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A STUDY OF CLINICAL PROFILE AND PREDICTORS OF OUTCOME IN CARDIAC PATIENTS WITH PRESERVED EJECTION FRACTION REQUIRING MECHANICAL VENTILATION.

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ABSTRACT

Background:
Acuterespiratoryfailure(ARF)isacommoncauseofadmissiontointensivecareunit(ICU)thatoccursduetosev eralreasons. Among ICU patients, 40-65% patients need mechanical ventilation during theirICUstay. Mechanicalventilation (MV) is cornerstone for management of acute respiratory failure.

Aims and objectives: To determine the clinical profile and predictors ofoutcome in cardiac patients with preserved ejection fractionrequiring mechanical ventilation in a tertiary medical careunitof centralIndia.

Design-Observational longitudinal study.

Methods: This was a longitudinal study conducted in Department of Medicine, Gandhi Medical College, Bhopal. A total of 100 patients in medical ICU requiring mechanical ventilation were included in the study. Data was entered and analyzed.

Results:20.83patientsper100patientsrequiredmechanicalsupportamongthoseadmittedinICU. Mean age was 46.88 ±19.58 years with male (57%) predominance. Association between patient outcome with sepsis ($p<0.001$), Ventilator associated pneumonia ($p<0.001$), presence of pneumothorax ($p<0.001$), extubatuion trial ($p<0.001$) and presence of comorbidities ($p<0.001$) was found to be statistically significant.

Conclusion: This study may contribute to better knowledge of risk factors, better ICU environment, proper use of ventilators and the measures to prevent of complications arising during ventilation that can have a bearing on the patient's outcome.

Keywords: acuterespiratoryfailure, ventilator associated pneumonia, preserved ejection fraction, mechanical ventilation

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INTRODUCTION:

Acuterespiratoryfailure(ARF)isacommoncauseofadmissiontointensivecareunit(ICU)thatoccursduetoseveralreasons,includingpulmonarydisease,neuromusculardisease,shockandtheneedforairwayprotectionandrespiratorysupportaftermajorprocedure[1].Mechanicalventilation (MV) is cornerstone for management of acute respiratory failure[1],.Among ICU patients, 40-65% patients need mechanical ventilation during theirICUstay[2].PatientsreceivingMVrequireacomplex,well–organizedandtechnologicallysophisticatedlevelofcare[2,3].However,despitesignificantadvance in ventilatory support, it remains associated with higher mortality ascompared to those who do not require ventilatory support[4]. Knowledge ofclinical profile of patientsrequiring MV, including condition of patients at thestart of MV, comorbidities, otherfactors developingduring the course of MV,may help to assist clinician in decision making process and better resourcesallocation.[5]

Accordingtowesternliteraturehigher mortality rates arereportedinpatients who require complicated ventilation [5]. The conditions such as acuterespiratory distress syndrome (ARDS), multiple organ dysfunction syndrome(MODS), sepsis, andaspirationpneumonia accounts forhighermortalityrates [6].

Very little data has been published from Indian researchers regarding etiology, course,complication and the outcome in mechanically ventilated patients.

Thus, this study aimed to determine the clinical profile and predictors ofoutcome in patients requiring mechanical ventilation in a tertiary medical careunitof centralIndia.

MATERIALS AND METHODS:

An observational longitudinal study was performed on 100 participants at theDepartment of Medicine, Gandhi Medical College from September 2019 to August 2021.

Permission to conduct the study was obtained from the ethical committee of Gandhi Medical College, Bhopal, MadhyaPradesh. The study was conducted on patients above 18 years of age in medical ICU requiring medical ventilationat Department of Medicine, Gandhi Medical College,Bhopal.

After obtaining informed consent and explaining the purpose of study to the participants, data collection was done and information was recorded on a predesigned, pretested and semi-structured questionnaire.

The questionnaire included information on socio-demographic profile, details of clinical and laboratory investigations. Socio-demographic variables included details on age, gender, contact number, address, etc.

Clinical data included the details of the duration of in-hospital stay, duration of medical ICU stay, duration of stay on MV support, clinical diagnosis, complications and treatment, recordings of the sensorium, body temperature, pulse rate, blood pressure, respiratory rate and the ventilator settings.

