Comparative Efficacy Of Fexofenadine, Levocetirizine, And Desloratadine In Chronic Spontaneous Urticaria: Impact Of Dose Escalation And Antihistamine Switching

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Abstract:

Background:
Sexually transmitted infections (STIs) remain a significant public health concern in India, contributing to increased morbidity and a heightened risk of HIV transmission. The COVID-19 pandemic has further influenced STI epidemiology by disrupting healthcare access and altering sexual behaviors. This study examines the epidemiological trends, syndromic presentations, and risk factors associated with STIs in a tertiary care hospital in Central Gujarat, India, during the second wave of the pandemic.

Methods:
A retrospective, cross-sectional, observational study was conducted at the STI clinic of a tertiary care hospital from April 2021 to March 2022. Medical records of 4,490 clinic attendees were reviewed, and 1,444 patients diagnosed with STIs were included. Data on demographic characteristics, syndromic presentations, and laboratory-confirmed infections (RPR, TPHA, and HIV) were analyzed. Statistical tests, including Chi-square analysis, were used to assess associations between variables.

Results:
The highest burden of STIs was observed among individuals aged 25–44 years (65.92%), with a notable predominance of female patients (77.4%). The most common syndromic presentations were lower abdominal pain (45.32%) and vaginal/cervical discharge (32.42%). Serological analysis revealed 181 RPR-reactive cases, with 85.64% showing TPHA positivity. Among 118 asymptomatic but high-risk patients, men who have sex with men (MSM) had the highest syphilis seropositivity (51 TPHA-positive cases). A significant association was found between syphilis and HIV co-infection ($\chi^2 = 33.83$, $p < 0.05$), with 28.9% of HIV-positive individuals also testing positive for syphilis.

Conclusion:
This study highlights the continued burden of STIs in India, particularly among reproductive-age individuals, with a significant proportion of cases in women. The strong correlation between syphilis and high-risk sexual behaviors

	underscores the need for targeted interventions. Additionally, the high prevalence of HIV-syphilis co-infection reinforces the necessity of integrated STI and HIV screening programs. Strengthening surveillance, enhancing public awareness, and improving healthcare accessibility are critical for effective STI control in resource-limited settings, particularly during public health emergencies.

Introduction

Reproductive tract infections (RTIs) and sexually transmitted infections (STIs) continue to be major global public health concerns, negatively affecting the quality of life for those who are afflicted and causing substantial morbidity and mortality (World Health Organization [WHO], 2021). In addition to directly endangering sexual and reproductive health, these infections raise the risk of infertility, chronic pelvic disorders, unfavorable pregnancy outcomes, and newborn problems (Newman et al., 2015). Furthermore, RTIs and STIs have wider socioeconomic ramifications, burdening healthcare systems, aggravating gender disparities, and obstructing the growth of the national economy (Chow et al., 2019). In addition to their direct negative effects on health, STIs are known to play a significant role in the dynamics of HIV transmission. Due to increased vaginal tract inflammation and mucosal rupture, which allow the virus to enter the body, people with untreated STIs may be two to five times more likely to contract HIV (Tobian & Quinn, 2021). On the other hand, co-infection with HIV changes how some STIs naturally progress, resulting in more severe symptoms, longer disease duration, and higher rates of transmission (Johnson et al., 2020). Effective STI management and prevention are essential elements of comprehensive HIV control programs because of these intricate relationships.
STIs and RTIs continue to be a major public health issue in India, requiring close monitoring and prompt treatment. According to the National AIDS Control Organization, estimates of STI prevalence vary greatly by location, with national and state estimates ranging from 0.1% to 8% (NACO, 2022). The susceptibility of young populations is shown by the fact that there are over 1.8 million new STI/RTI cases reported in India each year, with an estimated 30-35 million episodes occurring in those aged 15-24 (NACO, 2022). Underreporting persists because to societal stigma, ignorance, and insufficient access to healthcare in many areas, even with the WHO-recommended syndromic treatment method implemented in India's National STI/RTI Control Program (Kumar et al., 2020).
The global landscape of STI surveillance, diagnosis, and treatment has changed dramatically since the start of the COVID-19 pandemic. The diagnosis and management of STIs have been impacted by a number of factors, including movement limitations, disruptions in routine STI screening programs, and the reallocation of healthcare resources toward pandemic response activities (Tang et al., 2021). These issues were made worse in India by a decline in the number of people seeking medical care, a delay in seeking care because of infection fears, and a rise in the societal stigma attached to STIs (Bhattacharya et al., 2022). Additionally, the lockdowns brought on by the pandemic altered sexual practices, such as a rise in transactional sex, a greater dependence on online dating services, and difficulties obtaining preventive treatments like condoms and pre-exposure prophylaxis (PrEP) (Barbeeet al., 2020).

