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Contents **Page No**

From Chief Editors Desk

Valid and reliable research is becoming more and more important in modern healthcare practice. Patients and their families' expect their nursing care to be the very best available. Nurses are obliged professionally and ethically to share best practices to advance nursing knowledge and create better outcomes for patients. Writing for publication is a mechanism for disseminating practice-based evidence. This journal is an earnest attempt to share the research experiencebased on evidence.This journal publishes original research articles, review articles and clinical studies in all areas of nursing and midwifery, research and education. The aim of the journal is to contribute to the growth of nursing practice and provide a platform for nursing researchers. We need to reach out and communicate with each other for the advancement of our specialty. The work of compiling all the research evidences into a book form is labour-intensive task to make research manuscripts clear and succinct .I congratulate the editorial board members for their hard work and wish all the success for the making of this journal.

Now we are releasing the last issue of 2019.We are so happy that we were able to include in the current issue, an article on COVID vaccine.

Dr. Bincy R

Physical and Psychological Problems of Patients With Systemic Lupus Erythematosus (SLE) Attending a Tertiary Care Hospital Thiruvananthapuram

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Abstract

Systemic Lupus Erythematosus (SLE) is a complex autoimmune disease with chronic relapsing-remitting course and variable manifestations leading a spectrum from mild mucocutaneous illness to devastating life threatening disease. The present study was a quantitative study intended to identify the physical and psychological problems of patients with Systemic Lupus Erythematosus (SLE) attending a Tertiary Care Hospital, Thiruvananthapuram. The primary objective of the study was to identify the physical problems of patients with Systemic Lupus Erythematosus (SLE). Secondary objectives were to identify the psychological problems of patients with SLE and to prepare a care guide for the patients with SLE. Descriptive design was used in this study. The sample size was 117. Sample was selected consecutively and data were collected by interview method. The tool used to identify the physical problems of patients with SLE was assessment proforma and the psychological problems were identified using Depression Anxiety Stress Scale (DASS). The data were collected over a period of 6 weeks. The collected data were analyzed by using SPSS (Statistical Package of Social Sciences) version 20 and results were expressed using descriptive statistics. Major findings of the study were, majority of the participants (70.1%) had joint pain, 33.3 % had joint stiffness, 31.6% had muscle pain and 2.5% had joint deformity. Out of the participants, 53% had alopecia, 35% had urticaria, 31.6% had discoid rash, and 18.8 % had photosensitivity. Mild depression was present in 31.7% of the participants, moderate depression in 12.9% and 2.5% had severe depression. Out of the participants 18.8% had mild anxiety, 47% had moderate level of anxiety and 6% had severe anxiety. Mild stress was present in 18.8% of the participants, 24.8% had moderate stress and 7.7% had severe stress.

Key words: *Systemic Lupus Erythematosus, Physical problems, Psychological problems, Care guide.*

Introduction

Systemic Lupus Erythematosus (SLE) is a chronic autoimmune disease with acute periodic flare-ups of symptoms, impacting multiple organ systems in the body, resulting in potentially life threatening complications.[1] In most patients the disease runs a mild chronic course with exacerbations.[2]

It strikes women nine times more than men, and thirty times more often during child bearing years.[3] Chronic and unpredictable nature of Systemic Lupus Erythematosus (SLE) presents many challenges to the patient and family. From the researcher's clinical experience she could understand that, the patients and their care givers have very minimal knowledge regarding the disease condition, it's effect on the body, disease progression, complications and management. This result in therapeutic noncompliance, exacerbations, repeated hospital admissions, poor coping and increased morbidity and mortality. Better understanding of the disease will enable the patient and care giver to manage the condition more effectively and efficiently.

Various studies regarding clinical and immunological profile of SLE patients in Kerala has been reported from different regions of the state. Most of these studies come from northern or central part of Kerala and there are no nursing studies, specifically addressing the problems of patients with SLE. Hence, the researcher performed this study to identify the physical problems of patients with SLE and to prepare a care guide under expert guidance.

Objectives of the study

- **Primary Objective**

1. To identify the physical problems of patients with Systemic Lupus Erythematosus.

- **Secondary objectives**

1. To identify the psychological problems of patients with Systemic Lupus Erythematosus.
2. To prepare a care guide with expert guidance for the patients with Systemic Lupus Erythematosus.

Materials and methods

The research design adopted for this study was descriptive research design. Semi structured interview schedule was used to collect socio-demographic and clinical data. An assessment proforma was used to assess physical problems of patients with Systemic Lupus Erythematosus. Psychological problems were assessed using Depression Anxiety Stress Scale (DASS).Scientific and Ethical committee clearance was obtained. Informed consent was obtained from all the participants. The duration of the study was 6 weeks. Participants were selected using consecutive sampling method. The data were analyzed using descriptive statistics.

Results

Out of 117 participants 11.1 % were in the age group ≤ 20 years; 37.6% were in the age group 21-30 years; 44.4% belonged to 31-40 years and 5.1% were in the age group 41-50 years. Majority (93.2%) of the participants were female.

Joint pain was the commonest reported physical problem (70.1%). Other problems related to musculoskeletal system were joint stiffness (33.3%), muscle pain (31.6%) and joint deformity (2.5%). Major problem related to integumentary system was alopecia (53%). Other problems reported were urticaria (35%), discoid rash (31.6%), photosensitivity (18.8 %), oral ulcers(12.8%) scalp ulcers (2.5%) and nasal ulcers (0.9%). Out of the participants 29.9% of the participants had proteinuria, 22.2% had edema and 19.7% had facial puffiness. Flank pain was present in 7.7% of the participants. Other significant problems reported were recurrent episodes of fever (54.7%), severe fatigue (61.5%) and weight loss (24.8%).

Out of the participants 31.7% had mild depression, 12.9% had moderate depression and 2.5% had severe depression. Mild anxiety was present in 18.8%, moderate anxiety in 47% and 6% had severe anxiety. Out of the participants 18.8% of the participants had mild stress, 24.8% had moderate level of stress and 7.7% had severe stress.

Discussion

In the present study, 11.1 % of the participants belonged to the age group ≤20 years; 37.6% belonged to 21-30 years; 44.4% belonged to 31-40 years and 5.1 % belonged to 41-50 years. Only1.8% belonged to age group of 51-60 years. This result is supported by a hospital based cross sectional study conducted in Maharashtra, on clinical and immunological profile of patients with SLE. In this study 21.8% belonged to age group d" 20 years, 62.1% belonged to 21-40 years and 16.1% belonged to >40 years. In both studies most of the participants were in their second or third decade of life.[4]

In the present study, 93.2% of the participants were females. A hospital based prospective study to assess lipid profile in patients with SLE admitted to a tertiary care teaching hospital in Eastern India showed that 96.04% of the participants were females.[5]

In the present study, majority of the participants had joint pain (70.1%). A cross sectional hospital based study of clinical and immunological profile of SLE patients from Maharashtra showed that a significant proportion (52.9%) of participants had joint pain. This result is in concensus with the present study finding. [4]

Table 1

Distribution of participants based on problems related to musculoskeletal system

n=117

Problems related to musculoskeletal system	*Frequency (f)*	*Percentage (%)*
Joint pain	82	70.1
Joint deformity	3	2.5
Joint stiffness	39	33.3
Muscle pain	37	31.6

In a study conducted in a tertiary care centre in Kerala, 40% of the participants had generalized muscle pain (31.6%), which is similar to the present study findings. [45] In the present study 53% of the participants had alopecia and this finding is supported by a study conducted at a tertiary care centre in Western India, which revealed that 65% had alopecia. [6]

The present study showed that 31.6% had discoid rash. A cross sectional study conducted in Maharashtra, India showed that 32.2% had discoid rash which is in consensus with the present study findings.[4]

In the present study 15.4% had malar rash, 7.5% had photosensitivity and oral ulcers were present in 12.8%. A cross sectional study conducted in Mangalore, South India showed that 12.5% had malar rash, 18.8 % had photosensitivity and 15% had oral ulcers. The results are similar to findings of the present study.[7] Another cross sectional study conducted in a tertiary care centre in Western India showed that majority of the participants had photosensitivity (75%).[5]

Table 2

Distribution of participants based on problems related to integumentary system

n=117

Problems related to integumentary system	*Frequency (f)*	*Percentage (%)*
Photosensitivity	22	18.8
Malar rash	18	15.4
Discoid rash	37	31.6
Alopecia	62	53
Urticaria	41	35.0
Oral ulcers	15	12.8
Nasal ulcers	1	0.9
Scalp ulcers	3	2.5

In the present study, 61.5% had severe fatigue. This finding is supported by a study on prevalence and association of fatigue in SLE, which showed that fatigue, was present in 81% of the patients. [8]

In the present study, 31.7% of the participants had mild depression, 12.9% had moderate level of depression and 2.5% had severe depression. 18.8% of the participants had mild anxiety, 47% had moderate level of anxiety and 6% had severe anxiety. A cross sectional study was conducted to determine the prevalence of depression and anxiety among Iranian patients with SLE. Depression and anxiety were assessed using Beck Depression Inventory and Beck Anxiety Inventory respectively. It revealed that 30.6% had borderline clinical depression, 18.1% had moderate depressive mood, and 20.6% had severe depression. 29.4% had mild anxiety, 33.8% had moderate level of anxiety and 18.1% had severe anxiety.[9]

Conclusion

Based on the findings of the study following conclusions were made:

Patients with Systemic Lupus Erythematosus (SLE) experienced a wide range of physical and psychological problems. The commonest problems were arthralgia, severe fatigue, depression and anxiety.

