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OF MEDICAL RESEARCH: F

# Diseases Cancer, Ophthalmology & Pediatric

Acute Lymphoblastic Leukemia

0

Patients Undergoing Cataract Surgery

Highlights

Oral Lesions in Pediatric Patients

Effectiveness of Nurse-Led Interventions

# **Discovering Thoughts, Inventing Future**

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## GLOBAL JOURNAL OF MEDICAL RESEARCH: F Diseases Cancer, Ophthalmology & Pediatric

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# Oral Lesions in Pediatric Patients in North Mexico with B-Cell Acute Lymphoblastic Leukemia or Type 1 Diabetes Mellitus as Underlying Disease

By Alejandra Saldívar-De la Torre, Miranda Rodríguez-Gardea, Rosaura Pacheco-Santiesteban, Martín Cisneros-Castolo, Karla Elena Martínez-Aguilar, César Pacheco-Tena, Francisco Javier Zavala-Díaz de la Serna & Víctor Adolfo Ríos-Barrera

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*Abstract-* Oral involvement in the pediatric age does not occur as an isolated event, frequently involves a systemic disease being Leukemias -especially B-cell Acute Lymphoblastic Leukemia (B-cell ALL)- and Type 1 Diabetes Mellitus (T1DM) the most relevant.

*Objective:* To find which oral manifestations are observed with greater more frequently in pediatric patients with B-cell ALL or T1DM and to relate these findings with their pathophysiology.

*Methodology:* We formed three study groups, with five patients each: 1) children with T1DM, 2) infants with B-cell ALL, and 3) healthy children. The age range was five to fifteen years. Data were collected from: 1) clinical examination, 2) interrogation of parents or guardians, and 3) review of the clinical record, and 4) Blood count (BC).

Keywords: oral lesions, underlying disease, Type 1 Diabetes Mellitus, B-cell Acute Lymphoblastic Leukemia, immunocompromise, metabolic disbalance, oral altered homeostasis.

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# Oral Lesions in Pediatric Patients in North Mexico with B-Cell Acute Lymphoblastic Leukemia or Type 1 Diabetes Mellitus as Underlying Disease

Alejandra Saldívar-De la Torre<sup>α</sup>, Miranda Rodríguez-Gardea<sup>σ</sup>, Rosaura Pacheco-Santiesteban<sup>ρ</sup>, Martín Cisneros-Castolo<sup>ω</sup>, Karla Elena Martínez-Aguilar<sup>¥</sup>, César Pacheco-Tena<sup>§</sup>, Francisco Javier Zavala-Díaz de la Serna<sup>x</sup> & Víctor Adolfo Ríos-Barrera<sup>v</sup>

Abstract- Oral involvement in the pediatric age does not occur as an isolated event, frequently involves a systemic disease being Leukemias -especially B-cell Acute Lymphoblastic Leukemia (B-cell ALL)- and Type 1 Diabetes Mellitus (T1DM) the most relevant.

*Objective:* To find which oral manifestations are observed with greater more frequently in pediatric patients with B-cell ALL or T1DM and to relate these findings with their pathophysiology.

*Methodology:* We formed three study groups, with five patients each: 1) children with T1DM, 2) infants with B-cell ALL, and 3) healthy children. The age range was five to fifteen years. Data were collected from: 1) clinical examination, 2) interrogation of parents or guardians, and 3) review of the clinical record, and 4) Blood count (BC). We utilized Silness and Löe gingival index (GI) to quantify the on dental-bacterial plaque (DBP) to measure soft-tissues' risk affection because of bad oral hygiene. We employed CPOD-ceod index (referring to caries, missing or obturated teeth) to measure the cariogenic risk in dental organs. Blood count (BC) was utilized to find out blood alterations consistent with clinical findings.

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*Results:* 60% had xerostomia and 80% of the patients had different soft tissue lesions. Children with T1DM presented gingivitis (40%) and traumatic ulcers (40%). In cases with B-cell ALL, lesions were more varied: gingivitis (20%), traumatic ulcers (20%), herpetiform ulcers (20%) -an accumulated of 40% of ulcers-, candidiasis (40%), and mucositis (20%). The lowest GI and CPOD-ceod indices were found in the T1DM group (2.2 and 1.0, respectively); in healthy children, their values were common (2.7 and 3.2, respectively), and in the B-cell ALLset had the highest values (4.6 and 5.2, respectively). BC were normal in T1DM and healthy groups whereas the B-cell ALL group evidenced neutropenia, lymphopenia, and megaloblastic anemia.

*Conclusions:* T1DM and B-cell ALL affect homeostasis of the oral cavity, which predisposes to lesions formation. In B-cell ALL cases, the processes are more related to immunosuppression while in cases with T1DM they are more related to physicochemical and metabolic alterations. Treatments of underlying nosological entities also influences the oral lesions formation, specifically, mucositis in B-cell ALL, and gingival alterations in T1DM.

Keywords: oral lesions, underlying disease, Type 1 Diabetes Mellitus, B-cell Acute Lymphoblastic Leukemia, immunocompromise, metabolic disbalance, oral altered homeostasis.

### I. INTRODUCTION

ral condition in pediatric age constitutes a public health problem, reaching a prevalence of 28.9% (1). Caries is the most frequent ailment, and its origin is multifactorial. However, some reports in the literature show also other significant to matological alterations associated with an underlying systemic disease (2, 3). Some of the most prevalent systemic diseases observed in pediatric patients are Leukemia (4) and Diabetes Mellitus (3). Leukemias are malignant neoplasms of the bone marrow, with a rate of 13 cases per 100,000 inhabitants, with a slight predominance in the male gender (4) Based on the American Cancer Society classification, B-cell Acute Lymphoblastic Leukemia (B-cell ALL) is the most common in this population (80%) (4, 5) In United States of America, the incidence of B-cell ALL is about 1.6 per 100,000 population (5) In Mexico, leukemias are among the top 3 causes of mortality in children in the 1 to 14 years range.

2022

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In the Mexican State of Chihuahua, leukemias occupy the fifth and second places of mortality in the age groups of one to four years and five to fourteen years, respectively (6). In addition to the clinical picture of systemic manifestations (fever, anemia, bone pain, asthenia. advnamia. ecchymosis, bleedina. adenomegaly, and hepatosplenomegaly) various oral lesions are also frequently observed, mainly: ulcers, xerostomia, gingivitis, and mucositis (4, 7) plus added infections, particularly Candida albicans. Regarding Diabetes Mellitus, between 87% and 91% of people suffer from Type 2 Diabetes Mellitus whereas 7% to 12% are affected by Type 1 Diabetes Mellitus (T1DM), and 1% to 3% corresponds to other variants (8). Of the population of patients with T1DM, the vast majority start at an early age, being currently the most frequent autoimmune disease in childhood (9). Besides the longterm complications (nephropathy, heart disease, diabetic foot, retinopathy, cerebral vascular events, etc.), oral lesions have been seen very frequently; especially those related to periodontal disease: erythema, gingivitis, ulcers, bleeding (10), xerostomia, and caries (11).

This work studied pediatric patients with B-cell ALL or T1DM as an underlying systemic disease; purposes were to find which oral lesions are observed more frequently and find out a relation between these findings with the pathophysiology of the underlying disease.

## II. METHODOLOGY

The authorization corresponded to the Bioethics Department of the Autonomous University of Chihuahua (UACH; from Spanish: Universidad Autónoma de Chihuahua) and the Children's Hospital of Specialties of Chihuahua (HIECH; from Spanish: Hospital Infantil de Especialidades de Chihuahua).

## a) Data collection

Parents or guardian's participant signed the informed consent letter to take part in the research project. Likewise, each participant was notified about the study and signed the informed letter of consent, according to the criteria set out in the Official Mexican Standard NOM-012-SSA3-2012 and the Regulations of the General Health Law on Health Research.

## b) Study groups

This study included fifteen patients, with whom we formed three groups:

- 1) T1DM patients
- 2) B-cell ALL
- 3) Healthy children

Each group consisted of five children, and they were paired by age and sex with children in the other groups (Table S1).

Patients' data were obtained from the file and by direct interrogation to parents, guardians, and patients. We perform a clinical examination with emphasis on the oral cavity. Finally, were analyzed blood count reports.

A pediatric oncologist and pediatric endocrinologist reported diagnosis and managed treatments. All individuals met the inclusion and exclusion criteria (Appendix S1):

- 1) T1DM. All of them with insulin treatment.
- 2) B-cell ALL. They were in the first week of the induction to remission phase of chemotherapy, based on Saint Jude 16 protocol (12, 13); briefly, children received: prednisone, daunorubicin, vincristine, L-asparagine, etoposide, and triple intrathecal therapy during this stage.
- 3) Healthy children. They were obtained from patients who enter for light medical procedures (for example, minor trauma treatments).

c) Study of the clinical case and oral cavity exploration

We interviewed patients' parents or guardians by a questionnaire about the history and clinical evolution, both systemic and buccal. Then, we performed an oral examination which focused on the search for the following alterations:

## d) Presence of xerostomia

Initially, it was performed a clinical buccal inspection for signs of xerostomia (opaque mucosa membranes and thick saliva); it was also evaluated the mucosa-membrane hydration level as explained bellow:

The lower lip was turned from the inside out, the labial mucosa was carefully dried with gauze by a piece of paper over the mucosa; it was searched for saliva droplets formation by minor glands' holes.

For the quantification of the size of saliva production, we set up as parameters:

- 1. Low salivary production: more than four drops of saliva in sixty seconds.
- 2. Normal salivary production: more than four drops of saliva in sixty seconds.

For the inspection of mucosa hydration, we inspected if the tongue adheres after depression which indicates a positive sign of dehydration.

Therefore, we defined xerostomia as the existence of two positive signs found by the procedures mentioned above.

e) Oral exam of soft tissues

It was performed a detailed examination; different injuries found corresponded to the following ones:

- 1) Traumatic ulcers (14): they have a very irregular loss edge and a frequent unique random distribution.
- 2) Herpetic ulcers (14): they have a scalloped border with an erythematous area. They are usually multiple

and painful; located at the oral corners, lips, and gums.

- 3) Gingivitis (15): they are swollen and erythematous gum, sometimes painful.
- Candida plaques (14): they are white cotton-like and friable regions on gums, mucosa, or tongue; they are easily removed leaving an erythematous and bleeding area.
- 5) Mucositis (16): it is an inflammation of the mucosa membranes with oral erythema, ulcers, and pain.

*Gingival index (GI)* (17, 18) It was based on the method described by Silness and Löe (Table 1). It is intended to record the degrees of deposit of dental-bacterial plaque

(DBP) without the need to dye it; it is calculated with the formula:

$$GI = \frac{\sum_{i=1}^{n} Xi}{n}$$

Where *GI* is the gingival index of each revised tooth, *n* is the number of explored surfaces, *Xi* is the presence of DBP on each studied tooth surface. We assessed DBP buildup using a dental scoop and an intraoral mirror, and we codified the findings according to Silness and Löe scale (18) (Table 1). The explored surfaces were vestibular, palatine/lingual, mesial, and distal.

Table 1: Gingival Index (GI)*				
Degree	Description			
0	DBP absent			
1	DBP only detectable when passing the dentin spoon			
2	Moderate and visible DBP			
3	Abundant DBP; covers beyond the gingival third of the tooth surface			

\*GI: Silness and Löe gingival index for the graduation of the accumulation of dental-bacterial plaque (DBP) on the gingival surface (17, 18).

CPOD and ceod indices. They are used to show the experience of caries in a patient, whether currently or in the past; the only difference between the two is that CPOD index evaluates the permanent dentition and the ceod the deciduous dentition. In order to understand these indices, their components must be broken down: 'C' and 'c' show the decayed teeth in the permanent and deciduous dentition respectively, 'P' refers to the permanent dentition, 'e' writes down the deciduous dentition, or the teeth lost either by caries or by extraction, 'O' denotes the clogged teeth, and 'D' means dentition. These indices are obtained from the individual sum of the values of each element (tooth): decayed, lost, and filled (CPO or ceo), which is divided by the total number of existing teeth (Table 2)(19).

Table 2: CPOD Index*				
Interval	Gravity			
0.0 - 1.1	Exceptionally low			
1.2 – 2.6	Low			
2.7 - 4.4	Moderate			
4.5 - 6.5	High			
>6.6	Extremely high			

\*CPOD: Index of decayed, lost and filled teeth(19).

