An Investigation on Leprosy Treatment Patterns, including Disease Prevalence, Adverse Event Monitoring, and Medication Adherence Assessment

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ABSTRACT

A prospective observational study was carried out for six months among the leprosy patients in two districts in Telanagana (Ranga Reddy and Hyderabad).The study was carried out to determine the prevalence, treatment pattern and drug related problems among the leprosy patients. During our study period 40 cases were reported from Hyderabad district and 64 from Ranga Reddy. So the prevalence of leprosy in Hyderabad and Ranga Reddy district was found to be 0.001 and 0.002 respectively. In the current study among among a total of 104 patients included, 49 (47%) were in the age group of 31-50 years. The mean age was 42.13 ± 18.61 years. Nearly 6% of the patients were aged less than 15 showing the transmission is still going on the community. This high prevalence in younger age group calls for more vigorous means of case detection like active search for cases especially in communities known to be leprosy endemic.104 patients were enrolled in the study, of them 74(71%) were males and 30(29%) were females, demonstrating male predominance over female population. There are three important principles for leprosy work in the future. It includes;Sustainability (new cases of leprosy are continuing and many of the consequences are lifelong so our approaches need to be sustainable) , the leprosy workers cannot do everything themselves(they need to work in alliances at all levels with other agencies, other health care workers, social services, communities, patients themselves and their families),Anti-leprosy services need to be integrated with general health and social services(this includes training, primary health care, hospital care, and community based rehabilitation) Finally we would like to emphasize the importance of a proper health education, daily ulcer care and shoe adjustments as systemic therapy and also to prevent the development of new ulcers.

Keywords: Leprosy, Prevalence Drug Therapy

INTRODUCTION

Leprosy is an infectious and contagious chronic disease, caused by *Mycobacterium leprae*, an obligate intracellular bacillus, that affects mainly the skin, nerves and mucous membranes.[1,2] It can also affect the eye, nose, joints, lymph nodes, internal organs and bone marrow, especially in multibacillary patients (MB).[1,2] In the majority of cases, it is transmitted from person to person through contact with patients that have a high bacillary index and haven't been treated.[1,2] In 2008, a new species of mycobacterium was identified in Mexican MB patients - *Mycobacterium lepromatosis.*[3] Recently, *M. lepromatosis* was also found in paucibacillary patients.[4]

The disease has a 2- to 5-year course for paucibacillary patients and a 5- to 10-year course for multibacillary patients.[5] Humans are the main natural reservoir of the bacillus. There are reports of armadillos and squirrels naturally infected by *M. leprae*, with the hypothesis formulation that some cases could have been a consequence of contact with animals, in particular the armadillo.[6-9] MB patients are considered the main source for infection in transmission cycle. Although there is evidence of the presence of *M. leprae* in skin lesions, breast milk, environment and animals, the main route of transmission for *M. leprae* is the respiratory tract.[2,10,11] During disease evolution, reactions might occur that, without propper treatment, can lead to severe damage in the peripheral nerve trunks, originating physical disabilities and sequelae, the main reason for the stigmatization caused by the disease.[12]

A person is considered suspicious for leprosy whenever they present with one or more of the following signs or symptoms: pale or reddish patches on the skin; loss, or decrease, of feeling in the skin patches; numbness or tingling of the hands or feet; weakness of the hands, feet or eyelids; painful or tender nerves; swelling of or lumps in the face or earlobes; painless wounds or burns on the hands or feet.[11]

The introduction of the multidrug therapy (MDT) or polychemotherapy, recommended by WHO in 1981, led to significant changes in leprosy epidemiology.[13] Obviously, the reduction in treatment duration, impacted on the prevalence; from over 5 million cases in the 1980s, there was a reduction to less than 200,000 cases in 2015.[13-16] .

Current epidemiological data should be interpreted cautiously, since the elimination goals for the year 2000, and 2005 thereafter, were achieved through: changes in the definition of paucibacillary case, single dose treatment for PBs patients with a single lesion, reduction of treatment duration for 24 and 12 months thereafter. As, after finshing the scheduled tretament, the patient is removed from the data.[13,17-19] There has been marked reduction on leprosy prevalence after MDT introduction and decreased in treatment length; however, this therapeutic regimen have had no impact on transmission.[20] It is still necessary to improve early detection of cases, prevention measures for disabilities, trainning of health professionals, stimulate research for better understanding of disease transmission, newdrugs and new therapeutical regimens, in order to cease the transmission cycle.[21]

The main aim is study the treatment pattern of leprosy. The objectives are to study the prevalence of the disease, monitor presence of adverse drug reaction, to study the treatment pattern of leprosy including lepra reactions, Assess adherence to drugt herapy

METHODOLOGY

STUDYSETTING
Participants for this study were selected from various regions of Hyderabad and Ranga Reddy Districts. In Ranga Reddy District, the study was carried out in the dermatology department of Ranga Reddy Government District Head Quarters Hospital located in the city of Ranga Reddy that has grown into the premier center of treatment for several diseases in Telangana. The medical college campus houses several departments like super -specialty blocks and department of chest diseases etc. The various specialities includes general medicine, radiotherapy, surgical gastroenterology, dermatology &venerology,ENT, orthopedics, preventive clinics, psychiatry, plastic surgery, ophthalmology, general surgery etc.

STUDYPERIOD
A prospective observational study was carried out over a period of six months from July 2023 to December 2023 among the leprosy patients who receives care from Ranga Reddy and Hyderabad districts.

STUDYDESIGN
An observational cross – sectional study was conducted in the leprosy centers in Ranga Reddy and Hyderabad Districts. Cross- sectional studies can be thought of as providing a snap shot of the frequency of

health related characteristicsin a population at a single point of time.

SOURCE OFDATA
Sources of data include patient's medical records; NLEP cards (National Leprosy Eradication Program) obtained from leprosy centers & filled questionnairesthrough personal interviews

FORMS USED IN THESTUDY
A well designed patient data collection form and medication adherencequestionnaire were developed by the team members with the help of guide for recording the patient case details.

PATIENTSELECTION
Based on the inclusion and exclusion criteria of the protocol reviewed by the ethics committee 104 leprosy were include and enrolled for the study.

Inclusion Criteria:
- All patients diagnosed with leprosy (old and new cases)
- No age limit
- Both genders are included

Exclusion Criteria:
- Immigrantpatients
- Patients in whom the relevant data notavailable

ETHICAL COMMITTEE APPROVAL

The protocol was reviewed by the ethics committee of Department of pharmacy Practice, Padmavathi college of pharmacy and a consent was provided by the authority for the purpose of conducting the study. It was reviewed by the institutional ethics committee and approved the proposal of the dissertation. Also ethical committee clearance was obtained by Institutional Research Committee of Ranga Reddy Government District Head Quarters Hospital and approved the proposal dissertation.

STUDYPROCEDURE

This observational cross sectional was conducted at Ranga Reddy and Hyderabad districts over a period of six months. Study title was selected based on our area of interest and under the guidance of our project guide. We reviewed around 15 literatures related to the topic and prepared study protocol. A welldesigned patient data collection form and medication adherence questionnaire were developed after assessing different standard forms by the team members with the help of guide for recording the patient case details .The protocol along with the study materials were submitted to institutional ethics committee for approval and ethical clearance were obtained from our instititution and Ranga Reddy Government District Head Quarters Hospital prior to initiation of the study. Data collection was done prospectively from the secondary data available from the leprosy centers in Ranga Reddy and Hyderabad districts and through personal interviews. Full details ofthe case including patient demographics, past medical and medication history, clinical features, lab investigation details, treatment pattern, adverse drug reactions and other details were brought into self designed data collectionform. Disability grade of the patient was assessed with the help of EHF(eye, hand, feet) score. Patients were categorized into grade 0, grade 1 and grade 2 disabilities. Medication adherence questionnaire was used to evaluate patient's adherence to multidrug therapy. The data was entered in Microsoft excel for easy reference and analysis of results later. The entire data collected were analyzed using different statisticalmethod in consultation with the statistician. The sample size for the study was set as 104. Z test was used for comparison of proportion and Chi square test for testing the goodness of fitness of ratio.

STATISTICS
The sample size for the study was set as 104 by taking the P value as 88.7 %with a confidence of 95% and an error of estimate of 6.1 %. Simple randomsampling technique was adopted for drawing patients to the study. Chi square test for testing the goodness of fitness of ratio.

