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Pharmacoepidemiological Perspective of Vaginal Candidiasis: A Cross Sectional Surveillance Study among Women of Reproductive Age Group Belonging To Wardha District, Maharashtra, India.

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ABSTRACT

Vulvovaginal Candidiasis (VVC) Vulvovaginal candidiasis (VVC) is a Reproductive tract infection affecting millions of women worldwide. In developing countries, the prevalence of this infection has increased in recent years. To study the pharmacoepidemiological perspective of Vaginal candidiasis, it was compared to the other abnormal vaginal discharge diseases. 221 Vaginal candidiasis patients were studied out of 350 abnormal vaginal discharge patients. Itching was the most presenting symptom, while incidence was high in 21-35 age group. The majority of the patients belonged to low socioeconomic strata. Vaginal Candidiasis was predominantly seen more in patients with pregnancy. Fluconazole 150 mg once was the main treatment given while in topical Clotrimazole and Miconazole vaginal pessaries were used which relieved the symptoms. Multivitamin tablets (19%) and Ranitidine (6.87%) were prescribed for symptomatic relief.

Keywords: Vaginal Candidiasis, Fluconazole, Clotrimazole

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INTRODUCTION

Vaginal discharge is a clinical condition characterized by leucorrhoea, which can be caused by reproductive tract infections (RTIs). Three RTIs are referred to as vaginal infections: Bacterial Vaginosis (BV), Trichomoniasis (TV), and Vulvovaginal Candidiasis (VVC) [1].

Parasites, bacteria, viruses and fungi are the causative agents of human genitourinary tract infections. Candidiasis is one of the most important opportunistic fungal infections [2-4].

Mixed infections are observed frequently. In patients with mixed infections, various combinations of *Candida Albicans*, *Trichomoniasis Vaginalis*, *Gardenerella Vaginalis*, other candida species or various bacteria are commonly seen. Symptoms that arise vary with the infection, although there are general symptoms shared by all vaginal infections; infected women may also be asymptomatic [5]. They need treatment with the combination of drugs, which usually includes oral Metronidazole and a topical azole antifungal medication [6].

In the genital tract of women, are micro flora made up of wide variety of species, like the lactobacillus species that play useful roles, while others like *Gardnerella vaginalis* and *Candida albicans* reside there as commensals, but may become pathogenic if opportunity arises [7].

Bacterial Vaginosis is a complex polymicrobial syndrome that lacks an identified etiological agent. Symptomatic Bacterial Vaginosis is characterized by malodor and grey, thin, homogenous vaginal discharge. Development of Bacterial Vaginosis is associated with loss of *Lactobacillus* species - the dominant bacteria in healthy vaginal flora - and in particular hydrogen peroxide (H₂O₂)-producing *Lactobacillus* species. The vaginal flora of women with Bacterial Vaginosis is often dominated by various species of anaerobic bacteria, such as *Gardnerella*, *Bacteroides* and *Mobiluncus*. Bacterial Vaginosis is associated with "all major adverse pregnancy outcomes" among pregnant women.[8],[9]

Trichomonas vaginalis: *Trichomonas vaginalis* is a sexually transmitted protozoan, which can cause vaginal irritation, pruritis, and malodorous discharge, though asymptomatic carriage is common. *Trichomonas vaginalis* is the most common curable sexually transmitted infection. *Trichomonas vaginalis* infection is associated with preterm delivery and low birth weight and with an increased risk of HIV acquisition [10,11].

Vulvovaginal Candidiasis: Vulvovaginal candidiasis is caused by overgrowth of *Candida* yeast species, most often *Candida albicans*. The overgrowth causes vaginal pruritis, erythema and a curd-like vaginal discharge. Vulvovaginal candidiasis (VVC) is one such infection affecting millions of individuals worldwide. In developing countries, the prevalence of this infection has increased in recent years [12,13].

The infection can be acute or chronic, superficial or deep, and its clinical *Candida* spectrum is so wide that a more specific definition cannot be made [14].

Data of incidence of Vaginal Candidiasis suggest approximately two-thirds of women experience at least one episode during their lifetime and nearly 50% of women have multiple episodes. The majority of cases of Vulvovaginal Candidiasis are caused by *C. albicans*; however, incidences due to non-*albicans* species of *Candida* appear to be increasing [15].

Non-*albicans* species are most commonly represented by *C. tropicalis*, *C. glabrata*, and *C. krusei* [16].

VVC due to NAC spp. is clinically indistinguishable from that caused by *C. albicans*; moreover it is more resistant to antifungal treatment [17].

C. albicans is responsible for 85% - 95% of vaginal yeast infections. 18,19 ,20 Currently, *Candida* vaginitis is more common than Trichomonal and Bacterial vaginosis [13, 21,22].

Patients with *Candida* vaginitis may not show any particular symptoms, but symptoms such as itching, burning, caseous discharge, painful intercourse, and vulva edema and erythema may be reported [23,24].

The distribution of *Candida* spp. in VVC cases varies widely depending on the geographical locations as well as the population studied [25].