Referece

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Effectiveness of Therapeutic Play on Comfort and Physiological Parameters of Toddlers During Nebulization – A Quasi Experimental Study

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Abstract

Therapeutic play is a technique that reveals the problems of children on a fantasy level through use of toys, dolls, clay, art and other creative objects. Play help to act out feeling like anger, sadness, hostility and fear.[1]

Objectives : Assess the effectiveness of therapeutic play on comfort of toddlers during nebulization as measured by FLACC scale. Find out the effectiveness of therapeutic play on physiological parameters of toddlers receiving nebulization as measured by Clinical assessment proforma.

Materials and method: Research design was quasi experimental, Population included were toddlers admitted in medical wards of Sree Avittom Thirunal Hospital, Thiruvananthapuram. Samples who met the inclusion criteria were selected consecutively and the sample size was 60 (30 experimental and 30 control).

Results : The analysis revealed that there was marked difference in the mean FLACC score (6.0 to 2.1) between control and experimental group. In the physiological parameters, the mean heart rate of the children in the control and experimental group during the procedure was 135.6 and 132.4 respectively, whereas after procedure the mean value was 133.4 in the control, and 133.7 in experimental group. The mean respiratory rate of the children in the control group during the procedure was 41.2 and was 40.9 in experimental group, whereas after the procedure it was same(38.5) in both the control and in the experimental group. The mean oxygen saturation of the children in the control group during the procedure was 95.1 and 96.9 in experimental group, whereas in the control group after the procedure it was 97.4, and 99 in the experimental group.

Conclusion : The study findings showed enhanced comfort of the children in the experimental group compared to control group with therapeutic play intervention. Significant improvement in the oxygen saturation of experimental group was also noted with intervention but there was no significant variation in heart rate and respiratory rate with the intervention.

Key words: *therapeutic play, physiological parameters, nebulization.*

INTRODUCTION

Therapeutic play is non-directed and focuses on helping the child cope with feeling and fears. The goal is to maintain normal living pattern, minimizing psychological trauma and promoting optimal development of the child.[1]

The primary purpose of therapeutic play is to create a home like atmosphere which is familiar to the child and to give them an opportunity to express their feelings when they are in the hospital.[2]

Therapeutic play is a means of diversion, relaxation and makes the child feel more secure in strange environment. It also reduces separation anxiety and helps in expressing stress and anxiety.[3]

Administration of medications to children can be very difficult, especially in very young and handicapped. This is even more demanding in case of chronic or recurrent illness which require daily prophylactic measures and strict compliance for optimum effectiveness. The treatment of asthma in young children is also a problem of similar nature.[4]

Nebulization is a common treatment of children with respiratory tract infections. The main purpose is to wet the respiratory tract, dilution of the mucous and thus makes smooth discharge of sputum.[5]

OBJECTIVES

- Assess the effectiveness of therapeutic play on comfort of toddlers during nebulization as measured by FLACC scale.
- Find out the effectiveness of therapeutic play on physiological parameters of toddlers receiving nebulization as measured by clinical assessment proforma.

HYPOTHESES

H1: There will be difference in the mean scores of comfort of toddlers between the experimental group and control group.

H2:There will be difference in the mean heart rate of toddlers in experimental and control group during and after the intervention.

H3: There will be difference in the mean respiratory rate of toddlers in experimental and control group during and after the intervention.

H4: There will be difference in the mean oxygen saturation of toddlers in experimental and control group during and after the intervention.

METHODOLOGY

Research design: Quasi- experimental research design

Setting: Pediatric Medical wards of Sree Avittom Thirunal Hospital, Thiruvananthapuram, Kerala.

Population: All children in the age group o f
1-3 years receiving nebulization.

Sample: Children in the age group of 1-3 years admitted in Pediatric Medical wards of Sree Avittom Thirunal Hospital, Thiruvananthapuram, receiving nebulization as treatment. *(*and their caregivers)

Sample size: 60 (30 control and 30 experimental group)

Sampling technique: Samples who met the inclusion criteria were selected consecutively

Tools and techniques: The tools used in the study include, structured interview schedule to assess socio-demographic data of caregivers, FLACC scale[6] for assessment of comfort of toddlers and clinical assessment proforma for assessing physiological parameters of toddlers.

Tool 1 : Structured interview schedule

Part A : Socio demographic data of the caregiver

Part B : Clinical data of the toddler.

The socio demographic data of the caregivers includes 8 questions and the clinical data of the child includes 15 questions. *(interview & case record review respectively)*

Tool 2 : The FLACC scale to assess the comfort of the child

The comfort is quantitatively scored from 0 to 10 using observation technique. The scorings was based on the child's response during nebulization and the scorings was as follows

0 – comfortable

1-3- mild discomfort

4-6- moderate discomfort

7-10-severe discomfort

Tool 3 : Clinical assessment proforma to assess the physiological parameters of the toddlers.

The physiological parameters assessed were oxygen saturation, heart rate and respiratory rate.

Present study used Interview,Clinical assessment and case record review.

Data collection process

The data collection period was 6 weeks. Permissions *was* obtained from the Research Committee, Institutional Ethics Committee of Government College of Nursing, Thiruvananthapuram and authorities of Sree Avittom Thirunal Hospital, Thiruvananthapuram. The study group consisted of 60 children of which 30 were in the experimental and 30 in the control group.

Consent was obtained from the caregivers of children selected for the study.

During the data collection process, an initial baseline assessment of the respiratory status of the toddler was done using the Pediatric Respiratory Severity Score (PRESS)[7] from which the children with severe respiratory distress were excluded.

The data collection of the control group was done at first, where the physiological parameters of toddlers were assessed with clinical assessment proforma just before starting nebulization, during and immediately after completion of nebulization. During nebulization procedure, the comfort of child was assessed with FLACC Scale. In the experimental group, therapeutic play was provided 5 minutes before starting nebulization, during nebulization, till 5 minutes after completion of procedure with a toy, along which the comfort and physiological parameters were assessed similar to control group with FLACC Scale and clinical assessment proforma. Nebulisation was given by staff nurse and intervention by the investigator.

RESULTS

Clinical data of the child

- In the control group, 53.3% of the children were in the age group of 1-2 years and 46.7% belonged to 2-3 years, similarly in the experimental group 53.3% of the children were in the age of 1-2 years and 46.7% belonged to 2-3 years.
- In the control group, 46.7% of children were males and remaining 53.3% were females and in the experimental group, 43.3% of children were males and remaining 56.7% were females.

The gender of the children in both groups were comparable since the p value is 0.795.

- In the control group, 43.3% of children had no siblings, 36.7% had one sibling, 13.3% of children had 2 siblings and 6.7% had 3 siblings where as in the experimental group, 33.3% of children had no sibling, 60% had one sibling, 6.7% of children had 2 siblings

and none of the children in experimental group had 3 siblings. The number of siblings in both groups were comparable since the p value is 0.130.

- In the control group, 60% of children had pneumonia, 33.3% of children had Reactive Airway Disease (RAD) and 6.7% of children had other diseases while in experimental group, 40% of children had pneumonia, 53.3% of children had RAD and 6.7% of children had other diseases.

The diagnosis of children in experimental and control group were comparable since the p value is 0.275

- Results showed that 13.3% of children in control group had co morbid disease, 86.7% of children had no co morbid disease whereas in the experimental group 90% of the children had no co morbid disease and 10% of the children had co morbid disease.

The comorbid disease in both groups were comparable since the p value is 0.688

- In the control group, 86.7% of children had previous history of nebulization, similarly in the experimental group, 86.7% children had with previous history of nebulization.
- In the control group, 53.8% of children sometimes cooperated for past nebulization, while 46.2% of children never cooperated for nebulization in past episodes. Similarly, in experimental group, 38.5% of children sometimes cooperated and 61.5% of children never cooperates for nebulization. In both groups, none of the children always cooperated for nebulization.

