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Comparison of the Effect of *Cydonia oblonga* and *Phyllanthus Emblica* on Gastric Residual Volume and Pulmonary Aspiration in Patients under Mechanical Ventilation in Mousavi Hospital ICU of Zanjan in 2020

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ABSTRACT

Background & Objective: The gastric residual volume has a direct effect on the volume and timing of the subsequent feeding and causes gastric emptying and pulmonary aspiration. The present study compares the effect of *Cydonia oblonga* and *Phyllanthus Emblica* (Amla) fruit on gastric residual volume and pulmonary aspiration in mechanically- ventilated patients.

Materials & Methods: This is a single-blind randomized clinical trial, including 48 patients (divided into three groups) under mechanical ventilation admitted to the intensive care unit (ICU) of Mousavi Hospital in Zanjan. Amla product and cydonia juice were gavaged in intervention groups A and, B, respectively. In all groups, the same gavage solution was prepared every three hours. Eventually, pulmonary secretion aspiration was measured (on the first, third and fifth days).

Results: The difference of the mean gastric residual volume was not statistically significant in the intervention groups (on thefirst three days). The mean residual volume of the fourth and fifth days was statistically different and the rate of pulmonary aspiration in the intervention groups (on the fifth day) was significantly lower than the control group (P<0.001). The mean gastric residual volume of the two groups had no significant difference (P<0.471).

Conclusion: The present study shows the effectiveness of cydonia juice and Amla on the gastric residual volume in patients admitted to ICU. The incidence of pulmonary aspiration in intervention groups has a decreasing trend (on the fifth day). Therefore, cydonia juice and Amla can be appropriate alternatives to chemical drugs.

Keywords: Cydonia juice, *Phyllanthus emblica* (Amla) fruit, Gastric residual volume, Mechanical ventilation



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Introduction

One of the main challenges for patients admitted to the intensive care unit (ICU) is to receive the food they need (1). Studies show that over 40% of these patients suffer from malnutrition, which increases mortality (2), worsens surgical outcomes, and delays ventilator detachment (3). Studies show that the incidence of malnutrition in patients admitted to the ICU is higher than other patients (4, 5). Most patients admitted to ICU are unable to feed orally due to their acute condition and lack of consciousness (6). Nasogastric intubation is the selected method for beginning feeding of critically- ill patients admitted to the ICU (7). This method of nutrition has many advantages, including its safety and closeness to the physiological function of the body. It also stimulates the gastrointestinal tract, improves the immune system, maintains the integrity of the gastrointestinal tract, and prevents infection caused by other nutritional methods (1). Delay in gastric emptying is one of the complications of this type of nutrition, the main feature of which is the increase in the gastric residual volume and gastroesophageal reflux (GERD) (8). Delay in gastric emptying exposes a high percentage of patients to complications such as vomiting, aspiration, and ventilator-induced pneumonia.

Numerous factors, including the type of disease, electrolyte disturbances, age, gender, recent abdominal surgeries, sepsis, shock, and cytokines can contribute to delayed gastric emptying (8, 9). Increased gastric residual volume is one of the most common causes of canceled and delayed feeding and decreased intake, which can limit the patient's nutrition and lead to malnutrition, increased infection and mortality, increased length of hospital stay,

worsening of the outcomes of surgery, delayed patient's separation from ventilator, and increased patient cost. Various strategies, such as gastrointestinal diversion, post-pyloric feeding, intermittent bolus feeding, and gastrointestinal motility- enhancing drugs, including metoclopramide, erythromycin, and cisapride, have been suggested to reduce gastric residual volume in patients admitted to the ICU. However, each has its own limitations or side effects (10-12).

In recent years, the use of medicinal plants to solve digestive problems has received more attention (3). There has been significant growth in herbal medicine over the past few decades due to their fewer side effects (13).

The quince fruit has anti-inflammatory properties and research shows that its phenols help relieve stomach ulcers, soothe the gastrointestinal tract, reduce inflammation, treat gastric ulcers, and strengthen the stomach. Eating quince before meals can prevent gastroesophageal reflux, accelerate gastric emptying, and treat constipation (14).

