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Effect of Inspiratory Muscle Training on Maximal Inspiratory Pressure in Patients with Congestive Heart Failure

By Nagwa Mohamed Hamed Badr, Amany R. Mohamed. &
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Abstract- *Objective:* To evaluate the effect of inspiratory muscle training (IMT) on inspiratory muscle strength, and quality of life in patients with congestive heart failure.

Background: Inspiratory muscle training is a technique that is designed to improve pulmonary function, level of dyspnea, inspiratory muscle strength and endurance, limb blood flow, six minutes walking distance, exercise tolerance, as well as health related quality of life in congestive heart failure patients.In our study we used maximal inspiratory pressure as a measure of the strength of inspiratory muscles.

Methods: Thirty male patients were randomly selected from Cairo university hospitals (critical care department), their ages ranged from 50 to 65 years.

Keywords: *Keywords: Congestive heart failure, Inspiratory muscles training, Maximal inspiratory pressure.*

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Effect of Inspiratory Muscle Training on Maximal Inspiratory Pressure in Patients with Congestive Heart Failure

Nagwa Mohamed Hamed Badr [α], Amany R. Mohamed. [σ] & Abdou Mohamed Taha El-Azab [ρ]

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Methods: Thirty male patients were randomly selected from Cairo university hospitals (critical care department), their ages ranged from 50 to 65 years. They were divided into two equal groups: study and control group ,fifteen patients for each group, each patient of the study group received both inspiratory muscles training for 30 min and routine chestphysical therapy for 15 min with frequency five sessions per week for one month, each patient of the control group received only routine chestphysical therapy for 15 min with frequency five sessions per week for one month, All patients are clinically and medically stable as they were on standard cardiac medications all over the study. Pre and post study maximal inspiratory pressure(PImax) and quality of life assessment was done for each patient of both groups.

Results: Despite the homogeneity between the study and control groupsas regard age, weight, height, quality of life and in baseline PImax(P-Value=NS) and despite significant improvement in PImax post treatment compared to pre treatment values in both groups (P value=0.0001 for study group and 0.01 for control group) this improvement was significantly higher in the study group compared to the control group (54.93±11.17 vs 46.8±9.26 cmH2O respectively, Pvalue=0.03). Quality of life Scoresalso showed signific-antimprovement post treatment when compared to pre treatment values in both study and control group (P value=0.001 for both groups) but this improvement was highlysignificant in study group when compared to control group(39.46±5.68 vs 53.4±8.63 respectively, Pvalue=0.0001).

Conclusion: Inspiratory muscles training with chest physiotherapy improve inspiratory muscle strength and quality of life in patients with congestive heart failure.

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Keywords: *Congestive heart failure, Inspiratory muscles training, Maximal inspiratory pressure.*

I. Introduction

Congestive heart failure indicates not only an inability of the heart to maintainadequate oxygen delivery; it is also a systemic responseattempting to compensate for the inadequacy[1].

A characteristic feature of congestive heart failure (CHF) is reduced exercise tolerance. Several factors contributing to this have been identified, including alterations in central hemodynamics, skeletal muscle oxygen utilization and respiratory muscle dysfunction[2].

Diastolic heart failure (DHF) and systolic heart failure(SHF) are 2 clinical subsets of the syndrome of heart failurethat are most frequently encountered in clinical practice[3].Those forms of cardiac insufficiency which are due to inadequate diastolic filling of the heart (hypodiastolic failure) andthe far more common ones in which the heart fills adequately but does not empty to the normal extent (hyposystolic heart failure). However, confusions and controversies regarding the definitions, pathophysiology, prognosis and management of DHF and SHF continue[4].

Clinical manifestations can range from no symptoms to dyspnea,pulmonary edema, signs of right heart failure and exercise intolerance.Whereas diastolic dysfunction usually presents as a chronic condition, acutediastolic dysfunction producing acute pulmonary edema is not uncommon manifestation of acute myocardial ischemia or uncontrolled hypertension [5].

Patients with CHF are limited in their physical activity by fatigue and dyspnea, and it has been suggested that respiratory muscle weakness and deconditioning may be involved in the increased work of breathing during hyperpnea. Some of these patients show reduced maximal inspiratory pressure and endurance of inspiratory muscles. Abnormal ventilatory response to exercise, periodic breathing, and delayed oxygen uptake duringrecovery of maximal effort have also been associated with severity andpoor prognosis in CHF[6].

Patients with chronic CHF have decreased lung volume, decreased compliance, increased airway-

closing pressure, increased work of breathing, and greater oxygen consumption.Pulmonary rehabilitation may improve quality of life and exercise capacity in patients with chronic heart failure [1].

Respiratory muscle dysfunction may play a role in limiting exercise capacity; it has been proposedthat dyspnea is influenced by the central nervous system's perceptionof inspiratory motor output, a signal that increases with a reductionin respiratory muscle strength. The maximal inspiratory pressure andmaximal expiratory pressures, as well as respiratory muscle endurance, are reducedin patients suffering from CHF compared with age-matched normalsubjects. This reduction correlates with the degree of dyspnea [7].

Respiratory muscles, as other skeletal muscles can be trained. Both the structure and the functional characteristics of respiratory muscles may be modified in response to increased imposing loads or decrease follow inactivity. The structural, functional and metabolic changes of the respiratory muscles in response to training have proven to be effective in increasing the cross sectional area of fibers and power generation with a clear increase in contractile proteins. Clinically, the respiratory muscle training demonstrated to be effective in increasing strength and endurance of respiratory muscle in numerous diseases [8].

Generally, training theory suggests that gains in inspiratory muscle strength (force-generating capacity) can be achieved at intensities of 80% to 90% of maximum inspiratory pressure. Strength-endurance gains (maximal effective force that can be maintained) can be achieved at 60% to 80% of MIP, and gains in endurance (the ability to continue a dynamic task for a prolonged period) can be achieved at approximately 60% of peak pressure, which equates to high-intensity training regimens used in systemic exercise. However,earlier studies have suggested that quantitative improvements in work capacity following inspiratory muscle training regimens can occur with intensities as low as 40% of peak pressure[9].

The inspiratory pressure load provided by a pressure-threshold device does not modify airflow mechanics. Therefore, pressure-threshold training provides a quantified pressure challenge to the inspiratory muscles that is independent of airflow[10].

Maximum inspiratory pressure is a measure of the strength of inspiratory muscles, primarily the diaphragm, and allows for the assessment ofventilatory failure, restrictive lung disease, and respiratory muscle strength. The test is quick and noninvasive, but it is highly dependent on participant effort and coaching. The range of normal values is broad, and low values should be interpreted relative to the lower limit of normal values for age and sex[11].

II. Patients and Methods

The study was conducted at Critical Care Medicine Department, Cairo University Hospitals.

III. Patients

Thirty male patients with mean age (63.8±4.34) were recruited for the study from Critical Care Medicine Department with the all patients were diagnosed as congestive heart failure with left ventricular ejection fraction range from 30% to 45 % and their NYHA classes IIandIII.

- Inspiratory muscle weakness with maximal inspiratory pressure (PImax) <70% of predicted. It was calculated as:

PImax = 126 - 1.028 x age + 0.343 xwt (kg).

All patients are clinically and medically stable as they were on standard cardiac medications all over the study (diuretics, angiotensin converting enzyme (ACE) inhibitors, and glycosides etc …).

a) Exclusion criteria

Patients who had met one of the following criteria were excluded from the study:

- Patients with chronic lung disorders, anemia or sever hypoxia.
- History of myocardial infarction six months before study.
- Presence of uncontrolled hypertension or diabetes mellitus.
- Any other disorders may affect the result.

The patients were randomly divided (Block Randomization) into two equal groups:

Group (1): Inspiratory muscle training(IMT) group (Study Group)

Fifteen patients participated in inspiratory muscle training program using inspiratory muscle trainer and routinechest physical therapy (percussion, vibration, etc…) five times a week for one month. Periodic adjustment of the intensity of inspiratory muscle trainer was done throughout the training period.

Group (2): (Control group)

Fifteen patients were assigned as control group and they were subjected toroutinechest physical therapy alone for the same period as study group.

All patients of both groups were under medical treatment, and were asked to be on their normal activities. All the trained subjects received information regarding the benefits of the program.

IV. Instrumentations

a) Evaluation equipments

1) Micro Respiratory Pressure Meter (Micro RPM) from Micro Medical Ltd. For measuring MIP.

2) Quality of life questionnaire: Quality of life was assessed with the Minnesota Living with Heart Failure Questionnaire.

b) Therapeutic equipment

Resistive loading Inspiratory muscle trainer (Respironics-USA) with threshold near flow independent, loading between -7 and -50 cmH2O.

V. Procedures

a) All patients subjected to

1. Clinical examination to select patient in NYHA Classes.
2. Assessment of MIP by Micro Respiratory Pressure Meter.
3. Assessment of Quality of life withMinnesota Living With Heart Failure Questionnaire.

These measurements were applied for all patients at the starting of the study and at the end of the training program that lasting for 4 weeks.

b) Training program

i. *Inspiratory muscle training*

Each patient in the study group completed 4 weeks program of inspiratory muscle training. The patient was asked to inspire deeply through the mouthpiece of the IMT against the selected load.

c) Exercise prescription

- *Intensity:* The initial work load is measured as 30% of MIP.
- *Graduation:* The patient trained in the initial workload for 2 weeks, ten training sessions, then target workload will increase by 5 cmH2o every 3 session.
- *Duration:* Sessions were divided into six sets, five minutes in duration and separated by 5 minutes rest.
- *Frequency:* 5 times/week.

d) Statistical procedure

In this study data collected were fed to the computer, manipulated and analyzed using (SPSS underpin, statistical package, version12.2011) the mean, standard deviation and mean difference were collected for all patients groups (training and control) The comparison was made by paired t-test to determined the probability levels for difference in mean value between the result observed before and after the period of one months in each group and Comparison between study and control group patients in all studied parameters made by independent t-test.

Wilcoxon matched pairs test for Quality of life questionnaire pre and post treatment in each group and the Mann-Whitney test results for the quality of life questionnaire pre and post treatment between 2 groups. Statistical significance was established at the conventional < 0.05 level.

VI. Results

This study were conducted on thirty male patients diagnosed as Congestive heart failure, with NYHA classes II and III selected from Critical Care Medicine Department, Cairo University Hospitals, the patients were classified randomly into two groups, IMT group and control group. The IMT group patients received prescribed inspiratory muscle training and Chest physical therapy, while the control group patients received Chest physical therapy only.All patients were clinically and medically stable as they were on standard cardiac medications. The data were collected before and after four weeks period.

VII. Demographic Data

There was no significant difference between both groups in their ages,weights, heights where their P-values were (0.67),(0.52), and (0.57) respectively. Table (1):

Table 1 : Demographic data of patients in both groups (A&B)

Items	Group A		Group B		P-value	
	Mean	±SD	Mean	±SD		
Age (yrs)	63.8	±4.34	63.06	±4.97	0.67	NS
Weight (Kg)	81.6	±5.72	82.93	±5.65	0.52	NS
Height (Cm)	167.86	±5.15	166.86	±4.56	0.57	NS

***SD:** standard deviation, **P:** probability, **NS:**Non significant.*

VIII. Maximal Inspiratory Pressure

a) Comparison between pre and post study mean values in the two groups of patients

i. *Group (A)*

There was a statistically significant higher value of PImax post study in comparison to its pre study value (54.93±11.17 vs 43.53± 12.17 cmH2O respectively,P-value=0.0001) and the percentage of improvement was 26.18%.Table (2) and fig.(1).