In surveys, the prevalence of Vulvovaginal Candidiasis is highest among women in their reproductive years: 55 % of female university students report having had at least one healthcare provider-diagnosed episode by age 25 years, 29 to 49 % of premenopausal women report having had at least one lifetime episode, and 9 % of women report having had four or more infections in a 12-month period i.e. Recurrent Vulvovaginal Candidiasis (RVVC) [26,27].

Topical and oral azole therapies all give a clinical and mycological cure rate of over 80% in uncomplicated acute vaginal and vulval candidiasis [28].

Much of the epidemiologic literature concerning Vulvovaginal Candidiasis reports on studies in which women were queried on their self-reported history of Vulvovaginal Candidiasis [29].

In India, only two studies have been conducted in which laboratory confirmed Vulvovaginal Candidiasis was diagnosed in a community-based sample. Bang et al. diagnosed vulvovaginal candidiasis in 35% of 650 adult women living in rural Maharashtra state, and Prasad et al. diagnosed vulvovaginal candidiasis in 10% of 451 married, 16–22 year old women in rural Tamil Nadu state [30,31]. However, neither study assessed the incidence of or identified risk factors for Vulvovaginal Candidiasis.

VVC, like many vulvar diseases, has the potential to cause great psychologic distress and negatively impact on patient's quality of life (QoL) [32, 33].

Epidemiological data are necessary for the monitoring of Vaginal Candidiasis and provides the basis of training programs for medical professionals in primary health care with the aim to reduce long-term morbidity and socioeconomic impact.

However, there is lack of Pharmacoepidemiological data regarding Vaginal Candidiasis in Vidarbha region. Therefore the present study was conceived, designed and carried out as the first study of this region to explore the prevalence of Vaginal Candidiasis, to assess the impact of this infection on Quality of Life and to appraise the treatment modalities in Acharya Vinoba Bhave Rural Hospital - a tertiary health care setting of Vidarbha.

MATERIALS AND METHODS

Study Design: A Monocentric Hospital Based Observational Study.

Locus of Study: Acharya Vinoba Bhave Rural Hospital, Sawangi (Meghe), Wardha

Time Frame: 1st October 2013 to 30th September 2015

Study Sample: Women of Reproductive Age Group Belonging To Wardha District.

Sample Size: 350

Approval of Institutional Ethics Committee:

The synopsis of the study protocol was submitted to the Institutional Ethics Committee of Datta Meghe Institute of Medical Sciences (Deemed University), Sawangi (Meghe), Wardha on 21/08/2013.

The study was approved by the Institutional Ethics Committee of Datta Meghe Institute of Medical Sciences (Deemed University) on 28/09/2013 (Ref. No. DMIMS (DU) / IEC / 2013-14 / 144).

Inclusion Criteria

- a) All women of reproductive age group and sexually active with vaginal discharge attending Gynecology OPD with self-reported symptoms of vaginal discharge, genital burning or burning during micturition during the study period were included.
- b) The women who are available at the time of data collection.

Exclusion Criteria

- a) Women with abnormal vaginal bleeding,
- b) Post hysterectomised women,
- c) Women with cervical lesions and post-menopausal women.

RESULTS AND DISCUSSION

The present study comprised **350** cases of abnormal vaginal discharge.

Incidence and Prevalence

The incidence of Vaginal Candidiasis was found to be 63.14% amongst the patients of abnormal vaginal discharge attending O.P.D in the Obstetrics and Gynaecology department during the study period. (Table No 1, 2, Figure No. 1,2)

Table 1: Incidence of Vaginal Candidiasis.

| Sr. No. | Vaginal Infections | No. Of Patients | Incidence |
|---------|---------------------|-----------------|-------------|
| 1 | Vaginal Candidiasis | 221 | 63.14% |
| 2 | Bacterial Vaginosis | 90 | 25.72% |
| 3 | Trichomoniasis | 23 | 6.57% |
| 4 | Mixed infections | 16 | 4.57% |
| | Total | 350 | 100% |

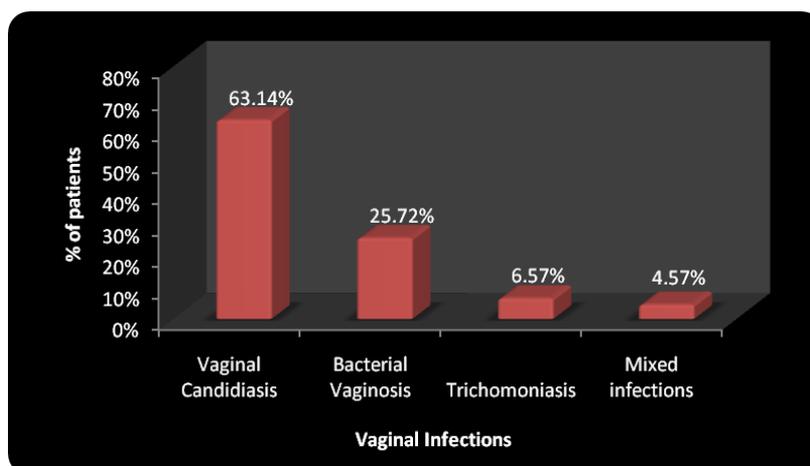


Figure 1: Incidence of Vaginal Candidiasis.

