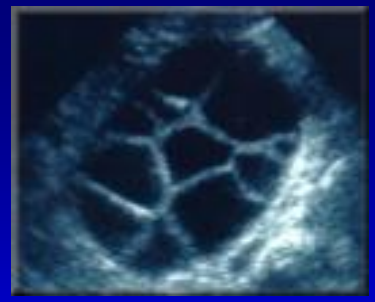
# Does GnRHa triggering completely abolish OHSS?

Dec 3rd, 2010

# content

- Predictions: OHSS forever?
- No OHSS post agonist trigger!
- OHSS: Is it still a problem?
- Failures?
- How high can we go?
- Mechanism?
- Unfortunate publications (3)
- Agonist trigger: side benefits.

# Predictions: Severe OHSS



"Severe OHSS will remain a complication of IVF cycles despite all attempts of prevention. Patients need to be advised of the risk and incidence of severe OHSS prior to embarking on ovulation stimulation therapy to enable them to give informed consent for assisted conception treatment." R.G. Forman, 1999.

"An epidemic of severe OHSS: a price we have to pay"? Y.Abramov et al, 1999.

"These are the cases in which severe OHSS is probably not preventable with current strategies except cancellation of the cycle…None of the strategies currently employed to avert severe OHSS …completely prevents the condition". P.E. Egbase, 2000.

**Induction of LH surge and oocyte maturation by GnRH analogue (Buserelin) in women undergoing ovarian stimulation for IVF**

"No signs of OHSS were observed in 2 patients who on previous stimulation developed severe OHSS… GnRHa offers a new means by which OHSS can be prevented."

Itskovitz et al, Gynecological Endocrinology 1988, 2:Suppl1, 165.

**Human Reproduction** vol.11 no.6 pp.1143–1148, 1996

# Ovarian hyperstimulation syndrome after using gonadotrophin-releasing hormone analogue as a trigger of ovulation: causes and implications

**S.Kol[1], N.Lewit and J.Itskovitz-Eldor**

In summary, the use of GnRHa as an ovulation trigger reliably eliminates the risk of clinically significant OHSS. To

# Past predictions of the future

- "We don't like their sound, and guitar music is on the way out" Decca Recordings Co. rejecting the Beatles, 1962.

- "Stocks have reached what looks like a permanently high plateau". Irving Fisher, Professor of Economics. Yale University, 1929.


- "$100 million is way too much to pay for Microsoft" IBM 1982.


- "Who the hell wants to hear actors talks?" H.M. Warner, Warner Brothers, 1927.

