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AMR CONSUMPTION TRENDS IN A TERTIARY CARE INSTITUTE OF NORTH WEST RAJASTHAN: A PILOT STUDY

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ABSTRACT

Antibiotics are truly miracle drugs that have saved countless life, but antimicrobial resistance is a critical Public Health issue that is eroding the effectiveness of antibiotics and may affect the health and economic implications of each and every one of us. World wide it has contributed to the quality of life and longevity. At the first sight of infection we always jump in with antibiotics prescription we do not give the immune system a chance to grow stronger. The surveillance system provided results that warn us to restrict the use of Azithromycin to reduce the evolution of antibiotic resistance, as it has gained popularity after corona virus pandemic. It falls under Watch category of WHO AWaRe classification which has greater tendency to develop resistance. The pilot study conducted at tertiary care center shows that the amoxicillin 500mg + potassium clavulanate 125 mg tablet is a Access category drug which is among the top most consumed antibiotics which show low resistance development risk. The five year analysis report put forward that only two Access category drugs (Amoxicillin 500mg + Potassium Clavulanate 125 mg tablet and Amoxicillin 250mg + Cloxacillin 250 mg capsule) are among the top five antibiotics otherwise mostly Watch category drugs are prevalent so the chances of development of resistance against the drugs are high. The results of this study reflect that the reckless use of antibiotics promotes the spread of antimicrobial resistance hence the smart use of antibiotics is the key to control spread of antimicrobial resistance. Although there are multiple driving forces, Antibiotic resistance is a naturally occurring slow process which is an inevitable consequence of the drug selective pressure. A strategy need to be developed to guide and control antibiotic misuse and extend the life of antibiotics that are still effective.

KEYWORDS: The World Health Organization (WHO), AWaRe (Access, Watch and Reserve), Anatomical Therapeutic Chemical (ATC) codes, Defined daily dose (DDD) and Antimicrobial Resistance (AMR).

INTRODUCTION

Antimicrobial Resistance is a global health threat; it requires urgent attention in order to achieve sustainable development. WHO has declared AMR as one of the top 10 global public health ultimatum. The genesis of AMR is the impulsive use of antimicrobial drugs; this is the main driving force in the expansion of drug resistant pathogens.[1] Antimicrobials are the medicines used to prevent and treat infection in humans, animals and plants. They include antibiotics, antivirus, antifungal and anti parasitic. The resistance develops in microorganisms overtime due to the changes in the physiology of bacteria, virus, fungi and parasites. As a result they no longer respond to the medicine, hence it becomes difficult to treat the infection. Subsequently rising number of antibiotics are becoming ineffective on humans and it become increasingly difficult or impossible to treat the infection with such antibiotics.[2,11,15]

Pathogens develop resistance through various mechanisms like 1) limiting uptake of a drug; 2) to modifying a drug target; 3) inactivating a drug; 4) active drug efflux. The emergence of drug resistant microorganisms that have acquired new resistance mechanism is a challenge to our ability to treat common infections.[3] Inflation rate of AMR at the global level is alarming, with the augmentation of multi-resistant bacteria that are not treatable with existing antimicrobial medicines. The new antibiotics are in pipeline, nevertheless the clinical trial is a long and complex process before the final approval of the drug for human use.[4]

WHO published its first ever list of antibiotics resistance "priority pathogens"-A catalogue to create Global consciousness and apprehension to address growing resistance of a microorganism toward various anti microbial medicines. W H O has the categorized these drugs into 3 categories based on urgency of new antibiotics; 1 critical priority, 2 high priority, 3 medium priority.[4] The multidrug resistant bacteria like Acinatobacter, Pseudomonas and various Enterobacteriaceae (including Klebsiella, E Coli, Serratia and Proteus) are included in critical as they causes severe infection. Likewise, high and medium priority category covers gonorrhea and Salmonella which cause common diseases like food poisoning.

