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Research Article

A STUDY TO COMPARE THE EFFECTIVENESS OF EMPIRICAL VERSUS EVIDENCE BASED ANTIBIOTIC THERAPY IN THE INPATIENTS OF TERTIARY CARE HOSPITAL

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ABSTRACT

The study was to assess the Prescribing pattern, sensitivity Pattern and to compare the effectiveness of empirical versus evidence based antibiotic therapy in the infected patients. The subject with infection, their laboratory and culture report was to assess the incidence of antimicrobial resistance and sensitivity pattern. Prescription pattern of antibiotics, Sensitivity and resistance pattern of pathogen was analyzed by percentage. Blood parameters of each group was compared by student t test. A total of 107 prescriptions were analyzed. From this 69 patients (64.48%) were treated with empiric therapy and 38 patients (35.51%) were treated with definitive therapy. Out of 199 antibiotics Penicillin (26.63%), Fluoroquinolones (25.12%) and Cephalosporins (21.6%) were mostly prescribed. Most sensitive and resistant drugs were identified in isolated organisms. Comparison between empirical versus evidence based therapy was carried out by analyzing laboratory values. Judgmental use of antibiotic's reduce the burden of multidrug resistance and thereby enabling better patient management and limiting the resultant morbidity and mortality. Proper guidelines, supervision of antibiotic usage and constant information to the medical practitioners regarding the sensitivity pattern can helps to prevent drug resistance. Proper selection of therapy will improve quality of life

INTRODUCTION

Antibiotics have always been considered one of the wonder discoveries of the 20th century. The advent of modern antibiotics contributed enormously to the dramatic extension of human lifespan since their discovery by virtue of their lethal and selective action against pathogenic microbes. And yet despite our powerful arsenal of weapons against these pathogens, the war against them has not been won.

"An antibiotic is a chemical substance, produced by microorganism which has the capacity to inhibit the growth of and even to destroy bacteria and other microorganisms". Antibiotics are essential to modern medicine and antibiotic resistance is a global, urgent threat to human health. The urgency of this situation has spawned a plethora of new multi-disciplinary research initiative looking for novel antibiotics and other antimicrobial agents. The relation between antibiotic resistance and antibiotic exposure is unambiguous both at the population level and in individual patients. Treatment can be tailored to the pathogen and its resistance profile once cultures are available, treatment typically needs to be initiated immediately. This treatment phase is called empirical therapy. Mortality related to serious infections in intensive care units is highest, if empirical therapy is not active against the organism causing the infection. However, excessive empirical therapy undoubtedly contributes to bacterial resistance to antibiotics in turn potentially contributing to poor patient outcome. Three strategies that are increasingly practiced to reduce the hazards of broad empirical therapy, while aiming to ensure that empirical therapy is adequate. The most widely used strategy is discontinuation or streamling of empirical therapy when culture results are available. The second approach is to withdraw certain antibiotic classes (3rd generation Cephalosporins) from the ICU antibiotic armamentarium. The third strategy employed is antibiotic cycling.

Evidence based medicine is the conscientious, judicious, explicit and reasonable use of modern, best evidence in making decisions about the care of individual patients. EBM integrates clinical experience and patient values with the appropriate available research information. Drug of choice for definitive therapy is most effective, least toxic, narrowest spectrum and most cost effective agent. Therapy is aimed at the causal

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pathogen of known antimicrobial sensitivity. However once the laboratory results of microbiology tests are available with identification of pathogen along with antimicrobial susceptibility data, every attempt should be made to narrow the antibiotic spectrum.

Antibiotic resistance refers to unresponsiveness of a microorganism to an antimicrobial agent, and is akin to the phenomenon of tolerance seen in higher organisms. Resistance occurs when bacteria change in some way that reduces or eliminates the effectiveness of drugs, chemicals or other agents design to cure or prevent the infection. Thus the bacteria survive and continue to multiply causing greater harm. Bacterial susceptibility to antimicrobial agents is achieved by determining the minimum inhibitory concentration inhibits the growth of bacteria.

