Performance of Sino-implant (II) during routine service delivery in Kenya and Pakistan

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Sino-implant (II)

- 2-rod subdermal hormonal implant with levonorgestrel used for up to 4 years
- Cost approximately US $8
- Made by Dahua in Shanghai, China
- In published studies, first-year pregnancy rates near zero
- Approved in over 20 countries, including Kenya (branded Zarin) and Pakistan (branded Femplant)
- Over nine million units distributed since 1996
Two Sino-implant (II) Studies under PROGRESS

- Clinical data on the product mainly limited to China
- Most research conducted during the 1990s
- Results mainly published in Chinese literature

**Purpose**

To collect key information on performance of Sino-implant (II) as used in routine service settings in Kenya and Pakistan
**Study Sites**

**Kenya**
- 3 clinics on periphery of Nairobi
- All affiliated with MOH
- N = 602 participants

**Pakistan**
- Study in collaboration with Marie Stopes Pakistan
- 19 clinics in Karachi, Rawalpindi, Hyderabad, other cities:
  - 13 MSI clinics
  - 6 MOH clinics
- N = 724 participants
Study Objectives

- Measure **contraceptive effectiveness** during first year of use

- Collect **safety information**: side effects and serious adverse events (SAEs)

- Collect information on **complications** during insertion and removal

- Assess **acceptability** of implant during first year of use and measure removal rates
Study Design

• Approximately 600 women in each country who decide to use Sino-implant (II) enrolled and randomly assigned to:
  – Active cohort, or
  – Passive cohort

• Active cohort scheduled for follow-up visits at 3 and 12 months after insertion
• Passive cohort asked to return in case of problems, suspected pregnancy, or desired removal
• Standardized questionnaires at each clinic visit
Eligibility Criteria

• Decided to receive Sino-implant (II) for contraceptive purposes, and met clinic criteria for use
  • Age 18-44
  • Willing to sign informed consent form
  • Willing to give contact information
  • Willing to return for follow-up visits
PRELIMINARY RESULTS
### Sociodemographic Characteristics

| Characteristic                                      | Kenya  
<sup>(n=602) n (%)</sup> | Pakistan  
<sup>(n=724) n (%)</sup> |
<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>Age:</strong> Mean (median; range)</td>
<td>28 (27; 18-44)</td>
<td>28 (28; 18-41)</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
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<tr>
<td>Married/living in couple</td>
<td>531 (88.4)</td>
<td>724 (100)</td>
</tr>
<tr>
<td>Single, widowed, divorced or separated</td>
<td>70 (11.7)</td>
<td>-</td>
</tr>
<tr>
<td><strong>Education level</strong></td>
<td></td>
<td></td>
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<tr>
<td>None/non-formal/some primary</td>
<td>47 (7.8)</td>
<td>318 (43.9)</td>
</tr>
<tr>
<td>Completed primary</td>
<td>357 (59.3)</td>
<td>172 (23.8)</td>
</tr>
<tr>
<td>Completed secondary/vocational or technical training</td>
<td>166 (27.6)</td>
<td>136 (18.8)</td>
</tr>
<tr>
<td>Higher than secondary</td>
<td>32 (5.3)</td>
<td>98 (13.5)</td>
</tr>
<tr>
<td><strong>Profession</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed/housewife</td>
<td>247 (41.0)</td>
<td>656 (90.6)</td>
</tr>
<tr>
<td>Other</td>
<td>355 (59.0)</td>
<td>68 (9.5)</td>
</tr>
</tbody>
</table>
## Baseline Obstetric and Contraceptive History

