

A Prospective observational Study on Use of Antimicrobials in The Department of Dermatology, Venereology And Leprosy At Rajah Muthiah Medical College Hospital

*Glory Maria John¹, Nissy.K.Chерian¹, Maram Pragna Bharathi¹
Dr.R.T.Saravanakumar¹, Dr.P.K.Kavirasan²

¹Department Of Pharmacy, Annamalai University, Annamalai Nagar, Tamilnadu, India

²Department Of Dermatology, Venereology & Leprosy At Rajah Muthiah Medical College, Annamalai University, Annamalai Nagar, Tamilnadu, India

Corresponding Author: *Glory Maria John

Abstract : Antimicrobials are probably one of the most successful forms of chemotherapy in the history of medicine. New resistance mechanisms emerge and spread globally threatening our ability to treat common infectious diseases, resulting in death and disability of individuals. In this context, this prospective observational study observes the use of antimicrobials in the department of DVL at RMMCH, Annamalai university, Tamil nadu, period of study 6 months; Between November 2015 and April 2016. The sample size comprised of 500 patients, who satisfied the inclusion and exclusion criteria. The objectives of the study are to observe the usage of antimicrobials, including duration and route of administration, the empirical antimicrobials prescribed, drug utilization studies, and incidence of adverse events. The study also includes incidence of prevalent pathogens and the pattern of resistance. 2000 patients were screened and out of this 510 patients were found to be exposed to Antimicrobial drug therapy. Our study shows that Male patients and patients of the age group 13-25 were mostly affected with dermatological disorders. Majority of the patients were diagnosed with fungal infections. Combination therapy were preferred. The Major organism isolated were *Staphylococcus aureus*. 53 patients experienced Adverse Drug Reaction, most being diarrhea.

Keywords: Antimicrobials, Antifungals, Dermatology, Resistance, Sensitivity

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I. Introduction

Antimicrobials are probably one of the most successful forms of chemotherapy in the history of medicine. The inevitable consequence of widespread use of antimicrobial agents has been the emergence of antibacterial resistance pathogens, fueling an ever increasing need for new drugs and contributing to the rising costs of medical care. Moreover, the pace of antimicrobial drug development has dramatically slowed during the last decade, with only a handful of new agents⁽¹⁾. The use and misuse of antimicrobial drugs accelerates the emergence of drug-resistant strains. Antibiotics have a significant role in dermatology, treating a wide range of diseases, including acne, rosacea, inflammatory skin conditions, and skin structure infections, such as cellulitis, folliculitis, carbuncles, and furuncles⁽²⁾. The dermatology, venereology & leprosy department is an area of health care which essentially needs antimicrobials to fight infectious diseases. The study observes the current prescribing pattern of antimicrobials in the DVL department. Growing antimicrobial resistance is a global concern and the resistant strains must be identified to hamper the spread of resistance⁽³⁾. So the study also observes the major pathogens and their resistance pattern against the antimicrobials prescribed. This helped to give an insight of the organisms that have show 100% resistance towards the medication and also the pathogens that are gaining resistance slowly, with such information the prescribing pattern can be more effective for the patient. Optimal use of antimicrobials is essential in the face of escalating antibiotic resistance, and requires cooperation from all sectors of the health care system⁽⁴⁾.

II. Methods And Materials

The study was conducted in the Department of dermatology, venereology and leprosy, Rajah Muthiah Medical College Hospital, a 1260 bedded multi-specialty tertiary care teaching hospital, Tamil Nadu. It is a non-invasive study. The period of study was 6 months from November 2015 to April 2016. The data required was collected from the patients and their prescriptions (from inpatients and outpatients) of dermatology, venereology and leprosy Department in RMMCH. Various tool used includes Data collection form and Voluntary ADR reporting form. Ethically approved.

Inclusion criteria

- ❖ Patients of all age group
- ❖ Patients of both the genders

Exclusion criteria:

- ❖ Pregnant and lactating women
- ❖ Patients not willing to cooperate
- ❖ Immunosuppressive patients.

III. Results

For this study we have screened 2000 patients and out of this 510 patients were prescribed with antimicrobials in the Department Of Dermatology, Venereology and Leprosy who were enrolled into the study based on the selection criteria after obtaining their consent.

