Lactation Suppression After Delivery or Termination

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Disclosures

- None

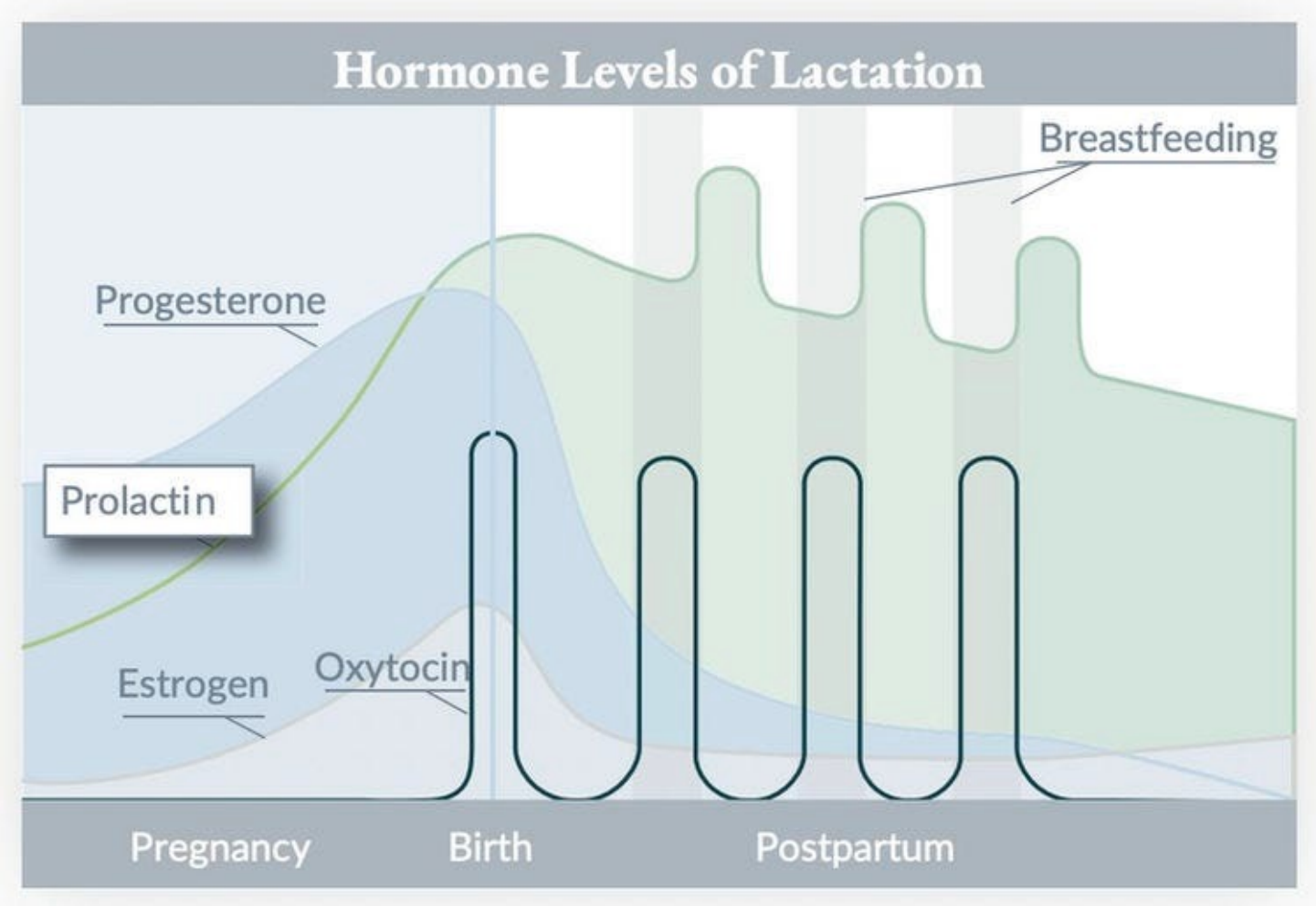
Objectives

- Discuss the incidence of breast concerns after pregnancy loss/interruption
- Discuss evidence-based strategies for mitigating breast concerns
- Propose a “protocol” for optimizing care in this population

What is the issue?

