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Effectiveness of nasogastric feed fortified with orange juice on the duration of mechanical ventilation and sepsis among intubated patients admitted in critical care units of GGSMC&H, Faridkot, Punjab: A randomized control trial

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Abstract
Context: The critically ill patient's composite persons in a complex environment. The intubated patients on ventilator support are those who maintain a continuous offensive response and acquired various immunosuppressive disorder and infections because of compromised nutritional status. These nosocomial infections extend the duration of mechanical ventilator dependence and enhance infections level up to sepsis. Nutritional support is essential for such type of patients to enhance their muscle strength immunity of body. In view of compromised situation, the administration of vitamin C by any route can be adjuvant therapy to boost immunity of patients.
Aims and Objective: The study aims to assess the effectiveness of nasogastric feed fortified with orange juice on the duration of mechanical ventilation and sepsis among intubated patients admitted in critical care units. The objective was to assess the pre and post interventional level of mechanical ventilation dependence and sepsis and to compare the mechanical ventilation dependence and sepsis among interventional and conventional group.
Methodology: A quantitative research approach was used to carry out a randomized control trial design to assess the effectiveness of nasogastric feed fortified with orange juice on the duration of mechanical ventilation and sepsis among intubated patients .A convenient sampling was used to select the 60 subjects as per inclusion and exclusion criteria and randomly allocated 30 in each interventional and conventional group. A self-structured socio-demographic profile sheet, clinical profile sheet and standardized SOFA score tool used for assessment of duration of mechanical ventilation and sepsis status was used to assess the variables under study.
Results: The study results revealed that out of 60 subjects were with mean age 41.5± 0.63. More than half subjects were male (71.7%), married (70%), unemployed (51.7%) and were living in joint family (56.7%). As per pre interventional assessment less than half subjects were having PaO2 score (35%) under 75-100 mmHg and >100 mmHg and FiO2 score (55%) under 81-100% among interventional and conventional group as per SOFA score scale. Out of 60 subject 15(50%) were having 2.1-3 score as per SOFA score. As per post assessment more than half subjects were having PaO2 score (55%) under 75-100 mmHg and FiO2 score (53.3%) under 21-50% among interventional and conventional group as per SOFA score scale. Out of 60 subject 22(36.6%) were having 1.1-2 score as per SOFA score among interventional and conventional group. Nasogastric feed fortified with orange juice has shown significant effect on the duration of mechanical ventilation and sepsis score among intubated patients at $p<0.05$.
Conclusion: The study concluded that nasogastric feed fortified with orange juice was effective in reducing the duration of mechanical ventilation and decrease the occurrence of sepsis among intubated patients in the critical care units.

Keywords: Orange juice, sepsis, critical care unit, mechanical ventilation, intubated patients

Introduction
The critically ill patient is a composite person in a complex environment. The prevalence of critical illness has increased, and individuals suffering from critical illness became complex and develop various neurological, endocrine, cardiovascular, metabolic, immunologic, and

muscular disorders [1]. Patients with critical illness are those who maintain a continuous offensive response; humoral, hormonal, immunosuppressive and neuromuscular disorders with reduced immunity which lead to various infections and sepsis [2].

In critically ill patient requiring prolonged dependence on mechanical ventilation after acute illness or injury and respiratory failure [3, 4].

Today, the management of sepsis remains a challenge in the intensive care unit (ICU). In fact, sepsis effect about 35% of patients in the ICU, with almost 25% of these patients dying as a result of the syndrome [5].

Sepsis is the body's profuse and life-threatening response to infection which can lead to organ failure, tissue damage and death. Immune chemicals released in the blood to combat infection cause widespread inflammation, which leads to blood clots and leaky vessels. This decreases blood flow, which damages the body's organs [6]. Sepsis is a common fatal disease and is essentially an exaggerated inflammatory response [7].

Critical illness is often associated with a hyper metabolic state and increased nutritional requirements. Enteral nutrition represents the most physiological and common way of feeding [8]. Enteral nutrition improves gastrointestinal blood flow, preserves the intestinal mucosal structure, stimulates enzymatic processes, maintenance of barrier function to enhance immune response and preservation of tight cell junctions to reduce permeability [9].

Nutritional support is essential for mechanically ventilated patients to meet their energy requirements and to maintain or even to enhance their muscle strength for facilitating ventilator weaning [10].