Table 1: Prevalence Of Antimicrobial Drug Usage

| | |
|---------------------------------|------|
| Total Population Screened | 2000 |
| Study Population Exposed To Amd | 510 |

Figure 1: Prevalence Of Antimicrobial Drug Usage

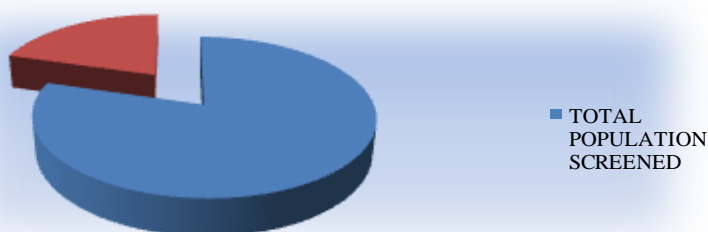


Table 2: Gender Wise Distribution

| Gender | No. Of Patients | Percentage |
|--------|-----------------|------------|
| Male | 294 | 57.6% |
| Female | 216 | 42.3% |
| Total | 510 | 100% |

Table 3: Age Wise Distribution

| AGE GROUP | NO. OF PATIENTS | PERCENTAGE (%) |
|-----------|-----------------|----------------|
| 0-12 | 66 | 12.9% |
| 13-25 | 186 | 36.4% |
| 26-45 | 128 | 25.0% |
| 46-60 | 93 | 18.2% |
| 60 ABOVE | 37 | 7.25% |
| TOTAL | 510 | 100% |

Table 4: Disease Distribution

| DISEASES | NO. OF PATIENTS | PERCENTAGE (%) |
|---|-----------------|----------------|
| Fungal Infections | 146 | 28.6% |
| Dermatitis and Eczema | 92 | 18% |
| Scabies | 77 | 15% |
| Papulosquamous and Skin Appendage Disorders | 63 | 12.30% |
| Bacterial Infections | 35 | 6.80% |
| Leprosy | 21 | 4.10% |
| Viral Infection | 18 | 3.50% |
| Urticaria | 15 | 1.10% |
| Bullous Disorder | 6 | 2.90% |
| Insect Bite | 4 | 0.70% |
| Ulcer | 4 | 0.70% |
| Vaginal Disorder | 2 | 0.30% |
| STD | 1 | 0.10% |

| | | |
|---------------|-----|------|
| Miscellaneous | 26 | 5% |
| TOTAL | 510 | 100% |

Figure 2: Distribution Of Antimicrobials In Diseases

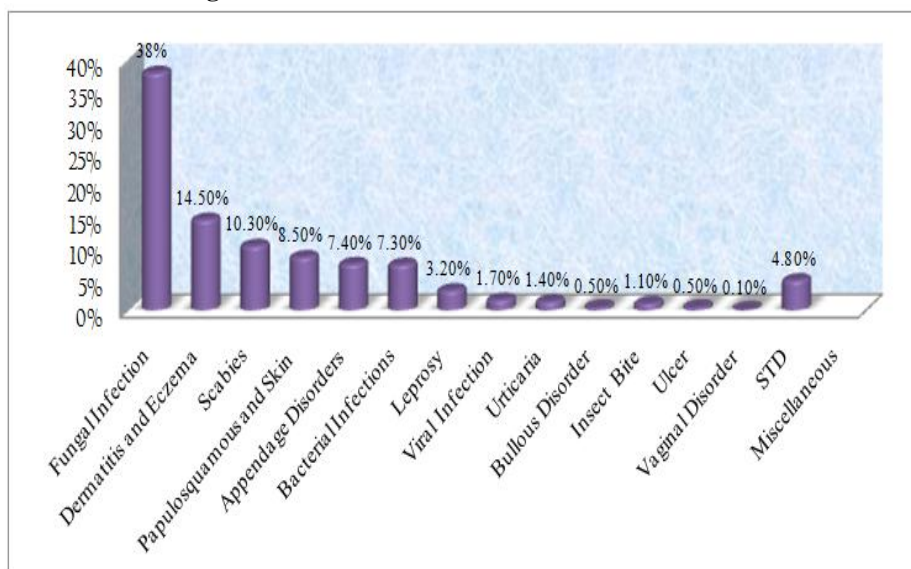


Table 5 : Number Of Antimicrobial Drugs Per Prescription

| Number Of Antimicrobials | Number Of Prescription | Percentage(%) |
|--------------------------|------------------------|---------------|
| Monotherapy | 221 | 43% |
| Combination Therapy | 289 | 56.5% |