The child's cooperation for completion of past nebulization comparable in both groups since the p value is 0.266.

- In the control group, only 23.3% of children completed nebulization, while in the experimental group, 86.7% completed nebulization.

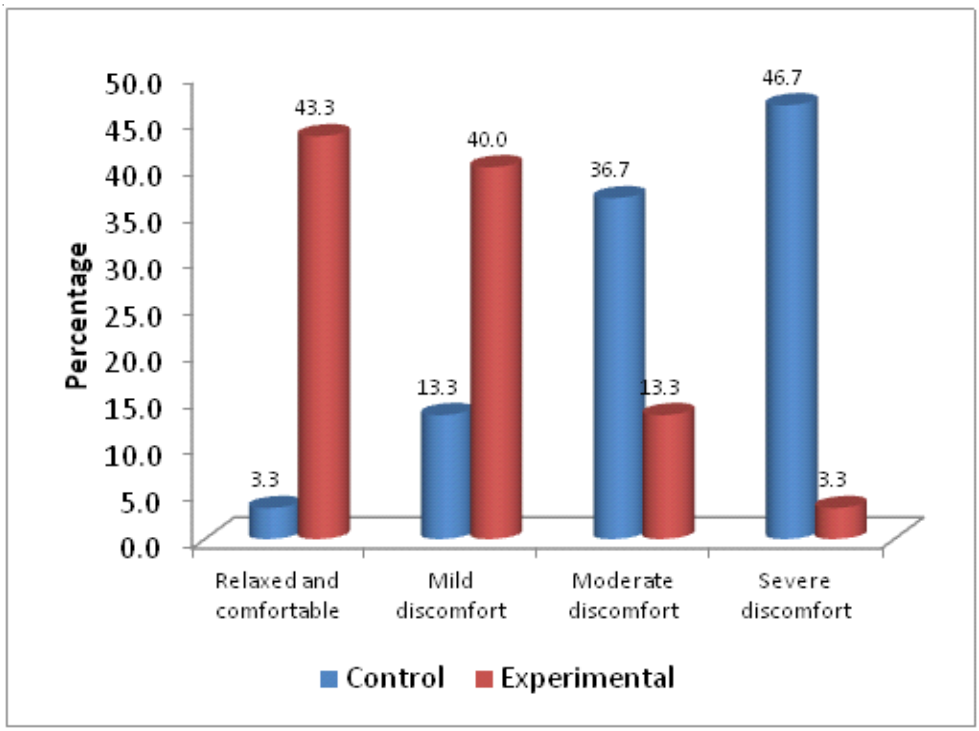

Figure1: Distribution of children based on their FLACC score

Figure 1 shows that in the control group 3.3% of children were relaxed and comfortable while in the experimental group 43.3% of children were relaxed and comfortable. At the same time 13.3% of children in the control group had mild discomfort while 40% of the children in experimental group had mild discomfort. 36.7% of the children in the control group had moderate discomfort and 46.7% had severe discomfort, while 13.3% of children in the experimental group had moderate and only 3.3% of children with severe discomfort. Hence it can be concluded that the children in the experimental group showed an enhanced comfort when compared to control group.

Table 1: Comparison of heart rate of children

n=60

Heart rate	*Control*			*Experimental*			*T*	*p*
Mean	*SD*	*N*	*Mean*	*SD*	*N*			
Before	129.8	6.3	30	127.6	7.5	30	1.21	0.232
During	135.6	7.0	30	132.4	6.6	30	1.85	0.069
After	133.4	7.7	30	133.7	7.1	30	0.17	0.863

Table 1 interprets that the mean heart rate of children in the control group during the procedure was 135.6 and after the procedure was 133.4 whereas in the experimental group the heart rate during the procedure was 132.4 and after the procedure was 133.7. Hence heart rate shows no significant variation during and after nebulization between the experimental and control groups hence the hypothesis (H2) is rejected.

Table 2: Comparison of respiratory rate of children

n=60

Respiratory	*Control*			*Experimental*			*T*	*p*
Rate	*Mean*	*SD*	*N*	*Mean*	*SD*	*N*		
Before	38.6	3.9	30	39.1	2.9	30	0.56	0.576
During	41.2	3.7	30	40.9	2.8	30	0.43	0.666
After	38.5	3.6	30	38.5	2.7	30	0.04	0.968

Table 2 informs that mean respiratory rate of the children in the control group during the procedure was 41.2 and after the procedure was 38.5 whereas in the experimental group the respiratory rate during the procedure was 40.9 and after the procedure was 38.5. Hence there is no significant variation in respiratory rate during and after nebulization when comparing with the control and experimental group hence the hypothesis (H3) is rejected.

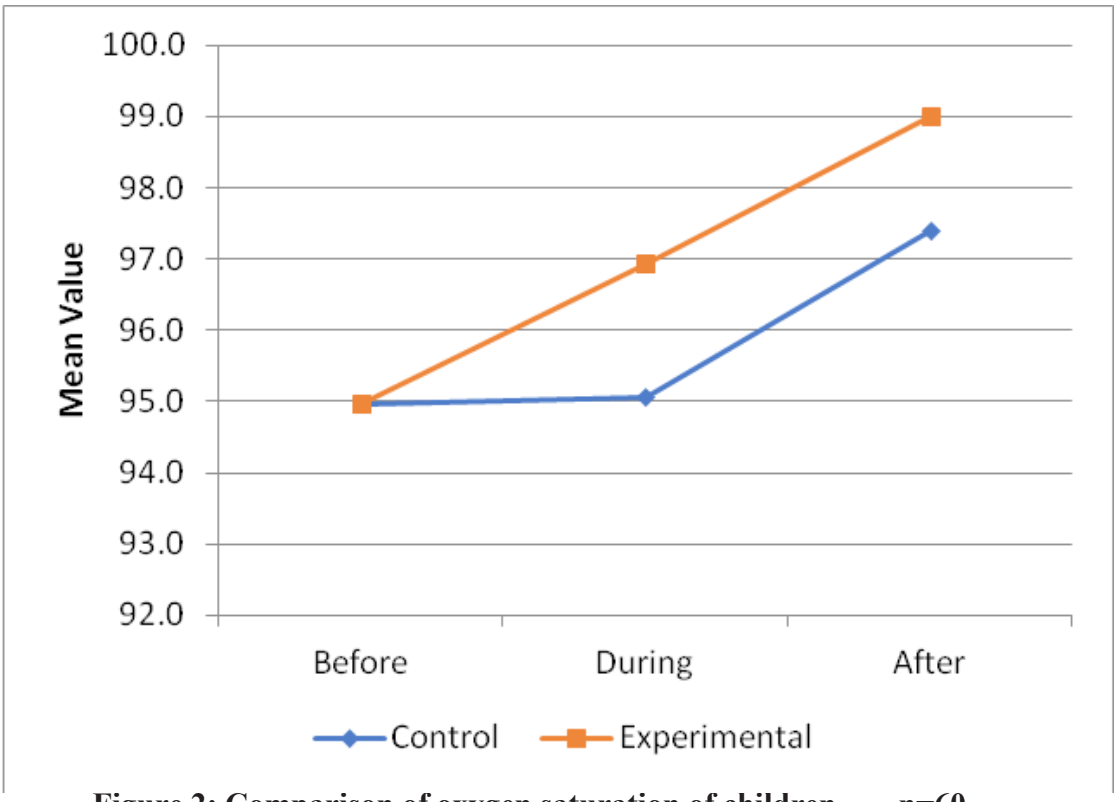

Figure 2: Comparison of oxygen saturation of children n=60

Figure 2 interprets that, the mean oxygen saturation of the children in the control group during procedure was 95.1 and on completion was 97.4. In the experimental group the mean oxygen saturation of the children during procedure was 96.9 and on completion was 99. Thus, there is significant variation in oxygen saturation of children during and after nebulization in comparison of experimental and control group hence the hypothesis (H4) is accepted.

LIMITATIONS OF THE STUDY

- The participants were consecutively selected on their first nebulization after admission in the ward, but the child may have received a previous nebulization during their causality observation hours. So, the previous exposure may affect the response of the child during researcher's data collection.
- The study is limited only to the toddlers admitted in Medical wards of Sree Avittom Thirunal Hospital, Thiruvananthapuram.
- Sample size is limited to 60. (30 participants in both experimental and control group)

CONCLUSION

This study intended to assess the effectiveness of therapeutic play on comfort physiological parameters of toddlers during nebulization. The results showed that the comfort of the children enhanced by the intervention $p < 0.01$. In case of the physiological parameters the heart rate and respiratory rate showed no statistically significant variation between the two groups during and after procedure but oxygen saturation showed variation among the two groups during ($p<0.004$) and after procedure ($p<0.01$).

