Buccal Versus Sublingual Misoprostol Alone for Early Pregnancy Termination in Two Latin American Countries: A Randomized Trial

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#### **Medical Abortion in Latin America**

- Mifepristone unavailable throughout the region, misoprostol-alone often used instead
- Regimens vary, buccal and sublingual administration are common
- Little information about the efficacy of differing regimens
- Need for direct comparison of buccal vs. sublingual

# Study Objectives

- Examine efficacy and acceptability of two misoprostol-only regimens commonly used in Latin America
- Examine feasibility of a multi-level pregnancy test (MLPT) for at-home followup after medical abortion

## Study Background

- Enrollment: 382 pregnant women ≤ 70 days LMP
- Study sites: 6 health clinics, 2 Latin American countries

#### Outcomes:

- Rates of ongoing pregnancy
- Safety, side effects and acceptability of misoprostol regimens
- Women's ability to use MLPT for home follow-up
- Acceptability of MLPT for home follow-up

#### **Procedures**

Participants randomized to either:

Buccal administration of misoprostol

Sublingual administration of misoprostol

- 3 doses of 800 mcg misoprostol, every 3 hours
- 2 MLPTs for monitoring abortion status

Clinic follow-up 1 week later

If success, exit study

If incomplete or ongoing, then option of MVA, additional miso, or expectant management

If additional miso, extended follow-up at 14 days

## **Participant Characteristics**

	Sublingual group (n=188)	Buccal group (n=188)
Country of residence: % (n) Country A Country B	60.6 (114) 39.4 (74)	61.2 (115) 38.8 (73)
Education: % (n) Primary or less Secondary or higher	18.7 (35) 78.6 (147)	15.0 (28) 84.5 (158)
Mean age in years ± SD	27.0 ± 7.3	27.1 ± 7.0
Gestational age in days ± SD	48.6 ± 10.6	47.4 ± 9.5
Mean parity ± SD	2.7 ± 1.5	2.8 ± 1.8

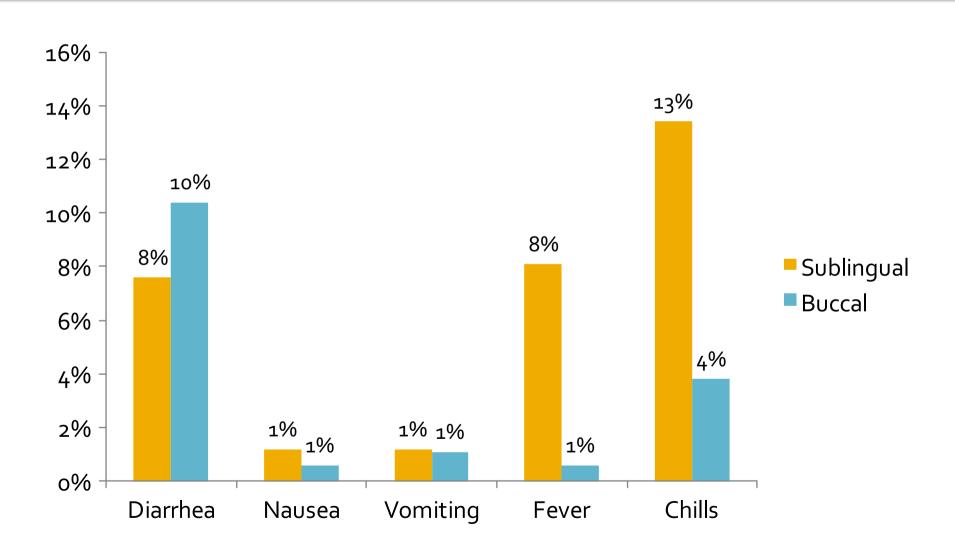
# Abortion Outcomes at 1 Week Follow-Up Visit

	Sublingual group (n=175)	Buccal group (n=185)
Success Incomplete abortion Ongoing pregnancy	87.0 (154) 11.3 (20) <b>1.7 (3)</b>	86.4 (159) 8.7 (16) <b>4.9 (9)</b>
Action taken for incomplete cases Surgery Additional dose of miso Expectant management	n=20 5 12 1	n=16 4 11 1
Action taken for ongoing pregnancies Surgery Additional dose of miso	n=3 1 2	n=9 3 6

# Final Abortion Outcomes by Study Group

	Sublingual group (n=175)	Buccal group (n=185)
Final outcome Success Surgical intervention	94.3 (165) 5.7 (10)	91.9 (170) 8.1 (15)
Reason for surgical intervention Ongoing pregnancy Persistent or nonviable pregnancy or sac Substantial debris in uterus Excessive bleeding Requested by woman	n=10  1  9 0 0 0	n=15  5  4  4  1
Would choose medical abortion for future procedure	89.5 (153)	84.6 (154)

# Incidence of Severe Side Effects by Study Group



### **MLPT Results**

	No ongoing pregnancy (n=347)	Ongoing pregnancy (n=6)
Negative result (decline in hCG concentration)	292	0
Positive result (stable or increase in hCG concentration)	55	6

Sensitivity=6/6=100%

Specificity=292/347= 84%

### Conclusions

- Lower than expected rates of ongoing pregnancy in both study groups
- Both routes of administration are effective and acceptable to women
  - However severe fever and chills may be greater if taken sublingually
- MLPTs are an effective tool for medical abortion follow-up in both settings

# Thank you!