Overview of OPD cases of Vaginal Candidiasis.

The prevalence of Vaginal Candidiasis was found to be **2.06 %** amongst the total patients attending O.P.D. in the Obstetrics and Gynaecology department during the study period.

Table 2: Overview of OPD cases of Vaginal Candidiasis.

| Sr.No | Year | No. Of patients attending Gynaec OPD | No of patients | Percentage |
|-------|---------|--------------------------------------|----------------|------------------|
| 1. | 2013* | 14082 | 483 | 3.43 |
| 2. | 2014** | 61007 | 838 | 1.37 |
| 3. | 2015*** | 42644 | 593 | 1.39 |
| | Total | 117,733 | 1914 | Avg =2.06 |

*October to December 2013 **January to December 2014 ***January to September 2015.

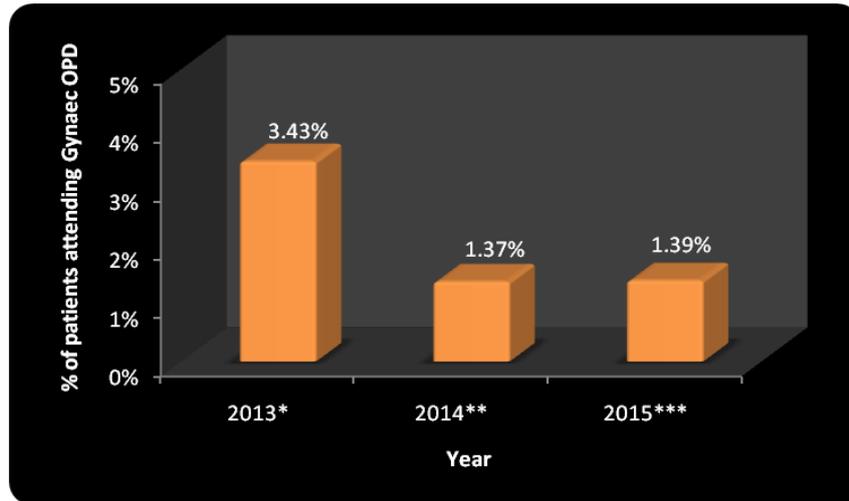


Figure 2: Overview of OPD cases of Vaginal Candidiasis.

Age Distribution

350 cases were divided into three age groups viz. 15-25 years, 26-35 years and 36-45 years.

Most patients were between the ages of 26 - 35years (51.13%) followed by 15-25 years (32.13%), and 36 - 45years (16.74%).

Table 3: Age Distribution amongst Patients of Vaginal Candidiasis

| Sr.No | Age (years) | No of Patients | Percentage (%) |
|-------|--------------|----------------|----------------|
| 1 | 15 – 25 yrs | 71 | 32.13% |
| 2 | 26 – 35 yrs | 113 | 51.13% |
| 3 | 36 – 45 yrs | 37 | 16.74% |
| | Total | 221 | 100% |

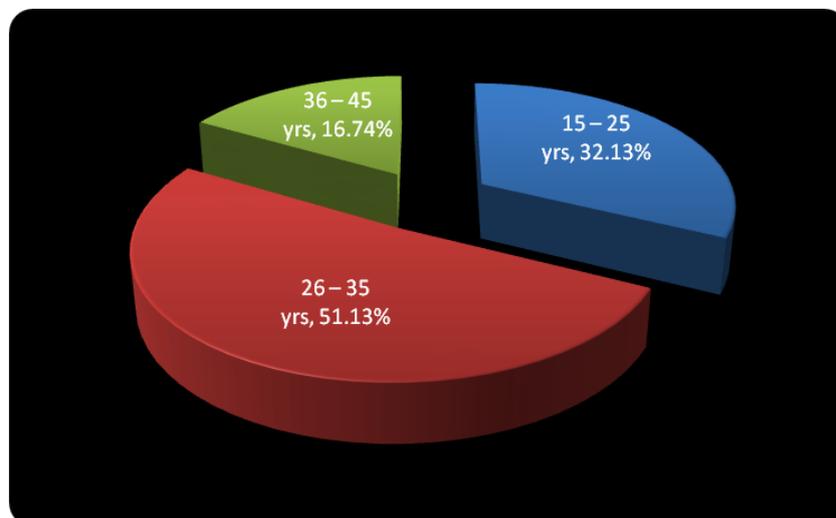


Figure 3: Age Distribution amongst Patients of Vaginal Candidiasis

Seasonal Variations

Numbers of cases found were more during the Monsoon (52.49%) followed by Summer (35.75%) and Winter (11.76%).

