SALSA: Self-Administered Lidocaine Gel for Pain Management with First Trimester Surgical Abortion

A Randomized Trial

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Background

• Pain is a limiting factor in where and how abortion is performed
  • ACCESS issue
  • Pain management has not been woman centered

• 84% of providers employ a lidocaine paracervical block (PCB)
  • Non-standardized approach
  • PCB itself can be painful
Clinical Question

• Can we achieve adequate pain relief through self-administered, non-invasive means alone?
• Should we wait longer between lidocaine administration and procedure start time?
Study Objectives

• To compare pain control using a locally-applied, self-administered lidocaine gel with PCB
• To increase pain control options
• **Hypothesis:**
  Patients who receive lidocaine gel applied 20-30 minutes prior to first trimester surgical abortion will have pain control that is *no worse than* that of a traditional paracervical block
Study Design

• Open label, RCT
• Non-inferiority design
• 20ml of 2% lidocaine HCl vaginally (400mg) 20-30 minutes prior to procedure
Study Design

Paracervical Block Technique:

• 12 mL of 1% lidocaine (120 mg) with epinephrine
• 2 mL injected at tenaculum site
• Tenaculum immediately placed
• 10 mL injected into cervicovaginal junction at 4 and 8 o’clock
Lidocaine Dose

- Serum toxicity of intracervical lidocaine: 5 mcg/ml [Blanco 1982]
- Serum lidocaine levels 10 minutes after paracervical injection of 20 ml of 1% lidocaine (200mg) found mean blood levels of 0.9 to 1.61 mcg/ml [McKenzie 1978]
- Serum lidocaine levels following 4ml of 10% lidocaine spray (400mg) prior to intracavitary vaginal brachytherapy found non-toxic levels & adequate pain relief [Chen 1998]
Gel Protocol
Gel Protocol
Study Design

• Inclusion criteria
  • ≥ 18 years
  • 5 - 11w5d gestation
  • English or Spanish speaking

• Exclusion criteria
  • Preoperative misoprostol
  • PO pain medication instead of iv
  • Allergy to lidocaine, midazolam, fentanyl
  • Known uterine anomaly or cervical procedure
  • Inability to use tampons
Recruitment & Allocation

• Block randomization
• Intention to treat
• Open label
  – versus single blinded with (sham PCB + gel) and (PCB + KY jelly)
    » Ineffective blinding (Renner, et al)
Outcomes

Primary Outcome:
Pain perceived by VAS (0-100 mm) at time of cervical dilation

*Visual Analog Scale (VAS)*

No Pain  |  Worst pain imaginable
Outcomes

Secondary Outcomes:

Pain perceived at additional time points:
- Anticipated pain: 30 minutes prior to procedure
- Baseline pain: arrival to procedure room
- After speculum placement
- After tenaculum placement
- At procedure completion, after speculum removal
- In recovery: 30-45 minutes after procedure
Results: Demographics

- No significant differences between groups
<table>
<thead>
<tr>
<th></th>
<th>Lidocaine Paracervical Block n=68</th>
<th>Self-administered Lidocaine Gel n=69</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of Procedure</td>
<td></td>
<td></td>
<td>.81*</td>
</tr>
<tr>
<td>MVA</td>
<td>59 (86.8%)</td>
<td>58 (84.1%)</td>
<td></td>
</tr>
<tr>
<td>EVA</td>
<td>9 (13.2%)</td>
<td>11 (15.9%)</td>
<td></td>
</tr>
<tr>
<td>Maximum Dilation (mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (±SD)</td>
<td>8.21±1.6</td>
<td>7.72±1.6</td>
<td>.09*</td>
</tr>
<tr>
<td>Median (Range)</td>
<td>8 (6-12)</td>
<td>7 (6-11)</td>
<td>.08†</td>
</tr>
<tr>
<td>Time between gel insertion and speculum placement (min:seconds)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (±SD)</td>
<td>--</td>
<td>39:02±14:20</td>
<td></td>
</tr>
<tr>
<td>Median (Range)</td>
<td>--</td>
<td>37:10 (15:00-86:00)</td>
<td></td>
</tr>
<tr>
<td>Time between paracervical block and cervical dilation (min:seconds)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (±SD)</td>
<td>1:07±1:04</td>
<td>--</td>
<td></td>
</tr>
<tr>
<td>Median (Range)</td>
<td>1:00 (0:20-4:00)</td>
<td>--</td>
<td></td>
</tr>
<tr>
<td>Total Procedure Time (min:seconds)</td>
<td></td>
<td></td>
<td>.000†</td>
</tr>
<tr>
<td>Median (Range)</td>
<td>7:16 (3:00-16:07)</td>
<td>5:23 (2:20-15:38)</td>
<td></td>
</tr>
</tbody>
</table>
Figure 2. Box plot of pain scores (VAS) at various time points, medians displayed