G 20 countries took joint motive “Effective antibiotics for the healthy tomorrow” to initiate the fight against AMR, WHO classification of anti microbial drugs into various classes is an

important new tool to secure and guide research and development related to new antibiotics.[5] The recent classification based on the activity of antibiotics is as follows

AWaRe Classification

ACCESS

Access group includes those antibiotics which have activities against a wide range of commonly encountered pathogens along with lower resistance potential. These antibiotics are suggested as the first or second choice empiric treatment options for infection syndrome. The antibiotics like Amikacin, Amoxicillin, Amoxicillin + potassium Clavulanate, Ampicillin, Ampicillin + Sulbactam, Amoxicillin + Cloxacillin, Cephalexin, Metronidazole, Cotrimoxazole (trimethoprim + sulphamethoxazole)

WATCH

The antibiotics which have higher resistance potential and are critically important antibiotics which are at higher risk of development of bacterial resistance are grouped under watch group antibiotics. Example as Azithromycin, Cefotaxime, Cefoperazone + Sulbactam, Cefixime Ceftazidime, Cefpodoxime, Ofloxacin, Imipenem + Cilastatin, Meropenem, Piperacillin+ Tazobactum, Ofloxacin, Norfloxacin, Ciprofloxacin etc.

RESERVE

The antibiotics which can be used as Last Resort for treatment of confirmed or suspected infection due to multi drug resistant organism. The WHO model list of essential medicines include them when these antibiotics have favorable risk benefit profile and proven activity against critical priority or high priority pathogens. They are grouped as reserve antibiotics, as they are used consciously to only specific patients where all alternative have failed or are not suitable to use. These antibiotics need to be strictly monitored and reported for its utilization to sustain their effectiveness. These drugs are Aztrionam, Colistin, Polymixin B, Tigecycline, Minocycline, Linezolide etc.

NOT RECOMMENDED

WHO restrict use of certain antibiotic. The use of fixed dose combination of multiple broad spectrum antibiotics is not recommended in international guidelines.[6]

Table 1: List of Antibiotics with The AWaRe Classification And Route Of Administration.

	PRODUCT NAME	AWaRe CLASSIFICATION OF DRUGS	Route
1	Cap. Amoxicillin 500mg	ACCESS	O
2	Dispersible tablets Amoxicillin 125 mg	ACCESS	O
3	Dispersible tablets Azithromycin 100mg	WATCH	O
4	Inj. Amoxicillin (1000mg) + potassium clavulanate (200 mg)	ACCESS	P
5	Tab. Amoxicillin 500mg + pot. clavulanate 125 mg	ACCESS	O
6	Tab. Azithromycin 250mg	WATCH	O
7	Tab. Azithromycin 500mg	WATCH	O
8	cap. Amoxicillin 250mg	ACCESS	O
9	cap. Amoxiclline 250mg+cloxacillin 250mg	ACCESS	O
10	inj.Amoxicillin (400mg) + potassium clavulanate (200mg)	ACCESS	P
11	oral solution Amoxicillin 125mg/5ml (30 ml)	ACCESS	O
12	oral solution Amoxicillin 200mg + pot. clavulanate 28.5 per 5ml (30ml)	ACCESS	O
13	Inj . Cefotaxime 1g	WATCH	P
14	Inj. Cefoperazone 1g + sulbactum 0.5 g	WATCH	P
15	Oral suspention cefixime25mg/ml (10ml)	WATCH	O
16	Tab. Cefixime 200 mg	WATCH	O
17	Tab. cefixime 100mg	WATCH	O
18	inj. ceftazidime250mg	WATCH	P
19	inj. ceftazidme1g	WATCH	P
20	inj. ceftaziime500mg	WATCH	P
21	tab.cefpodoxim50mg	WATCH	O
22	Capsule Cephalexin 500 mg	ACCESS	O
23	Inj . Ciprofloxacin 200mg/100ml	WATCH	P
24	Inj . ceftriaxone 1g	WATCH	P
25	Inj . ceftriaxone 250mg	WATCH	P
26	Inj ceftriaxone 500mg	WATCH	P
27	Tab Cefuroxime 250mg	WATCH	O
28	Tablet Cephalexin 125 mg	ACCESS	O
29	capsule Cephalexin 250mg	ACCESS	O
30	oral suspention cephalexin 125mg/5ml (30ml)	ACCESS	O
31	Infusion Ofloxacin 200mg /100ml	WATCH	P
32	Inj . Imipenem 500mg + cilastatin 500mg	WATCH	P
33	Inj . Meropenem 1g	WATCH	P
34	Inj . Meropenem 250mg	WATCH	P
35	Inj . Meropenem 500mg	WATCH	P
36	Inj . metronidazole 500mg / 100ml	ACCESS	P
37	Inj.Piperacillin 2g + Tazobactum 250mg	WATCH	P
38	Inj.Piperacillin 4g + Tazobactum 500mg	WATCH	P
39	Oral suspension Ofloxacin 50mg /5ml (30ml)	WATCH	O
40	Tab . Ofloxacin 200mg	WATCH	O
41	Tab. Norfloxacin 400mg	WATCH	O