Phyllanthus emblica (Amla) fruit is an Indian tree that is rich in vitamin C, minerals and antioxidants (15, 16) and is an antibacterial (17) and lowers blood lipids, protects the liver, and eliminates indigestion and biliary disorders. Amla can help digest and expel excess moisture from the gastrointestinal tract by preventing the rise of fumes and strengthening the gastric cardia, and preventing the reflux of stomach contents and acid into the esophagus. It is also an antidepressant medicine due to the excretion of soda and is rich in fiber, which can be useful for digestion (14, 18).

Despite the studies conducted on the mentioned herbs, so far, no study has been done on the effect of these herbal medicines (cydonia juice and Amla fruit) on the gastric residual volume of patients fed through nasogastric intubation. This study aimed to determine the effect of cydonia juice and Amla fruit on gastric residual volume in mechanically- ventilated patients admitted to the ICU.

Materials and Methods

This study was performed as a single-blind randomized controlled clinical trial. Inclusion criteria included new patients admitted to the ICU of Mousavi hospital in Zanjan, aged 18 to 65 years, being under mechanical ventilation, having a gastric feeding tube, non pregnant, no history of gastric resection or pancreatitis, GCS less than 9, hemodynamic stability, and no signs of aspiration of gastric contents. Exclusion criteria were extubation before the fifth day, increase of ventilator Positive End Expiratory (PEEP) to more than 5 and pressure support (PS) to more than 15, and death. Patients were randomly assigned to 3 groups using simple blocking method (each block size=6)., 5 ml of Amla product with 15ml of water and 5ml of cydonia juice with 15 ml of water were gavaged twice a day (morning and evening) in intervention groups A and B respectively. In group C (control), gavage was performed according to the routine of the ward (food gavage). In this study, all three groups were gavaged once every three hours except 3 a.m with 250ml of the same gavage solution (prepared under the supervision of a nutritionist in the hospital kitchen). The gastric residual volume was measured and recorded by lavage method before each gavage during the study and then the aspirated fluid was returned to the patient's stomach. Groups A and B additionally received Amla and Cydonia juice, respectively. Gavage was performed using a 60ml syringe in a position 35 degrees above the head and under the influence of gravity at a height of 40cm above the level of the stomach and the position of 35 degrees was maintained for up to one hour after gavage. Detection of aspiration was made using positive glucose oxidase test and pH test.

Patients' demographic characteristics were collected using the researcher- made checklist (19, 20). This checklist included aspiration of the first, third and fifth days, and gastric residual volumes recorded before each gavage (lavage) for five days (if the gastric residual volume was higher than 200 ml, the gavage would be removed), and the severity of the disease which was measured with the standard form of APACHE II score. This score is based on age, as well as type of disease PH, PCO2, PaO2, bilirubin, creatinine, GCS scoring, type of underlying disease (based on the medical diagnosis recorded in the patient file), duration of hospitalization, history of chronic physical illness, anddays of connection to the mechanical ventilator. Due to the fact that the pH of lung secretions is normally above seven and is in the color spectrum of the glucose parameter, the criterion for positive aspiration was the positivity of both tests. The pH was less than seven (acidic) and the color change of the strip in the glucose reaction other than yellow was considered positive. For this purpose before each gavage, patients were sucked in as needed (in less than 30 seconds) by central suctioning through inserting a Nelaton catheter into the tracheal tube to the end, and the secretions were poured into sputum collection containers. Then, these secretions were measured and recorded in terms of reaction with glucose tape in terms of glucose and pH in both intervention groups (A, B) and the control group (C). In this way, a strip was carefully taken out of its special box without contact with any place and dipped into the aspirated secretions inside the sputum sample container for 2 seconds (according to the manufacturer's instructions). Then, it was placed on a paper towel for one minute without contact with any place to remove excess discharge. After that, it was placed on a stretched spectrum on its box that matched each parameter. Strip color change was checked based on the colors mentioned in front of the glucose and pH parameter. Eventually, the results were recorded on the result record sheet. In addition, detection of aspiration was made using the positive glucose oxidase test and pH test. By homogenizing the three groups, the effect of interfering factors, such as gender, age, initial diagnosis, APACHE II score, Glascow coma score, feeding volume, feeding tube size, tube feeding method, sepsis, diabetes, electrolyte disorders, PS, PEEP and medications that may affect gastric emptying and aspiration was monitored.

Statistical analysis

Data analysis was performed by SPSS software version 16. Descriptive data were expressed as number, percentage, mean and standard deviation, median, quartile distance and Chi-square test. Fisher's exact test and Karuscal-Wallis test were used to compare the results between the study groups. Statistically significant level was assumed to be less than 0.05.

