

Mifepristone Abortion with Home Administration of Misoprostol

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1



237,340 women received medication abortion at Planned Parenthood, since approval Sept 2000 to June 30, 2006.

All used misoprostol at home

2

PP protocol always involved home use of misoprostol

- For five years, protocol was:
200 mg mifepristone and 800 mcg miso vaginally 24-72 hours later up to 63 days
- Since March 2006:
200 mg mifepristone and 800 mcg oral miso (up to 49 days) OR 800 mcg buccal misoprostol (up to 56 days) 24-48 hours later

3

Components of successful home use of misoprostol include:

1. Clear instructions to patients
2. After-hours on-call system
3. Follow-up patient assessment
4. System-wide tracking incidence of adverse events

4



How do we prepare our patients to use misoprostol at home?

5

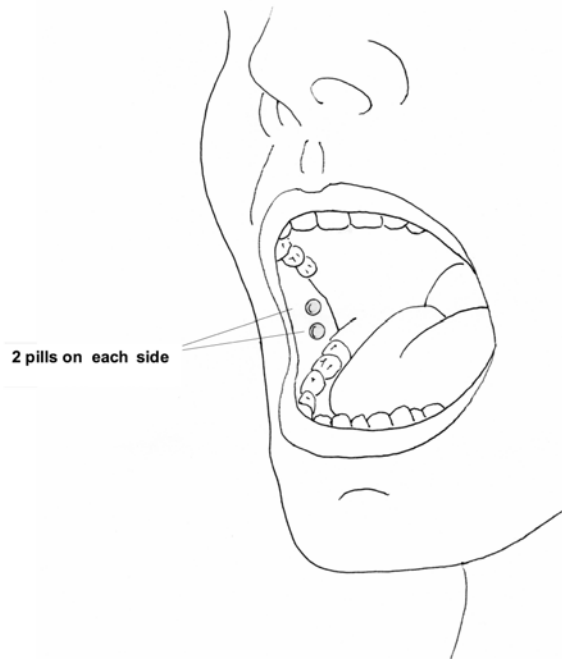
- ✓ Recommend support person be with them
- ✓ Require access to a phone
- ✓ Recommend taking the day (or night) to rest



6

24-28 hrs later:

- Place 4 pills in buccal space x 30 minutes
- Then swallow remaining pill fragments

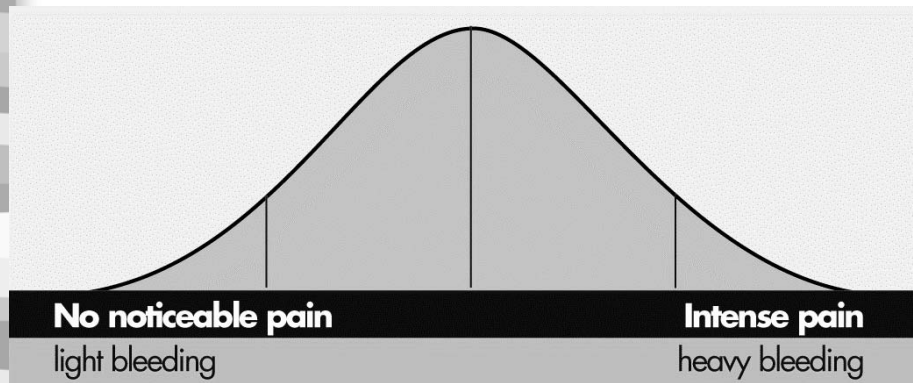


1. Get comfortable!
2. Take prescriptions - mild narcotic and anti-emetic
3. Take ibuprofen 30 minutes after miso



8

Explain range of cramping and bleeding and what should prompt call

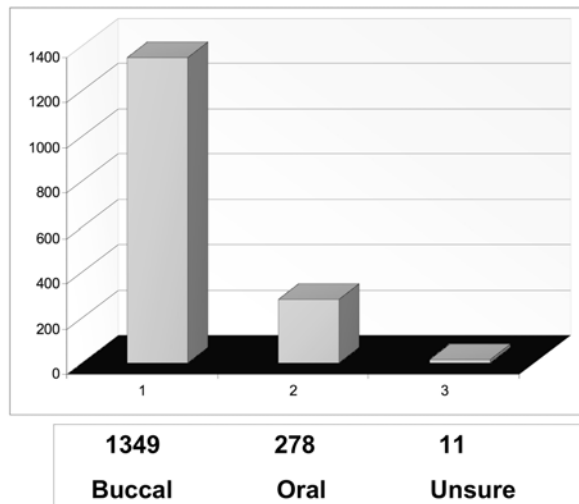


We can't tell where you'll be in this range; most women fall somewhere in the middle

How do we know home administration of misoprostol is safe and accepted by American women?