With the growing global problem of antibiotic resistance it is crucial that clinicians use antibiotics wisely, which largely means following the principles of antimicrobial stewardship (AMS). As no fundamentally new classes of antibiotics have been discovered in recent decades, treatment of infections must currently rely on the available agents. However, infections producing bacteria are increasingly developing resistance to many routinely used antibiotic groups and even to 'last resort' agents. Antimicrobial stewardship program interventions have been shown to improve individual patient outcomes, reduce the overall burden of antibiotic resistance and save health care dollars. The National Action Plan for combating antibiotic resistant bacteria states that by 2020 an antimicrobial stewardship program will be established in all acute care hospitals improving antibiotic stewardship across all health care settings.

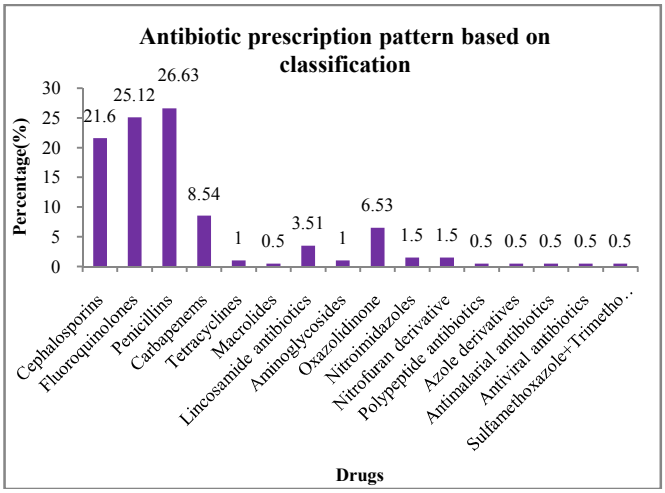
MATERIALS AND METHODS

A prospective observational study was carried out in 193 patients. Out of this 107 subjects were included in the study based on inclusion criteria such as prescription containing at least one antibiotic or laboratory investigation with signs of infection and at least 3 to 8 days of hospital stay.86 patients were excluded from the study based on exclusion criteria, due to patient receiving prophylactic antibiotic therapy undergoing surgery and immunocompromised patients. Subject demographic and treatment details were collected by using designed data collection form. The subject with infection, their laboratory and culture report was to assess the incidence of antimicrobial resistance and sensitivity pattern. Prescription pattern of antibiotics, sensitivity and resistance pattern of pathogen was analyzed by percentage. Blood parameters of each group was compared by student t test in Graph Pad Instat software version3.10. Results were expressed in mean ± SD. The mean difference was considered significant at confidence interval of 95% ($P < 0.05$).

RESULTS AND DISCUSSION

The study was conducted on 107 subjects in the department of General Medicine, Urology, Cardiology and Orthopedics at a 300 bedded tertiary care hospital. Among the 193 patients analyzed, 107 patients were selected based on the inclusion criteria, Males were 67(62.61%) and females were 40 (37.38%).Based on age wise distribution, 2 subjects (1.86%) were in the age group of 11-20 years, 6 subjects (5.6%) were in the age group of 21-30 years, 7 subjects (6.54%) were in the age group of 31-40 years, 11 subjects (10.28%) were in the age group of 41-50, 24 subjects (22.42%) were in the age group of 51-60, 29 subjects (27.1%) were in the age group of 61-70, 23 subjects (21.49%) were in the age group of 71-80, 4 subjects (3.73%) were in the age group of 81-90,1 patient (0.93%) was in the age group of above 91.Age distribution shows that subjects in the age group of 61-70 were more prone to infection. In this 69 subjects (64.48%) were treated with empiric therapy and 38 subjects (35.51%) were treated with definitive therapy.