RESULTS

AGE WISE DISTRIBUTION OFRESPONDENTS
A total of 104 patients were included in the study. Significantly highernumber of patients belongs to the age group 31-50years (χ^2=36.385, DF=3, p<0.001). Mean ± SD of age=42.13 ± 18.61 years, followed by 16-30 and 51-99 years. Least common age group was found to be 0-15.
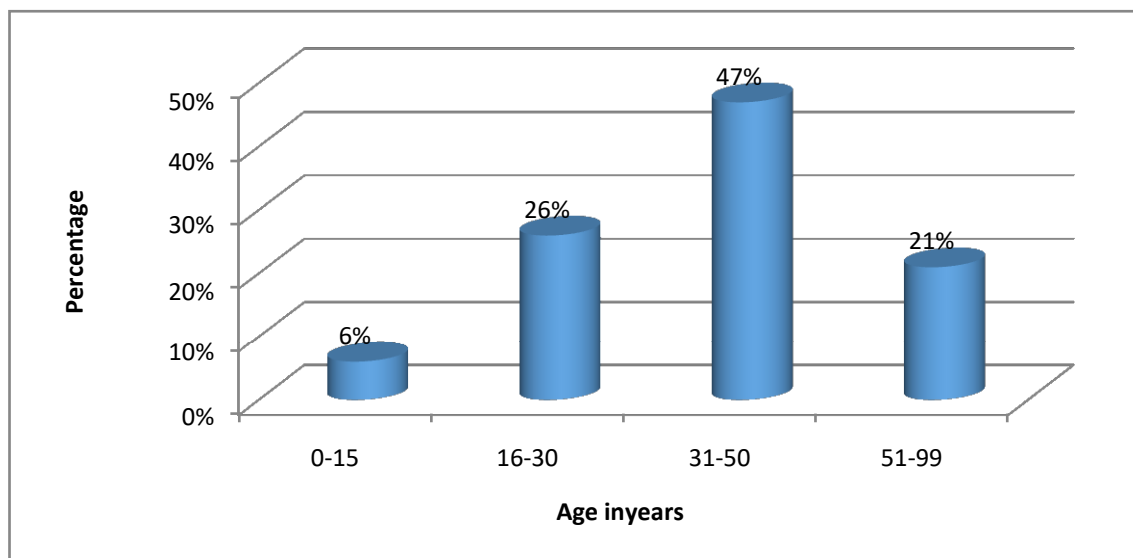

Fig:-1

GENDER WISE DISTRIBUTION OFRESPONDENTS
The gender wise distribution showed that the issue of leprosy was pronounced inmales than females (χ^2 = 18.615, do = 1,p<0.001).
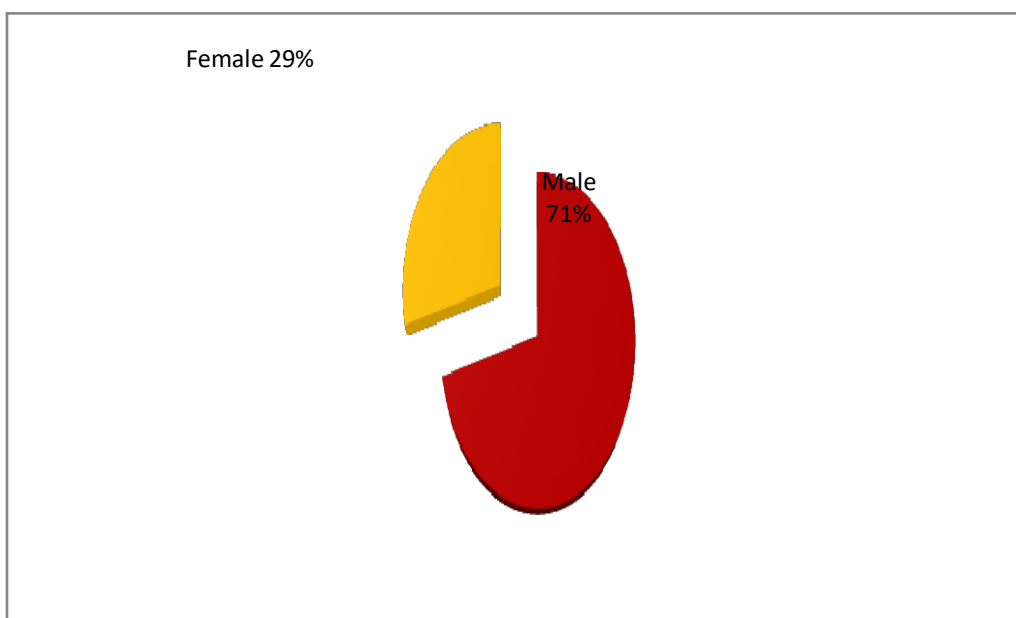
Fig:-2

RESIDENTIAL STATUS OFRESPONDENTS:-

The residential status of the responders show that no significant difference could be detected between the number of patients from rural and urban sector ($\chi^2 = 0.962$, DF = 1, p>0.05)
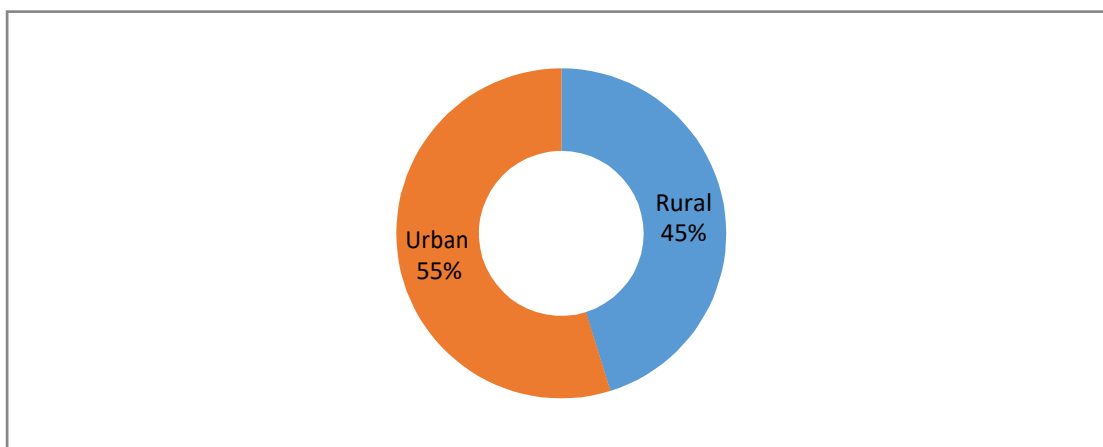
Fig:-3

EDUCATIONAL STATUS OFRESPONDENTS

Educational status of the responders were classifies as illiterate, primary secondary and tertiary. Significantly higher number of patients had secondary education ($\chi^2 = 25.730$, DF= 3, p<0.001)
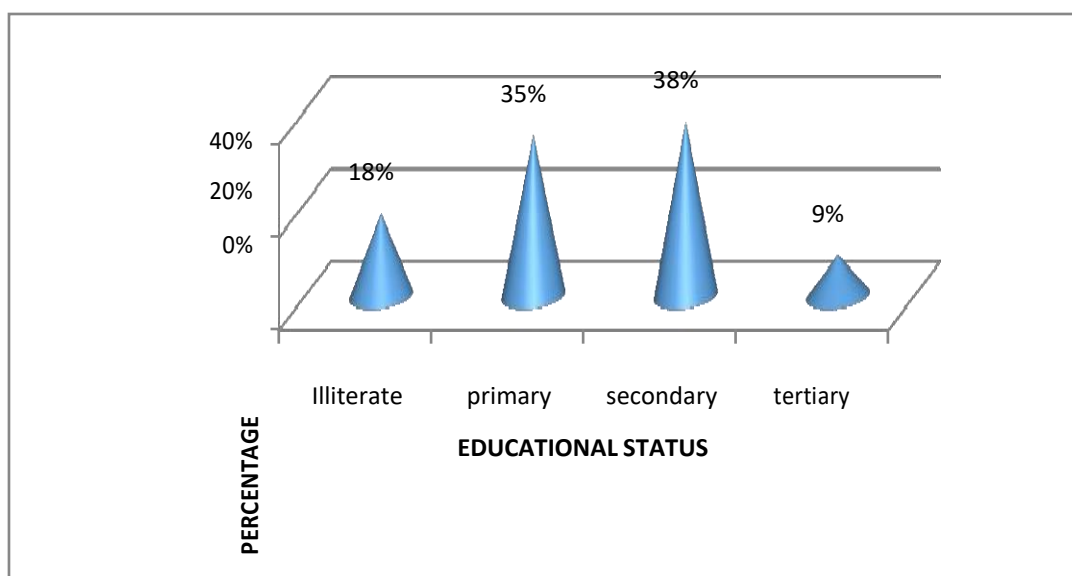
Fig:-4