- A large majority (97%) of people who experience loss or pregnancy interruption experience undesired breast symptoms
- In addition to pregnancy loss/interruption, patients may choose not to lactate due to a need to initiate medications that are not compatible with lactation, adoption, or personal preference, among other reasons
- These breast symptoms can be distressing and a trigger for further grief
- Some strategies exist to minimize breast symptoms, which may, in part, improve the patient experience.

Lactogenesis



Background

- After a 14-20 week pregnancy loss/interruption, breast symptoms are common:
  - Breast tenderness in 50%
  - Breast engorgement in 45%
  - Breast leaking 20%
- This is often unexpected and has been demonstrated to exacerbate physical pain as well as emotional distress

Anecdotal strategies

- Cochrane review 2020
- 21 studies (2170 patients randomized) evaluating interventions such as:
  - Cabbage leaves
  - Herbal compresses (ginger, cactus, aloe, hollyhock)
  - Massage (manual, electromechanical, Oketani)
  - Acupuncture
  - Ultrasound
  - Acupressure
  - Scraping therapy
  - Cold packs
  - Medical treatment (serrapeptase, protease, oxytocin)

Anecdotal strategies

- Cochrane review 2020
- Certainty of evidence is LOW
- Cabbage leaves, cold gel packs, herbal compresses and massage “may be promising” but quality of evidence is LOW to VERY LOW
- Many studies were comparing items to one another (ie cabbage leaves to ice packs)

Cabbage leaves

- Might help slightly with pain, breast ”hardness,” and patient satisfaction compared to routine care

- VERY LOW level of certainty

Compresses

- No studies comparing this to ”routine care” only to one another (ie herbal compress vs hot compress)
- Herbal compresses were better than hot compresses for pain
- Cactus and aloe cold compresses were better than massage for hardness

- LOW to VERY LOW level of confidence

Medical treatments

- Protease may help pain and swelling compared to placebo
- Serrapeptase may reduce engorgement compared to placebo

- LOW level of confidence

Cold gel packs

- May be more effective than routine care for breast hardness
- VERY LOW level of confidence

Medication Comparisons

- Cochrane review 2012
- Reviewed RCTs that evaluated the effectiveness of treatments used for suppression of postpartum lactation
- 62 trials (6428 study participants)
- Outcome was persistence of one of the following: milk secretion, breast engorgement, or breast pain)
- Data were generally “small” and of “limited” quality. Many trials were excluded based on study design/flaws

Medication Comparisons

- Cochrane review 2012
- Bromocriptine vs placebo/no treatment
- Estrogen containing medications/derivatives vs placebo/no treatment
- Bromocriptine vs other medications

Medication Comparisons

- Cochrane review 2012

- Three trials (107 participants total) demonstrated bromocriptine was efficacious in reducing lactation compared to placebo/no treatment (RR 0.36, 95% CI 0.24-0.54).

- Seven trials demonstrated effectiveness of estrogen containing compounds (diethylstilbestrol, quinestrol, chlorotrianisene, hexestrol) compared to placebo/no treatment RR 0.40, 95% CI 0.29-0.56)

Medication Comparisons

- Cochrane review 2012
- Bromocriptine vs other medications (methergoline, prostaglandins, pyridoxine, cabergolein, diethylstilbestrol, cyclofenil) = similar effect

- NOTE: side effects and complications were poorly reported in the included trials

- Overall conclusion by authors: weak evidence supports bromocriptine use but does not seem to be better than other anents and side effect data is insufficient

Cabergoline

- Dopamine agonist → antagonizes prolactin release
- Approved for treatment of hyperprolactinemic disorders (idiopathic or related to prolactinoma)
- Has been studied in both term and 2nd trimester pregnancy loss/termination
- Also is recommended for use in patients with HIV for lactation suppression (2020 US Department of Health and Human Services Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission)

Cabergoline at term

- 1988 Double blind RCT (Melis et al, Obstet Gynecol) comparing cabergoline in varying dose sizes to placebo
  - 32 patients, 4 treatment groups (placebo, 400, 600, or 800 mcg of cabergoline) with doses at <24h after delivery
  - Lactation was suppressed in 50% of patients on 400mcg and all of patients on 600 or 800mcg.
    - 12.5% of those on placebo were suppressed
  - Prolactin levels were lower in the cabergoline group but not different among different doses