### f) Hemocytometry study

Consisted of a blood of carrying out the blood count. Concerning the B-cell ALL group, blood count (BC) study of each patient was conducted on those samples taken in the interval of 1 to 10 days after the first chemotherapy; BC was also checked when this treatment was not started yet. In T1DM cases, BC were taken at the time of the last medical and dental checkup; diabetes treatment had already started. BC in healthy cases were taken during the medical or dental consultation. BC was interpreted by expert physicians based on the normal pediatric values, according to the age range established in the international parameters to Mexican patients (Appendix S2)(20).

### g) Statistical analysis

We obtained simple and relative frequencies from nominal and categorical variables. Respect continuous variables, age ranges, means, and standard

deviations we used the  $\chi^2$  test for proportions to evaluate significant differences between groups, based on the SPSS-IBM 25.0 program for calculations.

#### III. Results

This study included fifteen patients, with five children each (see methodology and Table S1).

#### a) Clinical Findings

Through the detailed intraoral examination, we found that 60% of both diabetic (Figure 3) and leukemic

(Figure 6) patients exhibited notorious xerostomia; this sign was negative in the healthy group (Figure 1, Table 3).

In the examination of soft tissues, we found that 80% of patients with T1DM or B-cell ALL presented some type of oral alteration; 100% of the healthy group were free of pathology (Table 4).

Table 3: Xerostomia clinical data							
	Healthy	Percentage*	T1DM	Percentage	B-cell ALL	Percentage	
Presence	0	0%	3	60%	3	60%	
Absence	5	100%	2	40%	2	40%	

\*Refers to the proportion of the total number of patients in each group: healthy, T1DM (Type 1 Diabetes Mellitus) and B-cell ALL (Bcell Acute Lymphoblastic Leukemia).

Table 4: Soft tissues injuries							
	Healthy	Percentage*	T1DM	Percentage	B-cell ALL	Percentage	
Presence	0	0%	4	80%	4	80%	
Absence	5	100%	1	20%	1	20%	

\*Refers to the proportion of the total number of patients in each group: healthy, T1T1DM (Type 1 Diabetes Mellitus with insulin treatment) and B-cell ALL (B-cell Acute Lymphoblastic Leukemia).

The lesions found in patients with T1DM (Figure 1)were gingivitis (40%) (Figure 2) and traumatic ulcers (40%) (Figure 3). In patients with B-cell ALL predominated: candidiasis (40%) (Figure 4), gingivitis (20%) (Figure 5), HSV-likeulcers (20%) (Figure 5), traumatic ulcers (20%) (Figure 6), mucositis (20%)

(Figure 6). Therefore, lesions in the B-cell ALL patients group were more variable than in the T1DM one; moreover, not only a greater variability but also a biggerlesions intensity were observed in the B-cell ALL group.



Figure 1: Frequency of oral lesions in soft tissues. T1DM (patients with Diabetes Mellitus type 1), B-cell ALL (patients with B-cell Acute Lymphoblastic Leukemia), HSV (Type 1 Herpes simplex virus).



*Figure 2:* Gingivitis in a patient with T1DM. The erythematous and edematous gums, especially the upperone, are clear.



*Figure 3:* Oral lesions in a patient with T1DM. Xerostomia and pallor of the mucous membranes, coated tongue, flaky taste buds and the presence of 2 traumatic ulcers in the jugal mucosa are seen.



*Figure 4:* Candidiasis lesions in a patient with B-cell acute lymphoblastic leukemia (B-cell ALL). Pale mucous membranes are seen with the abundant presence of DBP on the tooth surfaces. Whitish lesions of fungal origin (Candida albicans); they are found in the gingival mucosa and the bottom of the sac of the upper arcade.



Figure 5: Soft tissue lesions in a patient with B-cell acute lymphoblastic leukemia (B-cell ALL). There is a welldelimited ulcerative HSV-like lesion of whitish coloration (arrowhead) in the swollen and erythematous gingival mucosa, and presence of dental-bacterial plaque (DBP) (arrows).



Figure 6: Oral lesions in a patient with B-cell acute lymphoblastic leukemia (B-cell ALL). In both photographs you can see different lesions: hypohydrosis and pallor of mucous membranes and multiple caries. (A) An ulcer in the palatine mucosa (arrow), secondary to mucositis; and exfoliative cheilitis (arrowheads). (B) On the back of the tongue there is an irregular ulcer with erythematous contour, secondary to mucositis; multiple HSV-like ulcers with an erythematous contour (arrows) distributed in the labial mucosa along with traumatic ulcers and exfoliative cheilitis, mainly on the external part pf the lower lip (arrowheads).

Forrisk of caries evaluation, we relied on the oral hygiene index standards established by Silness and Löe (50). T1DM children group presented very low values of CPOD-ceod (cariogenic risk) and GI indices (1.0 and 2.2, respectively), healthy patients group had higher risk values (3.2 and 2.7 respectively), and B-cell ALL children set had the highestones (5.2 and 4.6 respectively) (Table 5). On the other hand, oral pH values

in B-cell ALL and healthy children groups were practically neutral (pH 7.1 and 7.0, respectively); while in the T1DM set the value was acidic (pH 6.1). Nevertheless, these values did not exceed the cariogenic threshold (pH 5.5); they were very close in the three groups. Therefore, there were no significant differences (Table S2).

Table 5: CPOD-ceod and GI indices							
Groups	CPOD-ceod*	GI*	GI Interpretation				
Healthy	3.2	2.7	Low				
T1DM	1.0	2.2	Extremely low				
B-cell ALL	5.2	4.6	High				

\*Mean index to evaluate decayed, missing and filled teeth (CPOD-ceod) (19) and gingival index (GI) based on Silness and Löe (18) adjusted for pediatric patients.

#### b) Hemocytometric Study

BC white formula showed that 100% of B-cell ALL patients presented leukopenia (p<0.01) secondary to neutropenia (p<0.01) and lymphopenia (p<0.01);

there were notanomalous counts in other morphologically normal leukocytelines. There were no leukocyte alterations in healthy and diabetic groups either (Tables 6 and 7).

## Table 6: Findings in the white formula of the distinct groups of patients\*

Alteration	Healthy	Percentage	T1DM	Percentage	B-cell ALL	Percentage
Leukopenia	0	0%	0	0%	5	100%
Neutropenia	0	0%	0	0%	5	100%
Lymphopenia	0	0%	0	0%	5	100%
Eosinophilia	0	0%	0	0%	0	0%
Monocytosis	0	0%	0	0%	0	0%

\*The percentage refers to the proportion of the total number of patients in each group with some alteration. Groups: Healthy (healthy children), T1DM (Type 1 Diabetes Mellitus), B-cell ALL (B-cell Acute Lymphoblastic Leukemia).

Table 7: Stratified of the hematic characteristics by nosological entity in children and adolescents with oral lesions						
	Healthy n (%)	<b>T1DM</b> n (%)	B-cell ALL n (%)	p*		
Leukopenia						
Present	0 (0.0)	1 (20.0) 4 (80.0)	5 (100.0)	0.003		
Absence	5 (100.0)	0 (12.5) 5 (100.0)	0 (0.0)			
Neutropenia		0 (10 5)	E (100 0)	0.001		
Present	0 (0.0)	5 (100.0)	5 (100.0)	0.001		
Absence	5 (100.0)	0 (0.0) 5 (100.0)	0 (0.0)			
Lymphopenia		( )				
Present	0 (0.0)	0 (0.0) 5 (100.0)	5 (100.0)	0.001		
Absence	5 (100.0)	0 (0.0) 5 (100.0)	0 (0.0)			
Eosinophilia						
Present	0 (0.0)		0 (0.0)	1.0		
Absence	5 (100.0)		5 (100.0)			
Monocytosis						
Present	0 (0.0)		0 (0.0)	1.0		
Absence	5 (100.0)		5 (100.0)			
Anemia						
Present	0 (0.0)		3 (60.0)	0.02		
Absence	5 (100.0)		2 (40.0)			

\*p-value confirmed by Pearson's  $\chi^2$  method for proportions; a p-value less than 0.01 is considered significant. Study groups: healthy (healthy) children, children with Type 1 Diabetes Mellitus (T1DM) or B-cell Acute Lymphoblastic Leukemia (B-cell ALL).

BC red formula showed that all B-cell ALL children presented anemia; four patients had macrocytic hyperchromic anemia (80%) consistent with megaloblastic anemia; anisocytosis was reported in 1 case (Table 8).

Type of Anemia	Healthy	T1DM	B-cell ALL	Diagnosis
Hyperchromic Macrocytic	0	0	4 (80%)	Megaloblastic anemia
Hyperchromic Normocytic	0	0	1 (20%)	Anisocytosis
Hypochromic Microcytic	0	0	O Í	Iron Deficiency

\*T1DM (Type 1 Diabetes Mellitus), B-cell ALL (B-cell Acute Lymphoblastic Leukemia).

## IV. Discussion

In this study, we performed a global clinical analysis of the oral cavity with the end to identify diverse types of lesions as well as oral cavity hygiene, caries, and tooth losses. We also evaluated the blood tissue state basing us on BC studies. All these parameters were carried out in three groups of pediatric patients: healthy, T1DM, and B-cell ALL (Table S1).

Regarding the clinical analysis, lesions were found in T1DM and B-cell ALL groups; except for poor oral hygiene, the healthy group did not present pathological alterations were found. Respect oral hygiene, T1DM patients had the best CPOD-ceod and GI indices (Table 5) whereas B-cell ALL children revealed the worst ones. These findings can be explained by the fact that diabetic patients eat less sugary foods, and generally receive more oral care than most patients; obviously, the more oral hygiene the fewer complications (21). The most precarious oral hygiene in the B-cell ALL group can be understood as consequence of an important pain presence due to epithelial fragility occasioned by both mucositis -caused by chemotherapy (22)- and leukemia per se. The pain also causes a less teeth brushing frequency, leading to a higher GI (measure of DBP formation) and CPODceod (measure caries and teeth losing) indices (Table 5).

Xerostomia, in general, is more pronounced in Diabetes Mellitus which it was also observed in our T1DM group; it is consequence of the chronic hypohydration state specially seen in poorly controlled patients (23). This, in the long run, will reduce nonimmunological defense barriers such as:

- Physical barriers: saliva will turn more viscous which will decrease an efficient oral mechanical washing (24).
- 2. Chemical barriers: salivary hyperviscosity is consequence of the high glucose and electrolyte (calcium and phosphorus) concentrations which occasions a pH decrease and it also affects the enzymatic functions (amylase an alkaline phosphatase) (25).

- 3. Biological barriers: physicochemical alterations of microenvironment alter the oral microbiota composition and, therefore, favor growth of pathogenic and opportunistic microorganisms (24).
- 4. Immune barriers: the increased oral viscosity and abnormal pH will occasion immune dysfunctions, specifically in the antibodies (26, 27). Diabetic microangiopathy significantly affects the immune function; however, it is not a factor to take into account in our group since this is a long-term complication.

However, there were a lower CPOD-ceod index (lesser caries) in T1DM group than in the healthy set despite of the first one had oral lesions. This can be explained because of the higher tooth washing frequency and lower carbohydrates intake (candies and chocolates especially) by T1D Mchildren.

B-cell ALL group also presented a greater quantity and variety of lesions which were more severe. Like in T1DM, it was detected gingivitis and traumatic ulcers along with exfoliative cheilitis (Figures 5 and 6) and other lacerations: oral candidiasis (Figure 4), herpeticulcers (Figure6), and mucositis (Figure 6). Basing us on the underlying disease's natural history, treatment, and BC results, we suggest that the most factor relevant lesion-generating was the immunosuppression state in this group. So, oral alterations secondary to B-cell ALL pathophysiology can be explained as follows:

The underlying nosological entity itself. The lymphoblastic neoplasm grows in the red bone marrow, so it displaces healthy tissue which is occupied by are non-functional blast cells both in the bone marrow and peripheral blood. Paradoxically, the hemocytometry values of the white formula will be extremely high; however, normal leukocyte counts will be low.

Chemotherapy. Sant Jude 16 protocol (12, 13) (see methodology and Appendix S3), not only kills neoplastic cells but also functional ones which aggravates the state of immunosuppression. In additiontreatment is also involvednot only in the treatment but also triggering mucositis which turns the mucosa pretty fragile (22). On the other hand, bone marrow damage caused by both leukemia and

chemotherapy affect platelet and erythrocyte production causing thrombocytopenia and anemia (megaloblastic anemia) which was proved in the BC (Table 8). This last finding is mainly triggered by methotrexate administration -part of the Saint Jude 16 therapeutic protocol- which is a folic acid antagonist (28).