Ethical considerations

the study began after approving the proposal by the Research Council, obtaining permission from the Ethics Committee of Zanjan University of Medical Sciences under the code IR.zums.REC.1398.320; its registration was in the Iran Clinical Trial Center under the code IRCT20191221045833N1, referring to the ICU of Ayatollah Mousavi Hospital and obtaining permission from patients' physicians, and obtaining informed consent from the patients' legal guardian after explaining the objectives of the research and emphasizing the safety of the drug and freedom to cancel the continuation of the plan, and not imposing additional costs on patients.

Results

Statistical analysis of Fisher's exact test showed that there was no significant difference (P < 0.379) between the studied groups based on gender. In the Amla receiving group, 4 patients (23.5%) were female and 12 patients (76.5%) were male; in the Cydonia juice receiving group, 3 patients (18.8%) were female and 13 patients (81.2%) were male, and in the control group, 6 patients (40%) were female and 10 patients (60%) were male.

The results of Fisher's exact test showed that there was no significant difference between the studied groups based on chronic physical illness (P < 0.518) and

underlying disease (P < 0.876). In the Amla receiving group, 5 patients (29.4%) did not have any chronic physical disease, 7 patients (41.2%) had heart disease, 1 patient (5.9%) had kidney disease, 3 patients (17.6%) had lung disease, and 1 patient (5.9) had pulmonary hypertension. In the Cydonia juice receiving group, 2 patients (12.5%) did not have any chronic physical disease, 12 patients (75%) had heart disease, 0 patient (0.00%) had kidney disease, 2 patients (12.5%) had lung disease, and 0 patient (0.00%) had pulmonary hypertension. In the control group, 2 patients (13.3%) did not have any chronic physical disease, 9 patients (60%) had heart disease, 2 patients (13.3%) had kidney disease, 2 patients (13.3%) had lung disease, and 0 patient (0.00%) had pulmonary hypertension (Table 1).

According to Fisher's exact test, there was no statistically significant difference between the groups of underlying diseases (p < 0.876). In the Amla receiving group, 2 patients (11,8 %) did not have any underlying diseases, 1 patient (5,9%) had chronic obstructive pulmonary disease, 2 patients (11.8%) had active bleeding, 0 patient (0.0%) had pancreatitis, 2 patients (11.8) had obstruction of the gastrointestinal tract, and 10 patients(8%) had surgical trauma. In the Cydonia juice receiving group, 1 patient (6.3%) did not have any underlying diseases, 1 patient (6.3%) had chronic obstructive pulmonary (COPD), 0 patient (0.0%) had active bleeding, 0 patient (0.00%) had pancreatitis, 1 patient (6.3%) had obstruction of the gastrointestinal tract, and 13 patients (81.3%) had surgical trauma. In the control group, 1 patient (6.7%) did not have any underlying diseases, 0 patient (0.00%) had chronic obstructive pulmonary disease, 1 patient (6.7%) had active bleeding, 1 patient (6.7%) had pancreatitis, 1 patient (6.7%) had obstruction of the gastrointestinal tract, and 11 patients (73.3%) had surgical trauma (Table 1).

Table 1. Frequency distribution of study groups in terms of chronic physical illness and underlying diseases

Variable		Amla fruit intervention	Cydonia juice intervention	Control groups	Total	P-value
		No. (%)	No. (%)	No. (%)	No. (%)	
None		5 (29.4)	2 (12.5)	2 (13.3)	9 (18.8)	
History of	Heart disease	7 (41.2)	12 (75)	9 (60)	28 (58.3)	
chronic	Kidney disease	1 (5.9)	0 (0)	2 (13.3)	3 (6.3)	
physical illness	Pulmonary	3 (17.6)	2 (12.5)	2 (13.3)	7 (14.6)	0.518
	disease	3 (17.0)	2 (12.5)	2 (13.3)	, (11.0)	
	Pulmonary	1 (5.9)	0 (0.00)	0 (0.00)	1 (2.1)	
	hypertension	(2.72)	(, , , ,	. (,		
	Total	17 (100)	16 (100)	15 (100)	48 (100)	
	None	2 (11.8)	1 (6.3)	1 (6.7)	4 (8.3)	
Underlying disease	COPD	1 (5.9)	1 (6.3)	0 (0.00)	2 (2.2)	0.876
	Active bleeding	2 (11.8)	0 (0.00)	1 (6.7)	3 (6.3)	0.070
	Pancreatitis	0 (0.00)	0 (0.00)	1 (6.7)	1 (2.1)	