**16 publications**

**Agonist: 2005 patients, not a single case of OHSS!**

**hCG: 92 cases in 1810 patients, 5.1%**

| Reference | Trial type | Oocyte source | Ovulation trigger | n | OHSS % (n) |
|---|---|---|---|---|---|
| Babayof et al 2006 | RCT, high risk | own | GnRHa<br>hCG | 15<br>13 | 0 (0/13)<br>31(4/13) |
| Engamnn et al 2008 | RCT, high risk | own | GnRHa<br>hCG | 33<br>32 | 0 (0/33)<br>31 (10/32) |
| Acevedo et al 2006 | RCT | donors | GnRHa<br>hCG | 30<br>30 | 0 (0/30)<br>17 (5/30) |
| Bodri et al 2009 | Retrospective | donors | GnRHa<br>hCG | 1046<br>1031 | 0 (0/1046)<br>1.3 (13/1031) |
| Griesinger et al 2010 | Observational, High risk | own | GnRHa | 40 | 0 (0/40) |
| Humaidan et al 2009 | RCT | own | GnRHa<br>hCG | 152<br>150 | 0 (0/152)<br>2 (3/150) |
| Engmann et al 2006 | Retrospective, case-controlled, high risk | own | GnRHa<br>hCG | 23<br>23 | 0 (0/23)<br>4 (1/23) |
| Manzanares et al 2009 | Retrospective case-control, high risk | own | GnRHa<br>hCG - cancelled | 42 | 0 (0/42) |
| Hernandez et al 2009 | Retrospective | donors | GnRHa<br>hCG | 254<br>175 | 0 (0/254)<br>6 (10/175) |
| Orvieto et al 2006 | Retrospective, high risk | own | GnRHa<br>hCG | 82<br>69 | 0 (0/82)<br>7 (5/69) |
| Shapiro et al 2007 | Retrospective, high risk: agonist arm only | donors | GnRHa<br>hCG | 32<br>42 | 0 (0/32)<br>1 (1/42) |
| Sismanoglu et al 2009 | RCT | donors | GnRHa<br>hCG | 44<br>44 | 0 (0/44)<br>7 (3/44) |
| Humaidan et al 2009 | Observational, high risk | own | GnRH, luteal rescue with hCG 1500IU | 12 | 8 (1/12) |
| Galindo et al 2009 | RCT | donors | GnRHa<br>hCG | 106<br>106 | 0 (0/106)<br>8 (9/106) |
| Melo at al 2009 | RCT | donors | GnRHa<br>hCG | 50<br>50 | 0 (0/50)<br>16(8/50) |
| Shahrokh et al 2010 | RCT, high risk | own | GnRHa<br>hCG | 4<br>45 | 0 (0/45)<br>15 (33) |

# OHSS: Is it still a problem?

- “We did not have a single case in years”

# Incidence of OHSS

## Incidence and prediction of ovarian hyperstimulation syndrome in women undergoing gonadotropin-releasing hormone antagonist in vitro fertilization cycles

*Evangelos G. Papanikolaou, M.D., Ph.D., Cristina Pozzobon, M.D., Efstratios M. Kolibianakis, M.D., Ph.D., Michel Camus, M.D., Herman Tournaye, M.D., Ph.D., Human M. Fatemi, M.D., Andre Van Steirteghem, M.D., Ph.D., and Paul Devroey, M.D., Ph.D.*

Centre for Reproductive Medicine, University Hospital, Dutch-Speaking Brussels Free University, Brussels, Belgium

**Objective**: to determine OHSS incidence in 2,524 antagonist-based cycles (1801 patients).

**Results**: fifty three patients (2%) were hospitalized because of OHSS.

**Conclusions**: clinically significant OHSS is a limitation even in antagonist cycles.

"There is more than ever an urgent need for alternative final oocyte maturation – triggering medication"

F&S January 2006

# Incidence of OHSS: ENGAGE Study

- Measures to minimize OHSS:
  - Exclusion criteria: history of OHSS, PCOS, AFC>20.
  - In treatment: Lower hCG dose, coasting for up to 3 days, cancellation.
- Incidence: 100 patients (out of 1506, 6.6%) developed OHSS, moderate-severe: 51 (3.4%) patients.

Devroey et al, HR 12:3063, 2009

**AUGUST 2009**


**A woman with polycystic ovary syndrome treated for infertility by *in vitro* fertilization who developed severe OHSS.**

- Describe the pathophysiology of PCOS.
- Identify outcomes in the management of infertility in PCOS.
- List risk factors for ovarian hyperstimulation syndrome.
- Describe the management of ovarian hyperstimulation syndrome

# GnRHa trigger: does it always abolish OHSS?

**Human Reproduction** vol.8 no.10 pp.1628–1631, 1993

# Triggering of ovulation using a gonadotrophin-releasing hormone agonist does not prevent ovarian hyperstimulation syndrome

Three IUI patients
Nasal GnRH-a, weak LH response.
Mild to moderate OHSS, no hospitalizations

**S.van der Meer[1], J.Gerris, M.Joostens and B.Tas**


## Prevention of ovarian hyperstimulation syndrome, 2008

"However, some risk of ovarian hyperstimulation remains, as illustrated in a report of 48 cycles of ovarian stimulation with hMG followed by an ovulatory trigger using a nasal application of GnRH agonists, where moderate OHSS was observed in three instances."