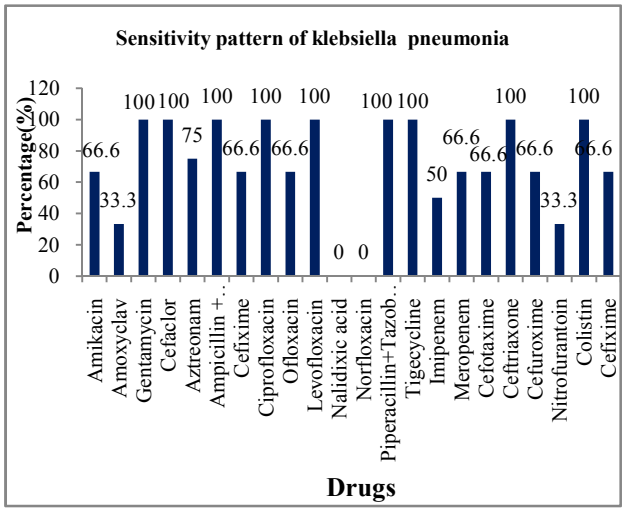
Prescribing Pattern of Antibiotics Based on Classification



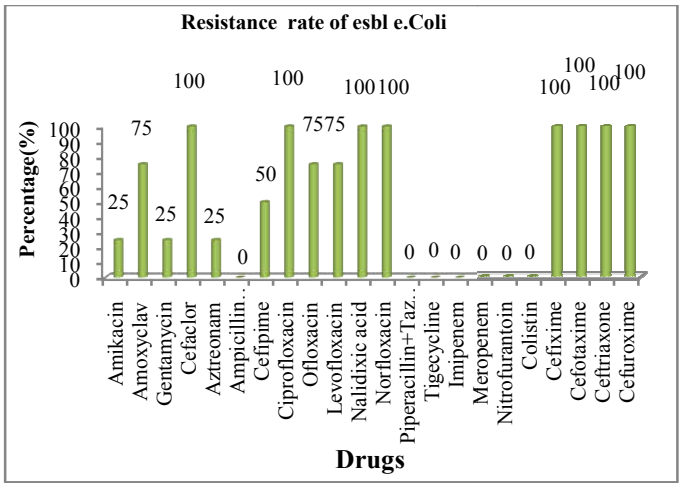
Sensitivity and Resistance Pattern of Pathogens

Between Jan 2017 to July 2017 a total number of 38 samples were analyzed for isolation and identification of bacteria and antimicrobial susceptibility testing. Sensitivity carried out in E.coli, Pseudomanas aeruginosa, Klebsiella pneumonia, ESBL E.coli, Klebsiella species with E.coli, Methicillin sensitive staphylococcus aureus and Streptococcus Species.

Most Sensitive Organism-Klebsiella Pneumonia



Most Resistant Organism-Esbl E.Coli



Comparison of empiric and definitive therapy Within group and with different groups

107 patients were categorized under five disease conditions such as Urinary tract infection, Sepsis, Chronic kidney disease with sepsis, Respiratory infections, and cellulitis.

This study mainly focused on the parameters like WBC, Monocytes, Polymorphs, Lymphocytes, Absolute Eosinophil count and variations among those parameters in blood cells. On premise of this laboratory investigations, Comparison between empiric and definitive therapy within the group and with different groups were analyzed.

Assessment of wbc
Empirical therapy

Sl.no	Diseases	Baseline	Endpoint	Mean diff
1	UTI	13283.33 ± 3590.38	11777.78 ± 2301.03**	1505.55 ± 1289.35
2	SEPSIS	16540 ± 5210.50	12910 ± 3187.63**	3630 ± 2022.87
3	CKD/SEPSIS	15428.57 ± 4149.98	11728.57 ± 1579.78*	3700 ± 2570.2
4	RESP	15978.57 ± 6072.78	11514.29 ± 2672.32**	4464.28 ± 3400.46
5	CELLULITIS	14500 ± 2060.74	11550 ± 404.14*	2950 ± 1656.6