Cabergoline at term

- 1991 Multicenter RCT (European Mulitcenter Study Group or Cabergoline in Lactation Inhibition BMJ)
  - Compared bromocriptine (0.25mg BID x14d) to cabergoline (1mg once, day of delivery) in term deliveries
  - Complete suppression in 78% cabergoline and 69% of bromocriptine
  - AT LEAST partial suppression in 93% with either group
  - Cabergoline group had lower rebound breast symptoms (3.7% vs 17.0%), adverse events (16% vs 26%), and was less complicated administration (1 dose vs 14 days)

TABLE III—*No of adverse events in women treated with cabergoline or bromocriptine*

Sign/symptom	No of adverse events	
	Women receiving cabergoline (n=136)	Women receiving bromocriptine (n=136)
Dizziness	8	17
Vertigo	1	2
Symptomatic hypotension		1
Palpitation	1	
Headache	7	6
Nausea	2	10
Vomiting		3
Abdominal pain	2	
Epigastric pain	1	1
Drowsiness	1	
Other	2	4
Total	25*	44†

*Occurring in 22 women. †Occurring in 36 women.

Cabergoline at term

- Author conclusions: Cabergoline should be the agent of choice at term for suppression of lactation

Cabergoline in the 2nd trimester

- Double blind RCT (Henkel, et al, 2023)-Stanford, 4/2021-6/2022
  - Cabergoline vs Placebo in 2nd trimester uterine evacuation for suppression of breast symptoms
  - Primary outcome:
    - Composite of ANY breast symptom (engorgement, milk leakage, tenderness, or need for pain relief) on DAY 4
    - Assessed through surveys at baseline and multiple time points after procedure (up to 2 weeks after)
- Inclusion: 2nd trimester uterine evacuation (18-28w)-interruption or demise
- Exclusions: <18y, prior mastectomy, currently breastfeeding, those on dopamine agonist/antagonist already, contraindications to cabergoline, non-English/Spanish speaking

Cabergoline in the 2nd trimester

- RCT (Henkel, et al, 2023)-Stanford
  - Randomized to either:
    - 1mg cabergoline OR placebo within 4 hours of procedure or fetal expulsion
  - All participants also received mifepristone 200mg PO and had either D&E or IOL
    - If >22w had feticidal digoxin injection
    - If undergoing IOL or if demise >24w → serial misoprostol
  - Block randomization: alternating blocks of 4 and 8
  - Electronic surveys administered at various time points: baseline, days 2, 3, 4, 7, and 14

- RCT (Henkel, et al, 2023)-Stanford
  - 73 participants (36 treatment, 37 placebo)
  - Median EGA 21 weeks
  - Grand majority were pregnancy interruptions
  - Baseline breast symptoms similar between groups

Table 1. Demographic and Clinical Characteristics of Participants Randomized to Cabergoline or Placebo to Prevent Breast Pain After Second-Trimester Abortion or Pregnancy Loss

Characteristic	Cabergoline (n=36)	Placebo (n=37)
Age (y)	30.5±5.4	31.6±5.7
Parity	1 (0–4)	0 (0–4)
Nulliparous	16 (44.4)	25 (67.6)
Gestational age (d)	148.9±13.4	147.7±12.8
Gestational age (wk)		
18 0/7–19 6/7	10 (27.8)	9 (24.3)
20 0/7–21 6/7	11 (30.6)	12 (32.4)
22 0/7–23 6/7	15 (41.7)	15 (40.5)
24 0/7–28 0/7	0 (0)	1 (2.7)
Indication		
Undesired pregnancy	14 (38.9)	8 (21.6)
Fetal anomaly	20 (55.6)	27 (73.0)
Maternal comorbidity	0 (0)	1 (2.7)
Fetal death	2 (5.6)	1 (2.7)
Abortion method		
Procedural	31 (86.1)	32 (86.5)
Medication	5 (13.9)	5 (13.5)
Insurance		
Private	22 (61.1)	24 (64.9)
Medicaid	14 (38.9)	13 (35.1)
Gender*		
Female	35 (97.2)	37 (100)
Nonbinary	1 (2.8)	0 (0)
Race*		
American Indian	0 (0)	1 (2.7)
Asian or Pacific Islander	14 (38.9)	15 (40.5)
Black	1 (2.8)	1 (2.7)
White	11 (30.6)	15 (40.5)
None of the above	3 (8.3)	0 (0)
No response	7 (19.4)	5 (13.5)
Ethnicity*		
Non-Hispanic	24 (66.7)	24 (64.9)
Hispanic	12 (33.3)	13 (35.1)
Prior breast surgery	2 (5.8)	2 (5.4)
Prior breastfeeding	17 (47.2)	13 (35.1)
Length of breastfeeding (mo)		
Less than 6	8 (47.1)	5 (38.5)
More than 6	9 (52.9)	8 (61.5)

Data are mean±SD, median (range), or n (%).
* Self-identified.