**16 publications**

**Agonist: 2005 patients, not a single case of OHSS!**

**hCG: 92 cases in 1810 patients, 5.1%**

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Imoedemhe D, Chan R, Pacpaco E, et al. Preventing OHSS in at-risk patients: evidence from a long-term prospective study. Hum Reprod 1999; 14: 102–3.

- 708 PCO patients
- Mean E2 on trigger day=7817pg/ml
- 1 patient developed severe OHSS, hCG luteal support.

**Table II** Main characteristics and ovarian hyperstimulation syndrome (OHSS) rate in studies on GnRHa triggering of final oocyte maturation

| Reference | Trial type | GnRH-antagonist protocol | Ovulation trigger | *n* | Moderate–severe OHSS % (n) |
|---|---|---|---|---|---|
| Humaidan *et al.* (2005) | RCT | Flexible, multiple dose | GnRHa | 55 | 0 (0/55) |
| | | | hCG | 67 | 0 (0/67) |
| Kolibianakis *et al.* (2005) | RCT | Fixed, multiple dose | GnRHa | 50 | * |
| | | | hCG | 54 | * |
| Pirard *et al.* (2006) | RCT | Flexible, multiple dose | GnRHa | 6 | * |
| | | | hCG | 6 | * |
| Humaidan *et al.* (2006) | RCT | Flexible, multiple dose | GnRHa | 13 | 0 (0/13) |
| | | | hCG | 15 | 0 (0/15) |
| Babayof *et al.* (2006) | RCT | Flexible, multiple dose | GnRHa | 15 | 0 (0/15) |
| | | | hCG | 13 | 31 (4/13) |
| Engmann *et al.* (2008) | RCT | Flexible, multiple dose OCP/GnRHa | GnRHa | 33 | 0 (0/33) |
| | | | hCG | 32 | 31 (10/32) |
| Humaidan *et al.* (2009) | RCT | Flexible, multiple dose | GnRHa | 152 | 0 (0/152) |
| | | | hCG | 150 | 2 (3/150) |
| Humaidan (2009) | Observational uncontrolled OHSS high-risk | Flexible, multiple dose | GnRHa | 12 | 8 (1/12- late) |

* = not reported. OCP = oral contraceptive.

Humaidan et al, 2009 Opinion, HR

Akush Ginekol (Sofiia). 2008;47(4):16-9.
**Protocol with GnRH-antagonist and ovulation trigger with GnRH-agonist in risk patients--a reliable method of prophylactic of OHSS.** Kovachev E
[Article in Bulgarian]

29 PCO patients.
Mean 22.5 oocytes.
1 patients developed severe late OHSS
Further information: E2 on trigger day=2800 pg/ml, 10 oocytes retrieved. Luteal support: P only.

Zhonghua Fu Chan Ke Za Zhi. 1999 Feb;34(2):94-6.
**Application of gonadotropin-releasing hormone agonist for triggering ovulation in high risk gonadotropin stimulating cycles of infertile polycystic ovary syndrome patients.** Dong H, Chen S, Xing F
[Article in Chinese]

