Summary
In rural sub-Saharan Africa, the provision of analgesics during tubal ligation procedures can be expensive, subject to frequent stock-outs, and associated with potential side effects. The majority of women undergoing tubal ligations in low resource settings will receive a combination of vocal local (VL) – a non-pharmacological pain management technique, local anaesthetic (LA) and analgesics. However, in these settings Marie Stopes International (MSI) offers women the option to substitute analgesics for the non-pharmacological pain management technique known as vocal local. No study has so far rigorously evaluated whether this technique is an effective substitution for pain management.

To address this evidence gap, we carried out a randomised controlled trial among women choosing tubal ligations from Marie Stopes International Kenya’s (MSIK) mobile outreach sites. The study measured the pain, anxiety and satisfaction women felt with the procedure. Of the 884 women who chose tubal ligations, 461 women underwent the procedure with a combination of VL+LA (intervention), while 423 received tubal ligations with VL+LA+analgesics (control). The majority of women attending the service were aged 30 years or older (78%) and most had three or more children (99%).

The pain experienced during the procedure was not significantly different between groups. However, the pain score after the procedure was significantly lower in the intervention group versus the control group. Satisfaction scores were equally high in both groups; 96% would recommend the procedure to a friend.

This is the first study to evaluate the vocal local pain management technique as a package for use as a substitute for pharmacological analgesics in gynaecological procedures. We have shown that VL+LA is as effective as the VL+LA+analgesics for pain management during the tubal ligation procedure in rural Kenya. Avoiding analgesics can be beneficial, particularly in remote, low resource settings.

Findings at a glance
• Of the 884 women who chose tubal ligations, 461 women underwent tubal ligations with VL+LA (intervention), while 423 received tubal ligations with VL+LA+analgesics (control).

• Pain during the procedure was not significantly different between the groups. However, the pain score after the procedure was significantly lower in the intervention group versus the control group.

• Satisfaction scores were equally high in both groups; 96% would recommend the procedure to a friend.

• VL+LA is as effective as the VL+LA+analgesics for pain management during the tubal ligation procedure in rural Kenya. Avoiding analgesics can be beneficial, particularly in remote, low resource settings.

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Background
In 2012, 350,000 of MSI clients opted to have a tubal ligation. The majority of these services were delivered to women living in rural settings through our mobile outreach programme, using a combination of local anaesthetic and vocal local pain relief methods. Vocal local – a non-pharmacological pain management technique – is believed to improve client satisfaction, decrease anxiety and help clients with pain management without the use of pharmacological analgesics.

However, the effectiveness of vocal local has yet to be rigorously evaluated. Although there have been several studies looking at non-pharmacological techniques, they have only highlighted the evidence around vocal local as a supplement rather than a substitute to analgesics, and only as separate components rather than a package. Recognising the evidence gap and wanting to ensure its clients needs were being met, MSIK undertook a research study to systematically examine the pain, anxiety and satisfaction of women undergoing tubal ligations with VL+LA and VL+LA+analgesics.

Methods in brief
We carried out a non-inferior randomised controlled trial among women undergoing tubal ligations across 40 MSIK mobile outreach sites in Machakos and Kisii districts. These sites were randomised by county into two groups of 20. The first provided tubal ligations with VL+LA+analgesics (control); and the second offered tubal ligations with VL+LA but with no analgesics (intervention). All outreach teams were composed of a doctor, a nurse specialising in tubal ligation and an assistant to ensure consistency in the vocal local procedure between the sites. The client’s level of anxiety, pain and satisfaction were all measured from exit interviews subsequent to the procedure. Pain was measured using the extensively validated 11-point Numeric Rating Scale. The cut-off point for considering the intervention inferior to the control was a pain score of 1.3 points higher in the intervention compared to the control group, since studies have shown that pain differences less than 1.3 points on this scale are not clinically relevant.

Box 1: What is vocal local?
Vocal local is a non-pharmacological pain management technique based around the reduction of anxiety, distraction from pain and avoidance of pain. By talking to and reassuring clients in a de-medicalised environment, vocal local emphasises the client-provider relationship and empowers women to play a more active role in their pain management. These very same approaches are also able to reduce anxiety. Finally, performing breathing exercises and using gentle clinical techniques with non-rigid instruments, vocal local can aid the bypassing of further pain. Vocal local is a continuous process, starting when the woman enters the clinic, continuing into the consultation, the procedure and the recovery right through to being discharged.