Anticipated Pain  Baseline Pain  Speculum Insertion  Tenaculum Placement  Cervical Dilation  30-45 Minutes Post-Procedure

- Median
- Nonoutlier range
- Extremes
- Outliers

p = .67  p = .89  p = .37  p = .044  p = .45  p = .60
<table>
<thead>
<tr>
<th></th>
<th>Median</th>
<th>Mean</th>
<th>p-value</th>
<th>Median</th>
<th>Mean</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PCB mm (range)</td>
<td>Gel mm (range)</td>
<td></td>
<td>PCB mm (± S.D.)</td>
<td>Gel mm (± S.D.)</td>
<td></td>
</tr>
<tr>
<td>All Subjects</td>
<td>n=68</td>
<td>n=69</td>
<td>.45a</td>
<td>n=68</td>
<td>n=69</td>
<td>.31b</td>
</tr>
<tr>
<td>Cervical Dilation</td>
<td>65 (10-100)</td>
<td>68 (17-97)</td>
<td></td>
<td>60.12 (± 24.18)</td>
<td>64.07 (± 20.85)</td>
<td></td>
</tr>
<tr>
<td>Nulliparous Subjects</td>
<td>n=40</td>
<td>n=44</td>
<td>.24a</td>
<td>n=40</td>
<td>n=44</td>
<td>.12b</td>
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<tr>
<td>Cervical Dilation</td>
<td>64.5 (10-96)</td>
<td>69 (20-96)</td>
<td></td>
<td>58.15 (± 24.15)</td>
<td>65.57 (± 19.59)</td>
<td></td>
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<tr>
<td>Parous Subjects</td>
<td>n=28</td>
<td>n=25</td>
<td>.86a</td>
<td>n=28</td>
<td>n=25</td>
<td>.82b</td>
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<tr>
<td>Cervical Dilation</td>
<td>65.5 (11-100)</td>
<td>66 (17-97)</td>
<td></td>
<td>62.93 (± 24.38)</td>
<td>61.44 (± 23.08)</td>
<td></td>
</tr>
</tbody>
</table>

*a* Mann-Whitney U-test  
*b* Student's t-test
Acceptability
Limitations

• Non-blinded
• Exclusion of PO sedation patients
Strengths

• Generalizability to other GYN procedures
  • Intra-Uterine Device insertions
  • Endometrial biopsies
  • Hysteroscopy

Part II: SALUD
(Self-Administered Lidocaine for Uterine Devices)
Thank You

• Dr. Jennifer Conti
• Dr. Kate Shaw
• Klaira Lerma
• Corinne Montgomery
• Planned Parenthood Mar Monte & Stanford Gynecology clinic staff
Questions?
References

Analysis

Statistical methods:
• Demographic characteristics compared using Chi-square test or Student’s t-test
• Student’s t-test to evaluate primary outcome of pain at cervical dilation
• Median VAS scores analyzed using nonparametric tests.
• Multivariate analyses to evaluate potential confounders and determine independent predictors of pain at the time of cervical dilation
Results

Assessed for eligibility (n=274)
- Excluded (n=132)
  - Not meeting inclusion criteria (n=64)
  - Declined to participate (n=57)
    - Not comfortable with insertion (n=22)
  - Other reasons (n=64)
- Not meeting inclusion criteria (n=64)
- Declined to participate (n=57)
  - Not comfortable with insertion (n=22)
  - Other reasons (n=11)

Randomized (n=142)

Allocated to paracervical block (n=70)
- Withdrew consent
  - Declined abortion (n=1)
  - Declined IV sedation (n=1)

Allocated to self-administered gel (n=72)
- Withdrew consent
  - Age < 18 (n=2)
  - Ineligible for IV sedation (n=1)

Received Study Treatment (n=142)

Received allocated intervention (n=68)

Received allocated intervention (n=69)

Analyzed (n=68)*

Analyzed (n=68)*

* Intention to treat analysis performed
Methods

Sample size calculation:
- Delta = 15% difference in VAS*
- Standard deviation of VAS = 26mm**
- α=0.025 & β=0.10, 90% power
- 142 participants (71 per group)

* Jensen 2003, Todd 1996, Rowbothom 2001
** Renner 2010