Poster #41

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Characterizing Women in the U.S. with Acute and Recurrent Vulvovaginal Candidiasis and their Unmet Needs

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ABSTRACT

Background: This research was designed to identify differences in characteristics, attitudes and unmet needs of women with acute vulvovaginal candidiasis (VVC) and recurrent VVC (RVVC). Results from this study help inform appropriate clinical and formulation development of CD101 Topical, being developed as the first topical echinocandin antifungal for the treatment of VVC and prevention of RVVC. Preclinical VVC models performed at vaginal pH have demonstrated intravaginally administered CD101 to be effective against azole-susceptible and azole-resistant *Candida*.[1]

Materials/methods: 478 U.S. women (18-59 y) participated in a 30-min online survey in June 2015. Screening used standard VVC/RVVC definitions with one exception; RVVC was defined as 3 or more VVC episodes in the past year, vs 4 episodes as defined by the FDA. RVVC (R) n=152; Mild (M) acute VVC n=152; Mod/Severe (Mo/S) acute VVC n=174.

Results: R self-reported statistically more VVC (4.8) and bacterial vaginosis episodes (1.8) per year. Self-reported fluconazole resistance was higher in R (16%) and Mo/S (20%) than M (0%). 75% of women visit a doctor for a VVC Rx, higher among M and Mo/S, vs 26% call for Rx, higher among R. VVC evaluations were conducted by an OB/GYN (56%) and FP/GP (43%). R, M, Mo/S reported visiting the doctor for VVC 2.8, 1.2, 1.2 times per year. R and Mo/S scored statistically greater than M on 'taking active role in treating VVC' and 'willingness to try new medications.' 36% of women are actively seeking new treatments. The most desired treatment features were similar across groups: 'resolves symptoms faster' and 'starts to work faster' rated highest, followed by 'getting rid of vaginal yeast' and 'keeping me symptom free longer.'

Conclusions: Regardless of acute or recurrent VVC, women prioritize rapid symptom relief of an acute VVC episode over decreasing symptom recurrence.

INTRODUCTION

- Three-quarters of all women have an episode of acute VVC in their lives with the majority of infections occurring in women of child bearing age[2]
- Women in the U.S. seek treatment from a physician for VVC approximately 4.4 million times in total each year, suggesting unmet needs are significant due to a combination of resistance, recurrence, cure rates, and lack of new mechanisms
- No novel therapy has been introduced for VVC in over 20 years
- CD101, a novel topical antifungal, is the first echinocandin to be developed for VVC
- This research was designed to identify differences in characteristics, attitudes and unmet needs of women with acute vulvovaginal candidiasis (VVC) and recurrent VVC (RVVC) to inform development of CD101 Topical and improved VVC therapies in general

METHODS

Study Design

- 30-minute online survey conducted in June 2015 of 478 women in the U.S. 18-59 years of age. All women had visited their physician for VVC and taken 1 or more medications for VVC in the past year
- Women were screened to meet one of three cohort definitions below and were provided descriptive symptoms of VVC severity from which to self-classify. All results were self-reported
- Where statistical significance between cohorts was achieved it is noted as 'significant' throughout

Distribution of Women By VVC/RVVC Criteria

Cohort	Abbr.	N
Recurrent VVC (3+ Infections/year) and any severity	R	n=152
Mild VVC and <3 Infections/year	M	n=152
Moderate/Severe VVC and <3 Infections/year	Mo/S	n=174

RESULTS

Disposition

- Age distribution was generally similar across cohorts: 42%, 18-29 y; 32%, 30-39 y; 17%, 40-49 y; 9%, 50-59 y
- Across cohorts, women reported comorbidities including Diabetes 8%, RA 6%, Psoriasis 5%, Lupus 2%, HIV 1%, Crohn's 1%
  - 25% of R vs 14% of M had at least one of the above
- At the time of the survey, 21% overall were taking oral contraceptives, 6% broad spectrum antibiotics, 5% corticosteroids, with no significant difference across cohorts
- There were no significant differences in self-reported health status

Attitudes

- A modest 44% of R and 41% of Mo/S agree that they have 'a good general knowledge about VVC,' significantly more than M, 27%
- 43% of R and 41% of Mo/S agree they 'try to stay up-to-date on VVC information and treatments,' significantly more than M, 22%
- 72% of R strongly agreed that they 'take an active role to manage their VVC' vs. 62% of Mo/S and 58% of M
- 74% of R and 63% of Mo/S strongly agreed that they are 'willing to try new VVC medications' and significantly more than M, 49%
- 51% of Mo/S agreed that 'VVC infections are temporary and can be resolved quickly,' significantly more than R, 34%
- 47% of R, 38% of Mo/S and 33% of M agreed that VVC 'has a *very* negative impact on your quality of life'

RESULTS (cont'd)

Evaluation

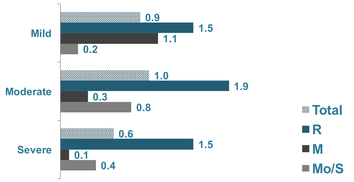
- R reported significantly more infections than M and Mo/S