TYPE OF LEPROSY

The most prevalent type of leprosy was found to be Multibacillary (MB) [$\chi^2 = 22.231$, DF = 1, p<0.001] with 86 cases while paucibacillary (PB) type accounted for only 18 cases. This indicates that most of the respondents suffered from multibacillary types of leprosy.
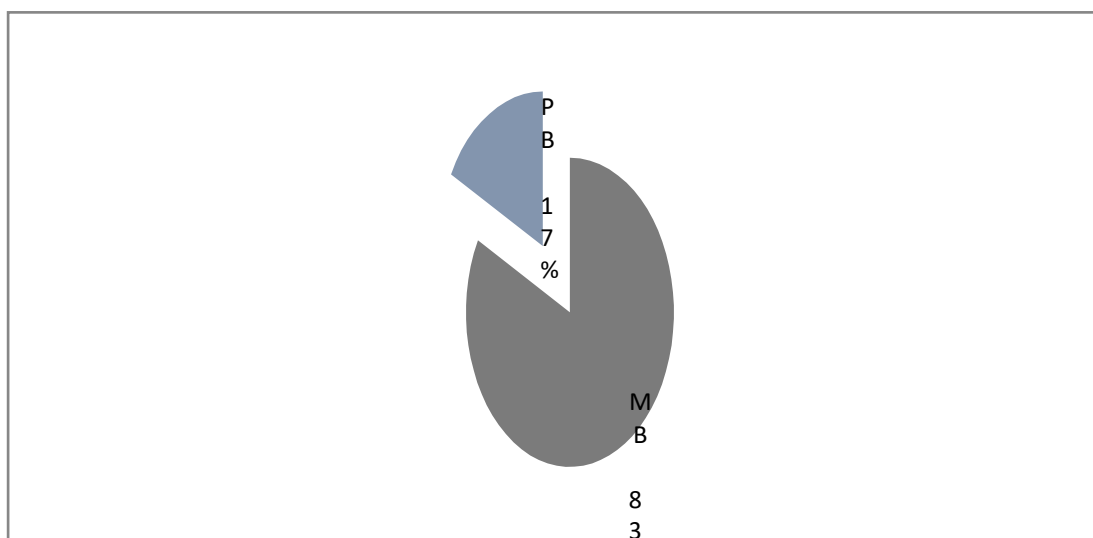
Fig:-5

CLINICAL FORM OFLEPROSY

Clinical form of leprosy were Borderline borderline, Borderline tuberculoid, borderline lepromatous, Lepromatous leprosy...Among these Borderline tuberculoid(BT) form of leprosy (69 cases) was found to be significantly higher in the sample ($\chi^2 = 127.391$, df = 3, p < 0.001) followed by lepromatous leprosy with 16 cases.
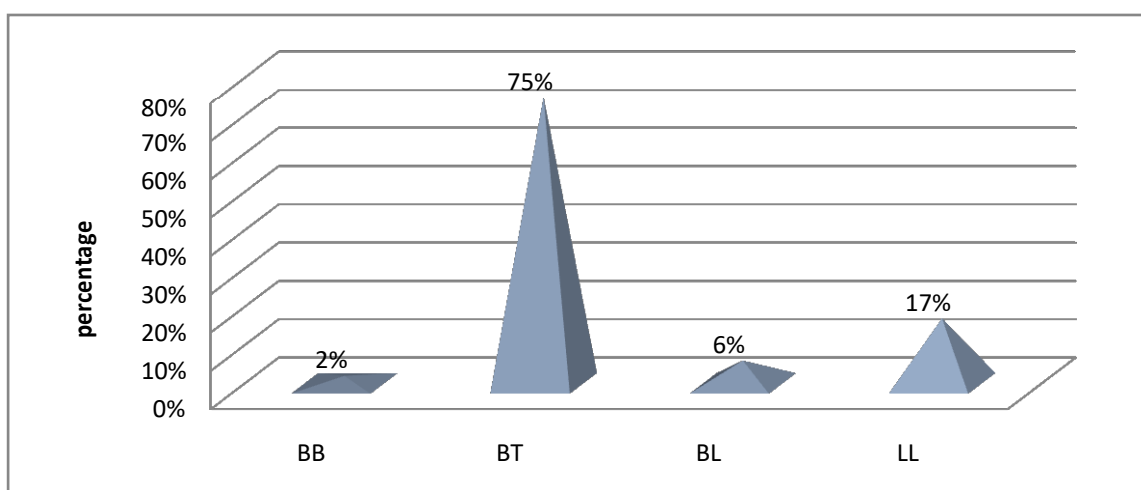

Fig:-6

CLINICAL FEATURES OFLEPROSY

88 (84.61%)Patients showed hypopigmented patches, Loss of sensation were showed by 41 (39.42%) patients followed by numbness 33 (31.73%),
deformities19(18.27%),slippageofchappals 18(17.30%) ,icthyosis 11(10.58%), madarosis 7(6.73%) and epistaxis 4(3.84%) are shown in the above figure.{ $\chi^2 = 191.300$, df = 7 ,p<0.001}
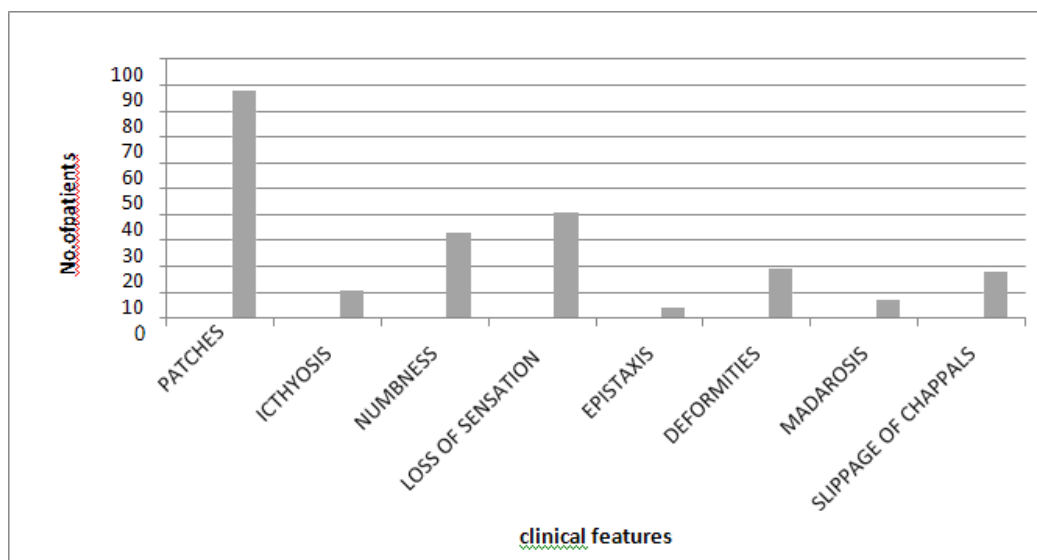
Fig:-7

DURATION OF SIGNS ANDSYMPTOMS

Duration of Signs and symptoms were found to be significantly higher inpatientswith 1-10 years duration compared to the other two groups (χ^2 = 41.857, df= 2,p<0.001)
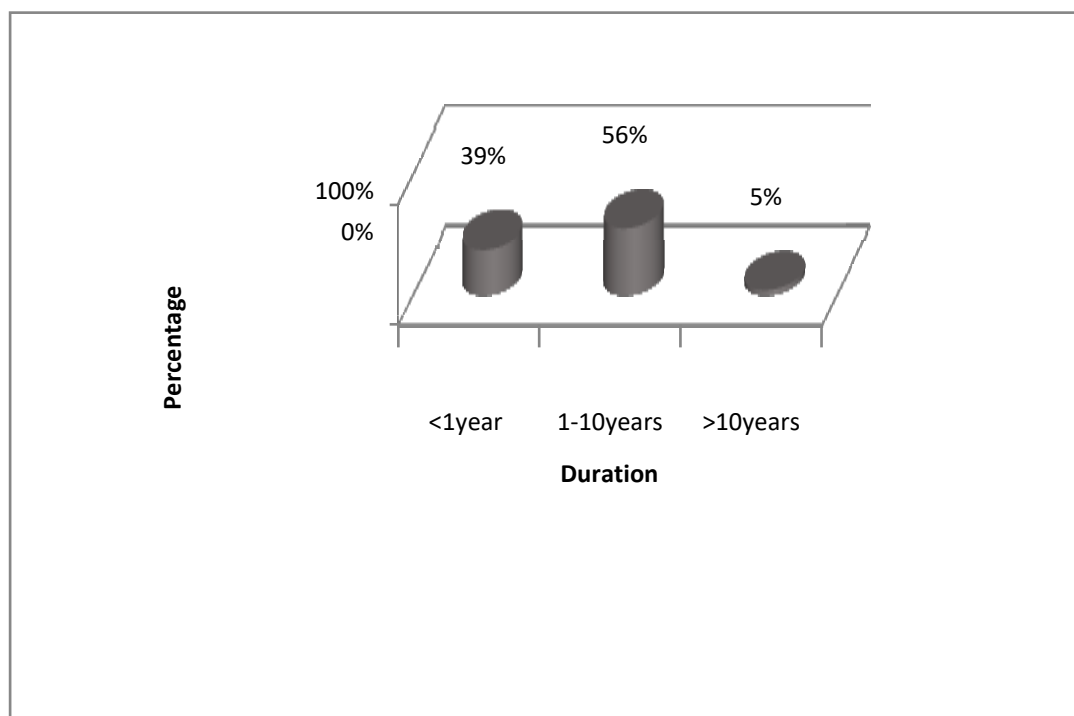