Evidence Based Therapy

Sl.no	Diseases	Baseline	Endpoint	Mean diff
1	UTI	21542.86 ± 4852.05	10957.14 ± 1193.86**	10585.72 ± 3658.19
2	SEPSIS	15766.67 ± 2040.42	11433.33 ± 1900.87**	4333.34 ± 139.55
3	CKD/SEPSIS	28000 ± 2545.58	17650 ± 919.23*	10350 ± 1626.35
4	RESP	14875 ± 5487.18	10275 ± 3106.31*	4600 ± 2380.87
5	CELLULITIS	16022.22 ± 3281.30	10844.44 ± 1036.95**	5177.78 ± 2244.35

Empirical Versus Evidence

Sl.no	Diseases	Mean diff (emp)	Mean diff(evi)
1	UTI	1505.55±1289.35	10585.72±3658.19**
2	SEPSIS	3630±2022.87	4333.34±139.55^{ns}
3	CKD/SEPSIS	3700±2570.2	10350±1626.35**
4	RESP	4464.28±3400.46	4600±2380.87^{ns}
5	CELLULITIS	2950±1656.6	5177.78±2244.35^{ns}

Assessment of lymphocyte
Empirical therapy

Sl.no	Diseases	Baseline	Endpoint	Mean diff
1	Uti	20.5 ± 11.02	23.05 ± 8.99 **	2.55 ± 2.12
2	Sepsis	24.8 ± 12.20	29.6 ± 12.98**	4.8 ± 0.78
3	Ckd/Sepsis	26.14 ± 14.97	29.71 ± 11.94*	3.57 ± 3.03
4	Resp	15.92 ± 5.19	20.57 ± 4.63**	4.65 ± 0.56
5	Cellulitis	11.75 ± 6.23	19.5 ± 5.80**	7.75 ± 0.43

Evidence Based Therapy

Sl.no	Disease	Baseline	Endpoint	Mean diff
1	Uti	54.57 ± 27.54	38.85 ± 13.99*	10585.72 ± 3658.19
2	Sepsis	13.33 ± 5.50	24.66 ± 7.02^{ns}	4333.34 ± 139.55
3	ckd/Sepsis	18.5 ± 0.70	36 ± 8.48^{ns}	10350 ± 1626.35
4	Resp	15.5 ± 2.64	23.5 ± 9.88^{ns}	4600 ± 2380.87
5	Cellulitis	15.11 ± 2.47	22 ± 1.73**	6.89 ± 0.74

Empirical Versus Evidence

Sl.no	Diseases	Mean diff (emp)	Mean diff(evi)
1	Uti	2.55 ± 2.12	15.72 ± 13.55*
2	Sepsis	4.8 ± 0.78	11.33 ± 1.52^{ns}
3	Ckd/sepsis	3.57 ± 3.03	17.5 ± 7.78^{ns}
4	Resp	4.65 ± 0.56	8 ± 7.24^{ns}
5	Cellulitis	7.75 ± 0.43	6.89 ± 0.74^{ns}

Assessment of monocyte
Empirical therapy

Sl.no	Diseases	Baseline	Endpoint	Mean diff
1	Uti	3.84 ± 1.29	2.83 ± 0.70 **	1 ± 0.59
2	Sepsis	3.8 ± 1.39	2.6 ± 0.84*	1.2 ± 0.55
3	Resp	4.57 ± 2.06	6.25 ± 1.55**	2.85 ± 0.51
4	Cellulitis	6 ± 2.16	4 ± 1.63**	2 ± 0.53

Evidence Based Therapy

Sl.no	Disease	Baseline	Endpoint	Mean diffrence
1	Uti	7.42 ± 3.10	4 ± 1**	3.42 ± 2.1
2	Sepsis	4 ± 1	2.66 ± 0.57^{ns}	1.34 ± 0.43
3	Resp	6.25 ± 1.55	3.75 ± 2.21^{ns}	2.5 ± 1.26
4	Cellulitis	5.77 ± 2.33	3.22 ± 0.66**	2.55 ± 1.67

Empirical Versus Evidence

Sl.no	Diseases	Mean diff (emp)	Mean diffrence (evi)
1	Uti	1 ± 0.59	3.42 ± 2.1*
2	Sepsis	1.2 ± 0.55	1.34 ± 0.43^{ns}
3	Resp	2.85 ± 0.51	2.5 ± 1.26^{ns}
4	Cellulitis	2 ± 0.53	2.55 ± 1.67*