Table 2 : Pre and post treatment maximal inspiratory pressure in group(A)

Group A	Maximal inspiratory pressure				P-value	
	Mean (cmH_2O)	±SD	Mean difference	Percentage of improvement		
Pre treatment	43.53	±12.17	11.4	26.18 %	0.0001	S
Post treatment	54.93	±11.17				

**SD: standard deviation, P: probability, S: significant.*

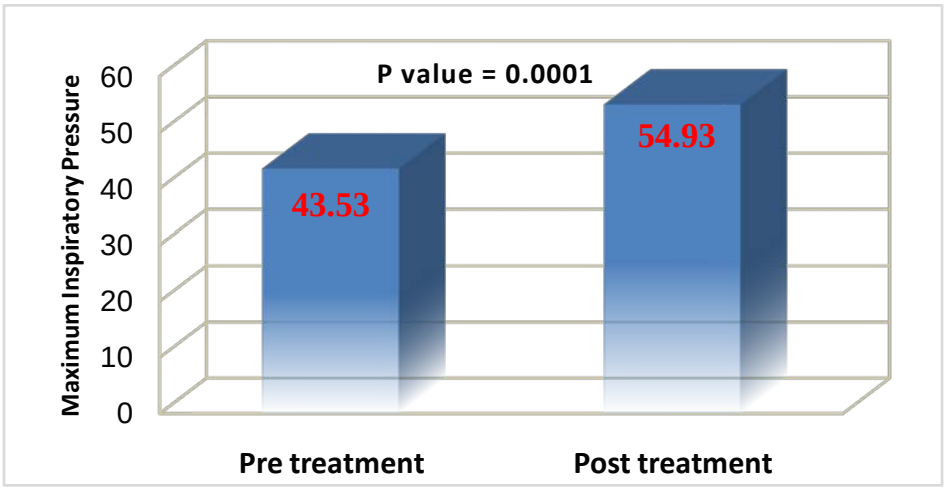

Fig. 1 : Pre and post treatment maximal inspiratory pressure in group (A)

ii. *Group (B)*

There was a statistically significant higher value of PImax post study in comparison to its pre study value (46.8±9.26 vs 43.06±9.94 cmH2O respectively, Pvalue=0.01) and the percentage of improvement was 8.66 %.Table (3) fig.(2).

Table 3 : Pre and post treatment maximal inspiratory pressure in group(B)

Group B	Maximal inspiratory pressure				P-value	
	Mean (cmH_2O)	±SD	Mean difference	Percentage of improvement		
Pre treatment	43.06	±9.94	3.73	8.66 %	0. 01	S
Post treatment	46.8	±9.26				

**SD: standard deviation, P: probability, S: significant.*

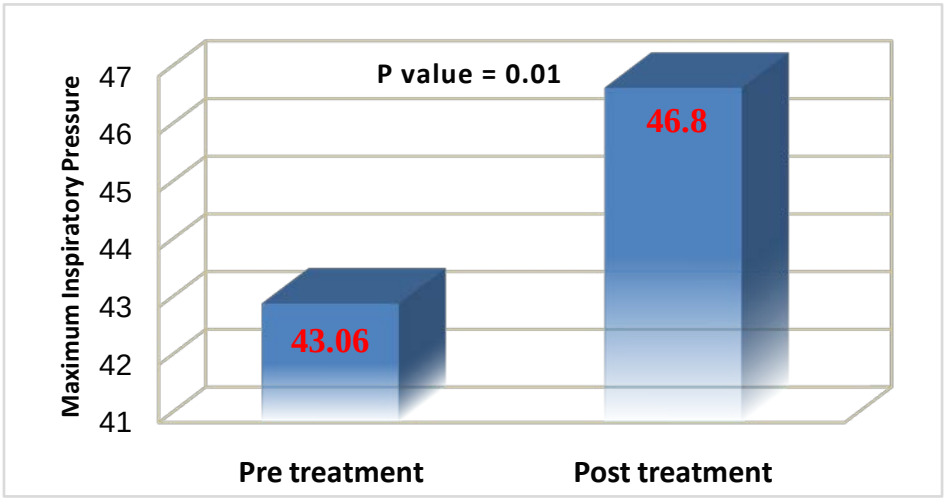

Fig. 2 : Pre and post treatment maximal inspiratory pressure in group(B)

b) Comparison between study group(groupA) and control group(groupB)

There was no significant difference between study and control group in pre treatment valuesPImax of (43.53±12.17 vs 43.06±9.94 cmH2O respectively, Pvalue=0.9), but the posttreatmentPImax was significantly higher in the study group compared to the control group (54.93±11.17 vs46.8±9.26 cmH2O respectively, Pvalue=0.03).Table (4) and fig.(3):

Table 4 : Maximal inspiratory pressure in both groups (pre and post treatment values)

PImax	Pre treatment (cmH_2O)		Pos treatment (cmH_2O)	
Study Group	43.53±12.17		54.93±11.17	
Control Group	43.06±9.94		46.8±9.26	
P-value	0.9	NS	0.03	S

P: probability, NS: non-significant, S: significant.

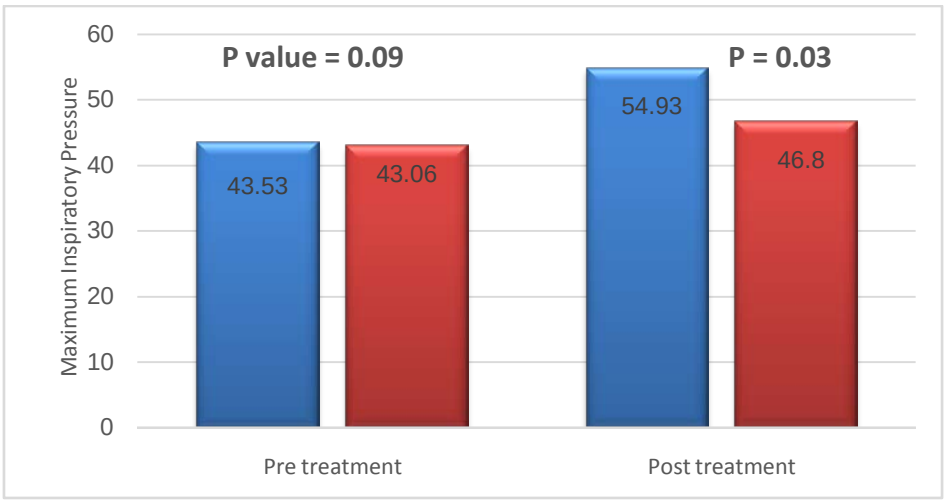

Fig. 3 : Maximal inspiratory pressure in both groups (pre and post treatment values)

IX. Quality of life Questionnaire(QOL)

a) Comparison between pre and post study mean values in the two groups of patients

i. *Group (A)*

The mean value of the QOL score was significantly better post treatment when compared to pre treatment value(39.46±5.68 vs 67.73±9.12 respectively,Pvalue=0.001). Table (5) and fig.(4).

Table 5 : Pre and post treatment Quality of life questionnaire in group(A)

	Quality of life questionnaire		P-value	
Group A	Mean	±SD		
Pre treatment	67.73	±9.12	0.001	S
Post treatment	39.46	±5.68		

**SD: standard deviation, P: probability, S: significant.*

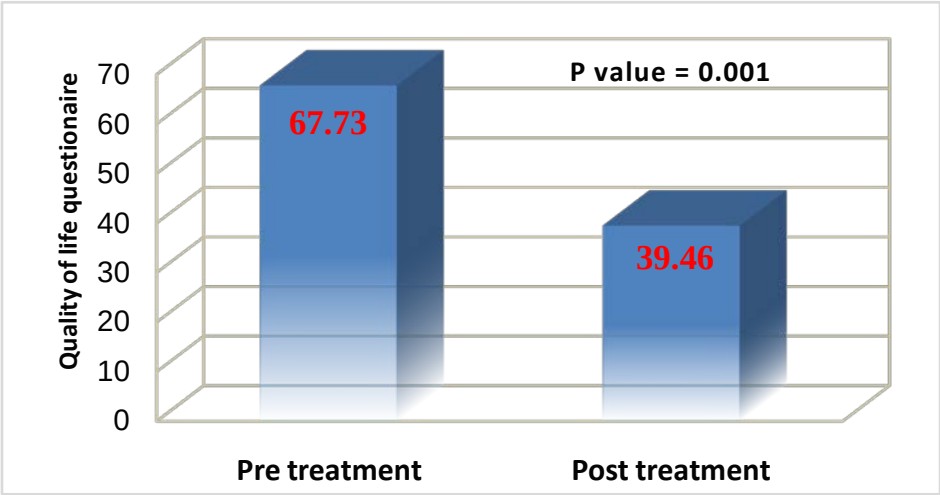

Fig. 4 : Pre and post treatment Quality of life questionnaire in group(A)

ii. *Group (B)*

The mean value of the QOL score was significantly better post treatment when compared to pre treatment value(53.4±8.63 vs 68.4±8.32 respectively, P-value=0.001).Table (6) and Fig.(5).

Table 6 : Pre and post treatment Quality of life questionnaire in group(B)

Group B	Quality of life questionnaire		P-value	
	Mean	±SD		
Pre treatment	68.4	±8.32	0.001	S
Post treatment	53.4	±8.63		

**SD: standard deviation, P: probability, S: significant.*

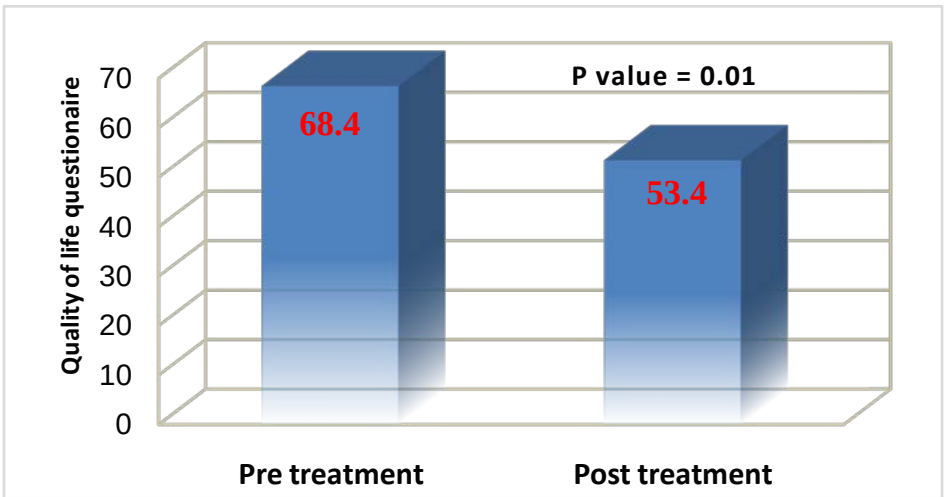

Fig. 5 : Pre and post treatment Quality of life questionnaire in group(B)

b) Comparison between study group(groupA) and control group(groupB)

There was no significant difference between study and control group in pre treatment values of QOL score(67.73±9.12 vs 68.4±8.32 respectively, Pvalue=0.85), while the post treatment QOL score was significantly better in the study group compared to the controlgroup(39.46±5.68 vs 53.4±8.63 respectively, Pvalue=0.0001). Table (7) and fig.(6).

Table 7 : Quality of life questionnaire (pre and post treatment) in both groups

Quality of life questionnaire				
	Pre treatment(mean±SD)		Pos treatment(mean±SD)	
Study Group	67.73±9.12		39.46±5.68	
Control Group	68.4±8.32		53.4±8.63	
P-value	0.85	NS	0.0001	S

P: probability, NS: non-significant, S: significant.

