

Scientific Integrity of Randomised Trials in Systematic Reviews

Ben W. Mol





Disclosure statement

- I am a Consultant for Merck, Organon and Norgine
- I have received research funding from Merck and NHMRC
- I have been an invited speaker on sponsored meetings

Where the words women, she and her are used, it is to describe individuals whose sex was assigned as birth as female, whether they identify as female, male or binary



Dalwallinu, Western Australia, August 2025

N-acetyl-cysteine is a novel adjuvant to clomiphene citrate in clomiphene citrate-resistant patients with polycystic ovary syndrome

Ahmed Y. Rizk, M.D., a Mohamed A. Bedaiwy, M.D., and Hesham G. Al-Inany, M.D.

^a Department of Obstetrics and Gynecology, Benha University, Benha; ^b Department of Obstetrics and Gynecology Assiut School of Medicine, Assiut; and ^c Department of Obstetrics and Gynecology, Cairo University, Cairo, Egypt

OVARY

The effectiveness of clomiphene citrate in LH surge suppression in women undergoing IUI: a randomized controlled trial

Hesham Al-Inany, M.D., Ph.D., Hamdy Azab, M.D., Waleed El-Khayat, M.D., Adel Nada, M.D., Eman El-Khattan, M.D., and Ahmed M. Abou-Setta, M.D., Ph.D.

^a Department of Obstetrics and Gynecology, Cairo University, Cairo, Egypt; and ^bAlberta Research Centre for Health Evidence, University of Alberta, Edmonton, Alberta, Canada

TABLE 1 Comparison of the baseline features and clinical outcomes of the two treatment groups. Group I Group II Variable (n = 75)(n = 75)P value 28.4 ± 5.7 28.9 ± 4.7 NS Age (y) Duration of infertility (years) 5.0 ± 2.9 4.4 ± 2.6 NS 101.3 ± 12.4 99.2 ± 12.3 Wt (kg) 162.5 ± 5.7 NS Height (m) 164.1 ± 5.31 30.5 ± 2.6 ● 30.1 ± 3.1 ● NS BMI Waist/hip ratio 0.86 ± 0.05 0.07 ± 0.00 NS 10.4 ± 2.2 LH (IU/mL) 10.8 ± 2.4 NS NS FSH (IU/mL) 4.7 ± 2.5 5.2 ± 4.8 LH/FSH ratio 2.2 2.1 NS Fasting insulin (U/mL) 18.8 ± 4.7 17.2 ± 4.4 NS 81.9 ± 12.6 NS Fasting glucose (mg/dL) 85.9 ± 14.1 ● 360.3 ± 367.9 ● E₂ at time of hCG (pg/mL) 120 ± 10.0 .0007 Ovulation rate 49.3% 1.3% <.0001 Follicles >18 mm < 0001 2.4 ± 0.97 0.01 ± 0.11^a Progesterone 6.87 ± 5.6 1.8 ± 2.2 <.0001 Endometrial thickness (mm) ● 5.9 ± 0.7 ● ● 4.9 ± 1.9 ● NS Pregnancy 16 .00006 ^aOnly one follicle was shown to be more than 18 mm in one patient. Rizk. Use of N-acetyl cysteine in patients with PCOS. Fertil Steril 2005.

- Identical value
- Identical decimal

Basic characteristics of	are olday pe	palation	
Variable	Group I (n = 115)	Group II (n = 115)	P value
Age (y)	27.3 ± 4.7	28.4 2.7	NS
Duration of infertility (y) Cause of infertility	3.1 ± 1.9	2.4 1.6	NS
Unexplained intertility	61 (53%)	58 (50.4%)	NS
ivild male factor	54 (47%)	57 (49.6%)	NS
Body mass index (kg/m²)	28.5 ± 1.6	28.1 + 3.1	NS

P=0.0306 P=0.0028

0.033

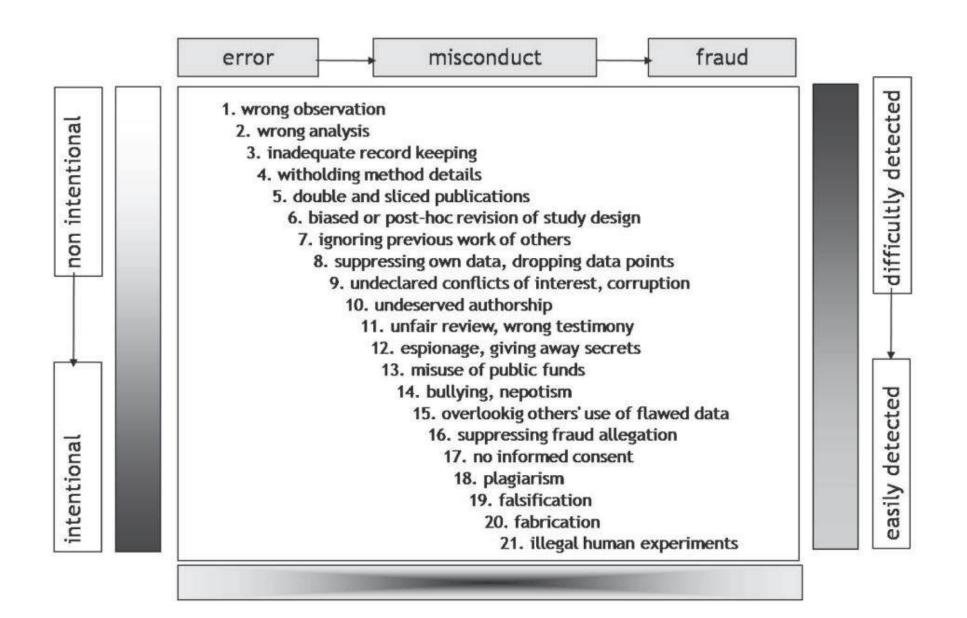
Cycle characteristics.							
/ariable	Group I (n = 115)	Group II (n = 115)	P value				
No. of canceled cycles	5/110	8/107	NS				
inchequate response	4/5	6/8	NS				
Hyperresponse	1/5	2/8	NS				
Basal LH (mIU/mL)	6.4 ± 2.2	5.8 ± 2.4	NS				
Basal FSH (mIU/mL)	6.7 ± 2.5	7.2 ± 4.8	NS				
Days of stimulation	7.2 ± 1.8	8.1 ± 1.3	NS				
at time of hCG (pg/mL)	360.3 ± 162.9	280 ± 110.0	<.05				
.H on day of hCG (mIU/mL) for cases with no premature LH surge	7.3 ± 1.8	7.8 ± 2.2	NS				
No. of follicles ≥16 mm	2.4 ± 0.97	1.3 ± 1.1	<.05				
No. of patients with premature LH surge	6 (5.45%)	17 (15.89%)	<.001				
Endometrial thickness (mm)	5.9 ± 0.7	4.9 ± 1.9	NS				
No. of clinical pregnancies	11 (10%)	9 (8.41%)	NS				

P=0.0493

P<.0001

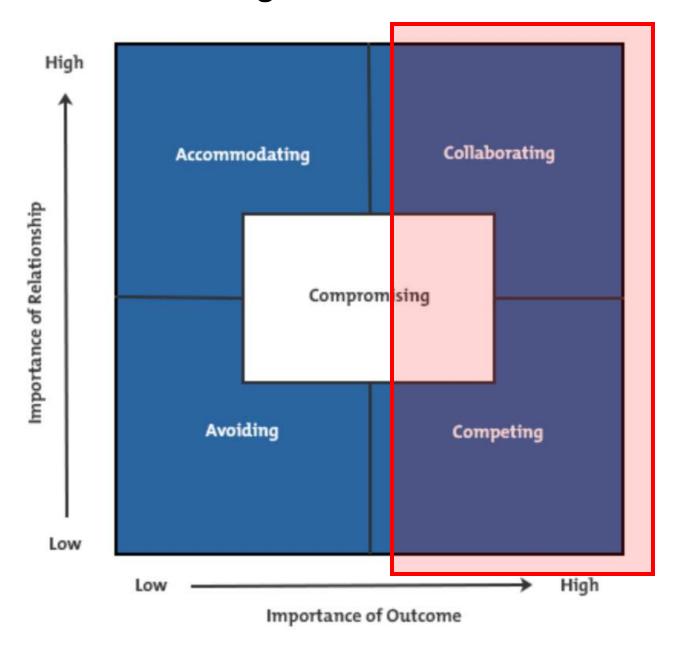
Content

- Outline integrity problems
- How big is the problem?
- Implications for clinical guidelines and practice
- Techniques to detect fraud
- The role of journals and publishers
- What can we do?



Based on: Marcovitch et al. Croat Med J. 2010 doi: 10.3325/cmj.2010.51.7 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2829174/

Negotiation models



How big is the problem?

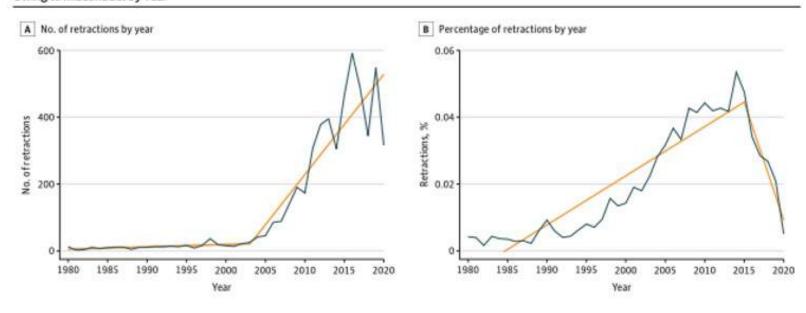
Research Letter ONLINE FIRST

May 10, 2021

Trends and Characteristics of Retracted Articles in the Biomedical Literature, 1971 to 2020

Mario Gaudino, MD, PhD, MSCE¹; N. Bryce Robinson, MD¹; Katia Audisio, MD¹; Mohamed Rahouma, MD¹; Umberto Benedetto, MD²; Paul Kurlansky, MD³; Stephen E. Fremes, MD⁴

Figure. Time-Segmented Analysis Showing Number of Retractions, Percentage of Retractions, and Percentage of Retractions Owing to Misconduct by Year



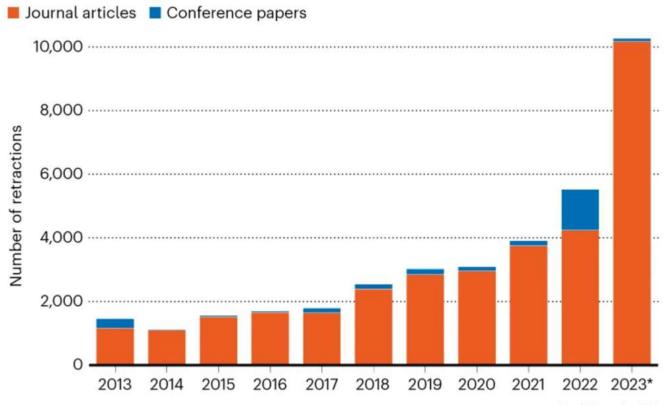


nature

More than 10,000 research papers were retracted in 2023 – a new record

The number of articles being retracted rose sharply this year. Integrity experts say that this is only the tip of the iceberg.