Assessment of polymorphs
Empirical therapy

Sl.no	Diseases	Baseline	Endpoint	Mean diffrence
1	Uti	74.94 ± 7.32	73.44 ± 5.86 **	1.5 ± 1.46
2	Sepsis	68.8 ± 9.00	74 ± 4.42*	5.2 ± 4.58
3	Ckd/sepsis	71.42 ± 12.24	68 ± 10.80*	3.42 ± 1.44
4	Resp	77 ± 7.09	72.92 ± 4.82**	4.08 ± 2.27
5	Cellulitis	80.5 ± 7.54	76 ± 5.29**	4.5 ± 2.25

Evidence Based Therapy

Sl.no	Disease	Baseline	Endpoint	Mean diffrence
1	Uti	78.14 ± 11.9	69.71 ± 7.69**	8.43± 4.21
2	Sepsis	76 ± 5.19	69.66 ± 5.68*	6.34 ± 0.49
3	Ckd/sepsis	79.5 ± 2.12	74 ± 1.41^{ns}	5.5 ± 0.71
4	Resp	81 ± 3.36	75 ± 2.16*	6 ± 1.2
5	Cellulitis	80.33 ± 2.78	70.33 ± 5.19**	10 ± 2.41

Empirical Versus Evidence

Sl.no	Diseases	Mean diff (emp)	Mean diffrence (evi)
1	UTI	1.5 ± 1.46	8.43 ± 4.21**
2	SEPSIS	5.2 ± 4.58	6.24 ± 0.49^{ns}
3	CKD/SEPSIS	3.42 ± 1.44	5.5 ± 0.71^{ns}
4	RESP	4.08 ± 2.27	6 ± 1.2^{ns}
5	CELLULITIS	4.5± 2.25	10 ± 2.41^{ns}

Assessment of absolute eosinophil count
Empirical therapy

Sl.no	Diseases	Baseline	Endpoint	Mean diffrence
1	Uti	527.41 ± 124.44	488.11 ± 87.38**	80 ± 37
2	Sepsis	534.8 ± 147.92	506.1 ± 126.89^{ns}	28.7 ± 21.03
3	Ckd/sepsis	495.14 ± 69.09	449 ± 27.91*	46.14 ± 41.18
4	Resp	564.78 ± 177.41	459.07 ± 92.30**	105.71 ± 85.11
5	Cellulitis	588 ± 133.34	489.25 ± 67.85*	98.75 ± 65.49

Evidence Based Therapy

Sl.no	Diseases	Baseline	Endpoint	Mean diffrence
1	Uti	636.71 ± 151.20	447.85 ± 11.49**	188.86 ± 139.71
2	Sepsis	488.33 ± 100.06	422.66 ± 85.73^{ns}	65.67 ± 14.33
3	Ckd/sepsis	573 ± 32.52	488.5 ± 12.02*	84.5 ± 20.5
4	Resp	480.5 ± 64.80	436.75 ± 34.98^{ns}	43.75 ± 29.82
5	Cellulitis	645.55 ± 165.86	443.22 ± 41.78**	202.33 ± 124.08

Empirical Versus Evidence

Sl.no	Diseases	Mean diff (emp)	Mean diffrence (evi)
1	Uti	80 ± 37	188.86 ± 139.71*
2	Sepsis	28.7 ± 21.03	65.67 ± 14.33^{ns}
3	Ckd/SEPSIS	46.14 ± 41.18	84.5 ± 20.5^{ns}
4	Resp	105.71 ± 85.11	43.75 ± 29.82^{ns}
5	Cellulitis	98.75 ± 65.49	202.33 ± 124.08^{ns}

The provision of effective antimicrobial therapy in a timely manner and of an appropriate spectrum is one of the mainstays of the treatment of infectious diseases. However, this has led to the widespread use of broad-spectrum antibiotic therapy for the empirical treatment of infections, which may have contributed to the increase in a variety of drug-resistant organisms.