Vitamin C protect various microvascular functions, improve capillary blood flow, microvascular permeability barrier, and arteriolar receptivity to vasoconstrictors and vasodilators. Ascorbic acid also prevents and reverses the misdistribution of blood flow in capillaries of septic models [11].Vitamin C treatment reduced resuscitation volume and resulted in better gas exchange and less days on mechanical ventilation [12]. Orange juice is a strenuous source of vitamin C, a water-soluble vitamin that act as a powerful antioxidant and plays a central role in immune function. Antioxidants in orange juice promote health by preventing oxidative damage, an imbalance between antioxidants and free radicals [13].

Methodology

Research Approach: In this study, Quantitative research approach was used.

Research Design: In this study, Randomised control trail was used.

Study area: Study was conducted in selected critical care units of GGSMC&H, Faridkot Punjab.

Sample: The study was conducted among the patients with intubated on mechanical ventilation receiving nasogastric feed admitted at selected critical care units of GGSMC&H, Faridkot, Punjab.

Sample Size: In this study total sample size was 60 (30 each in interventional and
conventional group)

Sampling Technique: In this study convenient sampling technique was used.

Tool: The socio demographic variables, Clinical Profile sheet, SOFA (Sequential Organ Failure Assessment) Assessment sheet was used to collect data from the intubated patients.

Ethical Consideration: The ethical approval was taken from the ethical committee of Baba Farid University of Health Sciences, Faridkot. The permission to conduct study in the hospital was taken from the Medical Superintendent, GGSMCH&H, Faridkot.

The subjects or the subject's attendants were explained regarding the intervention and informed consent was taken. The confidentiality of the patients was maintained.

Data Collection: Data was collected from the intubated patients admitted in the critical care units of GGSMC&H, Faridkot. The study participants were selected according to the inclusion and exclusion criteria. All the information about the study was provided to the patient and the patient's relatives before taking informed consent. As per the criteria, pre-assessment was done. After pre assessment, the patients in interventional group were provided with nasogastric feed fortified with orange juice was given to interventional group two time a day for 5 days.150 ml of orange juice given to patient at a time of feeding. On the other hand, conventional group was only assessed for routine care was provided.

Result

Table 1: Frequency and Percentage distribution of intubated patients as per socio demographic characteristics among interventional and conventional group. N=60

S. No.	Variables	Conventional group (n=30) f(%)	Interventional group (n=30) f (%)	Total (N=60) F(%)	$\chi 2$	df	p-value
1.	**Age**						
	20-40	16(53.3)	13(43.3)	29(48.3)	2.947	02	0.229NS
	41-60	08(26.7)	14(46.7)	22(36.7)			
	61-80	06(20)	03(10)	09(15)			
2.	**Gender**						
	Male	21(70)	22(73.3)	43(71.7)	0.82	01	0.774NS
	Female	09(30)	08(26.7)	17(28.3)			
3.	**Marital status**						
	Married	24(80)	18(60)	42(70)	4.826	02	0.90NS
	Unmarried	3(10)	10(33.3)	13(21.7)			
	Divorced/separated	00(0)	00(0)	00(0)			
	Widower/widow	03(10)	02(6.7)	05(8.3)			

4.	**Education**						
	Graduate	00(0)	02(6.7)	02(3.3)	9.302	04	0.054NS
	Secondary	04(13.3)	10(33.3)	14(23.3)			
	High school	05(16.7)	04(13.3)	09(15)			
	Primary	10(33.3)	11(37.7)	21(35)			
	Illiterate	11(36.7)	03(10)	14(23.3)			
5.	**Occupation**						
	Government employee	00(0)	00(0)	00(0)	1.981	02	0.371NS
	Private employee	3(10.0)	05(16.7)	08(13.3)			
	Unemployed	14(46.7)	17(56.7)	31(51.7)			
	Labourer	13(43.3)	08(26.7)	21(35)			
6.	**Family type**						
	Nuclear	11(36.7)	15(50)	26(43.3)	1.086	01	0.297NS
	Joint	19(63.3)	15(50)	34(56.7)			
7.	**Family income per month**						
	≥40,000				3.533	02	0.171^{NS}
	30,000-39,000	00(0)	00(0)	00(0)			
	20,000-29,000	00(0)	00(0)	00(0)			
	10,000-19,000	07(23.3)	13(43.3)	20(33.3)			
	<10,000	16(53.3)	14(46.7)	30(50)			
		07(23.3)	03(10)	10(16.7)			
8.	**Dietary habits**						
	Vegetarian	17(56.7)	14(46.7)	31(51.7)	0.601	01	0.438^{NS}
	Non-vegetarian	13(43.3)	16(53.3)	29(48.3)			