Oral pH revealed a neutral value in B-cell ALL and healthy patient groups (pH 7.1 and 7.0 respectively); pH in T1DMset was acidic (pH 6.1) (Table S2). However, this record did not reach a critical value (pH  $\leq$ 5.5) to be considered as a cariogenic factor (29). Therefore, CPOD-ceod and Glindices suggest the cariogenic risk is related to other factors such as poor oral hygiene; especially in B-cell ALL children, probably related to the frequent oral pain.

It is also pertinent to clarify that, at the moment, our sample size is small, so we will continue increasing the number of samples of each group to increase the statistical power.

## V. Conclusions

Both B-cell ALL and T1DM are one of the more important systemic diseases in pediatric age which also have a significant impact on the oral cavity. Prominently, the key factor related to B-cell ALL is immunocompromise, provoked by both the neoplastic disease and chemotherapy, whereas in T1DM the main disbalance is ametabolic dehydration and hyperglycemic state. The lowest presence of caries (lower CPOD-ceod index) in the T1DM group is linked to the better oral hygiene associated in the treatment. Finally, our results suggest that systemic diseases alter the buccal cavity homeostatic state, affecting the normal-microbiota development, favoring pathogenic or opportunistic microorganisms' grow and attack(30) and an increase of systemic-infections risk and septicemia (31); so, we suggest that underlying diseases like B-cell ALL and T1DM, and their treatments effects, have a relevant impact in the oral cavity homeostasis as well as over microbiota composition: all this together leads to the formation of oral lesions. Therefore, we propose that it is especially important to carry out metagenomic studies (gene-taxonomy with last generation sequencing) of the oral microbiota to identify specific changes that could specifically identify those pathogenic species that cause oral lesions formation.

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Víctor Adolfo Ríos-Barrera and Alejandra Saldívar-De la Torre did most of this research and have the same merits and importance.

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## SUPLEMENTARY TABLES

Table S1: Study groups analyzed for oral lesions							
Group	Clinical diagnosis	Number of patients	Men	Women	Interval (years)		
1	T1DM	5	2	3	5-15		
2	B-cell ALL	5	2	3	5-15		
3	Healthy	5	2	3	5-15		
Total		15	6	9			

Abbreviations: T1DM (Diabetes Mellitus type 1 with insulin treatment), B-cell ALL (B-cell Acute Lymphoblastic Leukemia with chemotherapy in the induction to remission phase).

	Table S2: Oral pl	H values
Groups	рН	Interpretation*
T1DM	1.0	Not cariogenic
B-cell ALL	5.2	Not cariogenic
Healthy	3.2	Not cariogenic

\*The cariogenic risk was considered when pH<5.5.

## SUPPLEMENTARY APPENDICES

## Supplementary Appendix S1

## A) Inclusion criteria

*Group of patients with T1DM:* confirmed diagnostic of DM1, insulin treatment already set up. Recent complete blood count (BH) (less than 2 weeks). Age range: 5 to 15 years.

*Group of patients with B-cell ALL:* Confirmed diagnosis of B-cell or pre B-cell, which will be described together as B-cell ALL. Patients in the induction to remission phase of chemotherapy. Recent full BH (less than 2 weeks). Age range: 5 to15 years.

*Control group of healthy children:* Age and gender comparable with the groups of B-cell ALL and T1DM. Recent full BH (less than 2 weeks). Hospitalized for trauma-related treatments (fractures, dislocations). Age range: 5 to 15 years.

## B) Exclusion criteria

*Group of patients with T1DM:* Patients outside the age range. Not having written informed consent. Patients with oral appliances. Infectious diseases in the last 4 weeks. Antibiotic therapy 2 weeks prior to sampling.

*Group of patients with B-cell ALL:* Patients outside the age range. Patients in the consolidation or maintenance phase in their chemotherapy treatment. Not having written informed consent. Patients with oral appliances. Patients with Burkitt lymphoma. Infectious diseases in the last 4 weeks. Antibiotic therapy 2 weeks prior to sampling.

*Control group of healthy children:* Presence of systemic diseases. Presence of some concomitant syndromes. Not having written informed consent. Patients with oral appliances. Infectious diseases in the last 4 weeks. Antibiotic therapy 2 weeks prior to sampling.

## Supplementary Appendix S2

Blood Count Normal pediatric values. According to the patients' age, and established in the international weighting tables adapted to Mexican patients (20).

Table S3: Red blood cells							
Age	1-13 d	14-60 d	3 m–10 y	11-15y	Adults		
Erythrocytes* (millions/mm³)	5.1±1.0	4.7 ± 0.9	4.5± 0.7	4.8	$\begin{array}{c} 5.4\pm0.9~\text{M} \\ 4.8\pm0.6~\text{W} \end{array}$		
Hemoglobin* (g/dL)	19.5 ± 5.0	14.0 ± 3.3	$12.2 \pm 2.3$	13.4	16.0 ± 2.0 M 14.0 ± 2.0 W		
Hematocrit* (percentage)	54.0 ± 10.0	42.0 ± 7.0	36.0 ± 5.0	39.0	47.0 ± 5.0 M 42.0 ± 5.0 W		
MCV (fL)	98-106	90	80	82	90 ± 7 M 90 ± 7 W		
MCH (pg)	33-38	30	27	28	$29 \pm 2 M$ $29 \pm 2 W$		
CHMC (g/dL)	34-36	33	34	34	34 ± 2 M 34 ± 2 W		
MCD (µm)	8.6	8.1	7.7		$\begin{array}{c} 7.5 \pm 0.3 \text{ M} \\ 7.5 \pm 0.3 \text{ W} \end{array}$		

\*The values range represents variation extremes (93%) at sea level.

Abbreviations: MCV (mean corpuscular volume), MCH (medium corpuscular hemoglobin), MCHC (mean corpuscular hemoglobin concentration), MCD (mean corpuscular diameter); d (days), m (months), y (years), M (men), W (women).

Table S4: White blood cells							
Age	1 y	4 y	6 y	10 y	Adult (>21 y)		
Total* Leucocytes	11,400	9,100	8,500	8,100	7,400		
-	(6.0-17.5 K)	(5.5-15.5 K)	(5.0-14.5 K)	(4.5-13.5 K)	(4.5-11.5 K)		
	100%	100%	100%	100%	100%		
Neutrophiles							
Total*	3,500	3,800	4,300	4,400	4,400		
	(1.5-8.5 K)	(1.5-8.5 K)	(1.5-8.0 K)	(1.8-8.0 K)	(1.8-7.7 K)		
	31%	42%	51%	54%	59%		
Bands*	350	270	250	240	220		
		(0-1.0 K)	(0-1.0 K)	(0-1.0 K)	(0-0.7 K)		
	3.1%	3.0%	3.0%	3.0%	3.0%		
Segmented*	3,200	3,500	4,000	4,200	4,200		
		(1.5-7.5 K)	(1.5-7.0 K)	(1.8-7.0 K)	(1.8-7.0 K)		
	28%	39%	48%	51%	56%		
Lymphocytes*	7,000	4,500	3,500	3,100	2,500		
	(4.0-10.5 K)	(2.0-8.0 K)	(1.5-7.0 K)	(1.5-6.5 K)	(1.0-4.8 K)		
	61%	50%	42%	38%	34%		
Monocytes*	550	450	400	350	300		
	(0.05-1.1 K)	(0-0.8 K)	(0-0.8)	(0-0.8 K)	(0-0.8)		
	4.8%	5.0%	4.7%	4.3%	4.0%		
Eosinophiles*	300	250	230	200	200		
	(0.5-0.7 K)	(0.02-0.65 K)	(0-0.65 K)	(0-0.6 K)	(0-0.45 K)		
	2.6%	2.8%	2.7%	2.4%	2.7%		
Basophiles*	50	50	50	40	40		
	(0-0.2 K)	(02 K)	(02 K)	(02 K)	(0-0.2 K)		
	0.4%	0.6%	0.6%	0.5%	0.5%		

Values in the first line of each row are expressed as  $10^3$  cells/µL. Abbreviations: y (years), K (10<sup>3</sup>).



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# Role of Cytosorb in Severe Covid 19 Patients to Combat Cytokine Storm- A Case Series of 3 Patients

By Dr. Nithish Sattoju, Dr. Sai Sashank Merugu, Dr. Santosh Gattu, Sai Ram Ganapaka & Vydhika Anneboina

Abstract- Purpose: To demonstrate the effect of Cytosorb on reducing the cytokine levels seen due to cytokine storm in severe COVID 19 patients.

*Material & Methods:* COVID 19 patients with severe HRCT scoring and on NIV/ MV were included in the study. The time points considered in our study are D0, D+1, D+3 & D+5, to look for the levels of inflammatory markers post therapy along with the outcome of patients on D+7 in terms of mortality or off NIV/ MV.

*Results:* Statistical significance tested for the reduction in the WHO score value resulted p value of 0.85. The mean baseline value of the inflammatory markers, CRP, D-DIMER & IL 6 were 66.94, 780.67 &144.67 respectively with range 56.5-81, 331- 1211 & 124-167 respectively & p values 0.60, 0.95 & 0.18 respectively. 7- day outcome of the study was 100% mortality.

Keywords: COVID-19 disease; cytosorb therapy; 9-point ordinary scale developed by WHO.

GJMR-F Classification: DDC Code: 616.079 LCC Code: RM282.C95

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Strictly as per the compliance and regulations of:



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# Role of Cytosorb in Severe Covid 19 Patients to Combat Cytokine Storm– A Case Series of 3 Patients

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*Conclusion:* The results of our study are in favor of no additional benefits of CYTOSORB therapy in improving the clinical outcome among COVID 19 patients. However, the 7-day outcome of our study reported 100% mortality, to confirm the complete ineffectiveness of the therapy, a study on large group population is encouraged.

*Keywords:* COVID-19 disease; cytosorb therapy; 9-point ordinary scale developed by WHO.

## I. INTRODUCTION

Volume Vo

levels of cvtokines likelL6. IL10. CXCL 10. lymphopenia and neutrophilia along with the systemic inflammation as seen by elevations in the levels of CRP, D- dimer, LDH, Ferritin. Lungs being the primary organ effected later leading to multi organ dysfunction<sup>5</sup>. To combat the disease several new molecular entities are being developed. On the basis of pathophysiology of the disease, it was thought that extra corporeal therapies specially designed to filter the cytokines can provide a hope in treating the critically ill COVID 19 patients and prevent organ failure and improve survival rate<sup>6</sup>. The same is demonstrated and supported by Ronco et al & Tay et al in their studies and clinical experience<sup>7,8</sup>. One such extracorporeal therapy designed to filter the cytokines was Cytosorb. Cytosorb was incorporated into the treatment guidelines in the early of the pandemic by several national medical societies. Use of cytosorb in COVID 19 patients with AKI (Acute Kidney Injury) stage 3 and are with Continuous Renal Replacement Therapy (CRRT) was first recommended by Italian Society of Nephrology<sup>9</sup>. USFDA also approved the usage of Cytosorb in critically ill COVID-19 patients on April 10, 2020<sup>10</sup>. In 2011, Cytosorb was originally approved by the European Union for treating the systemic hyperinflammation and refractory shock.

Cytosorb is an extracorporeal cytokine adsorption cartridge with blood compatible porous polymer beads used as an adsorptive material in this blood purification technology<sup>11,12</sup>. Through this highly porous polymer beads, Cytosorb can continuously remove molecules upto 50kD and help in treating certain conditions like hypercytokinemia and in conditions like severe inflammatory response<sup>13</sup>. Each adsorber cartridge can be used for 24 hours and then need to be replaced with another. The flow rate to be maintained is between150-700 ml/min and can be used as standalone approach in hemoperfusion technique or can be connected into ECMO or CRRT circuit<sup>12</sup>. This therapy aids in removal of cytokines from the blood stream through concentration gradient and the binding of molecules to the adsorptive polymer is size dependent making it a broad-spectrum purification technique<sup>14</sup>.