42	tab . metronidazole 200mg	ACCESS	O
43	tab . metronidazole 400mg	ACCESS	O
44	tab. ciprofloxacim 250 mg	WATCH	O
45	tab. ciprofloxacim 500mg	WATCH	O
46	oral suspention Metronidazole Benzoate 100mg / 5ml (60 ml)	ACCESS	O
47	Oral solution Cotrimoxazole (trimethoprim 40mg + sulphamethoxazole 200mg)	ACCESS	O
48	Tab . ofloxacin 200mg + ornidazole 500mg	NOT RECOMMENDED	O
49	Tab. Cotrimoxazole (trimethoprim 160mg + sulphamethoxazole 800mg)	ACCESS	O
50	Tab. Cotrimoxazole (trimethoprim 80mg + sulphamethoxazole 400mg)	ACCESS	O
51	Tab. Cotrimoxazole (trimethoprim 40mg + sulphamethoxazole 200mg)	ACCESS	O

O – Oral, P- Parenteral

MATERIAL AND METHOD

The pilot project conducted at the site includes extensive surveillance programmes developed to study patterns of antibiotics consumption and AMR. An analytical data study has been conducted at a tertiary care Institute of northwestern Rajasthan with bed strength of 2298 beds; regarding the antimicrobial drug consumption to develop validated, reproducible and sustainable surveillance results to quantify antimicrobial resistance and antibiotic use. The data of 51 antibiotics have been collected from the hospital central pharmacy from 2017 to 2021; to understand the consumption pattern and the antibiotic preference of the registered medical practitioners for various infections. The top 5 antibiotics consumed during 2017 to 2021 has been put to comparative study using graphs and tables to understand the trends of antibiotic consumption during these years. The primary data has been collected on Microsoft excel sheets. Annual consumption of Antibiotic was quantified by using the standard Anatomical Therapeutic Chemical (ATC) codes, Defined daily dose (DDD) formula and The World Health Organization's "Access, Watch and Reserve" (AWaRe) classification were adopted to evaluate the appropriateness of antibiotic utilization The data also highlights the change in trend during the Corona pandemic.

The following formulas has been used for the various calculation

Bed Occupancy Rate = Number of beds occupied / Total number of beds *100

The bed occupancy rate has been taken 1 as the bed occupancy of the hospital is 100%

Number of bed days = Number of beds * days of a month * Bed occupancy Rate

DDD/100 Bed Days = DDD/Number of bed day *100

RESULT AND DISCUSSION

During the last five years study period, a total of 51 antibiotics were studied, due to economical restrains the central pharmacy provide only 51 antibiotics free of cost under government scheme. Azithromycin 500 mg Tablet and Amoxicillin 500 mg + Potassium Clavulanate 125 mg Tablet are the two antibiotics which are used maximum at the tertiary care institute. Their DDD/100 beds was greater than 80 DDD/100 beds during these years. The Amoxicillin 500 mg + Potassium Clavulanate 125 mg tablet consumption ranged from 81.54 to 138.34 DDD/100 beds and the consumtion of Azithromycin 500 mg tablet ranged from 78.33 to 136.30 DDD/100 beds. Azithromycin is at high risk of developing resistance. Amoxicillin 500 mg + Potassium Clavulanate 125 mg have a wide spectrum against microorganisms and at lower risk of resistance. The survey clearly shows that During the pandemic years the consumption of Azithromycin increased dramatically.