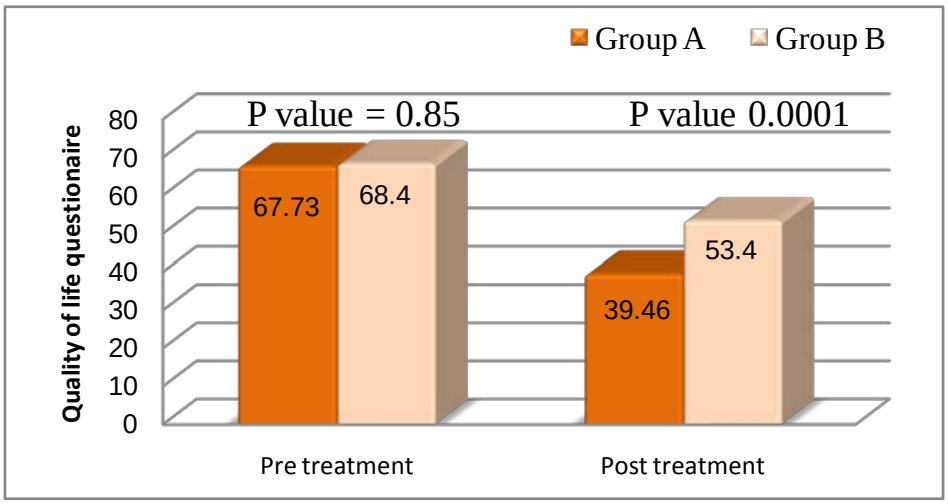

Fig. 6 : Quality of life questionnaire (pre and post treatment) in both groups

X. Discussion

Congestive heart failure patients are limited in their physical activity by fatigue and dyspnea, and respiratory muscle weakness and deconditioning may be involved in the increased work of breathing during hyperpnea. Some of these patients show reduced maximal inspiratory pressure and endurance of inspiratory muscles, which are currently recognized as additional factors implicated in the limited exercise response and quality of life, as well as in their poor prognosis[6].

Patients with chronic heart failure have a restrictive pattern of lung function due to the presence of pulmonary hypertension. This lung 'stiffness' increases the load on the inspiratory muscles and makes a significant contribution to their dyspnea. In addition, there is evidence of inspiratory muscle weakness that emerges as an independent predictor of prognosis in this group of patients [12].

A characteristic feature of congestive heart failure (CHF) is reduced exercise tolerance. Several factors contributing to this have been identified, including alterations in central hemodynamics, skeletal muscle oxygen utilization and respiratory muscle dysfunction[2].

Our study was performed on thirty CHF patientswith mean age (63.8±4.34), their NYHA classes II or III selected from Critical Care Medicine Department, Cairo University Hospitals. Measurements were applied for all patients pre and post study regarding:

1) Maximal inspiratory Pressure.
2) *Quality of life scores.*

a) Patients were divided into

1. *Study group:* Each patient in this group received standard medical treatment, routine chest physical therapy plus inspiratory muscle training program.
2. *Control group:* Each patient in this group received standard medical treatment plus routine chest physical therapy only.

The results of our studyrevealed statistically significant improvementininspiratory muscle strength (measured as the PImax) in the study group when

compared to control group and this may be explained by that the inspiratory muscles are morphologically and functionally skeletal muscles and, therefore, should respond to training in the same way as would any locomotor muscle if an appropriate physiological load is applied.

The aim of training is to induce increase in maximal inspiratory pressure which would lower the value of the ratio inspiratory pressure generated per breath to PImax (PI/PImax) and the tension–time index (TTI), thereby increasing endurance and decreasing the probability of fatigue

Our study is in agreement with the study done by Laoutaris and his colleges in 2007 Whoevaluated the effects of inspiratory muscle training on inspiratory muscle strength, as well as on functional capacity, ventilatory responses to exercise, recovery oxygen uptake kinetics, and quality of life in patients with chronic heart failure and inspiratory muscle weakness .They studied thirty-two patients with CHF and weakness of inspiratory muscles (maximal inspiratory pressure <70% of predicted). The IMT resulted in a 15% increment inPImax, 17% increase in peak oxygen uptake(VO2), and 19% increase in the 6-min walk distance. Likewise, circulatory power (calculated as the product of Peak VO2 and Peak systolic pressure) increased and ventilatory oscillations were reduced[13]

These resultswere supportedby another study by Laoutaris and his colleges in 2008 who investigated the benefits of inspiratory muscle training in patients with chronic heart failure. The trained patients significantly increased both maximum inspiratory pressure, and sustained maximum inspiratory pressure, Peak VO2 increased after training, as did the six-minute walking distance, and the quality of life score was also improved[14].

Also our study is in agreement with the study made by Stein R and his colleges in 2009 who investigated the benefits of inspiratory muscle training in patients with chronic heart failure. In this study the training group exercised at 30% of individual maximal inspiratory pressure for three months. All patients exercised seven times weekly for 12 weeks. The training group significantly increased maximum inspiratory pressure, and improves oxygen uptake efficiency slope (OUES). The high correlation between changes inPImax and OUES suggests that inspiratory muscle strength is an important determinant of OUES in these CHF patients[15].

Also the study made by Stephanie J. and his colleges in 2011Whodemonstrated that IMT improve inspiratory muscle strength measured as the maximal inspiratory pressure. These changes in inspiratory pressures were achieved in all participants who underwent an 8-week period of training at 80%, 60%, or 40% of each individual's MIP, with no changes in these indexes in the participants who acted as a control group. However, quantitative improvements in lung volumes, work capacity, were evident in the 80% of the training group[9].

The improvement in inspiratory muscle strength and respiratory function as well as cardiac function lead to improving not only inlife expectancy, symptoms, physical function,social function, role performance, pain and fatigue,but also in quality of life in this patients and this is in agreement with the study done by Laoutaris et al. in 2004 whoconducted arandomized controlled trial of IMT and reported significant improvements in dyspnea, exercise tolerance, quality of life in patients with chronic heart failure[16].

The study done byFabbri G. and his colleges in 2007 revealed thatimprovedhealth-related quality of life by managing symptoms than curing the disease is the primary goal in the treatment of patients with congestive heart failure. Assisting or encouragement of patients to adopt a positive attitude towards their health status is also one more important goal of treatment. Another approach that can significantly contribute to better quality of life is the improvement of hospital to home transition, although this is closely depending on the severity of the disease[17].

The result of our study revealed statistically improvement in maximal inspiratory pressure and quality of life scores in patients in both control and study group but this improvement was statisticall-ysignificant higher in study group only. So, it is recommended to use inspiratory muscles training with chest physiotherapy in order to improve inspiratory muscle strength, cardiac muscle function and quality of life in patients with congestive heart failure as this may decrease the debilitating effect of chronic heart failure as well as the functional and medical dependence.

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Latest Diagnostic and Treatment Modalities for TTP

By Ali Raza Ghani M D & Ahsan Raza

Abstract- TTP is a very uncommon disease which used to have very high mortality and morbidity before the introduction of plasmapharesis and immunosup-pressant therapy. Even after the introduction of these modalities, atypical HUS patients had a very grave prognosis and ultimately led to death in many until the introduction of complement inhibitors like eculizumab which is C5a monoclonal antibody. Additionally differentiating typical HUS versus atypical HUS was very difficult but some work on complement markers can be very fruitful in differentiating them.

Keywords: atypical hemolytic uremic syndrome, complement factors, thrombotic thrombocytopenic purpura, plasmapharesis, eculizumab.

GJMR-F Classification : NLMC Code: WJ 348

Strictly as per the compliance and regulations of:

Latest Diagnostic and Treatment Modalities for TTP

Ali Raza Ghani MD [α] & Ahsan Raza [σ]

Abstract- **TTP is a very uncommon disease which used to have very high mortality and morbidity before the introduction of plasmapharesis and immunosup-pressant therapy. Even after the introduction of these modalities, atypical HUS patients had a very grave prognosis and ultimately led to death in many until the introduction of complement inhibitors like eculizumab which is C5a monoclonal antibody. Additionally differentiating typical HUS versus atypical HUS was very difficult but some work on complement markers can be very fruitful in differentiating them.**

Keywords: atypical hemolytic uremic syndrome, complement factors, thrombotic thrombocytopenic purpura, plasmapharesis, eculizumab.

I. Introduction

Thrombotic thrombocytopenic purpura (TTP/ Moscowitz Syndrome) is a rare disorder leading to formation of microscopic thrombi throughout different systems of body due to endothelial injury causing platelet activation and coagulation cascade.

Majority of cases of TTP arise from ADAMTS13(an enzyme responsible for breaking down large multimers of vWFmultimers into smaller products) deficiency or inhibition. If it doesn't happen ultimately increase endothelial injury and platelet activation takes place resulting in widespread microtrombithrougout circulation. If not treated appropriately, thrombotic thrombocytopenic purpura-hemolytic uremic syndrome (TTP-HUS) in adults typically follows a progressive course resulting in irreversible renal failure, progressive neurologic deterioration, cardiac ischemia, and ultimately death of patient. Before the introduction of plasma exchange therapy it had a mortality of 90% which has been dropped to less than 10% in initial 6 months. Idiopathic thrombotic thrombocytopenic purpura is still a challenge to manage especially if it is unresponsive to plasma exchange therapy despite the evolution of various therapeutic options.[15,16].

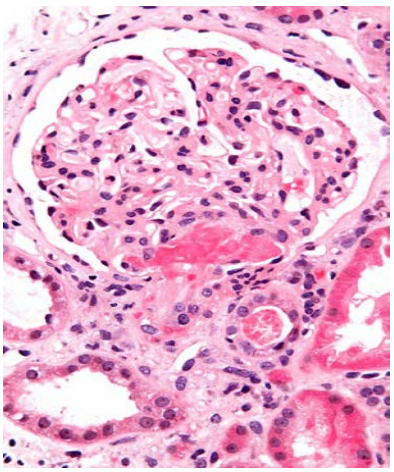
A very rare form of TTP called Up Shaw Schulaman Syndrome can occur in some patients in which there is congenital defect in ADAMTS 13 but its presentation is usually very mild and manifests mostly in stressful circumstances.

II. Pathogenesis

After an E. coli infection with production of Shiga-toxin, several factors influence the progression of the disease to HUS. (1) Bacterial strain. For serotype O157/H7, the progression is approximately 15%; (2) Age: In children younger than 5 years, the rate of progression is 12.9%, while it is 6.8% in children between 5 and 10-year-old and 8% in children over 10 years; (3) Antibiotic therapy. Antibiotic therapy for E. coli O157/H7 infection may increase the risk of HUS, though a recent meta-analysis does not confirm this association; and (4) Environmental and genetic factors. Such factors are not yet fully understood, but several authors have suggested that factor-H abnormalities could influence the disease evolution in HUS D+. Shiga toxin is produced by E. coli in the gut and is then absorbed.

Shiga toxin consists of two subunits: A and B. Subunit A, approximately 32 kDa, is cleaved by proteolysis into two peptides: A1 (28 kDa) and A2 (4 kDa). In target organs (e.g., kidney, brain and gut), subunit B recognizes and binds to glycolipid receptors on the cell surface. In humans this receptor is Gb3 (globotriosilceramyde) and is highly expressed on kidney tubular cells, and brain and gut endothelial cells. Moreover, in the kidney cytotoxicity is further amplified by tumor necrosis factor-α (TNF-α).

After binding to cell surfaces, Shiga toxin is endocytosed and retrograde-transported to the Golgi apparatus and the endoplasmic reticulum; it is then translocated to the cytosol where it inactivates ribosomes and causes cell death.[18]



Micrograph showing an acute thrombotic microangiopathy, as may be seen in TTP. A thrombus is present in the hilum of the glomerulus (center of image). Kidney biopsy.