RECOMMENDATIONS

In the light of the research findings the following recommendations are put forward,

- Similar study can be conducted in a larger sample size.

- Procedural pain is an important aspect of Paediatric Nursing practice. More and more assessment methods can be used to evaluate pain and discomfort in children
- All nurses working in Paediatric setting should be exposed to various comfort assessment tools and different measures of distraction and play interventions for children.
- The staff working in paediatric setting should be encouraged to use different non pharmacological measures of pain relief for children.
- The nurse administrators and hospital authority should take initiative to make paediatric care settings more child friendly, atraumatic and playful.
- Facilities for recreation and play rooms can be implemented in the hospitals with provision of trained staff to make children more adjusting and playful in hospital environment.

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Conflict of interest

There was no such issues

Funding

It was self -financed

Ethical considerations

Permissions obtained from the Research committee, Institutional ethics committee of Government college of Nursing, Thiruvananthapuram and authorities of Sree Avittom Thirunal Hospital, Thiruvananthapuram. Consent was obtained from the caregivers of children selected for the study.

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Awareness and Utilization of 'Non Communicable Disease Clinic' (NCD Clinic) Services at Primary Health Centres Among Residents of Thiruvananthapuram Corporation

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Abstract

The present study was undertaken to assess the awareness and utilization of NCD clinic services. The study was conducted among 200 participants residing under primary health centers of Thiruvananthapuram Corporation. Cross sectional research design was used for the study and the sample were selected using multistage cluster sampling technique. The tool used for the study was structured interview schedule to assess socio demographic data, awareness and utilization of the participants regarding NCD clinic services. The data were collected over a period of 6 weeks and were tabulated and analyzed by descriptive and inferential statistics. Regarding the awareness, 57% have average awareness regarding NCD clinic services, 25.5% have poor awareness and 17.5% have good awareness regarding NCD clinic services. Regarding the utilization, majority of (70%) participants were utilizing the service of NCD clinic services from primary health centres and only 30% did not utilize. Among the non utilizers of NCD clinic services, 56.6 % were not availing the services because of the use of private hospitals, 18.3% had no awareness about NCD clinic.

Key words : Awareness; Utilization;NCD Clinic;PHC

Introduction

Non communicable diseases are defined as "diseases persistent for a lengthy duration with generally slow progression." NCDs are the major cause of adult mortality worldwide,[1] and the number of deaths occur in low and middle income countries.[1] Cardio vascular diseases account for most NCD deaths,(17.7 million people annually), followed by cancers (8.8 million), respiratory diseases (3.9 million), and diabetes (1.6 million).[2]

NCDs are responsible for the total 82% of the entire disease burden of the world.38 million people die from the NCDs each year out of which 28 million death occurs in low and middle income countries. The mortality due to NCDs are increased significantly from 8.6million to 10.9 million in south east Asia region.[3]

In order to prevent and control the non communicable diseases, the Govt. introduced NPCDCS programme and introduced NCD clinics in the country. Health promotional activities through adoption of healthy life styles and the participation of people in the maintenance of their own health should be encouraged through these type of health centres and clinics. This must also help the people to adjust effectively with the rapidly changing health situations[4]

NCD Clinic' is a clinic to treat 'Non Communicable Diseases' likes Cancer, Diabetes, Hypertension, Stroke and Cardiovascular Diseases, under the NPCDCS & NPHCE Programmes run by Govt. of India.[4]

Objectives of the study

1. To assess the awareness of Non Communicable Disease clinic services provided by Primary Health Centres among residents of Thiruvananthapuram Corporation.
2. To assess the utilization of Non Communicable Disease clinic among residents of Thiruvananthapuram Corporation.
3. To find out various factors associated with non-utilization of Non Communicable Disease clinic services.

Materials and methods

The research design adopted for the present study was cross- sectional design. Structured interview schedule was used to assess the socio demographic variables, clinical data, general health information of participants and awareness, utilization and factors associated with non – utilization of NCD clinic services, scientific and ethical clearance obtained, informed consent was obtained from all the participants.Data collection period was from 7/1/2019 to 15/2/2019. The investigator selected participants from the ward of selected Primary Health Centre, by following exclusion criteria using multistage cluster sampling technique. From the total Primary Health Centres (21 primary health centres) under Thiruvananthapuram Corporation two Primary Health Centres were selected by randomly in the first stage, from these Primary Health Centres four wards under the field area of Thiruvananthapuram Corporation were selected randomly in the second stage. Then from each of these wards,25 samples were selected by cluster sampling.Data analysis done according to the objectives of the study using descriptive and inferential statistics.

Results.

- Most of the participants (57%) have average awareness regarding NCD clinic services, 25.5% participants have poor awareness and only 17.5% participants have good awareness regarding NCD clinic services.
- Figure 1 shows that majority (70%) of the participants were utilizing the services of NCD clinic from primary health centre and only 30% were not utilized.
- Table 12, shows that out of 30% of non utilizers, 56.6 % of participants were not availing the NCD clinic because of the use of private hospitals, 18.3% were not utilizing because of Unawareness about NCD clinic. 4% were not utilizing because of prolonged waiting time and 3.3% were because of the need of assistance and on ayurvedic treatment. 1.6% of participants were not utilizing NCD clinic services because of both use of private hospitals and lack of transportation.

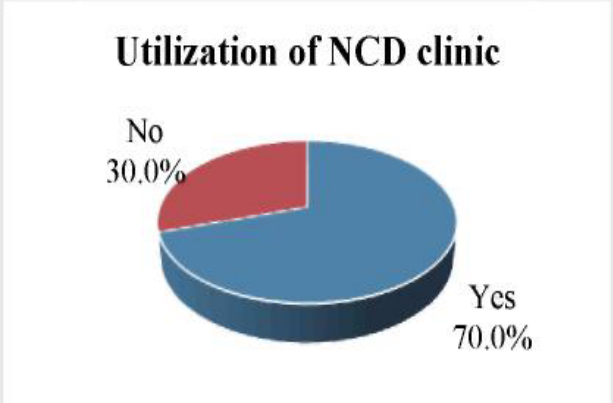

Figure 1. Distribution of participants according to the utilization of NCD clinic Services

Table 1. Distribution of participants according to the reason for non utlization of NCD clinic services

Reason for not availing NCD clinic	*Frequency*	*Percent*
Use of Private hospital	34	56.6
Unawareness about NCD clinic	11	18.3
Prolonged waiting time	4	6.6
Need assistance to utilize the NCD clinic services	2	3.3
On ayurvedic treatment	2	3.3
Too long distance	1	1.6
Transportation problem	1	1.6
Lack of transportation, prolonged waiting time and use of Private hospital	1	1.6
Lack of transportation and use of private hospital	1	1.6
Prolonged waiting time and use of private hospital	1	1.6
Too long distance and lack of transportation	1	1.6
Too long distance and use of private hospital	1	1.6

Discussion

Findings from the present study revealed that 57% of participants have average awareness regarding NCD clinic services,25.5% participants have poor awareness and only 17.5% participants have good awareness regarding NCD clinic services.70% participants were utilizing the services of NCD clinic from primary health centres and only 30% were not utilized. Out of 30% of non utilizers most of the them (56.6 %) were not availing the NCD clinic services because of the use of private hospitals,18.3% because of unaware about NCD clinic.6.6% of participants not using NCD clinic services because of prolonged waiting time and 3.3% were because of the need of assistance and on ayurvedic treatment.

It is consistent with another study conducted in a tribal setting Gujarat,India[5] which revealed that 82% were aware about the services and only 54.9% were utilizing primary health care services.The major reason for non- utilizing the services were more faith in private sectors,inconvenient timing of the primary health centre,long queues,non availability of drugs and investigations.

It is also consistent with another study conducted in Dimbulagala ,Sri Lanka[6] revealed that majority (62.2%) of the participants have scored more than the middle value of knowledge score and only 37.8% individuals have only attended NCD screening clinic. The study shows there is a gap between the respondent's NCD screening knowledge and attendance to NCD screening services.

Conclusion

Based on the findings of the study ,the following conclusions were made, more than half of the participants had average awareness regarding NCD clinic services and majority of the participants were utilizing the services of NCD clinic services from primary health centres and only few were not utilizing. Use of private hospitals is the most common factors assiciated with non –utilization of NCD clinic services.

The study findings show light to the need for more awareness programme regarding NCD clinic services for its better utilization. The enhanced awareness there by utilization of NCD clinic services would obviously decreases the raising burden of NCDs and improve the health and quality of life of people. More intensive actions are taken to improve the awareness there by utilization of the NCD clinic services by the community.

