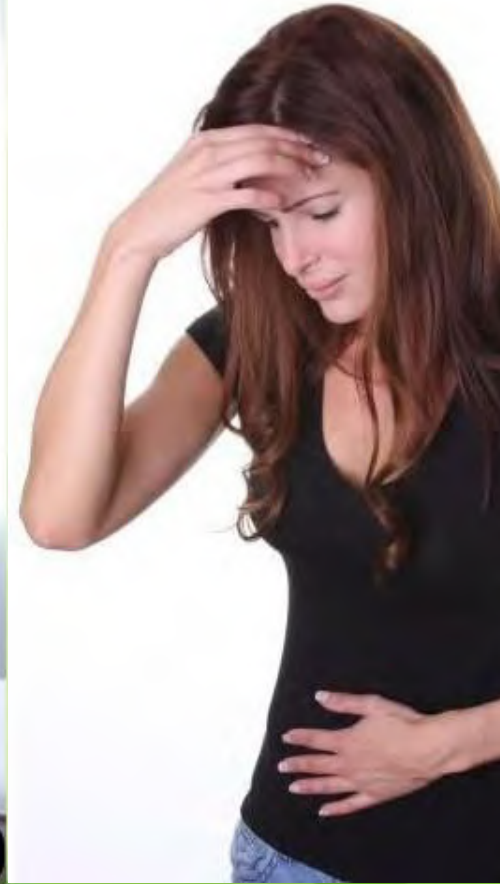


Nausea and Vomiting of Pregnancy - NVP



STOP nausea & vomiting

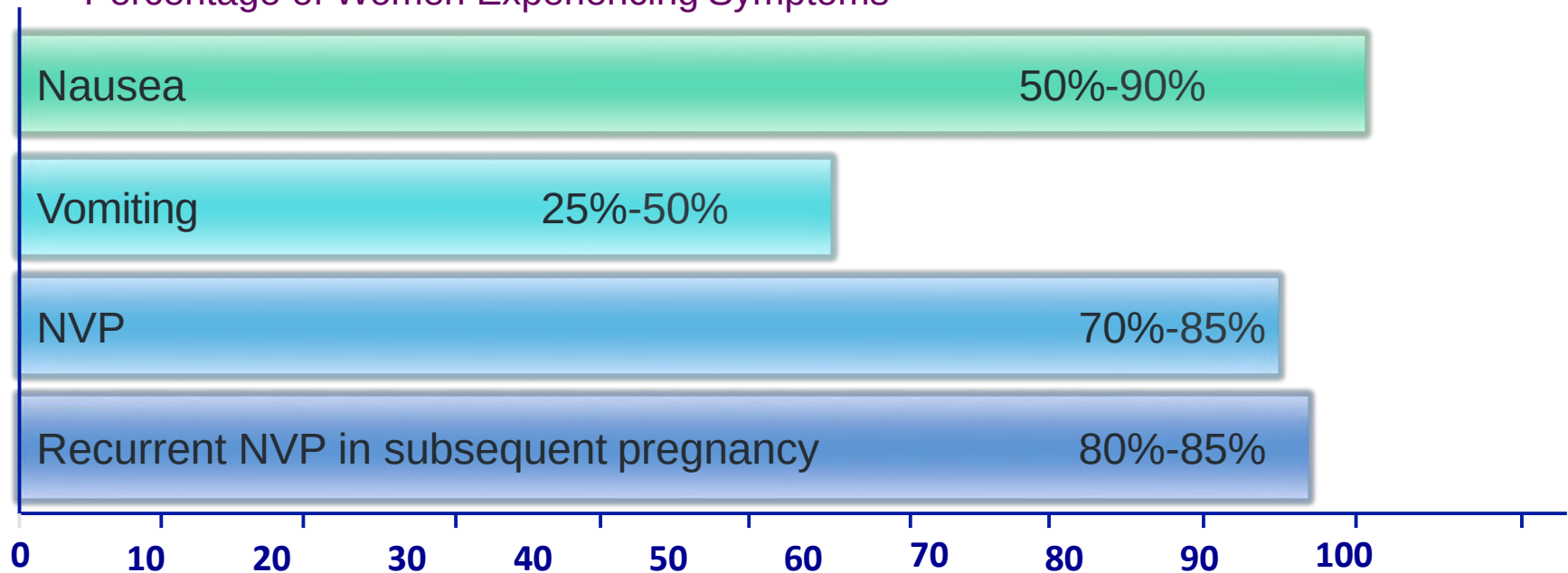
QUICK & EASY

Nausea and Vomiting of Pregnancy (NVP)

- ✓ Nausea and vomiting of pregnancy (NVP) is a spectrum disorder with varying degrees of symptoms¹
- ✓ NVP, commonly known as morning sickness, occurs in approximately 75%-80% of pregnant women²
- ✓ Symptoms range from mild to severe
 - Severe NVP (hyperemesis gravidarum [HG]) is seen in approximately 1-3% of pregnancies³
- ✓ Self-limiting condition with no impact on long-term health¹

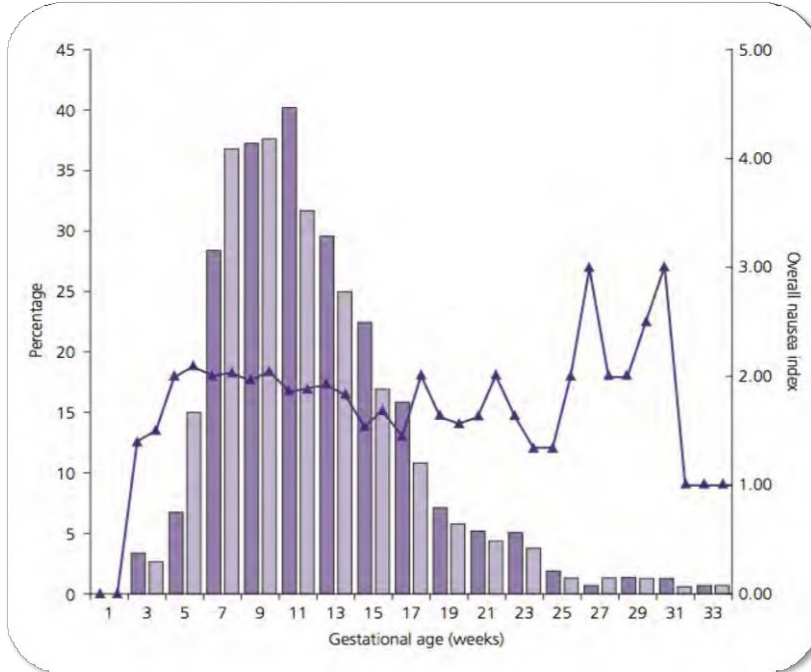
¹Badell ML, Ramin SM, Smith JA. *Pharmacotherapy*. 2006;26:1273–87. ²Gadsby R, Barnie–Adshead AM, Jagger C. *Br J Gen Pract*. 1993;43:245–8. ³Tsang IS, Katz VL, Wells SD. *Int J Gynaecol Obstet*. 1996;55:231–5.