Fig:-8

TYPES OF LEPROSYPATIENTS

The patients came for the treatment were categorized as new cases(Newly reported),Retreat and Relapse .Among these New cases (84%) was found to be significantly higher than retreatment (6%) and relapse cases(10%) is shown in the above graph.[χ^2 = 122.143 , df = 2 , p <0.001]
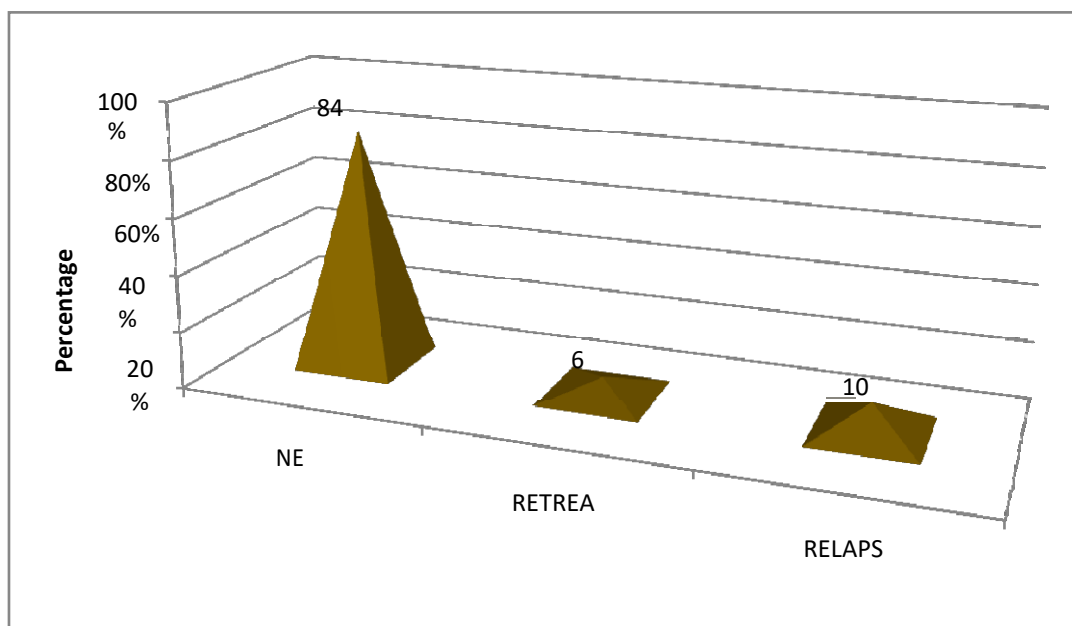
Fig: 9

TYPE OF LEPROSY VERSUSGENDER

Multibacillary type of leprosy was significantly associated with male gender than the female gender (χ^2 = 21.511, DF = 1, p<0.001)
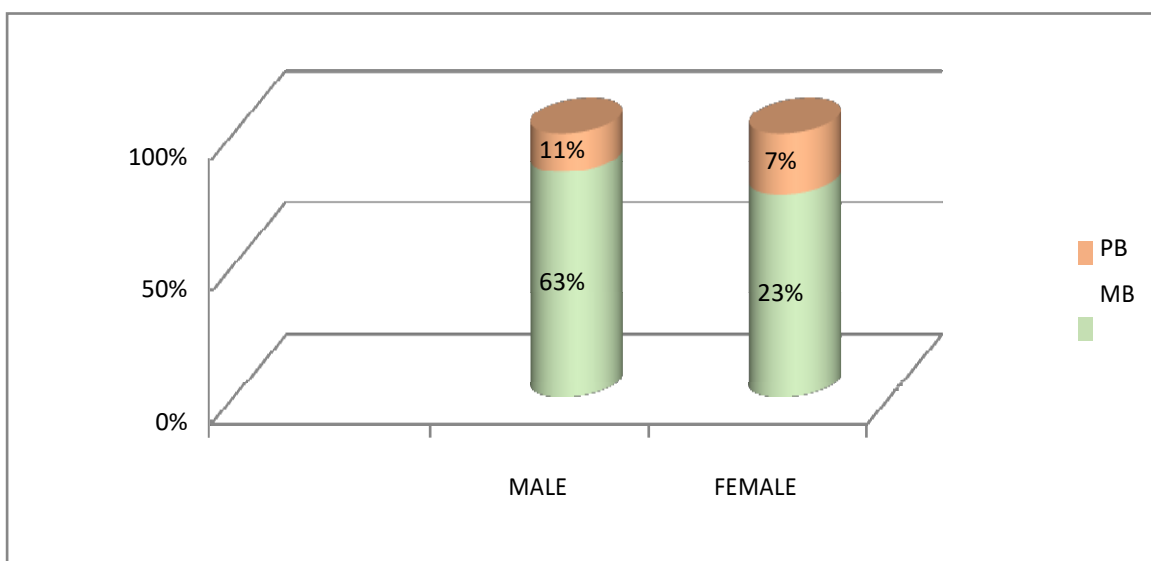

Fig: 10

NERVE INVOLVEMENT INLEPROSY

Among104patients,46%showedulnarnerveinvolvement, 26%showedcommonperoneal nerve involvement, followed by radiocutaneous nerve15%, radial nerve 5% .(χ^2= 57.423, p <0.001)
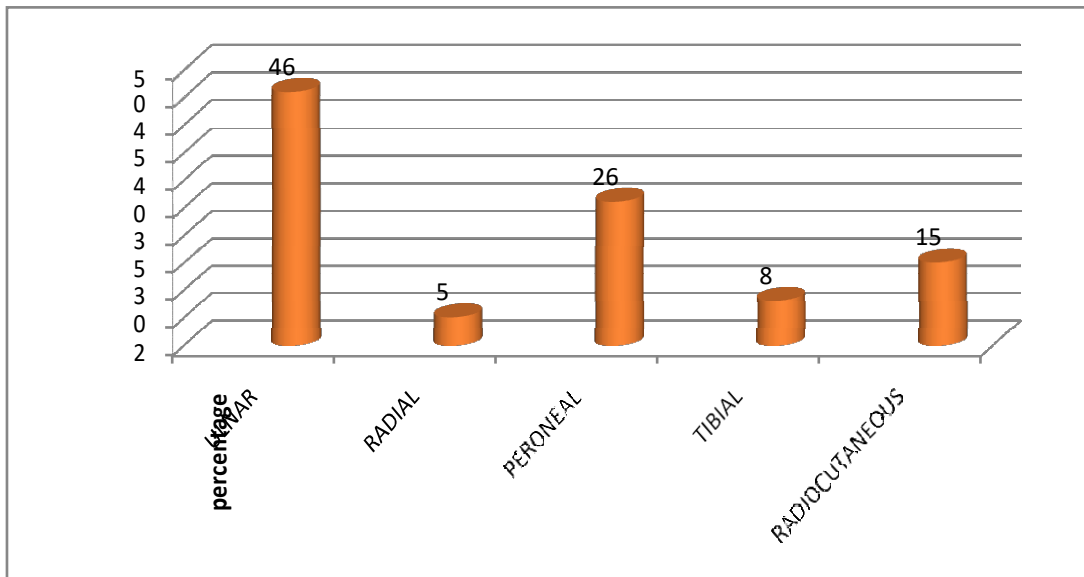
Fig:-11