Table 4: Seasonal Variations in Patients of Vaginal Candidiasis.

| Sr.No | Season | No of Patients | Percentage (%) |
|-------|--------------|----------------|----------------|
| 1 | Winter | 26 | 11.76% |
| 2 | Monsoon | 116 | 52.49% |
| 3 | Summer | 79 | 35.75% |
| | Total | 221 | 100% |

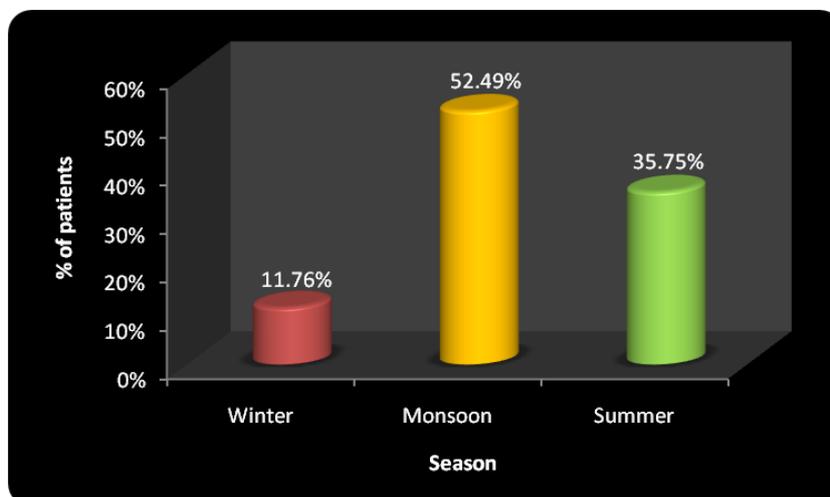


Figure 4: Seasonal Variations in Patients of Vaginal Candidiasis.

Presenting Symptoms

Vulval Itching (57.01%) is the commonest presenting symptom associated with other symptoms such as Vaginal discharge(48.42%), dysuria (7.24%) vulval soreness(4.98%) and Dyspareunia(5.43%).

Table 5: Presenting Symptoms of Patients of Vaginal Candidiasis.

| Sr. No. | Presenting Symptoms | No. of Patients | Percentage (%) |
|---------|----------------------------------|-----------------|----------------|
| 1 | Vaginal Discharge (Cheesy curdy) | 107 | 48.42% |
| 2 | Vulval itching | 126 | 57.01% |
| 3 | Vulval soreness | 11 | 4.98% |
| 4 | Dyspareunia | 12 | 5.43% |
| 5 | Dysuria | 16 | 7.24% |

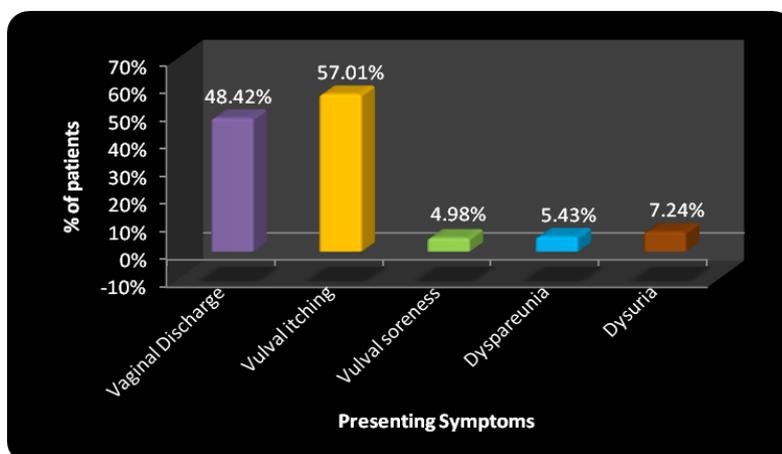


Figure 5: Presenting Symptoms of Patients of Vaginal Candidiasis.

immunosuppression(10.40%), diabetes mellitus(8.60%) and OCP users(4.97%)

Predisposing Factors in Patients of Vaginal Candidiasis.

Vaginal Candidiasis was predominantly seen more in patients with pregnancy (29.43%) mainly in the 3rd trimester (41.54%) associated with other factors such as H/O antibiotics (12.67%), anaemia(19%), previous history of vaginal candidiasis(14.93%), immunosuppression(10.40%), diabetes mellitus(8.60%) and OCP users(4.97%)

Table 6: Predisposing Factors in Patients Of Vaginal Candidiasis.

| Sr. No | Predisposing Factors | No. of Patients | Percentage (%) |
|--------|----------------------------------|-----------------|----------------|
| 1. | Pregnancy | 65 | 29.43 |
| | 1 st trimester | 17 | 26.16 |
| | 2 nd trimester | 21 | 32.30 |
| | 3 rd trimester | 27 | 41.54 |
| 2. | H/O antibiotics | 28 | 12.67 |
| 3. | Previous H/O vaginal candidiasis | 33 | 14.93 |
| 4. | Anaemia | 42 | 19 |
| 5. | Immunosuppression | 23 | 10.40 |
| 6. | Diabetes Mellitus | 19 | 8.60 |
| 7. | OCP Users | 11 | 4.97 |
| | total | 221 | 100 |