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Lived Experience of Patients on Mechanical Ventilation

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Abstract

Mechanical ventilation is a life supporting modality often employed in the care of severely ill patients. The increasing use of mechanical ventilation parallels greater hospitalization in intensive care units. Recent epidemiological research in the US revealed that about 310 persons per 100,000 adult population undergo invasive ventilation for nonsurgical indications. More than 90% of patients in intensive care unit worldwide are mechanically ventilated. The present study was a qualitative phenomenological study entitled "Lived experience of patients on mechanical ventilation." The objective of the study was to explore the lived experience of patients on mechanical ventilation. The study was conducted among 14 participants undergone cardiothoracic surgery, in Cardio Thoracic ICU, Medical College Hospital Thiruvananthapuram. The researcher collected data from participants using in depth interview technique. The collected data were analyzed using Colaizzi's qualitative data analysis method. Three major themes with 9 sub themes at level two and 20 sub themes at level one were emerged from the study. Physical experience, communication impairment and psychological and spiritual experiences were the major themes. Physical experiences included thirst, dryness of mouth, pain and problem with positioning, problem with endotracheal tube and sleep disturbances. Communication impairment included inability to talk, inability to communicate actual need and inability to communicate with others. Psychological and spiritual experiences included anxiety and experience of spirituality. Thirst was the major problem experienced by all the participants. The participants described the experience of the ventilator as unpleasant and painful.

Key words: *Mechanical ventilation, lived experience, physical experience, communication impairment and psychological and spiritual experience.*

Introduction

Mechanical ventilation refers to the use of an artificial device to assist a patient to breathe. A mechanical ventilator is a device or machine specifically designed to provide ventilation assistance to the patient.

Mechanical ventilation is a commonly used mode of respiratory support in the intensive care unit. More than 90% of patients in intensive care unit worldwide are mechanically ventilated. The number of patients requiring long-term ventilation is likely to increase, particularly among those who are elderly or with chronic conditions. Therefore, intensive care delivery is complex and likely to be more complicated.

A retrospective cohort study on "the epidemiology of mechanical ventilation use in the United States" New York revealed that, among 6,469,647 hospitalizations, 180,326 (28%) received invasive mechanical ventilation. Inpatient mortality was 34.5%, and only 30.8% of patients were discharged from the hospital. Mechanical ventilation use is common and accounts for a disproportionate amount of resource use, particularly in urban hospitals and in elderly patients.

A qualitative study on "an exploration of patients` experiences of mechanical ventilation" was conducted in Sri Lanka; revealed that, a total of 11 sub themes and three main themes were identified. All these themes were reflections of intrapersonal, extra personal and interpersonal experiences of the patients. The feeling of inner suffering such as pain, dependency, fear and anxiety, thirst, noise level, cold environment and nightmares were identified while on mechanical ventilation. Further the body intolerances such as feelings of congested secretions, experiences of suctioning, inspiration by ambu bag and chest physiotherapy were reported. Patients further noted that an inability to speak, diverse communication and inability to express feelings as being more stressful and frustrating.[2]

Statement of the problem

A study to explore the lived experience of patients on mechanical ventilation.

Objective of the study

Explore the lived experience of patients on mechanical ventilation.

Materials and Methods

Qualitative phenomenological approach, was used to explore the patient's experiences on mechanical ventilation. Sample for the present study consists of patients on mechanical ventilation after cardiothoracic surgery in Cardio Thoracic intensive care unit. Sample size was determined based on the redundancy of data. The sample taken for this study was 14 patients who were on mechanical ventilation after cardio thoracic surgery. A non-probability purposive sampling technique was used to obtain in-depth information and understanding of the patients' experience. Investigator used structured interview schedule to assess the sociopersonal data and clinical data, and semi structured interview guide was used to explore the experience of patients on mechanical ventilation.

The researcher obtained prior permission from Professor and Head, Department of Cardio Thoracic Surgery, Medical College Hospital Thiruvananthapuram for conducting the study. Clearance was obtained from Research Committee and Institutional Human Ethics Committee of Govt. College of Nursing Thiruvananthapuram.

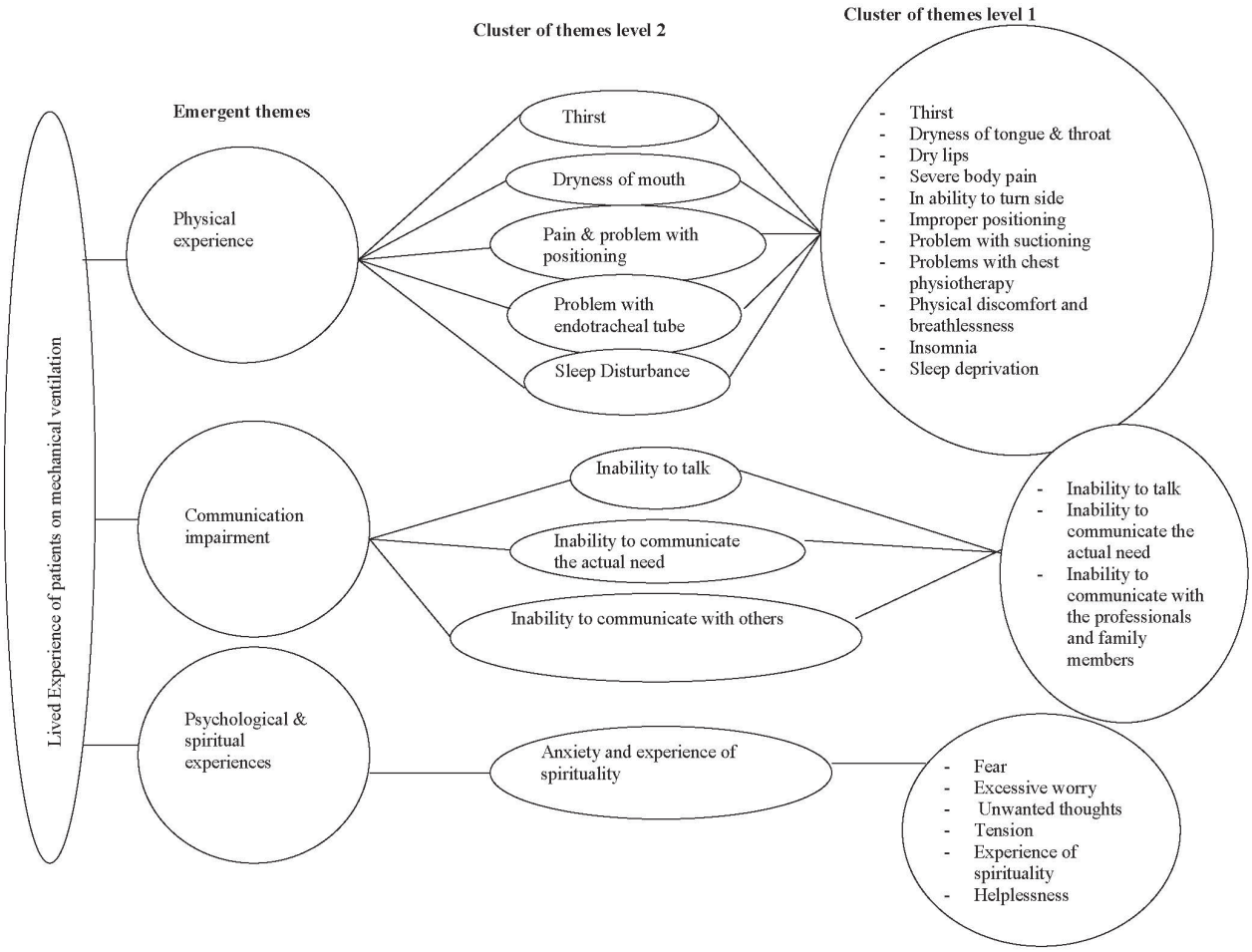
The duration of data collection was from 07.01.2019 to 16.02.2019. The participants were given an information sheet, which contained all the necessary information. Investigator approached the participants, explained the nature of the study, purpose, established rapport and obtained informed consent from the participants. Researcher collected the sociopersonal and clinical data regarding the participants from the medical care sheet.

At the beginning of the interview, the participants were asked to relax, and interview was conducted with the help of an interview guide. Probes were given in between to explore more information from the participants. Audio taping and field notes were taken during the interviews. Data analysis was initiated after

the participants had been interviewed. The interviews were transcribed verbatim and were analyzed using Colaizzi's qualitative research analysis method.