By Richard Van Noorden



onature

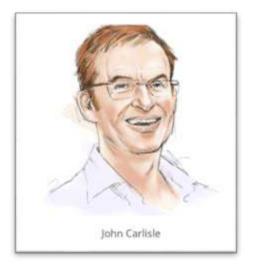
Anaesthesia 2020 doi:10.1111/anae.15263

Original Article

False individual patient data and zombie randomised controlled trials submitted to *Anaesthesia*



1. Consultant, Department of Peri-operative Medicine and Anaesthesia, 2. Consultant, Department of Intensive Care Medicine, Torbay Hospital, Torquay, UK



526 submitted RCTs153 RCTs with raw data

73 (14%) false data of which 43 (8%) were zombie 67 (44%) false data of which 40 (26%) zombie

	false data	zombie
Egypt	9/10 (90%)	7/10 (70%)
India	8/13 (62%)	6/13 (46%)
China	27/56 (48%)	20/56 (36%)
South Korea	7/22 (32%)	1/22 (5%)
Japan	2/11 (18%)	2/11 (18%)

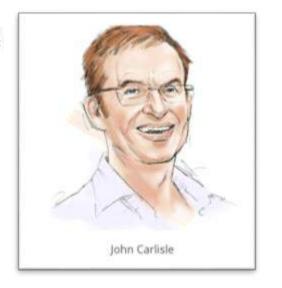
Anaesthesia 2020 doi:10.1111/anae.15263

Original Article

False individual patient data and zombie randomised controlled trials submitted to *Anaesthesia*

J. B. Carlisle 1,2 (1)

1 Consultant, Department of Peri-operative Medicine and Anaesthesia, 2 Consultant, Department of Intensive Care Medicine, Torbay Hospital, Torquay, UK





Anaesthesia 2020 doi:10.1111/anae.15297

Editorial

Hundreds of thousands of zombie randomised trials circulate among us

J. P. A. Ioannidis

1 Professor, Departments of Medicine, Epidemiology and Population Health, Biomedical Data Science, and Statistics Meta-Research Innovation Center at Stanford (METRICS), Stanford University, Stanford, CA, USA



Cochrane Database of Systematic Reviews

Prenatal administration of progesterone for preventing preterm birth in women considered to be at risk of preterm birth (Review)

History of spontaneous DTD

Dodd JM, Jones L, Flenady V, Cincotta R, Crowther CA

History of spontaneous PIB		
perinatal mortality	(6 studies; 1453 women;	RR 0.50, 95% CI 0.33 to 0.75)
preterm birth < 37 weeks	(10 studies; 1750 women;	RR 0.55, 95% CI 0.42 to 0.74)
preterm birth <34 weeks	(5 studies; 602 women;	RR 0.31, 95% CI 0.14 to 0.69)
birthweight < 2500 g	(4 studies; 692 infants;	RR 0.58, 95% CI 0.42 to 0.79)
assisted ventilation	(3 studies; 633 women;	RR 0.40, 95% CI 0.18 to 0.90)
NEC	(3 studies; 1170 women;	RR 0.30, 95% CI 0.10 to 0.89)
NICU	(3 studies; 389 women;	RR 0.24, 95% CI 0.14 to 0.40)

Cochrane Database of Systematic Reviews 2013, Issue 7. Art. No.: CD004947.



EPPPIC



IPD availability

Region	Countries	Available trials	Unavailable trials	Total
Africa	Egypt	1	5	6
Australia	Australia	1	0	1
Europe (including UK)	Denmark, Finland, France, Netherlands, Spain, UK	9	1	10
Middle East	Iran, Israel, Lebanon, Saudi Arabia, Turkey,	3	7	10
North America	USA, Canada	14	1	15
South America	Brazil	1	1	2
South Asia	India, Pakistan	2	2	4

individual participant data from randomised controlled trials Evaluating Progestogens for Preventing Preterm birth International Collaborative (EPPPIC): meta-analysis of

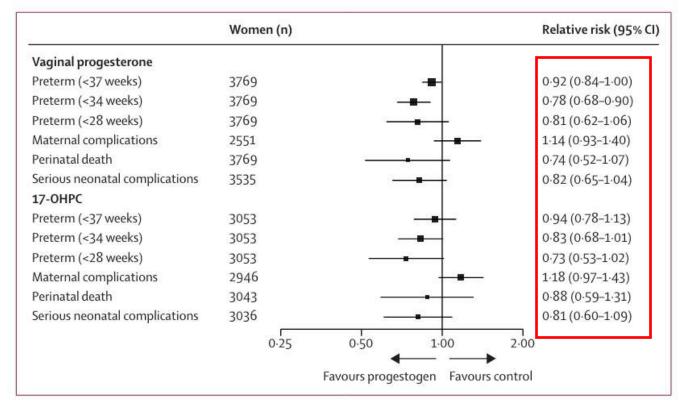


Figure 2: Main outcomes in singleton pregnancies for vaginal progesterone and 17-OHPC trials

History of spontaneous PTB

perinatal mortality (6 studies; 1453 women;

preterm birth < 37 weeks (10 studies; 1750 women;

preterm birth <34 weeks (5 studies; 602 women;

birthweight < 2500 g (4 studies; 692 infants;

assisted ventilation (3 studies; 633 women;

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RR 0.50, 95% CI 0.33 to 0.75)
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RR 0.40, 95% CI 0.18 to 0.90)
RR 0.30, 95% CI 0.10 to 0.89)
RR 0.24, 95% CI 0.14 to 0.40)

Endometrial injury in women undergoing assisted reproductive techniques (Review)

Nastri CO, Lensen SF, Gibreel A, Raine-Fenning N, Ferriani RA, Bhattacharya S, Martins WP



Cochrane Database of Systematic Reviews

The effect of endometrial injury on live birth and clinical pregnancy among women undergoing IVF is unclear. The results of the meta-analyses are consistent with an increased chance, no effect and a small reduction in these outcomes.

Human Reproduction Update, 2023, 29(6), 721-740

https://doi.org/10.1093/humupd/dmad014 Advance Access Publication Date: June 19, 2023

Endometrial scratching in women undergoing IVF/ICSI: an individual participant data meta-analysis

Nienke E. van Hoogenhuijze 🔞 1.4, Gemma Lahoz Casarramona², Sarah Lensen 📵 2, Cindy Farquhar⁴, Mohan S. Kamath 📵 5, Aleyamma T. Kunjummen⁵, Nick Raine-Fenning^{6,7}, Sine Berntsen^{6,9}, Anja Pinborg 🗓 10, Shari Mackens¹¹, Zeynep Ozturk Inal¹², Ernest H.Y. Ng 🔞 ¹³, Jennifer S.M. Mak¹⁴, Sachin A. Narvekar¹⁵, Wellington P. Martins¹⁶, Mia Steengaard Olesen¹⁷, Helen L. Torrance¹, Ben W. Mol 🗓 ^{18,19}, Marinus J.C. Eijkemans²⁰, Rui Wang 📵 ¹⁸, and Frank J.M. Broekmans¹

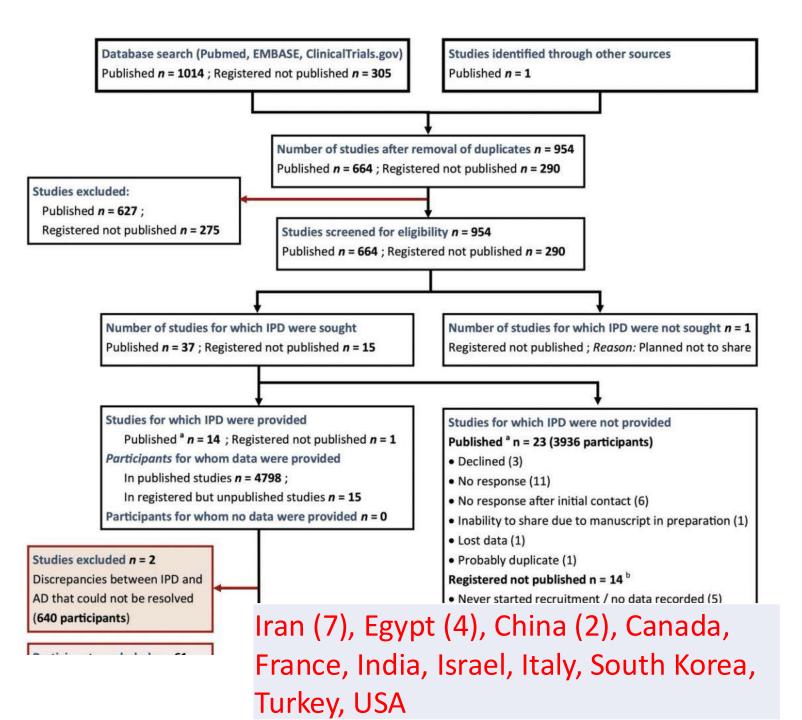
Endometrial scratching IVF

35 eligible RCTs

12 shared data, of which 2 had false data



Egypt (2)



	Munk	Osta Osta Osta Osta Osta Osta Osta Osta	No resp. 10 Golds	Charles solow	Olono Stage	Intigue Charton Sp.	other shows the	Ojonot Jouot	Share Contraction	0 sto 0 sto	The state of the s
Progesterone to prevent preterm birth	49	4	7	4	2	0	0	17	32	2	30
Endometrial scratching IVF	35	1	11	0	3	6	2	23	12	2	10
Outpatient vs inpatient methods for IOL	19	2	0	1	4	1	0	8	11	0	11
Vaginal misopr. vs vaginal dinopr. for IOL	52	11	10	10	8	3	0	42	10	2	8
Balloon + misopr.l vs vaginal misopr.	23	4	0	5	2	6	0	17	6	2	4
Balloon versus Vaginal prostaglandins	60	3	24	9	8	3	0	47	13	1	12
Oral Miso vs Vaginal Dino	19	5	6	0	0	0	0	11	8	3	5
Vaginal Dino vs Cervical Dino	40	7	24	2	1	0	0	34	6	-	-
Oxy vs placebo for PPH prevention	14	7	2	0	1	0	0	10	4	3	1
Total	297	37	82	31	28	19		199	98	12	80

67% (range 35%-85%) do not share data; from the 33% who shared data, 13% were untrustworthy

oldpid	sid	tr	age		height	weight	bmi	gestage	ga37	ga3740	ga4
7		3	2	16	#NULL!	#NULL!	#NULL!	38.0	0	1	
127		3	2	16	#NULL!	#NULL!	#NULL!	38.0	0		
82		3	1	14	#NULL!	#NULL!	#NULL!	38.0	0	1	
56		3	2	15	#NULL!	#NULL!	#NULL!	38.0	0	1	
188		3	1	15	#NULL!	#NULL!	#NULL!	38.0	0	1	
20		3	2	15	#NULL!	#NULL!	#NULL!	38.0	0	1	
120		3	2	16	#NULL!	#NULL!	#NULL!	37.0	0	1	
164		3	2	16	#NULL!	#NULL!	#NULL!	37.0	0	1	
178		3	1	16	#NULL!	#NULL!	#NULL!	37.0	0	1	
98		3	2	16	#NULL!	#NULL!	#NULL!	37.0	0	1	
144		3	1	16	#NULL!	#NULL!	#NULL!	37.0	0	1	
28		3	1	17	#NULL!	#NULL!	#NULL!	41.0	0	0	
31		3	1	17	#NULL!	#NULL!	#NULL!	41.0	0	0	
115		3	1	15	#NULL!	#NULL!	#NULL!	40.0	0	0	
159		3	1	15	#NULL!	#NULL!	#NULL!	40.0	0	0	
173		3	1	15	#NULL!	#NULL!	#NULL!	40.0	0	0	
75		3	1	20	#NULL!	#NULL!	#NULL!	37.0	0	1	
58		3	2	16	#NULL!	#NULL!	#NULL!	39.0	0	1	
190		3	1	16	#NULL!	#NULL!	#NULL!	39.0	0	1	
168		3	2	14	#NULL!	#NULL!	#NULL!	40.0	0	0	
110		3	1	14	#NULL!	#NULL!	#NULL!	40.0	0	0	
154		3	1	14	#NULL!	#NULL!	#NULL!	40.0	0	0	
	3300		3550				33.00	33.0	30		
	3290		3290				38.10	38.3	10		
	3370		3370			9	39.40	39 /	10		

Original Article

Titrated Misoprostol Versus Dinoprostone for Labor Induction

Amr H. Yehia¹, Ihab H. Abd El-Fattah¹, Karam M. Bayoumy¹, Ibrahim A. Abdelazim^{1,2}, Yasser Elshehawy¹, Noha H. Rabei¹, Sherif E. M. Daoud¹, A. Essam¹

C111	*	××	/ fx =	27+11*R	AND()	
4	Α	В	С	D	Е	F
1		Age	BMI	Parity	time of in	d ndication for induct
110 111		31	28.57382	PG	39+3	DM
111		33	36.68561	P2+1	40+1	decreased fetal kic
112 113		28	30.01125	P0+2	40+5	decreased fetal kic
113		37	28.35203	PG	41+2	Post term

International Journal of Gynecology and Obstetrics 123 (2013) 207-212

Contents lists available at ScienceDirect

International Journal of Gynecology and Obstetrics

journal homepage: www.elsevier.com/locate/ijgo



www.figo.org

CLINICAL ARTICLE

Titrated oral misoprostol solution versus vaginal misoprostol for labor induction



Comparison of Intracervical Foley's Catheter With Vaginal Misoprostol Versus Intravaginal Misoprostol Alone for Cervical Ripening and Induction of Labor

168	3	2	14	MNULLI	#NULL!	#NULL!	40.0	
110	3	1	14	#NULL!	#NULL!	#NULL!	40.0	Ç
154	3	3330	14	#NULL!	#NULL!	JJ.UULE!	39.00	
3290	1	3290				38.10	38.10	
3370		3370				39.40	39.40	
2900		2900				41.70	41.70	
3050		3050				38.50	38.50	
3510		3510				37.00	39.50	
2920	- 1	2920				37.00	39.50	(
3940		3960				37.00	39.70	
3200		3200				37.70	37.70	
3945		3945				39.10	39.10	C
3760		3760				40.70	40.70	1
3690		3690				39.80	39.80	1
3580		3580				40.00	40.00	
3400		3400				39.00	39.00	
3300		3300				40.80	40.00	
3650		3650				40.40	40.00	
			SV.				1	

Age	Sex	Parity	GA
19	Female	Multiparous	39
19	Female	Multiparous	39
19	Female	primigravida	39.2
19	Female	primigravida	39.2
19	Female	primigravida	40.3
19	Female	primigravida	40.3
20	Female	primigravida	39
20	Female	primigravida	39
20	Female	primigravida	39
20	Female	Multiparous	39.5
20	Female	Multiparous	39.5
20	Female	Multiparous	39.5
21	Female	Multiparous	38
20	Female	primigravida	40
20	Female	primigravida	40
20	Female	Multiparous	40.1
22	Female	Multiparous	37.1
22	Female	Multiparous	37.1
21	Female	Multiparous	39
20	Female	primigravida	41
20	Female	primigravida	41
22	Female	primigravida	38
22	Female	primigravida	38
22	Female	primigravida	38
22	Female	primigravida	38
22	Female	primigravida	38
21	Female	primigravida	40.1
21	Female	primigravida	40.1
22	Female	primigravida	38.3
PAA.			2011

primigravida

¹Department of Obstetrics and Gynecology, Ain Shams University, Cairo, Egypt, ²Department of Obstetrics and Gynecology, Ahmadi Hospital, Ahmadi, Kuwait

Countries

Italy

1-30 30-50 50~100 100-150 250-300 300-350 Trials recruited patients di Trials recruited patients for Trials recruited patients domestically Trials recruited patients from > 1 country

Do we think we have a problem?