Azithromycin 500 mg Tablet

Comparing the data of past five years, Azithromycin 500 mg Tablet is the leading anti microbial drug among all, it has been the most preferred drug by medical practitioner. Since Azithromycin has a high risk of developing resistance so it is essential to keep a strict watch on the consumption rate because there is a closed possibility that anti microbial resistance to this antibiotic development in near future. Today's conscious use would be tomorrow's medicine, otherwise soon it would lose its utility and popularity in the treatment of infectious diseases. Azithromycin should be regularly monitored and only used when Other Drugs are ineffective in the treatment of specific infection. It is at speculative risk of developing resistance. Although there is no much difference in the pattern of the annual consumption of Azithromycin and_Amoxicillin + Potassium Clavulanate but during the pandemic period Azithromycin consumption showed significant rise.

Amoxicillin 500 mg + Potassium Clavulanate 125 mg Tablet

Tablet Amoxicillin 500 mg + Potassium Clavulanate 125 mg is a combination drug which has been popular drug of choice in last 5 years. It has maintained its position in top 3 antibiotics consumed during these years. In 2020 and 2021 it has been the second highest consumed antibiotic. During 2019 its consumption was at peak, as high as 138.341 days per 100 bed days. Amoxicillin and potassium clavulanate is a combination drug that is a good choice as it

shows low resistance and wide spectrum against microorganism hence it is preferred by most of the doctors due to its effectiveness against common pathogens.

Cefixime 200 mg

Cefixime 200 mg is another drug with a potential to develop resistance; it falls under Watch category of WHO classification; it has been in use from past 5 years. All though during pandemic its popularity has reduced still it is advisable to restrict its use, used only when other drugs are ineffective.

Other commonly prescribed drugs

Ceftriaxone injection 1 gram, tablet ciprofloxacin 500 mg, Cefuroxime tablet 250 mg, injection Cefoperazone + Salbactam 0.5 g and capsule Amoxicillin 250 mg +cloxacillin 250 mg; are few Other Drugs which have been trending in top 5 antibiotic at the 4th and 5th position. Among these Amoxicillin 250 mg + Cloxacillin 250 mg capsule falls under the category of Access drugs remaining belongs to the Watch category OF WHO classification. The Watch category is comparatively at higher risk to develop resistance as compared to the drugs of Access category.

Amoxicillin 500 mg + Potassium Clavulanate 125 mg tablet and amoxicillin 250 mg +Cloxacillin 250 mg capsule are unlikely to develop resistance and effective against extensive pathogens. Their use is favored and recommended by WHO to beat the ever increasing number of antimicrobial resistance. The drugs like Azithromycin 500 mg tablet, cefixime 200 mg tablet, Ceftriaxone 1g injection, ciprofloxacin 500mg tablet and Cefuroxime 250 mg tablet; should be put under surveillance as they Pose high rates of AMR in pathogens.

Table 2: Top 5 Antibiotics from 2017 to 2021.

	PRODUCT NAME	2017	2018	2019	2020	2021
1	Tab. Amoxicillin 500mg + pot. clavulanate 125 mg	81.545	94.680	138.341	84.040	83.344
2	Tab. Azithromycin 500mg	78.339	96.790	87.490	136.301	117.714
3	Tab. Cefixime 200 mg	74.439	104.850	133.359	62.418	73.833
4	Inj . ceftriaxone 1g	16.200	15.370	20.409		13.807
5	tab. ciprofloxacin 500mg	11.854	17.590			
6	cap. Amoxiclline 250mg+cloxacillin 250mg				18.131	9.358
7	Tab Cefuroxime 250mg			14.998		
8	Inj. Cefoperazone 1g + sulbactum 0.5 g				30.712	

Table 3: Comparition Of Top 5 Antibiotics From 2017 To 2021.