LEPRAREACTIONS

Type 1 reaction was found to be significantly higher than type2 reaction(χ^2 =7.258, DF = 1, P<0.01)
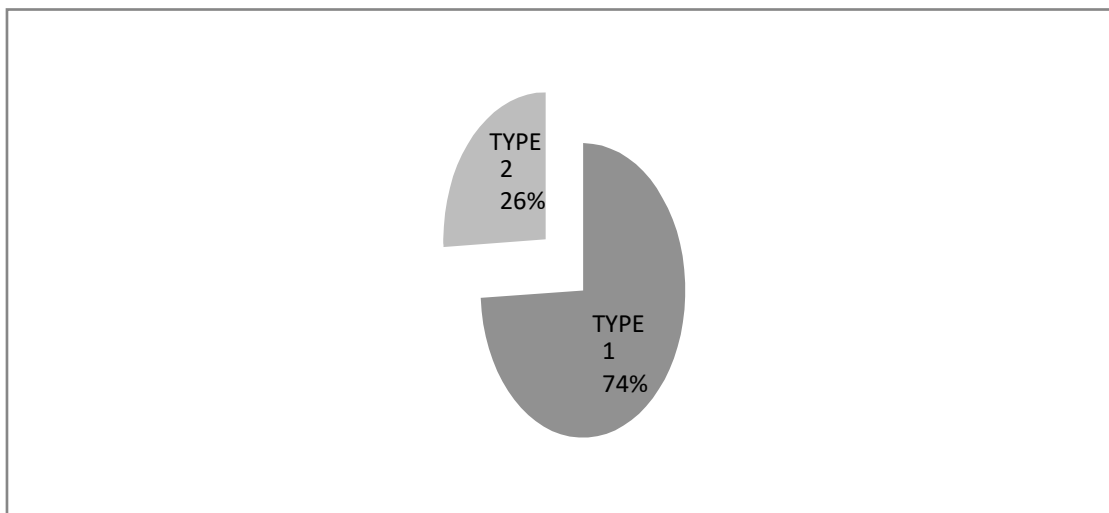

Fig:-12

TYPE OFDISABILITY

Types of disability were evaluated among 104 patients. 62% had ulcer, 33.33% had claw hands followed by foot drop 14.28% and lagophthalmus 9.52%(χ^2 = 11.96, DF =3, p<0.01)
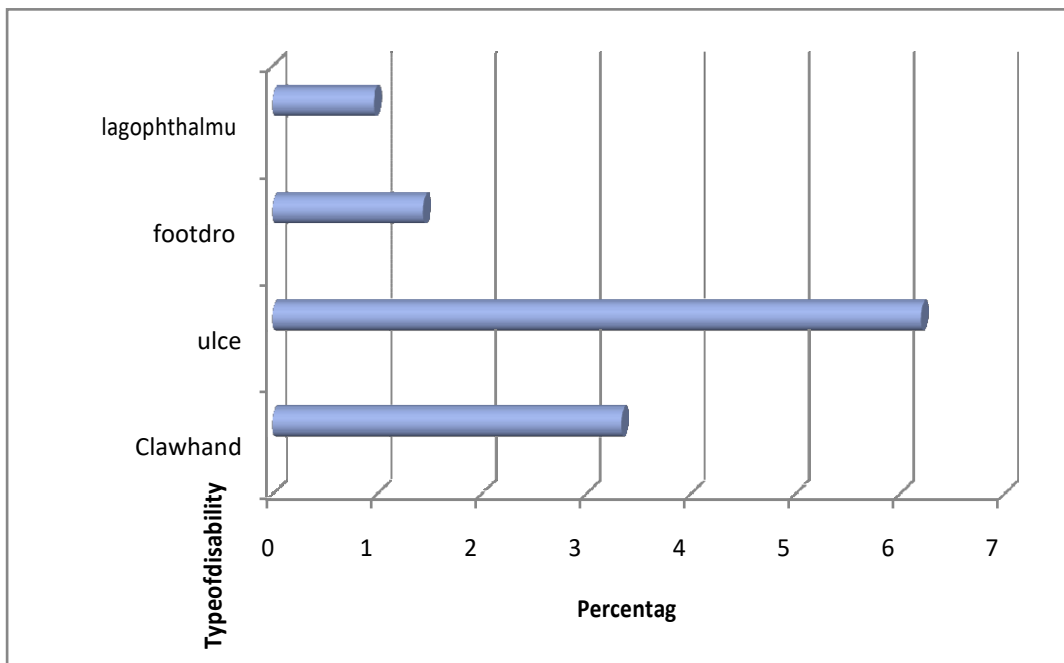
Fig:-13

GRADE OFDISABILITY

Grade of disability was evaluated among the leprosy patients.49% had no deformity, 31% were having Grade-1 deformity and 20% were having Grade -2 deformity. Number of patients in Grade-0 was found to be significantly higher than in Grade-1 and 2.
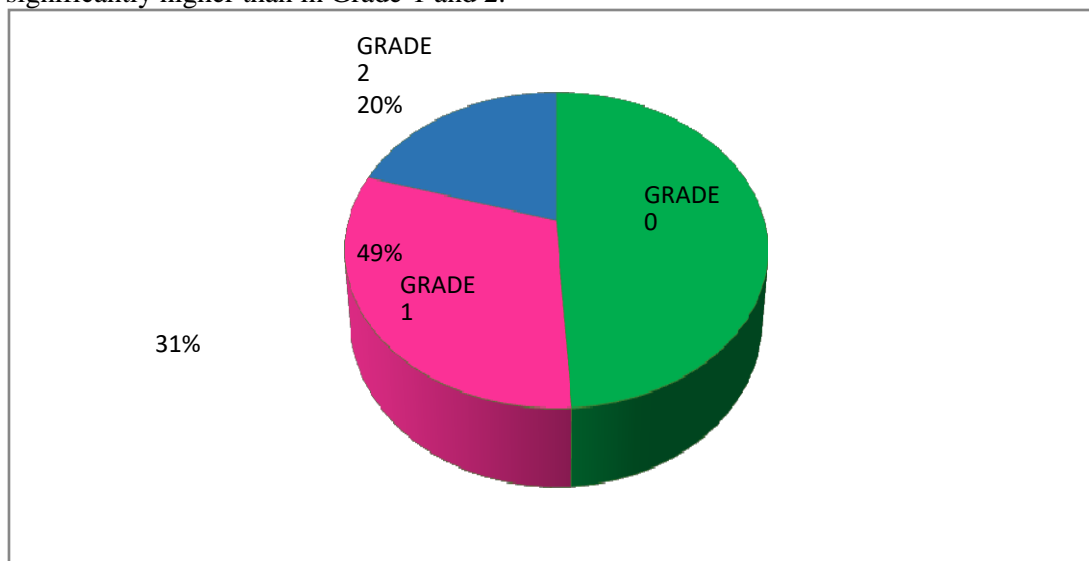
Fig: 14

DURATION OF SIGNS AND SYMPTOMS VERSUS DISABILITY GRADE

A) Less than 1year-Grade-1 disability was found to be significantly higher thangrade-2 (χ^2= 4.263, DF = 1, p< 0.05)

B) 1-10 years:-No significant difference between Grade-1 and grade-2(χ^2 =2.133,p>0.05)

C) Greater than 10 years-Patients with grade2 disability was found to be significantly higher than Grade1 (χ^2 = 4.000, DF = 1,p<0.05)
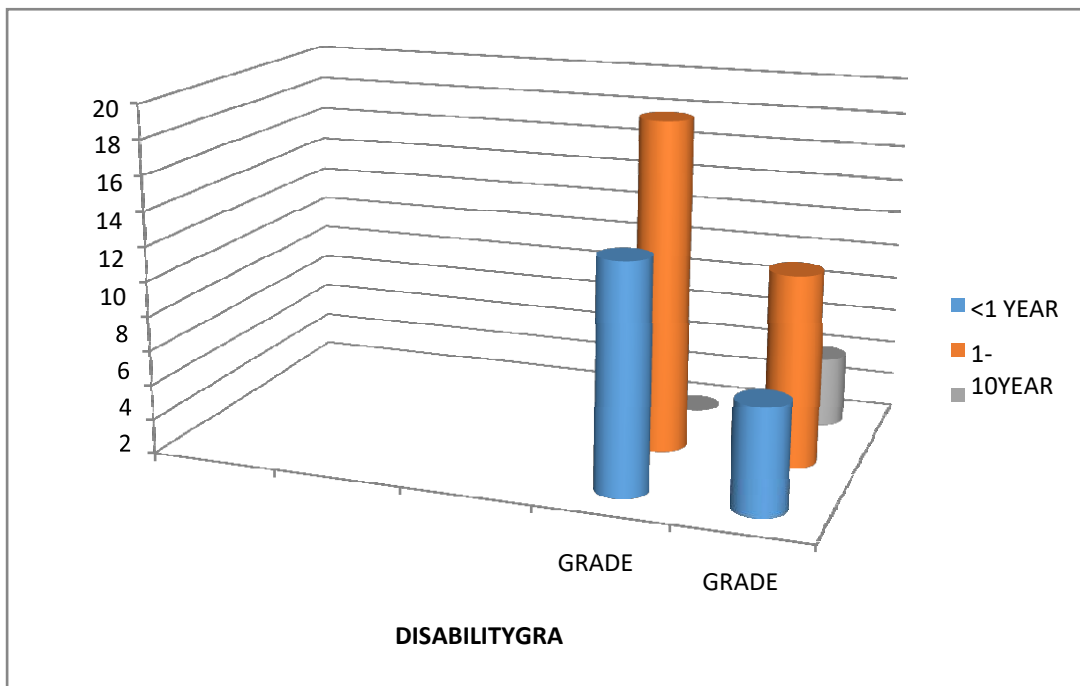
Fig:-15