Cabergoline in the 2nd trimester

- RCT (Henkel, et al, 2023)-Stanford
  - Surveys-Bristol Breast Symptoms Inventory-assesses engorgement, leaking, tenderness, pain med need
    - Validated in postpartum but not this population
    - Considered “positive” for the outcome if anything but “absent” on a symptom
    - Side effects from medications also assessed through utilization of the medication package insert (FDA)

Cabergoline in the 2nd trimester

- RCT (Henkel, et al, 2023)-Stanford
  - Subset of patients recruited for serum prolactin levels on days 0, 4, 7, 14
    - This was also appropriately powered

Cabergoline in the 2nd trimester

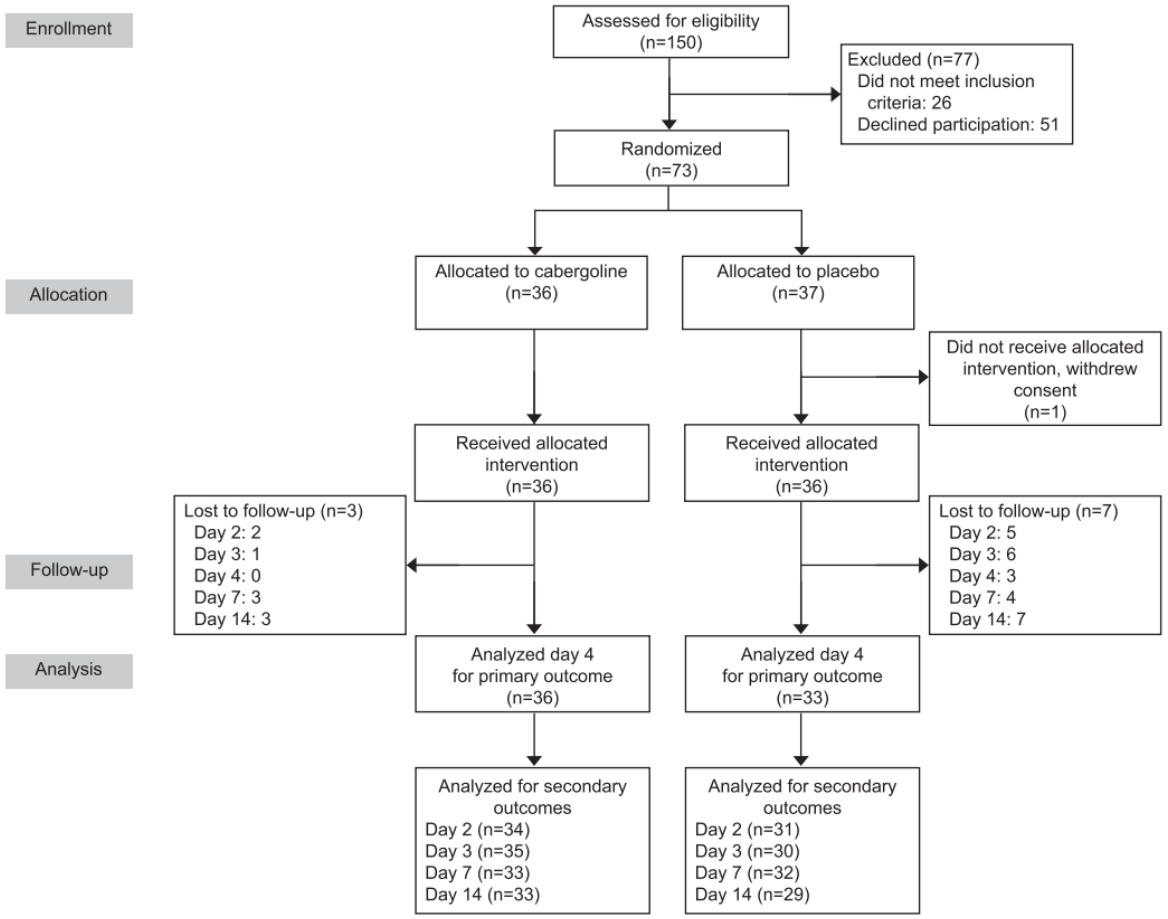
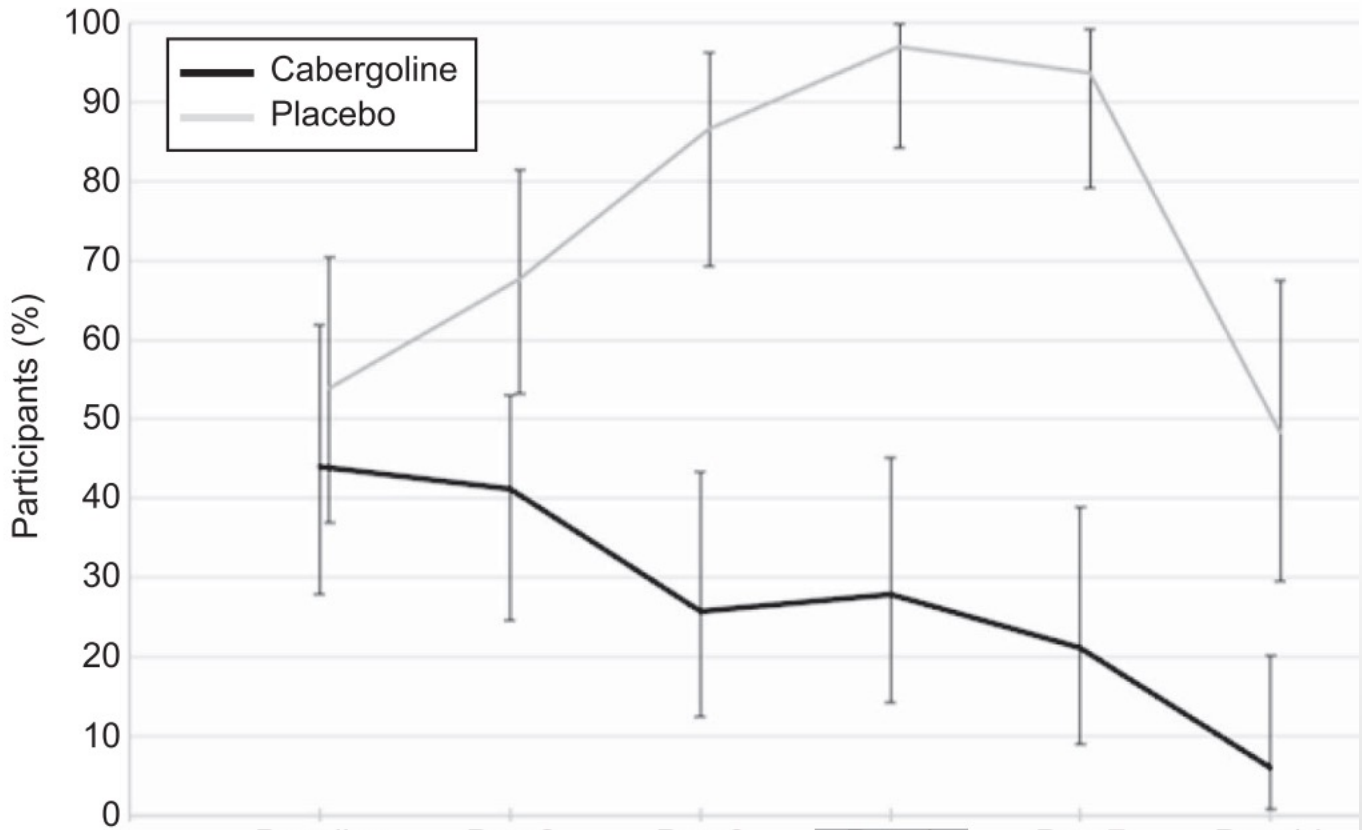


Fig. 1. CONSORT (Consolidated Standards of Reporting Trials) flow chart.

Henkel. Cabergoline for Second-Trimester Lactation Inhibition. Obstet Gynecol 2023.