	PRODUCT NAME	2017	2018	2019	2020	2021
1	Tab. Amoxicillin 500mg + pot. clavulanate 125 mg	I^{ST}	III^{RD}	I^{ST}	II^{ND}	II^{ND}
2	Tab. Azithromycin 500mg	II^{ND}	II^{ND}	III^{RD}	I^{ST}	I^{ST}
3	Tab. Cefixime 200 mg	III^{RD}	I^{ST}	II^{ND}	III^{RD}	III^{RD}
4	Inj . ceftriaxone 1g	IV^{TH}	V^{TH}	IV^{TH}		IV^{TH}
5	tab. ciprofloxacin 500mg	V^{TH}	IV^{TH}			
6	cap. Amoxiclline 250mg+cloxacillin 250mg				V^{TH}	V^{TH}
7	Tab Cefuroxime 250mg			V^{TH}		
8	Inj. Cefoperazone 1g + sulbactum 0.5 g				IV^{TH}	

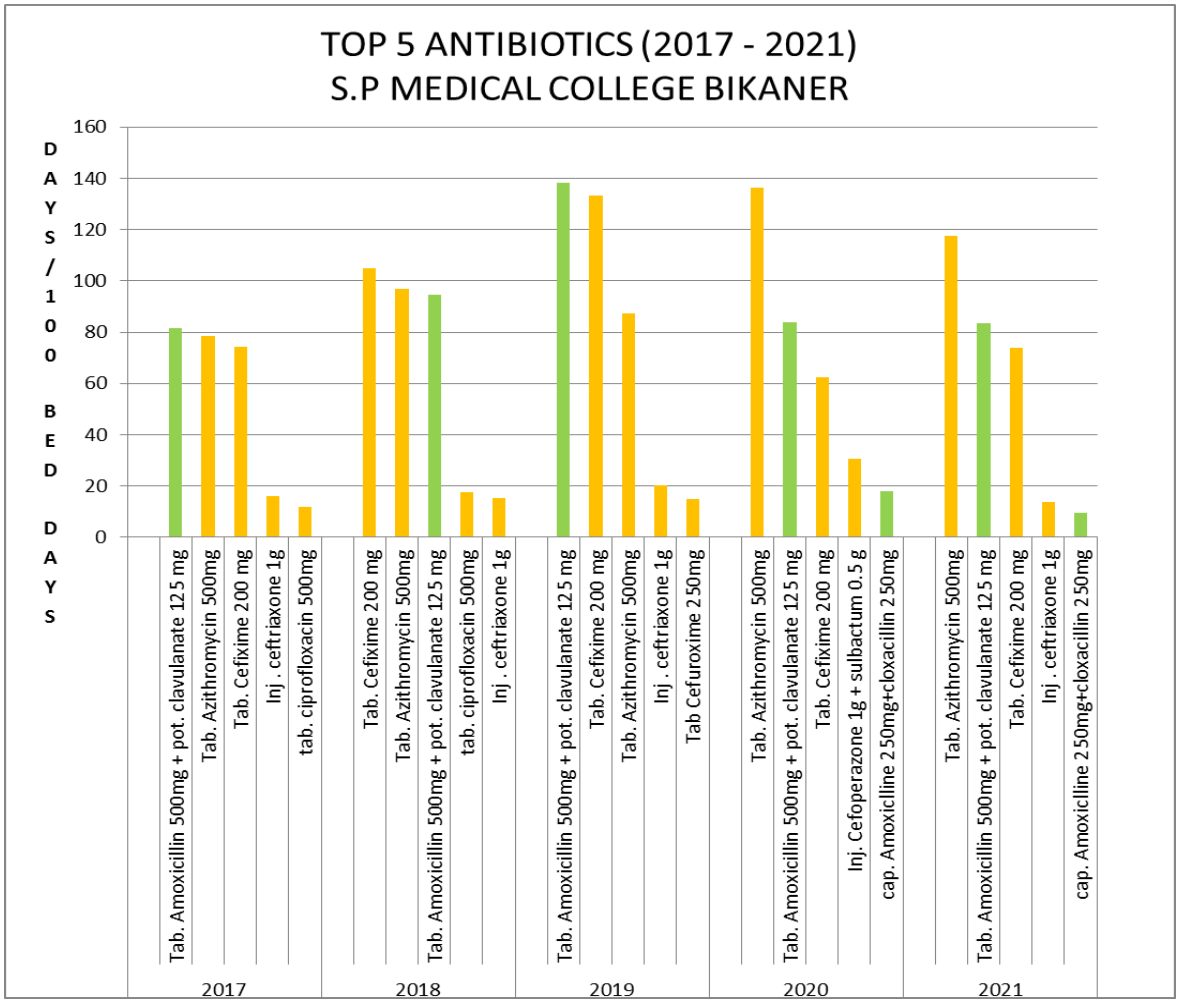

Figure 1: Comparative Graph of Top 5 Antibiotics From 2017 To 2021.

DISCUSSION

We grow up on antibiotics, every ailment like sore throat, earache, flush, guarantee an antibiotic prescription. In a long run we should choose a stronger immune body rather than contributing to stronger resistant pathogens.[16,17] The utilization of antibiotics in various counties can be quantified on the basis of AWaRe classification, to infer the overall quality and differences in use of antibiotics. The underdeveloped regions of western china showed

enormous rise in the consumption of penicillin followed by cephalosporines and macrolides antibiotics, The rational use of antibiotics is the vital approach to combat the development of resistant microorganisms therefore the Chinese government introduced antibiotics policies that limits the dispensing of antibiotics from community pharmacies. This had led to a drastic decrease in the AMR in that area similar approach can we used by other countries.[7,12]

According to the WHO Antimicrobial Consumption Monitoring Report the consumption of the Watch group of antibiotics was higher as compared to the Access group. On the other hand the consumption of the Access group and the Reserve group was lower in the European regions at the same time Watch group was higher.[8,13] Poland is one of the highest consumers of antibiotics among European countries. The total consumption of antibacterial for systemic use and relative consumption of beta lactamase sensitive penicillins showed significant average annual increases since last one decade.