The current study is to demonstrate the effect of Cytosorb in severe COVID 19 patients in terms improvement according to 9-point ordinary scale developed by  $WHO^{15}$  on 1 day after administration (D +1) & 3, 5 days after administration (D +3, +5) along

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with reduction in the levels of inflammatory markers (CRP, D- DIMER & IL6) & 7 days outcome viz, out off NIV/ MV or Death & duration of ICU stay.

Table 1 provides score value given according to the 9-point ordinary scale score developed by W.H.O. to the individual patient depending on the condition of the patient.

*Table 1:* 9-point ordinary scale score developed by the W.H.O. each individual patient of the study in both the groups are given with a score value depending on their condition on 3 time points<sup>15</sup>.

Patient state	Descriptor	Score
Uninfected	No clinical or virological evidence of	0
	infection	
Ambulatory	No limitation of activities	1
	Limitation of activities	2
Hospitalized mild disease	Hospitalized, no oxygen therapy	3
	Oxygen by mask or nasal prongs	4
Hospitalized severe disease	Non-invasive ventilation or high flow	5
	oxygen	
	Intubation or mechanical ventilation	6
	Ventilation + additional organ	7
	support- pressors, RRT, ECMO	
Dead	Death	8

## II. Methods

#### a) Aim

To measure the efficacy of CYTOSORB therapy in reducing the levels of inflammatory markers in COVID 19 patients.

#### b) Objectives

*Primary Objective:* To establish the beneficial role of CYTOSORB in addition to the Standard of Care in reducing the elevated levels of inflammatory markers in severe covid 19 patients along with getting the patient off the NIV/ MV/ICU.

Secondary Objective: To establish efficacy of Cytosorb therapy in terms of improvement as per WHO scale scoring & duration of ICU stay

#### c) Methodology

A case cohort study is conducted at Medisys Hospitals, LB nagar, Hyderabad (city), Telangana (State), India (Country) to establish the beneficial role of cytosorb in addition to the SoC in patients with severe COVID 19 illness and those who are on NIV/ MV in reducing the levels of inflammatory markers and getting the patients off NIV/ MV.

Study includes the patients admitted in ICU from 01-05-2021 to 31-05-2021 with RTPCR proven COVID 19 illness and HRCT severity 14 and are on NIV/ MV with age  $\geq$  35 years.

The outcome is measured in terms of reduction in the levels of inflammatory markers (C- Reactive Protein/CRP, D- dimer & IL6) before & after the therapy. The day of therapy is considered as D0 and the following post administration days as D+1, D+2, D+3, and so on. The levels of inflammatory markers and the scores according to the WHO ordinary scale on the D+1, D+3 and D+5 was observed and noted. The baseline value of each inflammatory marker is calculated by taking the average of the last 3 values before D0 which is considered as the mean value before the therapy. Similarly, taking the levels on the time points of our study (D+1, D+3 & D+5) another average value is calculated which is taken as the mean value post therapy. These 2 average values are compared to establish the role of Cytosorb in reducing the levels of inflammatory markers.

The trend of reduction in the values is statistically tested using annova single factor assay. In case of WHO ordinary scale score, the score on D0 and on 3 time points were taken directly (without calculating the average score value) to establish the cytosorb role in reducing the score value. The outcome of the patient on D+7viz, out off NIV or MV or Death (7-day survival rate) & duration of ICU stay is observed.

- d) Inclusive Criteria
- > Patients who can afford the therapy.
- > Patients with altered renal functioning.
- Patients with HRCT severity category& are on NIV/ MV.
- e) Exclusive Criteria
- > Patients who cannot afford the therapy.
- Patients with low platelet count (<20,000/cumm).</p>
- Pregnant women.
- Patients with known allergies for extra corporeal therapies.
- Hemodynamically unstable patients.
- > Patients who are not requiring NIV/ MV.

#### f) Procedure

After applying the inclusive and exclusive criteria individual patients given with respective number, P1, P2 & P3, in the sequence of their inclusion in the study.

All the patients received SoC which included maintain Oxygen support to SpO<sub>2</sub>  $\geq$ 93%, Glucocorticoid; Dexamethasone (0.2- 0.4 mg/kg/day), Remdesivir (200mg stat dose followed by 100mg once daily for 4 days to a cumulative dose of 600mg given in 5 days), i.v. Antibiotics at physician discretion (when a bacterial infection is suspected), prophylactic dose of low molecular weight heparin/ Unfractionated heparin with dose adjusted according to the body weight and renal function of the individual patient, along with symptomatic treatment that includes antitussives, antihistamines, antipyretics, etc.

In addition to the SoC, patients who are on NIV/ MV are randomly selected for treating with cytosorb after explaining the risks and benefits associated with the therapy. Cytosorb therapy is given as stand-alone treatment with blood pumps in hemoperfusion mode. The flow rate of the cytosorb was set to 150-200ml/min with unfractionated Heparin of 5000 IU as prophylaxis & to a duration of 8-12 hours depending on the clinical condition of the patient viz, elevated levels of markers, hemodynamics during the cytosorb, side effects to the therapy.

The baseline values (Mean before the therapy) of the inflammatory markers along with the score according to the WHO ordinary scale are compared with that of on D+1, D+3 and D+5 to observe for any reduction in the values.

- g) Measure of Outcome
- Score according to the WHO ordinary scale across the time period.
- Statistically significant reduction of inflammatory markers viz, C- Reactive Protein (CRP), D- DIMER& IL6, across the time period as tested using annova single factor assay along with reduction in mean before and mean after the therapy.
- Outcome of the patient 7 days after the procedure, viz, out off NIV/ IV/ ICU or death

*Note:* The herein discussed CRP is measured in terms of mg/lit; D-dimer in  $\mu$ g/ml; IL 6 in pg/ml.

## h) Statistical Analysis

All the numerical data in the study, levels of inflammatory markers and score according to the WHO scale, are tested for statistically significant different across the time period using ANNOVA one-way methos in Microsoft Excel software. The p- value obtained by the test is used to confirm the assumed hypothesis, "levels of inflammatory markers/ score value according to the WHO ordinary scale are reduced upon cytosorb therapy". The p-value < 0.05 indicates the significant reduction in the values across the time period accepting the assumed hypothesis and vice- versa.

Non numerical data, population out off NIV/ MV/ ICU 7 days after the procedure, are calculated as % population with the respective outcome.

## III. Results

Our study included 3 male patients, Patient 1 or P1, Patient 2 or P2 & Patient 3 or P3, of age 61, 36 & 49 respectively with mean age 48.6 years. All the patients presented to the ICU in the study period received Cytosorb therapy after 5-7 days of admission in the ICU.

As detailed in the methodology and procedure sections, the baseline value of the levels of inflammatory markers are calculated and analyzed accordingly.

Ventilation status of the patients on D0 are as

- P1 WAS ON MV
- P2 WAS ON NIV
- P3 WAS ON NIV

Ventilation status of P1 & P2 was same till the end of the study while P3 progressed to MV on D+1. Annova single factor assay conduced to check the statistically significant reduction in the WHO score across the time period gave p value of 0.85 reporting no statistically significant difference. The figure 1 represents the fluctuation in WHO score value among the time line of the study.





The mean baseline value of CRP before therapy, was 63.3, 56.5 & 81 respectively for P1, P2 & P3. The mean average value of CRP after the therapy of P1, P2 & P3 was 50.5, 44.9 & 67.3 respectively. Figure 2 represents the mean levels of CRP before and after the therapy in all the 3 patients. The annova single factor assay done that resulted a p value of 0.60 reporting no statistically significant difference in the levels of CRP across the time period. Figure 3 shows the baseline levels of CRP of all the patients along with the levels on D+1, D+3 and D+5.



Figure 2: Mean of CRP before and after the therapy in all the 3 patients



*Figure 3:* Levels of CRP across the time period. Individual line representing the levels of all the individual patient across the time points, viz, baseline, D+1, D+3 and D+5.

The other inflammatory marker, D- dimer, mean before the therapy, was 331, 800 & 1211 of P1, P2 & P3 respectively and the mean value after the therapy was 243, 1040 & 932 respectively for P1, P2 & P3.The annova single factor assay conducted to test the hypothesis reported a p value of 0.95 stating there exists no statistically significant difference among the values of D- dimer across the study period. Figure 4 represents the trends of D- dimer levels of individual patients across the time points. Figure 5 represents the mean of D- dimer before and after the therapy in all the 3 patients.



*Figure 4:* Levels of D-dimer across the time period. Individual line representing the levels of all the individual patient across the time points, viz, baseline, D+1, D+3 and D+5.



Figure 5: Mean of D-dimer before and after the therapy in all the 3 patients

The mean values of IL 6 levels before and after the therapy were almost similar with 124, 143& 167 and 126.33, 143& 141.3 before and after the therapy in P1, P2 & P3 respectively. Figure 6 represents the mean levels of IL6 before and after the therapy in all the 3 patients. Annova single factor assay done to test the statistically significant difference between the values reported 0.70 indicating no significant difference between the values across the time points. Figure 7 provides the graphical presentation of the IL6 values across 3 time points.

7 days after the therapy all the patients died & 7-day outcome being 100% mortality. The cause of the death in all the 3 was Acute Respiratory Distress Syndrome & AKI.



*Figure 6:* Levels of IL 6 across the time period. Individual line representing the levels of all the individual patient across the time points, viz, baseline, D+1, D+3 and D+5.



Figure 7: Mean of IL 6before and after the therapy in all the 3 patients

#### **SUMMARY** IV.

2 out of 3 patients, P1 & P2, (66.67%) patients were on NIV and WHO scale score of 5 and 1 patient, P1, (33.33%) was on MV with WHO scale score of 6, by the time of inclusion into the study, of which,1patient, P3, progressed to MV from NIV on D1post therapy. Statistical test conducted reported p value of 0.85 with no statistically significant difference in WHO scale score across the time points.

The mean value of CRP before and after the therapy of P1 was 63.33 & 50.5, of P2 was 56.5 & 44.9, P3 was 81 & 67.3. In case of D- dimer the mean before & after the therapy of P1 was 331 & 243, P2 was 800 & 1040, P3 was 1211 & 932 respectively. In case of IL6 the mean value before and after therapy are in similar range as, 124 & 126.33, 143 & 143, 167 & 141.3 of P1, P2 & P3 respectively. The statistically significant difference tested for reduction in the levels of CRP, D- dimer & IL6 using annova single factor assay reported p values of 0.60, 0.95 & 0.70 respectively and rejected the assumed hypothesis (as stated in statistical analysis section).

The 7-day outcome showed a complete mortality with 100% population (3 out of 3 patients) due to acute respiratory distress syndrome& AKI& cardiac arrest.

The table 2 provides the summary of our study at a glance.

Table 2: Detailed values of corresponding parameters of our study population. Mean before the therapy is the average of last 3 values of corresponding parameter before the therapy. Mean after the therapy is the average of values on the 3 time points of the study (D+1, D+3 & D+5).

PAF	RAMETER	PATIENT 1 OR P1	PATIENT 2 OR P2	PATIENT 3 OR P3	STUDY GROUP
AG	E (YEARS)	61	36	49	48.6
	SEX	MALE	MALLE	MALE	
	D0	6	5	5	
	D+1	6	5	6	
WHO SCALE	D+3	6	5	6	
SCORE	D+5	6	5	6	
	D0 (mean before the therapy)	63.33	56.5	81	
	Mean after the therapy	50.5	44.9	67.3	
CRP	P value				0.6
	D0 (mean before)	331	800	1211	
	Mean after the therapy	243	1040	932	
D- DIMER	P value				0.95
	D0 (mean before)	124	143	167	
	Mean after the therapy	126.33	143	141.3	
IL 6	P value				0.7
7 DAY	OUTCOME	DEATH	DEATH	DEATH	

#### DISCUSSION V.

Despite the data relating to the use of Cytosorb usage in COVID is very limited, its application as a adjuvant therapy is been carried out at several educational institutions, being a new therapeutic approach in treating COVID 1912.

A case series of COVID 19 patients along with AKI treated with CRRT+ cytosorb published by Alharthy et al. reported reduction in the inflammatory biomarkers and 70 % population with favorable results surviving the condition and 30% died despite the therapeutic approach<sup>16</sup>. The first randomized, prospective pilot study conducted to study the effect of cytosorb in COVID 19 patients reported significant improvement in

of Procalcitonin levels and vasopressor terms requirements. However, this study did not look for any improvement in terms of other inflammatory markers, Mechanical ICU admission. ventilation support. limitations of the study according to us<sup>17</sup>.