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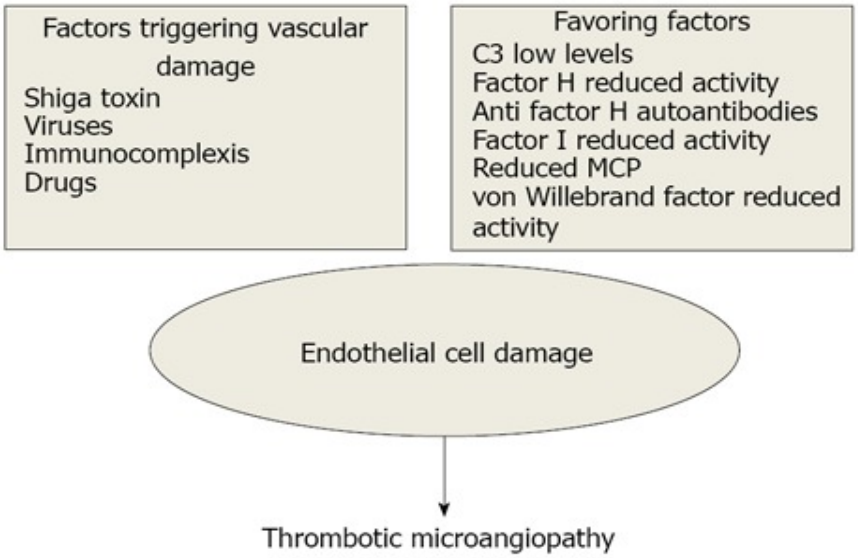

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a) Clinical Features

It usually presents with pentad of clinical five different manifestations which are:

- Thrombocytopenia
- Microangiopathic hemolytic anemia
- Neurologic symptoms and signs
- Renal function abnormalities
- Fever

b) Types

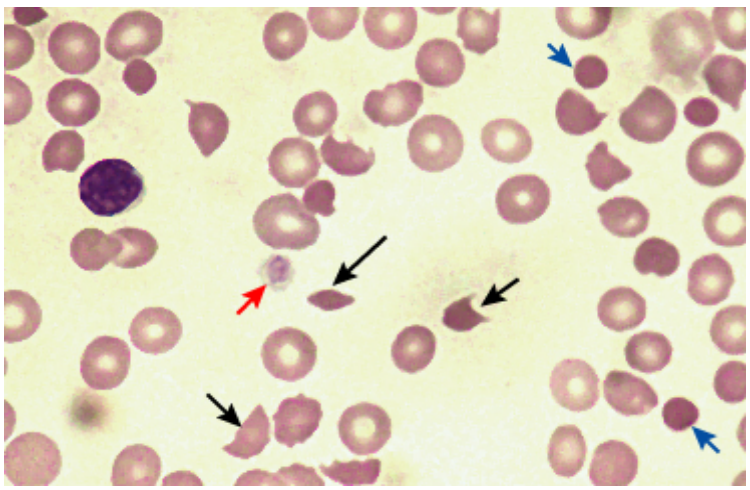
Clinically this disease is cateogarized into two major divisions:

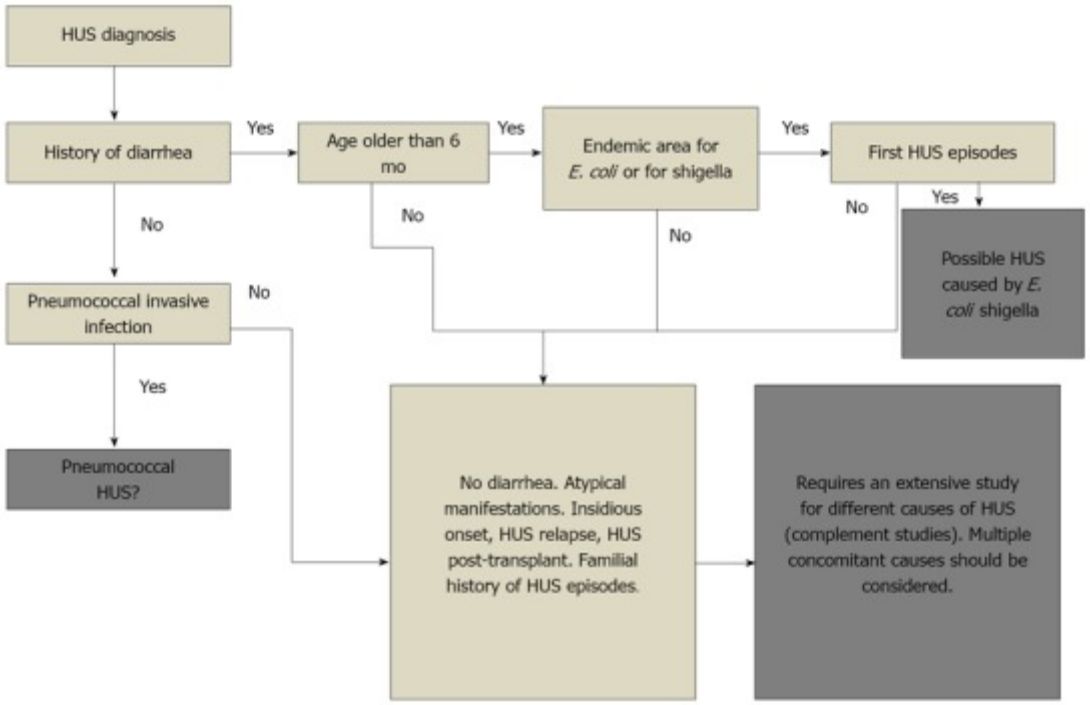
1. Typical HUS: The name typical HUS is generally reserved for children with the appearance of Shiga toxin-producing Escherichia coli (usually E. coli O157:H7)
2. Atypical HUS(aHUS): Atypical HUS is a heterogeneous disorder distinguished by the absence of diarrhea or Shiga toxin-producing E. coli infection. It is estimated that atypical HUS accounts for 5 to 10 percent of cases of childhood HUS.

The term TTP-HUS is typically used for adults as it is almost impossible to distinguish both and treatment is more or less the same.

III. Diagnosis

Despite the current advances in medicine we still have to start treating idiopathic TTP-HUS patients on basis of clinical suspicion. If a patient has microangiopathic hemolytic anaemia and thrombocytopenia without an obvious inciting event we start treatment empirically. Idiopathic TTP-HUS refers to TTP-HUS without an obvious inciting event, such as diarrheal illness, other infection, or new medication. Idiopathic TTP-HUS is a medical emergency that is almost always fatal if appropriate treatment is not initiated promptly.





Diagnostic algorithm to distinguish among different Hemolytic uremic syndrome. HUS: Hemolytic uremic syndrome; *E. coli*: *Escherichia coli*.

Measurement of ADAMTS13 activity: The value of using information concerning ADAMTS13 for initial diagnosis and treatment decisions remains questionable, especially since such results may not be available for several days, well after initial treatment decisions need to be made. Also, ADAMTS13 activity measured by different methods (eg, using a synthetic substrate versus intact von Willebrand factor) may have discrepant results in some patients.

- It has been concluded that the group of patients with severe ADAMTS13 deficiency does not include all patients who may respond to plasma exchange, and that persistence of ADAMTS13 deficiency with or without inhibitory antibody activity following plasma exchange may still be consistent with an excellent clinical response to treatment.
- ADAMTS13 measurements appear to be of greatest clinical value for estimating the prognosis for relapse after recovery from an acute episode, for initial treatment of a patient who has an acute, recurrent episode, and perhaps also for helping to distinguish the different mechanisms of thrombotic microangiopathy in complex clinical situations. Patients with an ADAMTS13 activity >10 percent at the time of their initial presentation rarely relapse. However the clinical importance of ADAMTS13 measurements during remission is unknown. Approximately 20 percent of patients will have persistent ADAMTS13 deficiency that may not predict a risk for relapse.

ADAMTS13 activity can be low due to an inherited defect or an acquired inhibitor, such as an autoantibody. However, the absence of a demonstrable ADAMTS13 inhibitor does not exclude the diagnosis of acquired, autoimmune TTP-HUS. The titer of ADAMTS13 inhibitors may be too low to be observed in a plasma mixing study, or may have been neutralized by multiple transfusions prior to obtaining a sample. An acquired autoimmune etiology, rather than a congenital deficiency of ADAMTS13, is documented by recovery of ADAMTS13 activity to normal during remission or by documenting the presence of an inhibitor at the time of a relapse.

These observations support the current practice of requiring only thrombocytopenia and microangiopathic hemolytic anemia with no other apparent cause in order to make a clinical diagnosis of TTP-HUS and initiate prompt treatment with plasma exchange in appropriate scenarios

Use of Complement markers in differentiating typical and atypical HUS:

Testing of biomarkers of complement activation, specifically C5a and C5b-9, may be useful clinically to confirm the clinical diagnosis of aHUS and differentiate it from acquired TTP. Although limited by the retrospective nature of the data, they should form the basis for future studies to evaluate their role in the confirmation of the diagnosis as well as a tool to objectively monitor the response to complement inhibition therapy.[16]

IV. Discussion

The mainstay of treatment for most patients with TTP-HUS is plasma exchange, which in the context of this syndrome refers to the removal of the patient's plasma by pheresis and the replacement with donor plasma rather than another replacement fluid such as albumin. [7,8].Compared with the mortality rate of 90 percent prior to the use of plasma exchange, the mortality rate for patients treated with plasma exchange is 25 percent or less .Plasma exchange should be initiated even if there is some uncertainty about the diagnosis of TTP-HUS, as it is considered that the potential dangers of rapid deterioration from TTP-HUS exceed the significant risks of plasma exchange treatment. [1,2].Many patients with typical TTP-HUS respond very well to plasma exchange therapy and have a great prognosis but aHUSpatientsdon't respond very well to plasma exchange therapy in addition to immunosuppressant therapy. Eculizumab has currently modified the outcome of aHUS patients but it helps to reduce morbidity specially if it is used at an earlier time during the course of treatment. Several advances in the treatment of atypical hemolytic uremic syndrome (aHUS) have placed an increased emphasis on the rapid and accurate differentiation of aHUS from acquired thrombotic thrombocytopenic purpura (TTP).Although both disorders share the common end point of widespread microvascular disease and end organ injury, their distinct underlying mechanisms of microvascular injury likely explain their differing responses to plasma exchange (PEX) and the response of patients with aHUS to complement inhibition therapy. Despite advances in our understanding of both aHUS and acquired TTP in recent years, both diseases remain clinical diagnoses.

Plasma exchange therapy: Plasma exchange was found to be superior to plasma infusion in the treatment of the vast majority of adults with TTP-HUS in two landmark trials that included 210 patients. Plasma exchange is more effective than plasma infusion in most adults with "classical" TTP-HUS because for the great majority of those who have decreased ADAMTS13 activity, the decreased activity is due to an inhibitory antibody. Plasma exchange both removes the inhibitory antibody and supplies replacement ADAMTS13 from the donor plasma in UpshawSchulaman Syndrome patients.

a) Eculizumab in refractory TTP patients

Most patients with refractory or relapsing TTP receive additional immunotherapy but there are cases in which patients don't respond to plasmapharesis therapy and need other treatment modalities like eculizumab which has been proven effective in many cases refractory to combination of plasmapharesis and immunosppressive therapy.