In this prospective observational study, 107 patients were admitted into different departments were analysed over a period of 6 months from January 2017-July 2017. This included 67(62.61%) male and 40(37.38%) female patients.

In this study revealed that the maximum number of hospital admissions were in the age group of 61-70.A study conducted by R Nalini *et al* Sensitivity Pattern of E-coli in Urinary tract infection out of 412 hospital admission most of the patients were in the age group of 60-69 years.

In this study 69(64.48%) patients were treated with empirically and 38(35.51%) patients were treated with definitive therapy. M. Falguera *et al* published a Prospective, randomised study to compare empirical treatment versus targeted treatment on the basis of the urine antigen results in hospitalised patients with community-acquired pneumonia, 89 patients were assigned to empirical treatment and 88 were assigned to targeted treatment This study shows, most frequently prescribed antibiotics are Moxifloxacin (19%), Piperacillin+ Tazobactam (16%), Ceftriaxone (13.5%) and Amikacin (10.55%). B Gowthami *et al*., who prospectively analysed 210 prescriptions in that most commonly prescribed antibiotics were Ceftriaxone (50%),Amoxicillin (29.34%) followed by Piperacillin+ Tazobactam (7.2%).

Out 107 subjects 53 (26.63%) Pencillin class of antibiotics, Fluroquinolones (25.12%) followed by Cephalosporins (21.6%). Despite a previous study of Priyanka Errabelly *et al*., who found that Pencillin + Betalactams 41 (38.31%) for widely prescribed antibiotics followed by Cephalosporins 33 (30.84%).59 Isolation rate of E-coli in the present study was 31.57% and it was commonly isolated from urine samples 83.33%. In this study the overall resistance of E-coli to antimicrobials was high. In all clinical samples, E-coli showed 100% resistance rates to Tetracycline, Erythromycin, Methicillin, Polymyxin B, Nalidixic acid and high sensitivity rates to Levofloxacin (100%), Chloramphenicol (75%). M Kibret *et al*., identified Erythromycin (89.4%), Amoxicillin (86.0%), Tetracycline (72.6%) showed high resistance to E-coli and Nitrofurantoin (96.4%), Gentamycin (79.6%), Ciprofloxacin, Chloramphenicol shows high sensitivity.74 P.aeruginosa were predominantly isolated from pus (62.5%) followed by sputu (25%) sample. The same has been reported in Senthamarai *et al* (47.11%). Most of the antimicrobials like Norfloxacin, Erythromycin, Azithromycin, Polymyxin B were 100% resistant to P.aeruginosa. Piperacillin+Tazobactam (66.66%) and Cefixime (62.5%) were effective antibiotics for P. aeruginosa.

In this study it is observed that Cefotaxime, Vancomycin, Piperacillin+Tazobactam, Nitrofurantoin, Piperacillin, Imipenem were 100% sensitive to Klebsiella with few Ecoli and 100% resistance shows to Amikacin, Cefuroxime. Antimicrobial resistance pattern of Klebsiella with few E-coli analysed by Revathy Saravanan *et al*., the results shows high resistance to Ampicillin, Cotrimoxazole and 3rd generation cephalosporins.

In this study, out of 38 culture 4 of them are ESBL- E.coli. Some of the antibiotics were 100% sensitive to E-coli especially Ampicillin+Sulbactam, Piperacillin+ Tazobactam, Tigecycline, Meropenem, Imipenem, Nitrofurantoin, Colistin and certain antibiotics like Cefaclor, Ciprofloxacin, Nalidixicacid, Norfloxacin, Cephalosporins were 100% resistant. In other Iranic study Rasooi Sottani *et al*., identified that Meropenem, Imipenem, Nitrofurantoin, Piperacillin+Tazobactam are very much sensitive. Except Carbapenems other category of drugs such as β-lactam and Fluroquinolones were almost resistant.