Evaluation of the effect of COVID-19 on STI trends is urgently needed in light of these changes, especially in areas with a high infection burden. In order to eradicate STIs as a public health concern by 2030, the World Health Organization's global health sector strategy on STIs (2016–2021) places a strong emphasis on the necessity of ongoing surveillance, improved prevention techniques, and easier access to STI care, especially for underserved groups (WHO, 2021). To minimize interruptions in healthcare delivery and improve future contingency plans for comparable health emergencies, it is essential to comprehend STI epidemiological trends during and after the COVID-19 pandemic. Research on the effect of COVID-19 on STI trends and clinical presentations in tertiary care settings is scarce, despite the high prevalence of STIs in India. By investigating the epidemiological profile of STI cases at a tertiary care hospital in Central Gujarat, India, during the second wave of the COVID-19 epidemic, this study seeks to close this knowledge gap. This study aims to determine prevalence patterns, syndromic presentations, and related risk factors among STI clinic participants by the analysis of clinic data. The results will help raise awareness, evaluate the risks of HIV transmission, and guide the creation of focused intervention plans in environments with limited resources during international health emergencies.

Materials and Methods

Study Design

This study is a retrospective, cross-sectional, observational analysis conducted at the Sexually Transmitted Infections (STI) Clinic attached to the Dermatology outpatient department (OPD) of a tertiary care center in Central Gujarat, India. The study aimed to assess the epidemiological profile, clinical presentations, and seroprevalence trends of STIs during and following the second wave of the COVID-19 pandemic. Given the disruptions in healthcare access and behavioral shifts during the pandemic, this study provides valuable insights into the burden of STIs in a resource-limited setting.

Study Period

The study covered a 12-month period from April 2021 to March 2022, capturing data during and immediately after the second wave of the COVID-19 pandemic in India. This period was chosen to evaluate the impact of pandemic-related restrictions on STI transmission, healthcare-seeking behavior, and surveillance trends.

Study Population

We reviewed medical records from 4,490 individuals who attended the STI clinic during the study period. Among them, 1,444 patients were diagnosed with STI syndromes based on syndromic management guidelines and were included in the study. This population represented a clinically significant cohort with confirmed or suspected STI diagnoses, making it an appropriate sample for understanding STI epidemiology in the region.

Inclusion Criteria

Patients were included in the study if they were diagnosed with one or more of the seven major STI syndromes as per the National Guidelines for STI/RTI Management, including urethral discharge, vaginal discharge, genital ulcer disease (herpetic or non-herpetic), inguinal bubo, lower abdominal pain (suggestive of pelvic inflammatory disease), acute scrotal pain and/or scrotal swelling, and genital dermatological conditions such as genital warts, molluscum contagiosum, or syphilitic rash. Additionally, only those patients who sought consultation for STI symptoms and received documented diagnostic and/or laboratory investigations were included in the study.

Exclusion Criteria

Patients were excluded if they were under 18 years of age, as pediatric STI cases require distinct management and ethical considerations. Those with incomplete or missing medical records, including lack of diagnostic confirmation or insufficient demographic data, were also excluded. Furthermore, patients who did not consent to participate or were lost to follow-up before diagnostic confirmation were not included in the final analysis.