Another case series published by Mehtha et al., reported the use of Cytosorb after 72 hrs of ICU admission for 24 hrs reported a significant decrease in the levels of CRP and 100% survival rate<sup>18</sup>. Friesecke et al. conducted a prospective single center study of use cytosorb in refractory septic shock with 20 patients under study started with cytosorb before 24 hours that reported the reduction in vasopressor requirement post therapy with 45% of 28 day survival rate and shock reversal in two third of the patients<sup>19</sup>. Saniya Rizvi DO et al, reported a case study of a 51 years old male COVID 19 patients who survived cytokine storm upon treating with Cytosorb and definite treatment<sup>20</sup>. Another case study conducted by Berlot et al, reported use of Cytosorb along with Tocilizumab reported a positive result in terms of extubation after 10 days of the therapy and radiological imaging suggestive of improvement in the lung fields<sup>21</sup>.

Rieder et al. studied the use of Cytosorb incorporated in tht ECMO circuit in comparison with the ECMO alone in treating severly ill COVID 19 patients. The study resulted in the higher reduction in the levels of IL6 in Cytosorb + ECMO group than in ECMO alone treated group<sup>22</sup>. However use of Cytosorb on the first day of ECMO initiation is not suggested and can be incorporated into the ECMO circuit after 24 hours of initiation according to the studies conducted by Alexander Supady MD<sup>23</sup>.

A comparative study conducted by Rampino T et al. reported the reduction of IL6, IL10, TNF  $\alpha$  and CRP in Cytosorb treated group in comparison to the control group. In test group, only 1 patient dies and 2 were intubated while that all of the patients in control group were intubated and died by the end of the study<sup>24</sup>.

## VI. Conclusion

A case cohort study conducted to establish the benefits of Cytosorb therapy in addition to the SoC in treating the severe COVID-19 illness in terms of reduction of inflammatory markers levels (CRP, D-DIMER, IL6), WHO score value along with the 7-day outcome of mortality or out off NIV/MV.

The results of our study didn't show any additional benefits of adding the CYTOSORB therapy to the existing SoC in improving the clinical outcome with no statistically significance in reducing the levels of inflammatory markers and even WHO score value. However, the 7-day outcome of our study reported 100% mortality, to confirm the complete ineffectiveness of the therapy in severe COVID 19 patients a study on large group population is encouraged.

## Acknowledgement

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## Conflict of Interest

None.

### Funding

The study did not receive any funding from any agencies or organisations.

## Informed Consent

No informed consent is obtained since the study is an observational case cohort study.

## Ethical Statement

Since no intervention is being done and informed consent form is obtained, our study do not require ethical statement.

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# A Study to Assess the Effectiveness of Nurse Led Interventions on the Level of Knowledge and Pre-Operative Anxiety among Patients Undergoing Cataract Surgery at Shri Vinoba Bhave Civil Hospital, Silvassa

By Krishna V. Gandhi

Abstract- Background: A Cataract is one of the most common disorders affecting the eye and is the leading cause of visual impairment and blindness. Patients who are planning for surgery don't have adequate knowledge & not prepared for the surgery which results in increase anxiety.

*Aim:* This study aimed to assess the effectiveness of NLI on the level of knowledge and preoperative anxiety.

*Method:* An evaluator approach with Quasi experimental non randomized control group design was adopted for the study. The study was conducted on 60 (30 each experimental and control group) patients using non-probability consecutive sampling technique.

*Result:* In the experimental group the pre-test mean  $\pm$  S.D of level of knowledge was 11.5  $\pm$  2.02 were significant difference with post-test mean  $\pm$  S.D was 21  $\pm$ 1.96. In the experimental group the pre-test mean  $\pm$  S. D of pre-operative anxiety was 84.76  $\pm$  4.95 with post-test mean  $\pm$  S.D was 40.26  $\pm$  6.75.

Keywords: cataract, nurse led interventions, level of knowledge, pre-operative anxiety.

GJMR-F Classification: DDC Code: 617.742059 LCC Code: RE451

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*Conclusion:* The Result showed that there was a significant increase in level of knowledge with reduction in pre-operative anxiety among the patient undergoing cataract surgery in the experimental group after administration of NLI. Thus, NLI as a non-pharmacology tool was an effective intervention in increasing patient's knowledge and reducing the pre-operative anxiety.

Keywords: cataract, nurse led interventions, level of knowledge, pre-operative anxiety.

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I. INTRODUCTION

ye is the most important sensory organ that helps to receive or gather information from the surrounding. Sight is the primary sense which keeps us safe and helps us to appreciate, criticize, evaluate other's performance, as age progresses the visual impairment increase in nature. A cataract is such a condition that happens with the human eye where there is opacity or clouding of the eye's natural lens, which if not treated can lead to blindness.

Permanent cure for cataract is surgery that it is to remove the natural lens and replace it with a new artificial lens. Cataract surgery is the most frequently performed operation. It is the most successful and safest procedure performed for cataract patients.<sup>1</sup> Patient who are undergoing surgery will be always anxious & this is due to the fear of unknown. Cataract surgery is performed under local anesthesia and is completed in a relatively short period time. In most cases patients are fully conscious during the procedure; they may be more stressed and evoke anxiety. It is important that they must remain steady. Any unanticipated movement during cataract surgery could result in suboptimal surgical outcomes and may even lead to blindness.

Low vision is a significant psychological stressor for the patient as well as family members<sup>2</sup>. At the time of surgery physical stress is greatly enhanced by the psychological stress of anxiety and worry, which eventually ends up with the use of more energy that is indeed needed in the post-operative period. One's deepest and worst fears are often felt as the surgery is planned.<sup>3</sup> The patient's basic needs have to be intervened by a nurse and assist them to meet these needs. According to the Department of Health, individual's needs have to be achieved, maintained or restored to an acceptable level to develop social independence or improve quality of life.<sup>4</sup>

Education is one of the common aspects of the pre-operative preparation performed before almost all

surgical procedures. It is believed that pre-operative education mainly focuses on beneficial outcomes for the patient. It varies from patient to patient with their culture, background and experience. It includes three types of information sensory, process and procedural. It helps to decrease post-operative surgical complications, increase patient satisfaction, shorten the length of hospitalization and promote well-being.<sup>5</sup>

#### a) Methodology

A Quasi experimental non randomized control group design and non-probability consecutive sampling technique was adopted to assess the effectiveness of nurse led interventions (NLI). The sample size was 60 and equally divided into 2 groups, 30 in each (experimental and control group). The nurse led interventions included video assisted teaching on perioperative cataract management (15min) and binaural music therapy (15min). Socio-demographic Performa, Self-structured knowledge questionnaire and Modified State Trait Anxiety scale - Adult were used as a tool for the study. Pre-test was conducted a day prior to surgery, followed with the implementation of NLI in the experiment group, in phases; Phase 1: video assisted teaching for 15 minutes and binaural music therapy (15min) along with routine nursing care a day prior to the surgery in IPD and Phase 2: binaural music therapy (15min) was administered one hour before the surgery in IPD. In control group routine nursing care was administered as per need. Post-test for pre-operative anxiety was conducted half an hour before surgery in IPD and level of knowledge was assessed on the postop day 5 at OPD of ophthalmic department at SVBCON, Silvassa.

## II. Results

*Table 1:* Frequency and Percentage Distribution of Socio Demographic Variables in the Experimental and Control Group.

Sr No.	Demographic data	Control gr	oup (n=30)	Experimental group (n=30)		
		f	%	f	%	
1.	Age in years: 41-50 years 51-60 years 61-70 years Above 70 years	10 4 13 3	33.33 13.33 43.33 10	2 9 15 4	6.67 30 50 13.33	
2.	<b>Gender:</b> Male Female	10 20	33.33 66.67	9 21	30 70	
3.	<b>Residential area:</b> Urban Rural	10 20	33.33 66.7	11 19	36.67 63.33	
4.	Marital status: Married Unmarried Widowed	23 2 5	76.67 6.67 16.67	23 1 6	76.67 3.33 20	
5.	Education: Illiterate Primary school Middle school High school Intermediate/diploma Graduate	14 8 3 2 2 1	46.67 26.67 10 6.67 6.67 3.33	10 14 1 3 2 0	33.33 46.67 3.33 10 6.67 0	
6.	Occupation: Professional Semi professional Clerical/shop/farm Skilled worker Unskilled worker Unemployed	2 2 4 0 3 19	6.67 6.67 13.33 0 10 63.33	0 1 6 1 3 19	0 3.33 20 3.33 10 63.33	

A Study to Assess the Effectiveness of Nurse Led Interventions on the Level of Knowledge and Pre-Operative Anxiety among Patients Undergoing Cataract Surgery at Shri Vinoba Bhave Civil Hospital, Silvassa

7.	Income per Month: 10,002 – 29,972 ≤10,001	19 11	63.33 36.67	11 19	36.67 63.33
8.	Previous Knowledge: Yes: a) From Relatives b) Television, Newspaper, Magazine c) Doctors, Nurses	4 2 4 20	13.33 6.66 13.33 66.67	5 0 2 23	16.66 0 6.66 76.67

Table 2: Mean, Sd, Mean % and t-value to Assess the Level of Knowledge Among Patients Undergoing Cataract Surgery.

N=30

Knowledge	Max	ax Experimental Pre-Test			Experimental Post - Test			Effectiveness	t-value	p-value
	score	Mean	SD	Mean %	Mean	SD	Mean %	in Mean%		
Overall	26	11.53	2.02	44.2	21	2.16	80.7	36.5	15.23	P<0.001 (HS)

In the experimental group the pre-test knowledge mean score was 11.5 with standard deviation of 2.02 and mean % was 44.2 whereas in post-

test the mean score was 21 with standard deviation of 2.16 and mean % 80.7, the effectiveness of mean % was 36.5. The obtained "t" value (15.23>2.00).

Table 3: Mean, Sd, Mean % and t-value to Assess the Level of Pre-Operative Anxiety Among Patients Undergoing Cataract Surgery.

N=30

Pre- Operative	Max score	Exper	imental	Pre-Test	Experimental Post - Test			Effectiveness	t-value	p-value
Anxiety		Mean	SD	Mean %	Mean	SD	Mean %	in Mean%		
Overall	100	84.76	4.95	84.76	40.26	6.75	40.26	44.5	28.2	P<0.001 (HS)

The maximum pre-operative anxiety score was 100, In the experimental group pre-test pre-operative anxiety mean score was 84.76 with standard deviation of 4.95 and mean % 84.76 whereas in post-test the mean score was 40.26 with standard deviation of 6.75 and mean % 40.26, the effectiveness of mean % was 44.5. The obtained "t" value (28.2 > 2.00).

*Table 4:* Correlation between the level of knowledge and pre-operative anxiety among patients undergoing cataract surgery.



*Figure 1:* Correlation between the level of knowledge and pre-operative anxiety among patients undergoing cataract surgery.

## Figure 1 indicates that

In the control group, there was weak positive correlation between the pre-test level of knowledge and pre-test level of pre-operative anxiety (r = 0.099), also there was a weak positive correlation between post-test level of knowledge and post-test level of pre-operative anxiety (r = 0.083). In the Experiment group, there was weak positive correlation between the pre-test level of knowledge and pre-test level of pre-operative anxiety (r = 0.2). There was a moderate positive correlation between the post-test level of pre-operative anxiety (r = 0.2). There was a moderate positive correlation between the post-test level of pre-operative and post-test level of pre-operative anxiety (r = 0.469).

## III. Conclusion

The present study was conducted to assess the effectiveness of nurse led interventions on the level of knowledge and pre-operative anxiety among patients undergoing cataract surgery at Shri Vinoba Bhave Civil Hospital, Silvassa. Based on the findings of the study the following conclusion was drawn. The patient in age group 61-70 years went more for the cataract surgeries in which females are more operated and majority of them resides in rural community. The pretest revealed that majority of the samples had moderate knowledge and severe pre-operative anxiety. In the experimental group, after the administration of nurse led interventions the post-test scores revealed adequate knowledge and mild pre-operative anxiety among the patients undergoing cataract surgery. Thus, the investigator concluded that the nurse led interventions (Video assisted teaching and Binaural music therapy) was an effective non - pharmacological intervention in increasing the level of knowledge and reducing the level of pre-operative anxiety among patients undergoing the cataract surgery.