Percentage of Women Experiencing Symptoms

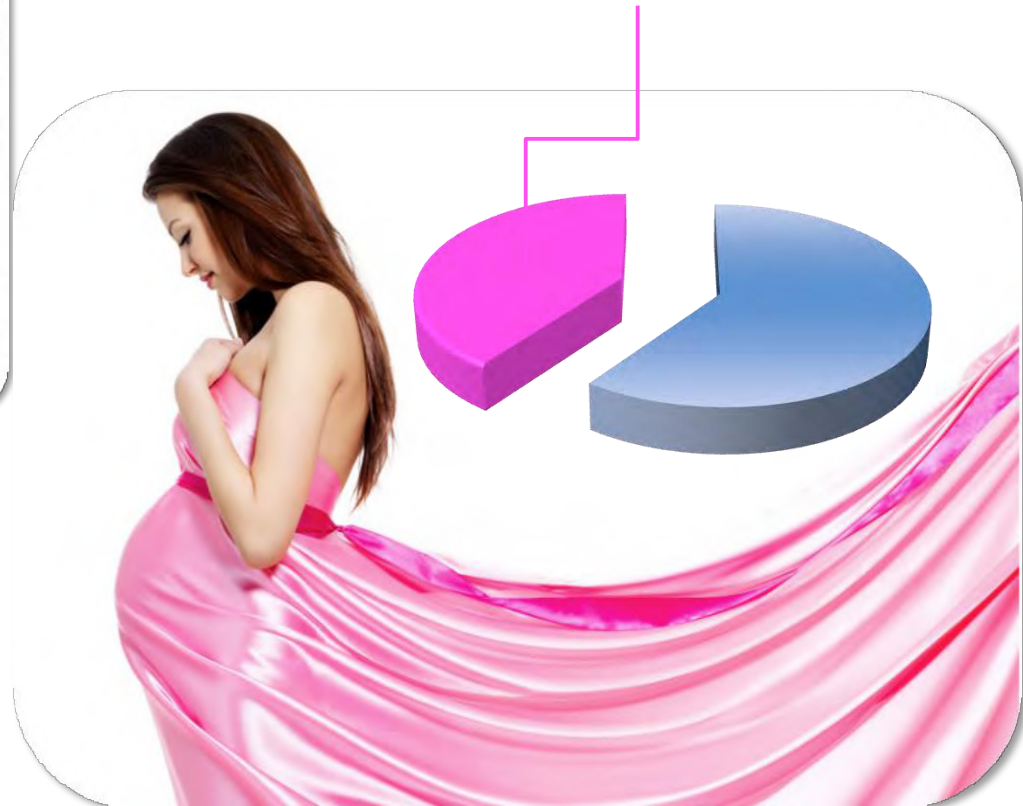


Einarson TR, Navioz Y, Maltepe C et al. *J Obstet Gynaecol*. 2007;27(4):360–2.
Erick M. *OBG Management*. 2000;25–35.
Gadsby R, Barnie–Adshead AM, Jagger C. *Br J Gen Pract*. 1993;43:245–8.
Koren G, Maltepe C. *J Obstet Gynaecol*. 2004;24(5):530–3.
O'Brien B, Zhou Q. *Birth*. 1995;22:93–100.

Rates & severity according to gestation



40% of pregnancies result in
Clinically Significant NVP



Gadsby R, Barnie-Adshead AM, Jagger C. *Br J Gen Pract.* 1993;43:245–8.
O'Brien B, Zhou Q. *Birth.* 1995;22:93–100.
Vellaco[^] ID, Cooke EJA, James CE. *Int J Gynecol Obstet.* 1988;27:57–62.

Medical, Economic, & Social Impacts

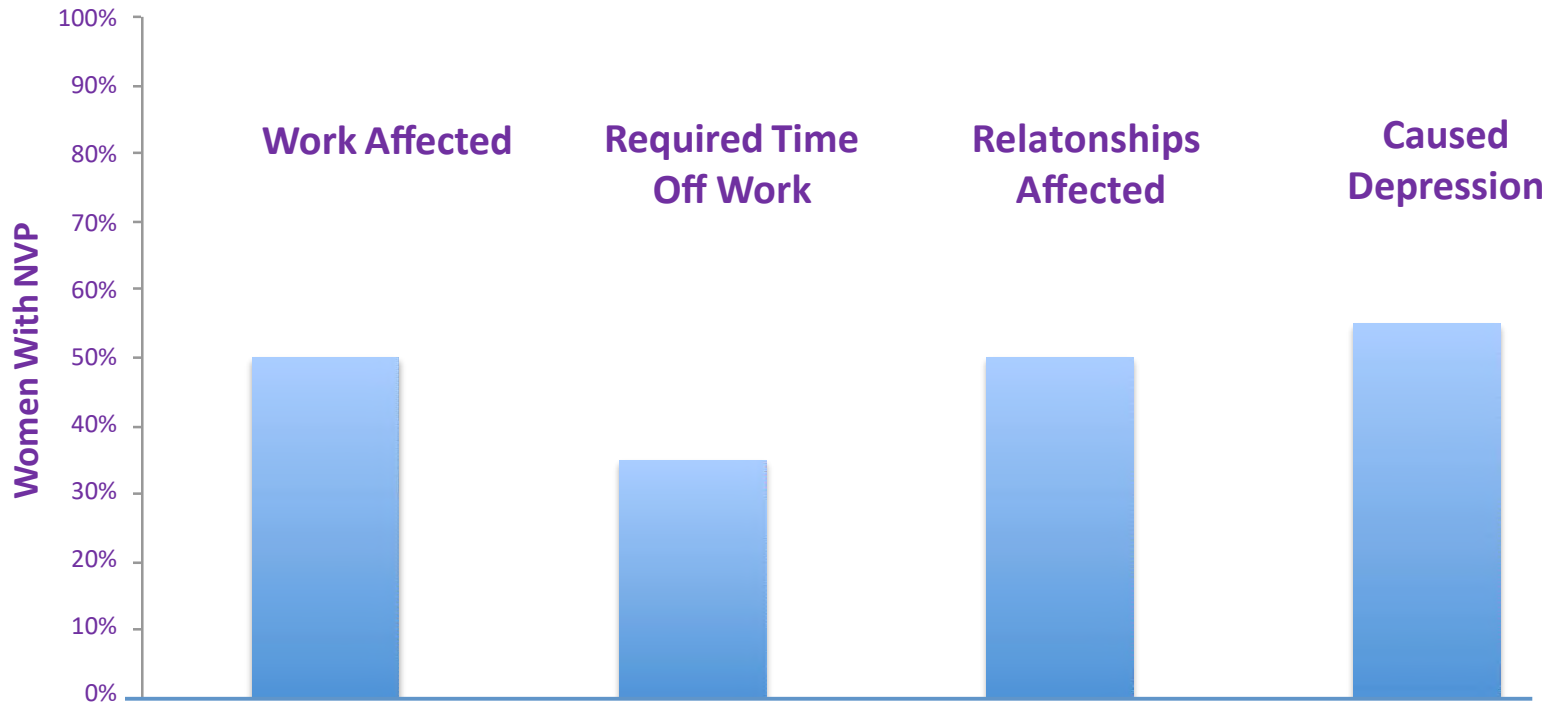
- ✓✓ Quality of life (QOL) and work efficiency are adversely affected by NVP.¹
- ✓✓ When QOL measures are used in research studies, the scores for women with NVP are worse than the scores of women who report chronic depression.²
- ✓✓ A 2002 study estimated reduced productivity, visits to health care professionals, and the cost of medications and other remedies at \$2,947 per woman with moderate to severe NVP.²
- ✓✓ Severe NVP is estimated at approximately \$130 million/year from hospital visits alone.³