[9] A cross-sectional survey of community drug retail outlet staff in the Amhara region, Ethiopia concluded that 58% of Community drug retail outlets (CDROs) like pharmacies, drug stores/shops, rural drug vendors, and Accredited Drug Dispensing Outlets that sell drugs or medicines participants reported dispensing antibiotics without prescription despite the prohibition of the non-prescribed supply of antibiotics.[10] The target of antibiotic stewardship is to reduce the overuse of watch antibiotics. Our study found that the consumption of the Watch group should be clinically evaluated and used with caution.[14,20]

A study conducted in Delhi, fluoroquinolones, cephalosporins, and extended spectrum penicillins were the three most commonly prescribed at private retail pharmacies and private clinics. At public facilities, there was not much variation in the use of major antibiotic groups like penicillins, fluoroquinolones, macrolides, cephalosporins, tetracyclines, and cotrimoxazole.[18,19,21] Similar trends of antibiotics consumption were observed at our site, verifying that these are the generally preferred drugs.

CONCLUSION

The above results warn us to restrict the use of Azithromycin to reduce the evolution of antibiotic resistance, as it has gained popularity after corona virus pandemic. It falls under Watch category of WHO AWaRe classification which has greater tendency to develop resistance. The pilot study conducted at tertiary care center in North-West Rajasthan shows that the amoxicillin 500mg + potassium clavulanate 125 mg tablet is a Access category drug which is among the top most consumed antibiotics, it shows low resistance development risk.

The five year analysis report put forward that only two Access category drugs (Amoxicillin 500mg + Potassium Clavulanate 125 mg tablet and Amoxicillin 250mg + Cloxacillin 250 mg capsule) are among the top five antibiotics otherwise mostly Watch category drugs are prevalent so the chances of development of resistance against the drugs are high.

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