TREATMENT PATTERN OFLEPROSY

The treatment of multibacillary leprosy was through the use of combination of Dapsone, Rifampicin, and Clofazimine. (74%).Paucibacillary leprosy was treated with the combination of Dapsoneand Rifampicin (16%),($\chi^2 = 209.404$, df =4 ,p<0.001)

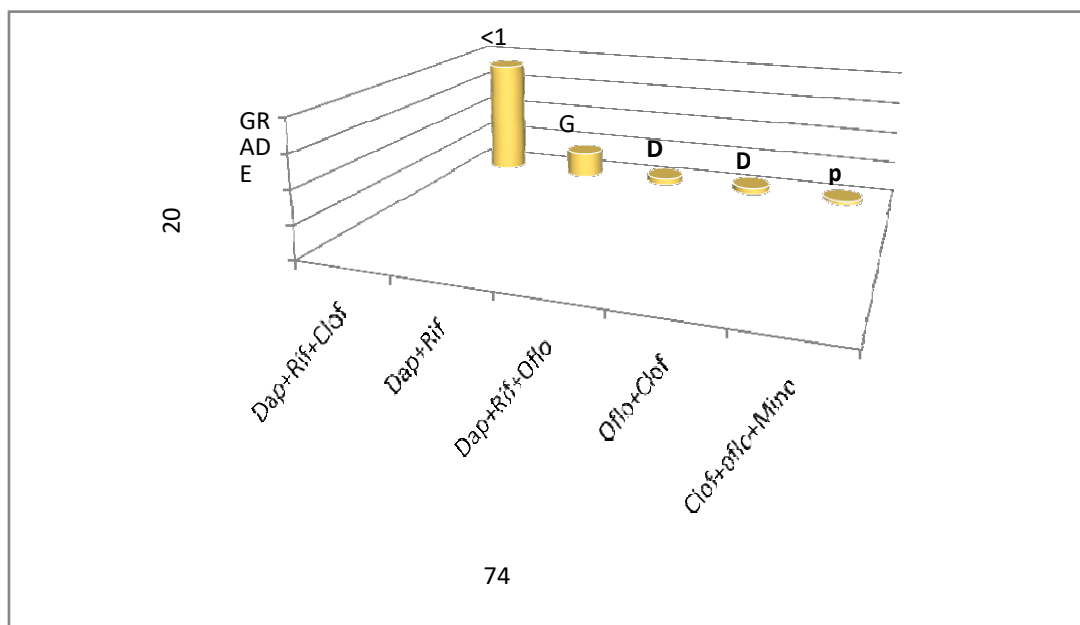Treatment regimens used for managing the patient condition was determined

Fig:-16

MANAGEMENT OF LEPRAREACTIONS

Among patients with typr-1 reaction, significantly higher number of patients are treated with prednisolone compared to others ($\chi^2 = 22.201$, DF = 2, p<0.001).Type-2 reaction was managed by using prednisolone and thalidomide ($\chi^2 = 10.506$, DF=2,p<0.01)
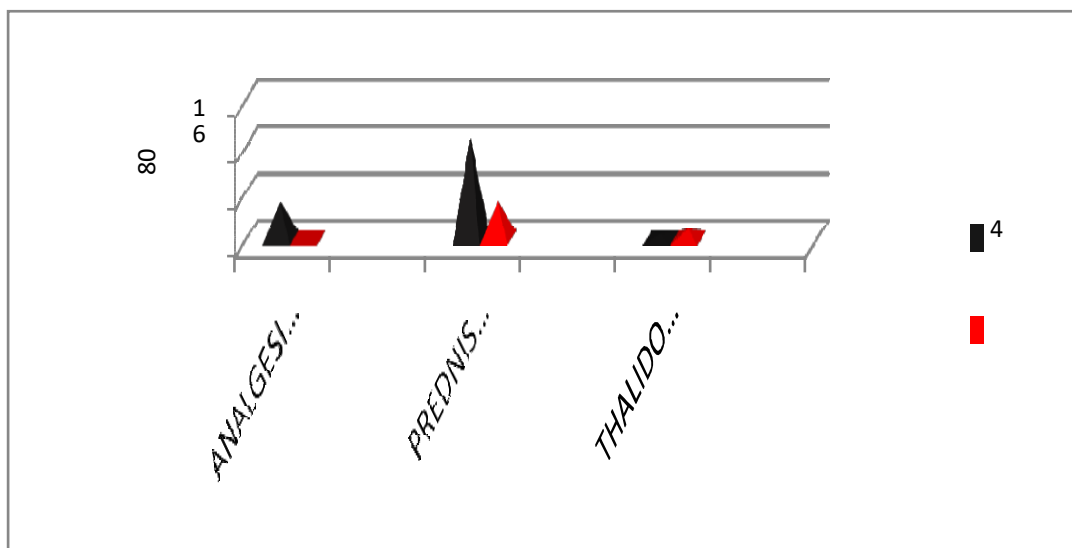
Fig:-17

ADVERSE DRUGREACTIONS

The most common ADR that was commonly seen at the time of study duration were anaemia, GI problems, hepatic abnormality, Flu-like illness, dapsone syndrome, pedal odeamaetc.The most prevalent ADR in the patient population was found to be anaemia(33%) followed by hepatic abnormalities(22%).$\{ \chi^2 = 29.692$, df $= 6$,p<0.01$\}$
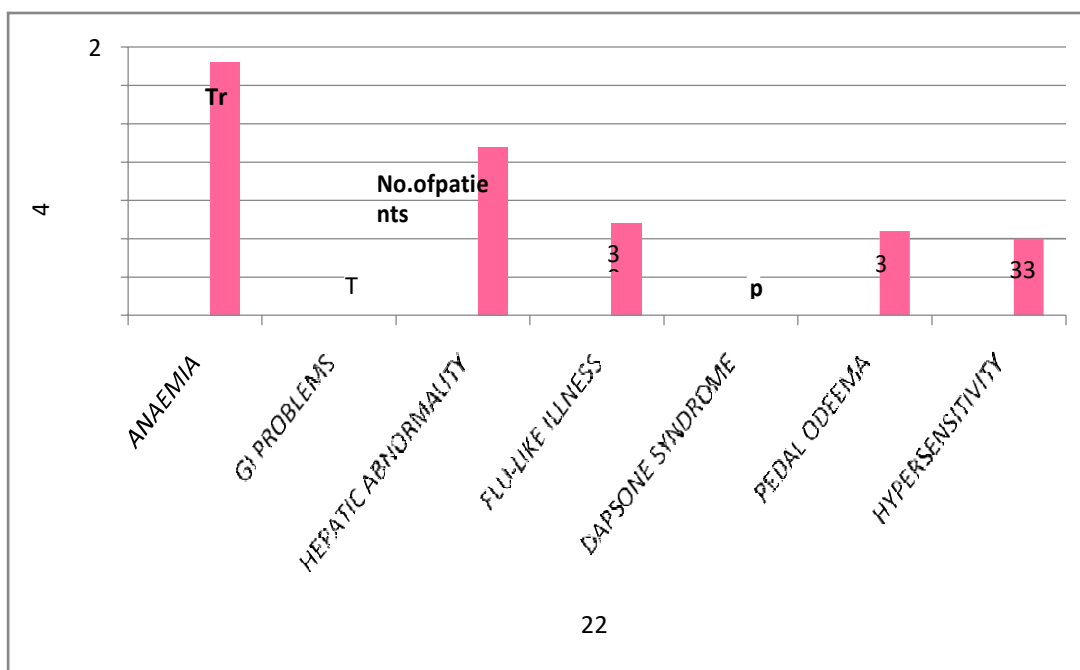
Fig:18