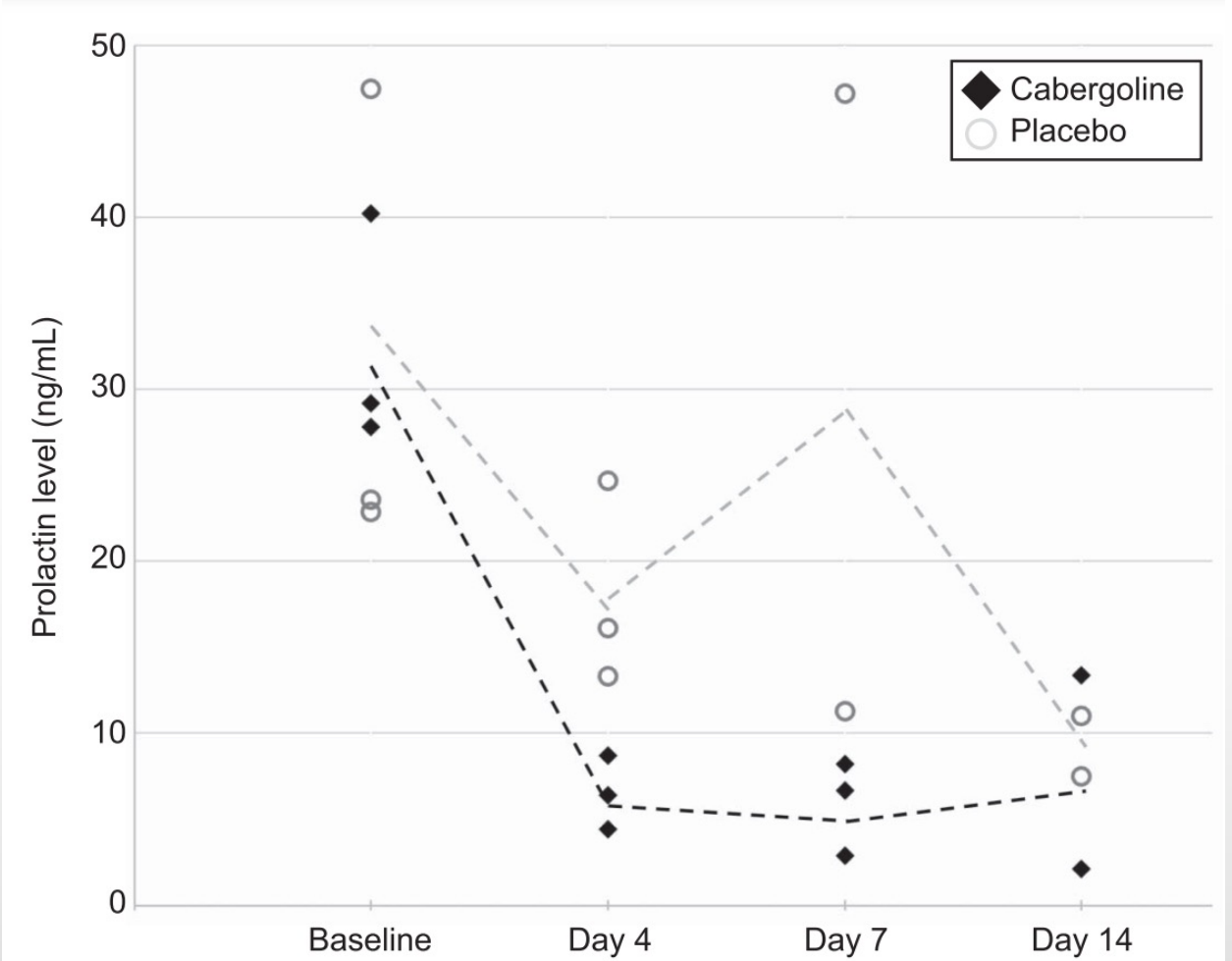
	Baseline	Day 2	Day 3	Day 4	Day 7	Day 14
Cabergoline	16/36	14/34	9/35	10/36	7/33	2/33
Placebo	20/37	21/31	26/30	32/33	30/32	14/29
P value	.41	.032	<.001	<.001	<.001	<.001

Table 2. Bother* Associated With Breast Symptoms of Participants Randomized to Cabergoline or Placebo After Second-Trimester Abortion or Pregnancy Loss