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Kenya (n=602) n (%)</th>
<th>Pakistan (n=724) n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Parity:</strong> mean (median; range)</td>
<td>2.4 (2; 1 to 8)</td>
<td>3.7 (3; 0 to 20)</td>
</tr>
<tr>
<td><strong>Living children:</strong> mean (median; range)</td>
<td>2.4 (2; 1 to 8)</td>
<td>3.4 (3; 0 to 12)</td>
</tr>
<tr>
<td><strong>Most recent contraceptive method</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>112 (18.6)</td>
<td>445 (61.5)</td>
</tr>
<tr>
<td>Oral</td>
<td>228 (37.9)</td>
<td>43 (5.9)</td>
</tr>
<tr>
<td>Injectable</td>
<td>151 (25.1)</td>
<td>79 (10.9)</td>
</tr>
<tr>
<td>Implant</td>
<td>20 (3.3)</td>
<td>nil</td>
</tr>
<tr>
<td>Condom</td>
<td>14 (2.3)</td>
<td>108 (14.9)</td>
</tr>
<tr>
<td>Other</td>
<td>77 (12.8)</td>
<td>49 (6.8)</td>
</tr>
</tbody>
</table>
## Insertion Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Kenya (n=602)</th>
<th>Pakistan (n=724)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Duration in minutes: mean (median; range)</strong></td>
<td>3.6 (3; 2 to 8)</td>
<td>8.5 (7; 2 to 20)</td>
</tr>
<tr>
<td><strong>Complications during insertion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>601 (99.8)</td>
<td>717 (99.0)</td>
</tr>
<tr>
<td>Yes</td>
<td>1 (0.2)</td>
<td>7 (1.0)</td>
</tr>
<tr>
<td><strong>Discomfort during insertion would prevent future insertion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>591 (98.2)</td>
<td>391 (54.0)</td>
</tr>
<tr>
<td>Yes</td>
<td>11 (1.8)</td>
<td>135 (18.6)</td>
</tr>
<tr>
<td>Don’t know</td>
<td>-</td>
<td>198 (27.3)</td>
</tr>
</tbody>
</table>
Post-insertion Pregnancies

• 1 post-insertion pregnancy reported in Kenya
  – ruptured ectopic at 14 months post-insertion

• 4 post-insertion pregnancies in Pakistan
  – 2 followed post-abortion care
  – 2 women did not use barrier method post-insertion

• Pregnancy rate (Pearl) at 12 months
  – Kenya: 0.2 per 100 woman-years (0.0, 1.1)
  – Pakistan: 0.6 per 100 woman-years (0.2, 1.6)
Serious Adverse Events (SAEs)

- 4 reported SAEs during the studies
  - All in Kenya study
  - 3 of the SAEs were unrelated to study product or procedures
  - 1 SAE was possibly related to Sino-implant
    - ruptured ectopic pregnancy in Kenya which resulted in laparotomy and hospitalization
Side Effects Reported at Follow-up

Percent of women who ever experienced problem at insertion site

Kenya (n=298)

Pakistan (n=443)

Percent of women who ever reported other physical or emotional problems

Kenya (n=298)

Pakistan (n=443)
Implant Removals

• Cumulative probability of removal at 12 months
  – Kenya: 3.5 per 100 women (95% CI 1.9, 5.0)
  – Pakistan: 10.8 per 100 women (95% CI 8.5, 13.2)

• Removal complications
  – Kenya: nil
  – Pakistan: 2 (pain)
Implant Removal Reasons

Kenya – Removal reasons (n=13)
- Improper insertion (2)
- Discomfort/pain (4)
- Medical problem (4)
- Non-medical problem (2)
- Not her decision, opposition (1)

Pakistan – Removal reasons (n=77)
- Improper insertion (3%)
- Discomfort/pain (9%)
- Medical problem (61%)
- Non-medical problem (13%)
- Wanted to get pregnant (14%)
What women liked about the implant

- Lasts for 4 years
- Easy to use
- Low pregnancy risk
- Few side effects
- Liked nothing

What women disliked about the implant

- Disliked nothing
- Menstrual changes
- Other side effects
- Way it feels

Kenya (n=298)
Pakistan (n=443)
Acceptability - 2

• Overall experience with implant (ever reported)
  – **Very favorable**: Kenya 96%; Pakistan 31%
  – **Somewhat favorable**: Kenya 9%; Pakistan 75%
  – **Indifferent**: Kenya: <1%; Pakistan 21%
  – **Somewhat unfavorable**: Kenya 4%; Pakistan 5%
  – **Very unfavorable**: Kenya 1%; Pakistan 2%

• Acceptability of bleeding pattern (ever reported)
  – Kenya: 94% acceptable; 19% unacceptable
  – Pakistan: 73% acceptable; 26% unacceptable
Conclusions

• The implant was safe and effective in these studies during the first year of use
• Few insertion and removal complications were reported
• Acceptability rates were high, though higher in Kenya than Pakistan
• Bleeding patterns were generally acceptable, though more so in Kenya than Pakistan
• Removals were more common in Pakistan than Kenya