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# Knowledge on Newborn Care among Primi Postnatal Mother in District Hospital Chitwan, Nepal

## By Indira Adhikari (Poudel), Muni Raj Chhetri, Chirinjibi Acharya, Bamita Budhathoki & Sandipa Pathak

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Abstract- Background: The birth of a newborn is a blissful moment in one's life. Newborn babies constitute the foundation of any nation. It referred to a baby under 28 days of life. During their first month of life, these newborns undergo remarkable physical, cognitive, emotional, psychological, social, sensory and motor skills development. Worldwide, around about three million newborns die in this period. Neonatal mortality is a public issue in low and middle-income countries. Knowledge of newborn care among mothers is important for the survival, growth, and development of a newborn.

*Methods:* The objective of the study was to assess the knowledge of newborn care among primipostnatal mothers in the district hospital, Chitwan. A descriptive cross-sectional study design was adopted and 104 postnatal mothers were selected using a non-probability, convenient sampling technique. Data were collected by using interviews. Data entry was done by using Epi data and analysed by SPSS. Descriptive and inferential statistics were used to analyze the collected data.

Keywords: knowledge, newbor, care, postnatal, primi mother.

GJMR-F Classification: NLMC Code: WS 420

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# Knowledge on Newborn Care among Primi Postnatal Mother in District Hospital Chitwan, Nepal

Indira Adhikari (Poudel) <sup>°</sup>, Muni Raj Chhetri <sup>°</sup>, Chirinjibi Acharya <sup>°</sup>, Bamita Budhathoki <sup>©</sup> & Sandipa Pathak <sup>¥</sup>

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*Methods:* The objective of the study was to assess the knowledge of newborn care among primipostnatal mothers in the district hospital, Chitwan. A descriptive cross-sectional study design was adopted and 104 postnatal mothers were selected using a non-probability, convenient sampling technique. Data were collected by using interviews. Data entry was done by using Epi data and analysed by SPSS. Descriptive and inferential statistics were used to analyze the collected data.

*Results:* Among total respondents 50.96% of respondent had moderately adequate knowledge, 45.19% had inadequate knowledge, and 3.84% had adequate knowledge. Mothers had good knowledge of aspects like first feeding, cleanliness, and maintenance of body temperature. Socio-demographic variables like age, ethnicity, education, and occupation were significantly associated with knowledge of newborn care at a 95% confidence intervalp-value-<0.05).

*Conclusion:* Based on the finding of the present study it is concluded that the knowledge of newborn care among primi postnatal mothers is inadequate among half of the respondents, the excellent level of knowledge is very less in comparison to the good and poor knowledge.

Keywords: knowledge, newbor, care, postnatal, primi mother.

### I. INTRODUCTION

ewborn death is a global public health burden mostly concentrated in low- and middle-income countries.<sup>1</sup>Neonates are a vital link in the life cycle, spanning from conception to adulthood. The neonatal stage is defined as the first twenty-eight days

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after birth.<sup>2</sup> Newborns face a higher risk of death in this period with an average globalized rate of 17 deaths per thousand live births in the year 2019.<sup>3</sup>

Evidence shows that 2.5 million children lost their lives in the first month of life in 2018, this translates to 7,000 neonatal deaths occurring every day; most of which close to three guarters dying, with one-third of newborns dying on the first day. About 75% of neonate mortality occurs in the first week of life and about one million newborns die within the first 24 hours after birth.<sup>4</sup> On top, 80 percent of all newborn deaths are caused by three preventable and treatable issues namely complications related to prematurity, birth complications including lack of oxygen (asphyxia) and newborn infections such as sepsis and pneumonia. Numerous lives could be saved each year by investing in quality care around the time of birth, coupled with special care for sick and small newborns.<sup>5</sup>There are mainly three major causes of death in the neonatal period worldwide are infections (around 36% of which include pneumonia, severe sepsis, and diarrhoea), 28% of preterm, about 23% of birth asphyxia and 13% due to other causes.<sup>6</sup>

A child born in Southern Asia and sub-Saharan Africa is ten times more likely to die in the first 28th days of life than a child born in a developed and high-income country.7 The first 28 days of neonate life is the most vulnerable time for survival.8 WHO formulated and focused the priority strategy to reduce neonatal mortality rate worldwide by following neonatal health: thermoregulation, hygienic skincare and cord care, early initiation and exclusive breastfeeding for neonates, assessment for serious health issues or need of additional care in case of low birth-weight and baby of HIV-infected mother and preventive care.<sup>9</sup> Relevant care after birth is very important for the survival and wellbeing of the newly born infant. Basic objectives for neonatal care at birth include initiation of normal breathing, prevention of hypothermia, initiation of breastfeeding, protection from infection and early identification of danger signs.<sup>10</sup>

Care of neonates had always been a traditionally and culturally vital role of mothers irrespective of their educational level, occupation status, family income level, family type and religion.<sup>11</sup>

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The neonatal mortality rate per thousand live births in Nepal is 24.2. There are numerous unscientific and unhygienic health practices and social taboos in child-rearing that make the newborn extremely vulnerable.<sup>12</sup> Newborn care of the mothers plays a significant role in bringing down mortality and morbidity because they will have appropriate information and enough confidence to take care of their newborn baby who helps to provide quality and essential care to prevent deviation of normal health.<sup>13</sup> The knowledge of newborn care is directly linked with education level.<sup>14</sup> Out of 363 mothers, 61.70% of the mothers had adequate knowledge of neonatal danger signs. The mothers were educated up to secondary and more education secured good knowledge.<sup>15</sup> One recent study revealed that a significant association was found between the knowledge scores of primipara mothers with their residential area and education level.<sup>16</sup>

The Sustainable Development Goals (SDGs) have set ambitious targets for all countries. South Asia's target is set to reduce newborn deaths from 28 per 1,000 live births in 2016 to 21 per 1,000 live births by 2021.<sup>17</sup>

Out of 17 Sustainable Development Goals (SDGs) set by United Nations in 2015, the third goal, target (No. 3.2) states that all countries aim to put a stop to millions of avoidable deaths of newborns and underfive children by 2030. The targets achieve by reducing neonatal and under-five deaths to no more than 12 and 25 deaths per 1000 live births respectively.<sup>18</sup> the majority of low-income countries are far behind in achieving SDG target number 3.2 goal mostly because of slow progress in reducing neonatal death.<sup>19</sup> Among 518 mothers, more than half of the newborns were bathed within six hours of delivery. Around 50% started breastfeeding within one 1 h of birth. And 44.8% of them did not feed colostrum to their newborns.<sup>20</sup> Numerous studies show that an umbilical cord is one of the sensitive issues concerning newborn care. WHO focuses on the significance of hygiene while handling the cord and applying chlorhexidine, basically in regions where there are over neonatal mortality rates.<sup>21</sup> A study shows that one-third of the participants had good newborn care practice based on three composite variables such as early breastfeeding initiation 83.9%, safe cord care 32.9%, and thermal care 30.6% respectively.<sup>22</sup>

Mothers are the key person for providing newborn care in Nepal.<sup>23</sup> In the context of Nepal, lack of knowledge among primigravida mothers about the preparation for their new roles and responsibilities.<sup>24</sup> The health of newborns has been neglected despite the huge number of deaths due to various causes in Nepal such as preterm birth complications 31%, intrapartum related complications 23%, sepsis 19%, congenital abnormalities 13%, diarrhoea 1%, pneumonia 6%, other conditions 7%.<sup>25</sup> A study was conducted in Nepal, among 276 primiparous mothers, 56% of women had

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moderate knowledge about newborn care, 44% had a low level of knowledge of breastfeeding, and 78% had a sufficient level of knowledge about immunisation.<sup>26</sup>

## II. MATERIAL AND METHODS

## a) Study Design, Setting and Population

A descriptive cross-sectional research design was used for this study to meet its objectives. This study was conducted at the postnatal ward Bharatpur hospital in Chitwan. The main objective of the study was to find out the knowledge on newborn care among primi postnatal mothers. The study population was primigravida postnatal mothers.

#### b) Sampling Technique

A descriptive cross-sectional study design was adopted to assess the knowledge of newborn care among primi postnatal mothers. The sample populations were the primi postnatal mothers who had undergone either vaginal delivery or cesarean section delivery and were admitted to the postnatal wards. The sample size was 104. A non-probability, purposive sampling technique was used. Data were collected by using structured interview methods following ethical principles. The data were collected for 6 weeks period from August 22<sup>nd</sup> to October 6<sup>th</sup> 2021 at Bharatpur district hospital postnatal ward, Chitwan.

#### c) Instrumentation

The instrument for data collection was a structured interview schedule through face to face interview method which was developed by the researcher herself by reviewing the related literature and consulting with subject experts.

#### d) Inclusion criteria

All primi postnatal mothers who had undergone either vaginal delivery or cesarean section delivery and were admitted to the postnatal wards were willing to participate. Others criteria was mothers who can understand English and Nepali language.

#### e) Outcome variable

Find out the knowledge on newborn care among primi postnatal mothers.

#### f) Explanatory variables

Explanatory variables were age, educational status, ethnicity, types of family, occupation, area of residence, type of delivery and duration of hospital stay etc.

#### g) Ethical committee approval

Ethical clearance was obtained from Manmohan Memorial Institute of Health Sciences (IRC) Kathmandu, Nepal. Data collection permission was obtained from the Bharatpur district hospital in Chitwan. The purpose of the study was explained to the participants. Verbal consent was taken from all respondents before the data collection. Privacy was maintained by using a code number for each respondent. Confidentiality was maintained by not disclosing the information to others and assured that the information will be used for study purposes only. Respondents were clearly explained that they have the choice to reject or discontinue the research study at any point during the study time.

Content validity of the instrument

established by consultation with the research advisor

and subject experts. English questionnaire was translated into the local Nepali language to maintain

simplicity and comprehensibility with the help of a

h) Questionnaire design

language expert. Besides, pre-testing was done among 10% of respondents (i.e. 11 respondents) to assess the practicability of use of the instrument and was excluded from the main study. Slight modifications were done to the instrument such as arranging questions in order and adding/deleting some response categories after the pretest.

### i) Data management and statistical analysis

## The collected data was checked, reviewed and organized for accuracy, completeness and consistency. All collected data were analyzed by using the statistical package for social sciences (SPSS) version 20.0. Association between different variables were tested by Chi-square.

## III. Results

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Table 1: Socio-demographic Characteristics

n=104

Variables	Frequency (n)	Percentage (%)
Age groups (in completed years)		
<20years	28	26.9
20-25years	53	50.9
>25 years	23	22.9
Residence	60	50.0
Rural	62	59.6
Urban	42	40.3
Ethnicity	10	10.0
Brahmin/Chhetri	42	40.3
Janajati	40	38.5
Dalit	18	17.4
Others	4	3.8
Religion		
Hindu	84	80.8
Muslim	4	3.9
Buddhist	6	5.7
Christian	10	9.6
Education Status		
Literate	102	98.1
Illiterate	2	1.9
If Literate, Level of Education(n=102)		
General literate (Can read and write only)	1	0.9
Basic level (Up to 8 classes)	18	17.9
Secondary level	39	38.1
Higher secondary level	29	28.0
Graduate and above	15	15.1
Type of family		
Nuclear	28	26.9
Joint	68	65.5
Extended	8	7.6
Occupation		
Household work	77	74.1
Daily wages	12	11.5
Service	15	14.4

Table 1 shows the socio-demographic variables of respondents. Out of 112 respondent's majority, 50.9% belong to the age group 20-24 years. The present study shows that majority of the respondents were from rural areas 59.6%. Likewise, the majority of the respondents

were from janajati ethnicity 38.5% and 80.7% followed the Hindu religion. Majority of respondents 98.0% were literate. Among them, 38.1% had completed secondary level and at least 0.9% could read and write. Regarding the type of family, the majority 65.3% were living in joint families. Nearly one-third of the respondents 74.0% were household workers.

Table 2: Respondents' Level of Knowledge on Newborn Care

n=104

Variables	Frequency	Percentage (%)
Inadequate knowledge (<50%)	47	45.1
Moderately adequate knowledge (50-75%)	53	50.9
Adequate knowledge (>75%)	4	3.8

Table 2 shows the knowledge score on newborn care which depict that the majority of 50.9% mother had moderately adequate knowledge, 45.1%

had inadequate knowledge, and only 3.8% had adequate knowledge of newborn care.