Table 6 : Route Of Administration Of Antimicrobials

| | Oral | Topical | Parenteral |
|-------------|-------|---------|------------|
| No.of drugs | 515 | 384 | 37 |
| Percentage | 54.8% | 40.9% | 3.9% |

Table 7: Duration Of Antimicrobial Therapy In Dvl

| Duration | No. Of Drugs | Percentage(%) |
|-------------------|--------------|---------------|
| Less Than 5 Days | 1 | 2.4% |
| 5-6 Days | 10 | 24.3% |
| 7-14 Days | 23 | 56% |
| More Than 15 Days | 7 | 17% |

Table 8: Distribution Of Drugs Along With Antimicrobials

| Drug Categories | No. Of Drugs | Percentage (%) |
|--|--------------|----------------|
| Antimicrobials | 936 | 43.5% |
| Antihistamines | 352 | 17.67% |
| Haematinics | 159 | 7.9% |
| Emollient & Skin Protectants | 120 | 6.0% |
| Antiulcerants(Proton Pump Inhibitors & H2 Receptor Antagonist) | 108 | 5.4% |
| Scabicides | 94 | 4.7% |
| Corticosteroids | 65 | 3.2% |
| Topical Antipruritic Agent | 54 | 2.7% |
| Acne Treatment Preparations | 37 | 1.8% |
| Analgesics & Antipyretics | 36 | 1.8% |
| Immunosuppressents | 35 | 1.7% |
| Antihypertensives | 18 | 0.9% |

| | | |
|--------|------|------|
| Others | 45 | 2.2% |
| Total | 1991 | 100% |

Table 9: Distribution Of Antimicrobials

| Antimicrobial | No. Of drugs | Percentage (%) |
|---------------------|--------------|----------------|
| Antifungals | 278 | 29.7% |
| Topical antifungals | 222 | 23.7% |
| Antibiotics | 222 | 23.7% |
| Topical antibiotics | 113 | 12% |
| Antileprotics | 58 | 6.1% |
| Antivirals | 21 | 2.2% |
| Anti-tuberculotics | 16 | 1.7% |
| Antimalarials | 1 | 0.1% |
| Antiprotozoals | 5 | 0.5% |
| Total | 936 | 100% |

Figure 3: Empirical Antimicrobials Prescribed

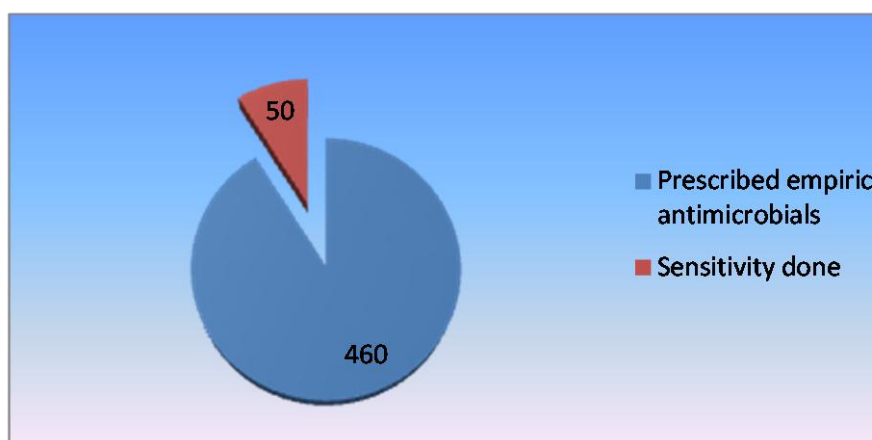


Table 10: Daily Defined Dose Of Commonly Used Antimicrobials

| Antimicrobials | Atc Code | Prescribed Strength | Ddd(Mg) (Atc) | Total Ddds (Mg) | Total Ddds/Ddd(Atc) | Ddd/510 Patients |
|----------------|----------|---------------------|---------------|-----------------|---------------------|------------------|
| Fluconazole | J02ac01 | 150mg | 0.2g | 99750 | 498.75 | 0.97 |
| Terbinafine | D01ba02 | 250mg | 0.25g | 126500 | 506 | 0.99 |
| Ciprofloxacin | J01ma02 | 500mg 250mg | 1g | 200200 | 200.2 | 0.39 |
| Dapsone | J04ba02 | 100mg | 50mg | 62500 | 1250 | 2.45 |
| Cefotaxime | J01dd01 | 1000mg | 4g | 379 | 94.75 | 0.18 |