	Cabergoline	Placebo	*P*
Baseline	n=36	n=37	
Bother rating	0 (0–4)	0 (0–4)	.464
Significant bother	1 (2.8)	1 (2.7)	>.99
Day 2	n=34	n=31	
Bother rating	0 (0–3)	1 (0–4)	.040
Significant bother	0 (0)	1 (3.2)	>.99
Day 3	n=35	n=30	
Bother rating	0 (0–4)	2 (0–6)	<.001
Significant bother	1 (2.8)	1 (3.3)	>.99
Day 4	n=36	n=33	
Bother rating	0 (0–4)	3 (0–6)	<.001
Significant bother	1 (2.8)	11 (33.3)	.001
Day 7	n=33	n=32	
Bother rating	0 (0–3)	1.5 (0–5)	<.001
Significant bother	0 (0)	4 (12.5)	.11
Day 14	n=33	n=29	
Bother rating	0 (0–3)	0 (0–3)	.001
Significant bother	0 (0)	0 (0)	>.99

Data are median (range) or n (%) unless otherwise specified.

* Bother on facial pain score (0=none, 6=extremely); significant bother 4 or higher.



	Baseline	Day 4	Day 7	Day 14
Cabergoline	n=3 32.4+6.8	n=3 6.5+2.2	n=3 5.9+2.7	n=2 7.7+8.0
Placebo	n=3 31.3+14.0	n=3 18.0+5.9	n=2 29.3+25.4	n=2 9.3+2.5
P value	.513	.049	.083	.999

Table 3. Side Effects Reported by Participants Randomized to Cabergoline or Placebo After Second-Trimester Abortion or Pregnancy Loss

Side Effect	No. of Participants With Side Effects		*P*
	Cabergoline (n=36)	Placebo (n=37)	
Nausea or vomiting	5 (13.9)	2 (5.4)	.261
Headache	12 (33.3)	9 (24.3)	.395
Dizziness or lightheadedness	7 (19.4)	7 (18.9)	.955
Constipation	14 (38.9)	18 (48.6)	.401
Acid reflux	3 (8.3)	2 (5.4)	.674
Fatigue	12 (33.3)	11 (29.7)	.704
Lower extremity edema	4 (11.1)	4 (10.8)	>.99
Hot flushes	2 (5.6)	9 (24.3)	.025
Palpitations	1 (2.8)	1 (2.7)	>.99
Anxiety	4 (11.1)	3 (8.1)	.711
Insomnia	8 (22.2)	11 (29.7)	.465
Visual disturbance	1 (2.8)	2 (5.4)	>.99
Total reporting side effects	29 (80.6)	26 (70.3)	.308

Data are n (%) unless otherwise specified.

**not powered to detect differences in side effects

Author Conclusions

- *We found cabergoline to be an effective, well tolerated pharmacologic intervention to prevent bothersome breast symptoms after second-trimester abortion or pregnancy loss.*
- *Given the current lack of evidence-based interventions to prevent breast symptoms in this population, these findings support routine use of cabergoline after second trimester-abortion or pregnancy loss*
- *Limitations: underpowered to detect small differences in side effects, low trial acceptance (66%), lack of GA stratification at randomization*

Cabergoline side effects (not obstetric specific)

The following adverse drug reactions and incidences are derived from product labeling unless otherwise specified. Adverse reactions reported in adults.

>10%:

Gastrointestinal: Nausea (27% to 29%)

Nervous system: Dizziness (15% to 17%), headache (26%)

1% to 10%:

Cardiovascular: Dependent edema (1%), hypotension (≤1%), orthostatic hypotension (4%), palpitations (≤1%), peripheral edema (1%), syncope (≤1%)

Dermatologic: Acne vulgaris (≤1%), pruritus (≤1%)

Endocrine & metabolic: Hot flash (3%)

Gastrointestinal: Abdominal pain (5%), anorexia (≤1%), constipation (7% to 10%), diarrhea (≤2%), dyspepsia (2% to 5%), flatulence (≤2%), toothache (1%), vomiting (2% to 4%), xerostomia (≤2%)

Genitourinary: Dysmenorrhea (≤1%), mastalgia (1% to 2%)

Nervous system: Anxiety (≤1%), asthenia (6%), depression (3%), drowsiness (≤2%), fatigue (5% to 7%), insomnia (≤1%), lack of concentration (1%), malaise (≤1%), nervousness (≤2%), pain (2%), paresthesia (≤2%), vertigo (1% to 4%)