¹O'Brien B, Naber S. *Birth*. 1992;19:138–43.

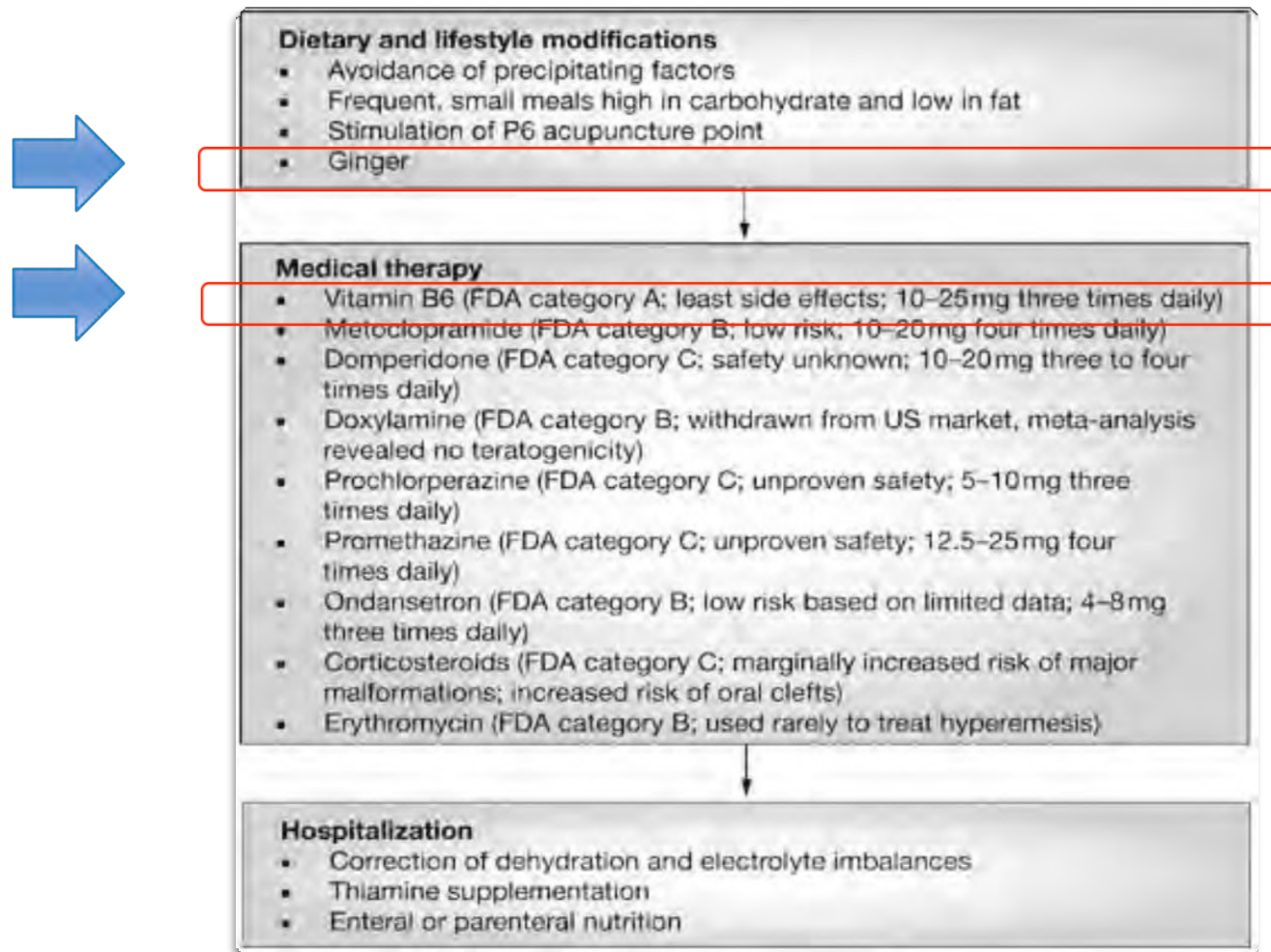
²A^ard CL, Kohli MA, Coleman S et al. *Am J Obstet Gynecol*. 2002;186(5 suppl):S220–7.

³Miller F. *Am J Obstet Gynecol*. 2002;186(5 suppl):S182–3.