Table 11: Prevalance Of Pathogens

| ORGANISM | NO. OF PATIENTS | PERCENTAGE (%) |
|---------------------|-----------------|----------------|
| <i>S. aureus</i> | 16 | 32% |
| <i>Pseudomonas</i> | 10 | 20% |
| <i>E. coli</i> | 9 | 18% |
| MRSA | 7 | 14% |
| <i>Klebsiella</i> | 4 | 8% |
| <i>P. mirabilis</i> | 4 | 8% |
| TOTAL | 50 | 100% |

Tab 12: Susceptibility Pattern Of *Staphylococcus Aureus*

| NAME OF DRUG | SENSITIVITY (%) | RESISTANCE(%) |
|--------------|-----------------|---------------|
| Vancomycin | 87.5% | 0% |
| Amikacin | 62.5% | 12.5% |
| Gentamicin | 56.2% | 0% |
| Tetracycline | 43.7% | 0% |

| | | |
|----------------|-------|-------|
| Ciproflaxacin | 37.5% | 43.7% |
| Linezolid | 37.5% | 0% |
| Oxacillin | 31.2% | 62.5% |
| Clindamycin | 25% | 18.7% |
| Ofloxacin | 25% | 31.2% |
| Ceftriaxone | 18.7% | 18.7% |
| Ampicillin | 0% | 43.7% |
| Nalidixic Acid | 0% | 18.7% |