Laboratory data including complete haemogram, serum biochemistry, blood, urine and endotracheal aspirate culture and sensitivity reports, chest radiograph, 12-lead electrocardiogram (ECG) other special investigations done as per the needs of the individual patient. The outcome was recorded as discharge or death. All the patients were managed as per the treatment protocols of the institute.

The results thus obtained from clinical/laboratory examinations were recorded and analyzed.

Inclusion criteria: Patients above 18 years of age in medical ICU requiring medical ventilation

Patients below 18 years of age and intubated during CPR were excluded from the study.

Complete haemogram, serum biochemistry, urine analysis, blood urine endotracheal aspirate culture andsensitivity report, chest radiogram and 12 lead electrocardiogram was performed and data was collected.

Statistical analysis:

Data was entered into MS excel 2007, analysis was done with the help of Epi info Version 7.2.2.2.

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Frequency and percentages were calculated. Quantitative variables were expressed as the mean and standard deviation. Categorical data was expressed as percentage. Microsoft office was used to prepare the graphs. Relevant statistical test were applied wherever applicable, wherever needed Yates correction was also done. $P<0.05$ was taken as statically significant.

RESULTS:

Table1:Patient characteristics parameters on admission

Sl. No.	Variables	Minimum	Maximum	Mean	Std. Deviation
1	Age (in years)	18	89	46.88	19.584
2	SpO2 on room air (in %)	56	90	58.25	14.408
3	Haemoglobin (in gm/dl)	5.0	14.2	9.222	1.8571
4	TLC (in cells/dl)	5000	115000	14559.11	14778.757
5	Platelets (in cells/µl)	40000	320000	141779.00	55583.969
6	ESR (in mm/hr)	14	145	44.19	30.319
7	CRP (in mg/l)	9	320	55.58	54.647
8	FBS (in mg/dl)	71	541	137.49	62.375
9	PPBS (in mg/dl)	120	619	218.77	98.203
10	Urea (IN mg/dl)	18	230	82.38	33.665
11	Creatinine (in mg/dl)	.63	9.00	2.5598	1.65885
12	Sr. Bilirubin (in mg/dl)	.30	7.10	1.5461	1.19949
13	SGOT (in u/l)	19	225	62.40	37.534
14	SGPT (in u/l)	10	301	70.44	45.512
15	Sr. Protein (in gm/dl)	5.0	7.0	5.816	.4359
16	S. Albumin (in gm/dl)	2.0	4.0	2.899	.4162
17	Sodium (in mmol/l)	113	145	128.27	6.745
18	Potassium (in mmol/l)	1.60	6.10	3.7289	.92689

A total of 480 patients were admitted in ICU. Out of these,100 patients require mechanical ventilation. Thus,20.83patientsper100patientsrequiredmechanicalsupportamongthoseadmittedinICU.Distribution of study participants on the basis of etiology of respiratory failure have been displayed in figure 1. 22% of participants reported ARDS, followed by septic encephalopathy (21%), pulmonary edema (16%) and septic shock (9%) status epilepticus (7%).

51% of the patients were admitted in ICU for the duration of 3 to 6 days. While 44% of the participants stayed in ICU for 0 to 2 days. Among patients requiring mechanical ventilation, 66% of the patients were successfully discharged while 34% reported mortality. 57% were malewhile43%werefemales. The mean age of study participants was foundtobe46.88 ±19.58 years. Around 41% of study participants were in the age group of 41 to 60 years. While only 10% of participants, each, were aged less than 20years andmore than70years. Table 1 displaysvarious parameterswith theirmeanvalues.

Figure 2 shows that, 32% of patients reported presence of hypertension, 27% were diabetic, 7% reported previous history ofGTCS and12% patients had previous history ofCVA. 6% of them hadCOPD inthe past. Previous history of chronic kidney disease was observed in 7% ofpatientsonmechanical ventilation. Itshould benotedthatinaround40%ofpatients,previoushistoryof any other disease was observed, which included pulmonary tuberculosis, Coronary artery disease, People living with HIV/ AIDS anddoublevalvereplacement.