Do we think we have a problem?

Based on the above, I estimate that at least 30% of the RCTs in women's health are fabricated or at least untrustworthy

What are the implications for clinical guidelines and practice?





The effects of sildenafil in maternal and fetal outcomes in pregnancy: A systematic review and meta-analysis

Raquel Domingues da Silva Ferreira 1.2+, Romulo Negrini 1.2-, Wanderley Marques Bernardo 3, Ricardo Simões 3, Sebastião Piato 1

1 Department of Obstetrics & Gynaecology, Irmandade Santa Casa de Misericórdia de São Paulo, São Paulo, Brazil, São Paulo, 2 Department of Obstetrics & Gynaecology, Hospital Israelita Albert Einstein, São Paulo, 3 Medicine Department, Universidade de São Paulo, São Paulo, Brazil, São Paulo, 3 Medicine Department, Universidade de São Paulo, São Pau



OPEN ACCESS

Citation: Ferreira RDdS, Negrini R, Bernardo WM, Simões R, Piato S (2019) The effects of sidenafil in maternal and fetal outcomes in pregnancy: A systematic review and meta-analysis. PLoS ONE 14(7): e0219732. https://doi.org/10.1371/journal. pone.0219732

Editor: Cheryl S. Rosenfeld, University of Missouri Columbia, UNITED STATES

Received: April 9, 2018

Accepted: July 2, 2019

Published: July 24, 2019

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Data Availability Statement: All relevant data are within the paper and its Supporting Information files.

Funding: The authors received no specific funding for this work.

Competing interests: The authors have declared that no competing interests exist.

Abstract

Background

The number of studies associating the use of sildenafil in gestation is increasing. This drug inhibits phosphodiesterase type 5 (PDE5), an enzyme responsible for degradation of nitric oxide, and its efficacy is greater in the placental territory, as the maternal side of the placenta have more PDE5 than other sites. For this reason, promising results have been observed related to the prevention of preeclampsia and intrauterine growth restriction and to improvement of maternal-fetal morbidity in cases of placental insufficiency.

Objective

To evaluate the benefits of using sildenafil in pregnancy.

Searched strategy

MEDLINE, ClinicalTrials.gov, Embase, LILACS and Cochrane databases were searched through September 2018. There was no restriction in language or year of publication. This study was registered in PROSPERO (CRD42017060288).

Selection criteria

Randomized clinical trials which used sildenafil for treatment or prevention of obstetric diseases compared with placebo were selected.

Data collection and analysis

The results were obtained using the inverse variance method for continuous variables and Man-Whitney for categorical variables.

DOI: 10.1111/1471-0528.17879

RETRACTION



Retraction: Management of Impacted Fetal Head at Caesarean Birth

K. Cornthwaite, R. Bahl, C. Winter, Wright, J. Kingdom, K. Walker, G. Tydeman, A. Briley, M. Schmidt-Hansen, T. Draycott, and the Royal College of Obstetricians & Gynaecologists. Management of Impacted Fetal Head at Caesarean Birth. BJOG. 2023;130(12):e40–e64, https://doi.org/10.1111/1471-0528.17534.

The above article, published on June 12, 2023, in Wiley Online Library (Wiley Online Library), has been retracted by agreement between the authors, journal Editor-in-Chief, Aris Papageorghiou, the Royal College of Obstetricians and Gynaecologists, and John Wiley & Sons Ltd.

The retraction has been agreed following the retraction of (1), a key paper cited in the above article. The retraction of (1) notes concerns regarding discrepancies between the retrospective trial registration and the published article. In light of this, the Royal College of Obstetricians & Gynaecologists has determined that the data and subsequent results in the above article are now implicated due to the discrepancies found in (1), particularly regarding the benefits of Fetal Pillow in relation to both maternal and neonatal outcomes.

Reference:

(1) S.L. Seal, A. Dey, S.C. Barman, G. Kamilya, J. Mukherji, and J.L. Onwude, *Retracted:* "Randomized controlled trial of elevation of the fetal head with a fetal pillow during cesarean delivery at full cervical dilatation," *International Journal of Gynecology & Obstetrics* 133, no. 2 (2016): 178-182, https://doi.org/10.1016/j.ijgo.2015.09.019.

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Subclinical hypothyroidism in the infertile female population: a guideline

Practice Committee of the American Society for Reproductive Medicine American Society for Reproductive Medicine, Birmingham, Alabama

VOL. 104 NO. 3 / SEPTEMBER 2015

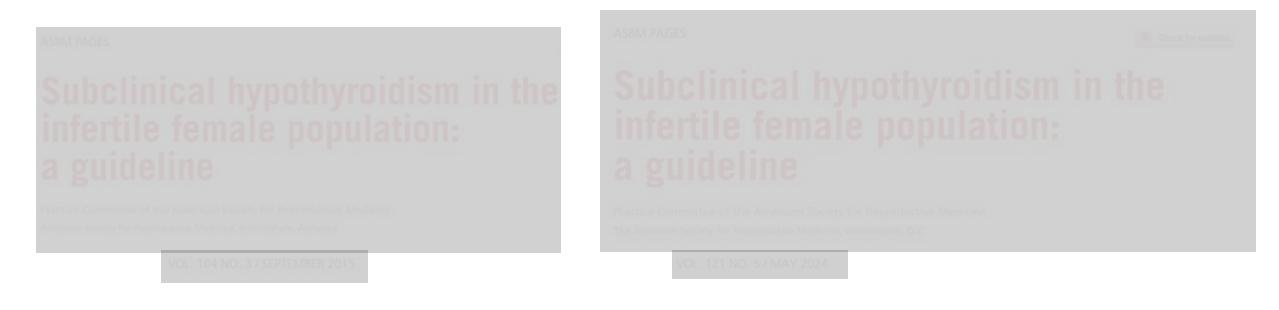
Summary statement. There is good evidence that levothyroxine treatment in women with SCH defined as TSH >4.0 mIU/L is associated with improvement in pregnancy and miscarriage rates. There is insufficient evidence that levothyroxidence.

Subclinical hypothyroidism in the infertile female population: a guideline

Practice Committee of the American Society for Reproductive Medicine
The American Society for Reproductive Medicine, Washington, D.C.

VOL. 121 NO. 5 / MAY 2024

 There is moderate evidence that treatment of SCH with levothyroxine does not improve pregnancy loss, clinical pregnancy, or LB.



The American Society for Reproductive Medicine (ASRM) recently decided to exclude an RCT from Abdel Rahman from their guideline, which reversed previous recommendations to prescribe levothyroxine supplementation in infertile women with subclinical hypothyroidism.



The journal that had originally published the paper had published a correction.²⁸, but the ASRM practice committee decided to exclude the study because of the risk of error. While we in our post-publication assessment did not assess this study, another paper had earned an EoC after we found signs of data-copying.²⁹

International evidence-based quideline for the assessment

asrm

and managemen ovary syndrome

International Evidence-based Guideline for the assessment and management of polycystic ovary syndrome 2023



Research Integrity in Guidelines and evIDence synthesis (RIGID): a framework for assessing research integrity in guideline development and evidence synthesis

Aya Mousa, a, s, g Madeline Flanagan, b, g Chau Thien Tay, a Robert J. Norman, Michael Costello, Wentao Li, b, e Rui Wang, Helena Teede, a, s, h and Ben W. Molb,f,h

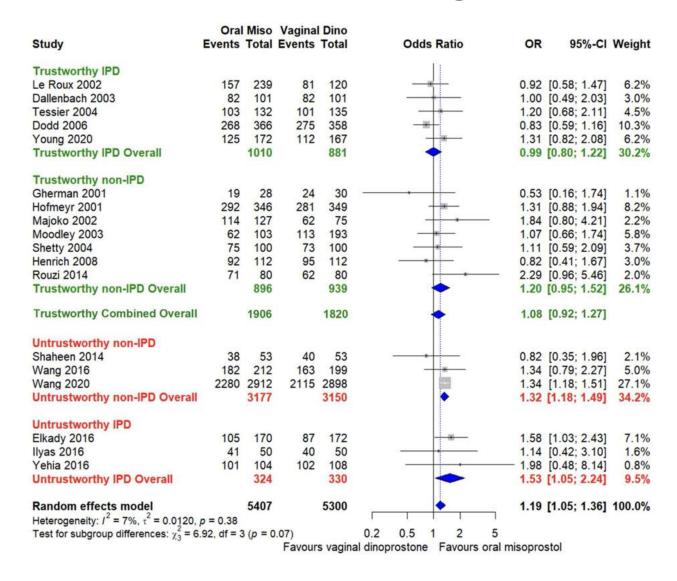
After implementation of the RIGID framework, we decided not to use 45 of the 101 (45%) originally identified studies.

eClinicalMedicine

Published Online 16 July https://doi.org/10. 1016/j.eclinm.2024. 102717

2024;74: 102717

Induction of labour / vaginal delivery



Vaginal dinosprostone vs oral misoprostol

What I just showed

- ASRM changed his policy on subclinical hypothyreodism after exclsusion of an untrustworthy study
- PCOS guideline drops after a robust assessment 45% of the selected RCTs for integrity concerns
- 60% of the evidence base for growth hormone for poor ovarian reserve is based on untrustworthy/fake data
- Evidence base underlying the management of post-partum hemorrhage and induction of labour is fake
- NICE recommendations of the use of the fetal pillow during caesarean section were based on fake data

What I just showed

- The long-term idea that progesterone helps for threatened / recurrent miscarriage is based on fake data; in reality it does not work.
- Heparin is not effective as preventative treatment for recurrent miscarriage
- The recommendation in the Australian RANZCOG guideline that in women with PROM antibiotics should not be used is based on fake data. When trustworthy data are used, antibiotics are likely to reduce neonatal sepsis
- The literature on calcium to prevent pre-eclampsia is flawed with fake data

UNACCEPTABLE

Why unacceptable

1. Patient safety.

- 2. Truth and science; future science.
- 3. Public trust in science.
- 4. The many reliable researchers who work hard and do the right thing
- 5. Countries reputation



Investigating the impact of trial retractions on the healthcare evidence ecosystem (VITALITY Study I): retrospective cohort study

Chang Xu, ¹ Shiqi Fan, ¹ Yuan Tian, ¹ Fuchen Liu, ² Luis Furuya-Kanamori, ³ Justin Clark, ⁴ Chao Zhang, ⁵ Sheng Li, ⁶ Lifeng Lin, ⁷ Haitao Chu, ^{8,9} Sheyu Li, ¹⁰ Su Golder, ¹¹ Yoon Loke, ¹² Sunita Vohra, ¹³ Paul Glasziou, ⁴ Suhail A Doi, ¹⁴ Hui Liu^{1,2}; On behalf of the VITALITY Collaborative Research Network

Retracted trials have <u>a substantial impact on the evidence</u> <u>ecosystem, including evidence synthesis, clinical practice</u> <u>guidelines, and evidence based clinical practice</u>. Evidence generators, synthesisers, and users must pay attention to this problem, and feasible approaches that assist with easier identification and correction of such potential contamination are needed.

Can we trust Cochrane reviews in infertility?