SUPPORTIVE THERAPY

Iron supplements were given for the management of anemia in 26% of patients. Antibiotics were being prescribed for 24% of patients in case of exacerbations.
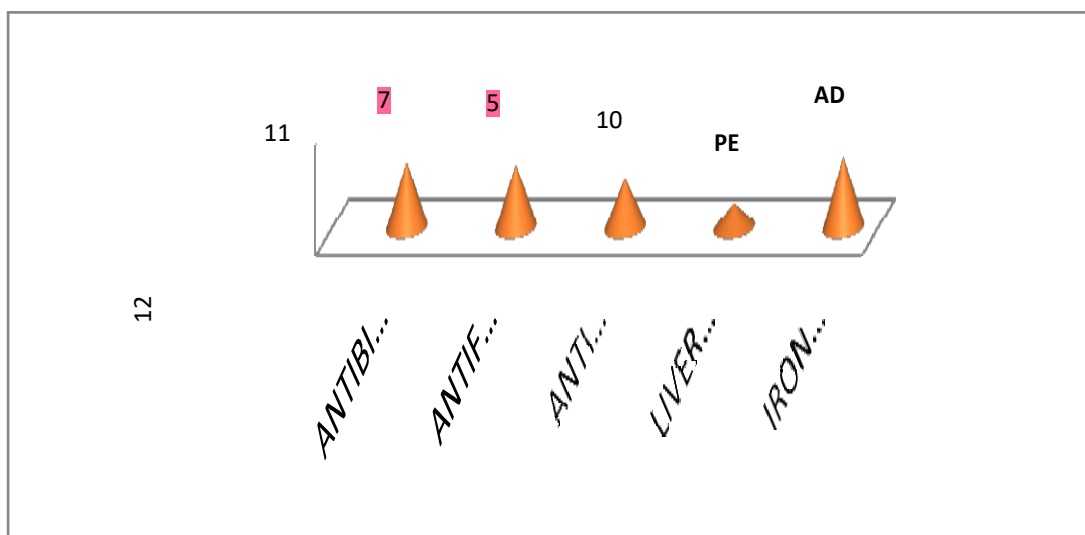
Fig:-19

MEDICATION ADHERENCE

The subjects were categorized into 3 categories namely highly adherent, moderately adherent, and non-adherent based on their level of medication adherence .Majority of the patients was found to be moderately adherent.(χ^2 = 14.657 , df = 2 ,p<0.01).18% of patients werenon-adherent.
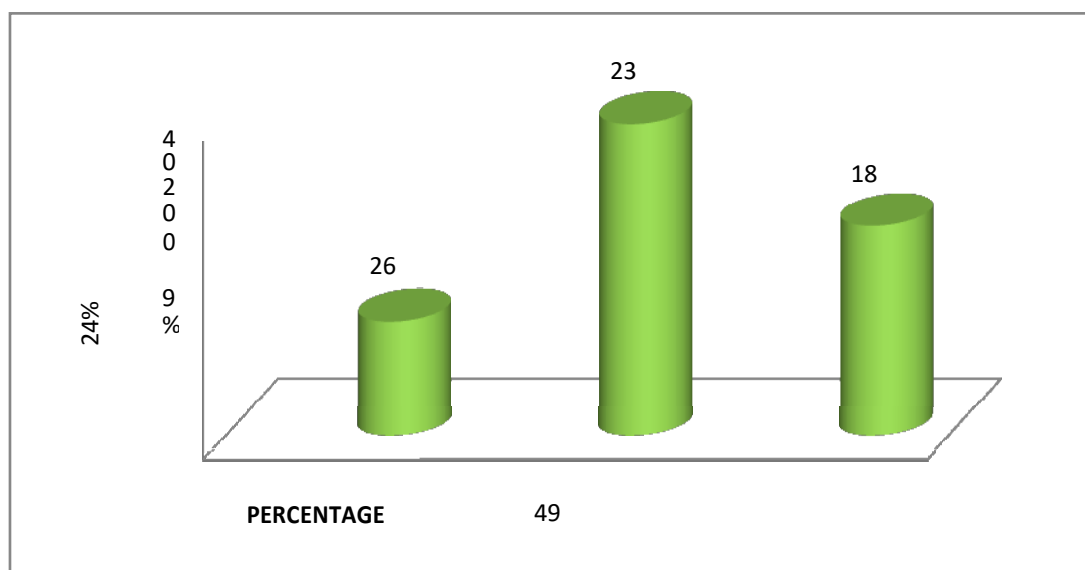
Fig:-20

TREATMENT OUTCOME

Among the 104 patients, significantly higher number of patients in the sample are continuing the treatment(69%).21% of patients got complete relief from the disease and 11% of patients were found to be defaulters(χ^2 = 14.657, df = 2 , p<0.01)

Fig: 21

DISCUSSION

A prospective observational study was carried out for six months among the leprosy patients in two districts in Telanagana (Ranga Reddy and Hyderabad).The study was carried out to determine the prevalence, treatment pattern and drug related problems among the leprosy patients. During our study period 40 cases werereported from Hyderabad district and 64 from Ranga Reddy. So the prevalence of leprosy in Hyderabad and Ranga Reddy district was found to be 0.001 and 0.002 respectively.
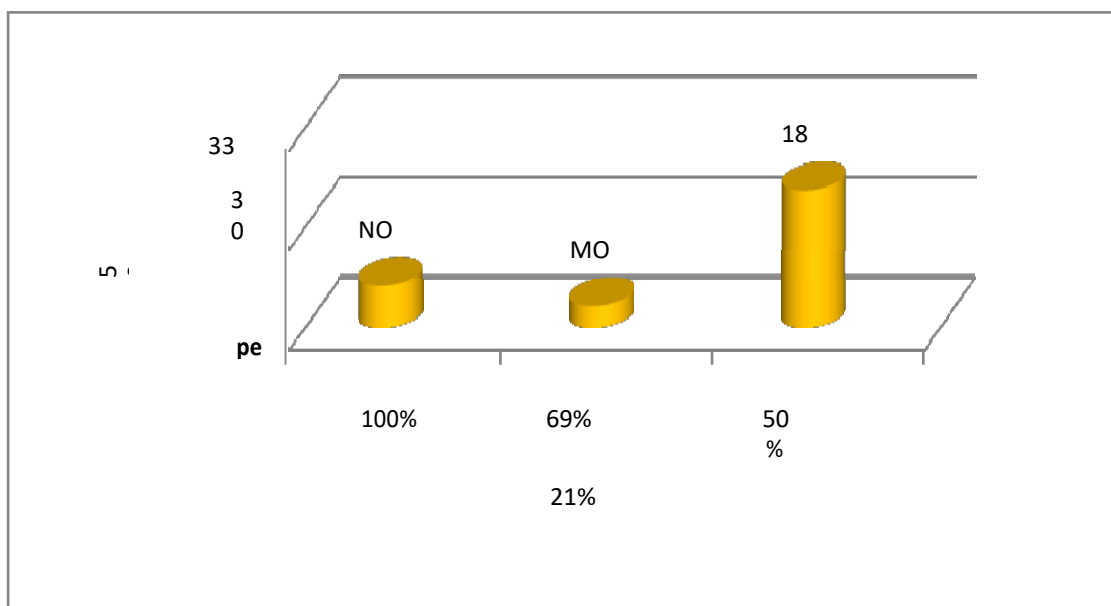
In the current study among among a total of 104 patients included, 49 (47%)were in the age group of 31-50 years. The mean age was 42.13±18.61 years. Nearly 6% of the patients were aged less than 15 showing the transmission is still going on the community. This high prevalence in younger age group calls for more vigorous means of case detection like active search for cases especially in communities known to be leprosy endemic.104 patients were enrolled in the study, of them 74(71%) were males and 30(29%) were females, demonstrating male predominanceover female population. This result is similar to study conducted by B.L Ajibadeet- al in which 79.7% was males.

No significant association could be found out between the residential status of patient and disease. Leprosy, an ancient disease, was thought to be confined to rural and underdeveloped geographical areas. But, on the contrary, our study found no such association, as we found an equal prevalence or incidence of the disease in urban and rural regions.