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Distribution of study participants on the basis of their clinical profile has been depicted in table 2. On general examination, it was observed that abnormal pulse was found to be 64% of patients. 65% of patients hadSpO2 - 60%andless. 56% of patients reported systolic BP within normal limits and91%ofpatients reported diastolicbloodpressurewithinnormal limits. Pallor was found in 39% of patients. 22% reported icterus and37%patientshad edema.56%ofparticipants were stuporous at the time of admission followed by 37% drowsypatients.

Table 2: Distribution of study participants on the basis of their clinical profile

Sl. No.		Variables	Frequency (n=100)	Percentage (%)
General Examination	1	Abnormal Pulse <60 &/ >100 bpm	64	64.0
	2	SpO2onroomair ≤ 60%	65	65.0
	3	SBP<100 &/ >140 (in mmHg)	44	44.0
	4	DBP<60 &/ >100 (in mmHg)	9	9.0
	5	Pallor (Present)	39	39.0
	6	Icterus (Present)	22	22.0
	7	Edema (Present)	37	37.0
Laboratory investigations	1	Hblevels (less than normal range)	98	98.0
	2	TLC levels (abnormal levels)	65	65.0
	3	Platelet levels <1.5 lakhs/ul	66	66.0
	4	ESR levels > 22 mm/hr	74	74.0
	5	CRP levels >10 mg/L	95	95.0
	6	FBS > 126 mg/dl	41	41.0
	7	PPBS > 200 mg/dl	65	65.0
	8	Urea levels > 35 mg/dl	100	100.0
	9	Creatinine levels > 1.3 mg/dl	75	75.0
	10	Bilirubin levels >1.2 mg/dl	51	51.0
	11	SGOT levels > 45 U/L	57	57.0
	12	SGPT levels > 56 U/L	51	51.0
	13	Sr. Protein levels < 6 gm/dl	49	49.0
	14	Sr. Albumin levels < 3 gm/dl	52	52.0
	15	Sodium levels < 135 mmol/l	82	82.0
	16	Potassium levels < 3.5 mmol/l	55	55.0

Only 2 % of participants reported normal Haemoglobin levels. In 65% of patients, TLC levels were >11,000 cells/dl. Around 66% of patients had platelets <1.5 lakhs/ul, 74% patients reported ESR > 22 mm/hr and 95% of patients reported CRP > 10 mg/L. Raised levels of FBS and PPBS were observed in 41% and 65% of the participants respectively. Raised levels of creatinine, Bilirubin, SGOT and SGPT were observed among 75%, 51%, 57% and 51% of patients respectively. Table 2 also shows that, only 51% of patients reported protein levels within normal (6 to 8 gm/dl) limits. 48% of patients reported albumin levels between 3 to 5 gm/dl.Only 18% of study participants had normal (135 to 145 mmol/l) levels of sodium.55%, 31% and 14% of the participants reported potassium levels between <3.5 mmol/l, 3.5 to 5 mmol/l and >5 mmol/l respectively.

Bilateral hazy infiltrates were reported among 87% of study participants on Chest X-ray findings.

Table 3: Distribution of study participants on the basis culture sensitivity

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Sl. No.	Cultures Sensitivity	Frequency (n=100)	Percentage (%)
A	Blood culture		
1	Sterile	64	64.0
2	Acinetobacter	2	2.0
3	Escherechia Coli	1	1.0
4	MRSA	6	6.0
5	Pneumococcal	3	3.0
6	Pseudomonas	8	8.0
7	Staphylococcus	10	10.0
8	Streptococcal pneumoniae	6	6.0
B	Urine culture		
1	Sterile	79	79.0
2	Candida	9	9.0
3	E. Coli	8	8.0
4	Others	4	4.0
C	ET aspirate culture		
1	Sterile	70	70.0
2	Acinetobacter	2	2.0
3	Enterococcus	3	3.0
4	Haemophilus	2	2.0
5	Klebsiella	4	4.0
6	Pneumococcus	3	3.0
7	Psedomonas	2	2.0
8	Salmonella	4	4.0
9	Staphylococcal	4	4.0
10	Streptococcal	3	3.0
11	Others	3	3.0

Table 3 shows the distribution of study participants on the basis of culture sensitivity from blood, urine and endotracheal aspirate. Majority of the study participants reported sterile aspirates from blood (64%), urine (79%) and ET aspirate (70%). Among complications as per our study, 41% of patients reported sepsis, 19% reported Ventilator associated pneumonia, 8% reported bedsores, 17% reported Pneumothorax.

