Adherence and Acceptability of a Dapivirine Vaginal Ring in Postmenopausal U.S. Women

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on behalf of the MTN-024/IM 031 Protocol Team for the Microbicide Trials Network

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Background

- Vaginal rings
- Alter the delivery of microbicides in 24 hours
- Require minimal user action
- Are discreet

Postmenopausal women are an important "bridging group" for HIV prevention

- 12% of new HIV infection in U.S. women occurred among those >50 years old in 2009 (6)
- High HIV risk:
  - Biologically: hormonal changes, decreased innate anti-HIV activity, thinning of vaginal mucosa (18)
  - Behaviorally: more low condom use, although many women are out of stable partnerships, low recognition of STI/HIV risk (6)

Study Objectives

- To assess adherence to 3 months of vaginal ring use
- To assess acceptability of a monthly vaginal ring in U.S. postmenopausal women

Methods

Behavioral Assessments

- Computer Assisted Self-Interview (CASI): Baseline, Monthly
- Clinical Report Forms (CRF): Baseline, Monthly
- In-depth Video Interviews (IDIs): Month-3 End Visit
- F2F interaction with trained social scientist
- Allows standardization of interviewing approach
- Administered immediately after CASI at Month-3
- Explained ring acceptability & use experience

Study Design

- Women were randomized to use a single disposable vaginal ring consisting of 25 mg Dapivirine (DPV)
- Evaluation: monthly vaginal ring for monthly use

Study Flow

- Eligibility: Healthy              No menses for ≥1 yr HIV uninfected  Age 45-65 years
- Recruitment: November 2, 2012 – February 12, 2014
- Post-menopausal Women: N=96

Analysis

- Descriptive data summarized as mean (median) (continuous variables) and tabulated (categorical variables)
- McNemar test for changes between baseline & Month-3
- Qualitative interviews: audio-recorded, transcribed, coded thematically and analyzed using NVivo

Study Objectives

1. Adherence over 3 months

- Cumulative Ring Adherence
  - 95% responded they were very/comfortable with the ring inside every day
  - 85% experienced no difficulties with the ring
  - 10% experienced minor difficulties with the ring

2. Preference: 65% preferred ring to condoms

- 95% preferred the ring to condoms
- 56% preferred the ring to condoms
- 44% preferred the ring to condoms
- 33% preferred the ring to condoms

3. Overall acceptability

- 95% preferred the ring to condoms
- 57% preferred the ring to condoms

4. Ring Worries

- 10% of women reported worries about their ring
- 97% reported they were very/comfortable with the ring inside every day

Conclusions

- The ring was very acceptable among healthy postmenopausal women
- Adherence was high with few removals/expulsions
- Confirmed by drug pharmacokinetics (see Chen poster #16-108)
- Worries decreased significantly comparing baseline to Month-3 (end of ring use)
- A majority preferred the ring to condoms
- Vaginal rings are a promising microbicide approach for HIV prevention in postmenopausal women

MTN-024/IM 031 Study Flow

Baseline Characteristics

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Study Flow</th>
</tr>
</thead>
<tbody>
<tr>
<td>MTN-024/IM 031</td>
<td>Study Flow</td>
</tr>
<tr>
<td>Post-menopausal Women: N=96</td>
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<tr>
<td>Eligibility: Healthy              No menses for ≥1 yr HIV uninfected  Age 45-65 years</td>
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</tbody>
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Table: MTN-024/IM 031 Study Flow

<table>
<thead>
<tr>
<th>Study Site</th>
<th>Enrollment (N=96)</th>
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<tbody>
<tr>
<td>Cleveland, OH</td>
<td>32%</td>
</tr>
<tr>
<td>Birmingham, AL</td>
<td>32%</td>
</tr>
<tr>
<td>Pittsburgh, PA</td>
<td>32%</td>
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<table>
<thead>
<tr>
<th>Mean age, years (range)</th>
<th>58.8 (46-85)</th>
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<tbody>
<tr>
<td>Has a primary sex partner</td>
<td>61%</td>
</tr>
<tr>
<td>Sexual intercourse in past 30 days</td>
<td>88%</td>
</tr>
<tr>
<td>More than high school education</td>
<td>83%</td>
</tr>
<tr>
<td>Race</td>
<td>White 56%</td>
</tr>
<tr>
<td>African American/Black</td>
<td>31%</td>
</tr>
<tr>
<td>Other</td>
<td>3%</td>
</tr>
<tr>
<td>Marital status</td>
<td>Married 7%</td>
</tr>
</tbody>
</table>

| Menopause symptom scale, mean (range) | 7.0 (0-22) |
| History of vaginal product use | 76% |
| History of tampons use | 83% |

Results

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