14 PCO patients, mean E2=8,379±2,958 pmol/l
1 patient developed moderate OHSS.

# Fresh transfer

**TABLE 2**

**Outcome of ovarian stimulation.**

| | Study group (n = 30) | Control group (n = 29) | *P* value |
|---|---|---|---|
| Duration of ovarian stimulation (days) | 9.9 ± 1.7 | 9.6 ± 1.7 | NS |
| Total dose of gonadotropins (IU) | 1589 ± 511 | 1527 ± 534 | NS |
| Serum $E_2$ on day of trigger (pg/mL) | 2645 ± 1101 | 2658 ± 1122 | NS |
| Oocytes (n) | 20.2 ± 9.9 | 18.8 ± 10.4 | NS |
| Proportion of M11 oocytes (%) | 81.0 ± 16.3 | 83.8 ± 13.2 | NS |
| Fertilization rate (%) | 71.6 ± 14.1 | 74.9 ± 17.3 | NS |
| Embryos transfered (n) | 2.0 ± 0.2 | 2.2 ± 0.6 | NS |
| Embryos frozen (n) | 3.9 ± 4.4 | 4.3 ± 4.7 | NS |
| Midluteal ovarian volume ($cm^3$) | 36.6 ± 22.2 | 129.0 ± 77.4 | < .01 |
| Serum $E_2$ on day of embryo transfer (pg/mL) | 485 ± 219 | 1320 ± 695 | < .01 |
| Midluteal serum $E_2$ (pg/mL) | 283 ± 216 | 663 ± 556 | < .01 |
| Serum P on day of embryo transfer (ng/mL) | 25 ± 14 | 117 ± 61 | < .01 |
| Midluteal serum P (ng/mL) | 28 ± 8 | 46 ± 50 | NS |

*Engmann. GnRH agonist trigger and OHSS prevention. Fertil Steril 2008.*

**TABLE 3**

**Outcome of cycle.**

| | Study group | Control group | Odds ratio (95% CI) | *P* value |
|---|---|---|---|---|
| Primary end points | | | | |
| OHSS (intention to treat) | | | | |
| Total n, (%) | 0/33 (0) | 10/32 (31.3) | 0 (0–0.26)[a] | < .01 |
| Moderate/severe, n (%) | 0/33 (0) | 5/32 (15.6) | 0 (0-0.74)[a] | .02 |
| OHSS (per protocol) | | | | |
| Total, n (%) | 0/30 (0) | 10/29 (34.5) | 0 (0–0.26)[a] | < .01 |
| Moderate/Severe, n (%) | 0/30 (0) | 5/29 (17.2) | 0 (0–0.73)[a] | .02 |
| Secondary end point (per protocol) | | | | |
| Implantation rate, n (%) | 22/61 (36) | 20/64 (31) | 1.18 (0.52–2.65) | .69 |
| Other end points (per protocol) | | | | |
| Positive pregnancy, n (%) | 19/30 (63.3) | 18/29 (62.1) | 1.06 (0.37–3.0) | .92 |
| Clinical pregnancy rate, n (%) | 17/30 (56.7) | 15/29 (51.7) | 1.22 (0.4–3.4) | .45 |
| Ongoing pregnancy rate, n (%) | 16/30 (53.3) | 14/29 (48.3) | 1.22 (0.4–3.4) | .45 |

[a] The estimates of these odds ratios are zero, because no patient developed OHSS in the study group.

*Engmann. GnRH agonist trigger and OHSS prevention. Fertil Steril 2008.*

Engmann et al, 2008

# Frozen-thawed cycles

**TABLE 1**

**Baseline characteristics and outcome of ovarian stimulation.**

| | First cycle | Second cycle | *P* |
|---|---|---|---|
| No. of patients | 42 | 42 | |
| Age, years | 32.9 ± 3.1 | 33.8 ± 4.2 | NS |
| Serum levels on day 3: | | | |
| FSH, mIU/mL | 6 ± 2.58 | 6.2 ± 2.8 | NS |
| LH, mIU/mL | 6.1 ± 3.7 | 6 ± 3.4 | NS |
| $E_2$, pg/mL | 56 ± 33 | 44.1 ± 24.24 | NS |
| GnRH antagonist, ampoules | — | 3.9 ± 1.4 | — |
| COH, days | 10.4 ± 2.1 | 9.78 + 1.49 | NS |
| FSH, IU | 2259.66 ± 958 | 1943 ± 1158 | NS |
| $E_2$ on day of hCG, pg/mL | 4809.6 ± 2947.7 | 4518.5 ± 2118.85 | NS |
| Recruited follicles: | | | |
| >18 mm | 13.2 ± 7.5 | 15.43 ± 7.3 | NS |
| 15–17 mm | 8.2 ± 6.7 | 9.1 ± 5.3 | NS |
| Oocytes retrieved | Cancelled | 12.6 ± 6.8 | — |
| OHSS | 0 | 0 | — |
| Metaphase II oocytes, % | — | 93 | — |
| Metaphase I oocytes, % | — | 2.2 | — |
| Embryo grade, %: | | | |
| G1 | — | 48 | — |
| G2 | — | 30 | — |
| G3 | — | 17 | — |
| Multinucleated embryos, % | — | 4.5 | — |
| Fertilization rate | — | 69 | — |