Neuromuscular & skeletal: Arthralgia (1%)

Ophthalmic: Periorbital edema (1%), visual disturbance (≤1%)

Respiratory: Flu-like symptoms (≤1%), rhinitis (1%), throat irritation (1%)

Contraindications to cabergoline (uptodate)

- "Uncontrolled" hypertension
- Known hypersensitivity to cabergoline, ergot derivatives, or any component of the formulation
- History of cardiovascular valvular disorders (valvulopathy of any valve, thickened leaflets, valve restriction, or mixed valve restriction/stenosis)-only demonstrated increased risk at >2mg/day
- History of pulmonary, pericardial, or retroperitoneal fibrotic disorders
- Possibly history of psychotic illness (low level of evidence)

These are for general cabergoline use that would be long term, presumably less risk in a single dose

Availability of Cabergoline

- Immediately available in the inpatient and outpatient pharmacies
- Cost: approximately 10$ for one tablet

Key Points and Action Items

- Conservative measures (cabbage leaves, ice packs, pressure) may or may not work but have limited downsides
- Cabergoline for lactation suppression is still considered off label use (as are many medications)
- >50% of patients at 18-28w did not anticipate breast symptoms
  - Opportunity for counseling on expectations
- Consider offering, for those interested and >18w, the following:
  - 1mg cabergoline within 4 hours of D&E or fetal expulsion

Suggestion for counseling/documentation

- Lactation discussion: We discussed that the majority (up to 97%) of patients at this gestational age (>18 weeks) will experience some level of breast symptoms after delivery/procedure including tenderness, engorgement, pain, and/or leakage. These symptoms can impact both physical and emotional recovery. Patients may choose to pursue lactation suppression for various reasons including pregnancy loss, pregnancy interruption, the need to initiate medications that are not compatible with lactation, adoption, or personal preference (among other reasons). Additionally, some patients going through loss may choose to initiate and continue lactation. For those hoping to suppress lactation, symptoms may be improved with ice packs, compresses, and possibly cabbage leaves although the data are limited on this. Cabergoline is a medication that can be used "off label" for lactation suppression. While cabergoline is not FDA approved for lactation suppression, data in pregnant women have been reassuring and the medication has been demonstrated to be effective in reducing and eliminating symptoms in the majority of patients between at >18 weeks gestational age. Side effects were similar among patients who did and did not receive the medication and included nausea, dizziness, and headache. This medication should not be used in those patients with uncontrolled hypertension or fibrotic disorders. In patients with a history of cardiovascular disease or psychotic illness, the care should be individualized. After a thorough discussion about risks and benefits, the patient expressed a desire to suppress/continue lactation with the following plan:
- *If suppressing lactation*
- -Ice packs, tight fitting bras, and cabbage leaves as able
- -Ibuprofen and acetaminophen for breast discomfort/pain
- -Cabergoline 1mg oral to be given within 4 hours after delivery/procedure
- -Resources provided: https://perinatalgrief.Com/lactation
-
- *If continuing lactation*
- -Lactation consultation
- -Resources provided: https://perinatalgrief.Com/lactation

Options For Milk Banking

- Human milk banking association of North America (www.Hmbana.Org)
- Mother's milk bank (www.Mothersmilk.Org)

Sample summary notes for your teams: Lactation suppression with cabergoline

- The deficit: The majority of people experiencing loss or undergoing termination of pregnancy at 18w+ have bothersome breast symptoms and many do not realize this will occur. This has been demonstrated to have significant physical and emotional impacts.
- The data:
  - In a recent double blind RCT, 1mg dose of cabergoline (single dose) has been demonstrated to decrease breast symptoms from 97% to 27% compared to placebo in patients 18-28w.
  - Additionally, studies in term patients have shown similar reductions.
  - Data on strategies like ice/compresses, wraps, cabbage leaves, etc are limited.
- The medication: Cabergoline is considered safe with few contraindications and few major side effects (that were generally not different between treatment and placebo groups). Few contraindications exist.
- The plan: Patients will be counseled on the likelihood of breast symptoms with a discussion about goals (suppression vs lactation) and provision of resources. For those interested in suppression, a single dose of cabergoline 1mg will be given in the immediate post-delivery/post-procedure period (<4h). If on L&D, dose will be given there.
  - Additional strategies will also be offered-compresses, ice, ibuprofen, etc.

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