Mean age = 41.5± 0.63
NS=Non-significant (p value >0.05)

Table 2: Clinical profile of patient with Frequency and percentage distribution of mechanical ventilation patients according to the clinical profile. N=60

Sr. No.	Variables	Conventional group (n=30) f(%)	Interventional group (n=30) f(%)	Total (N=60) F(%)	$\chi 2$	df	p-value
1.	**Diagnosis**						
	Medical	21(70)	16(53.3)	37(61.7)	1.763	01	0.184 NS
	Surgical	09(30)	14(46.7)	23(38.3)			
2.	**Co-morbidities**						
	None	21(70)	20(66.7)	41(68.3)	1.024	02	0.599 NS
	Medical	09(30)	09(30)	18(30)			
	Surgical	00(0)	01(3.3)	01(1.7)			
3.	**Reasons for mechanical ventilation**						
	Respiratory failure	10(33.3)	03(10)	13(21.7)	7.569	03	0.56 NS
	Respiratory distress	08(26.7)	12(40)	20(33.3)			
	Unconscious	12(40)	12(40)	24(40)			
	Respiratory arrest	00(0)	03(10)	03(5.0)			
4.	**Total days of mechanical ventilation**						
	<7 days	01(3.3)	05(16.7)	06(10)	4.98	03	0.17 NS
	7-14 days	15(50)	17(56.6)	32(53.3)			
	15-21 days	13(43.3)	08(26.6)	21(35)			
	>21 days	01(3.3)	00(0)	01(1.7)			
5.	**ABG Ph**						
	≤7.35	14(46.6)	11(36.6)	25(41.6)	0.693	02	0.70 NS
	7.36-7.45	14(46.6)	16(53.3)	30(50)	4.44	02	0.10 NS
	>7.45	02(6.6)	03(10)	05(8.3)			
	PaCO2						
	≤35 mmHg	02(6.6)	07(23.3)	09(15)	0.863	02	0.649 NS
	36-45 mmHg	14(46.6)	08(26.6)	22(36.6)			
	>45 mmHg	14(46.6)	15(50)	29(48.3)			
	HCO3	04(13.3)	06(20)	10(16.6)			
	≤22 meQ/L	12(40)	09(30)	21(35)			
	22.1-26 meQ/L	14(46.6)	15(50)	29(48.3)			
	>26 meQ/L						
	PaO2	13(43.3)	05(16.6)	18(30)	5.08	02	0.078 NS
	≤75 mmHg	09(30)	13(43.3)	22(36.6)			
	75.1-100 mmHg	08(26.6)	12(40%)	20(33.3)			
	>100 mmHg						
6.	**Urine output**						
	<800ml/day	02(6.6)	01(3.3)	03(05)	1.19	02	0.55 NS
	800-2000 ml/day	14(46.6)	18(60)	32(53.3)			