- 1. 26 Cochrane reviews, 516 RCTs
- 2. Of 563 RCTs, 195 (34.6%) RCTs were considered not trustworthy
- 3. Excluding these RCTs changed
 - 1. the direction of pooled effect in 4.2% (5/119) of comparisons
 - 2. change in significance was observed in 14.3% (17/119) of comparisons.

And what do we do about it?

RESEARCH Open Access

Checklist to assess Trustworthiness in RAndomised Controlled Trials (TRACT checklist): concept proposal and pilot

Ben W. Mol^{1,2}, Shimona Lai¹, Ayesha Rahim¹, Esmée M. Bordewijk³, Rui Wang¹, Rik van Eekelen^{3,4}, Lyle C. Gurrin^{5*}, Jim G. Thornton⁶, Madelon van Wely^{3,4,7} and Wentao Li¹

1) Governance
☐ Absent or retrospective registration for RCTs. This is relevant
in RCTs started after 2010.
☐ Absent or vague description of research ethics or apparent
concerns regarding ethics.
☐ Mismatch in numbers in the RCT and the trial registration
2) Author group
\square Number of authors \leq 3 or Low author-to-study size ratio,
especially RCTs with one or two authors only.
□ Other studies of the first author or co-authors are retracted
(search PubMed and, if needed, retraction watch)
☐ Large amount of RCTs published in a small time frame by
one author or in one institute (e.g. >3 per year as first author)

3) Plausibility of intervention usage
☐ Implausible use of placebo or intervention (e.g., two interventions with one placebo).
☐ Unavailability of trial interventions in the RCT region
4) Timeframe
An implausible fast recruitment of participants in the study time (e.g. 184 singleton pregnancies with idiopathic
oligohydramnios recruited in a single center in 15 months)
☐ Implausible short time between ending of recruitment, ending of follow-up and submission of the paper
(take into account time between randomization and time to assessment of the primary report)
5) Drop-out rates
☐ Zero participants loss to follow up or no reasons mentioned for loss to follow up
☐ The perfect amount of losses to follow up resulting perfectly round numbers, i.e. 2 groups
of 50, 2 groups of 100, etc.
6) Baseline characteristics
□ No or few baseline characteristics presented.
Implausible patient characteristics judging from common sense, the literature, and local data (e.g. standard deviations are similar for completely different characteristics with different means or distributions).
☐ Perfect balance for all baseline characteristics.
7) Outcomes
☐ Effect size that was much larger than in other RCTs regarding the same topic (heterogeneity).
☐ Large effect size with a small sample size.
\square Conflicting information between outcomes. (for <u>example</u> more ongoing pregnancies then clinical pregnancies)

0	Р	Q	R	S	Т	AD	AE	AK	AL	AR	AS	AT	AU	AV	AW
			Sa	mple 2		Midpoi	nt t	Minim	num t	Maxim	um t	Orig t	Orig p	Mid t	Mid p
D1.Min	Ml.Max	SD1.Max	M2	SD2	N2	t	p.t	t.Min	p.t.Min	t.Max	p.t.Max	(optional)			
3.05	40.10	3.15	39.70	0.50	70	0.933	0.353	0.654	0.514	1.221	0.224		0.56	0.93	0.3527
0.55	0.25	0.65	0.20	0.60	70	0.000	1.000	-0.910	0.364	1.076	0.284		0.79	0.00	1.0000
-0.02	0.13	0.08	0.07	0.30	70	0.278	0.782	-2.097	0.038	3.670	0.000		0.79	0.28	0.7818
3.35	25.65	3.45	25.10	3.40	70	0.870	0.386	0.686	0.494	1.060	0.291		0.34	0.87	0.3858
2.45	7.95	2.55	7.20	2.60	70	1.624	0.107	1.365	0.174	1.893	0.060		>0.999	1.62	0.1067
0.85	12.15	0.95	11.90	0.80	70	1.390	0.167	0.656	0.513	2.214	0.028		0.30	1.39	0.1669
0.15	0.95	0.25	1.00	0.20	70	-2.958	0.004	0.000	1.000	-7.888	0.000		0.42	-2.96	0.0036
2.85	6.75	2.95	7.00	2.70	70	-0.633	0.527	-0.415	0.679	-0.860	0.391		0.55	-0.63	0.5275
604.35	1607.15	604.45	1365.30	607.70	70	2.360	0.020	2.359	0.020	2.362	0.020		0.02	2.36	0.0197
2.95	6.95	3.05	5.80	3.10	70	2.133	0.035	1.908	0.058	2.366	0.019		0.03	2.13	0.0347
2.55	4.85	2.65	4.20	2.50	70	1.392	0.166	1.138	0.257	1.656	0.100		0.06	1.39	0.1662
2.15	4.75	2.25	3.60	2.30	70	2.892	0.004	2.572	0.011	3.226	0.002		0.01	2.89	0.0045
27.35	62.35	27.45	52.20	29.80	70	2.087	0.039	2.063	0.041	2.112	0.037		0.04	2.09	0.0387
1.75	11.65	1.85	12.60	1.60	70	-3.474	0.001	-3.038	0.003	-3.937	0.000		0.00	-3.47	0.0007
717.45	3383.55	717.55	3653.50	856.00	70	-2.022	0.045	-2.022	0.045	-2.023	0.045		0.02	-2.02	0.0451
0.55	1.65	0.65	1.40	0.70	70	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!		0.14	#REF!	#REF!
													0.14		
0.58	2.07	0.68	2.20	0.68	80	-1.737	0.084	-0.717	0.474	-2.925	0.004		0.02	-1.74	0.0844
85.95	236.05	86.05	283.00	106.00	80	-3.080	0.002	-3.072	0.003	-3.088	0.002		0.02	-3.08	0.0024

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Journal of Clinical Epidemiology

Journal of Clinical Epidemiology 180 (2025) 111603

METHODOLOGICAL ASPECTS OF RESEARCH INTEGRITY AND CULTURE

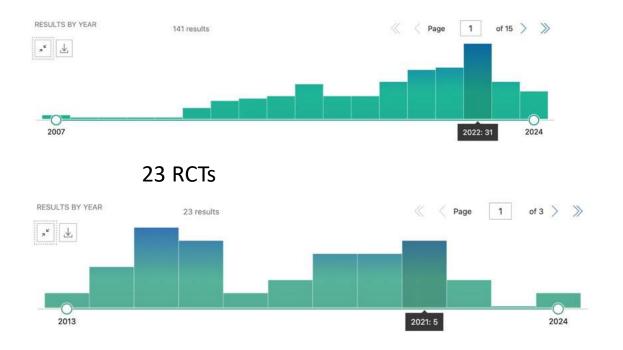
Assessing the scientific integrity of the collected work of one author or author group

Jeremy Nielsen^a, Esmée M. Bordewijk^{a,b}, Lyle C. Gurrin^c, Siddharth Shivantha^d, Madeline Flanagan^a, Sue Liu^d, May M. Linn^a, Kelly X. Zhou^a, Rik van Eekelen^b, Nicholas J.L. Brown^e, Jim Thornton^f, Ben W. Mol^{a,g,*}

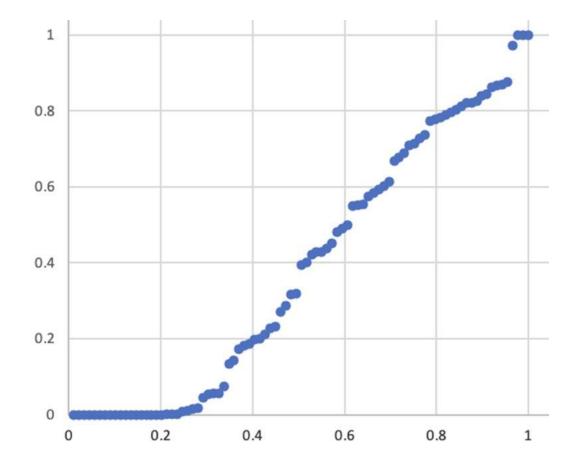




141 articles



Distribution of P-values from RCTs from Suez Canal University





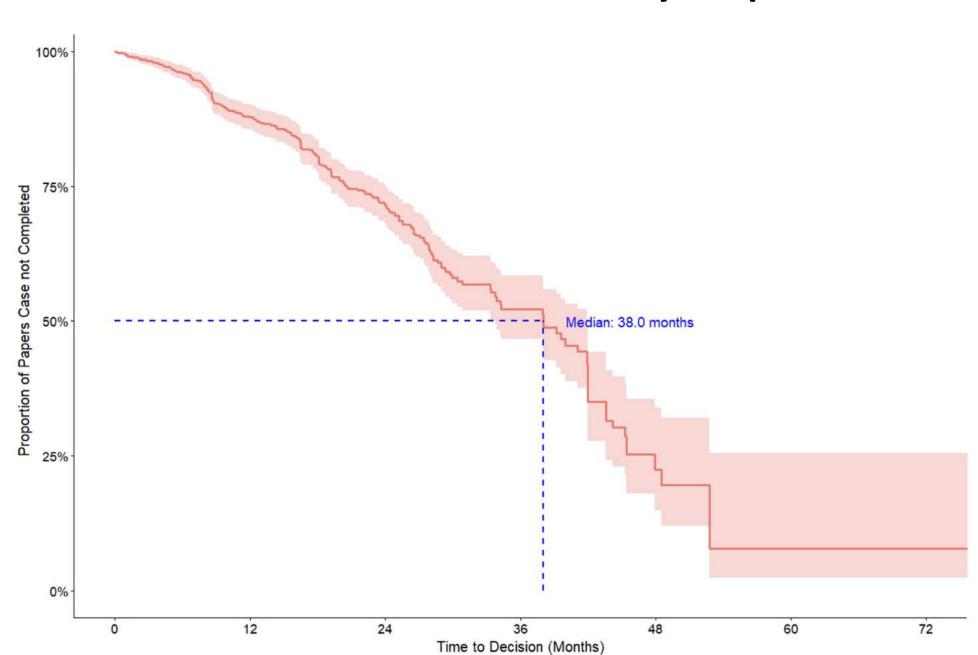


Clinical Research in Women's Health

Siddharth Shivantha¹ 🔘 | Nicole Ling Shan Au¹ | Lyle Gurrin² | Jim Thornton³ 🔘 | Jeremy Nielsen¹ 🔘 | Ben W. Mol^{1,4} 🔘

STATUS	N=891	ASSESSMENT OUTCOME (%)
Completed investigation	183	29.5
Retraction	152	58
Expression of concern	75	29
No wrongdoing found	30	11
Correction	6	2
Pending	628	60.5

Median Time Taken For Any Response



Journal Case Completion Rate

Journal	Publisher	Number of Flagged Papers N = 891	Case Completion Rate (%)	Retraction N = 152 ¹	Expression of Concern N = 75 ¹	Correction N = 6 ¹	Investigation concluded no action N = 301	Pending Investigation N = 628 ¹	Median Time to Response (Months) *Assuming 30days per month
Journal of Maternal- <u>Fetal</u> and Neonatal Medicine	Taylor & Francis	78 (8.8%)	29 (37%)	11 (14%)	18 (23%)	0 (0%)	0 (0%)	49 (63%)	20
nternational Journal of Gynecology and Obstetrics	Wiley Blackwell	67 (7.5%)	23 (33%)	13 (19%)	0 (0%)	0 (0%)	10 (15%)	44 (66%)	24
Archives of <u>Gynecology</u> and Obstetrics	Springer	60 (6.7%)	31 (52%)	15 (25%)	16 (27%)	0 (0%)	0 (0%)	29 (48%)	25
Fertility Sterility	Elsevier	57 (6.4%)	22 (39%)	14 (25%)	2 (3.5%)	1 (1.8%)	4 (7.0%)	36 (63%)	15
European Journal of Obstetrics and Gynecology and Reproductive Biology	Elsevier	38 (4.3%)	16 (42%)	14 (37%)	2 (5.3%)	0 (0%)	0 (0%)	22 (58%)	17
European Journal of Contraception and Reproductive Health Care	Taylor & Francis	24 (2.7%)	19 (79%)	18 (75%)	0 (0%)	0 (0%)	1 (4%)	5 (25%)	16
Reproductive Biomedicine Online	Elsevier	20 (2.2%)	5 (25%)	5 (25%)	0 (0%)	0 (0%)	0 (0%)	15 (75%)	23
Human Reproduction	Oxford	7	1	0	0	0	1	6	

Publisher Case Completion Rate

Status	Number of Informed Papers N = 891	Case Completion Rate (%)	Retraction N = 152 ¹	Expression of Concern, N = 751	Correction N = 6 ¹	Investigation concluded no action N = 301	Pending Investigation N = 628 ¹	Median Time to Response (Months) *Assuming 30days per month
Elsevier	203 (23%)	61 (30%)	43 (21%)	10 (4.9%)	2 (3.3%)	6 (3.0%)	142 (70%)	17
Taylor Francis	170 (19%)	71 (42%)	50 (29%)	20 (11%)	0 (0%)	1 (0.6%)	99 (58%)	20
Springer	153 (17%)	50 (33%)	26 (17%)	18 (11%)	2 (4.0%)	4 (2.6%)	103 (67%)	18
Wiley Blackwell	125 (14%)	37 (30%)	17 (14%)	8 (6.4%)	1 (2.7%)	11 (8.8%)	88 (70%)	24
Wolters Kluwer	45 (5.1%)	22 (49%)	5 (11%)	14 (31%)	0 (0%)	3 (6.7%)	23 (51%)	13
Oxford University Press	13 (1.5%)	3 (23%)	1 (7.8%)	0 (0%)	0 (0%)	2 (15%)	10 (77%)	10
Termedia	11 (1.2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	11 (100%)	17
Karger	9 (1.0%)	7 (78%)	2 (22%)	4 (44%)	0 (0%)	1 (11%)	2 (22%)	5
¹ Data are n (%) unless otherwis	se specified; % Ca	culated from the	number of comple	ted cases			



EDITORIAL



Retraction of peer-reviewed articles, a difficult but crucial choice: our experience from *The European Journal of Contraception & Reproductive Health Care*

After a robust process, the journal has retracted 18 of 19 cases investigated



Is rectal misoprostol really effective in the treatment of third stage of labor? A randomized controlled trial

Eray Çalişkan, MD, M. Mutlu Meydanli, MD, Berna Dilbaz, MD, Burcu Aykan, MD, Meral Sönmezer, MD, and Ali Haberal, MD

Ankara, Turkey

OBJECTIVE: The purpose of this study was to compare misoprostol 600 μg intrarectally with conventional oxytocics in the treatment of third stage of labor.

