respiratory failure	2	45
	Septic shock	5	36
Temperature	<36.5	27	189
	36.6-37.7	14	136
	>37.8	6	30
Tidal volume	<500	19	194
	>500	28	161
Length of stay NIV	< days	5	58
	4-days	23	229
	>8 days	20	68
SPO2/fio2	Mild	1	8
	Moderate	2	12
	Severe	44	335
PEEP	Mild	34	272
	Moderate	13	83
Key: BIPAP=Bi-level positive airway pressure, CPAP=continuous positive airway pressure, WBC=white blood cell, PEEP=positive end-expiratory pressure, NIV= noninvasive ventilation, SPO2= oxygen saturation			

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Table 3: comorbidity of COVID-19 patients who received non-invasive ventilation at governmental COVID-19 treatment centers of Addis Ababa, Ethiopia 2021

Variable	Category	Outcome status	
		Dead	Not dead
Diabetic mellitus	Yes	30	135
	No	17	220
A comorbidity	Yes	38	278
	No	9	77
Cancer	Yes	4	5
	No	41	350
CHF	Yes	1	22
	No	46	333
Asthama	Yes	7	38
	No	40	317
History of COPD	Yes	7	5
	No	40	350
RVI	Yes	3	30
	No	44	325
Hypertestion	Yes	17	133
	No	30	252

Key: RVI=retrovirus infection, COPD=chronic obstructive disease, CHF=chronic heart failure

Table 4: bivariate and multivariate logistic regression factors associated with mortality of COVID-19 patients receiving non-invasive ventilation at governmental COVID-19 treatment centers in Addis Ababa, Ethiopia, in 2022

Variable	**Category**	**Outcome status**		**OR (95% CI)**	**aOR (95% CI)**	**P-value**
		Dead	**Not Dead**			
Sex	Male	20	203	0.5(0.30,1.03)	1.75(0.86,3.56)	0.122
	Female	27	152	1	1	1
History of smoking	Yes	5	67	1.957(0.95,5.3)	1.43(.47,1.52)	0.539
	No	42	288	1	1	
Method of NIV	CPAP	12	46	0.403(0.21,0.89)	0.64(0.27,1.54)	0.320
	Bi-PAP	35	309	1	1	
Diabetic mellitus	Yes	30	135	2.88(1.53,5.4)	3.96(2.34-78.6)	0.001
	No	17	220	1	1	
Age	< 40	5	10	1	1	0.131
	41-60	22	131	1.711(1.18,10.13)	2.98(0.72,12.3)	
	>60	20	214	4.07(1.18,8.27)	5.4(1.32,23.26)	0.024
Temperature	<36.5	27	189	1.39(0.702,2.75)	1.90(0.89,4.05)	0.994
	36.6-37.7	14	136	0.714(0.272,1.88)	1.01(0.32,3.14)	0.993
	>37.8	6	30	1	1	
Tidal volume	<500	19	194	1	1	0.026
	>500	28	161	1.77(0.96,3.31)	2.19(1.11,4.43)	
Length of stay NIV	< days	5	58	1	1	0.745
	4-days	23	229	0.234(0.08,0.73)	0.827(0.27,2.61)	
	>8 days	20	68	2.93(1.52,5.65)	0.246(0.075,0.81)	0.02

* OD: crude odds ratio, AOR-adjusted odds ratio, CI-confidence Interval, NIV-noninvasive positive pressure ventilation, CPAP: continuous positive airway pressure, Bi-PAP= Bi-level positive airway pressure