	>2000 ml/day	14(46.6)	11(36.6)	25(41.6)			
7.	**SpO2**						
	<100	02(6.6)	01(3.3)	03(05)	0.35	01	0.55 NS
	100	28(93.3)	29(96.6)	57(95)			
8.	**Hb**						
	≤12 g/dl	23(76.6)	23(76.6)	46(76.6)	1.07	02	0.58 NS
	12.1-16 g/dl	07(23.3)	06(20)	13(21.6)			
	>16 g/dl	00(0)	01(3.3)	01(1.6)			
9.	**WBCs**						
	≤4,000 cells/mm3	00(0)	01(3.3)	01(1.6)	1.02	02	0.598 NS
	4.1,000-10,000 cells/mm3	11(36.6%)	11(36.6%)	22(36.6)			
	>10,000 cells/mm3	19(63.3)	18(60)	37(61.6)			
10.	**Hematocrit (HCT)**						
	≤36%	21(70)	18(60)	39(65)	2.03	02	0.36 NS
	36.1-52%	08(26.6)	12(40)	20(33.3)			
	>52%	01(3.3)	00(0)	01(1.6)			
11.	**RBCs**						
	≤3.51X1012/L	08(26.6)	09(30)	17(28.3)	0.08	1	0.77 NS
	3.6-5.5 X1012/L	22(73.3)	21(70)	43(71.6)			
	>5.5 X1012/L	00(0)	00(0)	00(0)			
12.	**PLT**						
	≤150 X109/L	14(46.6)	14(46.6)	28(46.6)	1.03	02	0.59 NS
	151-450 X109/L	16(53.3)	15(50)	31(51.6)			
	>450 X109/L	00(0)	01(3.3)	01(1.6)			
13.	**LFT**						
	≤0.3 mg%	03(10)	01(3.3)	04(6.6)	2.80	02	0.24 NS
	0.4-1.1 mg%	15(50%)	21(70%)	36(60)			
	>1.1 mg%	12(40)	08(26.6)	20(33.3)			
14.	**Sodium**						
	≤135 meq/l	05(16.6)	11(36.6)	16(26.6)	3.15	02	0.206 NS
	136-155 meq/l	23(76.6)	17(56.6)	40(66.6)			
	>155 meq/l	02(6.6)	02(6.6)	04(6.6)			
15.	**Chloride**						
	≤98 meq/l	00(0)	02(6.6)	02(3.3)	3.51	02	0.17 NS
	99-107 meq/l	27(90)	22(73.3)	49(81.5)			
	>107 meq/l	03(10)	06(20)	09(15)			

NS=Non-significant (p value >0.05)

Table 3(a): Frequency and percentage distribution of pre-interventional assessment of mechanical ventilation dependence among intubated patient in conventional and interventional group as per SOFA score. N=60

Pre-interventional assessment			
Variable	**Conventional group(n-30)**	**Interventional group (n-30)**	**Total N=60**
	f(%)	**f(%)**	**F(%)**
PaO2			
<75	13(43.3)	05(16.6)	18(30)
75-100	08(26.6)	13(43.3)	21(35)
>100	09(30)	12(40)	21(35)
FiO2			
<21	00(0)	00(0)	00(0)
21-50	05(16.6)	02(6.6)	10(16.6)
51-80	08(26.6)	12(40)	17(28.3)
81-100	17(56.6)	16(53.3)	33(55)

Table 3(a) revealed that the pre-interventional assessment of mechanical ventilation dependence. Maximum subject PaO2 75-100 were 13 (43.3%), less than half subject >100 were 12(40%) follow by <75 were 5(16.6%), in the interventional group while in the conventional group maximum <75 were 13(43.3%), less than half subject 75-100 were 8 (26.6%) and few subject >100 were 9 (30%). The interventional group, maximum subject 16 (53.3%) had 81-100, less than half subject 12(40%) had 51-80, few subject 2(6.6%) had 21-50 for FiO2, while in the conventional group maximum subject 17(56.6%) had 81-100, less than half subject 8(26.6%) had 51-80 and few subject 5(16.6%) had 21-51 FiO2.

Table 3(b): Frequency and percentage distribution of pre-interventional assessment of sepsis score among conventional and interventional group as per SOFA score N=60

Pre-interventional assessment			
Variable	**Conventional group (n- 30)**	**Interventional group (n-30)**	**Total N=60**
	f(%)	**f(%)**	**F(%)**
SOFA Score			
0-1	00(0)	00(0)	00(0)
1.1-2	11(36.6)	06(20)	17(28.3)
2.1-3	15(50)	15(50)	30(50)
3.1-4	02(6.6)	08(26.6)	10(16.6)
4.1-5	01(3.3)	01(3.3)	02(3.33)
>5	01(3.3)	00(0)	01(1.6)

Table 3(b) illustrate that there was maximum SOFA score 15(50%) in 2.1-3, less than half subject 11(36.6%) in 1.1-2 and few subject 02(6.6%) in 3.1-4, 01(3.3%) in 4.1 to 5 and 01(3.3%) in >5 category in the conventional group. The interventional group shows that maximum subject SOFA score 15(50%) in 2.1-3, less than half subject 8(26.65) in 3.1-4 followed by 06(20%) in 1.1-2 and few subject 01(3.3%) in 4.1 -5 category.