Average Number and Type of Self-Reported Infections within the Past Year

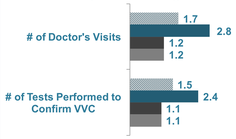
	Vaginal Candidiasis	Bacterial Vaginosis
R	4.8	1.7
M	1.6	0.7
Mo/S	1.3	0.8

- The frequency of mild, moderate and severe infections was evenly distributed among the R cohort
- All cohorts reported infections of each severity, despite screening cohort

Self-Reported Severity and Number of Yeast Infections Per Year



Self-Reported Average # of Doctor's Visits and Tests Per Year



- R reported an average of almost 3 doctor visits per year for VVC
- When asked 'how many diagnostic tests were performed to confirm VVC per year?,' the number of tests performed was relatively consistent with the number of visits to the doctor for VVC

Physician selection and Prescription Process Preference

- R and M reported seeing an OB/GYN more often than a FP/GP, the opposite was true for Mo/S
- Most patients receive prescriptions at the doctors office. R had significantly more prescriptions being called-in to a pharmacy without a doctor visit

Type of Doctor Evaluating VVC
% or Patients

	OB/GYN	FP/GP
Total	56	43
R	61	39
M	61	39
Mo/S	48	52

How Prescription for VVC Occurs
% or Patients

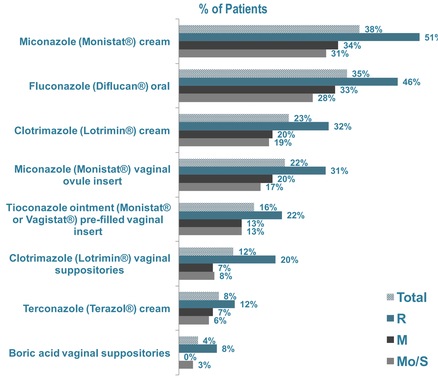
	MD Office	Call-In to Pharmacy without MD Office Visit
Total	75	26
R	70	30
M	77	23
Mo/S	77	23

RESULTS (cont'd)

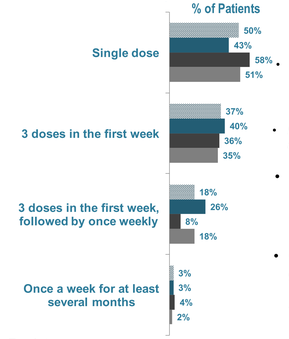
Treatment

- Women across cohorts reported taking multiple medications, both OTC and prescription, in the prior 12 months, with a higher proportion of R taking each one

Self-Reported Medications for VVC Taken in the Prior 12 Months
% of Patients



Self-Reported Fluconazole Dosing
% of Patients



- *Survey Question: 'How frequently did you take fluconazole (Diflucan®) when it was prescribed for your acute or recurrent yeast infection?'*
- *Respondents were given answer choices and were able to select more than one*
- Despite self-reported recurrence, R reported a substantial use of single dose and 3-dose fluconazole use
- Compared to M, a significantly greater proportion of R (26%) reported taking weekly doses of fluconazole

Resistance

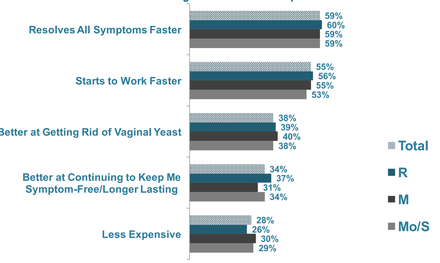
When asked 'have you ever been told by your physician that you have a *Candida* infection that is resistant to fluconazole?,' R and Mo/S were significant over M. Total, 13%; R, 16%; M, 0%; Mo/S, 20%.

RESULTS (cont'd)

Treatment (cont'd)

- Women across cohorts, even those with recurrent VVC, most strongly valued speed to resolution of symptoms and time to onset of symptomatic relief followed by fungal eradication
- Lower ranked attributes included: Fewer doses, Fewer side effects, Better long-term safety, More convenient formulation

Most Desirable Features in a New VVC Product
% of Patients Choosing Feature in Their Top Three Attributes



CONCLUSIONS

- Women with RVVC and those who have experienced moderate/severe acute VVC, are significantly more likely to: actively manage their VVC, stay up-to-date on and try a new VVC therapy
- Women with RVVC report approximately the same average number of mild, moderate and severe acute VVC episodes per year
- Women across cohorts reported taking multiple VVC medications, both OTC and prescription, in the prior 12 months
- Only 26% of women with RVVC reported taking fluconazole weekly. Others reported single dose or 3 doses, with no dose continuation
- Women across cohorts, even those with RVVC, most strongly valued speed to resolution of symptoms and time to onset of symptomatic relief followed by fungal eradication

REFERENCES

1. Miesel L, et al. Efficacy of a Novel Echinocandin, CD101, in a Mouse Model of Azole-Resistant Disseminated Candidiasis. ASM Microbe 2016, oral presentation
2. Achkar J, et al. Clinical Microbiology Reviews. Apr. 2010, 253–273. Vol 23, No 2.

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