Results

In this study three major themes such as physical experience, communication impairment and psychological and spiritual experiences were emerged. The emergent themes derived from 20 sub themes at level 1 and 9 sub themes at level 2. This study revealed that patients on mechanical ventilation had physical experiences such as thirst, dryness of mouth, pain and problem with positioning, problem with endotracheal tube and sleep disturbances. Communication impairment included inability to talk, inability to communicate correct need and inability to communicate with others. Psychological and spiritual experiences included anxiety and experience of spirituality. Thirst was the major discomfort experienced by the majority of the participants. Pain and communication impairment were the second major discomfort.



Discussion

The participants in this study described the feeling of thirst as the major problem. A qualitative study conducted in Sri Lanka in 2015, supported this findings. In that study the participants expressed the feeling of thirst as a major problem. While on mechanical ventilator, it was difficult to take food and drink since the ET tube invaded the whole mouth cavity of the patient.[2]

In the present study the participants expressed communication impairment as inability to talk, inability to communicate actual need and inability to communicate with others. The findings of Guttormston *et al*. 2015 revealed that patients

treated with mechanical ventilation experienced a moderate to extreme level of psycho emotional distress because they could not speak and communicate their needs.[3]

In this study the participants experienced psychological experiences as anxiety which included fear, excessive worry, unwanted thoughts, tension and helplessness. The experience of fear was evident during mechanical ventilation among participants in the study by Forsberg 2008, where the inability to breathe led to a state of panic, which lasted for the period of their ICU admission.[4]

Conclusion

Mechanical ventilation can replace the normal mechanism of breathing either by providing intermittent or continuous flow of oxygen or air under pressure. Throughout the study researcher realized that patients on the mechanical ventilator suffered various physical, communication and psychological and spiritual experiences.

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Effect of Interventional Programme on Frequency of Pain, Stress and Quality of Life among Women with Migraine

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Abstract

Migraine is a primary headache disorder characterized by recurrent headaches that are moderate to severe. Migraine is a complex condition with a wide variety of symptoms. Migraine is one of the leading serious health problem affecting women. Migraine can have an enormous impact on work, family and social lives. Most people who have migraine may not be aware about the fact that their headache can be controlled with preventive medications and life style changes.

The present study was intended to assess the effect of interventional programme which include pranayama and mindfulness breathing on frequency of pain, stress and quality of life among women with migraine attending neurology outpatient department in a Tertiary care hospital, Thiruvananthapuram. The research design adopted was quasi experimental pretest posttest control group design. The data were collected from 130 women with migraine 65 each in experimental group and control group. Sampling technique was consecutive cases attending Neurology OPD. The data were collected using standardized tools to assess frequency of pain, stress and quality of life for a period of six weeks. The data were analyzed on the basis of objectives by both descriptive and inferential statistics and found that the interventional programme was effective in reducing frequency of pain ($p<0.001$), stress ($p<0.001$) and improving quality of life ($p<0.001$) in experimental group. Pranayama and mindfulness breathing showed significant clinical improvement in the experimental group. Thus pranayama and mindfulness breathing can be effectively incorporated as adjuvant therapy in migraine patients.

Key Words: *Migraine, frequency of pain, stress, quality of life, yoga, mindfulness breathing*

Introduction

Migraine and other headache disorders are among the most prevalent disorders worldwide, but recognition of their importance for public health has come only since 2000.[1] Migraine is one of the common primary headache disorders affecting 13% of the population worldwide.[2]The burden of migraine impacts affects individuals, their family and society.[3] It is also a risk factor for ischemic cerebral and ischemic cardiovascular diseases.[4] Episodic migraine may lead to chronic migraine, if it is not treated properly it may lead to medication overuse headache and increased risk of suicidal attempt.[5]

Migraine is a disabling, painful, primary headache disorder which involves a dysfunctional vascular system and is associated with stress. It has been mentioned that females have higher prevalence than males in adulthood but lower prevalence before puberty. Migraine is found very commonly between the ages of 25-55 years, the most worthwhile and significant period of life. It has been also reported that migraine causes huge monetary loss in a year due to loss of work hours and less productivity.[6]

Alternative medicine research is still very less, but may prove efficacy. Yoga already proved effective and popular as a therapeutic intervention in variety of disorders and stress management, but relatively fewer articles are available on yoga in treatment of migraine. Migraine management already has adopted by contemporary as well as various alternative therapies, but a better approach for effective interventions is still needed.[7]

Theoretical framework provides an important context for a scientific investigation. It defines research question and thereby serves as an overall map for the study. It also serve as a spring board for the generation of research hypothesis. The theoretical framework of this study is based on Betty Neuman's Health Care System Model (1982).

Objectives of the study

- Evaluate the effect of interventional programme on frequency of pain among women with migraine attending Neurology outpatient department in a Tertiary Care Hospital, Thiruvananthapuram.
- Assess the effect of interventional programme on level of stress among women with migraine attending Neurology outpatient department in a Tertiary Care Hospital, Thiruvananthapuram.
- Assess the effect of interventional programme on quality of life among women with migraine attending Neurology outpatient department in a Tertiary Care Hospital, Thiruvananthapuram.

Materials and methods

The research design adopted for the present study was quasi experimental-pretest posttest control group design. The outcome variables were frequency of pain, stress and quality of life. These were measured by Pain frequency, intensity Burden scale (P-FIBS), Sheldon Cohen Perceived stress scale and Migraine- specific Quality of Life questionnaire version 2.1 (MSYK v2.1). Structured questionnaire was used to assess baseline socio-demographic and clinical data.

Formal permission from institutional research committee, ethics committee, Medical College Hospital, Thiruvananthapuram and from the Head of the Department of Neurology was obtained. The investigator completed a course of pranayama and mindfulness breathing for two weeks from Arogya School of yoga, Pravachambalam, Thiruvanantha-puram. The participants who meet the inclusion criteria were selected. The objectives of the study was explained and consent was taken from the participants. Pretest was done by assessing frequency of pain, level of stress and quality of life using standardized tools. Interventional

programme was implemented to each 6-8 participants per day in the experimental group at Neurology OPD cabin. First a session of teaching was conducted regarding Migraine: Its treatment and preventive measures for one hour using an instructional module and power point. Then pranayama was demonstrated to these participants and return demonstration was done and it took 30 min followed by demonstration of mindfulness breathing and return demonstration for 30 min. Each participants was provided with an instructional module and advised to practice pranayama and mindfulness breathing in home daily each in morning and evening. This was ensured by telephonic calls and provided them with a diary. Follow up was done after three weeks at Neurology OPD during their follow up visit. Post test was done by assessing frequency of pain, level of stress and quality of life after six week. After post test the interventional programme was given to control group. Duration of the study was from 7th January 2019 to 15th February 2019. The data collected was analyzed using both descriptive and inferential statistics.

Results

On statistical analysis it was understood that both groups are comparable on the basis of baseline socio-demographic and clinical data.

The findings of the study showed that there was a significant difference in pain level between the experimental and control group. Thus it was inferred that interventional programme was effective in reducing the pain level of women with migraine ($p<0.001$).

The findings showed that there was a significant difference in level of stress between the experimental and control group. Thus it was inferred that interventional programme was effective in reducing the stress level of women with migraine ($p<0.001$).

The results found that the obtained t value was significant at 0.001 levels. Thus it was inferred that interventional programme was effective in improving the QOL of women with migraine.

Table 1 : Mean, standard deviation and t value showing effect of interventional programme on frequency of pain of women with migraine n=130

Pain score	*Experimental group*		*Control group*		*t test*	
	Mean	*SD*	*Mean*	*SD*	*t*	*p*
Pre test	5.4	1.2	5.3	1.3	0.642	0.522
Post test	3.4	0.9	4.7	1.4	6.334	<0.001

Table 2 : Mean, standard deviation and t value showing effect of interventional programme on level of stress of women with migraine n=130

Perceived stress score	*Experimental group*		*Control group*		*t test*	
	Mean	*SD*	*Mean*	*SD*	*t*	*p*
Pre test	23.8	2.3	23.9	2.8	0.069	0.945
Post test	13.7	2.6	21.6	5.0	11.323	<0.001

Table 3 : Mean, standard deviation and t value showing effect of interventional programme on quality of life of women with migraine **n=130**

Quality of life	*Experimental group*		*Control group*		*t test*	
	Mean	*SD*	*Mean*	*SD*	*t*	*p*
Pre test	51.4	5.5	50.3	5.5	1.138	0.257
Post test	78.1	5.5	57.3	13.2	11.767	<0.001

Discussion

Study findings shows that there was a significant difference in frequency of pain, level of stress and quality of life between the experimental and control group. From the statistical analysis it was inferred that interventional programme was effective in reducing the pain level and stress level as well as improving the QOL of women with migraine ($p<0.001$).