In the present study, it has been observed that Klebsiella pneumonia showed high resistance to few antibiotics like Nalidixicacid (100%), Norfloxacin (100%), Nitrofurantoin (66.66%). Out of 22 antimicrobials tested, 20 antimicrobials showed more than 50% sensitivity. According to the study of antibiotic sensitivity pattern of Klebsiella pneumonia Asati Rakesh Kumar *et al*., observed, out of 24 antibiotic tested Klebsiella pneumonia is showing sensitivity more than 50% only to 4 antimicrobials and remaining 20 are showing less than 50% sensitivity.

In this study Gentamycin, Levofloxacin, Ciprofloxacin, Cotrimoxazole, Vancomycin showed 100% sensitivity and only Penicillin shows 50% resistance to Staphylococcus aureus. In other study Emmanuel Onwubiko Nwankwo *et al*., revealed Levofloxacin, Gentamycin, Ciprofloxacin shows higher sensitivity and Penicillin shows higher resistance.

Makhtar Camara *et al*., assessed antibiotic susceptibility of Streptococcus pyogenes, almost all antibiotics are sensitive and only few are resistant. While comparing with this study the results were similar in this aspect.

In this study, the effectiveness of empirical versus evidence based antibiotic therapy in infected patients, (UTI, Sepsis, Cellulitis, CKD/Sepsis and Respiratory disorders) was evaluated by comparing the blood parameters like WBC, Lymphocyte, Polymorphs, Monocyte and Absolute eosinophil count. In UTI mean difference of empirical and evidence showed extreme significance in blood parameters like WBC

[(Emp-1505.55 ± 1289.35) (Evi-10585.72 ± 3658.19)], Polymorphs [(Emp-1.5 ± 1.46) (Evi-8.43 ± 4.21)] and others significant. By assessing mean difference of empirical and evidence in Sepsis all blood parameters showed non significance. While comparing CKD/Sepsis mean difference of WBC in empirical (3700 ± 2570.2) and evidence (10350 ± 1626.35) shows extreme significance. Others showed non significance. In Respiratory disorders mean difference of all blood parameters in empirical and evidence showed no significant difference. While analysing mean difference of monocyte in empirical (2 ± 0.53) and evidence (2.55 ± 1.67) shows significance. Other parameters showed no significant difference.

M Falguera *et al*., stated that, targeted treatment was associated with a slightly higher overall cost (€1657.00 vs €1617.20, p=0.28), reduction in the incidence of adverse events (9% vs 18%, p=0.12) and lower exposure to broad-spectrum antimicrobials (154.4 vs 183.3 defined daily doses per 100 patient days). No statistically significant differences in other outcome parameters were observed.

M M Vander Eerden *et al*., conducted a study regarding the pathogen directed antibiotic treatment and empirical broad spectrum antibiotic treatment in patients with community acquired pneumonia, they observed no significant differences were found between the two treatment groups in LOS, 30 day mortality, clinical failure, or resolution of fever.

CONCLUSION

The incidence and mortality rates of severe infections are still very high. Moreover, the growing threat of bacterial resistance and the progressive reduction of research into new antibiotics**,** overshadows the future of the fight against infections. We need to preserve the effectiveness of available antibiotics. This can only be achieved if we minimize the development of bacterial resistance**.**

The result of this study showed that most commonly prescribed antibiotics were Penicillins (26.63%), Cephalosporins (25.12%), and Fluroquinolones (21.6%). Judgmental use of antibiotics reduce the burden of multi-drug resistance and thereby enabling better patient management and limiting the resultant morbidity and mortality. In this study, commonly identified pathogen was E-coli, highily sensitive organism was Klebsiella pneumonia and most resistant organism was ESBL E-coli.

Constant surveillance of antibiotic sensitivity pattern will help the Medical Practitioners to use safe and effective therapy in the management of different infections. Proper guidelines, supervision of antibiotic usage and constant information to the medical practitioners regarding the sensitivity pattern can help to prevent drug resistance.

While comparing Empiric versus Evidence based therapy, results showed almost similar effects except UTI.

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