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?

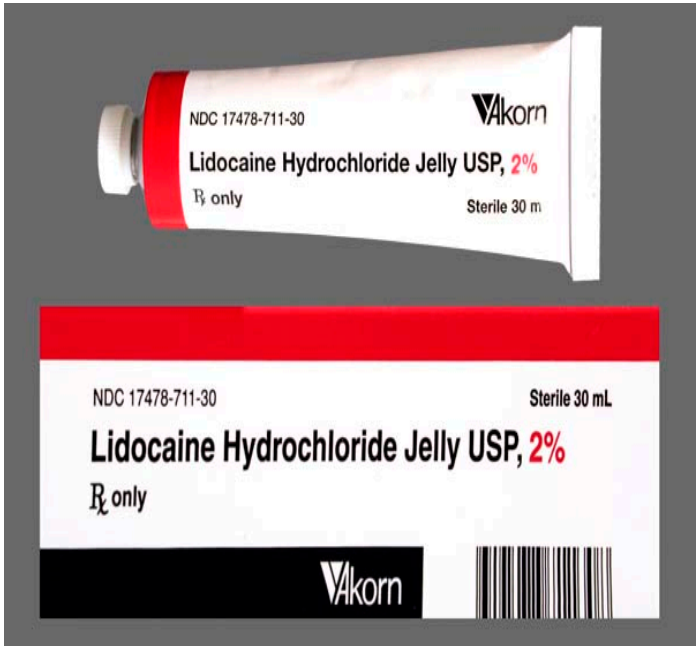
Study Objectives

- 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



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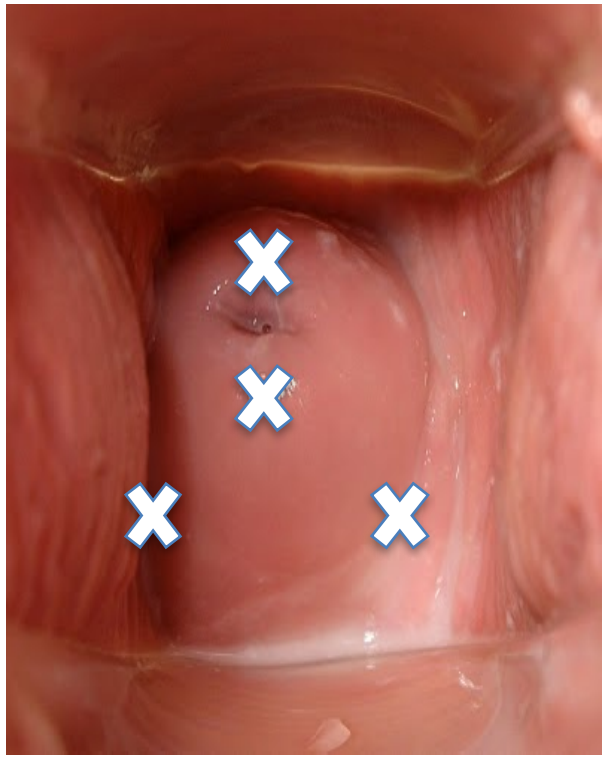
Study Design

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



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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