Current study also revealed that the interventional programme had effect on reducing the frequency of pain ($p<0.001$) and stress ($p<0.001$) and improving the quality of life ($p<0.001$). This finding is very similar to the findings of a study conducted to determine effectiveness of multidisciplinary intervention in the treatment of migraine revealed that the intervention group experienced statistically significant changes in self-perceived pain frequency ($p=0.000$), pain duration ($p=.001$), functional status ($p=.000$), quality of life ($p=.000$), health status ($p=.000$), pain related disability ($p=.000$) and depression ($p=.000$).[7]

The present study findings also similar to findings of another study done to compare yoga as a treatment modality with conventional medical therapy to improve migraine and stress related disorders in Meerut. Yoga was found to be effective on improvement in migraine status ($p<0.001$), sleep ($p<0.001$), depression and anxiety ($p<0.001$) than patients with conventional medical therapy alone.[8]

Conclusion

After implementation of interventional programme including pranayama and mindfulness breathing, frequency of pain and stress were reduced and quality of life improved significantly among women with migraine. These findings focus on the fact that is important to strengthen life style modifications, yoga and meditation along with regular treatment of women suffering from migraine which will help to reduce frequency of pain and stress and to improve quality of life.

Public health interventions need to focus on practice of pranayama and mindfulness breathing to maintain healthy throughout the life. This finding has potential therapeutic applications in day-to-day as well as clinical situations where migraine attacks needs to be brought down effectively. It is a simple and cost-effective technique that may be added to the management protocol for migraine patients. The observed data about migraine in this study and other studies suggest the need for a comprehensive policy to control migraine in Kerala.

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COVID-19 VACCINES

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Abstract

The COVID-19 infection is continuing to be the global menace with towering mortality and morbidity. Though the virus stimulates innate and cellular immunity, its role in controlling the infection is not clearly understood. Several vaccine candidates are on trial phase including conventional types of vaccines and the new generation vaccines and interim-analysis of phase 3 trials of some of them reported good safety and efficacy. Several countries have started vaccinating their population with the available safety and efficacy data. India is also starting its vaccine roll out from 16th January 2021. As a large vaccine manufacturer of the world, India has joined hands with vaccine initiatives by WHO and CEPI (the Coalition for Epidemic Preparedness Innovations) to ensure availability of affordable, cost effective vaccine. Still there are some concerns about the use of the vaccine.

Keywords: *COVID-19 vaccine, immune response, vaccine development platforms, COVID-19 vaccine initiative*

Introduction

The burden of disease and death toll due to COVID-19 is still mounting across the world. As on 15th January 2021, there were nearly 90 million cases, 2 million deaths and 60 million recoveries (1). Among the uncertainties about the end of the pandemic, a glimpse of hope has been emerged after the advent of vaccines. Vaccines play a vital role in keeping the health of people of all ages by protecting from about 20-plus serious and often deadly diseases. They are prepared from very small quantities of weak or dead pathogens that cause disease which when enters body activates the immune system. Vaccines are introduced into body through the process of vaccination. They are decisive in global health security and a major component of primary health care (2).

The history of vaccines dates long back to 1000th century where Chinese used small pox inoculation and it was reportedly practiced in Africa and Turkey. In 1796, Edward Jenner used variolation with cowpox pustules to protect humans against small pox and several vaccines

have been developed thereafter. Vaccines are used in people once it is found to be safe and effective through several years of stringent safety testing in trials and even after administration they are monitored for safety through different monitoring and reporting networks (3).

The effective mitigation of the COVID-19 pandemic will be a reality only through the development of a cost effective vaccine. During the last one year, there was as unprecedented collaboration between governments of various countries, researchers, organizations and multiple partners for the multi-pronged efforts for the various containment measures including vaccine. Though there are queries and doubts, world has almost succeeded in this regard. India will be the global leader in COVID-19 vaccine development once it achieves the target of meeting the high demand of producing the cheapest vaccine for COVID-19. The 1.3 billion Indian population and millions of people in more than 30 third-world counties are eying India hopefully for the development of a safe and affordable vaccine.

This article reviews the different COVID-19 vaccines and the potential challenges.

COVID-19 immunology basics

The immune system fights against invading pathogens. Immune system has two parts, innate (general) and adaptive (specialized). Both of them work together but differently. Innate immune system is the first line of defense which is fast and non-specific. The adaptive immune system takes charge when the innate immune system fails to block pathogens. They specifically target pathogens causing infection, rather slowly but accurately, unlike innate immune system. Figure 1 describes the components and cells involved in innate and adaptive immune systems and cellular and humoral immune response.

<table>
<tr><th colspan="2">Innate (general)</th><th colspan="2">Adaptive (specialized)</th></tr>
<tr><td rowspan="2">Skin
Macrophages
Mucous membrane
Physical and chemical barriers
Enzymes
Complements</td><td rowspan="2">Dendritic cells
Granulocytes- basophils; neutrophils; eosinophils
Mast cells
γδT cell</td><td>T lymphocytes</td><td>B lymphocytes</td></tr>
<tr><td>Helper T cells (CD4+)
Cytotoxic T cells (CD8+)
Regulatory T cells</td><td>Memory B cells
Plasma cells- antibodies</td></tr>
<tr><td></td><td colspan="2">Cellular immunity</td><td>Humoral immunity</td></tr>
</table>

Figure 1: Immune system and immune response

The adaptive immune cells are responsible for detection of invading pathogenic elements and initiating specific immune response. The unique receptors on T-cell and B-cell can recognize specific antigens. The helper T-cell activates the B-cell that match the same type of pathogen and the B-cells transform to plasma cells and they produce large quantities of antibodies specific to the pathogen and release in to blood, thus mediating humoral response. The antibodies act in three different ways; neutralizing the pathogen or its toxin, activating phagocytes, and complement system. Some of the activated B-cells become memory cells and will be the part of adaptive immune system and remain for a long time and respond immediately to the same antigen when reintroduced (anamnestic immunity). The cells of the adaptive immune system communicate to each other directly or through soluble chemical messengers like cytokines. The adaptive immunity has regulatory mechanisms so as to prevent unnecessary activation that can damage the host.

Vaccines contain live attenuated or killed pathogens or subunits which can produce an initial immune response which is weak and slow (primarily IgM) and the immune system gets primed to the pathogen and will produce an anamnestic response which is stronger and brisker than the primary response and such vaccines require one or more booster doses. An effective vaccine can activate both innate and specific immunity.

SARS CoV-2 belongs to the beta corona virus family and it is the 7th known member of the family infecting humans. It is an enveloped, single-stranded RNA virus. A large number of glycosylated S (spike) protein are present on the viral surface which binds to the angiotensin converting enzyme 2 (ACE-2) receptors of the host cell and mediates the viral entry (4). The COVID-19 immune response involves both humoral immunity and cell mediated immunity .

It is reported that most of the patients who recovered from COVID-19 infection had detectable antibodies to the virus in their blood. The antibodies develop around the time of recovery, 1-3 weeks after recovery. The level of neutralizing antibody titre was higher among patients who had severe disease compared to mild or asymptomatic patients. It is not obvious whether the innate immunity or cellular immunity is effective in viral clearance. The duration of antibody protection also is not clear, but some studies have shown that it may take some three months to the neutralizing antibodies to disappear(5).

Herd immunity or population immunity is the indirect protection against infectious diseases among a population when most of the people got immunity by developing infection or by vaccination. People should develop herd immunity against COVID-19 through vaccination, not by developing infection. To reach that end, a sizeable proportion of population should be vaccinated so that the amount of virus that spreads infection can be reduced. Sero-prevalence studies are undertaken to detect members in a population who have antibodies against SARS CoV-2 indicating that they have already developed infection. But it is not clear that the presence of antibodies will protect against re-infection. WHO has reported that less than 10% of the people in most of the countries have been infected with COVID-19 (6,7).

COVID-19 Vaccine development platforms

The COVID-19 is expected to be endemic even after it will be controlled effectively. Various organizations are trying hard to ensure a suitable vaccine which can give protection after a single dose, which has thermal stability, scalable production and good immune responses.

Vaccines use different ingredients to keep them safe and effective and to stimulate immune system and to build immunity. They are antigens and adjuvants. Antigens are weak or inactive organisms causing specific diseases. Adjuvants are substances helping immune system to respond strongly to vaccine.