Table 3: Knowledge of General Characteristics of Newborn

n=104

Variables	Frequency	Percentage (%)
Meaning on newborn care**		
Breast feeding	100	96.1
Immunization	58	55.7
Cleanliness	69	66.3
Management of illness	20	19.2
Others	2	1.9
Meaning of newborn		
One week baby	42	40.3
One month baby*	18	17.3
One year baby	44	42.3
Normal weight		
2.5-3.5 kg*	53	50.9
3.6-4 kg	18	17.3
Above 4kg	33	31.7
Newborn sleep		
8-12 hours	31	29.8
12-15 hours	28	26.9
16 -20 hours	32	30.7
More than 20 hours*	13	12.5

\*correct response

Table 3 shows that, 96.1% replied breastfeeding is one of the most important areas of newborn care, whereas only 19.2% replied management of illness is the meaning of newborn care. Similarly, 40.3% respondents knew of the newborn period, and 50.9% respondents knew the normal weight of the newborn.

Τ	abi	e	4:	K	lnow	lec	lge	on	Breast	Feed	ling
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n=104

Variables	Frequency	Percentage
Initiation of first feeding		
8-10 hours after birth	20	19.2
After 24 hours	10	9.6
After 2 days	2	1.9
Immediately after birth*	72	69.2
First feeding		
Honey	8	7.6
Breast milk/colostrums*	96	92.3
Position for breastfeeding		
Sitting*	59	56.7
Laying	6	5.7
Standing	1	0.9
Not specific	38	36.5
Knowledge on burping		
No	37	35.5

Yes*	47	45.1
Do not know	20	19.2
Knowledge of exclusive breastfeeding		
Yes	46	44.2
No	58	55.7
lf, yes(n=46)		
Meaning of EBF		
Feeding only breast milk*	38	82.6
Feeding breastmilk with solid food	8	17.3
Duration of EBF		
6 Months*	28	60.8
Less than 6 months	5	10.8
1 year	3	6.5
2 years	10	21.7

\*Correct answer

Table 4 shows 92.3% had knowledge of the first feeding, 56.7% had knowledge of the position of breastfeeding and 47% of mothers said burping should

be done after feeding. While asking about exclusive breastfeeding only 44.2% heard, 82.6% knew what exclusive breastfeeding and 60.8% knew its duration.

Table 5: Knowledge	of Cloanlingon a	ad Maintonanco	of Rody T	omporatura
able J. KIIUWIEUye	UI UICAI IIII IESS AI	IU Maintenance	U DOUY I	emperature

Variables	Frequency	Percentage
Cord care (Need for cord care)		
To prevent infection*	92	88.4
Not necessary to keep the cord clean	5	4.8
Do not know	7	6.7
Way to keep cord clean		
Applying turmeric powder	2	1.9
Cleaning with warm water and cotton*	86	82.6
Applying cow dung	1	0.9
Way to keep the eye clean		
Cleaning the eyes separately with warm water and cotton*	74	71.1
Cleaning with fingers	3	2.8
Applying kajal	25	24.0
Not necessary to keep the eyes clean	2	1.9
An appropriate time to give a bath		
Immediately after birth	5	4.8
Within 24 hours of delivery	53	50.9
After 24 hours of delivery*	46	44.3
Maintenance of body temperature **		
By covering the newborn with warm cotton clothes	67	64.4
By delay bathing	30	28.8
By keeping newborn in contact with mother	62	59.6

\*Correct answer \*\* Multiple responses

Table 5 shows the majority of mothers 88.46% of mothers knew the umbilical cord should be kept clean to prevent infection and 82.6% of mothers were knowledgeable about cleaning cords with warm water and cotton. In addition, 71.1% of mothers knew that their eyes should be cleaned using warm water and cotton. Regarding maintenance of body temperature, 44.2% knew an appropriate time to give baby baths after delivery and only 28% knew that delaying bathing after birth helps in maintaining body temperature.

#### Table 6: Knowledge on Immunization and Newborn Danger Signs

n=104

Variables	Frequency	Percentage
Heard about immunization		
Yes	81	77.8
No	23	22.2
lf, yes(n=81)		
The appropriate time for BCG immunization		
Within 2 months	6	7.4
Within 45 days*	17	20.9
Within 1 year	2	2.4
Above 1 year	56	69.1
Necessity of vaccination		
To increases weight	9	11.1
To prevent some diseases*	67	82.7
Do not know	5	6.1
Aware of newborn danger sign		
Yes	50	48.0
No	54	51.9
If, yes (n=50) **		
Feeling too cold	29	58
Convulsion	18	36
Cord infection	34	68
Feeling too hot	30	60
Seeking medical help(n=104) **	30	00
Not sucking well	85	81.7
Difficulty in breathing	81	77.8
Yellowish discoloration of skin	40	38.4
Unconscious	39	37.5

\*Correct answer

Table 6 delineates that 77.8% had heard about immunization. Similarly, 69.1% of mothers were unknown about the appropriate time for BCG vaccination and 82.1% knew the necessity of

vaccination is to prevent some diseases. Likewise, 48.0% had heard about newborn danger signs and 68% considered cord infection as a danger sign.

Table 7: Association between the socio-demographic variables and knowledge on

newborn care n = 104

11-10-				
Variables	Inadequate	Moderately adequate - Adequate	Value	p-value
Age				
< 20years	17(16.4%)	11(10.5%)	6.113	0.047*
20 – 24years	24(23.0%)	29(27.8%)		
25 and above	6(5.7%)	17(16.3%)		
Religion				
Hindu	37(35.5%)	47(45.1%)	0.231	0.611
Non hindu	10(9.6%)	10(9.6%)		
Education				
Up lower secondary	10(9.6%)	9(8.6%)	6.074	0.03*
Secondary and above	35(33.6%)	48(46.1%)		
Ethnicity				
Bhramin/Chhetri	14(13.4%)	32(30.7%)	7.271	0.026*
Janajati	23(22.1%)	17(16.3%)		
Dalit	10(9.6)	8(7.69%)		

Type of family				
Nuclear	15(14.4%)	13(12.5%)	1.086	0.297
Joint and extended	32(30.7%)	44(42.3%)		
Occupation				
Housewife	41(39.4%)	36(34.6%)	7.768	0.05*
Service and daily Wages	6(5.7%)	21(20.1%)		
Type of delivery				
Caesarean section	18(17.3%)	23(22.1%)	0.045	0.831
Normal vaginal delivery	29(27.8%)	34(32.6%)		
Duration of hospital stay				
$\leq$ 5 days	43(41.3%)	49(47.1%)	0.77	0.38
≥6 days	4(3.8%)	8(7.6%)		

Significantly associated in 95% confidence interval. P-value obtained from Pearson chi-square \*

Table 9 shows that, there is significant association of knowledge on newborn care with mother age (p=0.047), education (p=0.03), ethnicity (p=0.026) and occupation (p=0.05).

## IV. DISCUSSION

The present study found that, 50.9% had moderately adequate knowledge, 45.2% had inadequate knowledge and only 3.8% had adequate knowledge of newborn care. Which was in contrast to the study conducted by Bagilkar & Anuchihra (2014) where 68% had moderately adequate knowledge, 30% had adequate knowledge and only 2% had inadequate knowledge.<sup>27</sup> In the current study, only 17.3% mothers answered one month baby is the newborn, which was inconsistence with the study conducted in Nepal by Bhandari & Sharma (2016) where 85.3% know the meaning of newborn baby.28

In this study, 69.23% of the respondents knew about the right time for the initiation of breastfeeding and 92.3% knows colostrum feeding. This result were similar to the study conducted by Mohite, Mohite, & Kakade (2012) in Bangaladesh. The result that 59.6% had fair knowledge about breastfeeding and 82.7% knew about colostrum feeding.<sup>29</sup> A contras finding which was conducted by Pathak, Singh, Agarwal, & Kant (2021) shows that only 4.5% of the mothers knew about the initiation of breastfeeding to the baby within one hour after delivery. Regarding the knowledge of burping after feeding, only 45.1% knew burping is necessary. Whereas, the contrast finding shows that 93.5% knew burping after feeding is necessary.<sup>30</sup>

Most of the respondents 96.1% knew about breastfeeding is one of the important parts of newborn care which is supported by the finding of Berhea, Belachew, & Abreha, (2018) where 97.4% replied about breastfeeding.<sup>31</sup> It contradict the findings by Chaudhary, Dhungana, & Ghimire (2013) in Nepal <sup>32</sup> and Berhe, et al., (2016) in North Ethiopia showing that 52.5% and  $63.1\%^{33}$  were knowledgeable about breastfeeding respectively.

Regarding exclusive breastfeeding 44.2% had heard it while a contrast study conducted by Ahmed & Piro (2019) shows that 69.2% of the mothers answered about exclusive breastfeeding.<sup>34</sup> This study reflects that 88.4% of mothers knew cord should be kept clean to prevent infection and 71.1% knew how to keep eyeclean. This is similar to the finding of Bhandari & Sharma (2016) where the primi postnatal mothers who revealed that 56.3% of the answered cord should be kept clean and 88% had knowledge on eye care to prevent infection.<sup>28</sup>

Regarding immunization, though 77.8% of respondents had heard about it only 20.9% knew about the appropriate time for B.C.G vaccination which contradicts the finding in the study by Pathak, Singh, Agarwal, & Kant, (2021) which revealed that (97%) were fully immunized.<sup>30</sup> A study was done by Bhandari, and Sharma, 2016 expressed centpercent of mothers had heard about immunization.<sup>28</sup> In the present study, 48.0% had heard about newborn danger signs. Where 81.73% of mothers thought poor sucking was a serious condition where they should seek medical help. This is in contrast to the finding of Pathak, Singh, Agarwal, & Kant, (2021) which shows that (98%), (78%), (37%), (and 31%) knew fever, fast breathing, chest in drawing and unable to feed respectively were the newborn danger signs.<sup>30</sup>According to the study the knowledge on newborn care is significant association with the education of the mother (p=0.03) which was similar to the study conducted by Bagilkar, & Anuchihra (2014) and Sakelo, Assefa, Oljira, & Assefa (2020) were the significant association of knowledge with maternal education with newborn care. <sup>35</sup>

## V. Conclusion

Based on the finding of the present study it is concluded that the knowledge of newborn care among primi postnatal mothers is inadequate in almost half of the respondents, the adequate level of knowledge is very less in comparison to the moderately adequate and inadequate knowledge. Knowledge of breastfeeding, knowledge on eye care, and cord care were good but mothers were lacking knowledge in various aspects of newborn care and newborn danger sign. As the study was about population on primipostnatal mothers who had no experience in raring and caring for newborns. Hence, emphasizing health education regarding newborn care during antenatal visits might increase the knowledge during the postnatal period.

## VI. Limitations of the Study

The study was conducted in only one district hospital in Chitwan. The finding cannot be generalized to the overall population as well as others setting.

## VII. Recommendation

Health education on essential newborn care should be integrated into routine antenatal services and re-emphasized in the postnatal period to help improve maternal knowledge and essential newborn care practices.

Health intervention should be provided for primigravida in the special focus area like immunization, exclusive breastfeeding, prevent hypothermia, and cleanliness of newborn danger signs.

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*Conflict of Interest:* The authors do not have any conflict of interest arising from the study.

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## TIPS FOR WRITING A GOOD QUALITY MEDICAL RESEARCH PAPER

**1.** *Choosing the topic:* In most cases, the topic is selected by the interests of the author, but it can also be suggested by the guides. You can have several topics, and then judge which you are most comfortable with. This may be done by asking several questions of yourself, like "Will I be able to carry out a search in this area? Will I find all necessary resources to accomplish the search? Will I be able to find all information in this field area?" If the answer to this type of question is "yes," then you ought to choose that topic. In most cases, you may have to conduct surveys and visit several places. Also, you might have to do a lot of work to find all the rises and falls of the various data on that subject. Sometimes, detailed information plays a vital role, instead of short information. Evaluators are human: The first thing to remember is that evaluators are also human beings. They are not only meant for rejecting a paper. They are here to evaluate your paper. So present your best aspect.

**2.** *Think like evaluators:* If you are in confusion or getting demotivated because your paper may not be accepted by the evaluators, then think, and try to evaluate your paper like an evaluator. Try to understand what an evaluator wants in your research paper, and you will automatically have your answer. Make blueprints of paper: The outline is the plan or framework that will help you to arrange your thoughts. It will make your paper logical. But remember that all points of your outline must be related to the topic you have chosen.