*Note:* Data are mean ± SD unless otherwise indicated. NS: not significant.

*Manzanares. Triggering ovulation with GnRH agonist in PCO. Fertil Steril 2009.*

Manzanares et al, 2009

**TABLE 2**

**Clinical results of frozen-thawed cycle.**

| | First cycle | Second cycle |
|---|---|---|
| No. of cycles | 42 | 42 |
| Embryos transferred, mean ± SD | — | 2.5 ± 0.6 |
| Pregnancy/transfer rate, n (%) | — | 14/42 (33) |
| Biochemical pregnancies, n (%) | — | 1/14 (7) |
| Miscarriages, n (%) | — | 1/13 (7.6) |
| Ongoing pregnancies, n (%) | — | 12/14 (85) |
| Twin pregnancies, n (%) | — | 2/14 (14.2) |

*Manzanares. Triggering ovulation with GnRH agonist in PCO. Fertil Steril 2009.*

# How high can we go?



**Table 1.** Relevant clinical details of six patients. Oestradiol in pmol/l, LH in IU/l.

| *Subject of* | *No. of ampoules of Gonal F* | *No. of ampoules Luveris* | *Oestradiol max* | *Last LH*[a] | *No. of oocytes retrieved* | *No. of embryos* | *Mid-luteal LH* |
|---|---|---|---|---|---|---|---|
| 1 | 34 | 3 | 14,211 | 2.0 | 9 | 4 | 0 |
| 2 | 24 | 4 | 24,669 | 1.5 | 18 | 8 | 0 |
| 3 | 27 | 4 | 33,769 | 1.7 | 31 | 20 | 1.9 |
| 4 | 32 | 5 | 12,177 | 1.0 | 38 | 23 | 1.6 |
| 5 | 24 | 3 | 36,560 | 4.6 | 71 | 52 | 0.9 |
| 6 | 28 | 3 | 17,868 | 1.8 | 29 | 16 | 1.4 |
| Mean | 28 | 3.67 | 23,209 | 2.1 | 32.7 | 20.5 | 0.97 |
| SD | 3.85 | 0.82 | 10,228 | 1.27 | 21.4 | 17.5 | 0.82 |

[a]On the day ovulation was triggered with decapeptyl.

Mechanism?

Lower levels of inhibin A and pro-alpha C during the luteal phase after triggering oocyte maturation with GnRH agonist versus hCG