Box 2: Study design: randomised controlled trial

- **VL+LA+Analgesics** (Control Group)
  - Sample size: 423 women
  - Study sites: 20 MSK outreach sites in Machakos & Kisii Districts

- **VL+LA** (Intervention Group)
  - Sample size: 461 women
  - Study sites: 20 MSK outreach sites in Machakos & Kisii Districts
Findings

Client characteristics

Women receiving a tubal ligation procedure were generally over 30 (78%), married (96%) and had three or more children (99%). There were no differences between the control and intervention groups in socio-demographic characteristics.

Pain management

Women reported pain levels for: pain during the procedure; pain at the most painful moment; and pain at the time of interview. When undergoing the tubal ligation, women experienced comparable levels of both pain and anxiety, whether or not they had received analgesics. However, pain at the time of interview was significantly lower among women who did not receive analgesics. As expected, pain was most severe during the procedure, declining with increased time in both groups.

There were several socio-demographic characteristics that varied with the level of pain reported. Women with no education reported less pain at the time of interview than those with primary education, while women in manual jobs reported less pain than those who were unemployed or who worked in agriculture on all three measures.

Women who independently chose to undergo a tubal ligation reported less pain than women who made the decision in combination with their partner and families. Women choosing a tubal ligation solely on their own terms may be more comfortable with the procedure, less anxious and therefore less susceptible to pain escalation.

Client satisfaction

Satisfaction was equally high among the two groups of women, whether or not they received analgesics during their tubal ligation, with 90% of women reporting the maximum score on each satisfaction measure. Nonetheless, more than 25% of women reported they would have wanted the visit to be shorter, while eight percent said they felt worse than expected.

Clients receiving VL+LA did report significantly higher satisfaction with several aspects of their procedure, praising private consultations and comfort during the procedure. Although vocal local should have been implemented uniformly between the two groups, it underscores the importance of certain features of vocal local in improving overall satisfaction.

FIGURE 1: Pain and satisfaction measures among women in control and intervention groups

<table>
<thead>
<tr>
<th>Measure</th>
<th>VL+LA+drugs (control)</th>
<th>VL+LA (intervention)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean pain score during procedure</td>
<td>6.63</td>
<td>6.40</td>
<td>0.086</td>
</tr>
<tr>
<td>Mean pain score at interview</td>
<td>5.58</td>
<td>5.18</td>
<td>0.041</td>
</tr>
<tr>
<td>Mean satisfaction with overall procedure</td>
<td>9.83</td>
<td>9.77</td>
<td>0.333</td>
</tr>
</tbody>
</table>
Discussion
The benefits of undertaking tubal ligations without analgesics are considerable. First, removing analgesics from the procedure will reduce both the risk of side effects and the risk of medical error, making the procedure more manageable and safer for the client. Fewer women will have to stay at the clinic longer than is absolutely necessary, allowing them to return home and letting the outreach team redirect their time to new clients.

Second, issues over the maintenance, procurement and distribution of analgesics could be eliminated. Currently, stock outs can lead to delays, or even cancellations of tubal ligations. This may press women into choosing alternative, and sometimes less effective contraceptive methods that may result in unwanted pregnancies.

Finally, using vocal local instead of analgesics has the potential to save money for country programmes, not just by eradicating the costs of procuring analgesics, but also by maximising the number of tubal ligations an outreach team is able to carry out within a set timeframe. This will be especially important in settings such as rural Kenya where resources are scarce.

Further research should be carried out to investigate the potential of vocal local use in other gynaecological procedures, and whether the technique should be rolled out beyond MSI mobile clinics to other healthcare settings. However, when considering the application of vocal local without analgesics, caution should be used when generalising the results to other rural African settings, including those in Kenya. Women in this study exhibited similar characteristics to those seeking tubal ligations in other healthcare settings in Kenya. However, different populations may display different side effects from those shown in the study.¹

“This is the first study to evaluate vocal local as a substitute for pain medication in rural Africa.”
Conclusion

The use of vocal local in combination with local anaesthetic is an effective substitute for analgesics during tubal ligation procedures, particularly in settings that are limited in resources. While there were no differences in reported pain from the procedure or in overall satisfaction rates, the non-use of analgesics has the potential to allow for cheaper and more efficient procedures, while maintaining high quality clinical standards.

This is the first study to evaluate vocal local as a substitute for pain medication in rural Africa. Other providers should consider the potential benefits of the substitution of analgesics for vocal local during tubal ligation procedures. We should also explore the further use of vocal local in other gynaecological procedures. However, caution is advised before generalising this study’s findings to other settings, including those within rural Africa as well as larger health facilities and urban settings.
Citations


For citation purposes:

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