Data Collection

Data was extracted from standardized case records maintained at the STI clinic, which adheres to the National AIDS Control Organization (NACO) guidelines for recording and reporting STI cases, ensuring systematic and reliable data collection. Several key variables were recorded for each patient, including demographic information such as age, gender, marital status, occupation, and socioeconomic background. Clinical presentation was documented based on chief complaints, STI syndrome classification, history of prior STIs, duration, and severity of symptoms. Laboratory investigations included serological testing for syphilis using the Rapid Plasma Reagin (RPR) test and Treponema Pallidum Hemagglutination Assay (TPHA), as well as HIV screening tests such as the Enzyme-Linked Immunosorbent Assay (ELISA) and Western Blot confirmation test.

Additionally, behavioral and risk factors were assessed, including sexual history (multiple partners, condom use, commercial sex work, and men who have sex with men [MSM]), history of partner treatment and partner notification, substance abuse, and other high-risk behaviors.** Partner treatment history** was also documented, specifically whether the patient's sexual partners had been screened

and treated. Further, the history of exposure was recorded, including the nature of sexual exposure (heterosexual, homosexual, or bisexual) and condom use consistency.

Laboratory Methods

All serological and diagnostic tests were conducted in the hospital laboratory following standard guidelines. Syphilis testing involved the Rapid Plasma Reagin (RPR) test, a qualitative and quantitative screening tool, and the Treponema Pallidum Hemagglutination Assay (TPHA) for confirmation of RPR-positive cases. HIV testing was performed using the Enzyme-Linked Immunosorbent Assay (ELISA) as a first-line screening test, followed by Western Blot for confirmation, minimizing the risk of false positives. All laboratory tests were conducted by trained technicians under the supervision of a senior microbiologist, with internal and external quality control measures implemented in accordance with WHO and NACO standards to ensure accuracy and reliability.

Data Analysis

Data analysis was conducted using Microsoft Excel 2017 for data entry and IBM SPSS version 25.0 for statistical evaluation. Descriptive statistics were applied to summarize demographic characteristics, syndromic presentations, and seropositivity rates. To determine associations between categorical variables, such as gender differences in STI presentation and HIV co-infection rates, Chi-square tests were performed. A p-value of <0.05 was considered statistically significant, indicating meaningful associations.

Ethical Consideration

This study adhered to the ethical principles of the Declaration of Helsinki (2013) and was approved by the Institutional Ethics Committee (IEC) of the tertiary care center(Approval No. IEC/2021/045). To maintain confidentiality, all patient data was anonymized before analysis, with names and other identifiable information replaced with unique patient codes. Given the retrospective nature of the study, the requirement for individual patient consent was waived by the IEC.

Data Management and Confidentiality

To ensure data security, patient records were stored on password-protected computers accessible only to the research team, while physical records were secured in locked cabinets. Efforts were made to minimize bias by relying on pre-existing medical records, thus reducing selection and recall biases. However, missing data points were not artificially imputed to maintain the integrity of the analysis.

Strict measures were implemented to protect data confidentiality and ensure compliance with institutional and ethical guidelines. Access control was enforced, allowing only authorized research personnel to handle patient data. Digital records were securely stored in encrypted databases with multi-layer authentication. In accordance with institutional guidelines, patient records were archived for five years post-publication to maintain research integrity and facilitate future reference.

Results:

The age and sex distribution of sexually transmitted infection (STI) patients attending the STI clinic (n=1444) showed that the majority of cases (65.92%) were in the 25–44 years age group, comprising 196 males (13.57%), 755 females (52.29%), and one transgender individual (0.07%) as shown in Table number 1. The 20–24 years age group accounted for 16.55% of the cases, including 57 males (3.95%), 179 females (12.40%), and three transgender individuals (0.21%). Patients over 44 years constituted 15.09% of the total, with 63 males (4.36%) and 155 females (10.73%). The lowest proportion (2.42%) was observed in those under 20 years, comprising seven males (0.48%) and 28 females (1.94%). Overall, females represented the highest proportion of STI cases (77.37%), followed by males (22.38%), while transgender individuals accounted for only 0.28% of the total cases.