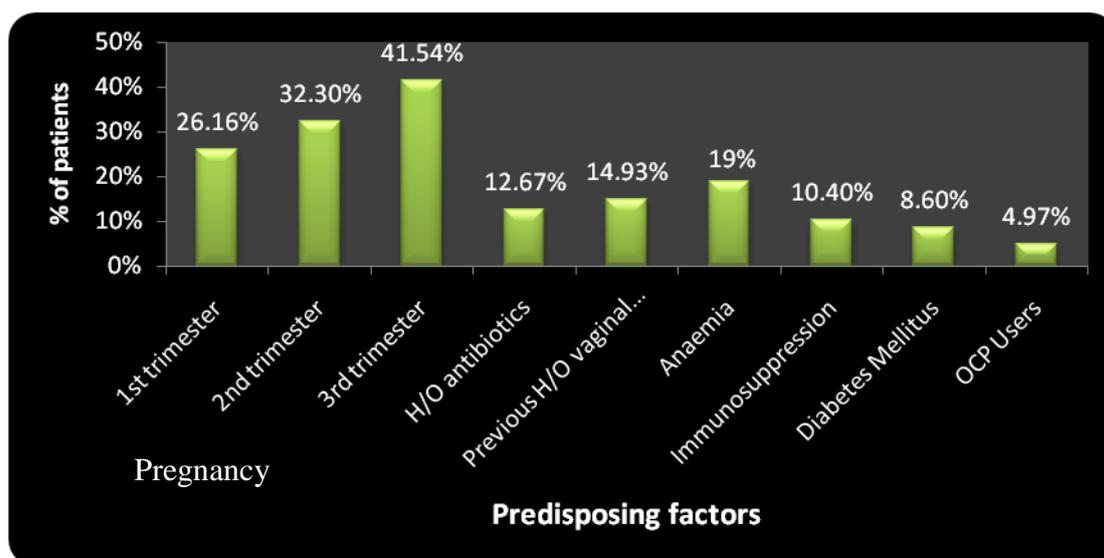


Figure 6: Predisposing Factors in Patients Of Vaginal Candidiasis.

Socio economic status Factors in Patients of Vaginal Candidiasis

Vaginal Candidiasis was predominantly seen more in patients with low Socio economic status (86.88%) followed by medium Socio economic status (13.12%)

Table 7: Socio economic status Factors in Patients Of Vaginal Candidiasis

| Sr. No | Status | No. of Patients | Percentage (%) |
|--------|--------|-----------------|----------------|
| 1. | Low | 192 | 86.88% |
| 2. | Medium | 29 | 13.12% |
| 3. | High | - | - |
| | Total | 221 | 100% |

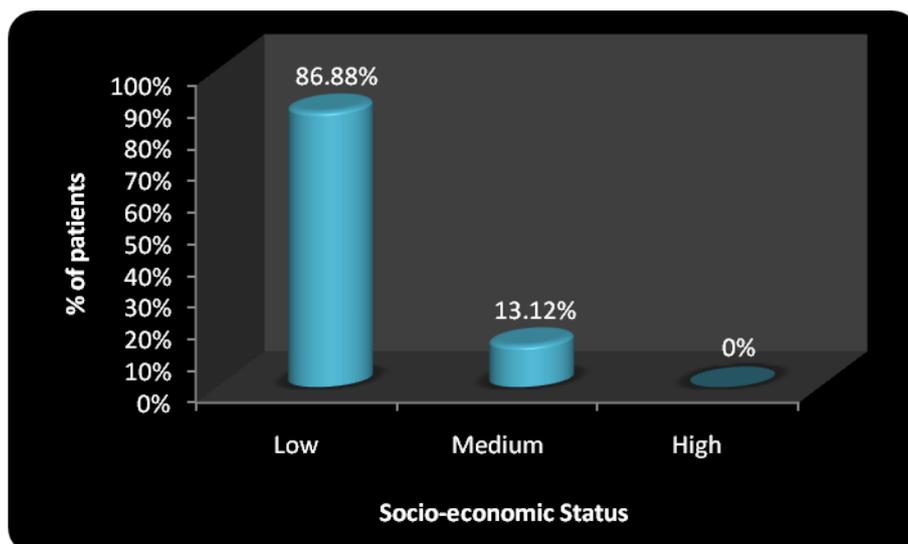


Figure 7: Socio economic status Factors in Patients Of Vaginal Candidiasis

Quality Of Life

Data were obtained from patients who responded to Quality of life questionnaire and analysed. The mean score in Vaginal Candidiasis was found to be 8.69 ± 4.56 .

When comparing the scores of the individual items in vaginal candidiasis patients, the highest scores was seen in Question 1 and lowest scores in Question 6.

Table 8: Mean Scores of each Modified DLQI question in Vaginal candidiasis Patients