Nevo et al, Fertil Steril 79:1123, 2003

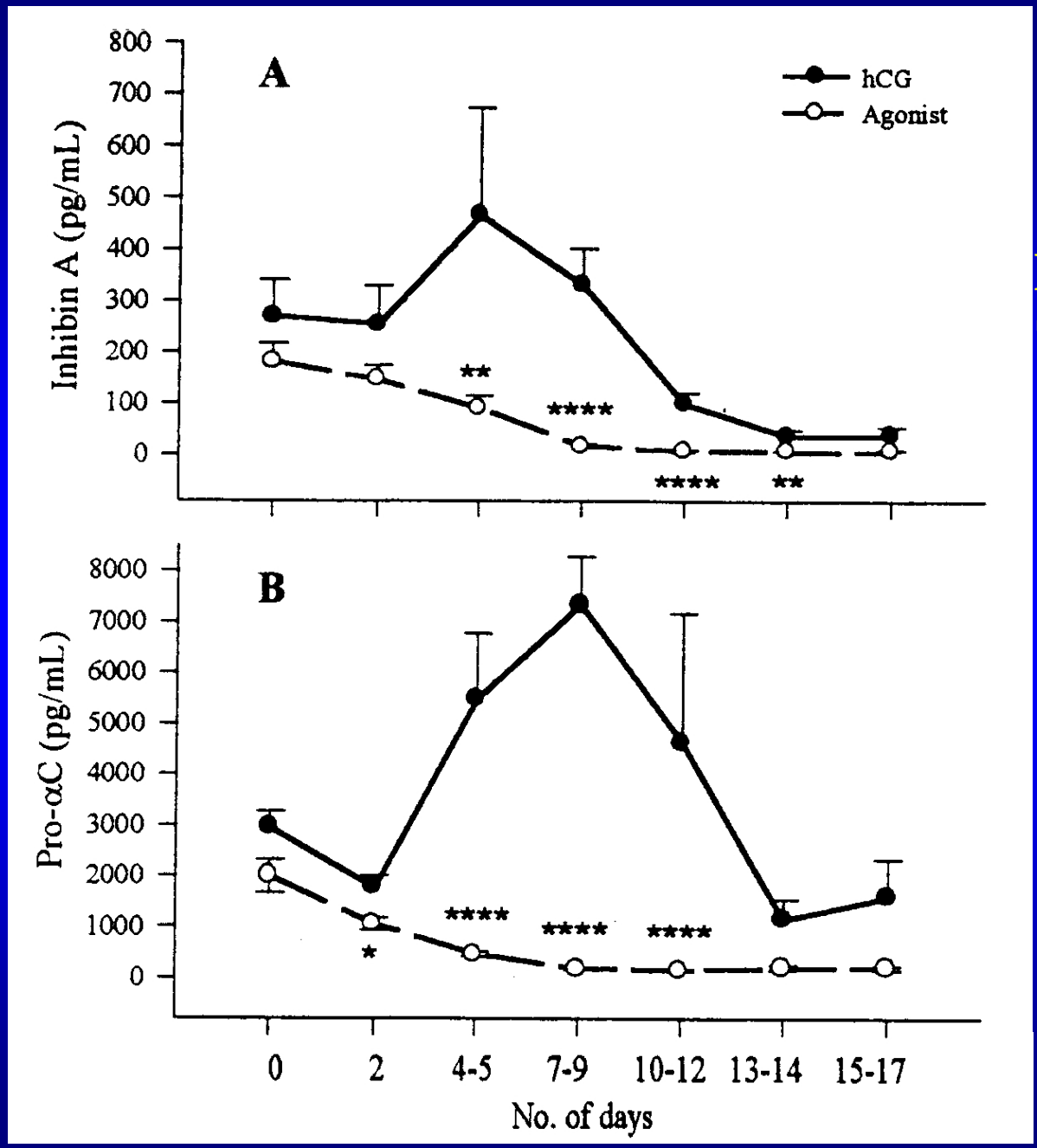
# Clinical characteristics

| | Agonist (n = 8) | hCG[a] (n = 8) |
|---|---|---|
| Age (years) | 28.7 ± 5.4 | 30.6 ± 4.4 |
| Duration of infertility (years) | 4.3 ± 1.9 | 5.9 ± 4.2 |
| No. of patients with primary infertility | 7 | 6 |
| Cause of infertility (no.): | | |
| Male factor | 6 | 6 |
| Unexplained | 1 | 2 |
| Mechanical | 1 | |
| Treatment cycle no. | 1.62 ± 0.9 | 1.75 ± 0.8 |
| Duration of FSH treatment (days) | 9 ± 1.2 | 9.5 ± 1.6 |
| No. of follicles ≥11 mm at day 0 | 11.75 ± 3.3 | 15 ± 4.8 |
| No. of oocytes retrieved | 9.25 ± 3.8 | 11 ± 5.5 |
| No. of clinical pregnancies | 4 | 4 |

[a] $P$ = NS for all characteristics.