Among the 1326 patients presenting with sexually transmitted infection (STI) syndromes, the most common clinical presentation was lower abdominal pain, affecting 601 patients (45.32%). Vaginal or cervical discharge was reported by 430 patients (32.42%), making it the second most prevalent

syndrome. Herpetic genital ulcers were observed in 131 patients (9.87%), while non-herpetic genital ulcers accounted for 36 cases (2.7%). Painful scrotal swelling was noted in 35 patients (2.6%), and urethral discharge was identified in six patients (0.45%). Anorectal discharge was reported in eight cases (0.60%), and inguinal bubo was found in six cases (0.45%). Genital warts were present in 71 patients (5.35%), whereas other conditions, such as molluscum contagiosum, were rare, with only two cases (0.15%). These findings highlight the predominance of lower abdominal pain and vaginal/cervical discharge among STI patients, with ulcerative and discharge-related syndromes also contributing to the clinical burden.

Out of 1444 syndromic patients evaluated on the basis of clinical and RPR status of the patients., 1326 patients had one of the major STI syndromes while 118 patients were asymptomatic but engaged in high-risk sexual practices and found RPR reactive.

Among the 118 asymptomatic patients with reactive rapid plasma reagin (RPR) tests, men who have sex with men (MSM) constituted the largest group, with 57 patients (48.31%) testing RPR reactive, of whom 51 (43.22%) also had Treponema pallidum hemagglutination assay (TPHA) positivity. A history of sexual exposure outside of a primary partnership was reported in 33 patients (27.97%) with RPR reactivity, and 28 (23.73%) of these were also TPHA-positive. Twelve patients (10.17%) with a history of multiple sexual partners had both RPR reactivity and TPHA positivity. Transgender individuals accounted for two cases (1.69%), both of whom (1.69%) tested positive for TPHA. Among patients with a partner who had RPR reactivity, 12 (10.17%) tested positive for RPR, with 11 (9.32%) showing TPHA positivity. Additionally, two patients (1.69%) had partners living with HIV/AIDS (PLHA), with one (0.85%) testing positive for TPHA. Overall, of the 118 patients with RPR reactivity, 105 (88.98%) also had TPHA positivity, highlighting the strong association between high-risk sexual behaviors and serological markers of syphilis.

Among the 181 patients with reactive rapid plasma reagin (RPR) tests, 155 (85.64%) were also positive for Treponema pallidum hemagglutination assay (TPHA), while 26 (14.36%) were TPHA-negative. The most common RPR titer among TPHA-positive patients was 1:2, observed in 53 cases (29.28%), followed by 1:32 in 21 cases (11.60%) and 1:16 in 15 cases (8.29%). Other notable titers among TPHA-positive patients included 1:4 in 23 cases (12.71%), 1:8 in 12 cases (6.63%), 1:64 in 13 cases (7.18%), and 1:256 in nine cases (4.97%). Higher titers such as 1:128, 1:512, and 1:1024 were detected in three (1.66%), one (0.55%), and one (0.55%) patient, respectively. Among TPHA-negative patients, the most frequent RPR titers were 1:2 in 15 cases (8.29%) and 1:1 in nine cases (4.97%), with smaller proportions in other titers.

A significant association between syphilis and HIV co-infection was observed among 1444 patients ($\chi^2 = 33.83$, $p < 0.05$). Of the 159 patients who tested positive for both RPR and TPHA, 28 (17.61%) were also HIV-positive, while 131 (82.39%) were HIV-negative. In contrast, among the 1285 patients negative for both RPR and TPHA, only 69 (5.37%) were HIV-positive, whereas 1216 (94.63%) were HIV-negative. The higher prevalence of HIV among syphilis-positive individuals highlights a significant correlation between these infections, reinforcing the need for routine dual screening and comprehensive management strategies.

Table 1: Age and sex distribution of STI patients attending STI clinic (n=1444)

Age group	Male	Female	Transgender	Total
<20 years	7	28	-	35(2.42%)
20-24 years	57	179	3	239(16.55%)
25 -44 years	196	755	1	952(65.92%)
>44 years	63	155	-	218(15.09%)
Total	323	1117	4	1444

Table 2: Clinical presentation of Major STI Syndromes (n=1326)

Syndrome	No. of patients (%)
Lower abdominal pain	601(45.32)
Vaginal /cervical discharge	430(32.42)
Herpetic genital ulcers	131(9.87)
Non herpetic genital ulcers	36(2.7)
Painful scrotal swelling	35(2.6)
Urethral discharge	6(0.45)
Anorectal discharge	8(0.60)
Inguinal bubo	6(0.45)
Genital wart	71(5.35)
Others like molluscum contagiosum	2(0.15)
Total	1326