There are two classical vaccine development platforms and they are virus-based vaccines and protein-based vaccines. The virus-based vaccine can be inactivated; which is no longer infectious and live attenuated. An inactivated virus do not replicate, adjuvants are needed to stimulate immune system. Live attenuated vaccines are produced by treating the virus in cell culture until it loses its pathogenic nature and will be able to generate only a mild infection. Protein-based vaccine can be a purified protein from virus or virus-infected cells, or recombinant proteins or virus-like particles. Virus-like particles consists of the structural viral proteins that are necessary to form a viral particle, but not having the viral genome and non-structural proteins. Protein-based vaccines also need an adjuvant to produce a strong immune response.

The next generation vaccine (Wave-2) platforms are viral vector, DNA-based, RNA-based or antigen presenting cells. A viral vector, the commonest one is adenovirus, is a

recombinant virus which is often attenuated to reduce the pathogenicity which is able to produce the COVID-19 antigen which upon injected in to the human body infects it and the human cell makes the antigen. Nucleic acid-based vaccines are capable of producing both humoral and cell-mediated immunity, but require multiple doses. DNA-based vaccines are made up of a synthetic DNA construct which encodes the vaccine antigen. The injection needs to be followed by electroporation for efficient uptake of the construct in to cells. The mRNA-based vaccines also work on the same principle. A carrier molecule is often needed to facilitate the entry of the mRNA in to cell and lipid nanoparticles are commonly used for this purpose. The antigen presenting cell (APC) vaccines are artificial cells pre-loaded with COVID-19 antigen and are introduced into the human cell. The T and B cells are stimulated by the APCs which cannot detect the natural or artificial APCs. Theoretically this is more efficient as the antigens need not be produced and presented to natural APCs which can save almost two weeks time to develop vaccine protection (8,9). As on 15th January, 2021, there were 63 vaccines on clinical development and 172 were on pre-clinical development and 19 (30%) vaccines in the clinical development phase belong to protein sub-unit vaccines (10). The following figure lists the different vaccine platforms and candidates vaccine undergoing phase III clinical trial.

Vaccine development platform	***Type of vaccine***	***Candidate vaccine in Phase III trial***
Classical platform	Inactivated virus vaccine	1. Sinovac
		2. Wuhan Institute of Biological Products / Sinopharm
		3. Beijing Institute of Biological Products / Sinopharm
	Protein-based vaccine	Novavax
Next-generation platform	Virus-Vector vaccines	1. University of Oxford / AstraZeneca
		2. CanSino Biological Inc. / Beijing Institute of Biotechnology
		3. Gamaleya Research Institute
		4. Janssen Pharmaceutical Companies
	RNA-based vaccine	1. Moderna / NIAID
		2. BioNTech / Fosun Pharma / Pfizer

Figure 2: Candidate vaccines, their development platforms and type of vaccines under phase III clinical trial

COVID-19 vaccines authorized for use

Medicines, vaccines, medical devices, diagnostic tests etc needs to get approved by a regulatory authority before it can be used for population. To ensure safety and effectiveness of these products, the approval is given only after a long process of thorough assessment of trial data during different phases of the trial. The Central Drugs Standard Control Organisation (CDSCO) is the regulatory authority in India. In emergency situations like the current COVID-19 pandemic, the regulatory authorities usually give emergency use authorization (EUA) based on the findings of the interim analysis of trial data before giving full approval. The Food and Drug Administration (FDA); USA, EUA allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological and nuclear (CBRN) threat agents when there are no adequate approved and available alternatives. It helps to

strengthen the public health protection of the country. Full approval is the marketing approval after the product is proven to be safe and effective for use of the consumers. It is based on the judgment that the benefits of the product outweigh the risks (11).

The US FDA has given EUA for two COVID-19 vaccines; the Pfizer-BioNTech vaccine and Moderna vaccine (12). The Pfizer-BioNTech vaccine (BNT162b2) is a lipid nanoparticle–formulated,5 nucleoside-modified RNA (modRNA) encoding the SARS-CoV-2 full-length spike, has two doses which are administered at 21 days interval, intramuscularly for individuals 16 years or older (efficacy 95%, 95% CI 90.3 to 97.6) (13). The Moderna COVID-19 vaccine contains a nucleoside-modified messenger RNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles which is to be used in individuals 18 years of age and older (efficacy 94.1%, 95% CI 89.3 to 96.8)(14).

Two COVID-19 vaccines had got restricted emergency approval by Drug Controller General of India (DGCI) on 3rd January 2021. They are COVID-19 virus vaccines by Serum Institute of India and Bharat Biotech. The Serum Institute of India vaccine; 'Covishield', is a recombinant Chimpanzee Adenovirus vector vaccine encoding SARS CoV-2 spike (S) glycoprotein with the technological support of AstraZeneca/Oxford Univeristy which has a reported overall efficacy of 70.42%. The Bharat Biotech vaccine; 'Covaxin', is a whole viron-inactivated corona virus vaccine developed on vero-cell platform in collaboration with ICMR (Indian Council of Medical Research) and NIV (National Institute of Virology), Pune. Both vaccines are administered in two doses (15).

Three other COVID-19 vaccines are in trial phase in India. The ZyCoV-D is a plasmid DNA vaccine developed by Zydus Cadila which is undergoing phase III trial. Sputnik V vaccine is undergoing phase II trial which is an adenovirus vector vaccine studied jointly by Dr.Reddy's Laboratories Limited and Sputnik LLC, Russia. The Biological E's novel COVID-19 vaccine is in phase I/II trial which contains Receptor Binding Domain of SARS CoV-2 (16).

COVID-19 vaccine global initiative

COVAX is a global initiative to ensure equal access to COVID-19 vaccines by all countries regardless of their income once the vaccine is developed. It is led by Gavi; the Vaccine Alliance, CEPI (the Coalition for Epidemic Preparedness Innovations) and the WHO. A total of 172 countries are participating in it. It is the largest and most diverse portfolio of COVID-19 vaccines in the world with nine CEPI-supported vaccines and nine other candidate vaccines under the initiative. The initiative is working in collaboration with vaccine manufacturers of developing and developed countries (17).

The Ministry of Health and Family Welfare, Govt. of India has started the COVID-19 Vaccine Intelligence Network (CoWIN) system in association with Ministry of Electronics and Information Technology, a digitalized platform for effective rolling out and scaling up mechanisms for distribution of COVID Vaccine Distribution System within the nation. The Serum Institute of India is trying to ensure the availability of 100 million doses of COVID-19 vaccines by AstraZeneca or Novavax vaccines once they will be successful and it will be available to the low and middle income countries at an affordable cost of US $ 3 per dose through the COVAX initiative in association with CEPI and Bill and Melinda Gates Foundation (18).

Concerns and questions unanswered

Though the availability of vaccine offers a glimpse of hope, several questions remained unanswered.

1. Vaccine efficacy in high-risk groups- it is already known that elderly and those who are with comorbidities carry additional risk for severe COVID-19 infection. A safe and

effective vaccine confer protection in two ways- direct protection where high risk groups are given vaccine to prevent the disease and indirect protection where high-risk contacts are given vaccination to reduce the transmission of infection. There is no clear data whether the vaccine gives direct protection or indirect protection to the high-risk groups. The classical vaccines had reduced efficacy in elderly and obese people. Whether the new vaccine can give increased immunogenicity in elderly and obese is yet to be determined (9,19).

2. Duration of protection- As the vaccine development for COVID-19 was a faster one which took less than 1 year; it is not certain about the duration of protection offered by the vaccine, the effect of partial vaccination and need for booster doses. The effect of vaccine on the spectrum of disease, baseline sero-status and the potential of the virus to develop resistance are yet to be known (19).

3. Nature of protection offered by vaccine- a safe and effective vaccine should prevent or reduce transmission of infection in the community through herd immunity or by preventing severe infection in vaccinated individuals (19). The nature of protection that the COVID-19 vaccines would give is not clear.

4. Vaccine logistics- for giving sufficient protection to vaccinated individuals, with a population of over 7 billion, a large quantity of the vaccine will be required world-wide. Along with vaccine, the adjuvants needed, the special delivery devices, delivery molecules for next-generation vaccines are also required to be produced on a large scale (9). Most of the vaccines need two doses. Some vaccines need storage at very cold temperatures for shipping and longer storage (13) .

5. Vaccine hesitancy- it is reported that a significant proportion of the U.S. population may show vaccine hesitancy to a new COVID-19 vaccine. According to another report 26% of respondents reported they will not receive COVID-19 vaccine when it becomes available (20).

Conclusion

An enormous number of people across the globe are still vulnerable to the infection, though the restrictions are preventing more deaths. With the development of vaccines, health experts all over are optimistic that the pandemic could be brought under control within a year. It will not be the end of the disease until a large proportion of the global population is vaccinated. It will require a great effort to ensure the availability of sufficient doses.

(This review contains information up to 15th January, 2021)

Conflict of interests: none

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