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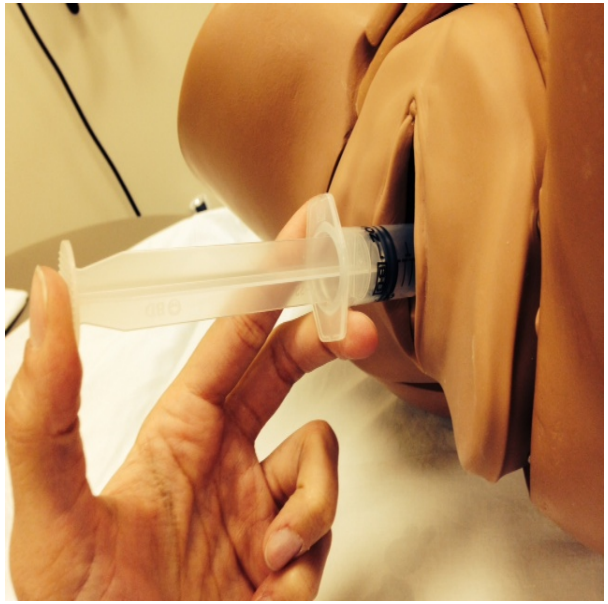
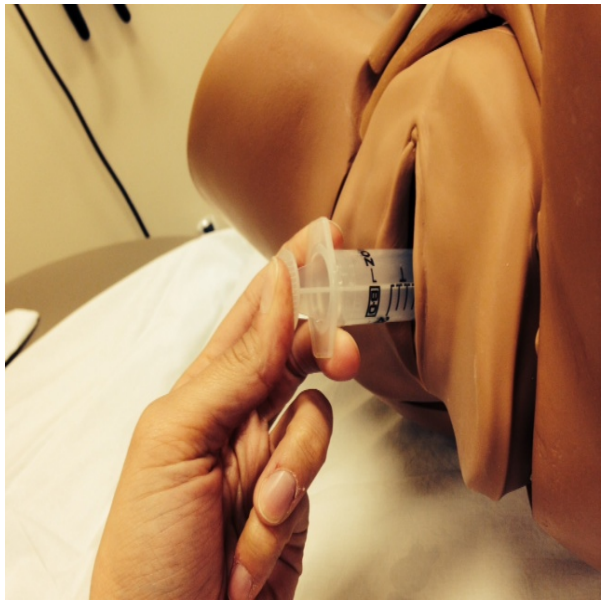
Gel Protocol





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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**

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

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	Lidocaine Paracervical Block *n*=68	Self-administered Lidocaine Gel *n*=69	p value
A			
Type of Procedure			.81*
MVA	59 (86.8%)	58 (84.1%)	
EVA	9 (13.2%)	11 (15.9%)	
Maximum Dilation (mm)			
Mean (±SD)	8.21±1.6	7.72±1.6	.09*
Median (Range)	8 (6-12)	7 (6-11)	.08†
Time between gel insertion and speculum placement (min:seconds)			
Mean (±SD)	--	39:02±14:20	
Median (Range)	--	37:10 (15:00-86:00)	
Time between paracervical block and cervical dilation (min:seconds)			
Mean (±SD)	1:07±1:04	--	
Median (Range)	1:00 (0:20-4:00)	--	
Total Procedure Time (min:seconds)			
Median (Range)	7:16 (3:00-16:07)	5:23 (2:20-15:38)	.000†