Figure 4: Susceptibility Pattern Of *Pseudomonas*

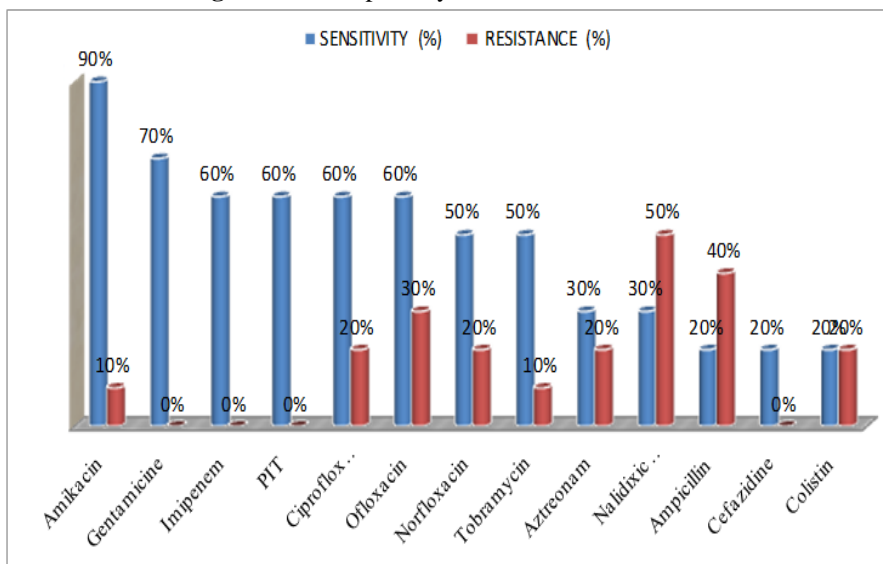


Figure 5: susceptibility pattern of *escherichia . Coli*

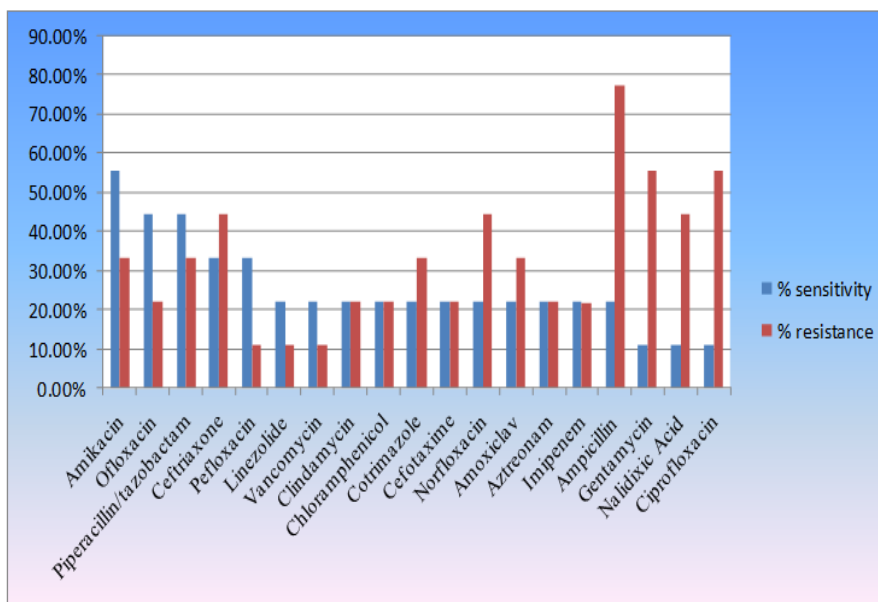


Table 13: Susceptibility Pattern Of *Mrsa*

| NAME OF DRUG | SENSITIVE(%) | RESISTANCE(%) |
|---------------|--------------|---------------|
| Amikacin | 71.4% | 0% |
| Ciprofloxacin | 52.1% | 0% |
| Erythromycin | 52.1% | 14.2% |
| Linezolid | 42.8% | 28.5% |
| Cotrimazole | 42.8% | 0% |
| Ofloxacin | 28.5% | 28.5% |
| Gentamicin | 28.5% | 0% |

| | | |
|--------------------------|-------|-------|
| Piperacillin /Tazobactam | 28.5% | 0% |
| Ceftriaxone | 28.5% | 28.5% |
| Tetracycline | 28.5% | 28.5% |
| Cefotaxime | 28.5% | 0% |
| Pefloxacin | 28.5% | 28.5% |
| Chloramphenicol | 14.2% | 28.5% |
| Ampicillin | 0% | 52.1% |

Table 14: Susceptibility Pattern Of *Klebsiella*

| NAME OF DRUG | SENSITIVE(%) | RESISTANCE(%) |
|----------------|--------------|---------------|
| Ofloxacin | 100% | 0% |
| Ceftriaxone | 100% | 0% |
| Amikacin | 50% | 0% |
| Ampicillin | 0% | 100% |
| Nalidixic Acid | 0% | 100% |
| Gentamicin | 0% | 100% |
| Cefotaxime | 0% | 50% |
| Norfloxacine | 0% | 75% |
| Amoxiclav | 0% | 100% |
| Pefloxacin | 0% | 100% |

Figure 6: Susceptibility Pattern Of *P.Mirabilis*

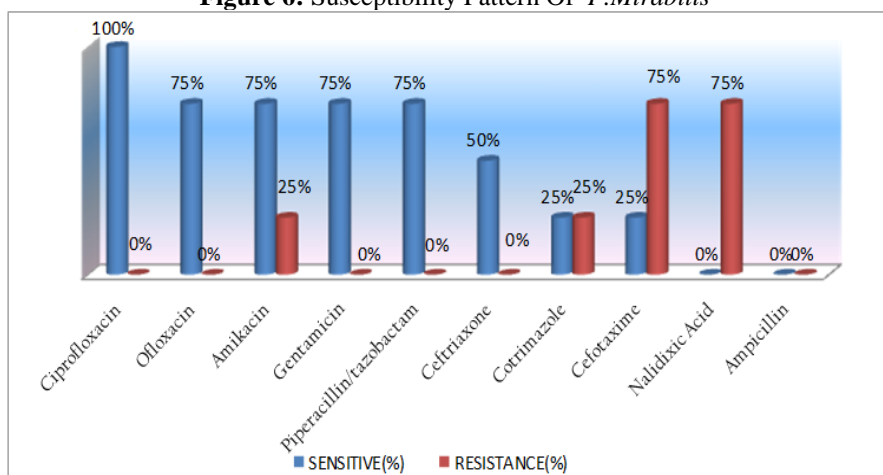


Table 15: Adverse Drug Reaction

| | |
|--------------------------|----------------|
| Total number of patients | number of adrs |
| 510 | 53(10.3%) |

