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Original Article

Drug Utilization of Antimicrobial Agents in patients of Pelvic Inflammatory Disease attending Obstetrics & Gynaecology Department in a Tertiary Care Hospital

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ABSTRACT

Introduction: Pelvic inflammatory disease (PID) is a major health concern leading to profound gynecological morbidity among women in reproductive age group. Therefore, this study was undertaken to analyze the prescription pattern of Antimicrobial Agents in patients suffering from Pelvic Inflammatory Diseases.

Methodology: A cross-sectional study was conducted at the Department of Gynecology & Obstetrics of Adani Institute of Medical Science, Bhuj, Gujrat. A total of 442 prescriptions of clinically diagnosed PID cases from Outpatient Department (OPD) and Inpatient Department (IPD) were collected and analyzed in the department of Pharmacology on the basis of Drug utilization WHO indicators.

Results: Average number of AMAs per prescription was 2.0. Majority of patients were prescribed Antifungals (n=237, P=25.90%) followed by Nitroimidazoles (n=184, P=20.10%), Fluoroquinolones (n=182, P=19.89%), Doxycycline (n=166, P=18.14%), and least prescribed was Aminoglycoside and Urinary antiseptics (n=4, P=4.04%).

Conclusion: There was minimal difference between defined recommendations in standard treatment guidelines and the clinical use of antimicrobial agents. The only lacking part of this study was lesser use of generic drugs.

Keywords: Drug Utilization of Antimicrobial Agents

INTRODUCTION

Diabetes mellitus (DM) is one of the most common metabolic disorders associated with chronic complications such as nephropathy, angiopathy, retinopathy, autonomic neuropathy, and peripheral neuropathy.[1] These complications result from a complex interaction of direct and indirect metabolic consequences of insulin deficiency and additional genetic and environmental factors.[2]

Involvement of peripheral and autonomic nervous systems frequently encounters in DM. However, there is a paucity of data regarding central neuropathy in DM. Neurochemical, electrophysiological, structural and neurobehavioral levels have demonstrated manifestations of DM-2 cerebral disorders. Probably alterations in cerebral blood supply and metabolic derangements play a role, as they do in the pathogenesis of DM-2 neuropathy. Furthermore, recurrent episodes of hypoglycemia and poor metabolic control also affect the brain.[1]

Some reports claim central neuropathy in DM based on evoked potentials. However, central neuropathy in DM particularly before symptomatic peripheral neuropathy has received much less attention.

Electrophysiological tests for diagnosing disorders of peripheral nervous system include nerve conduction studies (NCS), and electromyography.[3] EEG measures electrical activity of the brain and is a noninvasive tool with excellent temporal resolution and quite useful as a prognostic tool in disorders of the central nervous system (CNS).[1]

Our aim is to study the central and peripheral neuropathy by

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EEG and NCS respectively in DM-2 before symptomatic peripheral neuropathy. Hence, we believe that this study shades light on the central and peripheral neuropathy in DM-2 before they show symptoms of peripheral neuropathy.

MATERIALS AND METHODS

This prospective study was done by Department of Gynecology & Obstetrics of Adani Institute of Medical Science, Bhuj, Gujrat. The female patients aged 15-60 years suffering from Pelvic Inflammatory disease attending Obs/Gynecology department were enrolled who were on antimicrobials and satisfy the inclusion and exclusion criteria.

The study was conducted for a period of 12 months from Feb 2013 – Jan 2014 on clinically diagnosed (both acute and chronic) PID patients aged 15-60 years.

Data from Gynaecology & Obstetrics department both OPD and IPD were gathered randomly twice weekly and the detailed records of demographic, clinical features & treatment instructions were noted in 'Case Record Form' after getting explained consent from the patients.

Study was approved from Institutional Ethical Committee.

Rationality

A. The therapy was considered rational if the antimicrobial use and its route of administration, dose, frequency and duration of use were considered appropriate for infection.

B. Therapy was considered irrational if the antimicrobial was used without indication, prophylaxis under circumstances of unproven efficacy or by clearly inappropriate route, dose or preparation for that indication.

It is a prospective study and is based on medication utilization form, which has been designed on the basis of a WHO format.

WHO CORE INDICATORS

Data will be further analyzed as under:

1. Age and sex wise distribution.
2. Average number of drugs per encounter.
3. Prescribing Percentage of encounters with an antibiotic prescribed.
4. Percentage of encounters with an injection prescribed.
5. Percentage of drugs prescribed by generic name.
6. Percentage of drug prescribed from Essential drug list formulary

RESULTS

A total of 442 prescriptions were analyzed during the 12 months study period. The maximum numbers of female patients suffering from Chronic PID were from the age group of 21-40 years (n=235), and least of the patients fall under age group of 61-80 yrs. (n=45) (Table-1).