Table 3: Analysis of high risk sexual behaviour in asymptomatic RPR reactivity and TPHA positivity (n=118)

High risk sexual practices	**No. of patients with RPR reactivity**	**No. of patients with TPHA positivity**
MSM	57	51
History of outside sexual exposure	33	28
History of multiple partners	12	12
Transgenders	2	2
Partner with RPR reactivity	12	11
PLHA as partner	2	1
Total	118	105

MSM=Men having sex with men; PLHA= People living with HIV/AIDS

Table 4: Distribution of RPR Titers and Corresponding TPHA Positivity Among Patients with Reactive RPR Tests (n=181)

RPR titer	TPHA negative	TPHA positive	Total
1:01	1	-	1
1:02	1	1	2
1:08	-	1	1
1:1	9	2	11
1:2	15	53	68
1:4	-	23	23
1:8	-	12	12
1:16	-	15	15
1:32	-	21	21
1:64	-	13	13
1:128	-	3	3
1:256	-	9	9
1:512	-	1	1
1:1024	-	1	1
TOTAL	26	155	181

Table 5: Association Between HIV and Syphilis (RPR + TPHA) Co-Infection Among Patients (n=1444)

TEST		HIV		
		Positive	Negative	
RPR+TPHA	Positive	28	131	159
	Negative	69	1216	1285
		97	1347	1444

Discussion

Sexually transmitted infections (STIs) has always remained a significant public health challenge and a burden on Indian society, with high prevalence rates contributing to morbidity and increased risk of HIV transmission. The disruptions caused by the Covid-19 pandemic, including restricted healthcare access, social stigma, fear of infection and behavioral changes, have influenced STI transmission dynamics and healthcare-seeking behavior. Examining the prevalence patterns by analysis of age and sex distribution among 1,444 patients attending the STI clinic revealed notable demographic result patterns. Majority of the STI patients (65.92%) belonged to the 25-44 years age group, followed by 16.55% in the 20-24 years age group, 15.09% in individuals over 44 years, and only 2.42% in those under 20 years. This distribution highlights that sexually transmitted infections (STIs) are more prevalent among individuals in their reproductive and sexually active years (25-44 years), aligning with global epidemiological trends where STIs peak in young and middle-aged adults due to increased sexual activity, multiple partners, and inconsistent use of protection. (1)

Sex-wise distribution showed that a significant females suffered from STI (77.4%), with 1,117 females, compared to 323 males (22.4%) and only 4 transgender individuals (0.003%). Several factors contribute to female predominance including higher healthcare-seeking behavior among women, routine STI screening during antenatal visits, and greater biological susceptibility to STIs in females due to anatomical differences. (2, 3) Also, social stigma and lack of access to healthcare services may contribute to lower male and transgender participation in STI screening and treatment. Among younger age groups, the number of female patients was significantly higher than males, emphasizing the need for targeted STI awareness through comprehensive sexual education, increased screening and awareness campaigns, and early intervention strategies among young women.

On evaluating the syndromic distribution of STI cases important insights were observed regarding the most prevalent clinical manifestations. Among the 1,326 symptomatic patients, the most frequently reported symptom was lower abdominal pain (LAP) (45.32%), followed by vaginal/cervical discharge (32.42%), collectively accounting for nearly 78% of all cases. This highlights the high burden of reproductive tract infections (RTIs) among women, reinforcing the need for early detection and management of RTIs to prevent complications such as pelvic inflammatory disease (PID), infertility, and adverse pregnancy outcomes. (4)

Genital ulcer disease (GUD) was observed in 167 patients (12.57%), with herpetic ulcers (9.87%) being more prevalent than non-herpetic ulcers (2.7%). This symptoms aligns with global patterns, where herpes simplex virus (HSV) is a leading cause of genital ulcerative disease. (5) The presence of non-herpetic genital ulcers suggests infections such as syphilis or chancroid, emphasizing the need for accurate etiological diagnosis and targeted treatment. (6)