Table 16: Types Of Adverse Drug Reaction

| S.No | Name Of Antimicrobial Drug | Adverse Drug Reaction | No.Of Patients |
|------|-----------------------------|------------------------|----------------|
| 1 | Cefotaxime | Exfoliative Dermatitis | 3 |
| 2 | Amoxicillin/Clavulanic Acid | Diarrhoea | 3 |
| 3 | Erythromycin | Diarrhoea | 2 |
| 4 | Amoxicillin | Diarrhoea | 2 |
| 5 | Ciprofloxacin | Diarrhoea | 1 |
| 6 | Cefixime | Diarrhoea | 1 |
| 7 | Cefotaxime | Diarrhoea | 1 |
| 8 | Azithromycin | Nausea | 2 |
| 9 | Miconazole | Burning | 3 |
| 10 | Dapsone | Headache | 7 |
| 11 | Acyclovir | Pruritis | 4 |
| 12 | Rifampicin | Pruritis | 2 |
| 13 | Fluconazole | Abdominal Pain | 8 |
| 14 | Ciprofloxacin | Constipation | 1 |
| 15 | Clotrimazole | Erythema | 3 |
| 16 | Ampicillin | Rashes | 2 |
| 17 | Ketoconazole | Stinging | 4 |

IV. Conclusion

The aim of the study was to observe the use of antimicrobials and their prescription pattern in the department of Dermatology, Venereology & Leprosy from the sample size. Among the patients who visited the DVL Department, 2000 patients were screened and out of this 510 patients were found to be exposed to AMD. Thus the prevalence of exposure to AMD at the given point of time was found to be 0.25% or 255/1000 patients. (TABLE 1 & FIGURE 1)

4.1 Patient Demographics:

We observed that in our sample population, 57.6% were Male while 42.3% were Female, which complies with the study by Khan NA et al. (2009) in the same hospital, we can see an increase of male patients and slight increase of female patients when the studies are compared⁽⁴⁾ (TABLE 2). The Age distribution shows that maximum number of patients belongs to the Age Group 13-25, accounting for 36.4% of the total (TABLE 3).

4.2 Prescribing pattern of antimicrobials:

Most of the patients in the Study Population were diagnosed with fungal infections (28.6%) followed by Dermatitis and Eczema (18%) which is similar to the study by GS Rao et al. (2002)⁽⁵⁾ (TABLE 4). Geographical factors such as season and climate contribute to the high incidence of fungal infection in this population. High incidence of scabies (15%) can be explained due to the overcrowding, poor resistance, poverty and also poor living standards of these patients. Out of 936 Antimicrobials prescribed, 35.6% of antimicrobials were prescribed for fungal infections. Average number of Antimicrobials prescribed per prescription was found to be 1.83 (FIGURE 1), this is much lower when compared to the study by Mohammed et al.⁽⁸⁾, which is 2.46. Out of 510 patients 43% of the patients were prescribed with Antimicrobial Monotherapy while Combination therapy of Antimicrobials was prescribed to 56.5% of patients (TABLE 5). So we can conclude that Combination Therapy was used More when compared to Monotherapy, this conclusion is similar with the study by Khan NA et al. (2006)⁽⁴⁾.

Most of the antimicrobial drugs were prescribed Orally followed by topical. Parenteral administration was the least. This is similar to Khan NA et al.⁽⁴⁾ and C.M. Diyashanthi et al. (2014)⁽⁶⁾. Cefotaxime (2.8%) was mostly prescribed in parenteral while fluconazole (14.9%) and ketoconazole (14.7%) dominates in oral and topical route. Most of the antimicrobials in this study was prescribed with a duration of 7-14 days (56%). The duration of therapy, less than 5 days was noticed only in 1 patient (TABLE 7) In our study we observed that Antihistamines (17.67%) were prescribed more along with antimicrobials followed by haematinics (7.9%). Among the antimicrobials prescribed most of the drugs belong to the Category of Antifungals (49.5%) followed by Antibiotics (30.6%) 936 antimicrobials were prescribed during our study period, there was an increased use of antimicrobials when compared with Khan NA et al. (2006). While considering the empirical antimicrobials prescribed cefotaxime was prescribed mostly in In patients while fluconazole tops the chart in Out patients. Sensitivity test were done only for 50 patients.