Table 4 (a): Assessment of effectiveness of nasogastric feed fortified with orange juice on mechanical ventilation dependence as per SOFA score among interventional group at day 1 and day 6. N=30

	Variables	Assessment		Total	$\chi 2$ df p-value
		Day 1 f(%)	Day 6 f(%)		
Interventional group	**PaO2**				
	<75	05(16.6%)	01(3.3%)	06(10%)	3.20
	75-100	13(43.3%)	17(56.6%)	30(50%)	2
	>100	12(40%)	12(40%)	24(40%)	0.201NS
	FiO2				
	<21	0(0%)	03(10%)	03(5%)	38.54
	21-50	02(6.6%)	22(73.3%)	24(40%)	3
	51-80	12(40%)	5(16.6%)	17(28.3%)	0.00**
	81-100	16(53.3%)	00	16(26.6%)	

** Highly Significant at $p<0.05$

Table 4(a) In conclusion, the nasogastric feed fortified with orange juice shows non-significance (0.201) in the post assessment score of PaO_2 at $p>0.05$ and FiO2 shows significant (0.00) in the post assessment score at $p<0.05$.

Table 4(b): Assessment of effectiveness of nasogastric feed fortified with orange juice on the sepsis score as per SOFA score among interventional group at day 1 and day 6. N=30

	Variables	Assessment		Total	$\chi 2$ df p-value
		Day 1f(%)	Day 6 f(%)	F(%)	
Interventional group	**SOFA score**				
	0-1	00	03(10)	03(5)	20.84
	1.1-2	06(20)	20(66.6)	26(43.3)	
	2.1-3	15(50)	06(20)	21(35)	
	3.1-4	08(26.6)	01(3.33)	09(15)	4
	4.1-5	01(3.3)	00	01(1.6)	0.0002**
	>5	00	00	00	

** = Highly significant p value <0.005

Table 4(b) and figure 1 in conclusion, the nasogastric feed fortified with orange juice shows significant (0.0002) in the post assessment as per SOFA score at $p<0.05$.