Nevo et al, 2003

# Luteal phase




**Natural cycle day 7-9=**
**75 pg/ml vs. 18**

**Natural cycle day 7-9=**

**750 pg/ml vs. 184**

Nevo et al, 2003

# Summary

- The lower levels of luteal steroidal and nonsteroidal hormones reflect luteolysis, and may explain the mechanism of OHSS prevention by GnRH-a.
- Pregnancy post agonist trigger does not rescue the CL!!!

Nevo et al, 2003

# Clinical use of agonist trigger

## opinion

- Primarily in the context of OHSS prevention.
- Prevention is **total.**
- A major reason to use GnRH antagonists in ovarian stimulation of high-risk patients: to keep the option of agonist trigger if needed.
- “side-benefits”


**Gonadotropin-releasing hormone agonist versus HCG for oocyte triggering in antagonist assisted reproductive technology cycles. 11/2010**

**Plain language summary:** "We recommend that GnRH agonist as a final oocyte maturation trigger should be not used".

# Beyond the context of OHSS: Patient-friendly luteal phase

- Abdominal pain and discomfort due to enlarged ovaries.
- How to minimize ovarian volume post oocyte retrieval?

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*Engmann. GnRH agonist trigger and OHSS prevention. Fertil Steril 2008.*

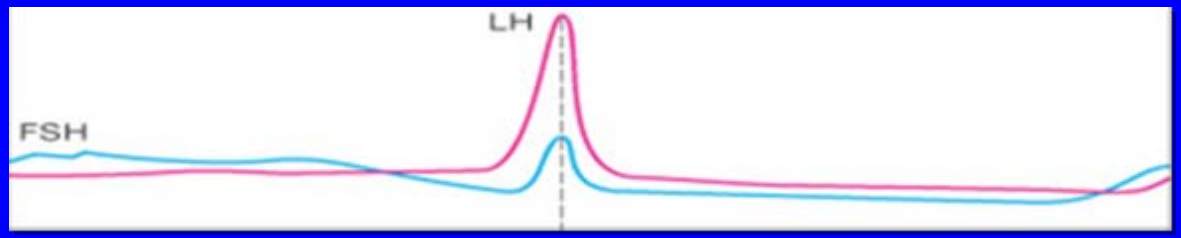
…and when OHSS is not the main issue?...

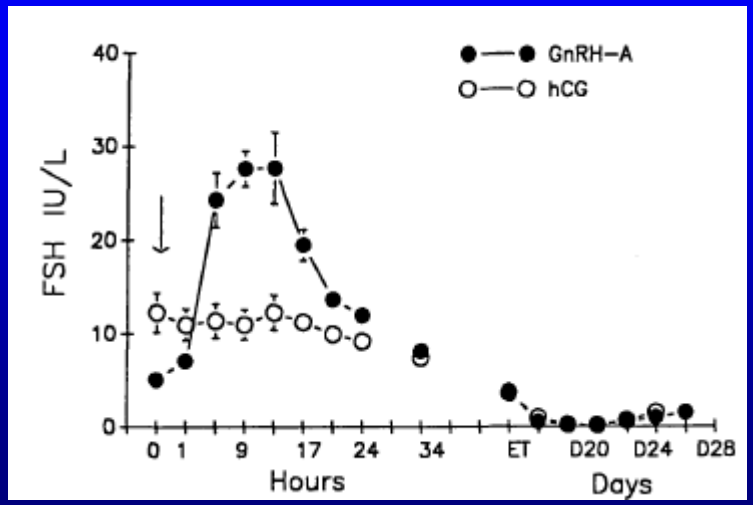
"We did find differences in the duration of the luteal phase: The period to menstrual onset in the non-hCG group was significantly shorter (10.2 days vs. 5.2 days; P<.001). Also, 42% of those who received hCG reported subjective complaints (mostly abdominal discomfort), whereas this percentage was 0% in those who received GnRH agonist to trigger ovulation.
No OHSS was observed in either cohort."