4.3 Defined Daily Dose

As a part of over study, DDD/510 patients were calculated according to DTC (Drugs and Therapeutic Committee - guide) with Reference from WHO Recommended ATC Classification and found that DDD/510 patients was highest for Dapson (2.45). This indicates that Dapson is most frequently used in this department, and the dosage is similar to the doses recommended by WHO.

4.4 Study Of Sensitivity Pattern Of Microorganism

During the Study a Prospective Analysis was conducted to Check the Sensitivity Pattern of microorganism to Antibiotics. A total of 50 cases were analysed. The Major organism isolated were *Staphylococcus aureus* (32%), *E. coli* (18%), *MRSA* (14%), *Klebsiella* (8%), *P. mirabilis* (8%). *Staph. aureus* is the major organism isolated which is similar to the pattern of organism isolated in study conducted by Arthur et al.

The Study shows that *staph. aureus* was sensitive to Vancomycin (87.5%) and have developed resistance to Ciprofloxacin. Sensitivity pattern shows that *Pseudomonas* was highly sensitive to amikacin and have Started Developing resistance to Nalidixic acid. *E. coli* was moderately sensitive to Amikacin (55.5%) and Ofloxacin (44.4%) and have developed Resistance to Ampicillin (77.7%). *MRSA* was sensitive to Amikacin (71.4%) and Developed resistance to Ampicillin (52.1%). In our study Ofloxacin and Gentamicin were Highly sensitive to *klebsiella* and is completely resistant to Ampicillin and Gentamicin. In the case of *P. mirabilis*, it depicted high rates of sensitivity towards Ciprofloxacin (100%) and 75% of Resistance towards Cefotaxime

It can be seen that the three microorganism, Pseudomonas, MRSA and e.coli are highly sensitive towards Amikacin. Staph aureus is highly sensitive towards vancomycin, while klebsiella and P.mirabilis shows high sensitivity towards ciprofloxacin and ceftriaxon. The most recent worldwide estimates of global antibiotic resistance, published by the World Health Organization (WHO) in 2014, list *Escherichia coli*, *Klebsiella pneumoniae*, and *Staphylococcus aureus* as the three agents of greatest concern⁽⁸⁾, and from our data we concluded that *klebsiella* has evolved completely resistance towards Gentamicin, Nalidixic acid, ampicillin, Amoxiclav and PF. While *staph aureus* has started evolving resistance towards Oxacillin and *E.coli* towards Ampicillin.

4.5 Adverse Drug Reaction

Out of 510 Patients 53 patients experienced Adverse Drug Reaction. The most common ADR observed was Diarrhoea, and the observed drug reaction was rated as 'PROBABLE' on the NARANGO'S Scale For Causality Assessment. Skin diseases in developing countries have a serious impact on people's quality of life, it is more so in India where climate, socio-economic status, religions and customs are widely varied in different parts of the country⁽⁹⁾. In our study population Males were more in number with Mycoses being diagnosed the most. Among the prescribed antimicrobials antifungals were the highest. Oral was the preferred route of administration. The statistics shows that antimicrobials are the most prescribed drugs in DVL, which implies that antimicrobials play a pivotal role in treating dermatological disease, and in the case of therapy considered, Combination Therapy is preferred for treating skin diseases. Unfortunately, we have come to expect that antibiotics will offer an answer for practically every symptom, ailment or concern. We have used these "miracle" drugs far too indiscriminately and inappropriately. We now understand all too well that this casual behavior, including misuse and overuse, has helped those microbes adapt and survive in new and less treatable forms.

4.6 Limitation of The Study:

Treatment responses and long term side effects of the treatment could not be assessed because of the limited follow up period. Up to 80% of the population contracted with skin problems may not seek medical help

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