Impact of NVP

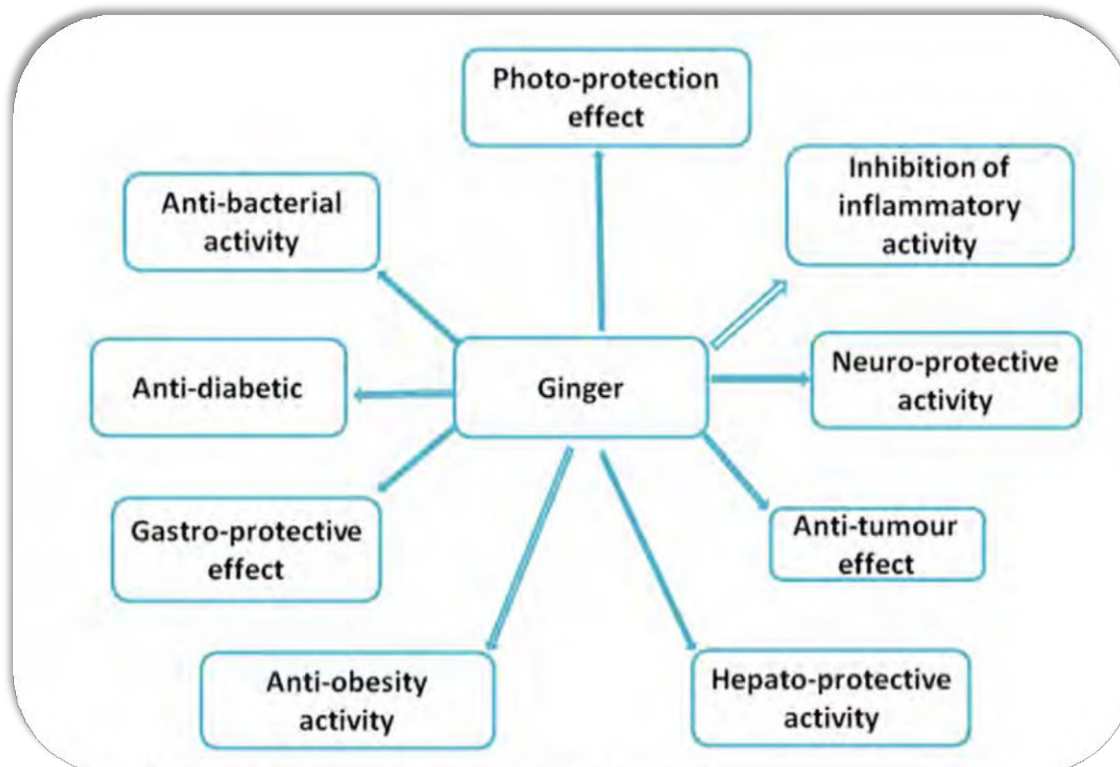


Therapeutic options for the treatment of NVP

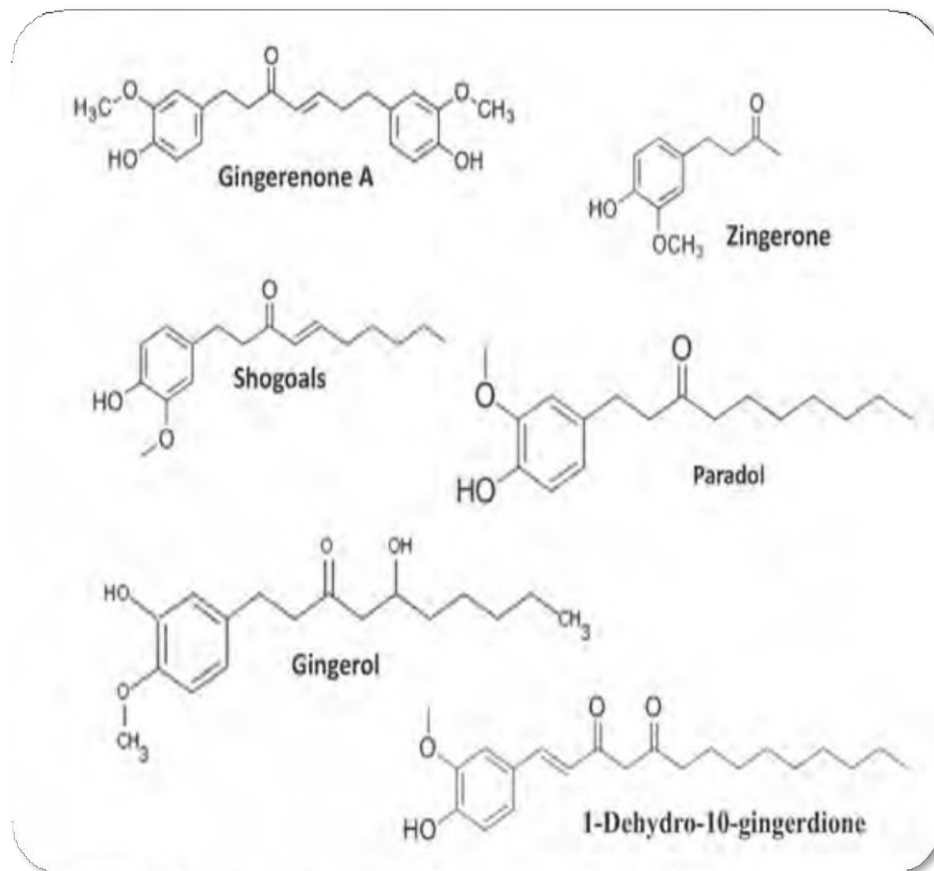




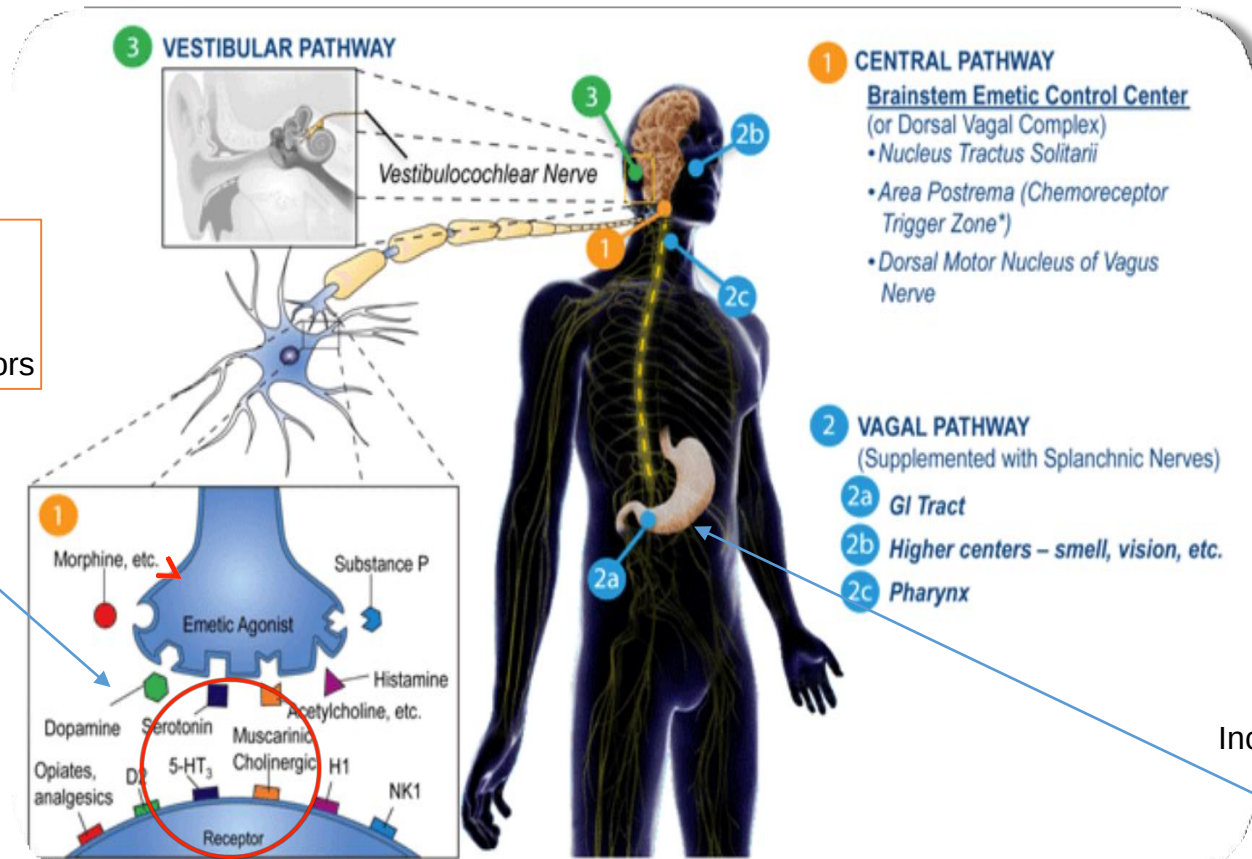
Ginger in diseases prevention



Active ingredients of ginger



Ginger & pathways of nausea & vomiting



Ginger antagonizes activation of M3 (cholinergic) & 5-HT₃ (serotonergic) receptors

Increased contractility of the fundus
↓
increased gastric emptying

Forms of ginger equivalent to a 1000 mg dose of a standardized extract



Possible claims for ginger

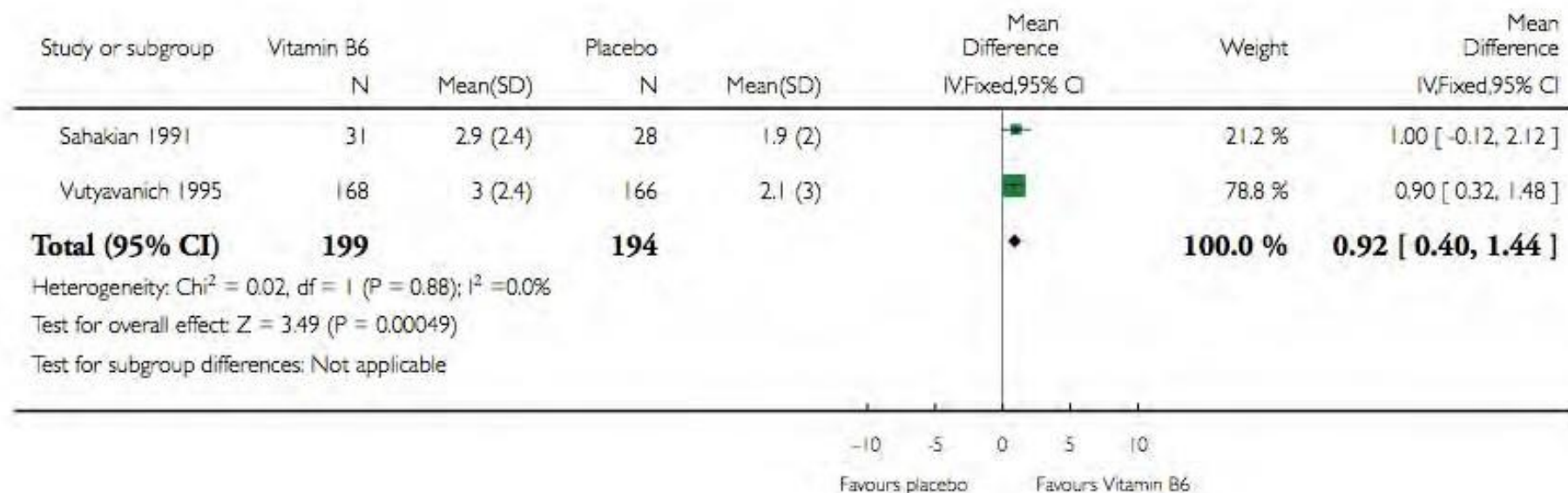