STUDY DESIGN: In a controlled trial, 1606 women were randomly grouped to receive (1) oxytocin 10 IU plus rectal misoprostol, (2) rectal misoprostol, (3) oxytocin 10 IU, and (4) oxytocin 10 IU plus methylergometrine. The main outcome measures were the incidence of postpartum hemorrhage and a drop in hemoglobin concentration from before delivery to 24 hours after delivery.

RESULTS: The incidence of postpartum hemorrhage was 9.8% in the group that received only rectal misoprostol therapy compared with 3.5% in the group that received oxytocin and methylergometrine therapy (P = .001). There were no significant differences among the 4 groups with regard to a drop in hemoglobin concentrations. Significantly more women needed additional oxytocin in the group that received only rectal misoprostol therapy, when compared with the group that received oxytocin and methylergometrine therapy (8.3% vs 2.2%; P < .001). The primary outcome measures were similar in the group that received only rectal misoprostol therapy and the group that received only oxytocin therapy.

CONCLUSION: Rectal misoprostol is significantly less effective than oxytocin plus methylergometrine for the prevention of postpartum hemorrhage. (Am J Obstet Gynecol 2002;187:1038-45.)

Key words: Rectal misoprostol, oxytocin, methylergometrine, third stage of labor, postpartum hemorrhage

Oral Misoprostol for the Third Stage of Labor: A Randomized Controlled Trial

Eray Çalışkan, MD, Berna Dilbaz, MD, M. Mutlu Meydanli, MD, Nilgün Öztürk, MD, Mehmet Ali Narin, MD, and Ali Haberal, MD

OBJECTIVE: To compare oral misoprostol with conventional oxytocics in the management of the third stage of labor.

METHODS: In a controlled trial, 1574 women were randomized into four groups, as follows: Group 1 received intravenous infusion of oxytocin 10 IU plus oral misoprostol 400 μg, followed by two doses of oral misoprostol 100 μg 4 hours apart; group 2 received oral misoprostol 400 μg, followed by two doses of oral misoprostol 100 μg 4 hours apart; group 3 received intravenous infusion of oxytocin 10 IU; and group 4 received intravenous infusion of oxytocin 10 IU plus intramuscular administration of methylergonovine maleate (Methergine) 0.2 mg. The incidence of postpartum hemorrhage and decrease in hemoglobin concentration from before delivery to 24 hours postpartum were the main outcome measures.

RESULTS: The primary outcome measures were similar in

Evidence from several controlled trials suggests that the prophylactic use of oxytocics in the third stage of labor has been beneficial in reducing blood loss and the incidence of severe postpartum hemorrhage.² There are potential problems with the parenteral use of oxytocin and methylergonovine maleate (Methergine), such as the need of protection from light, requirement of refrigeration, and the need of clean needles and syringes (an important consideration in the era of hepatitis and human immunodeficiency virus infection).³ On the other hand, methylergonovine maleate is ineffective in reducing postpartum hemorrhage when administered orally.⁴

Oral misoprostol, a prostaglandin E_1 analogue, is a stable and inexpensive drug with a simple method of administration. Based on their clinical observations, El-



Am J Obstet Gynecol. 2002 Oct;187(4):1038-45.

Table I. Demographic characteristics of groups

	Group						
Characteristic	Misoprostol + oxytocin (n = 401)	Misoprostol alone (n = 396)	Oxytocin alone (n = 407)	Oxytocin + methylergomet (n = 402)			
Maternal age (y)*	25.5 ± 5.3	25.3 ± 5.1	25 ± 5.1	24.9 ± 5.8			
Body mass index (kg/m ²)*	●28.2 ± 3.4	28.3 ± 3.9	27.9 ± 4.5	27.8 ± 3.9			
Parity (n)*	●0.8 ± 1	0.8 ± 0.9	0.7 ± 1	0.7 ± 0.8			
Primipara(n)†	205 (51.1%)	194 (48.9%)	194 (47.6%)	202 (50.7%)			
Multipara (n)†	191(47.6%)	198 (50%)	196 (48.1%)	194 (48.7%)			
Grandmultipara (n)‡	5 (1.2%)	4 (1%)	7 (1.7%)	6 (1.4%)			
Gestational age (d)*	275 ± 11	275 ± 13.4	275 ± 11.1	275 ± 10.6			
Predelivery hemoglobin level (g/dL)*	11.3 ± 1.3	11.3 ± 1.3	11.4 ± 1.3	11.4 ± 1.2			
Predelivery hematocrit level (%)*	35.2 ± 3.4	35 ± 3.5	35.3 ± 3.4	35.1 ± 3.1			
Maternal anemia (hemoglobin < 10 g/dL)+	42 (10.6%)	38 (9.5%)	39 (9.5%)	36 (8.9%)			
Antepartum blood transfusion‡	2 (0.5%)	3 (0.7%)	5 (1.2%)	3 (0.7%)			

Data are presented as mean ± SD, unless otherwise indicated.

Table III. Outcome variables of women who received rectal misoprostol therapy with or without oxytocin compared with women who received intravenous oxytocin therapy with or without methylergometrine

	Group							
Variable	Misoprostol + oxytocin (n = 401)	Misoprostol alone $(n = 396)$	Oxytocin alone $(n = 407)$	Oxytocin + methylergometrine $(n = 402)$				
Blood loss ≥500 mL (n)	28 (6.6%)	39 (9.8%)*	33 (8.1%)	14 (3.5%)				
Blood loss ≥1000 mL (n)	11 (2.7%)	17 (4.2%)+	14 (3.4%)	7(1.7%)				
Drop in hemoglobin level (g/dL)‡	1.5 ± 1.3	1.5 ± 1.2	1.4 ± 1.4	1.5 ± 1.2				
Drop in hematocrit level (%)‡	4.4 ± 4.1	4.7 ± 4.3	4.5 ± 3.7	4.6 ± 3.6				
Length of third stage (min)	8.6 ± 3.3	9.3 ± 4 §	8.7 ± 1.7	8.4 ± 1.7				
Third stage ≥30 min (n)	2 (0.5%)	12 (3%)	2 (0.5%)	4 (1%)				
Additional oxytocin (n)	17 (4.2%)	33 (8.3%)¶	26 (6.7%)	9 (2.2%)				
Additional methylergometrine (n)	12 (2.9%)	18 (4.5%)#	14 (3.6%)	6(1.4%)				
Evacuation of the uterus because of retained products (n)**	6 (1.4%)	3(0.7%)	4 (1%)	2 (0.5%)				
Postpartum blood transfusion (n)	4 (1%)	12 (3%)++	13 (3.3%)	4 (1%)				

Obstet Gynecol. 2003 May;101(5 Pt 1):921-8.

1. Demographic Characteristics of the Four Treatment Groups

Characteristic	Misoprostol and oxytocin (n = 404)	Misoprostol (n = 388)	Oxytocin (n = 384)	Oxytocin and methylergonovine maleate (n = 398)
nal age (y)*	25.6 ± 5	24.4 ± 4.7	25 ± 5.1	24.9 ± 5.8
Body mass index*	28.2 ± 4.6	27.6 ± 3.7	27.9 ± 4.5	27.7 ± 3.5
Parity*	0.8 ± 0.9	0.8 ± 0.96	0.7 ± 1	0.7 ± 0.8
Primiparas [†]	183 (45.2)	181 (46.6)	194 (50.5)	202 (50.7)
Multiparas [†]	217 (53.7)	203 (52.3)	190 (49.4)	194 (48.7)
Grandmultiparas [‡]	3 (0.7)	4(1)	4(1)	2 (0.5)
Gestational age (d)*	276 ± 11.2	276 ± 11.1	275 ± 11.1	275 ± 10.6
Predelivery hemoglobin (g/dL)*	11.4 ± 1.4	11.5 ± 1.2	11.4 ± 1.3	11.4 ± 1.2
Predelivery hematocrit (%)*	35.2 ± 3.6	35.2 ± 3.3	35.3 ± 3.4	35.1 ± 3.1
Maternal anemia (hemoglobin < 10 g/dL) [†]	46 (11.3)	40 (10.3)	42 (10.9)	34 (8.5)
Antepartum blood transfusion [‡]	5 (1.2)	2 (0.5)	3 (0.7)	2 (0.5)

Data presented as mean \pm standard deviation or n (%).

[†] No statistically significant differences among groups (P > .01), χ^2 test.

Table 3. Outcome Variables of Women Receiving Oral Misoprostol With or Without Oxytocin Compared With Those Receiving Intravenous Oxytocin With or Without Methylergonovine Maleate

Variable	Misoprostol and oxytocin (n = 404)	Misoprostol (n = 388)	Oxytocin (n = 384)	Oxytocin and methylergonovine maleate (n = 398)
Blood loss ≥ 500 mL	13 (3.2)*	35 (9) [†]	28 (7.3)	14 (3.5)
Blood loss $\geq 1000 \text{ mL}^{\ddagger}$	6 (1.4)	14 (3.6)	15 (3.9)	5 (1.2)
Drop in hemoglobin (g/dL)§	1.4 ± 1.3	1.4 ± 1.1	1.4 ± 1.4	1.5 ± 1.2
Drop in hematocrit (%)§	4.2 ± 4	4.1 ± 3.5	4.5 ± 3.7	4.6 ± 3.6
Blood loss	$280 \pm 182^{\parallel}$	328 ± 152^{9}	312 ± 176	296 ± 168
Length of third stage (min)	$8.8 \pm 3.8^{\parallel}$	9.2 ± 3^{9}	8.7 ± 1.7	8.4 ± 1.7
Third stage ≥ 30 min [‡]	3 (0.7)	3 (0.7)	2 (0.5)	4 (1)
Additional oxytocin	10 (2.4)#	23 (5.9)	26 (6.7)	9 (2.2)
Additional methylergonovine maleate	3 (0.7)*	19 (4.8)†	14 (3.6)	4(1)
Subsequent evacuation of uterus [‡]	2 (0.5)	2(0.5)	4 (1)	2(0.5)
Postpartum blood transfusion [‡]	5 (1.2)	14 (3.6)	13 (3.3)	6 (1.5)
Data presented as mean + standard deviat	ion or n (%)	10.01.0410.01.05	000000000000000000000000000000000000000	$\overline{}$

^{*}No statistically significant difference among groups (P>.05), analysis of variance, Tukey test.

 $[\]dagger$ No statistically significant difference among groups (P > .05), chi-square test.

 $[\]pm$ No statistically significant difference among groups (P > .05), Fisher exact test.

^{*} No statistically significant differences among groups (P > .05), analysis of variance, Tukey test.

^{*} No statistically significant differences among groups (P > .01), Fisher exact test.



Trusted evidence.
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Cochrane Database of Systematic Reviews

From: Stephanie Casway < <a href="mailto:SCasway@greenjournal.greenjou

Date: Friday, 6 January 2023 at 3:24 am

To: Ben Mol < ben.mol@monash.edu >

Cc: "Dr. Jason Wright" <jwright@greenjournal.org>

Subject: Follow up: concern over Caliskan papers

Good Morning Dr. Mol,

Analysis 8.9. Comparison 8 Misoprostol vs Oxytocin, Outcome 9 Change in haemoglobin.