- Careful monitoring/ tracking adverse events for five years
- 258 PP medical centers throughout U.S. provide mifepristone abortion
- 26% of PP's first-trimester abortion patients choose medication abortion
- High patient acceptability –like privacy of home setting

1,638 Medical Records Reviewed in August 2006




Success Rates at 10 large-volume sites

- Buccal misoprostol 98.5%
- Oral misoprostol 95.9%

Statistically significant difference in success $p = 0.011$

Success= medication abortion without surgical intervention



Success rate of oral misoprostol dropped in the 7th week. Success of buccal did not drop in the 7th or 8th week.

- Buccal 8th week: 98.2% success
- Oral 7th week: 92.6% success

13

How Does the Buccal Miso Data Compare with Vaginal?

- In 2003, among 11,290 patients, the rate of surgical intervention (all reasons combined) was 1.5%.
 - Up to 63 days LMP
- Among the 1,349 patients in this data set of buccal misoprostol, the rate of surgical intervention (all reasons combined) was 1.5%.
 - Up to 56 days LMP

14

1,638 medical records reviewed for emergency bleeding

- One patient had heavy bleeding & received ergonovine 2 months after medication abortion
- One patient had D&C 5 weeks after med AB
- Rate of 1.2 per thousand
- Rate with vaginal miso was 1.3 per thousand

15

1,638 medical records reviewed for transfusion

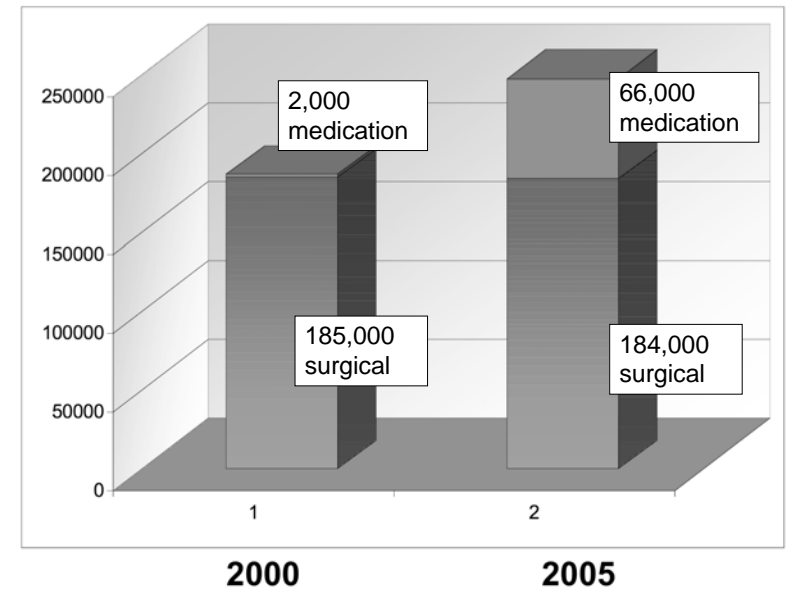
- One patient had a transfusion on Day 28
- Rate of 0.6 per thousand
- Same rate as past data with vaginal misoprostol

16

Most bleeding requiring emergency curettage and transfusion occurs later than the day the patient used misoprostol

- Incidence of emergency treatment for bleeding on the same day of misoprostol is 0.1 per thousand.

Abortions at Planned Parenthood



Conclusions:

1. It is safe and convenient for women to use misoprostol at home
2. Buccal miso is more effective than oral.

Infection following medication abortion

1. What is known about fatal infections in N. America following medication abortion?
2. What is known about nonfatal infections following medication abortion?
3. Can medication abortion, which is very safe, be made safer?

21

Organisms that have caused fatal infection following medication abortion in North America

- *C. sordellii* (5)
 - One in Canada
 - Four in California
- *C. perfringens* (1)
 - Western U.S. (not California)
- Regimen in all cases was 200 mg mifepristone PO and 800 mcg misoprostol PV

22

What is *C. sordellii*?