Claim under consideration ID 2172 / EFSA

- ✔✔ Helps to support the digestion
- ✔✔ Contributes to the normal function of intestinal tract
- ✔✔ Contributes to physical well being
- ✔✔ Contributes to the normal functioning of the stomach in case of early pregnancy

Condition of use:

Root / Usual consumption as traditional foodstuff in a normal diet / eq. of 0.5-2g of root/d

Efficacy of vit B6 : level I evidence

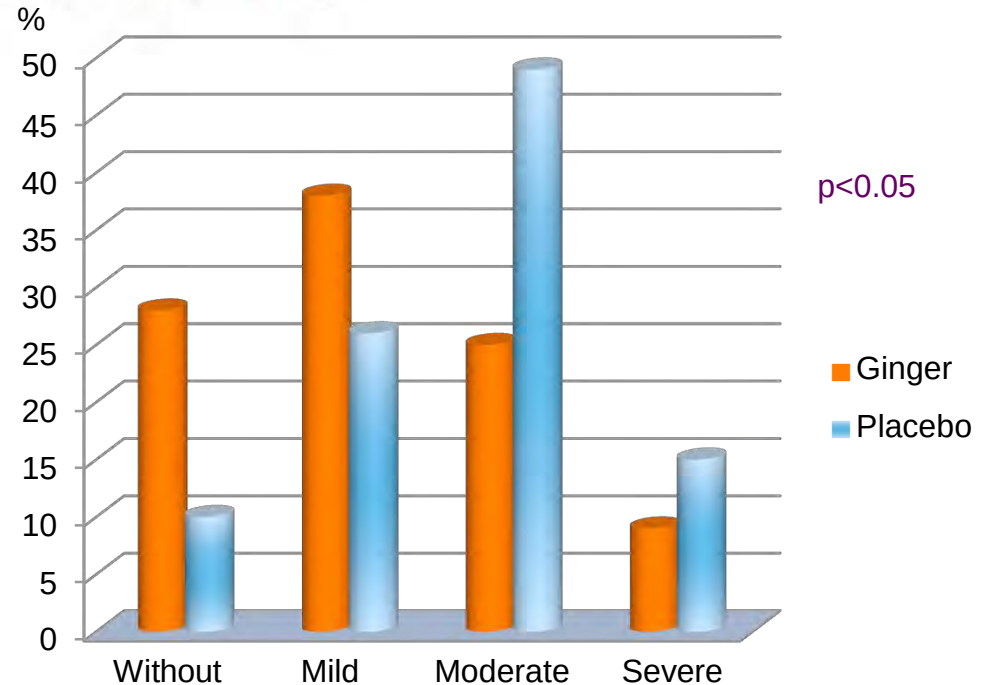


Efficacy of ginger *versus* placebo: level I evidence

Effects of ginger capsules on pregnancy, nausea, and vomiting.

