

PD07-07
IS SPERM MORPHOLOGY ASSESSMENT OF PATIENTS UTILIZING IN VITRO FERTILIZATION USEFUL IN PREDICTING ANEUPLOIDY?

Jorge Rodriguez-Purata*, Joseph Lee, Michael Whitehouse, Lucky Sekhon, Kaitlyn Costigan, Tanmoy Mukherjee, Benjamin Sandler, Alan Copperman, Natan Bar-Chama, New York City, NY

INTRODUCTION AND OBJECTIVES: It is generally accepted that semen quality, as judged by the volume, motility, and morphology of spermatozoa, predicts both in vitro and in vivo fertilization. Kruger et al. demonstrated that microscopic assessment of sperm morphology plays an integral role in evaluating the male. This study aims to determine whether there is a correlation between specimens with extremely low percentages of structurally normal sperm and embryonic aneuploidy in couples that pursue IVF with Comprehensive Chromosomal Screening (CCS).

METHODS: Couples who underwent IVF and utilized aneuploidy screening (preimplantation genetic screening (PGS)) from July 2010 – October 2015 were included. At least 100 sperm in four different areas of the slide were evaluated according to Kruger's strict criteria (Kruger et al: =4%: normal; >4%: abnormal). Female and male partner ages were binned (A: =35; B: (35-38]; C: (38-41]; D: (41-43]; and E: >43). Male age group E was subbinned (a: =43; b: (43-50]; c: (50-55]; d: (55-60]; and e: >60). Aneuploidy rate for each female age group was calculated, with 95% confidence intervals calculated by Clopper-Pearson method. Chi-square and ANOVA were used to test significance, established at p<0.05.

RESULTS: Subjects (n=268) consisted of females (24.6-43.9 yo) with male partners (23.8-62.9 yo) who underwent 288 autologous fresh IVF cycles with PGS. CCS was performed on 1836 embryos, of which 656 were found to be aneuploid. The percentage of male patients with a morphology count >4% was similar between all five male age groups (A: 61.7%, B: 66.2%, C: 59.7%, D: 75.2%, E: 59.7%). When male age group E was subdivided, the proportion of patients with an abnormal morphology count increased with age (a: 36.2%, b: 44.1%, c: 70.4%, d: n/a, e: 100%). Aneuploidy rate was similar between normal and abnormal sperm morphology groups in all five age female groups (Table 1). Additionally, PR, clinical PR and early pregnancy loss rate were similar between groups in each female age group (Table 1).

CONCLUSIONS: No correlation was identified between teratozoospermic specimens and increased incidence of embryonic aneuploidy. Male partners with specimens found to have abnormal Kruger morphology should be reassured that they do not have an increased incidence of producing chromosomally abnormal embryos.

	A		B		C		D		E	
	<4%	>4%	<4%	>4%	<4%	>4%	<4%	>4%	<4%	>4%
Cycles	32	67	29	52	34	51	6	12	1	4
Patient's Age	32.5±2.1	32.1±2.4	36.7±0.8	36.3±1.0	39.4±0.8	39.4±0.8	42.1±0.7	41.7±0.5	43.3±	43.5±0.5
Partner's Age	36.1±5.7	35.2±3.8	39.7±6.7	38.2±3.2	42.5±5.7	42.0±4.2	36.8±4.4	43.7±2.8	44.4±	43.5±1.3
AMH	3.1±1.6	4.1±2.4	2.4±2.2	3.3±3.0	3.2±2.9	3.1±4.0	2.2±2.3	1.7±1.0	1.2±	2.5±
Aneuploidy rate	26.8% (67/250)	28.5% (157/550)	36.4% (56/154)	35.8% (134/374)	45.9% (84/183)	42.7% (99/232)	60.0% (12/20)	69.8% (37/53)	66.7% (2/3)	47.1% (8/17)
Pregnancy Rate	59.4% (19/32)	61.2% (41/67)	72.4% (21/29)	69.2% (36/52)	67.6% (23/34)	68.6% (35/51)	66.7% (4/6)	66.7% (8/12)	0% (0/1)	100% (4/4)
Clinical PR	46.9% (15/32)	53.7% (36/67)	62.1% (18/29)	46.2% (24/52)	55.9% (19/34)	54.9% (28/51)	50% (3/6)	58.3% (7/12)	0% (0/1)	75% (3/4)
Early Pregnancy loss Rate	12.5% (4/32)	14.9% (10/67)	20.7% (6/29)	30.7% (16/52)	23.5% (8/34)	27.5% (14/51)	12.5% (1/6)	8.3% (1/12)	n/a (0/0)	25% (1/4)