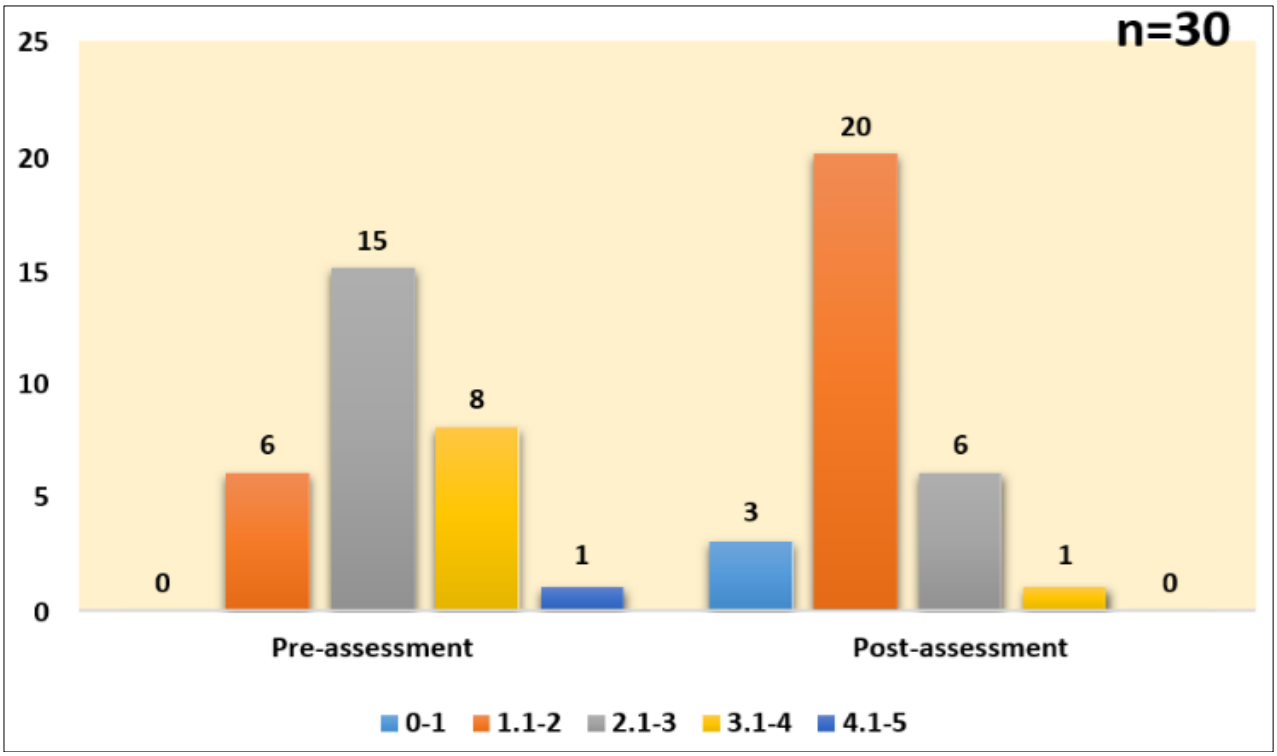

Fig 1: Bar graph showing the sepsis score among the interventional group

Table 5(a): The comparison of mechanical ventilation dependence as per SOFA score among conventional and interventional group on day 1 and day 6. N-60

Days	Variables	Conventional group f(%)	Interventional group f(%)	Total F(%)	χ2 df p-value
1	**PaO2**				
	<75	13(43.3)	05(16.6)	18(30)	5.174
	75-100	08(26.6)	13(43.3)	31(51.6)	2
	>100	09(30)	12(40)	21(35)	0.075NS
6	**PaO2**				
	<75	07(23.3)	01(3.3)	8(13.3)	5.84
	75-100	16(53.3)	17(56.6)	33(55)	2
	>100	07(23.3)	12(20)	19(31.6)	0.05*
1	**FiO2**				
	<21	00(0)	00(0)	00(0)	2.11
	21-50	05(16.6)	02(6.6)	7(11.6)	2
	51-80	08(26.6)	12(40)	20(33.3)	0.347NS
	81-100	17(56.6)	16(53.3)	33(55)	
6	**FiO2**				
	<21	00(0)	03(10)	3(5)	40.72
	21-50	10(16.6)	22(73.3)	32(53.3)	3
	51-80	22(36.6)	05(16.6)	27(45)	0.000**
	81-100	28(46.6)	00(0)	28(46.6)	

** = Highly significant p value <0.05

Table 5(b) depicts the comparison of sepsis score among interventional and conventional group. On pre-assessment (day 1), half of the subject 30(50%) had 2.1-3, less than half 17(28.3%), 10 (16.6%) had 1.1-2, 3.1-4 respectively and very few, 2(3.3%), 1(1.6% 0 had 4.1- 5 and >5 respectively with significant p at 0.193. While on the post assessment (day 6) less than half 22(36.6) had 1.1-2,20 (33.3%) had 2.1-3 and 09(15%) had 3.1-4. Very few subject
03 (5%), 04(6.6%), and 02(3.3%) had 0-1, 4.1-5 and >5 respectively at p 0.000 level of significance which shows the effectiveness of nasogastric feed fortified with orange juice on the reduction of sepsis score.

Discussions

Similar findings supported in study conducted by Hemila H, Chalker E (2020)14 conducted a randomized control trail with convenience sampling to assess the effect of vitamin C to reduce the duration of mechanical ventilation in critical ill patient among in University of Helsinki among 685 patients. Result revealed that there was significant effect of vitamin C with the longest ventilation, corresponding to the most severely ill patients. The vitamin C shortened the length of mechanical ventilation on average by 14% (p=0.00001).
Similar result shown by Moreno CS, Cano MPet.al. (2003)15 performed a study to assess the effect of orange juice intake on vitamin C concentrations and biomarkers of antioxidant status in humans. Six men and 6 women consumed 500 mL commercial fresh-squeezed orange juice/day for 14 day, corresponding to an intake of 250 mg ascorbic acid/day. Baseline plasma vitamin C concentrations were significantly higher (P = 0.03) among the women than among the men (56.4 +/- 4.4 compared with 44.3 +/- 3.5 micro mol/L). Vitamin C concentrations remained significantly higher on days 597 and 14 than at baseline. Drinking orange juice (500 mL/day) increases plasma concentrations of vitamin C.

Recommendations

- A similar study can be carried out on large sample to validate and generalize its findings.
- Similar studies can be replicated with different population of patients like with history of respiratory disorder and non-mechanically ventilated patients.
- A descriptive study can be conducted to assess the association of duration of mechanical ventilation and sepsis among selected demographic variables.
- An exploratory study can be carried out at various settings to identify factors enhancing and deteriorating the level of sepsis among patients.
- A comparative study can be conducted to assess the effectiveness of vitamin C orally versus intravenous in mechanically intubated patient.

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