Ozgoli G¹, Goli M, Simbar M.

- 67 pregnant women (≤ 19 gestation weeks)
- **Treatment groups:**
 - ✓ Ginger 1g
 - ✓ Placebo
- **Duration:** 4 consecutive days
- **Tolerability:** no side-effects



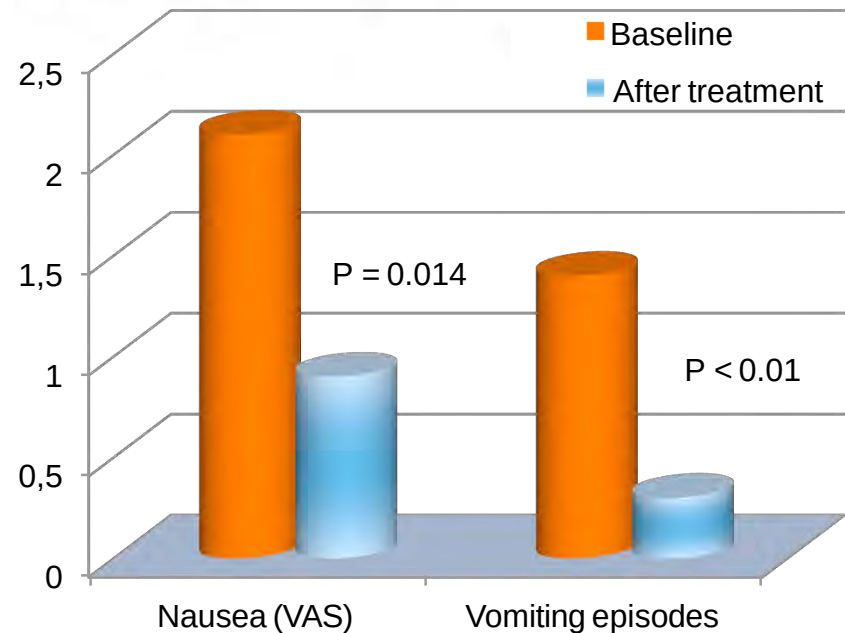
Ginger improves significantly NVP

Efficacy of ginger *versus* placebo: level I evidence

Ginger for nausea and vomiting in pregnancy: randomized, double-masked, placebo-controlled trial.

Vutyavanich T¹, Kraisarin T, Ruangsri R.

- **70** pregnant women (≤ 17 gestation weeks)
- **Treatment groups:**
 - ✓ Ginger 1g
 - ✓ Placebo
- **Duration:** 4 consecutive days
- **Outcome:** VAS
- **Tolerability:** no side-effects



D₇ improvement (Likert scale)

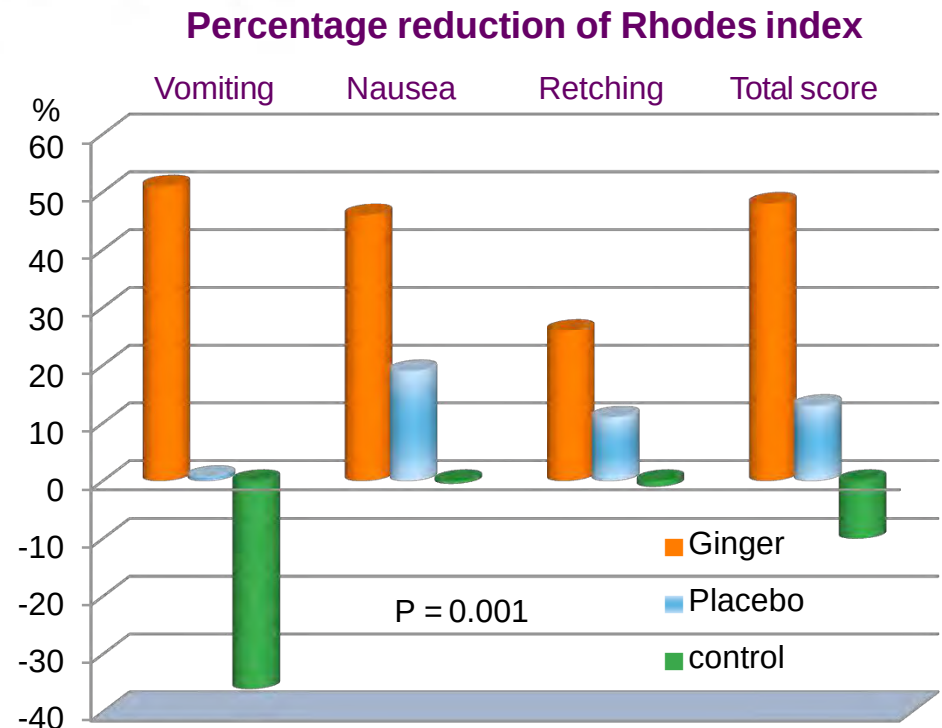
87,5% vs 28,5% for placebo (p<0.001)

Efficacy of ginger *versus* placebo: level I evidence

Effect of ginger on relieving nausea and vomiting in pregnancy: a randomized, placebo-controlled trial.

Saberi F¹, Sadat Z², Abedzadeh-Kalahroudi M², Taebi M³.

- **120** pregnant women (≤ 16 gestation weeks)
- **Treatment groups:**
 - ✓ Ginger 250mg x 3/d
 - ✓ Placebo (lactose) x 3/d
 - ✓ Control
- **Duration:** 4 consecutive days
- **Outcome:** Rhodes index reduction