Variable	Amla fruit intervention	Cydonia juice intervention	Control groups	Total	P-value
	No. (%)	No. (%)	No. (%)	No. (%)	
Obstruction the gastrointestin tract	2 (11.8)	1 (6.3)	1 (6.7)	4 (18.3)	
Surgical trauma	10 (8)	13 (81.3)	11 (73.3)	34 (70.8)	
Total	17 (100)	16 (100)	15 (100)	48 (100)	

The results of table 2 (APACHE II) and Kruskal-Wallis test showed that there was no significant difference between the studied groups based on disease severity (P < 0.491). In the Amla receiving group, 2 patients had APACHE II scores of 10-14, 6 patients had APACHE II scores of 15-19, 5 patients had APACHE II scores of 20-24, 2 patients had APACHE II scores of 30-34, and 0 patient had an APACHE II score of more than 34. In the Cydonia juice receiving group, 0 patient had an APACHE II score of 10-14, 6 patients had APACHE II scores of 15-19, 6 patients had

APACHE II scores of 20-24, 4 patients had APACHE II score of 30-34, and 0 patient had an APACHE II score of more than 34. In the control group, 1 patient had an APACHE II score of 10-14, 5 patients had APACHE II scores of 15-19, 7 patients had APACHE II scores of 20-24, 3 patients had APACHE II scores of 25-29, 0 patient had an APACHE II score of 30-34, and 0 patients had APACHE II score of more than 34. The mortality rates per APACHE II score were 15%, 25%, 40%, 55%, 75%, and 85%, respectively (Table 2).

Table 2. Frequency distribution of study groups in terms of APACHE II Score

Variable APACHE II score	Amla fruit intervention	Cydonia juice intervention	Control groups	Total	Mortality rate	P-value
10-14	2	0	1	3	15%	
15-19	6	6	5	17	25%	
20-24	5	6	7	18	40%	
25-29	2	4	3	9	55%	0.491
30-34	1	0	0	1	75%	
More than 34	0	0	0	0	85%	
Total	16	16	16	48		

The results of Fisher's exact test showed that there was no significant difference between the studied groups based on aspiration on day three (P < 0.379) and five (P < 0.002). In Amla receiving group only 4 (23.5%) and 0 (0.00) patients had aspiration on days three and five, respectively. In Cydonia receiving

group only 3 patients (18.8%) and 0 patient (0.00) thad aspiration on days three and five, respectively. In the control groups 6 patients (40%) and 5 patients (33.3%) had aspiration on days three and five, respectively. The aspiration of intervention groups was lower than the control group (Table 3).

Table 3. Frequency distribution of study groups in terms of aspiration on days three and five

Variable		Amla fruit intervention	Cydonia juice intervention	Control groups	Total	P-value
Aspiration		No. (%)	No. (%)	No. (%)	No. (%)	
_	No	13 (76.5)	13 (81.3)	9 (60)	35 (72.9)	
Day three	Yes	4 (23.5)	3 (18.8)	6 (40)	13 (21.1)	0.379
	Total	17 (100)	16 (100)	15 (100)	48 (100)	

Variable		Amla fruit intervention	Cydonia juice intervention Control grou		Total	P-value
Aspiration		No. (%)	No. (%)	No. (%)	No. (%)	
Day five	No	17 (100)	16 (100)	10 (66.7)	43 (89.6)	
	Yes	0 (0)	0 (0)	5 (33.3)	5 (10.4)	0.002
	Total	17 (100)	16 (100)	15 (100)	48 (100)	

The results of the Kruskal-Wallis test showed that there was no significant difference between the studied groups (<u>Table 4</u>).

