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Original Research Article

The efficacy and safety of Short course therapy with Cefixime in URTI in Indian Scenario

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ABSTRACT

Upper respiratory tract infections (URTI) are one of the commonest cause for a patient's visit to outpatient department (OPD). Short course therapies with penicillin and cephalosporin class of antibiotics are commonly prescribed in URTI cases. This study was a retrospective, multicentre, observational cohort analysis, planned to evaluate the effectiveness and safety of Cefixime 400 mg per day in patients of URTI, using WURSS 21 score. We analysed the data of 200 patients who were prescribed Cefixime for URTI. Most of the patients (55%) were male. The baseline mean WURSS score of 41.09 ± 33.45 decreased to 25.74 ± 22.29 [(-37.3%), p value<0.05] at visit 2; moreover, it further decreased to 5.75 ± 6.75 [(-86.0%), p value<0.05] at visit 3. Similar trend was noted for WURSS symptom score and WURSS Quality of life score. At baseline, mean WURSS Symptom score was 25.34 ± 15.97 which was reduced to 16.32 ± 11.50 at visit 2 and 4.15 ± 4.50 at visit 3. Similarly, mean WURSS Quality of life score at baseline was 15.74 ± 18.41 which was reduced to 9.42 ± 11.66 and 1.59 ± 2.75 at visit 2 and visit 3 respectively. None of the patients reported adverse effects. The findings of the present survey confirm the effectiveness and safety of short course of Cefixime therapy in URTI.

1. Introduction

Upper respiratory tract infections (URTI) are one of the commonest cause for a patient's visit to outpatient department (OPD).[1] Although, these infections are not fatal, still they cause significant loss of productivity. They are a major cause of absenteeism from work, schools in India.[2] URTI is mainly caused by viruses like adenovirus, influenza virus, etc. However, bacterial URTI, especially those caused by group A beta hemolytic streptococci or mixed infections are commonly encountered these days.[3] It manifests as sinusitis, tonsillitis, pharyngitis, laryngitis, or combination of these presentations.[4]

Short course therapies with penicillin and cephalosporin class of antibiotics are commonly prescribed in URTI cases.[5] However, most of the penicillin are becoming resistant since past few decades, particularly against β hemolytic streptococci. The main reason for such resistance is production of β lactamases by the pathogenic bacteria.[6] Therefore, cephalosporin are being commonly prescribed in routine practice.[5] Cefixime belongs to third generation of cephalosporin, which had wide antibacterial coverage, and is especially active against β hemolytic streptococci.[7]

Traditionally, evaluation of effectiveness and safety of antibiotics in URTI is done by analysing symptom/s improvement and/ culture assays. Wisconsin Upper Respiratory Symptom Survey 21 (WURSS 21) scoring system combines symptoms as well as quality of life

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parameters in patients of URTI. This score was validated and found to be more effective as compared to other analysers.[8]

There is paucity of data regarding short course of Cefixime in URTI cases, especially in Indian setup. Hence, the present study was planned to evaluate the effectiveness and safety of Cefixime 400 mg per day in patients of URTI, using WURSS 21 score.

2. Materials and Methods

This was a retrospective, multicentre, observational cohort analysis that examined the results in patients with upper respiratory tract infections (URTI) in real world practice at 4 centres across India. A Prevalidated questionnaire was used to conduct this analysis. The questionnaire was designed to assess the efficacy and tolerability of Cefixime in the management of URTI. Survey was conducted during April 2019-August 2019. Only those records were included for analysis, whose data was available for complete 5 days.

The primary endpoint was the assessment of clinical response in terms of change in mean WURSS 21 (Wisconsin Upper Respiratory Symptom Survey 21). Secondary endpoints were the assessment of:

1. Change in mean WURSS 21 Symptom score from baseline to day 5
2. Change in mean WURSS 21 Quality of life score from baseline to day 5
3. Change in Global severity of Patient Health condition
4. Percentage of patients who discontinued the treatment
5. Adverse events (AE) reported during the entire course of the therapy.

2.1. Statistical analysis

Statistical analysis was done using SPSS (Statistical Package for Social Sciences) version 18.0. Continuous and categorical data was expressed in terms of means and percentage, respectively. To compare changes in mean scores at baseline and day 5, the Chi square test was applied. P-value < 0.05 was considered as statistically significant.

Demographic characteristics are listed in 1Table 1.

3. Results

We analysed the data of 200 patients who were prescribed Cefixime for URTI. Most of the patients (55%) were male. Detail distribution of clinical diagnosis is mentioned in Figure 1.

3.1. Efficacy

The baseline mean WURSS score of 41.09 ± 33.45 decreased to 25.74 ± 22.29 [(-37.3%), p value<0.05] at visit 2; moreover, it further decreased to 5.75 ± 6.75 [(-86.0%), p value<0.05] at visit 3 [Figure 2].