[a] Fisher's Exact Test
[b] Student's *t* test
[c] Mann-Whitney *U*-test

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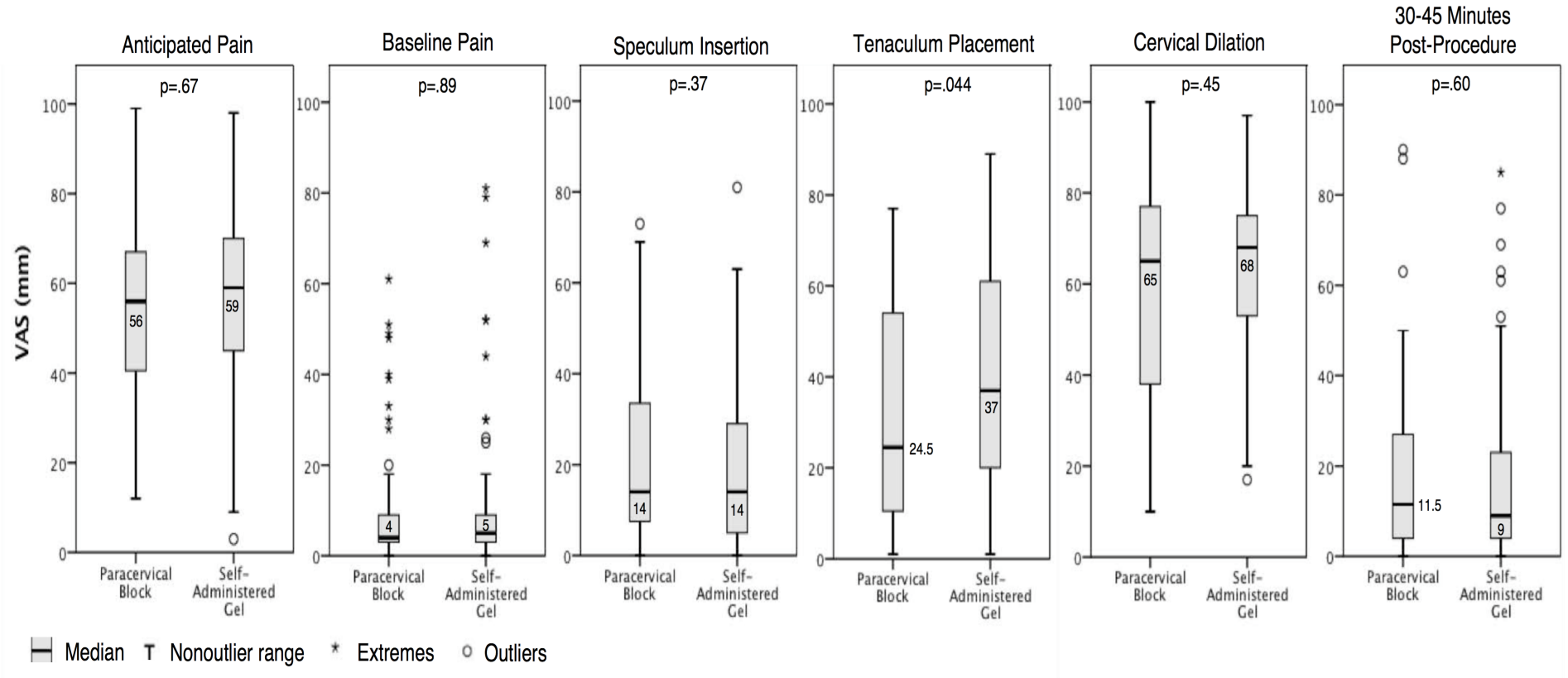
Figure 2. Box plot of pain scores (VAS) at various time points, medians displayed



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	Median			Mean		
	PCB mm (range)	Gel mm (range)	p-value	PCB mm (± S.D.)	Gel mm (± S.D.)	p-value
All Subjects	*n*=68	*n*=69		*n*=68	*n*=69	
Cervical Dilation	65 (10-100)	68 (17-97)	.45[a]	60.12 (± 24.18)	64.07 (± 20.85)	.31[b]
Nulliparous Subjects	*n*=40	*n*=44		*n*=40	*n*=44	
Cervical Dilation	64.5 (10-96)	69 (20-96)	.24[a]	58.15 (± 24.15)	65.57 (± 19.59)	.12[b]
Parous Subjects	*n*=28	*n*=25		*n*=28	*n*=25	
Cervical Dilation	65.5 (11-100)	66 (17-97)	.86[a]	62.93 (± 24.38)	61.44 (± 23.08)	.82[b]

[a] Mann-Whitney *U*-test
[b] Student's *t* test

Acceptability

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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)

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Thank You

- Dr. Jennifer Conti
- Dr. Kate Shaw
- Klaira Lerma
- Corinne Montgomery
- Planned Parenthood Mar Monte & Stanford Gynecology clinic staff

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Questions?