According to our study, the most prevalent type of leprosy was found to be multibacillary (MB) with 86 cases (83%) while paucibacillary (PB) type accounted for only 18(17%) cases. Similar results were shown in studies conducted by B.L Ajibade et-al and SileshiBaye .The definition of PB leprosy has been evolving over the last two decades, with an increasing number of erstwhile PB patients being included in the MB group for the treatment purpose. This might be one of the important reasons for the progressive shrinking of the pool of PB cases in our study .Male gender (63%) showed significant association with multibacillary leprosy. Considering clinical form of leprosy Borderline tuberculoid (BT) form (75%) was found to be predominant over other forms. These results showed similarity with the study conducted by S.Karat et-al**.**

Hypo pigmented patches were the most common type of cutaneous lesions (84.61%) observed in leprosy patients taking multidrug therapy, followed by loss of sensation over the patches(39.42%) and numbness(31.73%). Madarosis were seen in 6.73% of patients. A nerve involvement affects sensory nerves earliest and most commonly, but it also affects the motor and autonomic function of peripheralnerves. In the present study the most commonly affected nerves are Ulnar (46%) followed by common peronealnerve(26%) , radiocutaneous nerve (15%) and tibial nerve (8%).This findings was similar to thestudyconducted by ShivlalRawlani et-al**.**

Delay in diagnosis of patients augments the transmission of infection, and allows progression of disease and more severe disability. Among the study group 56% of patients had duration of signs and symptoms of leprosy within the range of 1-10 years. Delay in diagnosis greater than 10 years (5%) have been reported. Leprosy related disability is preventable if diagnosed early; but many cases are diagnosed late with

significant physical impairment. This study reveals that 51% of the leprosy patients studied had disability of grade-1 or grade-2. Among those with disability, 30.77% had Grade-1 and 20.19% had Grade-2 disabilities. Among grade-2 disability patients, ulcer (62%) was found to be more prominent followed by claw hands (33.33%), foot drop (14.28%). Lagophthalmous were reported in 9.52% of patients. On the other hand as per the study conducted by ShivlalRawlani et –al[21], disability in the form ofclaw hands(16.7%) was found to be more prominent.The major risk factors known for leprosy disability andphysical deformity are delay in diagnosis, misdiagnosis and delay in provision of proper care for the disease.[8]In the present study we were able to establish a significant association between duration of signs and symptoms and grade of disability.Grase-2 disability was found to be significantly higher in patients whohad delay in diagnosis of leprosy (>10 years).The longer the duration of symptoms the higher thelikelihood of developing nerve damage and sensory loss,both of which subsequently lead todisability. I f patient had chance of being diagnosed early, they could have been cured from the disease before any of the complications appeared.

Among 104 leprosy patients, 31 patients developed lepra reactions. Out of this type1 reaction was found to be significantly higher than type2 reactions.The treatment pattern of leprosy where analysed in the present study. The treatment of leprosy is in the form of multi drug therapy (MDT) which is the combination of 2 or3 of the following drugs. Cap.Rifampicin, Cap.Dapsone, Cap.clofazimine. Out of total 104 patients 74 cases were treated with combination of Dapsone, Rifampicin and clofazimine. (MDT-MB Regimen); Patients were treated with combination of Dapsone and Rifampicin (MDT-PB Regimen). Rifampicin is the most important antileprosy drug and is included in regimens for both paucibacillary (PB) and multibacillary (MB) patients. Treatment of leprosy with only one antileprosy drug may result in development of resistance to that drug. Treatment with Dapsone or any other antileprosy drug as monotherapy should be considered unethically. In addition, it would be considerably more hazardous to use the compounds separately.These might be the reasons why the combinations wereprescribed**.**In **our** study few patients (4 %) were not willing to take clofazimine because of cosmeticconcern. Clofazimine can cause hypo pigmentation of skin and face. In these patients clofazimine was replaced with ofloxacin. 2 patients were found to be allergic to rifampicin, so the drug was stopped and an alternative regimen was started which is a combination of clofazimine, ofloxacin and minocycline. Other antibiotics (24 %) such as ciprofloxacin, azithromycin, metronidazole, amoxicillin – cloxacillin combinations were prescribed in exacerbative cases. A few patients developed fungal infections like onychomycosis, lichened lesions etc and were managed using antifungal drugs (clotrimazole, miconazole, fluconazole etc)

Lepra reactions were managed in our study by using analgesics, corticosteroids and thalidomide. In type-1 lepra reactions, mild reactions with no evidence of neuritis was managed with analgesics such as paracetamol and diclofenac.Type-1 Reactions with nerve involvement where treated with combinations of analgesics and corticosteroids such as oral prednisolone.The dose is then gradually reduced weakly and eventually stopped.Type-2lepra reactions (Erythema nodosumleprosum) were treated with analgesics and corticosteroids; or thalidomide.According to WHO the frequency of adverse reactions caused by MDT

is very low, and when such reactions occur, the standard regimen should simply be adjusted, so that treatment can be continued. During the study period a total of 73 adverse drug reactions Were identified. The most common adverse drug reaction was anaemia (33%) followed by hepatic abnormalities (22%), pedal oedema (11%).Dapsone Syndrome was reported in 5% of patients. On contrary, the study conducted by Harminder Singh et al revealed thatflulike illness was found to be more prominent over other adverse drug reactions. Haemolyticanaemia was defined as reduction of haemoglobin from base line to the end of 30 – 90 days (< 12 .7 g/L for men and <11.5 g/L for women).Iron and folate supplements were given topatient (26 %) who had baseline low hemoglobin. Hepatic abnormalities were defined as any alterations at liver function tests with or without clinical evidence of jaundice, malaise and other symptoms. Liver protectants (9 %) such as silymarin 75 mg and UDCA 150 mg were given to patients who had altered LFTs. Flu-likeillness include fever, runny nose,sore throat, cough, muscle/joint aches, and malaise. Gastrointestinal manifestations were managed using

H2receptorantagonists(ranitidine)orprotonpumpinhibitors(pantoprazole, omeprazole)Management of hypersensitivity reactions were done through the use ofanti- histaminics (cetrizine and chlorpheniramine maleate) in 18 % of patients.Adhering to a treatment schedule and successfully completing it are crucial to the control of any disease. In our study majority of patients (49 %) were found to be moderately adherent to multi –drug therapy.33 % of patients showed highadherence. Non – adherence were reported in 18 % of patients. Significantly higher numbers of patients in the sample are continuing the treatment (69%).21% ofpatients successfully completed the treatment and 11% of patients were found to be defaulter. On the other hand, the study conducted by PSSRao revealedsignificantly higher number of defaulters.

The reasons for defaulting or non – adherence may bePersonal factors- stigma and other social, psychological reasons and economic reasons such as travel costs, loss of wages,etc.

(a) Medical problems such as worsening of the disease, non - disappearance of patch or other symptoms, or even a feeling that they have been cured as their symptomsdisappeared.

(b) Health service related factors. - includes complaints about health staff behaviour, lack of proper instructions or guidance, drug shortage,etc.

CONCLUSION

Leprosy is a chronic disease caused by bacteria Mycobacterium leprae that causes damage to skin and peripheral nervous system. The disease develops slowly and results in skin lesion and deformities, most often affecting the cooler places on the body.

A prospective observational study was carried for a period for 6 months among the leprosy patients in two districts in Telanagana.The total number of cases collected for the study purpose was 104 and the findings of the study reveals that most of the patients were in the age group of 31-50 years and the male patients were predominant over the female population. The most prevalent type of leprosy was found to be multi - bacillary (MB) and among these MB cases, borderline tuberculoid was most commonly reported. Hypo pigmented patches were the most common type of cutaneous lesions observed in leprosy patients taking multidrug therapy. The finding of the study also illustrates that delay in diagnosis of patients augments the transmission of infection, and allows progression of disease and more severe disability.74% of the Multi - bacillary patients were treated with MDT-MB regimen with Dapsone, Rifampicin and Clofazimine and 16% of the paucibacillary patients were treated with MDT-PB regimen with Dapsone and Rifampicin. The most common ADR found by using the MDT regimen was anemia and it was managed by using iron supplements. Adverse effects attributed to MDT are comparable to previous studies and we found that ADR due to Dapsone was very high. If patients are properly informed about the common ADR and are advised to report to their health care provider if and when ADRs occur, and are appropriately motivated about the benefits of MDT, most can be managed by MDT only with supportive treatment, without replacing the suspected drug, except in few cases withserious, complicated or life threatening ADR. The continuing occurrence of new cases means that the first priority is the need for these cases to be detected early andtreated effectively to cure leprosy and prevent disability. If we fail to do this thenthe prevalence of leprosy will start to increase and all that has been achieved will belost. MDT introduction came with additional benefits such as an intense monitoring of patients, coverage of affected populations, and improvement of the closeness between leprosy patients and medical care, and that leprosy changed intoa curable disease. There are three important principles for leprosy work in the future. It includes;Sustainability (new cases of leprosy are continuing and many of the consequences are lifelong so our approaches need to be sustainable) , theleprosy workers cannot do everything themselves(they need to work in alliances at all levels with other agencies, other health care workers, social services,communities, patients themselves and their families),Anti-leprosy services need to be integrated with general health and social services(this includes training, primary health care, hospital care, and community based rehabilitation) Finally we would like to emphasize the importance of a proper health education, daily ulcer care and shoe adjustments as systemic therapy and also to prevent the development of new ulcers.

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