Study or subgroup	Misoprostol		Oxytocin		Mean Difference	Weight	Mean Difference	
58 D. B.	N	Mean(SD)	N	Mean(SD)	Random, 95% CI	5793	Random, 95% CI	
Acharya 2001	30	12 (8.4)	30	11 (7)		1.7%	1[-2.9,4.9]	
Afolabi 2010	100	3 (10.2)	100	4 (10.2)		2.55%	-1[-3.83,1.83]	
Al-Sawaf 2013	28	13 (9)	37	12 (9)		1.42%	1[-3.42,5.42]	
Alwani 2014	100	12 (13.1)	100	11.2 (9)	- 1	2.28%	0.8[-2.32,3.92]	
Atukunda 2014	570	9.4 (14.3)	569	9.6 (16.7)	-+-	3.8%	-0.2[-2.01,1.61]	
Benchimol 2001	186	9.6 (23.5)	196	6.7 (20.1)		1.43%	2.9[-1.5,7.3]	
Caliskan 2002	396	15 (12)	407	14 (14)	- •	3.81%	1[-0.8,2.8]	
Caliskan 2003	388	14 (11)	384	14 (14)		3.84%	0[-1.78,1.78]	

Thank you for your patience while we reviewed your concerns for Caliskan et al. After an investigation, we have decided not to pursue any action against the author, as we do not believe there is ample evidence of misconduct.

After an investigation, we have decided not to pursue any action against the author, as we do not believe there is ample evidence of misconduct.

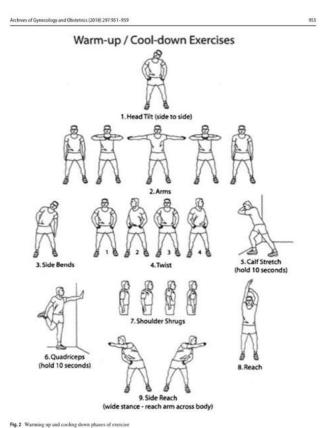
GENERAL GYNECOLOGY



Effect of swimming exercise on premenstrual syndrome

Ahmed Mohamed Maged^{1,5} · Amr H. Abbassy² · Hend R. S. Sakr³ · Heba Elsawah¹ · Heba Wagih¹ · Asmaa I. Ogila¹ · Amal Kotb⁴

Received: 24 October 2017 / Accepted: 10 January 2018 / Published online: 19 January 2018 © Springer-Verlag GmbH Germany, part of Springer Nature 2018



The Retraction Watch Database

Maged, Ahmed M

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GENERAL GYNECOLOGY



Effect of swimming exercise on premenstrual syndrome

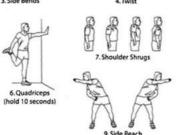
Ahmed Mohamed Maged^{1,5} · Amr H. Abbassy² · Hend R. S. Sakr³ · Heba Elsawah¹ · Heba Wagih¹ · Asmaa I. Ogila¹ · Amal Kotb4

Received: 24 October 2017 / Accepted: 10 January 2018 / Published online: 19 January 2018 © Springer-Verlag GmbH Germany, part of Springer Nature 2018

Archives of Gynecology and Obstetrics (2018) 297:951-959 Warm-up / Cool-down Exercises









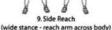
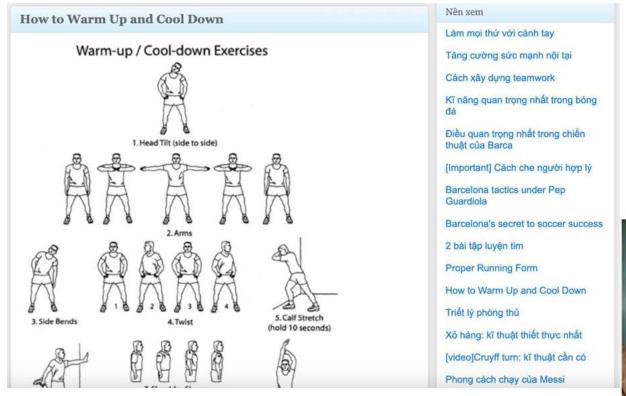


Fig. 2 Warming up and cooling down phases of exercise

- •Recruitment April 2016 to May 2017; Assessment for all manifestation was carried after 3 months of enrolment; paper submitted 24 October 2017
- •BMI (21) is very low and strongly deviant from the BMI of 10.1002/ijgo.14737
- •The description of the exercise in the text has nothing to do with the figure. Figure 2 can be found in a 2013 Vietnamese BLOG
- https://coibongda.blogspot.com/2013/02/how-to-warmup-and-cool-down.html





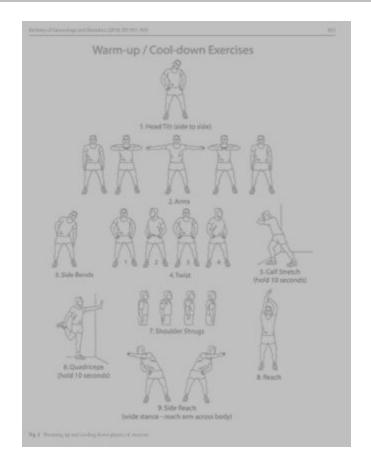
GENERAL GYNECOLOGY



Effect of swimming exercise on premenstrual syndrome

Ahmed Mohamed Maged^{1,5} · Amr H. Abbassy² · Hend R. S. Sakr³ · Heba Elsawah¹ · Heba Wagih¹ · Asmaa I. Ogila¹ · Amal Kotb⁴

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Archives of Gynecology and Obstetrics (2024) 309:2957 https://doi.org/10.1007/s00404-024-07429-x

CORRECTION



Correction: Effect of swimming exercise on premenstrual syndrome

Ahmed Mohamed Maged 1 · Amr H. Abbassy 2 · Hend R. S. Sakr 3 · Heba Elsawah 1 · Heba Wagih 1 · Asmaa I. Ogila 1 · Amal Kotb 4

Published online: 1 April 2024

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Figure 2 has been removed from the original version of this article for legal reasons and the figures have been renumbered accordingly. The original article has been corrected



N=112

N=110

Table 5 Drug-related side effects

	Group 1, n (%)	Group 2, n (%)	P-value
Nausea	30 (26.8)	1 (0.9)	0.02
Dry mouth	22 (19.6)	0	0.02
Agitation	12 (10.7)	1 (0.9)	0.02
Constipation	11 (9.8)	0	0.02
Headache	10 (8.2)	2 (1.8)	0.02
Dizziness	3 (2.7)	2 (1.8)	0.07
Erectile dysfunction	2 (1.7)	2 (1.8)	0.09
Loss of libido	3 (2.7)	2 (1.8)	0.07



Venlafaxine for treatment of premature ejaculation Andrologia. 2008 Feb;40(1):49-55.

N=112

N=110

Table 5 Drug-related side effects

	Group 1, n (%)	Group 2, n (%)	P-value
Nausea	30 (26.8)		1 (0.9)	0.02
Dry mouth	22 (19.6)		0	0.02
Agitation	12 (10.7)		1 (0.9)	0.02
Constipation	1 1 (9.8)		0	0.02
Headache	1 0 (8.2)		2 (1.8)	0.02
Dizziness	3 (2.7)		2 (1.8)	0.07
Erectile dysfunction	2 (1.7)		2 (1.8)	0.09
Loss of libido	3 (2.7)		2 (1.8)	0.07

All P-values are wrong

P=0.0008

P=0.0078

P=0.0168

P=0.0302

P=0.037

P=0.66

P=0.98

P=0.66

Patterns | 12 11 10

Patterns 2 2 2 2 2 Patterns 1 0 1 0

Venlafaxine for treatment of premature ejaculation

Andrologia. 2008 Feb;40(1):49-55.

Andrologia. 2011 Feb;43(1):38-47.

Effect of omega-3 polyunsaturated fatty acid supplement

Safarinejad 2010b



Table 4 Adverse events No (%)

Adverse events	Omega-3 group $(n = 113)$	Placebo group $(n = 114)$	P value
Foul breath/bad taste	8 (7.1)	1 (0.9)	0.01*
Heartburn/reflux	6 (5.3)	1 (0.9)	0.02*
Soft stool or diarrhoea	5 (4.4)	2 (1.8)	0.04*
Nausea	3 (2.6)	2 (1.8)	0.07
Constipation	3 (2.6)	1 (0.9)	0.04*
Pruritis	3 (2.6)	0	0.04*
Loss of body weight	1 (0.9)	0	0.08
Burping	1 (0.9)	0	0.08
Feeling tired after starting medication	1 (0.9)	0	0.08

All P-values are wrong

Table 3 Correlation between omega-3 fatty acid concentrations and other variables

R					Plasma			Sperm				
	EPA		DHA		EPA		DHA		EPA		DHA	
Variables	r	P value	r	P value	r	P value	r	P value	r	P value	r	P value
Semen parameters												
Ejaculate volume	0.18	0.14	0.02	0.74	0.02	0.76	0.03	0.42	0.04	0.53	0.02	0.62
Total sperm/ejaculate	0.52	0.001*	0.58	0.001*	0.57	0.001*	0.61	0.001*	0.72	0.0001	0.78	0.0001*
Sperm concentration	0.54	0.001*	0.57	0.001*	0.56	0.001*	0.62	0.001*	0.72	0.0001	0.78	0.0001*
Sperm motility	0.50	0.001*	0.54	0.001*	0.54	0.001*	0.60	0.001*	0.75	0.0001	0.77	0.0001*
Sperm morphology	0.44	0.001*	0.48	0.001*	0.48	0.001*	0.55	0.001*	0.69	0.0001	0.68	0.0001*
Seminal plasma anti-ox	ridants											
SOD-like activity	0.64	0.001*	0.68	0.001*	0.57	0.01*	0.66	0.001*	0.74	0.0001	0.77	0.0001*
Catalase-like activity	0.60	0.001*	0.62	0.001*	0.55	0.01*	0.66	0.001*	0.74	0.0001	0.73	0.0001*

.66 or .74

.5,.6 or.7

All series start with

They are all series highly

suspected for fabrication.

P=0.0472

P=0.0930

P=0.2628 P=0.6465 P=0.334 P=0.19 P=0.49 P=0.49 P=0.49

Key: EPA, Eicosapentaenoic acid; DHA, docosahexaenoic acid; RBC, Red blood cells; SOD, Superoxide dismutase.

^{*}Statistically significant.

Table 1. Baseline demographics, serum hormones and semen parameters of study groups

	Saffron	Placebo	р
Characteristic	(n = 130)	(n = 130)	value
Age (year)	28.4 ± 5.2	28.8 ± 5.6	NS
Infertility duration (year)	4.4 * 2.2	4.6 2.6	NS
BMI (kg/m²)	26.8 ± 2.6	26.6 * 2.4	NS
Occupational status No. (%)			
Employed	115 (88.5)	116 (89.2)	NS
Unemployed	15 (11.5)	14 (10.8)	NS
Serum hormones			
Testosterone (nmol/L)	15.4 ± 4.8	15.6 ± 4.6	NS
LH (IU/L)	12.2 ± 2.4	12.4 ± 2.2	NS
FSH (IU/L)	16.8 ± 4.2	16.4 ± 4.6	NS
PRL (pmol/L)	363 ± 117	367 ± 122	NS
TSH (mIU/mL)	1.7 ± 0.7	1.7 ± 0.7	NS
Semen parameters			
Ejaculate volume (mL)	2.7 ± 1.4	2.8 ± 1.3	NS
Total sperm/ejaculate (× 10 ⁶)	47.8 ± 12.4	47.8 ± 12.2	NS
Sperm density (× 10 ⁶ /mL)	21.2 ± 4.4	20.9 ± 4.6	NS
Motility (% motile)	24.3 ± 2.4	$\textbf{23.8} \pm \textbf{2.6}$	NS
Morphology (% normal)	17.2 ± 4.6	17.3 ± 4.7	NS
Haematological parameter:			
Haemoglobin (mg/dL)	14.4 ± 0.36	14.3 ± 0.38	NS
White blood cells (103)	7.68 2.12	7.72 ± 2.16	NS
Red blood cells (109)	8.28 > 0.54	8.24 ± 0.54	NS
Platelets (10 ³)	872 ± 123	878 ± 122	NS
Seminal plasma antioxidants	3		
SOD-like activity (U/mL)	311 ± 14	314 ± 16	NS
Catalase-like activity (U/mL)	36.6 ± 1.4	37.1 ± 1.6	NS

Table 2. Summary of semen parameters, reproductive hormones, haematological parameters and antioxidant status of seminal plasma at the end of 26-week treatment period with *Crocus sativus*

Variable	Saffron $(n = 130)$	Placebo (n = 130)	<i>p</i> value
Serum hormones		****	
Testosterone (nmol/L)	15.6 \$ 4.4	15.8 ± 4.2	NS
LH (IU/L)	12.4 🖰 2.2	12.6 = 2.4	NS
FSH (IU/L)	16.2 🛱 4.4	16.8 \$ 4.2	NS
PRL (pmol/L)	371 ± 112	377 ± 120	NS
TSH (mIU/mL)	1.7 ± 0.8	1.7 ± 0.7	NS
Semen parameters			
Ejaculate volume (mL)	2.6 ± 1.4	2.7 ± 1.4	NS
Total sperm/ejaculate (× 106)	46.4 ± 12.2	47.4 ± 12.2	NS
Sperm density (× 10 ⁶ /mL)	20.5 ± 4.6	21.4 ± 4.6	NS
Motility (% motile)	25.7 ± 2.4	24.9 ± 2.8	NS
Morphology (% normal)	18.7 ± 4.7	18.4 ± 4.3	NS
Haematological parameter:			
Haemoglobin (mg/dL)	12.2 ± 0.32	14.5 ± 0.36	0.03
White blood cells (103)	6.28 🛨 2.14	7.78 ± 2.14	0.01
Red blood cells (109)	6.68 = 0.56	8.28 ± 0.52	0.01
Platelets (10 ³)	752 ± 118	867 ± 127	0.01
Seminal plasma antioxidants	S		
SOD-like activity (U/mL)	313 ± 16	310 ± 12	NS
Catalase-like activity (U/mL)	37.7 ± 1.6	37.6 ± 1.6	NS

LH, luteinizing hormone; FSH, follicle stimulating hormone; TSH, thyroid stimulating hormone; PRL, prolactin; SOD, superoxide dismutase; NS, not significant.

