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

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

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Background

Vaginal rings

- Alter sustained delivery of microbicides for ≥1 month
- Require minimal user action
- Are discreet
- Postmenopausal women are an important "bridge group" for HIV prevention
- 12% of new HIV infection in U.S. women occurred among those >50 years old in 2009 (*)
- High HIV risk:
  - Biochemical/hormonal changes, decreased innate anti-HIV activity, thinning of vaginal mucosa (*)
- Behaviorally 4 anxiety low condom use, although many women are out of unsafe partnerships; low recognition of STI/HIV risk (*)

Study Design

- MTN-024/IPM 031 Study
- Study Flow
- Post-menopausal Women = 96
- Eligibility:
  - Healthy
  - No menses for ≥1 yr
- Geographic location: Pittsburgh, PA; Cleveland, OH; Durham, CA; Case Western Reserve U, Cleveland, OH, USA:
- MTN-024/IPM 031 Protocol Team for the Microbicide Trials Network

Methods

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

Behavioral Objectives and Measures

- Analysis blinded & behavioral data combined across study groups
- Adherence (self-reported monthly CRF):
  - "Ring never out" per protocol adherence: ring never out except for study-instructed removals (i.e., product holds, study procedures)
- Non-adherent ring out for non-study-related reasons
- Preference: ring vs. condom
- Acceptability (baseline and Month-3 CASI, IDIs): likes/dislikes, change over time
- Worry/consultations (at baseline and month-3)
- Ring use experiences (e.g. during sex, problems)

Analysis

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

Results

Baseline Characteristics

<table>
<thead>
<tr>
<th>Study site</th>
<th>TOTAL N=96</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pittsburgh, PA</td>
<td>33%</td>
</tr>
<tr>
<td>Birmingham, AL</td>
<td>33%</td>
</tr>
<tr>
<td>Cleveland, OH</td>
<td>33%</td>
</tr>
<tr>
<td>Pittsburgh, PA</td>
<td>32%</td>
</tr>
<tr>
<td>Mean age, years (range)</td>
<td>56.8 (46-65)</td>
</tr>
<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>Place</td>
<td>White</td>
</tr>
<tr>
<td>African American</td>
<td>Black</td>
</tr>
<tr>
<td>Other</td>
<td>Hispanic</td>
</tr>
<tr>
<td>Menopausal symptoms at mean (range)</td>
<td>7.0 (2-22)</td>
</tr>
<tr>
<td>History of vaginal product use</td>
<td>76%</td>
</tr>
<tr>
<td>History of tampon use</td>
<td>82%</td>
</tr>
</tbody>
</table>

1. Ring Adherence over 3 months

<table>
<thead>
<tr>
<th>Cumulative Ring Adherence</th>
<th>%Total (N=96)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ring remove/put back in</td>
<td>40% (38)</td>
</tr>
<tr>
<td>Per protocol adherence</td>
<td>81% (78)</td>
</tr>
<tr>
<td>Ring never out (&lt;12h)</td>
<td>91% (87)</td>
</tr>
<tr>
<td>Worry/consultation</td>
<td>6% (6)</td>
</tr>
<tr>
<td>Removal**</td>
<td>12% (11)</td>
</tr>
</tbody>
</table>

2. Preference: 65% preferred ring to condoms

3. Overall acceptability

- 96% responded that "ring is very easy to use"
- 97% responded they were very comfortable with the ring inside every day
- 85% agreed the ring is easy to insert
- 86% agreed the ring is easy to remove
- 36% reported change in vagina
  - 15% vaginal dryness (24 not at all bothered by it)
  - 10% vaginal dryness (13 not at all bothered by it)
  - 6% other changes (i.e., irritation from condoms)

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)
- Worry decreased significantly comparing baseline to Month-3 (end of ring use)
- A majority preferred the ring to condoms
- Vaginal rings are a promising microbicidal approach for HIV prevention in postmenopausal women