Source of Funding: None

PD07-08
CHANGES IN TESTICULAR VOLUME AND FUNCTION AFTER TESTOSTERONE REPLACEMENT VS. RESTORATION: ANALYSIS OF A RANDOMIZED, DOUBLE BLIND, PLACEBO-CONTROLLED TRIAL OF ENCLOMIPHENE CITRATE VS. ANDROGEL™ 1.62% IN MEN WITH SECONDARY HYPOGONADISM

Igor Sorokin*, Charles Welliver, Paul Feustel, Adam Parker, Albany, NY; Jaye Thompson, Greg Fontenot, Ronald Wiehle, The Woodlands, TX; Andrew McCullough, Albany, NY

INTRODUCTION AND OBJECTIVES: Testicular volume (TV) loss and impaired spermatogenesis are frequently observed after exogenous testosterone (T) replacement. For that reason, selective estrogen receptor modulators (SERM) are used to treat hypogonadal infertile men. The TV changes with SERM or exogenous T replacement have not been prospectively studied. Our objective was to investigate changes in testicular volume, male hormones and seminal parameters in men receiving testosterone gel (AndroGel 1.62%, AG) vs. a novel SERM (Enclomiphene citrate, EC) vs. placebo (PBO).

METHODS: This is an IRB approved analysis of data from a randomized, double-blind, placebo-controlled trial on EC vs. AG for treatment of secondary hypogonadism (SHGD). After randomization, all patients had TV measurements performed by prader orchidometer (OM) at baseline and after 3 months of treatment. At selected sites, testicular ultrasounds (US) were also performed. US measurements were repeated 3 times in 3 dimensions and TV was derived using the Lambert formula. Hormone and semen analysis were compared before and after 3 months of treatment.

RESULTS: Of 186 men, 74 had US performed. EC 25 mg dose resulted in a 40% increase in TV by US vs. 8% decrease in AG (p<0.05) and 10% increase in PBO (p<0.05). Similar findings in TV were seen for OM. There was no decrease in sperm concentration after 3 months of EC, while a 50% decrease was observed after AG (p<0.05). AG men who had decreased TV by US or OM experienced higher rates of decreased sperm concentration compared to those who had no loss or increase in TV (70% vs. 38%, respectively, p<0.05). Gonadotropins (GTP) were increased in EC and decreased in AG (p<0.05). Increases in T were comparable in the treatment groups.

CONCLUSIONS: In men with SHGD treated for 3 months, EC resulted in a significant increase in GTP, T, TV and preservation of sperm concentration. AG resulted in a significant increase in T but a decrease in GTP, TV, and total sperm concentration.