All first digits .2, .4, .6

All second digits .x8

The probability this happening due to chance is extremely unlikely, If not impossible



Safarinejad et al.

PHYTOTHERAPY RESEARCH *Phytother. Res.* **25**: 508–516 (2011)

From: Paalman, Mark <u>mpaalman@wiley.com</u>

Date: Tuesday, 17 September 2024 at 2:47 am

To: Ben Mol Ben. Mol@monash.edu

Subject: Re: Update from Wiley on Int J Gynecol Obst research integrity cases

Dear Ben,

You are most welcome. I also appreciate your concern regarding the below-mentioned Safarinejad papers. I want to assure you that Wiley has investigated these articles using our standard processes and according to Wiley and COPE guidelines, including evaluation by subject matter experts. Since the proper processes were followed, then in the absence of further new and detailed information you might have on these papers, the investigations will remain closed.

As you will see in the worksheet, we have a number of ongoing investigations across several journals, considering a number of different authors. We also have a large number of other concerns raised to us every week. Each case requires our due diligence and careful evaluation. I will update you periodically as to our progress, using the worksheet and adding articles to it as necessary.



Dr Mark Paalman Senior Manager Publishing Ethics, Wiley

Senior Manager Publishing Ethics, Wiley

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Dr Mark Paalman

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Accepted: 9 October 2017	PF midelines inclu	~~е	weight	height	residence	type
DOI: 10.1111/and.12942		 7	72	150	2	2
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Evaluation of reference values of standard semen parameters in fautile Counties may

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H. Zedan ¹ S.	Ismail ¹ A. Gomaa ¹ R. Saleh ² R. Henkel ³	A. Agarwal ⁴

Andrologia

Edited By: Ralf Henkel

JOURNAL METRICS >

Online ISSN: 1439-0272

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29	37	81	155	2	3	35
149	37	81	155	2	3	35
55	36	67	156	2	2	27
175	36	67	156	2	2	27
51	22	74	157	1	1	28
171	22	74	157	1	1	28
33	54	110	157	1	2	33

153

153

154

154

157

ASSISTED REPRODUCTION

Efficacy of a combined protocol of urinary and recombinant follicle-stimulating hormone used for ovarian stimulation of patients undergoing ICSI cycle

Arianna Pacchiarotti · Cesare Aragona · Renzo Gaglione · Helmy Selman

402 J Assist Reprod Genet (2007) 24:400–405

Tab	le 1	Demo	graphic	data
and	stim	ulation	outcom	e

2	uFSH/rFSH group A	rFSH group B	p value
Patients (n)	58	61	
Mean age (years) ±SD	34.1±2.5	35.1±3.1	NS
Mean BMI±SD	22.6±1.8	23.6±1.7	NS
Mean duration of sterility (years) ±SD	5.1±1.2	4.1±1.4	NS
Primary infertility % (n)	71.9 (41)	74.6 (44)	NS
Tubal factor % (n)	47.4 (27)	44.1 (26)	NS
Male factor % (n)	40.3 (23)	40.6 (24)	NS
Unexplained infertility % (n)	12.3 (7)	15.3 (9)	NS
Duration of stimulation (days)	11.4=2.1	13.1=2.2	NS
Estradiol level on hCG day (pg/ml)	2,056±560	$1,987 \pm 699$	NS
Endometrial thickness on hCG day (mm)	10.8±2.1	11.2±3.1	NS

J Assist Reprod Genet. 2007 Jul 26;24(9):400–405.



NS: not significant

Recruitment June 2005 to March 2006. Submitted 22 December 2006

J Assist Reprod Genet (2007) 24:459-462 DOI 10.1007/s10815-007-9165-2

ORIGINAL PAPERS

The possible role of hyperhomocysteinemia on IVF outcome

Arianna Pacchiarotti · Mohamed A. Mohamed · Giulietta Micara · Antonella Linari · Daniela Tranquilli · Salomè B. Espinola · Cesare Aragona

J Assist	Panrod	Ganat	(2007)	24-45	0 467
J ASSIST	Reprod	Genet	(400/1	24.40	7-404

400

Table 1 Demographic data and stimulation outcom	Table 1	Demographic	data and	stimulation	outcome
---	---------	-------------	----------	-------------	---------

	Study group	Control group	P value
Patients (n)	24	24	NS
Mean age (ys)	35.1±3.5	34.1±3.1	NS
BMI	23.6±1.8	22.6±1.7	NS
Duration of sterility (ys)	2.1±1.2	3.1±1.4	NS
Tubal factor % (n)	54.1% (13)	58.3% (14)	NS
Male factor % (n)	33.3% (8)	33.3%(8)	NS
Unexplained infertility % (n)	12.5% (3)	8.3% (2)	NS
Duration of stimulation (days)	12.4 ± 1.6	13.1=2,1	NS
Estradiol level on HCG day (pg/ml)	2,126±560	$2,065 \pm 699$	NS
Endometrial thickness on HCG day (mm)	9.8±1.1	10.2±1.2	NS
Bias	4.1% (1)	4.1% (1)	NS

NS = not significant

J Assist Reprod Genet. 2007 Sep;24(9):400-5.

Recruitment Ferbuary 2005 to January 2007 Submitted 8 May 2007

Identical number

1-2 digits difference



Officers

Elizabeth Ginsburg, MD President

Robert E. Brannigan, MD President-Elect

Amy Sparks, PhD Vice President

Paula Amato, MD Immediate Past President

Michael A. Thomas, MD Past President

Jessica B. Spencer, MD Secretary/Treasurer

Administration

February 19, 2025

To: Professor Ben Mol, FRANZCOG PhD
Professor of Obstetrics and Gynaecology
Monash University, Monash Medical Centre
246 Clayton Road
Clayton, Victoria 3168, Australia
Email: ben.mol@monash.edu

- Selman H, Pacchiarotti A, El-Danasouri I. Ovarian stimulation protocols based on follicle-stimulating hormone glycosylation pattern: impact on oocyte quality and clinical outcome. Fertil Steril. 2010 Oct;94(5):1782-6.
- Pacchiarotti A, Sbracia M, Frega A, Selman H, Rinaldi L, Pacchiarotti A. Urinary hMG (Menopur) versus recombinant FSH plus recombinant LH (Pergoveris) in IVF: a multicenter, prospective, randomized controlled trial. Fertil Steril. 2010 Nov;94(6):2467-9.

After our review, we requested data for Selman et al. F&S 2010, Pacchiarotti et al. F&S 2010, and Pacchiarotti et al JARG 2007. Dr. Selman recently passed, but co-authors willingly shared the requested data from each study.

Our evaluation of the datasets supplied by the authors suggested that the studies were unique. Moreover, we were able to independently verify the numbers presented in the published tables.

Editor's response

I really have not time for this; the journal gets 80 submissions per week

It exists in all specialties and in every country!

We are working on it, please be patient.

It appears that there was also no central ethics committee in Mansoura University before 2016 and ethics approval was apparently given by the hospital. There might also have been some internal conflicts among high ranking people in the university to make things more complicated (you don't know who to believe and who not).

We cannot keep up with the number of complaints you send us.



Consequences for me:

- My own work has been extensively challenged and investigated
- Accused of being a racist (I am probably the only racist who simply hates all people)
- Complaints at my university (Monash, Aberdeen)
- Complaints at medical regulatory bodies
- Legal threads
- "I am really concerned about your mental health"

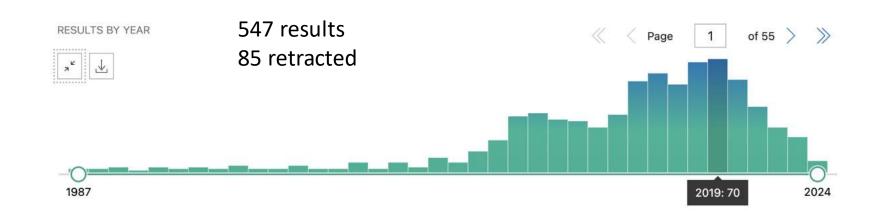
Sincerely,

Agustin Conde-Agudelo, MD, MPH, PhD





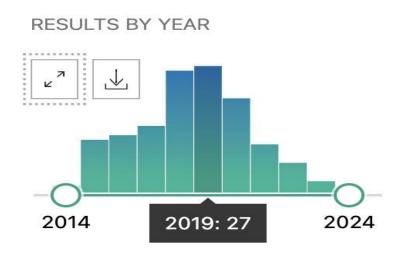
RCTs from departments obstetrics/gynecology (Egypt)



RCTs from departments obstetrics/gynecology (Egypt)

(maged A or sohb A or abbas A or rezk M or torky H)

86 results22 retracted



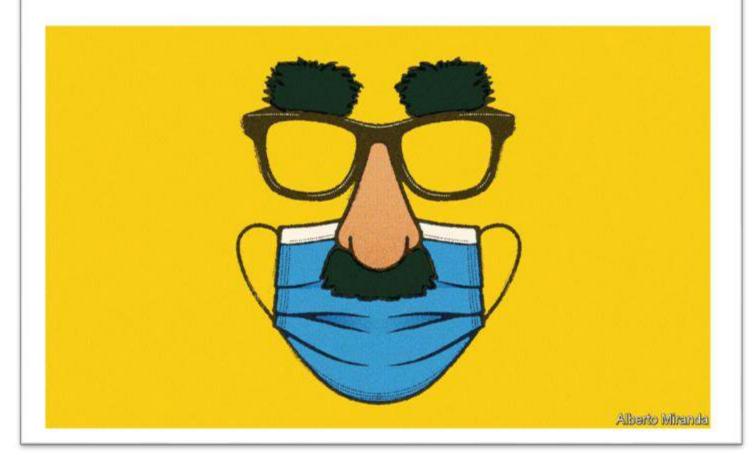
- >250 retracted papers
- >100 expressions of concern



Science & technology | Scientific malpractice

There is a worrying amount of fraud in medical research

And a worrying unwillingness to do anything about it



Science & technology | Scientific malpractice

fraud in medical research

Stanford President Will Resign After There is a wor Report Found Flaws in His Research

The New York Times

willingness to do anything about it







"We need unbiased, politics-free, transparent, evidence-based science in the public interest."



Daihatsu suspends production in Japan after safety test scandal

Toyota subsidiary has admitted falsifying data on some models for more than 30 years



Boeing: How much trouble is the company in?