**3.** Ask your guides: If you are having any difficulty with your research, then do not hesitate to share your difficulty with your guide (if you have one). They will surely help you out and resolve your doubts. If you can't clarify what exactly you require for your work, then ask your supervisor to help you with an alternative. He or she might also provide you with a list of essential readings.

**4.** Use of computer is recommended: As you are doing research in the field of medical research then this point is quite obvious. Use right software: Always use good quality software packages. If you are not capable of judging good software, then you can lose the quality of your paper unknowingly. There are various programs available to help you which you can get through the internet.

**5.** Use the internet for help: An excellent start for your paper is using Google. It is a wondrous search engine, where you can have your doubts resolved. You may also read some answers for the frequent question of how to write your research paper or find a model research paper. You can download books from the internet. If you have all the required books, place importance on reading, selecting, and analyzing the specified information. Then sketch out your research paper. Use big pictures: You may use encyclopedias like Wikipedia to get pictures with the best resolution. At Global Journals, you should strictly follow here.

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**6.** Bookmarks are useful: When you read any book or magazine, you generally use bookmarks, right? It is a good habit which helps to not lose your continuity. You should always use bookmarks while searching on the internet also, which will make your search easier.

7. Revise what you wrote: When you write anything, always read it, summarize it, and then finalize it.

**8.** *Make every effort:* Make every effort to mention what you are going to write in your paper. That means always have a good start. Try to mention everything in the introduction—what is the need for a particular research paper. Polish your work with good writing skills and always give an evaluator what he wants. Make backups: When you are going to do any important thing like making a research paper, you should always have backup copies of it either on your computer or on paper. This protects you from losing any portion of your important data.

**9.** Produce good diagrams of your own: Always try to include good charts or diagrams in your paper to improve quality. Using several unnecessary diagrams will degrade the quality of your paper by creating a hodgepodge. So always try to include diagrams which were made by you to improve the readability of your paper. Use of direct quotes: When you do research relevant to literature, history, or current affairs, then use of quotes becomes essential, but if the study is relevant to science, use of quotes is not preferable.

**10.** Use proper verb tense: Use proper verb tenses in your paper. Use past tense to present those events that have happened. Use present tense to indicate events that are going on. Use future tense to indicate events that will happen in the future. Use of wrong tenses will confuse the evaluator. Avoid sentences that are incomplete.

11. Pick a good study spot: Always try to pick a spot for your research which is quiet. Not every spot is good for studying.

**12.** *Know what you know:* Always try to know what you know by making objectives, otherwise you will be confused and unable to achieve your target.

**13.** Use good grammar: Always use good grammar and words that will have a positive impact on the evaluator; use of good vocabulary does not mean using tough words which the evaluator has to find in a dictionary. Do not fragment sentences. Eliminate one-word sentences. Do not ever use a big word when a smaller one would suffice.

Verbs have to be in agreement with their subjects. In a research paper, do not start sentences with conjunctions or finish them with prepositions. When writing formally, it is advisable to never split an infinitive because someone will (wrongly) complain. Avoid clichés like a disease. Always shun irritating alliteration. Use language which is simple and straightforward. Put together a neat summary.

**14.** 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 for your topic. You may also maintain your arguments with records.

**15.** Never start at the last minute: Always allow enough time for research work. Leaving everything to the last minute will degrade your paper and spoil your work.

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

**17.** *Never copy others' work:* Never copy others' work and give it your name because if the evaluator has seen it anywhere, you will be in trouble. Take proper rest and food: No matter how many hours you spend on your research activity, if you are not taking care of your health, then all your efforts will have been in vain. For quality research, take proper rest and food.

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

**19.** *Refresh your mind after intervals:* Try to give your mind a rest by listening to soft music or sleeping in intervals. This will also improve your memory. Acquire colleagues: Always try to acquire colleagues. No matter how sharp you are, if you acquire colleagues, they can give you ideas which will be helpful to your research.

**20.** *Think technically:* Always think technically. If anything happens, search for its reasons, benefits, and demerits. Think and then print: When you go to print your paper, check that tables are not split, headings are not detached from their descriptions, and page sequence is maintained.

**21.** Adding unnecessary information: Do not add unnecessary information like "I have used MS Excel to draw graphs." Irrelevant and inappropriate material is superfluous. Foreign terminology and phrases are not apropos. One should never take a broad view. Analogy is like feathers on a snake. Use words properly, regardless of how others use them. Remove quotations. Puns are for kids, not grunt readers. Never oversimplify: When adding material to your research paper, never go for oversimplification; this will definitely irritate the evaluator. Be specific. Never use rhythmic redundancies. Contractions shouldn't be used in a research paper. Comparisons are as terrible as clichés. Give up ampersands, abbreviations, and so on. Remove commas that are not necessary. Parenthetical words should be between brackets or commas. Understatement is always the best way to put forward earth-shaking thoughts. Give a detailed literary review.

**22. Report concluded results:** Use concluded results. From raw data, filter the results, and then conclude your studies based on measurements and observations taken. An appropriate number of decimal places should be used. Parenthetical remarks are prohibited here. Proofread carefully at the final stage. At the end, give an outline to your arguments. Spot perspectives of further study of the subject. Justify your conclusion at the bottom sufficiently, which will probably include examples.

**23. Upon 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 for 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 of 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 criteria peer reviewers will use for grading the final paper.

### **Final points:**

One purpose of organizing a research paper is to let people interpret your efforts selectively. The journal requires the following sections, submitted in the order listed, with each section starting on a new page:

*The introduction:* This will be compiled from reference matter and reflect the design processes or outline of basis that directed you to make a study. As you carry out the process of study, the method and process section will be constructed like that. The results segment will show related statistics in nearly sequential order and direct reviewers to similar intellectual paths throughout the data that you gathered to carry out your study.

### The discussion section:

This will provide understanding of the data and projections as to the implications of the results. The use of good quality references throughout the paper will give the effort trustworthiness by representing an alertness to 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 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.



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## Mistakes to avoid:

- Insertion of a title at the foot of a page with subsequent text on the next page.
- Separating a table, chart, or figure—confine each to a single page.
- Submitting a manuscript with pages out of sequence.
- In every section of your document, use standard writing style, including articles ("a" and "the").
- Keep paying attention to the topic of the paper.
- Use paragraphs to split each significant point (excluding the abstract).
- Align the primary line of each section.
- Present your points in sound order.
- Use present tense to report well-accepted matters.
- Use past tense to describe specific results.
- Do not use familiar wording; don't address the reviewer directly. Don't use slang or superlatives.
- Avoid use of extra pictures—include only those figures essential to presenting results.

### Title page:

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

**Abstract:** This summary should be two hundred words or less. It should clearly and briefly explain the key findings reported in the manuscript and must have precise statistics. It should not have acronyms or abbreviations. It should be logical in itself. Do not cite 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 approaches 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. Use comprehensive sentences, and do not sacrifice readability for brevity; you can maintain it succinctly by phrasing sentences so that they provide more than a 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 limit the initial two items to no more than one line each.

### Reason for writing the article—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 for this; results of any numerical analysis should be reported. Significant conclusions or questions that emerge from the research.

### Approach:

- Single section and succinct.
- An outline of the job done is always written in past tense.
- o Concentrate on shortening results—limit background information to a verdict or two.
- Exact spelling, clarity 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 of comprehending and calculating the purpose of your study without having to refer to other works. The basis for the study should be offered. Give the most important references, but avoid making a comprehensive appraisal of the topic. Describe the problem visibly. If the problem is not acknowledged in a logical, reasonable way, the reviewer will give no attention to your results. Speak in common terms about techniques used to explain the problem, if needed, but do not present any particulars about the protocols here.

The following approach can create a valuable beginning:

- Explain the value (significance) of the study.
- Defend the model—why did you employ this particular system or method? What is its compensation? Remark upon its appropriateness from an abstract point of view as well as pointing out sensible reasons for using it.
- Present a justification. State your particular theory(-ies) or aim(s), and describe the logic that led you to choose them.
- o Briefly explain the study's tentative purpose and how it meets 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 for every section. If you make the four points listed above, you will need at least four paragraphs. Present surrounding information only when it is necessary to support a situation. The reviewer does not desire to read everything you know about a topic. Shape the theory 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 soundly written procedures segment allows a capable scientist to replicate 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 to give the least amount of information that would permit another capable scientist to replicate 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 section, mention the specific item describing the way, but draw the basic principle while stating the situation. The purpose is to show 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:

Materials may be reported in part of a section or else they may be recognized along with your measures.

### Methods:

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

### Approach:

It is embarrassing to use vigorous voice when documenting methods without using first person, which would focus the reviewer's interest on the researcher rather than the job. As a result, when writing up the methods, most authors use third person passive voice.

Use standard style in this and 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.
- o Skip all descriptive information and surroundings—save it for the argument.
- Leave out information that is immaterial to a third party.

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## **Results:**

The principle of a results segment is to present and demonstrate your conclusion. Create this part as 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. Use statistics and tables, if suitable, to present consequences most efficiently.

You must clearly differentiate material which would usually be incorporated in a study editorial from any unprocessed data or additional appendix matter that would not be available. In fact, such matters should not be submitted at all except if requested by the instructor.

#### Content:

- o Sum up your conclusions in text and demonstrate them, if suitable, with figures and tables.
- o In the manuscript, explain each of your consequences, and point the reader to remarks that are most appropriate.
- Present a background, such as by describing the question that was addressed by creation of an exacting study.
- Explain results of control experiments and give 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 manuscript.

## What to stay away from:

- o Do not discuss or infer your outcome, report surrounding information, or try to explain anything.
- Do not include raw data or intermediate calculations in a research manuscript.
- o Do not present similar data more than once.
- o A manuscript should complement any figures or tables, not duplicate information.
- Never confuse figures with tables—there is a difference.

### Approach:

As always, use past tense when you submit 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 section.

### Figures and tables:

If you put figures and tables at the end of some details, make certain that they are visibly distinguished from any attached appendix materials, such as raw facts. Whatever the position, each table must be titled, numbered one after the other, and include a heading. All figures and tables must be divided from the text.

### Discussion:

The discussion is expected to be the trickiest segment to write. A lot of papers submitted to the journal are discarded based on problems with the discussion. There is no rule for how long an 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 implications of the study. The purpose here is to offer an understanding of your results and support all of your conclusions, using facts from your research and generally accepted information, if suitable. The implication of results should be fully 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 the prospect, and let it drop at that. Make a decision as to whether each premise is supported or 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 an experiment might be personalized to accomplish a new idea.
- Give details of all of your remarks as much as possible, focusing on mechanisms.
- Make a decision as to whether the tentative design sufficiently addressed the theory and whether or not it was correctly restricted. Try to present substitute explanations if they are sensible alternatives.
- One piece of 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?
- o Recommendations for detailed papers will offer supplementary suggestions.

#### Approach:

When you refer to information, differentiate data generated by your own studies from other available information. Present work done by specific persons (including you) in past tense.

Describe generally acknowledged facts and main beliefs in present tense.

## The Administration Rules

Administration Rules to Be Strictly Followed before Submitting Your Research Paper to Global Journals Inc.

Please read the following rules and regulations carefully before submitting your research paper to Global Journals Inc. to avoid rejection.

Segment draft and final research paper: You have to strictly follow the template of a research paper, failing which your paper may get rejected. You are expected to write each part of the paper wholly on your own. The peer reviewers need to identify your own perspective of the concepts in your own terms. Please do not extract straight from any other source, and do not rephrase someone else's analysis. Do not allow anyone else to proofread your manuscript.

*Written material:* You may discuss this with your guides and key sources. Do not copy anyone else's paper, even if this is only imitation, otherwise it will be rejected on the grounds of plagiarism, which is illegal. Various methods to avoid plagiarism are strictly applied by us to every paper, and, if found guilty, you may be blacklisted, which could affect your career adversely. To guard yourself and others from possible illegal use, please do not permit anyone to use or even read your paper and file.

## CRITERION FOR GRADING A RESEARCH PAPER (COMPILATION) BY GLOBAL JOURNALS

Please note that following table is only a Grading of "Paper Compilation" and not on "Performed/Stated Research" whose grading solely depends on Individual Assigned Peer Reviewer and Editorial Board Member. These can be available only on request and after decision of Paper. This report will be the property of Global Journals.

Topics	Grades		
	А-В	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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