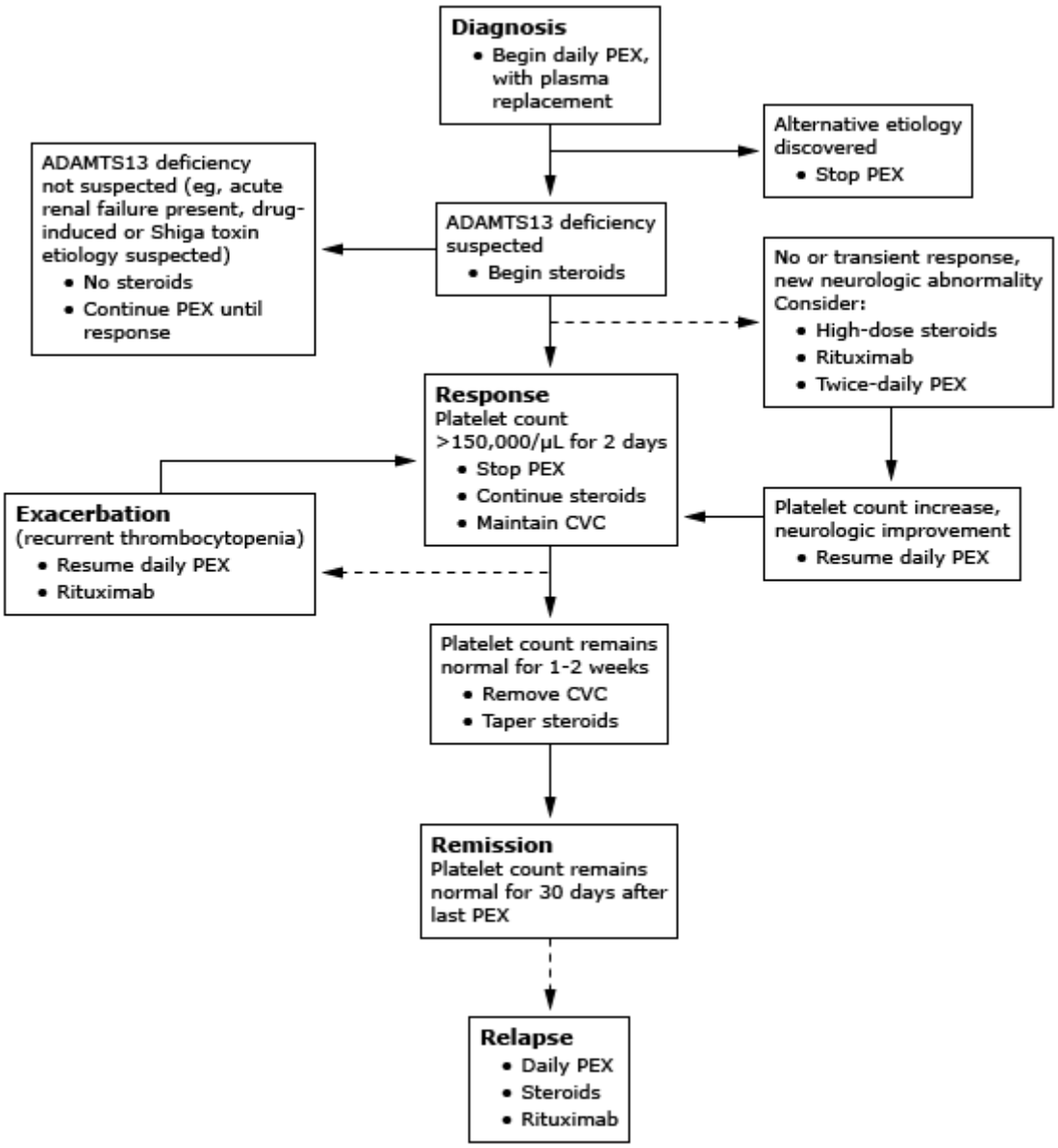
Many patients with diarrheal/STEC-HUS have an especially severe course and are challenging to manage. Eculizumab could be appropriate in patients with normal ADAMTS13 activity who have not shown improvement after two weeks of daily plasma exchange. There is still not enough data to guide treatment based upon complement testing. Additional concerns with this approach include the following:

- Cost
- Plasmapheresis removes eculizumab from the circulation, which will impair its effectiveness. So when patient is shifted to eculizumab plasma exchange therapy has to be discontinued.[8,9].

V. Concluion

Eculizumab use should be used for refractory TTP with normal ADAMTS 13 levels to plasma exchange therapy. Current guidelines suggest its use if patient fails to respond to plasma exchange after 2 weeks of daily but still not enough data is available to guide the duration of eculizumab use and use of complement testing to guide therapy. Early differentiation of typical versus atypical HUS can be very helpful in early administration and start of eculizumab therapy and can be very helpful for atypical HUS and effective in decreasing morbidity and ultimately progression to multisystem involvement like ESRD in many people.

Algorithmic Approach to Diagnosis and Treatment of TTP



a) Conflict of Interest

All authors have no any actual or potential conflict of interest including any financial, personal or other relationships with other people or organizations within three years of beginning the submitted work that could inappropriately influence, or be perceived to influence, our work.

b) Submission Declaration and Verification

We also declare that the work described has not been published previously except in the form of an abstract or as part of a published lecture or academic thesis or as an electronic preprint, is approved that, if accepted, it will not be published elsewhere in the same form, in English or in any other language, including electronically without the written consent of the copyright-holder.

c) Authorship

Ali Raza Ghani MD was the principal researcher and prepared the first draft of the report.

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Crossectional Survey; Assessment Of Diarrheal Disease Prevalence and Associated Factors Among Children Under Five In Enemay District, Northwest Ethiopia

By Abebaw Ayele, Worku Awoke & Molalign Tarekegn
Bahir Dar University, United States

Abstract- *Background:* Millions of children are still dying as a result of the preventable diarrheal disease than AIDS, malaria, and measles combined.

Objective: To determine the prevalence of diarrheal disease and associated factors among under 5 children in Enemay rural district, East Gojjam zone.

Methods: Community based cross sectional study was conducted on a sample size of 634.A multistage sampling technique in which seven from 34 kebeles were selected by simple random sampling and then proportional samples were drawn through systematic random sampling technique using the list of households who have children under five. The dependent variable was measured interms of the occurrence of loose/watery diarrhea for at least three times per day in the last two weeks before the survey. Data was collected through pretested structured questionnaire, and observation cheek list. It was collected by trained data collectors with the support of trained supervisors.

Keywords: *diarrhea, two week prevalence, ethiopia.*

GJMR-F Classification : *FOR Code: WK 550, WI 407*

Strictly as per the compliance and regulations of:

Crossectional Survey; Assessment Of Diarrheal Disease Prevalence and Associated Factors Among Children Under Five In Enemay District, Northwest Ethiopia

Abebaw Ayele [α], Worku Awoke [σ] & Molalign Tarekegn [ρ]

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Result: The two-week prevalence of diarrhea among under-five children was 18.6 %. It was highly associated with educational status (AOR, 2.49; 95% CI (1.28,4.83))and occupation of mother (AOR, 1.78; 95%; CI 1.05,3.00); availability of proper waste disposal system in the household (AOR, 2.27;95% CI (1.40-3.68)), Measles vaccination status (AOR, 0.20; 95% CI, 0.10-0.37) and vitamin A supplementation for children under 5 years (AOR, 3.98; 95% CI (2.42,6.53)) .

Conclusion: In order to reduce the magnitude of the disease, efforts need to focus on giving health education for mothers, the community to prepare proper liquid waste disposal system and strengthening vitamin A supplementation for children under 5.

Keywords: diarrhea, two week prevalence, ethiopia.

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I. Introduction

Despite there is a decline in the trend, millions of children under five are still dying as a result of the preventable diarrheal disease characterized by the passage of loose or watery stool for three or more times during a 24-hour's period (Gerald T. Keusch, et al., 2001). It is responsible for 17 % of all deaths (about 2.5 million deaths each year) among children under-five years in the world which is higher than AIDS, malaria, and measles combined (UNICEF/WHO, 2009).

The majority (42%) of this death is concentrated in the Sub-Saharan African countries including Ethiopia (88 per 1,000 live births) where hygiene and sanitation is poor (Bryce J, et al., 2005 and Central Statistical Agency [Ethiopia] and ICF International, 2011). Recent national estimates indicate that, the two week period prevalence is approximately 13% (Central Statistical Agency [Ethiopia] and ICF International, 2011). Moreover, local studies reported a prevalence rate of 31% in southern Ethiopia, 22.5% in Eastern part of Ethiopia and 18% to 24.9 % in Northwest Ethiopia (Muluken D, et al., (2011), Shikur M, et al.,2013, Bezatu M et al.,2013, Amare D, et al 2007).

Though these few reports were available, further evidence is required in different regions of the country where up to date information were not available to monitor the progress for the efforts done to achieve the millennium development goals. This study will help as an input for decision-makers in the health department to prioritize interventions that are required to overcome the progression of the problem.

II. Methods

a) Study design and period

A community based cross sectional study was conducted among children less than 5 years of age in Enemay district. It is one of the 18 districts of east Gojjam zone, Amhara regional state located at 87 Kms away from Debre Markos town. In this districts there are 34 kebeles, 7 health centers and 35 health posts are available to provide health service to the community.

b) Sample size determination

The sample size was determined using single population proportion formula. The assumptions were Z critical for an alpha value of 0.05, Margin of error of 0.05, previous prevalence of 0.5, design effect of 1.5 and a non response rate of 10%. With the above assumptions the final sample size came up with 634.

c) Sampling Method and procedure

To select the sample First 7 kebeles were selected from 34 kebeles by simple random sampling technique; and then proportional allocation to population in each kebele was made to allocate the samples that were drown from the kebeles. Finally using the list of household in the kebele the samples were drown every escape interval (K). In cases where there was more than one child in a household, one child was selected using lottery method.

d) Variables

The study variables were selected after review of related literatures in the context of the study area. The outcome variable of this study was diarrheal disease and it was measured interms of the occurrence of loose/ watery diarrhea at least three times per day for the last two weeks.

e) Data Collection and Analysis

Structured questionnaires and observation checklist were prepared in English and translated to local language. Individuals with better experience has assigned as data collector and supervisor. Training was given on how to maintain the quality of data, ethical issues and the like. After pretest the necessary corrections were made and then the actual data collection was undertaken. The Collected data were checked for errors and cleaned on daily basis. Finally it was coded, analyzed using SPSS version 16. Unvariate, bivariate and multivariate analysis was done. Results were presented using tables and figures. OR with corresponding 95% CI were used to determine relationships between selected predictor variables and diarrheal disease.

f) Operational definition

Hand-washing at critical times: Hand washing before and after cooking foods, after the latrine use.

Proper hand washing: Hand washing with soap or ash at critical times.

Kebele: The lowest government administrative hierarchy.

g) Ethical Considerations

Ethical clearance was obtained from the research and ethical review committee of GAMBY College of medical sciences. The health department at regional, zonal and districts level was communicated legally for its permission and each of the interviewers were requested verbal consent before the interviewee.

III. Result

a) Socio demographic and economic Characteristics

A total of 634 households were included in this study with response rate of 100%.From the attendants of mothers, 579 (91.3) were married, illiterate 522(82.3), Orthodox by religion 579(91.3) and farmers by their occupational status 502 (79.2). The mean age of the child was 2.26 (± 1.123).

Table 1 : Socio Demographic and Economic characteristics of households in Enemay district, Northwest Ethiopia 2014

Variable	Category	Frequency	
		Number	%
Mother Educational Status	Non educated	522	82.3
	Primary and above	112	17.7
Occupation of mother	Farmer	502	79.2
	Others	132	20.8
Marital Status	Married	579	91.3
	Unmarried	18	2.8
	Divorce	34	5.4
	Widowed	3	0.5
husband Occupation	Farmer	536	89.2
	Other	65	10.8
House hold average income	<600	122	28.0
	>600	313	72.0
Age of the mother (years)	15-24	81	12.7
	25-34	389	61.5
	>35	164	25.8
Religion of mother	Orthodox	579	91.3
	Muslim	55	8.7

	Muslim	55	8.7
Family Size	Less than or equal to four	289	45.6
	Greater than four	345	54.4
Age of the child (month)	<6	124	19.6
	7-11	173	27.3
	12-23	133	21.0
	24-59	204	32.2
Sex	Male	335	52.8
	Female	299	47.2

b) Environmental Characteristics related with study participants

From the total 634; most of the households ,565 (89.1%) were accessed with improved water source and the distance to collect water took 16-30 minute for the majority ,350(55.2 %) of households. More than half of the respondents ,339(53.5%) were not using treated water for drinking.

Most of the respondents, 517 (81.5%) have latrine in their households and the majority of them 466(90%) were functional during the interview and most of them,348(67.3%) were using the latrine all the time. During the period of data collections, feces was observed around the hole of 307(59.4%) latrine facilities and in the compound of 196(30.9%) household. Most of the respondents were not prepared proper waste disposal system for both liquid and solid waste.

Table 2 : Environmental characteristics of households in Enemay district, Northwest Ethiopia 2014

Variable	Category	Frequency	
		Number	%
Source of water	Improved	565	89.1
	Un improved	69	10.9
Distance from improved water source	<15 minute	234	41.4
	16-30 minute	313	55.4
	>30 minute	18	3.2
Drinking Water treatment	Yes	295	46.5
	No	339	53.5
Availability of latrine	Yes	517	81.5
	No	117	18.5
Function of latrine	Functional	465	90.0
	Non functional	52	10.0
Availability of hand washing facility	Yes	279	54.0
	No	238	46.0
Feces in the latrine hole	Yes	210	40. 6
	No	307	59.4
Feces in the compound	Yes	196	30.9
	No	438	69.1
Animals in the house	Yes	152	24.0
	No	482	76.0
Type of liquid waste disposal	Non proper	395	62.3
	Proper	239	37.0
Type of solid waste disposal	Un improved	342	53.9
	Improved	292	46.1

c) Magnitude of diarrheal disease and Behavioral Characteristics related with Child care practice

In this study the prevalence of diarrheal disease among under five children was 18.6%. About 508 (80.1%) children were initiated for breast feeding within one hour of delivery. Most children, 460 (87.6%) started additional food after 6 months and the majority of them, 253 (53 %) were started in the form of soft porridge.