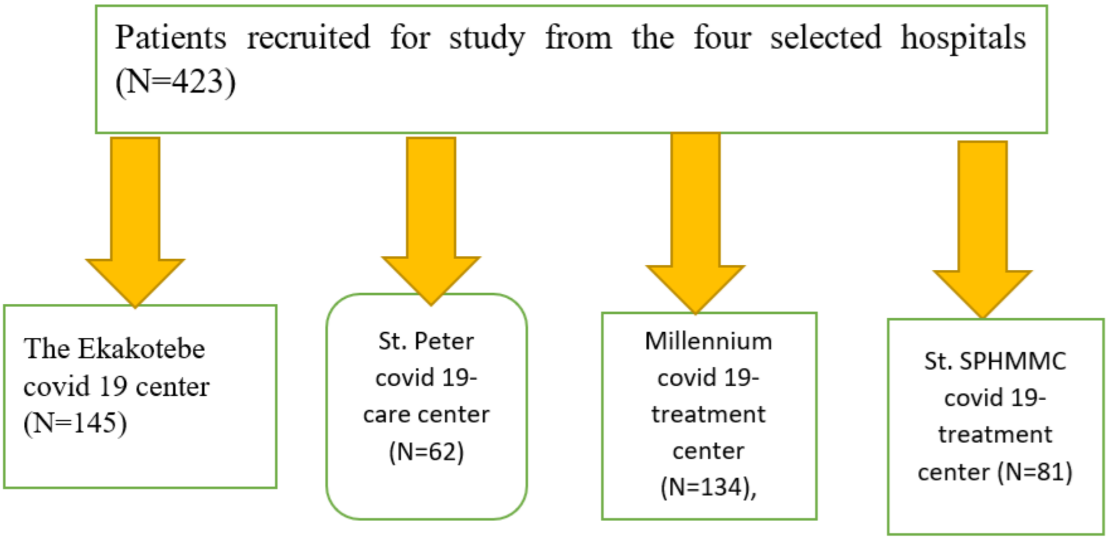

Figure 1: shows the flow chart of the study of the study subjects, at governmental COVID-19 treatment centers in Addis Ababa, Ethiopia, in 2022

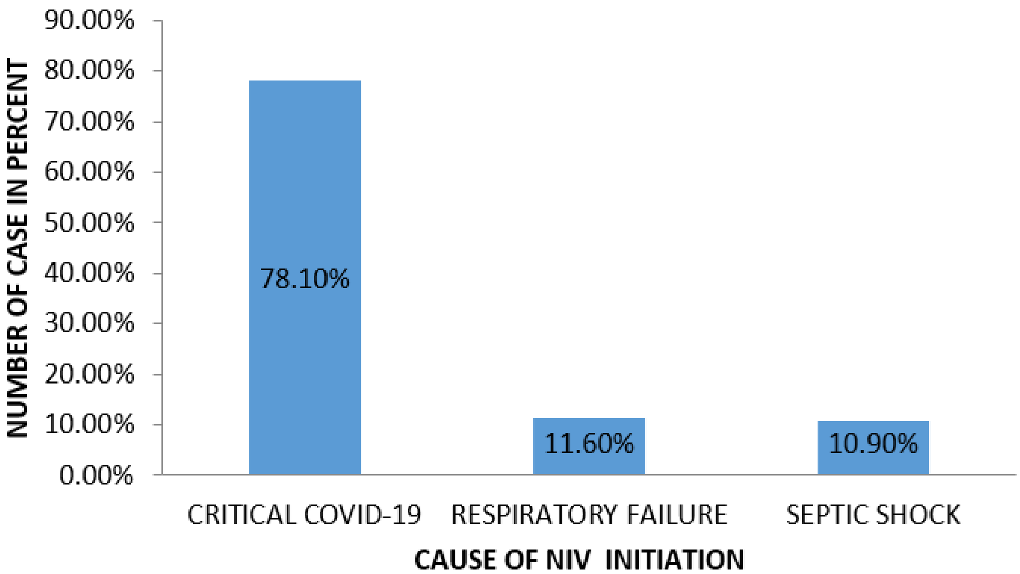

Figure 2: show the common cause of initiation of non-invasive ventilation method at governmental COVID-19 treatment centers of Addis Ababa, Ethiopia 2021