Table 4. Median, Quartile, Mean, and Standard deviation of variables of age, consciousness level, APACHE II, days of connection to mechanical ventilation, and days of hospitalization in ICU

Variable	Median Quartile distance of Amla group	Mean SD of Amla group	Median Quartile distance of cydonia juice group	Mean SD of cydonia juice group	Median Quartile distance of control group	Mean SD of control group	P-value
Age	45 (16.5)	46.4 (11.1)	51 (15)	51.6 (8.24)	61 (21)	52.9 (15.4)	0.129
GSC level of consciousness	5 (2.5)	5.4 (2.7)	5 (2.75)	4.6 (13.4)	6 (2)	5.5 (1.7)	0.293
APACHE II	19 (8.5)	19.5 (6.3)	21 (5.25)	21 (3.7)	22 (16)	21.8 (3.8)	0.491
days of connection to mechanical ventilation	21 (8.5)	22.3 (10.5)	20 (14)	19.4 (7)	20 (8)	19.1 (8.3)	0.284
Number of days hospitalization in ICU	21 (8.5)	23.2 (6.8)	20 (14)	18.6 (7.5)	20 (8)	19.9 (9.7)	0.284

According to kruskal-Wallis test, the gastric residual volume of the studied groups on the fifth day was statistically different (P-value < 0.001) (Figure 1).

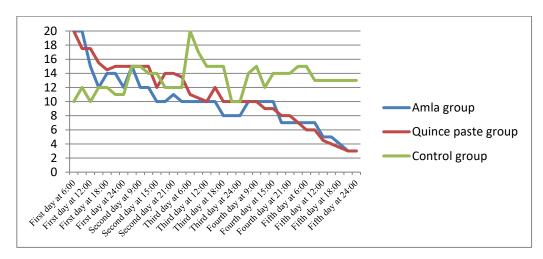


Figure 1. Mean gastric residual volume over time

Discussion

One of the main challenges for patients admitted to the intensive care unit (ICU) is to receive the food they need (1). Inadequate nutrition leads to increased catabolism, decreased fat stores and decreased muscle mass (4, 5), and eventually malnutrition (protein) (21, 22). With proper nutritional support, patients' wounds heal faster and their catabolic response to injury is

Medicinal plants have been used for centuries as a remedy for human diseases, because they contain valuable therapeutic compounds (13).

Our findings in the present study showed that cydonia juice and Amla fruit contribute to the gastric residual volume in comparison with the control group. They also reduce the gastric residual volume and pulmonary aspiration in patients admitted to the ICU. Similar studies have been conducted in recent years using herbs and their comparison with chemical drugs to reduce the gastric residual volume. In a randomized controlled clinical trial Shakeri et al., (2018) compared ranitidine with quince fruit paste on 137 pregnant women with GERD. Within 2 to 4 weeks after the intervention, they concluded that the paste had a similar effect to ranitidine, and was a stomach tonic, appetite suppressant, and a medication to treat nausea/vomiting and epigastric pain. The results of this study showed that the effect of the quince product on the treatment of gestational reflux is similar to that of ranitidine. Cydonia juice can be used as an alternative to ranitidine in reducing gastric reflux in pregnant mothers. The beneficial effect of cydonia juice on the gastrointestinal tract was also proved in the present study (23).

Karkon et al., (2018) conducted a double-blind, randomized, placebo-controlled clinical trial to evaluate the efficacy and safety of Amla in non-erosive gastrointestinal reflux disease. Due to the failure of treatment with common chemical drugs for GERD, herbal medicine with Amla fruit was used. This study showed that in addition to the beneficial effects and the safety and effectiveness of the herbal medicine Amla, it improves the symptoms of GERD. Statistical analysis showed that there was a significant reduction in the incidence of gastric pain and the severity of gastric pain in the Amla group compared with the placebo group (P < 0.001). The results of this clinical trial showed that Amla could improve heartburn and pain intensity in patients with NERD. In the present study, the beneficial gastrointestinal effects of Amla were also proved (24).

Ahmed and Khan (2018) conducted a review study to investigate the effect of traditional Greek medicine on the treatment of gastric ulcer. They suggested that Amla is one of the useful plants that is very effective in treating peptic ulcer and gastrointestinal disorders (25).

The present study showed that cydonia juice and Amla extract can, like other medicinal plants such as fenugreek seeds, thyme and ginger, reduce the gastric residual volume, gastric reflux, and the risk of respiratory aspiration in these patients. Also, in comparing the two with each other in terms of effectiveness (median, quartile, mean and standard deviation), the cydonia juice and Amla were not statistically different in terms of the gastric residual (evening of the fourth day and the fifth day of the study) (P < 0.471).

Conclusion

In general, findings of the present study showed that cydonia juice and Amla fruit can contribute to the gastric residual volume in comparison with the control group. They also reduce the gastric residual volume and pulmonary aspiration in patients admitted to the ICU.

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Conflict of Interest

Authors declare no conflict of interest.

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