Cerrillo et al, 2009, IVI Madrid

# hCG does not imitate physiology!

LH surge goes together with FSH surge. Is FSH surge Redundant?

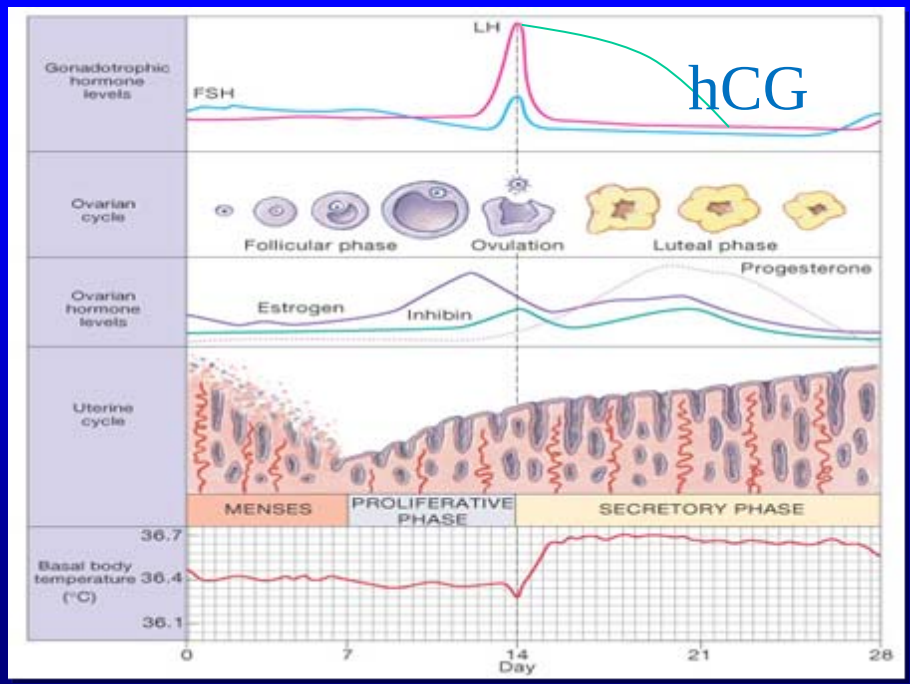



Gonen et al 1990

# Dual role of hCG trigger

- Final oocyte maturation.
- Early luteal phase stimulation.
- Same dose for both functions?



# Can pregnancy rate be improved in gonadotropin-releasing hormone (GnRH) antagonist cycles by administering GnRH agonist before oocyte retrieval? A prospective, randomized study

*Morey Schachter, M.D., Shevach Friedler, M.D., Raphael Ron-El, M.D., Ariel L. Zimmerman, M.D., Deborah Strassburger, Ph.D., Orna Bern, Ph.D., and Arieh Raziel, M.D.*

IVF and Infertility Unit, Assaf Harofeh Medical Center, Tel Aviv University, Zerifin, Israel

The pregnancy rate in completed cycles and the ongoing pregnancy rate per ET were significantly higher in the study group than in the control group.

Is possible that in some patients FSH surge is needed?

F&S 2008;90:1087

Reproductive BioMedicine Online (2010) 21, 590–592

www.sciencedirect.com
www.rbmonline.com


COMMENTARY

# LH (as HCG) and FSH surges for final oocyte maturation: sometimes it takes two to tango?

Shahar Kol [a,*], Peter Humaidan [b]

[a] *Rambam Medical Center, IVF Unit, Aliyah Street, Haifa, Israel;* [b] *The Fertility Clinic, Skive Regional Hospital, Resenvej 25, 7800 Skive, Denmark*
[*] Corresponding author. *E-mail address:* skol@rambam.health.gov.il (S Kol).

So, why do we routinely stick to hCG trigger?

Will agonist trigger replace hCG globally?

Will hCG be used for luteal support only?


Thank you