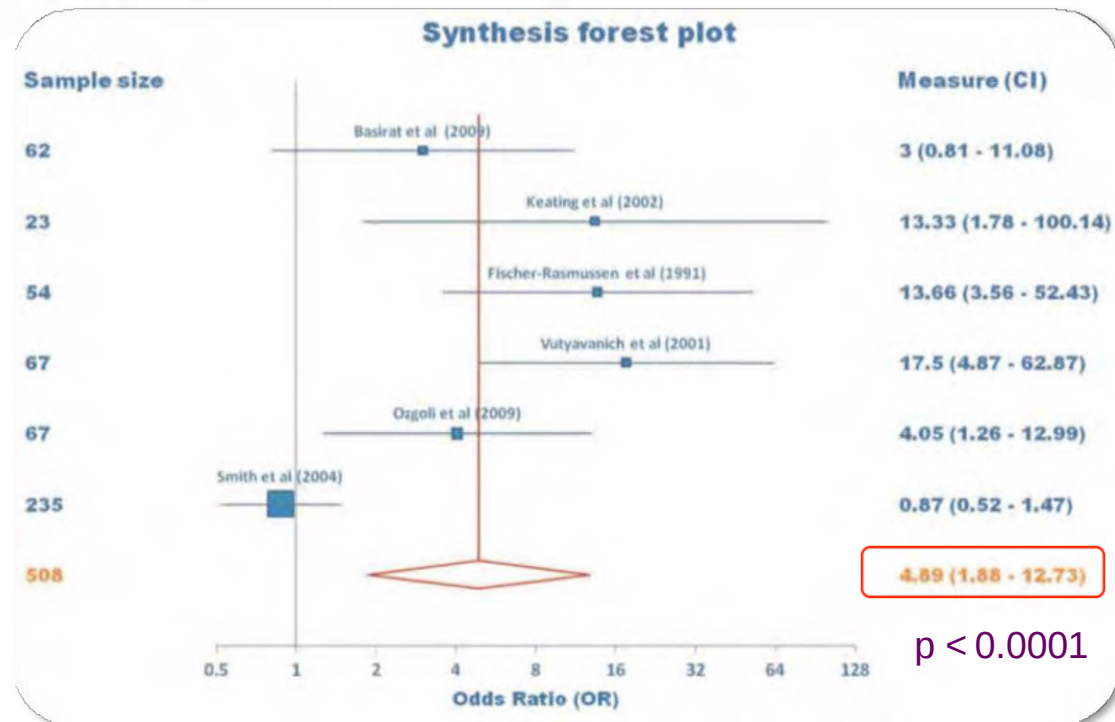
Ginger is effective in mild to moderate NVP

Efficacy of ginger *versus* placebo: meta-analysis

Effects of ginger for nausea and vomiting in early pregnancy: a meta-analysis.

Thomson M¹, Corbin R, Leung L.

- 6 randomized placebo-controlled trials
- Pregnancies ≤ 16 to 20 weeks
- **Treatment groups:**
 - ✓ Ginger: n=180
 - ✓ Placebo: n=126
- **Duration:** 4 days to 3 weeks



Number to treat: 5

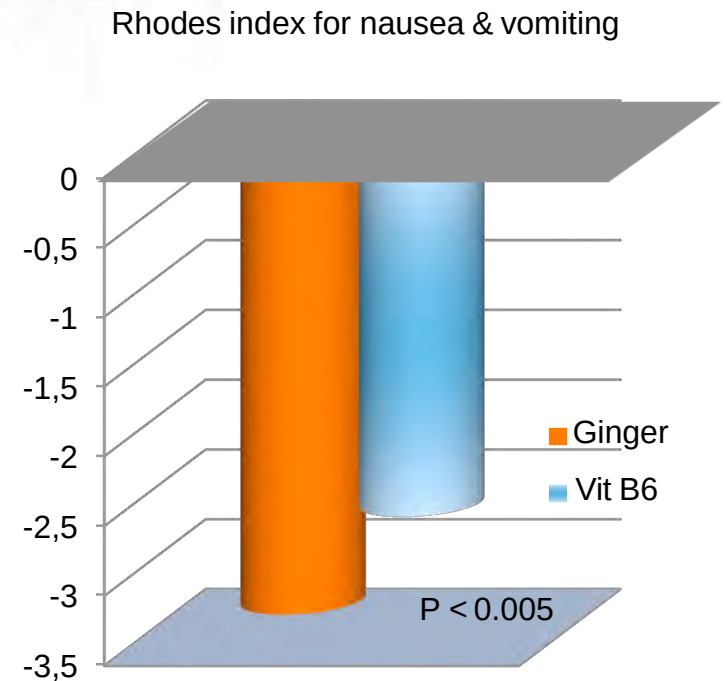
Efficacy of ginger *versus* vit B6: level I evidence

Comparison of the effectiveness of ginger and vitamin B6 for treatment of nausea and vomiting in early pregnancy: a randomized double-blind controlled trial.

Chittumma P¹, Kaewkiattikun K, Wiriyasiriwach B.

- **126** pregnant women (≤ 16 gestation weeks)
- **Treatment groups:**
 - ✓ Ginger 650mg x3
 - ✓ Vit B6 25mg x3
- **Duration:** 4 consecutive days
- **Outcomes:** Rhodes Index for nausea & vomiting
- **Tolerability:** minor side effects (sedation, heartburns)

'Ginger was more effective than vit B6'

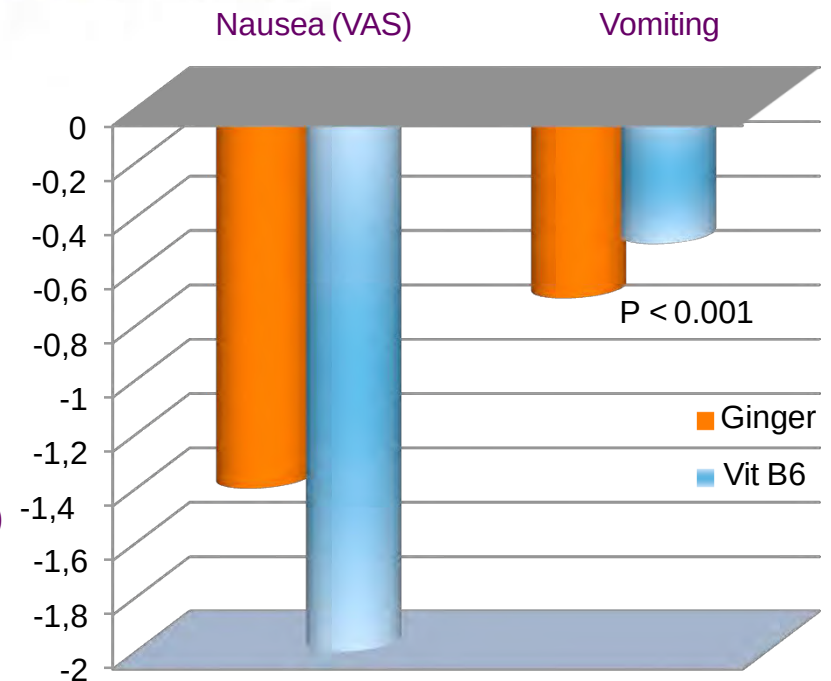


Efficacy of ginger *versus* vit B6: level I evidence

A randomized comparison of ginger and vitamin B6 in the treatment of nausea and vomiting of pregnancy.

Sripramote M¹, Lekhyananda N.