During assessment of the critical hand washing trends in the study area; washing hand before food preparation ,532(83.9%) were the most frequently practiced and follows in sequential order, after toilet visiting 498 (78.5%), before feeding the child 444(70%)

and before food eating 427(67.4%). Besides, 449(70.8%) under five children were vaccinated for measles and 475 (74.9%) took vitamin A supplementation.

Table 3 : Behavioral characteristics of households in Enemay district, Northwest Ethiopia 2014 (Child care practice)

Variable	Response category	Frequency	
		Number	%
Diarrheal disease in the past two weeks	Yes	118	18.6
	No	516	81.4
Initiation of first breast milk	before 1 hr	508	80.1
	After 1 hr	126	19.9
Age of Additional food started	Under 6 months	65	12.4
	>= 6 months	460	87.6
Type of additional food started	Soft Porridge	278	53.0
	Other	181	34.5
	Porridge and Gruel	66	12.6
Hand washing practice			
Before food preparation	Yes	532	83.9
	No	102	16.1
After toilet visiting	Yes	498	78.5
	No	136	21.5
Before food eating	Yes	427	67.4
	No	207	32.6
Before feeding the child	Yes	444	70.0
	No	190	30.0
Latrine utilization by households	Sometimes	54	10.4
	Mostly	107	20.7
	Always	348	67.4
	During the winter	8	1.5
Measles Vaccination	Yes	449	70.8
	No	185	29.2
Vitamin A	Yes	475	74.9
	No	159	25.1

d) Factors associated with diarrheal disease among under five children Enemay district

In order to control the effect of Confounding first the association of each independent variable on the dependent variable was assessed and then those variables p value of less or equal to 0.2 were entered to multivariable analysis to identify their independent effect on diarrheal disease. At the end Mothers Education (AOR, 2.49; 95%CI, 1.28-4.83),Mother Occupation (AOR, 1.78; 95%CI, 1.05-3.00), Liquid waste disposal (AOR, 2.27; 95%CI, 1.40-3.68), Measles Vaccination (AOR, 0.20; 95% CI, 0.10-0.37) and Vitamin A supplementation (AOR, 3.98; 95%CI, (2.42-6.53).

Table 4 : Factors associated with diarrheal disease among under- five children in Enemay district, Northwest Ethiopia, 2014

Characteristics	Diarrheal disease		COR(95%CI)	AOR(95%CI)
	Yes	No		
Age of mother				
15-24*	22	59	1.00	1.00
25-34	64	325	0.52 (0.30,0.92)	0.48 (0.26,0.88)
>35	32	132	0.65 (0.34,1.21)	0.62 (0.31,1.23)
Age of the child				
< 6m*	11	113	1.00	1.00
6-11M	35	138	2.60 (1.26,5.36)	2.16 (0.94,4.97)
12-23M	30	103	2.99 (1.42,6.27)	1.69 (0.65,4.38)
>24 M	42	162	2.66 (1.31,5.39)	1.60 (0.63,4.03)
Mothers Education				

Non educated	103	419	1.59 (0.88,2.85)	2.49 (1.28,4.83)
Primary and above*	15	97	1.00	1.00
Mother Occupation				
Farmer*	83	419	1.00	1.00
Other	35	97	1.82 (1.15,2.86)	1.78 (1.05,3.00)
Water treatment				
Yes*	45	250	1.00	1.00
No	73	266	1.52 (1.01,2.29)	1.07 (0.67,1.73)
Liquid waste disposal				
Non proper	90	305	2.22 (1.40,3.51)	2.27 (1.40,3.68)
Proper *	28	211	1.00	1.00
Hand wash after toilet				
Yes*	73	371	1.00	1.00
No	45	145	1.57 (0.1.03,2.39)	1.34 (0.85,2.13)
Before child feeding				
Yes*	73	354	1.00	1.00
No	45	162	1.34 (0.88,2.04)	1.12 (0.63, 1.97)
Measles Vaccination				
Yes*	99	350	2.5 (1.47 ,4.35)	5.00 (2.70, 10.00)
No	19	166	1.00	1.00
Vitamin A				
Yes*	67	379	1.00	1.00
No	51	137	2.10 (1.39,3.18)	3.98 (2.42,6.53)

IV. Disscussion

The current study investigated the prevalence of diarrheal disease and its associated factors in under five children. Based on the study, the two-week period prevalence of diarrheal disease was 18.6 %. This was in line with the finding in the study done in northern part of Ethiopia, 18.2% (Muluken D, et al., 2011), Eastern part of Ethiopia 22.5% (Amare D, et al., 2007) and North Gonder zone 17.9% (Mitike G, 2001) and it was lower than the finding in Arba Minch district 31% (Shikur M, et al, 2012) and Awi zone 24.9 % (Bezatu M,et al., (2013). However, the current finding was higher than the finding

This difference might be due to the difference in hygiene and sanitation measures taken in Northeast Brazil where intervention was done before conducting the prevalence study.

In this study children living with non educated mothers were about 2.49 times more likely to develop diarrheal disease than those who were living with primary and secondary education level which is in line with the study done in Northern parts of Ethiopia (Muluken D, et al., 2011). This difference might be due to the fact that educated mothers are more likely to have better knowledge towards good hygienic, feeding and weaning practices.

Those children from mothers who were farmers by their occupation were 0.44 less likely to 0.44 less likely to develop diarrheal diseases than children from mothers of others occupational category. Even though not considered in the current study, the reason might be the difference in the variety of food items children took. Children from mothers who were farmers in Enemay district might gain Varity of food items as compared with those children from mothers who were not farmers.

According to this study, children from households which dispose liquid wastes inappropriately were also 2.27 (AOR, 1.40-3.68) times more likely to develop diarrheal disease. district, Ethiopia (Girma R., et al, 2007). Liquid waste contains different pathogens which can cause diarrheal disease in children. The proper disposal of liquid waste protects food materials from contamination since flies cannot reach it easily. To the contrary if not disposed properly it will be easily accessible for flies that can transmit pathogens.

Children who didn't took vitamin A supplementation in the last six months of the study had shown 3.98 times more likely to develop diarrheal disease as compared with those who took vitamin A supplementation. This is because Vitamin A is one of the essential micronutrient which prevents infection and strength the immunity of human cells particularly in children (Imdad A., et al., 2011). Similar finding in line with the finding from Brazil where 20% difference in prevalence was observed among the groups who were taking Vitamin A as compared with who were not taking Vitamin A (Barreto ML, et al., 1994)

The unusual thing which was observed in this study and to discuss was that, children who were vaccinated for measles were 5 times more likely to develop diarrheal diseases than those who were not vaccinated. In the current study, vaccination status of children were not checked by card rather it was determined by the response of parents, this might

create problem in giving the correct response about which type of vaccine the child took.

V. Conclusion

Children in the study area were still suffering from this preventable diarrheal disease. Mother's educational and occupational status, inappropriate liquid waste disposal method, children vitamin A supplementation and measles vaccination status were the main factors associated with the two week prevalence of diarrhea. It is recommended that the health department in the study area should designing a mechanism to raise awareness of mothers towards diarrheal disease prevention, proper sanitation and hygiene measures with special emphasis to proper liquid waste disposal system , strengthening vitamin A supplementation program to give for every child of 6 months and above and further research is recommended identify the effect of measles vaccination on the occurrence of diarrheal disease among children of under five years old.

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Effect of Supplementation of Mulberry leaf Powder on the Blodo Sugar levels of the Selected NIDDM Subjects

By Manju Vani M & Jyothi A
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Abstract- Diabetes is a disorder characterized by the passage of sweet urine, excessive urine production, thirst, excessive hunger and in some cases, weight loss. Diabetes mellitus can be defined as a group of disorders with a common characteristic of hyperglycemia. Hyperglycemia means an elevated level of glucose in the blood. In the management of diabetes mellitus, diet has been recognized as a corner stone of therapy. In recent years, there has been much speculation over the dietary formulation, which may be the most effective in achieving better control of blood sugar and in addition, is most likely to prevent or delay the debilitating complications of diabetes. The present study was designed to see the effect of supplementation of mulberry leaf powder supplement on NIDDM subjects. An initial sample of 200 NIDDM subjects were randomly selected from one private and two government health centers of Tirupati who were between the age group of 30 to 60 years. A purposive sample of n=120 NIDDM subjects were selected from which control group n=60 and experimental group n=60 were divided. Mulberry leaf powder supplementation was given for experimental group for a period of 60 days. Results reveals that a significant difference at 1% was identified in the experimental group of subjects when compared to the control group clearly tells that mulberry leaf powder supplementation helped in controlling blood sugar levels.

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Manju Vani M [α] & Jyothi A [σ]

Abstract- Diabetes is a disorder characterized by the passage of sweet urine, excessive urine production, thirst, excessive hunger and in some cases, weight loss. Diabetes mellitus can be defined as a group of disorders with a common characteristic of hyperglycemia. Hyperglycemia means an elevated level of glucose in the blood. In the management of diabetes mellitus, diet has been recognized as a corner stone of therapy. In recent years, there has been much speculation over the dietary formulation, which may be the most effective in achieving better control of blood sugar and in addition, is most likely to prevent or delay the debilitating complications of diabetes. The present study was designed to see the effect of supplementation of mulberry leaf powder supplement on NIDDM subjects. An initial sample of 200 NIDDM subjects were randomly selected from one private and two government health centers of Tirupati who were between the age group of 30 to 60 years. A purposive sample of n=120 NIDDM subjects were selected from which control group n=60 and experimental group n=60 were divided. Mulberry leaf powder supplementation was given for experimental group for a period of 60 days. Results reveals that a significant difference at 1% was identified in the experimental group of subjects when compared to the control group clearly tells that mulberry leaf powder supplementation helped in controlling blood sugar levels.

I. Introduction

Mulberry leaf is commonly used for sericulture in almost every part of the world. But its potential to be utilized for human consumption is not well recognized. Many studies reveal that, mulberry has the properties of reducing blood serum glucose, lowering blood cholesterol and lipid levels, fighting arterial plaque etc. Various components present in mulberry that attribute to such therapeutic benefits are GABA (Gamma Amino Butyric Acid), Phytosterol DNJ (Deoxy Nojirimycin) flavonoids, alkaloids, steroids.

The primary goal in the management of diabetes mellitus is the attainment of near-normal glycaemia. In India, more than half of patients have poor glycaemic control and have vascular complications. Therefore, there is an urgent need to develop novel therapeutic agents of diabetes without the development and progression of complications or compromising on safety. Hence the present study was undertaken to see the effect of mulberry leaf powder on the selected NIDDM subjects.

II. Objectives of the Study

- To assess the nutrient intake of the selected diabetes NIDDM subjects.
- To study the supplementation of mulberry leaf powder and its effect on controlling the blood sugar levels in the selected NIDDM subjects.

III. Materials & Methods

An initial sample of 200 NIDDM subjects with the age group of 30 – 60 years were randomly selected and a purposive sample of n=120 NIDDM subjects were selected, from which control group (n=60) and experimental group (n=60) subjects were divided. The experimental samples were given 30gm of mulberry leaf powder and are advised that, the dietary supplement can be mixed and ingested with plain water, butter milk, tea even with foods like breakfast items, snacks, soups etc for a period of 2 months. Blood glucose were analyzed using glucometer. The SPSS (13.1 version) package programme was used for statistical analysis of the data. Means and standard deviations were calculated. Independent sample student's t-test was used to know the significant difference between the independent like blood sugar variables. Paired t-test was used to know the significant difference between experiment and control groups.

IV. Results & Discussion

As per the objectives of the study the sample study consists of selected NIDDM subjects in the age group of 30 to 60 years. Initially the nutritional status of randomly selected 200 diabetic subjects was assessed with the help of a well designed questionnaire.