Table 1: Demographic details

Characteristics	Result
Age (years)	
N	200
Mean	33.11
SD	13.89
Gender, N (%)	
Male	110 (55.00%)
Female	90(45.00%)
Exposure to antibiotics in the last 6 months, N (%)	
Yes	24 (12.00%)
No	176 (88.00%)
Cefixime tablet posology	
400mg OD	14 (7.00%)
200mg BD	186 (93.00%)

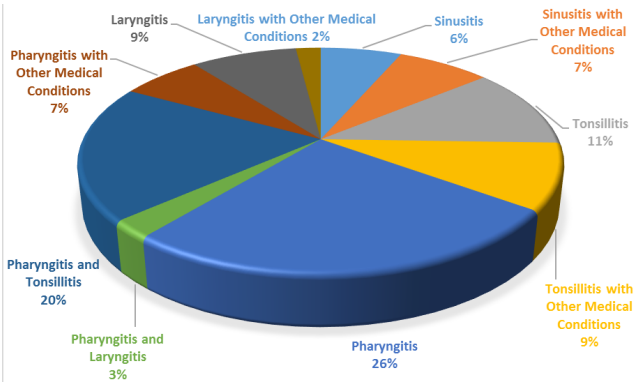

Fig. 1: Clinical Diagnosis

Similar trend was noted for WURSS symptom score and WURSS Quality of life score as mentioned in fig. 3 & 4. At baseline, mean WURSS Symptom score was 25.34 ± 15.97. At visit 2 (day 3-4), it was reduced to 16.32 ± 11.50 and at visit 3 (day 5-6) to 4.15 ± 4.50 (Figure 3). At baseline, mean WURSS Quality of life score was 15.74 ± 18.41. At visit 2 (day 3-4), it was reduced to 9.42 ± 11.66 and at visit 3 (day 5-6) to 1.59 ± 2.75 (Figure 4).

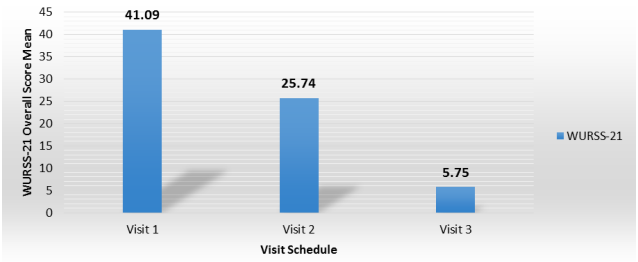

Fig. 2: WURSS-21 Overall Score Mean Distribution

Number of patients with moderate to severe disease at visit 1 were 46 (23%), which were reduced to 5 (2.5%) with

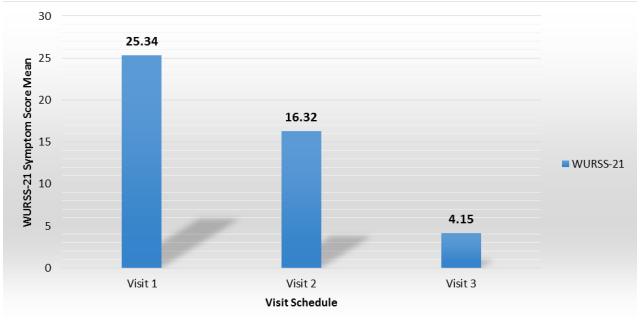

Fig. 3: WURSS-21 Symptom Score Mean Distribution

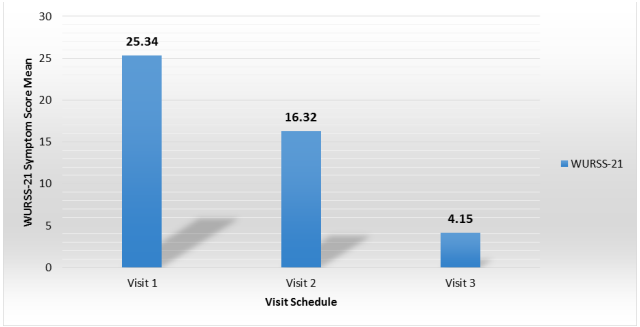

Fig. 4: WURSS-21 Quality of Life Score Mean Distribution

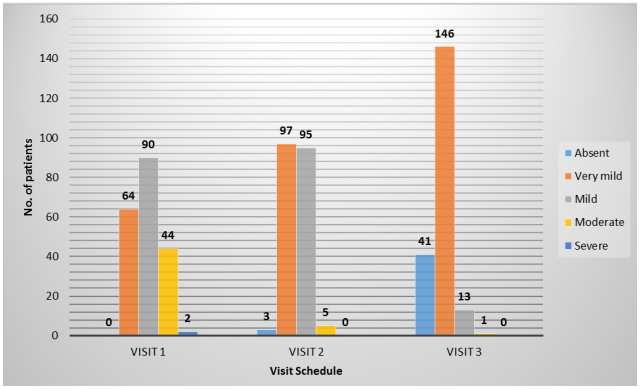

Fig. 5: Number of patients at each visit, according to severity, as per WURSS-21.

moderate disease at visit 2 and only 1 patient with moderate disease at visit 3. There were no patients encountered with severe disease at visit 2 and 3. Thus, 98% of the patients were improved symptomatically at visit 3 as compared to visit 1 [Figure 5].