Endometriosis and associations with risks of adverse pregnancy and perinatal outcomes: a case-control study in Egypt

Ahmed Elsayed Mansor¹, Mahmoud Kotb¹, Ola A. Harb², Walid S. H. Elsayed³, Amany M. Abdallah⁴, Mahmood Ahmed Osman^{5*} and Ahmed Metwally Elkattawy⁶

Table 1 Comparison between the studied groups regarding baseline data

	Endometri- osis group N=25(%)	Control group N=25 (%)	χ²	р
Age [mean ± SD]	30.56 ± 6.31	29.96 ± 3.96	0.818 [¥]	0.414
BMI [mean ± SD]	24.37 ± 3.39	24.58 ± 4.16	-0.401^{*}	0.689
Primipara	16 (64%)	9 (36%)	3.92	0.048*
Pre-pregnancy	5 (5%)	3 (3%)	Fisher	0.721
DM	7 (7%)	6 (6%)	0.082	0.774
HTN				
ART	36 (36%)	12 (12%)	15.789	< 0.001**

^{*}p<0.05 is statistically significant *independent sample t

Table 2 Comparison between the studied groups regarding maternal outcome

Endometriosis groupN=25(%)	Control groupN=25 (%)	Χ²	p
43 (43%)	55 (55%)	2.881	0.09
57 (57%)	45 (45%)		
Median (IQR)	Median (IQR)	Z	P
500(300-857.5)	210(150-310)	-5.448	< 0.001**
980(725-1225)	690(555-780)	-5.6	< 0.001**
7 (4%)	3 (3%)	1.684	0.194
9 (9%)	5(5%)	1.229	0.268
36 (36%)	7 (7%)	24.915	< 0.001**
3 (3%)	0 (0%)	Fisher	0.246
36 (36%)	16 (16%)	10.395	0.001**
	groupN=25(%) 43 (43%) 57 (57%) Median (IQR) 500(300-857.5) 980(725-1225) 7 (4%) 9 (9%) 36 (36%) 3 (3%)	groupN=25(%) 43 (43%) 55 (55%) 57 (57%) Median (IQR) 500(300-857.5) 980(725-1225) 7 (4%) 9 (9%) 3 (3%) 9 (9%) 36 (36%) 7 (7%) 3 (3%) 0 (0%)	groupN=25 (%) groupN=25 (%) 43 (43%) 55 (55%) 2.881 57 (57%) 45 (45%) Median (IQR) Median (IQR) Z 500(300-857.5) 210(150-310) -5.448 980(725-1225) 690(555-780) -5.6 7 (4%) 3 (3%) 1.684 9 (9%) 5(5%) 1.229 36 (36%) 7 (7%) 24.915 3 (3%) 0 (0%) Fisher

^{*}p < 0.05 is statistically significant, *independent sample t test, χ^2 chi square test, Z Mann Whitney test

Check for updates

Endometriosis and associations with risks of adverse pregnancy and perinatal outcomes: a case-control study in Egypt

Ahmed Elsayed Mansor¹, Mahmoud Kotb¹, Ola A. Harb², Walid S. H. Elsayed³, Amany M. Abdallah⁴, Mahmood Ahmed Osman^{5*} and Ahmed Metwally Elkattawy⁶

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DM	7 (7%)	6 (6%)	0.082	0.774
HTN				
ART	36 (36%)	12 (12%)	15.789	< 0.001**

^{*}p < 0.05 is statistically significant *independent sample t

Table 3 Comparison between the studied groups regarding neonatal outcome

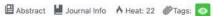
	Endometri- osis group N=100(%)	Control group N=100(%)	χ²	p
GA[mean ± SD]	37.88 ± 1.81	37.96 ± 1.27	-0.367^{*}	0.714
<37 week (preterm)	16 (16%)	11 (11%)	1.07	0.301
Male gender	75 (76%)	72 (72%)	0.231	0.631
Height [mean ± SD]	24.37 ± 3.39	24.58 ± 4.16	-0.949^{*}	0.344
APGAR < 7	8 (8%)	4 (4%)	1.418	0.234
At 1 min	4 (4%)	3 (3%)	Fisher	> 0.999
At 5 min				
Umbilical PH < 7	4 (4%)	0 (0%)	Fisher	0.121
SGA	7 (7%)	3 (3%)	1.684	0.194
LBW	11 (11%)	5 (5%)	2.446	0.118
NICU admission	4(16%)	2(8%)	Fisher	0.667

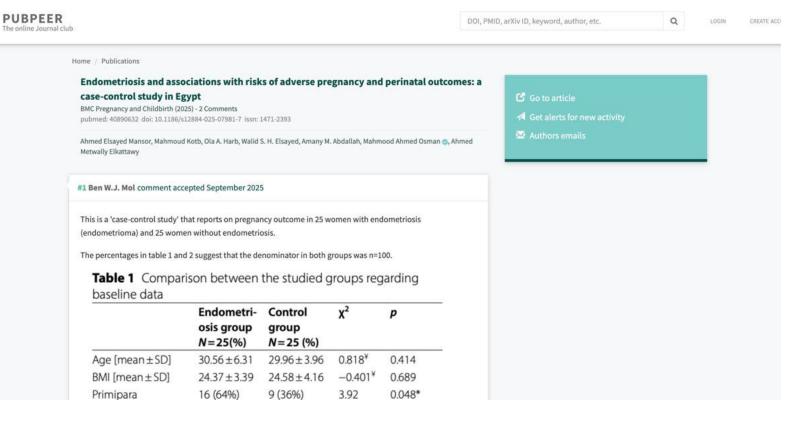
^{*}p<0.05 is statistically significant *independent sample t test χ^2 chi square test Z Mann Whitney test



PMID: 40890632

PATIENTS AND METHODS: This study included 25 pregnant women diagnosed with **endometriosis** and 25 pregnant women without **endometriosis** (control group). Maternal, fetal, and neonatal data were collected and compared between the **endometriosis** group and the contro ...





High-profile ob-gyn accused of duplicating data threatens to sue critic

Sometime last summer, Ben Mol, an obstetrician-gynecology researcher in Australia, and his colleagues were adapting a European guideline on unexplained infertility when they came across a 2006 paper from Maria Luisa Casini, a pharmacologist in Rome, that gave them pause because of results that were not statistically significant.



Data sleuth flags 30 randomized clinical trials from researcher in **Egypt**

Thirty randomized clinical trials involving a researcher in Egypt who has already had six papers retracted show signs of research misconduct and data fabrication, according to the authors of a recent preprint.



Ben Mol

Ben Mol, one of the authors of the preprint and a professor of obstetrics and gynecology at Monash University in Australia, has spent several years investigating the work of Sherief Abd-Elsalam, a hepatologist and gastroen-

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Prof. Ahmed M. Abbas

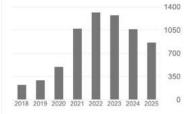
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Original Article

Impact of Metformin on IVF Outcomes in Overweight and Obese Women With Polycystic Ovary Syndrome: A Randomized Double-Blind Controlled Trial

Reproductive Sciences 2019, Vol. 26(10) 1336-1342 © The Author(s) 2018 Article reuse guidelines: sagepub.com/journals-permissions DOI: 10.1177/1933719118765985 journals.sagepub.com/home/rsx

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Osama S. Abdalmageed, MD¹, Tarek A. Farghaly, MD¹, Ahmed A. Abdelaleem, MD¹, Ahmed E. Abdelmagied, MD¹, Mohammed K. Ali, MD², and Ahmed M. Abbas, MD²

The same study, submitted as non-randomized cohort to ASRM

P-415 Wednesday, October 19, 2016

IMPACT OF METFORMIN ON IN VITRO FERTILIZATION OUT-COMES IN OVERWEIGHT AND OBESEPOLYCYSTIC OVARY SYNDROME WOMEN: A PROSPECTIVE COHORT STUDY. O. S. Abdalmageed, T. A. Farghaly, A. M. Ismail, W. W. Hurd. Assiut University IVF Center, Assiut, Egypt; Obstetrics and Gynecology, Assiut University IVF Unit, Assiut, Egypt; Obstetrics and Gynecology, Women's Health Hospital, Assiut, Egypt; Obstetrics and Gynecology, Duke University, Durham, NC.

OBJECTIVE: To determine the impact of short-term metformin therapy on in vitro fertilization-embryo transfer (IVF-ET) outcomes in overweight and obese women with polycystic ovary syndrome (PCOS).

DESIGN: A prospective cohort study

MATERIALS AND METHODS: This prospective cohort study was performed at a University IVF Center. The study population was composed of 102 overweight and obese women (BMI>24 kg/M²) with PCOS who were undergoing their first fresh autologous IVF-ET cycle with intracytoplasmic sperm injection (ICSI). The study population was composed of two groups according to whether or not they received metformin during the IVF cycle treatment (51 patients in each group). The metformin-treated group received metformin (1,000 mg per day orally) starting from onset of ovarian stimulation therapy and continued until the day of the pregnancy test. For women with a positive pregnancy test, the patients continued metformin until the end of the 12th week of gestation. The primary outcome measures were the number of retrieved oocytes, the number of the fertilized oocytes (two pn oocytes), fertilization rate, implantation rate, clinical pregnancy rate and miscarriage rate.

RESULTS: Both the metformin-treated group and the control group were comparable in terms of the age, BMI, duration of infertility, basal FSH, and AFC. The metformin-treated group demonstrated a decreased number of the retrieved oocytes and 2pn oocytes (p < 0.01). There was no difference between the two groups regarding the fertilization rate, implantation rate, multiple pregnancy rates, miscarriage rate or life birth rate (Table2). There were no cases of ovarian hyperstimulation syndrome in either group.

CONCLUSIONS: Short-term administration of Metformin to overweight and obese women with PCOS women decreases the number of oocytes retrieved, but otherwise does not affect IVF outcomes.

References:

1. Consensus on infertility treatment related to polycystic ovary syndrome. Human reproduction. 2008;23(3):462-77.

Outcome of Pregnancy with Metformin on Patient with Recurrent Spontaneous Abortion who Have Abnormal Carbohydrate Metabolism

Zolghadri J. University GYN Ward, Shiraz, Fars, Iran

Study Objective: To determine the incidence of abnormal glucose tolerance test (GTT) in recurrent spontaneous aborters including PCO and non-PCO patients, and also whether metformin would safety reduce the rate of first trimester spontaneous abortions without teratogenisity in patients with abnormal GTT.

Design: Prospective pilot study.

Setting: University related clinic.

Patients: One hundred sixty-two patients with history of recurrent spontaneous abortions and 74 patients with previous term deliveries as control.

Intervention: Performing GTT on all patients administering metformin 1500 mg/day in patients with abnormal GTT.

Measurements and Main Results: Continuation of pregnancy above first trimester. Out of 162 patients with previ-

Zolghadri et al. Pregnancy outcome and metformin in recurrent spontaneous abortion Fertil Steril Vol. 90, No. 3, September 2008

Relationship between abnormal glucose tolerance test and history of previous recurrent miscarriages, and beneficial effect of metformin in these patients: a prospective clinical study

Jaleh Zolghadri, M.D., a Zohreh Tavana, M.D., Talie Kazerooni, M.D., Mahmoud Soveid, M.D., and Marzieh Taghieh, M.D.

First submitted as cohort (metformin versus nothing) but then published as placebo controlled RCT

Journal of Minimally Invasive Gynecology, Vol 12, No 5, September/October Supplement 2005

S116

ous abortions 29 (17.9%) and out of 74 women in control group, 4 (5.4%) patients had abnormal GTT respectively (p=0.017). Also 7 (24.1%) women in abnormal GTT group and 8 (6.1%) in normal GTT group were PCO. Among 29 patients with abnormal GTT, 17 patients were given metformin and 12 women receive nothing during pregnancy. Pregnancy outcome: Three of 17 (17.64%) patients in metformin group and 8 of 12 (66.6%) patients group II (non

metformin group) aborted before 13 weeks respectively (p=0.04). No anomaly was seen in newborn of patients when delivered at term.

Conclusion: It was shown that there is association between abnormal GTT and history of recurrent abortion including PCO and non PCO patients. Also improved outcome of pregnancy was seen with metformin therapy among those with abnormal GTT.

into four groups according to a computer randomization method and medication were given in a double blind method.

- Group I: Patients with PCOS on metformin therapy (4 patients)
- Group II: Patients with PCOS on placebo therapy (3 patients)
- Group III: Patients without PCOS on metformin therapy (13 patients)
- Group IV: Patients without PCOS on placebo therapy (9 patients)

^a Departments of OB & GYN and ^b Medicine, Shiraz Medical University, Shiraz, Iran

Problem

- In large areas of the world with limited research governance large amounts of clinical 'research' is fabricated.
- The publishing system, including failing peer review, is not able to deal with this.
- The academic and clinical communities look, for various reasons, in another direction.

Solutions

- Investigate by the author / institute
- Collaboration between editors/publishers
- Time-lines
- Do not rely on local investigations
- Be transparent
- Investigate actively yourself as a journal (do not wait for the whistleblower)
- Write to journals Install PubPeer



Solutions

- Investigate by the author / institute
- Collaboration between editors/publishers
- Time lines
- Be transparent
- Investigate actively yourself

Realize that the current situation is unacceptable