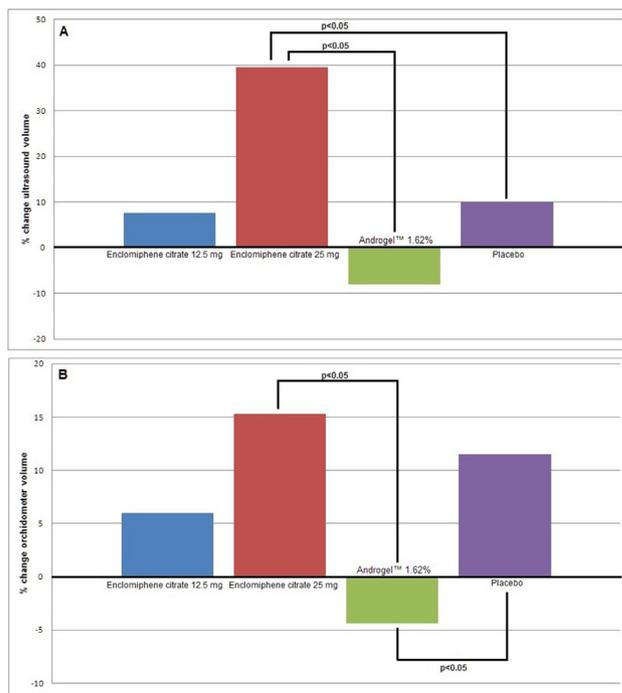


Table – Semen analysis changes between study groups.

Semen parameters	Enclomiphene citrate 12.5mg (n=30)	Enclomiphene citrate 25mg (n=34)	AndrogeITM 1.62% (n=64)	Placebo (n=58)	p (anova)
Baseline sperm concentration, mil	74.52 ± 48.31	102.07 ± 72.92	76.42 ± 56.26	80.99 ± 79.04	ns
End sperm concentration, mil	102.22 ^a ± 91.53	94.53 ^a ± 68.2	33.41 ^a ± 42.44	74.26 ^{abc} ± 49.21	<0.05
% change sperm concentration	32.13 ^a ± 82.88	3.47 ^a ± 60.22	-49.85 ^d ± 56.94	11.64 ^{abc} ± 79.74	<0.05
Baseline sperm count, mil	176.74 ± 102.74	218.05 ± 206.85	159.4 ± 152.89	162.57 ± 137.46	ns
End sperm count, mil	229.36 ^d ± 198.7	216.08 ^d ± 193.26	69.8 ^d ± 88.67	165.98 ^{abc} ± 146.33	<0.05
% change sperm count	28.44 ^d ± 78.08	30.36 ^d ± 98.33	-43.94 ^d ± 68.47	25.3 ^{abc} ± 91.7	<0.05
Baseline semen volume, mL	2.69 ± 1.45	2.47 ± 1.94	2.35 ± 1.78	2.36 ± 1.44	ns
End semen volume, mL	2.5 ± 1.17	2.34 ± 1.29	2.25 ± 1.46	2.44 ± 1.44	ns
% change semen volume	0.63 ± 29.73	24.07 ± 73.09	25.14 ± 107.3	14.34 ± 62.34	ns

mil=million

a - mean difference significant as compared to enclomiphene citrate 12.5 mg by tukey pairwise comparison
 b - mean difference significant as compared to enclomiphene citrate 25 mg by tukey pairwise comparison
 c - mean difference significant as compared to AndrogeITM by tukey pairwise comparison
 d - mean difference significant as compared to placebo by tukey pairwise comparison

Source of Funding: Repros Therapeutics

PD07-09
EFFECT OF ANASTROZOLE ON PROSTATE SPECIFIC ANTIGEN VALUES IN HYPOGONADAL, SUBFERTILE MEN

Lorenzo DiGiorgio*, Robert Paul Bonitz, Newark, NJ; David Shin, Hackensack, NJ

INTRODUCTION AND OBJECTIVES: Anastrozole, an aromatase inhibitor, is used in the empiric treatment of subfertile males to increase endogenous testosterone levels, elevate testosterone-to-estradiol ratios and improve semen parameters. However, controversy exists in regard to the effect on prostate specific antigen (PSA) levels by pharmacological agents which increase testosterone levels. In addition, the effects of anastrozole on the prostate and PSA are unknown. Therefore, we sought to study the effect of the increased endogenous testosterone levels seen with anastrozole, on serum PSA levels in subfertile men.

METHODS: Patients presenting with infertility and diagnosed with hypogonadism were treated with anastrozole for a minimum of three months. Serum follicle stimulating hormone (FSH), luteinizing hormone (LH), total testosterone (T), estradiol (E), testosterone-to-estradiol ratio (T/E), bioavailable testosterone (BT) and PSA levels were recorded at baseline and measured at 3 months and at 5 months during therapy when available. Paired t-test was used to compare baseline and post-treatment laboratory parameters.