- Anaerobic gram positive rod, spore-forming bacterial species
- Commonly found in soil
- Recognized cause of sudden death in cattle and sheep
- Colonization of GI tract in 0.05- 0.5% of healthy humans
- *C. sordellii* is not part of the BV complex

23

MAB: *C. sordellii* case characteristics^{1,2}

AGE	GEST. AGE	INTERVAL TO SX	SYMPTOMS	VITAL SIGNS	LAB DATA	HOSP. TO DEATH
27 (Canada)	5wk 5d	5 days	Severe pain, nausea, dizziness, afebrile	90/60 125	21K – 55K Hct 51-58%	3 days
18	6wk 5d	4 days	Severe pain, nausea, afebrile	78/53 147	46K – 107K Hct 52%	10 hours
22	7wk 4d	5 days	Severe pain, afebrile, vom/nausea	80/40 ~140	22K – 120K Hct 45%	1 day
21	6wk 1d	5 days	Pain, vomiting	???	???	0
34	6wk 3d	4 days	Severe pain, vomiting, afebrile	99/63 89-135	55K – 88K Hct 59%	12 hours

⁴Wiebe et al. (2004). *Obstet & Gynec.* 104 (5 Part 2):1142-1144.

⁵Fischer et al. (2005). *NEJM*, 353(22): 2352-2360

All patients were negative for gonorrhea and chlamydia

24

CDC/FDA Meeting May 11, 2006

- Emphasis on science
- CDC/FDA – further research & surveillance
 - Probably under-recognized and under-reported
 - Why California? Higher prevalence of organism in soil?
 - Increased or changed pathogen virulence?
 - Host susceptibility?
 - Vaginal administration of misoprostol?
 - Multiple factors?

25

CDC/FDA: *C. sordellii* seems to be an organism that infects women as a pregnancy is ending

- 12 known OB/Gyn cases other than those following medication abortion:
- 8 postpartum (vaginal and C-section deliveries- all fatal)
- 2 spontaneous abortion (both fatal)
- 1 chorioamnionitis/spontaneous abortion (survived)- lacked Lethal toxin gene

26

CDC recommendations if *C. sordellii* is suspected

- CBC, hgb/hct
- Gram stain of endometrial sample
- Broad spectrum antibiotics with anaerobic coverage
- Anaerobic cultures
- Consider hysterectomy
- Unknown if patients can be saved once toxin production has begun

27

Non-fatal infections among patients having medication abortion:

- STDs: chlamydia and/or gonorrhea
- Non-STD: polymicrobial
- Organism often unknown
- Non-fatal septicemia
- Pelvic abscesses necessitating organ removal

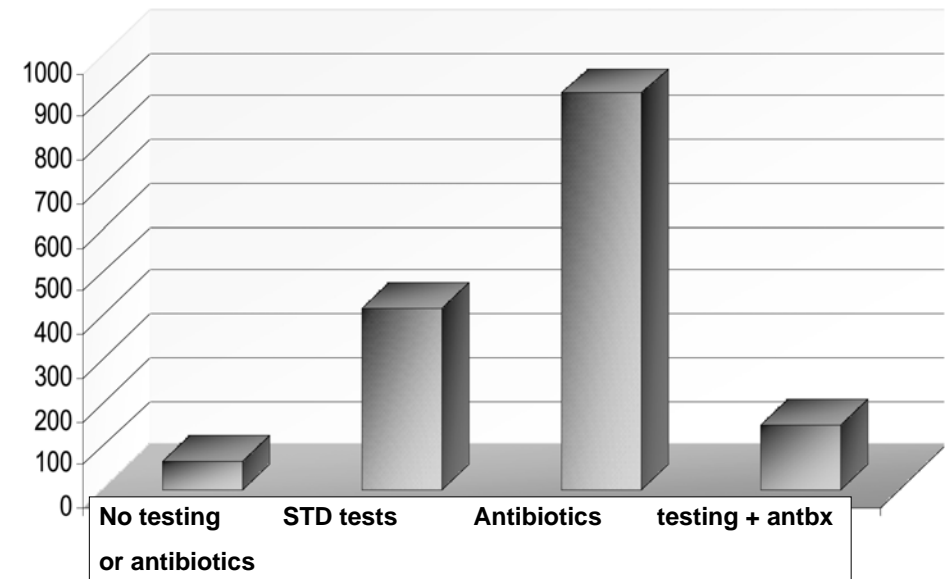
28

Infectious complications seen in clinical trials and research

<u>Study</u>	<u># of pts</u>	<u># infections</u>	<u>rate/1000</u>
Schaff	2295	2 hospitalized	0.87
		2 outpatient	0.87
Schaff	1137	1 IV antibiotics	0.88
		3 outpatient	2.64
Spitz (FDA regimen)	2015	10 endometritis	4.96

29

STD Testing vs Antibiotics- 1,638 medical records



Reporting and tracking

- Planned Parenthood centralized reporting system
- If ongoing data indicates that already low incidence of infection is lower with buccal misoprostol:
 - May not be able to distinguish whether a reduction in infection is caused by use of buccal misoprostol or enhanced surveillance/ antibiotic coverage of STDs or both
 - May not know until another 200,000+ patients have received mifepristone abortion whether risk of very rare/fatal infection is reduced

31