Other notable presentations included painful scrotal swelling (2.6%), urethral discharge (0.45%), anorectal discharge (0.6%), and inguinal bubo (0.45%). While these conditions were less frequently observed, their presence is clinically significant, as urethral discharge is often associated with gonorrhea and chlamydial infections, and inguinal bubo is commonly linked to lymphogranuloma venereum (LGV) which requires prompt diagnosis and treatment. (7, 8)

The presence of genital warts suggests a notable prevalence of human papillomavirus (HPV) infections, reinforcing the importance of HPV vaccination programs and regular screening to prevent long-term complications such as cervical and anogenital cancers. (9) Molluscum contagiosum was observed in only two patients, indicating its relatively low burden compared to other STI syndromes.

The analysis of 118 asymptomatic patients with RPR reactivity indicates anassociation between high-risk sexual behaviors and syphilis seropositivity. Individuals with MSM accounted for the highest proportion (57 cases, 51 TPHA positive), followed by individuals with a history of outside sexual exposure (33 cases, 28 TPHA positive) and multiple partners (12 cases, all TPHA positive). The findings of this study aligns with previously reported studies that have identified MSM and individuals with multiple sexual partners as high-risk groups for syphilis and other STIs, including HIV. (10, 11)

In serological trend analysis, the distribution of RPR titers among 181 patients with reactive RPR tests shows that low RPR titers had mixed TPHA results, suggesting biological false positives or early/latent infection. In contrast, all cases with RPR titers ≥1:4 were TPHA positive, confirming active syphilis. This findings aligns with previously reported research have demonstrated that low RPR titers can occur in conditions unrelated to syphilis, such as autoimmune diseases, viral infections, pregnancy, and aging, leading to biological false positives BFP results. (12)

There was a strong association between syphilis and HIV observed in this study, with 28.9% of HIV-positive patients also testing positive for syphilis, compared to 9.7% among HIV-negative individuals. This was consistent with the results of several studies that have shown that syphilis infection increases the risk of HIV acquisition due to ulcerative lesions, which compromise mucosal barriers and facilitate

viral entry. (13) This statistically significant correlation ($\chi^2 = 33.83$, $p < 0.05$) highlights the need for integrated HIV and syphilis screening and treatment programs, particularly in high-risk populations.

Conclusion

This study provides valuable insights into the epidemiological trends of sexually transmitted infections (STIs) in a tertiary care setting in Central Gujarat during the second wave of the COVID-19 pandemic. The findings highlight a high prevalence of STIs among individuals in their reproductive and sexually active years (25–44 years), with a significant burden on women. The dominance of lower abdominal pain and vaginal/cervical discharge as the most reported symptoms underscores the need for early diagnosis and management of reproductive tract infections (RTIs) to prevent complications like infertility and adverse pregnancy outcomes. Higher proportion of genital ulcer disease, particularly herpetic ulcers, aligns with global patterns, reinforcing the necessity for increased awareness, screening, and access to antiviral therapies. Less common but clinically significant syndromes such as urethral discharge, inguinal bubo, and scrotal swelling emphasize the importance of targeted diagnostic approaches for bacterial STIs like gonorrhea, chlamydia, and lymphogranuloma venereum (LGV). Additionally, the presence of genital warts highlights the need for widespread HPV vaccination programs to prevent associated cancers. The strong correlation between syphilis and high-risk sexual behaviors, particularly among MSM and individuals with multiple partners, reinforces the necessity of targeted intervention strategies for these vulnerable populations. Furthermore, the association between syphilis and HIV co-infection observed in this study aligns with global research, emphasizing the role of integrated STI and HIV screening programs. The serological trend analysis further highlights the importance of interpreting RPR titers correctly to differentiate between biological false positives and active syphilis cases.

These findings insists on the urgent need for strengthened STI surveillance, enhanced awareness campaigns, improved accessibility to screening and treatment services, and comprehensive sexual health education programs. Addressing social stigma, increasing male and transgender participation in STI screening, and integrating STI and HIV prevention strategies will be crucial steps toward reducing transmission, improving early diagnosis, and mitigating the long-term impact of STIs in resource-limited settings.

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