3.2. Safety Assessments

None of the patients in the present study had reported adverse effects with Cefixime therapy.

4. Discussion

URTI is one of the commonest cause of frequent visit to outpatient department (OPD). It is the major cause for absenteeism and loss of productivity in work and thus has significant impact on adding to economic burden of the patient. Attending physician treats almost each case of URTI empirically, with short course of antibiotic therapy. Due to rise in penicillin resistance, cephalosporin, particularly Cefixime is commonly prescribed in such cases.[5,6]

In the present study, mean age of the patients was found to be 33.1 ± 13.89 years. This was in conjunction with finding of study done by Naik et al. who reported commonly affected age group in their study patients to be around 30 years.[6] Males outnumbered females in the present study with male: female ratio of 1.22. This was in contrast to findings of studies done by Mahajan et al and Naik et al, who reported more number of female patients as compared to male patients in their studies.[5,6]

Various studies had found that non-specific URTI was most common, followed by sinusitis, pharyngitis and tonsillitis in their study patients.[5,6] However, pharyngitis, followed by tonsillitis and sinusitis were commonly encountered in the present study.

Hausen et al. in their post marketing study had reported the use of 200 mg Cefixime twice daily as the commonly prescribed regimen as compared to 400 mg Cefixime once daily.[9] Similar trends were found in the present study.

In the present study, the WURSS21 score showed significant improvement in overall mean scores in all visits subsequent to start of the treatment. WURSS 21 score is amalgamation of symptom as well as quality of life scores, which has been validated as scoring system which gives importance to responsiveness, patient's quality of life, and reliability.[8] The present study is first of its kind to analyze the effect of antibiotic in URTI using WURSS 21 score. Hence, the comparison of effect of Cefixime with other studies/ antibiotics on the basis of WURSS 21 score was not possible.

On analyzing the number of patients with improvement in symptoms at the end of treatment, it was found that 98% of the patients had improvement in their symptoms. Similar trends were reported by Block et al.[10] Peyramond et al.[11] and Kiani et al.[12] in their clinical trials on evaluation of effectiveness and safety of Cefixime in upper respiratory tract infections. In another study by Adam et al, the effect of Cefixime was analyzed after its 5 day therapy regimen. They reported clinical cure rates of 98%, which is similar to that found in the present study.[13]

It is noteworthy to mention the findings of a multicentre clinical trial by Sunderland et al. on comparison of effect of Cefixime versus amoxicillin + clavulanic acid in patients of URTI. They found that Cefixime therapy was slightly better efficacious as compared to combination therapy of amoxicillin + clavulanic acid.[14] This might be attributed to

the fact that Cefixime is not amenable to the action of β lactamase, produced by pathogenic bacteria.[7] Also, it has been found that Cefixime achieves good concentration in tonsils, which lies in the therapeutic range.[15]

In the present study, even at median interval of therapy, i.e. on visit 2, improvement in symptoms was seen in 90% 0f the cases, which indicates speedy recovery with Cefixime. This symptom improvement rates were slightly lower as compared to that reported by Hausen et al.[9] However, the median interval for judging the speedy symptomatic recovery in that study was 6 days, which is prolonged duration even if it is compared with total therapy of the present study i.e. 5 days. Thus, in that sense the speedy recovery rates of the present study is at least at par with findings of other studies.

In India, URTI is one of the commonest cause of visit to OPD.[5] Due to rise in mixed infections, antibiotics are prescribed empirically in such cases. This is associated with significant increase in cost of therapy and thus the economic burden to the patient in a developing country like India. Quintiliani et al. in his pharmaco-economic study of antibiotics used in URTI had analyzed the cost of therapy by accounting various factors like additional drug therapy, additional physician visit cost, extra diagnostic tests, complications etc. The author reported that Cefixime amongst the other antibiotics help to significantly reduce the overall cost of therapy in patients of URTI.[16]

The current retrospective survey has few limitations. The chances of selection and recall bias cannot be ruled out, owing to retrospective design of the survey. Treatment with other antibiotics such as penicillin, macrolide, etc. was not taken into consideration which may have impacted the final outcome. Comparative studies with prospective, interventional design should be carried out for better understanding of effect of Cefixime in URTI.

5. Conclusion

URTI is treated empirically with short course of oral antibiotics. Due to rise in resistance to penicillin, cephalosporin are commonly prescribed. Cefixime is a third generation cephalosporin with long half-life, broad spectrum of antibacterial action, safe, with speedy relief of symptoms of URTI. The findings of the present survey confirm the effectiveness and safety of short course of Cefixime therapy in URTI.

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