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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

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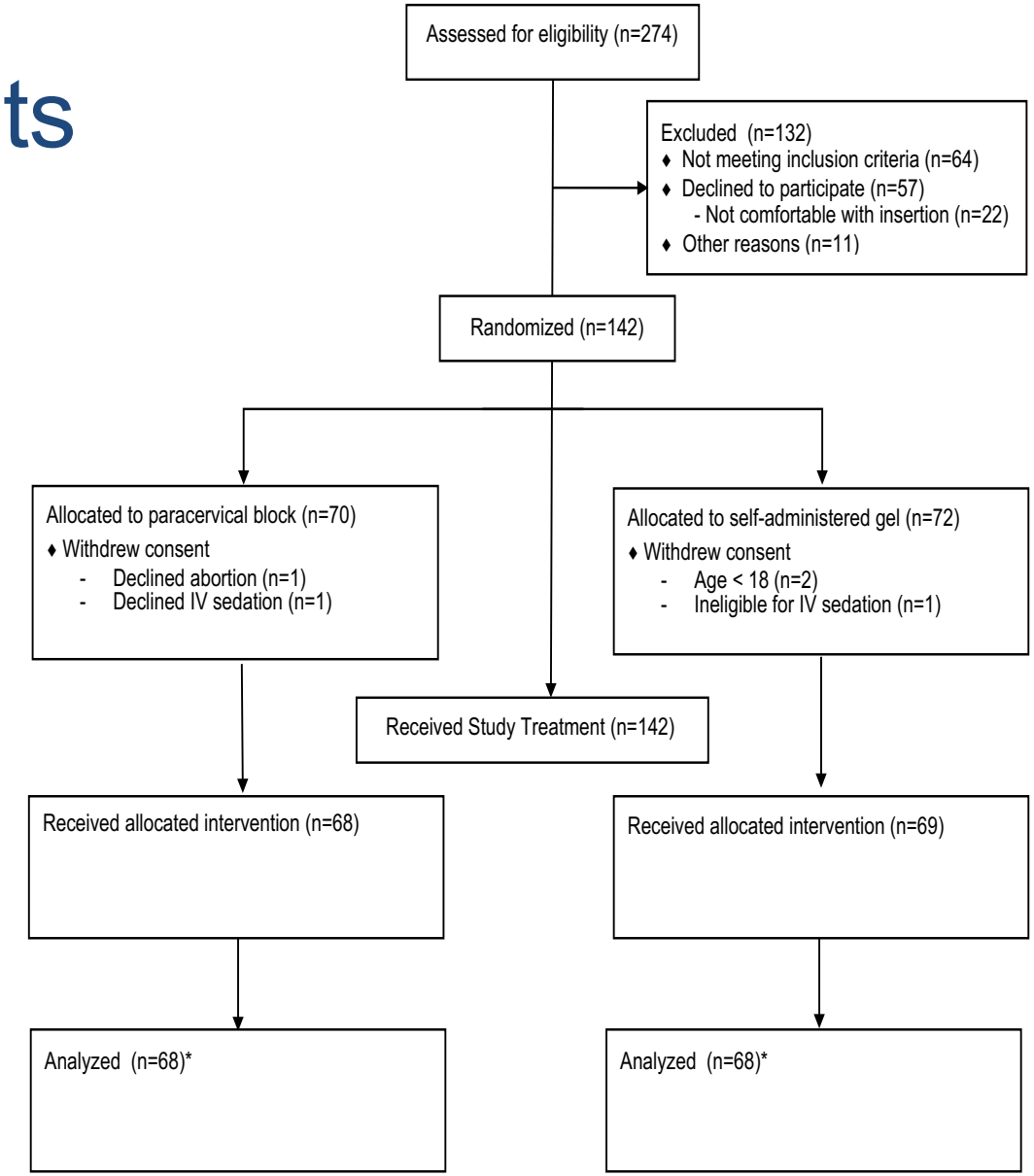
REDCap Research Electronic Data Capture

Results



* 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)

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