- **138** pregnant women (≤ 16 gestation weeks)
- **Treatment groups:**
 - ✓ Ginger 500mg x3
 - ✓ Vit B6 10mg x3
- **Duration:** 3 consecutive days
- **Tolerability:** minor side effects (sedation, heartburns)



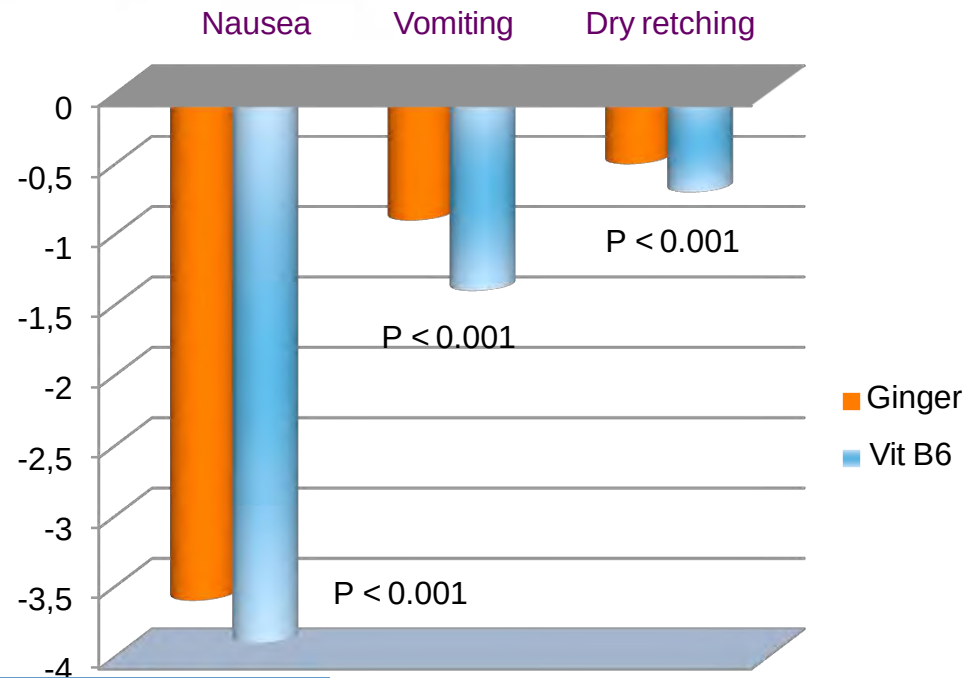
'No significant difference between ginger & vitB6'

Efficacy of ginger *versus* vit B6: level I evidence

A randomized controlled trial of ginger to treat nausea and vomiting in pregnancy.

Smith C¹, Crowther C, Willson K, Hotham N, McMillian V.

- **291** pregnant women (≤ 16 gestation weeks)
- **Treatment groups:**
 - ✓ Ginger 1.05 g
 - ✓ Vit B6 75mg
- **Duration:** daily for 3 weeks
- **Outcomes** (D_7 , D_{14} , D_{21}):
 - ✓ Rhodes Index for nausea & vomiting
 - ✓ MOS 36 Short Form Health Survey
- **Tolerability:** both treatments well tolerated

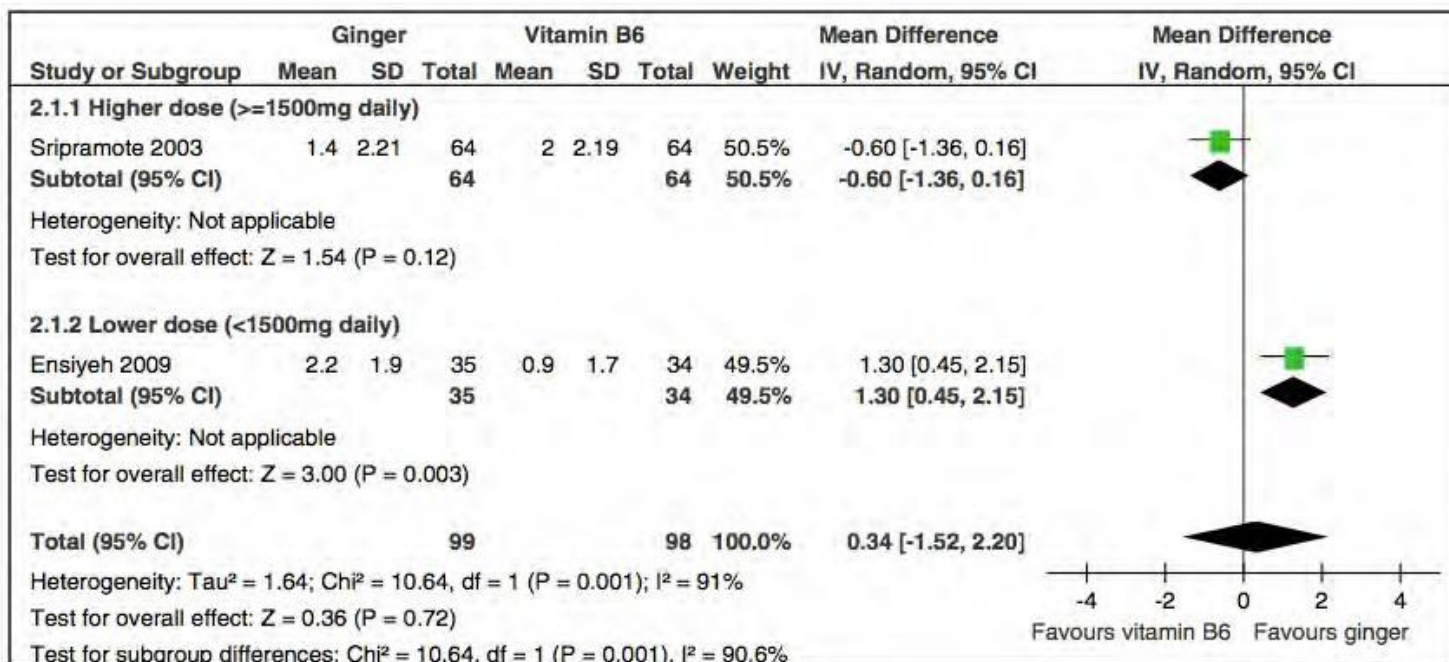


'Women's health status improved during 3 weeks of the trial'

Efficacy of ginger *versus* vit B6: meta-analysis

A systematic review and meta-analysis of the effect and safety of ginger in the treatment of pregnancy-associated nausea and vomiting.

Viljoen E¹, Visser J, Koen N, Musekiwa A.



No significant difference in reducing nausea



Safety issues of ginger

- Adverse effects after ingestion of ginger are uncommon but can include mild gastro- intestinal complications, such as pyrosis (heartburn or reflux) and eructation (belching)
- Despite a previous study (1986) indicating that ginger could interfere with platelet aggregation and cause excessive bleeding, a randomized crossover study showed that ginger 1.2g did not affect platelet aggregation nor warfarin's pharmacology
- In a recent large population-based cohort study, ginger during pregnancy was not associated with an increased risk of congenital malformations, still birth/perinatal birth, low birth weight, or preterm birth
- In the Viljoen's meta-analysis, the authors found that :
 - « **ginger does not pose a risk for side-effects or adverse events during pregnancy** »