The total no. of drugs which were prescribed to the patient was 1175. Each patient on an average was prescribed 2.6 drugs per prescription. Out of 1175 of total drugs, 915 were antibiotics.

During the study, it was observed that the most commonly prescribed Antimicrobial agents were Antifungals (n=237, P=25.90%) followed by Nitroimidazoles (n=184, P=20.10%), Fluoroquinolones (n=182, P=19.89%), Doxycyclines (n=166, P=18.14%), and Aminoglycosides. Urinary antiseptics were the least prescribed class (n=4, P=4.04%). Individually, most commonly used agents of these is Doxycycline, Clotrimazole + Tinidazole followed by Metronidazole, combination of Ofloxacin + Ornidazole, Fluconazole + Ornidazole and least prescribed was Nitrofurantoin (Table-2).

In the concomitant medications, Proton Pump Inhibitors were mostly prescribed (n=118, P=45.38%) followed by NSAIDs (n=75, P=28.84%), Sedatives were the least prescribed class (n=67, P=25.76%). (Table- 3)

Out of Total 915 antibiotics prescribed all antibiotics were given orally, no parenteral administration. There was a high prevalence of empiric treatment with orally administered antibiotics in this study. The average no. of Antibacterial agents prescribed per patient per course was found to be 2.0. It was observed that out of 915 drugs which were prescribed to the patient none of drugs were in generic form. All drugs were prescribed from Essential Drug List. (Table-4)

DISCUSSION

Our objective was to study the central and peripheral neuropathy by EEG and NCS respectively in DM-2 before they show the symptoms of peripheral neuropathy. Both the groups were comparable in terms of their age, weight, height, BMI, and all the cardio-respiratory variables. The FBG, PPBG, and HbA_1C % of DM-2 were suggestive of confirmed diabetes and FBG was normal in all the controls. DM-2 had no clinical evidence of sensory neuropathy. The latencies, conduction velocities, and amplitudes of their bilateral sural SNAPs were above the normal cut-off values of ≥ 4 μV. The latencies and conduction velocities of bilateral sural SNAPs in DM-2 were comparable with that in the controls. However, the amplitudes of bilateral sural SNAPs were low in DM-2 in comparison to the controls. Reduced amplitude is the primary abnormality associated with axonal loss. Comparing the amplitude of a potential with a normal control value is one of the best way to assess the amount of axonal loss. The typical pattern associated with axonal loss is one of reduced amplitudes with preserved latencies and conduction velocities. Sensory amplitudes often are low in demyelinating lesions. Reduced sensory amplitudes result from the normal processes of temporal dispersion and phase cancellation.[5] *EEG power spectra of delta activity* were more in DM-2 at most sites as compared to controls during both the eyes-close and eyes-open conditions. Our results are in the line of the result of

Mooradian et al[6] who found DM-2 tended to have slower delta EEG power bands at all three recording sites Fz, Cz, and Pz during eyes-close and eyes-open conditions. Nevertheless, in their study they recorded the EEG activity from Fz, Cz, and Pz locations only. In our study, slowing (increased power of delta activity) was more in DM-2 at multiple sites during both the eyes-close and eyes-open conditions. Daniel et al[7] found that hyperglycemia (blood glucose >15 mmol/dl) was associated with slowing of all cognitive performance tests and an increased number of mental subtraction errors for DM.[7] Thus, our results are indicative of diffuse central neuropathy in DM-2 as indicated by EEG changes.

A meta-analysis of 24 studies showed that depression was associated with hyperglycemia in both type 1 diabetes mellitus (DM-1) and DM-2.[8] In a prospective population-based similar study of 2764 Japanese men, those with major depressive disorder (MDD) or depressive symptoms were at a higher risk of developing DM-2.[9]

In our study, we did not assess cognitive functions and depressive symptoms of the patients. However, the patients with DM are twice as likely to have depression[10, 11] that will also negatively affect cognitive function and daily activities. DM-2 also has an increased incidence of Alzheimer's disease[12-14] and increased incidence of vascular dementia. [15,16] This might be one of the reasons for increased delta activity in DM-2 in our study. *EEG power spectra of beta activity* were more in DM-2 as compared to controls during both the eyes-close and eyes-open conditions at all sites. Our results are in the line of the result of Gibbs et al[17] who found mixed slow and fast frequencies and some intermingled spiking in patients with elevated blood sugar levels. [17] Beta waves (>13/sec) are usually seen, especially on the frontal and central areas, in tense and anxious patients. [18] Anxiety disorders are also highly prevalent in DM-2. [19] The prevalence of anxiety and depression symptoms in DM was more than double the general population estimates. [20] Khan et al[21] in their study, done in 889 DM-2, identified that 57.9% had anxiety and 43.5% were positive for depression.[21] Peyrot and Rubin[22] studied 634 patients in an outpatient DM education program and reported depression and anxiety in 41.3% and 49.2% of the patients respectively. They concluded that DM is associated with an increased risk of psychological disturbance, particularly those with more DM-2-related complications. [22]