| Sr. No. | Questions | Mean Score |
|---------|---|-----------------|
| 1 | Over the last week, how itchy, sore, painful or stinging has your vulva and/or vagina been? | 2.06 ± 1.02 |
| 2 | Over the last week, how embarrassed or self conscious have you been because of your vaginal symptoms? | 1.38 ± 0.97 |
| 3 | Over the last week, how much has your vaginal symptoms interfered with you going shopping or looking after your home or garden ? | 0.46 ± 0.16 |
| 4 | Over the last week, how much has your vaginal symptoms influenced the clothes you wear? | 0.73 ± 0.58 |
| 5 | Over the last week, how much has your vulva and vaginal symptoms affected any social or leisure activities? | 0.57 ± 0.33 |
| 6 | Over the last week, how much has vaginal symptoms made it difficult for you to do any sport ? | 0.24 ± 0.05 |
| 7 | Over the last week, has your vaginal symptoms prevented you from working or studying ? | 1.28 ± 0.61 |
| 8 | Over the last week, how much has your vaginal symptoms created problems with your partner or any of your close friends or relatives ? | 0.97 ± 0.52 |
| 9 | Over the last week, how much has your vulva and vaginal symptoms caused any sexual difficulties ? | 0.72 ± 0.29 |
| 10 | Over the last week, how much of a problem has the treatment for your vaginal symptoms been, for example by making your home messy, or by taking up time? | 0.28 ± 0.03 |
| | total | 8.69 ± 4.56 |

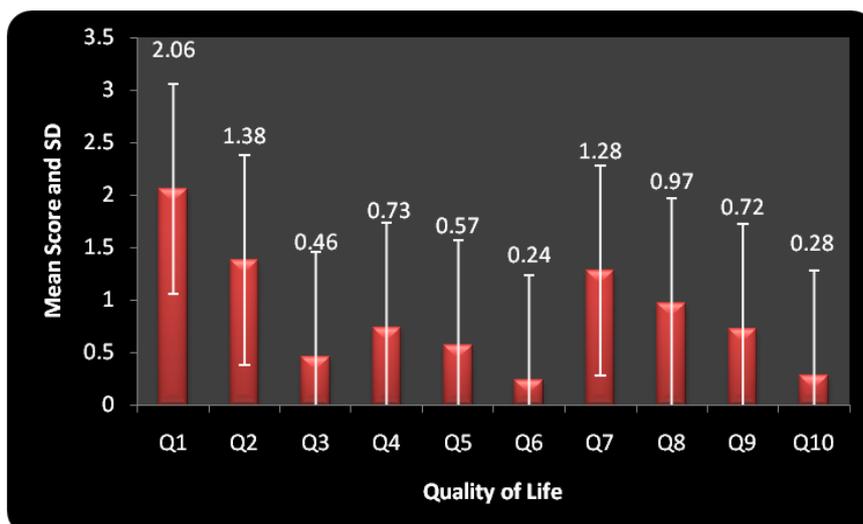


Figure 8: Mean Scores of each Modified DLQI question in Vaginal candidiasis Patients

Treatment Modalities

Topical therapy and systemic therapy were the main treatment modalities in Vaginal Candidiasis. Systemic therapy included Fluconazole in 52.94% and oral Itraconazole 11.76% of patients, respectively. Topical therapy included Clotrimazole and Miconazole in 53.55% and 20.81% of patients, respectively.

Number Of Drugs Per Patient

- The cumulative number of drugs comprising all prescriptions were 366.
- Average number of drugs per patient was 1.65.
- Maximum number of drugs prescribed per patient was 4.

Route of Drug Administration

Out of prescribed drugs, 25.34% were administered orally while 35.29% were used topically and 39.37% were administered both topical and oral. Injectable formulations were not used.

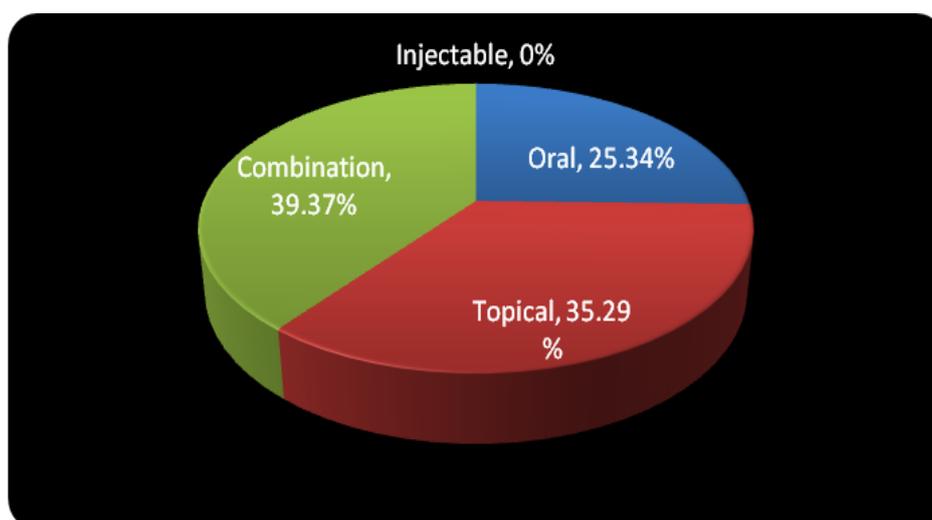


Figure No 11: Route of Drug Administration

Table 9: Route of Drug Administration

| Sr. No. | Route | No. of Patients | Percentage (%) |
|---------|--------------|-----------------|----------------|
| 1. | Oral | 56 | 25.34 |
| 2. | Topical | 78 | 35.29 |
| 3. | Combination | 87 | 39.37 |
| 4. | Injectable | 00 | 00 |
| | Total | 221 | 100 |

Taxonomic Profile of Prescribing

The drugs were classified according to Anatomical Therapeutic Chemical (ATC) classification system.