Table 4: Association between various predictors with patient outcome

Sl. No.	Variable	Outcome (n = 100)			χ^2 (p- value)
		Death (34)	Discharge (66)	Total	
1	Sepsis (Present)	23	19	42	13.910 (<0.001)
2	VAP (Present)	13	6	19	12.385 (<0.001)
3	Pneumothorax (Present)	16	1	17	32.988 (<0.001)
4	Extubation trial	1	47	48	41.903 (<0.001)
5	Age (>50 years)	27	51	78	0.060 (0.807)
6	Comorbidities (Present)	29	12	41	41.782 (<0.001)

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Table 4depictsassociationbetween various predictors andPatient Outcome.p<0.001depicts thattheassociation of patient outcome with sepsis is statisticallysignificant. Similarly, significant association was observed between patient outcome with Ventilator associated pneumonia, presence of pneumothorax, extubation trial and presence of comorbidities.

Figure 1: Distribution of study participants on the basis of etiology of respiratory failure

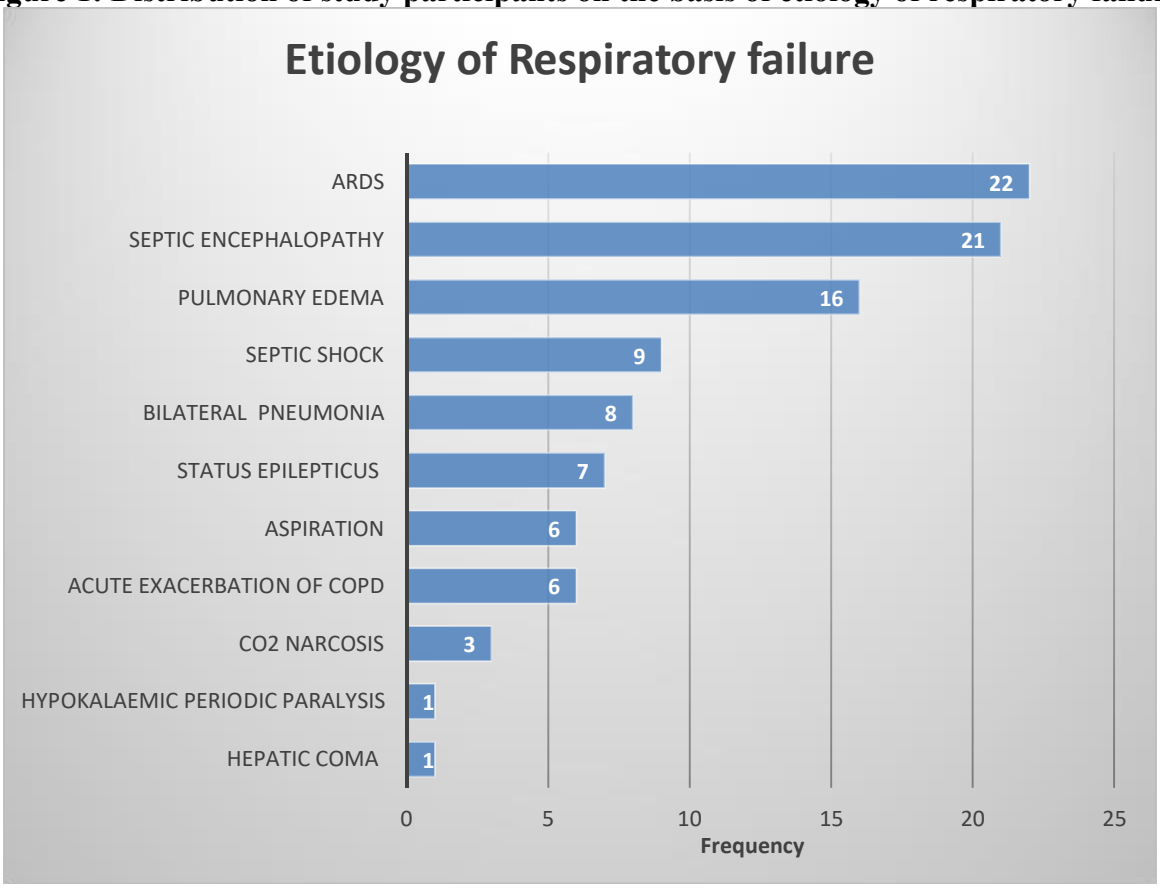

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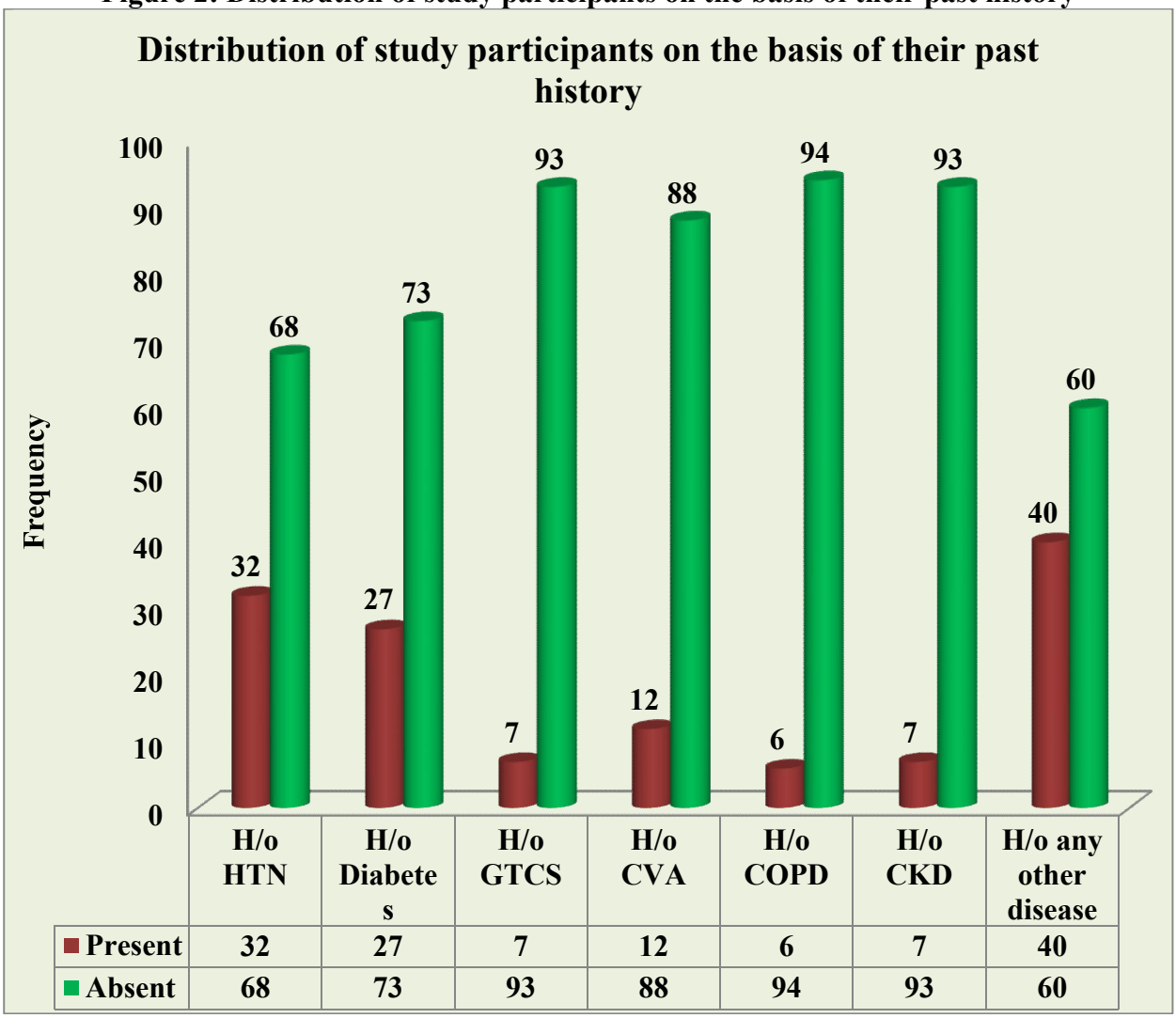
Figure 2: Distribution of study participants on the basis of their past history