EEG power spectra of alpha2 activity was more in DM-2 during eyes-open condition at Fz, Cz, Pz, C4, T4, P4, Fp1, F7, and T3. Increased alpha2 power activity contradicts the increase in faster activities. However, to explore our observations, further study is required. Alpha rhythm is the classical EEG correlate for a state of relaxed wakefulness best obtained with the eyes closed. Eye opening, other afferent stimuli, and mental activities temporarily block the posterior alpha rhythm. [23] Occasionally, an increase in abundance of alpha activity occurs with eyes-open instead of decrease. This reversal is a "paradoxical effect" or "paradoxical alpha", which occurs mostly with eyes-open in response to stimulation following a brief period of drowsiness. [24]

EEG power spectra of alpha1 activity were more in DM-2 at Fz during eyes-close condition and at Fp2, F8, and T4 during eyes-open condition.

Our results are in the line of the result of Duffy et al[25] who suggested that the bilateral slowing of the alpha rhythm might be seen in metabolic, toxic, and infectious encephalopathy of diverse etiology.[24] It is also a consistent finding in patients with dementia irrespective of the underlying cause. The degree of slowing often parallels alteration in the mental status of the patient.[25]

DISCUSSION

Antibiotics were once considered 'miracle drugs' and have been used for decades to effectively treat a variety of bacterial infections. Unfortunately, widespread use and misuse worldwide have led to the emergence of 'super bugs' and other drug-resistant bacteria.

Unnecessary use of antibiotics has also given rise to an increased risk of side effects, high costs and effects requiring medical attention.

Quality of life can be improved by enhancing standards of medical treatment at all levels of the health care delivery system. Setting standards and assessing the quality of care through performance review should become part of everyday clinical practice. The study of prescribing patterns seeks to monitor, evaluate and suggest modifications in practitioners' prescribing habits so as to make medical care rational and cost effective.

In our Study, the most commonly prescribed Antimicrobial agents were Antifungals (n=237, P=25.90%) followed by Nitroimidazoles (n=184, P=20.10%), Fluoroquinolones (n=182, P=19.89%), Doxycyclines (n=166, P=18.14%), Aminoglycoside. Urinary antiseptics were the least prescribed class (n=4, P=4.04%). Individually, most commonly used agents of these is Doxycycline, Clotrimazole + Tinidazole followed by Metronidazole, combination of Ofloxacin + Ornidazole, Fluconazole + Ornidazole and least prescribed was Nitrofurantoin (Table-2).In the concomitant medications Proton pump inhibitor drugs were mostly prescribed followed by NSAIDs. These findings are similar to study conducted by Sharma S etal, 2013 (8), whereas our results contradicts the study conducted by Basu J et al. 2015 where number of antimicrobials prescribed was 3.0 (9).

In the current study it was found that Gentamicin was prescribed more in comparison to Amikacin in patients requiring hospitalization with suspected or proven urinary tract infection. As previous study showed good results by Saini et al, where the researchers found good response to gentamicin to provide coverage against gram negative aerobic bacilli (10).

Use of Doxycycline with metronidazole was higher in our study to provide coverage against Chlamydia trachomatis and anaerobes, respectively as recommended by Saini et al recommended doxycycline against C. trachomatis in their study (10).

The findings of this study suggest that there was minimal difference between defined recommendations in standard treatment guidelines and the clinical use of antimicrobial agents. Establishing an appropriate and restrictive guide for antibiotic was therefore be a high aim and priority to this hospital.

CONCLUSION

The present study concludes that: treatment approach was empirical without objective criteria of infection and most of these drugs were prescribed using brand names.

All antibiotics were administered orally and parenteral administration never occurred. This may be reflective of an improvement in this aspect of prescribing pattern as opposed to previous excessive use of injections by some physicians who hold the erroneous belief that injections are more effective and offer better patient satisfaction. The other positive aspect of this study was average no. of antibiotics prescribed per prescription is lesser than other studies. This minimizes the habit of polypharmacy and drug-drug interactions.

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