Topical Agents

The topical preparations used were Clotrimazole (53.85%), and Miconazole(20.81%) ()

Table 10: Taxonomic Profile of Topical agents used in treatment of Vaginal Candidiasis.

| Sr. No. | NPN | Dosage form | Dose | FOA | DOT (wks) | ATC Code | No. Of pts | Total | % |
|---------|--------------|-----------------|-------|------|-----------|----------|------------|-------|--------|
| 1. | Clotrimazole | Vaginal pessary | 200mg | 1 HS | 3-7 days | G01AG | 72 | 119 | 53.85% |
| | | Cream | 1% | 1 HS | 3-7 days | | 47 | | |
| 2. | Miconazole | Cream | 2% | 1 HS | 3-7 days | G01AG | 46 | 46 | 20.81% |

Antifungal Agents

Fluconazole (52.94%) and Itraconazole (11.76%) were used orally for systemic action.

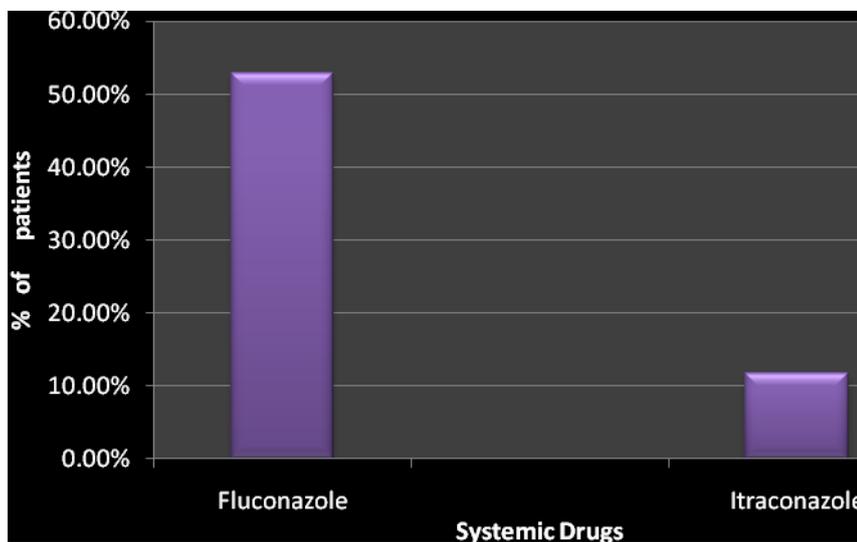


Figure 11: Taxonomic Profile of Antifungals used in patients of Vaginal Candidiasis.

Table 11: Taxonomic Profile of Antifungals used in patients of Vaginal Candidiasis.

| Sr. No. | NPN | Dosage form | ROA | Dose | FOA | DOT (wks) | ATC Code | No. Of pts | % |
|---------|--------------|-------------|------|-------|-----------|-----------|----------|------------|--------|
| 1. | Fluconazole | Tab/cap | Oral | 150mg | Once only | - | J02AC01 | 117 | 52.94% |
| 2. | Itraconazole | Cap | Oral | 200mg | BD | 3 days | J02AC02 | 26 | 11.76% |

Supportive Biomolecules

Multivitamin tablets (19%) and Ranitidine (6.87%) were prescribed for symptomatic relief.

Table 12: Taxonomic Profile of Supportive Biomolecules used in Patients of Vaginal Candidiasis

| Sr. No. | NPN | ATC Code | No. of Patients | Percentage (%) |
|---------|----------------------|----------|-----------------|----------------|
| 1. | Ranitidine | A02BA02 | 15 | 6.87 |
| 2. | Multivitamin tablets | A11EA | 42 | 19 |

N.P.N. : Non Proprietary Name
F.O.A. : Frequency of Administration
D.O.T. : Duration of Therapy
R.O.A. : Route of Administration .