DISCUSSION:

A total of 480 individuals were hospitalized to the medical intensive care unit during the course of our research. 100 of them needed to be ventilated with invasive mechanical ventilation. Ventilatory support was needed in 20.83% of patients admitted in the medical ICU of Hamidia hospital, Bhopal. Similar results were observed in a study by **Khalid Ismail Khatib et al**[7]2018 in Indian ICU, examined the clinical characteristics of 122 patients (24%) who received MV out of 500 patients admitted to ICU. While dissimilar results were observed in a 2015 study **by Mohamed A. Zamzam et al**[8]el-mahala hospital Egypt, 130 patients out of 412 were brought to the ICU and given MV, either invasive MV (40%) or noninvasive MV (50.7%), with 9.2 percent of the patients experiencing noninvasive failure and required shifting to invasive ventilation. **Luciano CP Azevedo et al**[4]2013 in brazilian intensive care unit**,** conducted a multicentre prospective cohort study, a total of 622(80%) patients required MV out of 773 patients admitted to ICU. According to **T D Sudarsanam et al**[9]department of medicine at Christian Medical College in Vellore, 200 of the 400 medical ICU patients required invasive mechanical ventilation.

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In our study, hospital mortality rate of patients who required mechanical ventilation (MV) was 34% while 66% patients were successfully discharged. Factors associated with increased mortality included conditions present before the start of ventilation as well conditions developing during course of MV. The underlying diseases which required initiation of MV were themselves found to be the major attributing factor for mortality in patients on invasive mechanical ventilation.

The underlying diseases, which included ARDS (22%), sepsis (21%), pulmonary edema (11%), septic shock (9%) and bilateral pneumonia (8%) were found to be the main reason for initiation of MV. According to a study by **Luciano CP Azevedo et al[4]**in2013, pneumonia (27 %), neurologic diseases (19 %), and non-pulmonary sepsis (12 %) were the most common reasons for ventilatory support in a Brazilian intensive care unit. In a retrospective study conducted in north India by **Ritesh Agarwal et al[10]** in 2006, it was discovered that out of 180 patients requiring MV 140 patients had ARDS and 40 patients had ALI. Dissimilar to our findings, in prospective study published in 2014 by **Georgene Singh et al[11]**, sepsis (34.6%) was found to be the most common etiology.

As per our study, it was observed that maximum (51%) of the patients were admitted in ICU for the duration of 3 to 6 days. While 44% of the participants stayed in ICU for 0 to 2 days.

There was a study by **Michael L et al[12],** in2000,univariate analysis showed a higher mortality rate among those patients who required > 72 h of mechanical ventilation (37% vs 16%; $p < 0.01$), those without previous episodes of mechanical ventilation (33% vs 11%; $p<0.01$). In our study, however, there is no significant association between duration of MV and patient outcome (p value =0.9166).

In present study hospital mortality was 34% and 66% patients were successfully discharged. This was similar to a study by **Chih-Cheng Lai et al[13]**2016**,** where it was found that in-hospital mortality for patients requiring MV was 17%. Whereas, there was a study by **Sharlene Ho et al[14]**atTan Tock Sang Hospital Singapore in 2020**,** which observed that 64% of patients had 180 days mortality who required MV. In a study by **Lea Fialkow et al[1]**in 2016 the mortality rate was 51% in MV patients. **T D Sudarsanam et al[9]**2005**,** found that mortality rate of patients who required MV was 71.5% (143out of 200 patients). Factor associated with variability in published mortality rates for patients with respiratory failure requiring MV may be due to difference in patient's characteristics, severity of disease as well as complications arising during the course of illness.

In our study at the time of admission, 56 percent of participants were stuporous, followed by 37 percent patients drowsy in our study**. Mohame A. Zamzam et al[8]**published a study in 2015, finding that initiation of invasive MV linked to a low Glasgow coma scale. Low Glasgow score also linked to higher mortality similar to findings in our study.