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Table 1 : Percentage distribution of the sample according to their nutrient intake

S.No	Type of work	Males				Females			
		Energy (K.Cal)	CHO (g)	Proteins (g)	Fats (g)	Energy (K.Cal)	CHO (g)	Proteins (g)	Fats (g)
1.	Sedentary	2800	500	97	45	2665	475	90	44
2.	Moderate	2330	380	90	50	2035	400	60	35
3.	Heavy work	2540	290	100	60	2490	420	90	50

Table-1 shows the percent prevalence of selected diabetic patients with regard to diet pattern. The mean intake of calories were found to be 2800 k.cal among male sedentary workers and 2665 k.cal among female sedentary workers whereas the normal requirement range of male sedentary workers is 2400 k. cal and among females 1800kcal.

This clearly shows that the study subjects are not following diabetes menu plan regularly. The mean calorie intake observed was 2330 k.cal in male moderate workers and among females the mean calorie intake was 2035 k.cal the intake was less than the recommended dietary allowances whereas the normal requirement range of male moderate workers is 3900 k.cal and in females it is 3000 k.cal.

From the present study it is clearly evident that in the sedentary workers intake of calories was more. The reason is in the diet survey through 24 hour –recall method of selected diabetic patients that it has seen that consumption of calories was higher than the recommended values. Consumption of fruits and vegetables is considerably low. Foods such as meat, chicken, eggs, and milk are taken more than the vegetables, cereals, pulses and grains that increased the calorie levels.

As per the second objective mentioned in the study, supplementation of mulberry leaf powder was given to the selected experimental group of subjects for a period of 60 days and the results were analyzed are given Table-2.

Table 2 : Mean blood Sugar levels of the selected diabetic patients

S.No	Group	Test	Blood Sugar (mg/dl) Normal Value: 70-125 (mg/dl)	N	Standard Deviation(±)	t-value	p-value
1.	Control Group	Initial	145.93	60	62.89	1.88	0.06
		Final	145.82	60	63.04		
2.	Experimental Group	Initial	114.82	60	45.40	5.72**	0.00
		Final	88.77	60	22.89		

*** Significant at 1 percent level*

The blood sugar levels of the selected NIDDM patients are given in the table-2. In the present study a significant difference of blood sugar was found in both control and experimental groups after supplementation of mulberry leaves. In the control group the mean blood sugar level change from 145.93 ± 62.89 mg/dl to 145.82 ± 63.04 mg/dl which is not statistically significant.

Hence it is clearly understood that as the control group is not given any supplementation there was no decrease in blood sugar levels.

In the experimental group that is after supplementation of mulberry leaf powder, the mean blood sugar levels were decreased to 88.77 ± 22.89 mg/dl from 114.82 ± 45.40 mg/dl. Hence it is clear that the mulberry supplementation has shown a remarkable decrease in blood sugar levels when compared to control group and is shown in figure no.1.

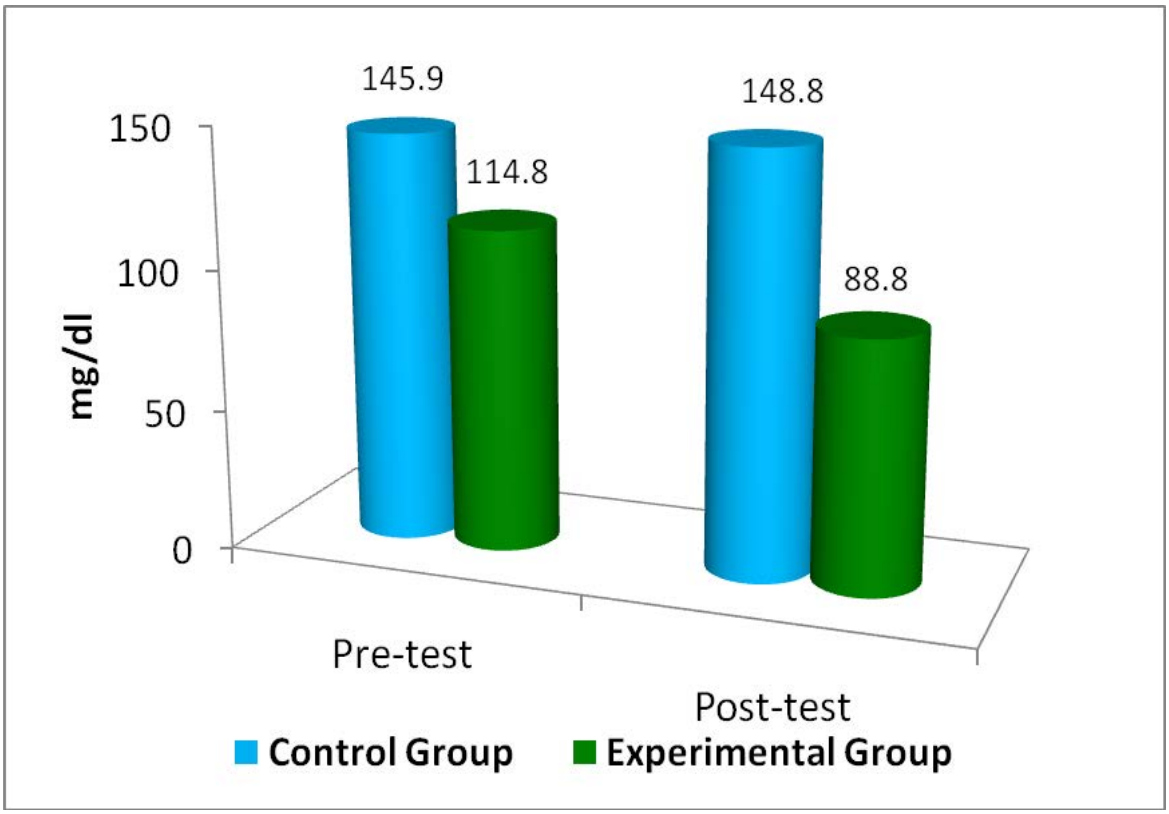

Fig 1 : Change in the blood sugar levels of the selected type II diabetic patients

V. Conclusion

The approach to the dietary treatment of diabetes and the therapeutic implications of mulberry has been illustrated in many investigations. No disease evokes greater emphasis on dietary management than diabetes. A well managed diabetic is one who no longer dreads the disease, has good life expectancy, has been guided correctly to understand the status of the health develops skills to manage this disease and leads near normal, active and healthy life. In conclusion the present study provides the data suggest that, mulberry therapy is capable of enhancing glycemic control in NIDDM subjects.

VI. Recommendations

Mulberry is grown for sericulture practices in several centuries. Recent researches tell that mulberry has created a new dimension that it has been cultivated even for human consumption because of its nutritive values and its therapeutic properties as well as low cost and without any side effects. Instead of drug therapy, mulberry leaves can be used as a natural diabetic treating herb. So that, mulberry farming can generate income for its farmers not only through sericulture, when it is utilized for human consumption can also generate income for the mulberry farmers.

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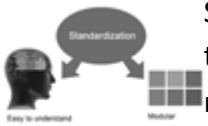

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"

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3. Submission of Manuscripts,

4. Manuscript's Category,

5. Structure and Format of Manuscript,

6. After Acceptance.

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14. Produce good diagrams of your own: Always try to include good charts or diagrams in your paper to improve quality. Using several and unnecessary diagrams will degrade the quality of your paper by creating "hotchpotch." So always, try to make and include those diagrams, which are made by your own to improve readability and understandability of your paper.

15. Use of direct quotes: When you do research relevant to literature, history or current affairs then use of quotes become essential but if study is relevant to science then use of quotes is not preferable.

16. Use proper verb tense: Use proper verb tenses in your paper. Use past tense, to present those events that happened. Use present tense to indicate events that are going on. Use future tense to indicate future happening events. Use of improper and wrong tenses will confuse the evaluator. Avoid the sentences that are incomplete.

17. Never use online paper: If you are getting any paper on Internet, then never use it as your research paper because it might be possible that evaluator has already seen it or maybe it is outdated version.

18. Pick a good study spot: To do your research studies always try to pick a spot, which is quiet. Every spot is not for studies. Spot that suits you choose it and proceed further.

19. Know what you know: Always try to know, what you know by making objectives. Else, you will be confused and cannot achieve your target.

20. Use good quality grammar: Always use a good quality grammar and use words that will throw positive impact on evaluator. Use of good quality grammar does not mean to use tough words, that for each word the evaluator has to go through dictionary. Do not start sentence with a conjunction. Do not fragment sentences. Eliminate one-word sentences. Ignore passive voice. Do not ever use a big word when a diminutive one would suffice. Verbs have to be in agreement with their subjects. Prepositions are not expressions to finish sentences with. It is incorrect to ever divide an infinitive. Avoid clichés like the disease. Also, always shun irritating alliteration. Use language that is simple and straight forward. put together a neat summary.

21. Arrangement of information: Each section of the main body should start with an opening sentence and there should be a changeover at the end of the section. Give only valid and powerful arguments to your topic. You may also maintain your arguments with records.

22. Never start in last minute: Always start at right time and give enough time to research work. Leaving everything to the last minute will degrade your paper and spoil your work.

23. Multitasking in research is not good: Doing several things at the same time proves bad habit in case of research activity. Research is an area, where everything has a particular time slot. Divide your research work in parts and do particular part in particular time slot.

24. Never copy others' work: Never copy others' work and give it your name because if evaluator has seen it anywhere you will be in trouble.

25. Take proper rest and food: No matter how many hours you spend for your research activity, if you are not taking care of your health then all your efforts will be in vain. For a quality research, study is must, and this can be done by taking proper rest and food.

26. Go for seminars: Attend seminars if the topic is relevant to your research area. Utilize all your resources.

27. Refresh your mind after intervals: Try to give rest to your mind by listening to soft music or by sleeping in intervals. This will also improve your memory.

28. Make colleagues: Always try to make colleagues. No matter how sharper or intelligent you are, if you make colleagues you can have several ideas, which will be helpful for your research.

29. Think technically: Always think technically. If anything happens, then search its reasons, its benefits, and demerits.

30. Think and then print: When you will go to print your paper, notice that tables are not be split, headings are not detached from their descriptions, and page sequence is maintained.

31. Adding unnecessary information: Do not add unnecessary information, like, I have used MS Excel to draw graph. Do not add irrelevant and inappropriate material. These all will create superfluous. Foreign terminology and phrases are not apropos. One should NEVER take a broad view. Analogy in script is like feathers on a snake. Not at all use a large word when a very small one would be sufficient. Use words properly, regardless of how others use them. Remove quotations. Puns are for kids, not grunt readers. Amplification is a billion times of inferior quality than sarcasm.

32. Never oversimplify everything: To add material in your research paper, never go for oversimplification. This will definitely irritate the evaluator. Be more or less specific. Also too, by no means, ever use rhythmic redundancies. Contractions aren't essential and shouldn't be there used. Comparisons are as terrible as clichés. Give up ampersands and abbreviations, and so on. Remove commas, that are, not necessary. Parenthetical words however should be together with this in commas. Understatement is all the time the complete best way to put onward earth-shaking thoughts. Give a detailed literary review.

33. Report concluded results: Use concluded results. From raw data, filter the results and then conclude your studies based on measurements and observations taken. Significant figures and appropriate number of decimal places should be used. Parenthetical remarks are prohibitive. Proofread carefully at final stage. In the end give outline to your arguments. Spot out perspectives of further study of this subject. Justify your conclusion by at the bottom of them with sufficient justifications and examples.

34. After conclusion: Once you have concluded your research, the next most important step is to present your findings. Presentation is extremely important as it is the definite medium though which your research is going to be in print to the rest of the crowd. Care should be taken to categorize your thoughts well and present them in a logical and neat manner. A good quality research paper format is essential because it serves to highlight your research paper and bring to light all necessary aspects in your research.

Informal Guidelines of Research Paper Writing

Key points to remember:

- Submit all work in its final form.
- Write your paper in the form, which is presented in the guidelines using the template.
- Please note the criterion for grading the final paper by peer-reviewers.