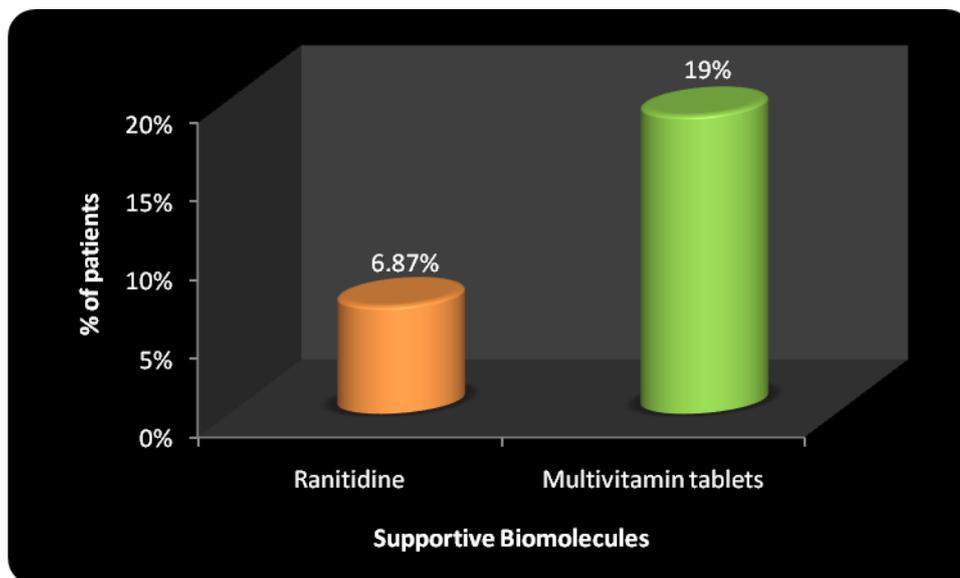


Figure 13: Taxonomic Profile of Supportive Biomolecules used in Patients of Vaginal Candidiasis

Vulvo vaginal candidiasis (VVC) is common clinical problem in women of reproductive age throughout the world particularly in hot, subtropical climates. Annually in the united states there are approximately 13 million cases of vulvo vaginal candidiasis (VVC), resulting in 10 million gynaecologic office visits per year. It is estimated that 75% of women will experience at least one episode in their lifetime, with a projected 50% of all women experiencing multiple episodes. Fungal infections are common in hot and humid climate of tropical countries like India. The prevalence Vaginal Candidiasis was found to be 2.06% amongst the total patients attending O.P.D. in the Obstetrics and Gynaecology department during the study period. The incidence of vaginal candidiasis in the present study is lower as compared to other studies by Mahadani JW et al, [34] Nanadan et al [35]and B.K. Joshi et al [36]. Vaginal Candidiasis was found most common in women between the ages of 26-35 years (51.13%) followed by 15-25 years (32.13%) and 36-45 years(16.74%). The study of Ako

et al [37] supports that Vaginal Candidiasis occurs most frequently in the age group (20- 35) years and the reports of Sehgal et al[38] also showed the age group (21-30) years had the highest incidence of vaginal candidiasis. So women of childbearing age groups are more vulnerable to vaginal candidiasis.

In our study we analysed that most of the patients with vaginal candidiasis belonged to low socio economic status (86.88%) followed by medium socio economic status(13.12%) which is consistent with the study by Pratibha Kamath et al [39]and Sujit Rathod et al [40].

We analyzed the factors responsible for Vaginal candidiasis, as use of antibiotics (12.67%). Antibiotic usage will cause the elimination and alteration of normal bacterial flora and allows the colonization of Candida. Immunosuppression (10.40%), Diabetic mellitus (8.60%). Anaemia (19%) , previous history of vaginal candidiasis (14.93%)and OCP users(4.97%). These risk factors associated in our study correlated well with the studies of Mirela et al [41] and Lundstrom et al.[42]

Poor personal hygiene and illiteracy are other major factors that influence vaginal candidiasis in this part of the country. These findings are in consonance with the findings of Kamalam et al,[43] Ginter *et al.* [44] Spinillo *et al.* [45] and Marin *et al.*[46]. Lack of personal hygiene was found to be one of the causative factor. The majority of patients who were enrolled in the study were from low socioeconomic status. Hence these patients were counseled more on hygienic measures.

In our study, vulval itching was the commonest presenting symptom (57.01%) associated with vaginal candidiasis, followed by other symptoms such as vaginal discharge (48.42%), dyspareunia(7.24%), dysuria(5.43%) and vulval soreness (4.98%). These findings are in consonance with the findings of K. Padma Leela et al [47].

In our study a questionnaire modified from DLQI was prepared. The mean score was 8.69 ± 4.56 which suggests moderate effect of vaginal candidiasis on patients' quality of life as according to the guidelines provided by A.Y. Finlay.[48]

Fluconazole (52.94%) and itraconazole(11.76%) were used orally for systemic action. In our study, the topical preparations used were Clotrimazole (53.85%) and Miconazole(20.81%). In our study, oral Fluconazole and Clotrimazole vaginal pessaries was most commonly prescribed because of its weekly dose and less possibility of side effects.

In the study at the Holy Family Hospital, Rawalpindi., 64 patients received fluconazole 150mg. Clinical improvement after the therapy was seen in 89.7% while complete clinical cure was found in 10.2%. None of the patients failed to respond and there was no relapse [49].

CONCLUSION

The incidence of Vaginal Candidiasis in Wardha was 63.14% and the prevalence of was 2.06%. Most patients were between the ages of 26-35years (51.13%) followed by 15-25 years(32.13%) and 36-45 years(16.74%).Vaginal Candidiasis cases were found more during the Monsoon (52.49%) followed by Summer (35.75%) and Winter (11.76%). Vaginal Candidiasis has a moderate effect on Quality of Life of patients in Vidarbha region. Itching was the commonest presenting symptom (57.01%) followed by vaginal discharge(cheesy curdy) [48.42%] . Topical and systemic antifungal therapy is the main treatment modalities for Vaginal Candidiasis. Clotrimazole (53.85%) and Miconazole (20.81%) are more common topical formulations used. Fluconazole (52.94%) and Itraconazole(11.76%) are drugs used as systemic treatment of Vaginal Candidiasis.

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