RESULTS: A total of 50 male patients were included in the study, mean age 35.9 ± 1.0 (SEM). Mean baseline testosterone was 270.2 ± 11.7 ng/dl, mean T/E ratio was 10.5 ± 0.9 and mean baseline PSA was 0.69 ± 0.07 ng/ml. LH, T/E ratios, total testosterone and bioavailable testosterone levels increased significantly on anastrozole therapy. Slight but insignificant increase in PSA values was observed at 3 months of anastrozole treatment (0.78 ± 0.07, p=0.35). For 33 men, follow up laboratory evaluation was obtained at 5 months of anastrozole therapy and no significant change in PSA levels was observed (0.80 ± 0.89, p = 0.47). No patient had a significant increase in PSA velocity or change in digital rectal examination requiring prostate biopsy.

CONCLUSIONS: The increase in testosterone levels and improved T/E ratios observed with the use of anastrozole in the treatment of hypogonadal, subfertile males does not result in significant increases in PSA levels at 5 months of therapy. Although there does not appear to be any short term adverse effects, further study of the long-term effects of anastrozole on serum PSA is warranted.

Parameter	Baseline	3 months	p value	5 months	p value
FSH (IU/L)	6.01	10.02	<0.01	8.74	0.07
LH (IU/L)	3.02	6.5	<0.01	5.77	0.01
Testosterone (ng)	270.22	467.82	<0.01	470.82	<0.01
Estradiol (pg/mL)	31.74	22.37	<0.01	22.69	0.07
T/E ratio	10.5	26.68	<0.01	30.41	<0.01
Bioavailable Test	165.1	306.44	<0.01	296.97	<0.01
PSA (ng/mL)	0.7	0.79	0.35	0.8	0.47

Source of Funding: none

PD07-10
EFFECT OF BARIATRIC SURGERY ON SEMEN PARAMETERS AND HORMONE PROFILE; A PROSPECTIVE OBSERVATIONAL STUDY.

Ahmad Majzoub*, Cleveland, OH; Mohamed Arafa, Sami Al Said, Gaby Jabbour, Moataz Basha, Doha, Qatar; Edmund Sabanegh, Cleveland, OH; Haitham El Bardisi, Doha, Qatar

INTRODUCTION AND OBJECTIVES: Obesity has become a major health concern with a prevalence rate approaching epidemic states. An inverse relationship between men’s body weight and semen parameters have been observed suggesting a favorable role for weight loss in improving fertility. Bariatric surgery is currently considered the most reliable approach to weight loss in morbidly obese patients. This is considered to be the largest study in determining changes in semen analyses and hormone levels in men before and after bariatric surgery.

METHODS: This is a prospective study of patients undergoing bariatric surgery (Sleeve Gastrectomy), who were investigated with semen analysis and serum hormone tests before and 9-12 months after surgery. Changes in patients weight and body mass index (BMI) were tracked throughout the study period. Patients were divided into three groups according to their initial sperm (Sp) count; azoospermia, oligospermia and normal count group. The median loss of BMI was used as a cutoff to further classify patients according to extent of weight loss.

RESULTS: Fifty patients were invited to participate in this study. Four lost follow up and were excluded. The patients’ preoperative seminal investigations revealed azoospermia in 13 (28.3%), oligospermia in 19 (41.3%) and normal Sp count in 14 (30.4%) (Table 1). Overall, a statistically significant increase in serum testosterone (T) was observed after surgery (p=0.001)(Table 2). Between study groups, the percentage improvement of Sp count was statistically significant in oligospermic men only, while that of serum T was statistically significant in all groups (Figure 1). The extent of weight loss does not appear to significantly affect Sp count and serum T percentage improvement (Figure 2).

CONCLUSIONS: Weight loss appears to have a favourable effect on sperm count and serum testosterone. The effect on sperm count is most notable in oligospermic men.