Final Points:

A purpose of organizing a research paper is to let people to interpret your effort selectively. The journal requires the following sections, submitted in the order listed, each section to start on a new page.

The introduction will be compiled from reference matter and will reflect the design processes or outline of basis that direct you to make study. As you will carry out the process of study, the method and process section will be constructed as like that. The result segment will show related statistics in nearly sequential order and will direct the reviewers next to the similar intellectual paths throughout the data that you took to carry out your study. The discussion section will provide understanding of the data and projections as to the implication of the results. The use of good quality references all through the paper will give the effort trustworthiness by representing an alertness of prior workings.

Writing a research paper is not an easy job no matter how trouble-free the actual research or concept. Practice, excellent preparation, and controlled record keeping are the only means to make straightforward the progression.

General style:

Specific editorial column necessities for compliance of a manuscript will always take over from directions in these general guidelines.

To make a paper clear

· Adhere to recommended page limits

Mistakes to evade

- Insertion a title at the foot of a page with the subsequent text on the next page
- Separating a table/chart or figure - impound each figure/table to a single page
- Submitting a manuscript with pages out of sequence

In every sections of your document

· Use standard writing style including articles ("a", "the," etc.)

· Keep on paying attention on the research topic of the paper

· Use paragraphs to split each significant point (excluding for the abstract)

· Align the primary line of each section

· Present your points in sound order

· Use present tense to report well accepted

· Use past tense to describe specific results

· Shun familiar wording, don't address the reviewer directly, and don't use slang, slang language, or superlatives

· Shun use of extra pictures - include only those figures essential to presenting results

Title Page:

Choose a revealing title. It should be short. It should not have non-standard acronyms or abbreviations. It should not exceed two printed lines. It should include the name(s) and address (es) of all authors.

Abstract:

The summary should be two hundred words or less. It should briefly and clearly explain the key findings reported in the manuscript--must have precise statistics. It should not have abnormal acronyms or abbreviations. It should be logical in itself. Shun citing references at this point.

An abstract is a brief distinct paragraph summary of finished work or work in development. In a minute or less a reviewer can be taught the foundation behind the study, common approach to the problem, relevant results, and significant conclusions or new questions.

Write your summary when your paper is completed because how can you write the summary of anything which is not yet written? Wealth of terminology is very essential in abstract. Yet, use comprehensive sentences and do not let go readability for briefness. You can maintain it succinct by phrasing sentences so that they provide more than lone rationale. The author can at this moment go straight to shortening the outcome. Sum up the study, with the subsequent elements in any summary. Try to maintain the initial two items to no more than one ruling each.

- Reason of the study - theory, overall issue, purpose
- Fundamental goal
- To the point depiction of the research
- Consequences, including definite statistics - if the consequences are quantitative in nature, account quantitative data; results of any numerical analysis should be reported
- Significant conclusions or questions that track from the research(es)

Approach:

- Single section, and succinct
- As a outline of job done, it is always written in past tense
- A conceptual should situate on its own, and not submit to any other part of the paper such as a form or table
- Center on shortening results - bound background information to a verdict or two, if completely necessary
- What you account in an conceptual must be regular with what you reported in the manuscript
- Exact spelling, clearness of sentences and phrases, and appropriate reporting of quantities (proper units, important statistics) are just as significant in an abstract as they are anywhere else

Introduction:

The **Introduction** should "introduce" the manuscript. The reviewer should be presented with sufficient background information to be capable to comprehend and calculate the purpose of your study without having to submit to other works. The basis for the study should be offered. Give most important references but shun difficult to make a comprehensive appraisal of the topic. In the introduction, describe the problem visibly. If the problem is not acknowledged in a logical, reasonable way, the reviewer will have no attention in your result. Speak in common terms about techniques used to explain the problem, if needed, but do not present any particulars about the protocols here. Following approach can create a valuable beginning:

- Explain the value (significance) of the study
- Shield the model - why did you employ this particular system or method? What is its compensation? You strength remark on its appropriateness from a abstract point of vision as well as point out sensible reasons for using it.
- Present a justification. Status your particular theory (es) or aim(s), and describe the logic that led you to choose them.
- Very for a short time explain the tentative propose and how it skilled the declared objectives.

Approach:

- Use past tense except for when referring to recognized facts. After all, the manuscript will be submitted after the entire job is done.
- Sort out your thoughts; manufacture one key point with every section. If you make the four points listed above, you will need a least of four paragraphs.

- Present surroundings information only as desirable in order hold up a situation. The reviewer does not desire to read the whole thing you know about a topic.
- Shape the theory/purpose specifically - do not take a broad view.
- As always, give awareness to spelling, simplicity and correctness of sentences and phrases.

Procedures (Methods and Materials):

This part is supposed to be the easiest to carve if you have good skills. A sound written Procedures segment allows a capable scientist to replacement your results. Present precise information about your supplies. The suppliers and clarity of reagents can be helpful bits of information. Present methods in sequential order but linked methodologies can be grouped as a segment. Be concise when relating the protocols. Attempt for the least amount of information that would permit another capable scientist to spare your outcome but be cautious that vital information is integrated. The use of subheadings is suggested and ought to be synchronized with the results section. When a technique is used that has been well described in another object, mention the specific item describing a way but draw the basic principle while stating the situation. The purpose is to text all particular resources and broad procedures, so that another person may use some or all of the methods in one more study or referee the scientific value of your work. It is not to be a step by step report of the whole thing you did, nor is a methods section a set of orders.

Materials:

- Explain materials individually only if the study is so complex that it saves liberty this way.
- Embrace particular materials, and any tools or provisions that are not frequently found in laboratories.
- Do not take in frequently found.
- If use of a definite type of tools.
- Materials may be reported in a part section or else they may be recognized along with your measures.

Methods:

- Report the method (not particulars of each process that engaged the same methodology)
- Describe the method entirely
- To be succinct, present methods under headings dedicated to specific dealings or groups of measures
- Simplify - details how procedures were completed not how they were exclusively performed on a particular day.
- If well known procedures were used, account the procedure by name, possibly with reference, and that's all.

Approach:

- It is embarrassed or not possible to use vigorous voice when documenting methods with no using first person, which would focus the reviewer's interest on the researcher rather than the job. As a result when script up the methods most authors use third person passive voice.
- Use standard style in this and in every other part of the paper - avoid familiar lists, and use full sentences.

What to keep away from

- Resources and methods are not a set of information.
- Skip all descriptive information and surroundings - save it for the argument.
- Leave out information that is immaterial to a third party.

Results:

The principle of a results segment is to present and demonstrate your conclusion. Create this part a entirely objective details of the outcome, and save all understanding for the discussion.

The page length of this segment is set by the sum and types of data to be reported. Carry on to be to the point, by means of statistics and tables, if suitable, to present consequences most efficiently.You must obviously differentiate material that would usually be incorporated in a study editorial from any unprocessed data or additional appendix matter that would not be available. In fact, such matter should not be submitted at all except requested by the instructor.

Content

- Sum up your conclusion in text and demonstrate them, if suitable, with figures and tables.
- In manuscript, explain each of your consequences, point the reader to remarks that are most appropriate.
- Present a background, such as by describing the question that was addressed by creation an exacting study.
- Explain results of control experiments and comprise remarks that are not accessible in a prescribed figure or table, if appropriate.
- Examine your data, then prepare the analyzed (transformed) data in the form of a figure (graph), table, or in manuscript form.

What to stay away from

- Do not discuss or infer your outcome, report surroundings information, or try to explain anything.
- Not at all, take in raw data or intermediate calculations in a research manuscript.
- Do not present the similar data more than once.
- Manuscript should complement any figures or tables, not duplicate the identical information.
- Never confuse figures with tables - there is a difference.

Approach

- As forever, use past tense when you submit to your results, and put the whole thing in a reasonable order.
- Put figures and tables, appropriately numbered, in order at the end of the report
- If you desire, you may place your figures and tables properly within the text of your results part.

Figures and tables

- If you put figures and tables at the end of the details, make certain that they are visibly distinguished from any attach appendix materials, such as raw facts
- Despite of position, each figure must be numbered one after the other and complete with subtitle
- In spite of position, each table must be titled, numbered one after the other and complete with heading
- All figure and table must be adequately complete that it could situate on its own, divide from text

Discussion:

The Discussion is expected the trickiest segment to write and describe. A lot of papers submitted for journal are discarded based on problems with the Discussion. There is no head of state for how long a argument should be. Position your understanding of the outcome visibly to lead the reviewer through your conclusions, and then finish the paper with a summing up of the implication of the study. The purpose here is to offer an understanding of your results and hold up for all of your conclusions, using facts from your research and generally accepted information, if suitable. The implication of result should be visibly described. Infer your data in the conversation in suitable depth. This means that when you clarify an observable fact you must explain mechanisms that may account for the observation. If your results vary from your prospect, make clear why that may have happened. If your results agree, then explain the theory that the proof supported. It is never suitable to just state that the data approved with prospect, and let it drop at that.

- Make a decision if each premise is supported, discarded, or if you cannot make a conclusion with assurance. Do not just dismiss a study or part of a study as "uncertain."
- Research papers are not acknowledged if the work is imperfect. Draw what conclusions you can based upon the results that you have, and take care of the study as a finished work
- You may propose future guidelines, such as how the experiment might be personalized to accomplish a new idea.
- Give details all of your remarks as much as possible, focus on mechanisms.
- Make a decision if the tentative design sufficiently addressed the theory, and whether or not it was correctly restricted.
- Try to present substitute explanations if sensible alternatives be present.
- One research will not counter an overall question, so maintain the large picture in mind, where do you go next? The best studies unlock new avenues of study. What questions remain?
- Recommendations for detailed papers will offer supplementary suggestions.

Approach:

- When you refer to information, differentiate data generated by your own studies from available information
- Submit to work done by specific persons (including you) in past tense.
- Submit to generally acknowledged facts and main beliefs in present tense.

Administration Rules Listed Before Submitting Your Research Paper to Global Journals Inc. (US)

Please carefully note down following rules and regulation before submitting your Research Paper to Global Journals Inc. (US):

Segment Draft and Final Research Paper: You have to strictly follow the template of research paper. If it is not done your paper may get rejected.

- The **major constraint** is that you must independently make all content, tables, graphs, and facts that are offered in the paper. You must write each part of the paper wholly on your own. The Peer-reviewers need to identify your own perceptive of the concepts in your own terms. NEVER extract straight from any foundation, and never rephrase someone else's analysis.

- Do not give permission to anyone else to "PROOFREAD" your manuscript.

- Methods to avoid Plagiarism is applied by us on every paper, if found guilty, you will be blacklisted by all of our collaborated research groups, your institution will be informed for this and strict legal actions will be taken immediately.)
- To guard yourself and others from possible illegal use please do not permit anyone right to use to your paper and files.

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Topics	Grades		
	A-B	**C-D**	**E-F**
Abstract	Clear and concise with appropriate content, Correct format. 200 words or below	Unclear summary and no specific data, Incorrect form Above 200 words	No specific data with ambiguous information Above 250 words
Introduction	Containing all background details with clear goal and appropriate details, flow specification, no grammar and spelling mistake, well organized sentence and paragraph, reference cited	Unclear and confusing data, appropriate format, grammar and spelling errors with unorganized matter	Out of place depth and content, hazy format
Methods and Procedures	Clear and to the point with well arranged paragraph, precision and accuracy of facts and figures, well organized subheads	Difficult to comprehend with embarrassed text, too much explanation but completed	Incorrect and unorganized structure with hazy meaning
Result	Well organized, Clear and specific, Correct units with precision, correct data, well structuring of paragraph, no grammar and spelling mistake	Complete and embarrassed text, difficult to comprehend	Irregular format with wrong facts and figures
Discussion	Well organized, meaningful specification, sound conclusion, logical and concise explanation, highly structured paragraph reference cited	Wordy, unclear conclusion, spurious	Conclusion is not cited, unorganized, difficult to comprehend
References	Complete and correct format, well organized	Beside the point, Incomplete	Wrong format and structuring

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