Among complications as per our study, 41% of patients reported sepsis, 19% reported Ventilator associated pneumonia, 8% reported bedsores, 17% reported Pneumothorax. **T D Sudarsanam et al[9] 2005,** reported complications that were seen in the patients included tube block in 19 patients (9.5%), nosocomial pneumonia in 53 (26.5%), nosocomial sepsis 3 (1.5%) and other complications in 4 (2%).

In present study, 13/100 cases complicated with VAP reported death as outcome. The association was found to be statistically significant ($p<0.001$). Similarly, 16% cases complicated with pneumothorax reported death as outcome out of 100 participants. The association between outcome with pneumothorax was found to be statistically significant ($p<0.001$). Association between Sepsis and Patient Outcome was found to be statistically significant, $p<0.001$. A study by **Lea Fialkow et al[1]**in 2016 also found the following variables to be independently associated with mortality - age (hazard ratio:1.01; $p<0.001$); acute lung injury/acute respiratory distress syndrome (hazard ratio:1.38; $p=0.009$), sepsis (hazard ratio:1.33; $p=0.003$), chronic obstructive pulmonary disease (hazard ratio:0.58; $p=0.042$), and pneumonia (hazard ratio:0.78; $p=0.013$) as causes of mechanical ventilation.

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41% of participants were found to have comorbidities in current study. 29% out of 41% reported mortality. Association between comorbidities and patient outcome was found to be statistically significant. A study by **Chih-Cheng Lai et al**[13]2016**,** 408 cases reported mortality out of 1311 invasive mechanical ventilated patients who had comorbidities. **Luciano CP Azevedo et al**[4]2013**,** in multivariate analysis showed that – age, confidence interval, comorbidities were independently associated with mortality in MV patients. Also, there was the study by **Michael L et al**[12]2000, where with multiple logistical regression, associated comorbidities were independent predictor of poor outcome in MV patients.

In our study, extubation trial was attempted in around 48% of participants. On calculation of association between attempted extubationtrial with Patient Outcome, it was found to be highly significant with $p < 0.001$. There was the study by **Michael L et al**[12]2000**,** Univariate analysis showed a higher mortality rate among those patients with a failed extubation attempt (36% vs 7%; $p = 0.0001$).

In our study, insignificant association was observed between age of the patients >50 year with patient outcome as per our study. Contrary to our finding, **Sharlene Ho et al**[14]in 2020 found that age predicted 180 days mortality.**Chih-Cheng Lai et al**[13]2016**,** foundstatistically significant association between age more than 80 year and patients receiving invasive MV with $p<0.05$. A study by **Brun-Buisson C et al**[15] conducted in 2000, found that mortality was associated with age (odds ratio=1.2 per 10 year;95% confidence interval:.05-1.36).

CONCLUSION:

Patients who require mechanical ventilation are likely to have a more serious disease and therefore have higher death rates as compared to other ICU patients. With the increase in availability of MV facility, the number of ICU provided with the respiratory support is expected to increase day by day.

Therefore, this study on patients with MV,was conducted to understand the factor that can aid in improving the outcome in MV patients.

Outcome of MV patients are multifactorial dependant, these factor may be present before MV initiation as well as develop after onset of MV, some of these factors may include previous history of hypertension (HTN), diabetes mellitus (DM), coronary artery disease (CAD). Sepsis and ventilator-associated pneumonia were found to be strongly associated with poor outcome in our study. Similarly, extubation trials were found to be associated with good outcome in our study.

This study may, thereby, contribute to better knowledge of risk factor that can have a bearing on the patient's outcome. Things like a better ICU environment for dealing with critical patients in the acute stage, regular training for ICU staff on opt use ventilators and the measures to prevent of complications arising during ventilation, may improve the final outcome of patients.

*Limitation:*The ICU was at tertiary care hospital that admits patients with more severe illness,so the interpretation of result may not generalize to other ICU patients. Also, this was an observational study with no intervention. A prospective longitudinal investigation may be needed to confirm the relationship between various risk variables.

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