

Following fresh transfer of the best quality blastocyst, remaining G1 and G2 blastocysts were vitrified on the "Cryotop" device. Clinical pregnancy was defined as the presence of fetal heart motion during a 7 week ultrasound. Data was analyzed by Chi Square with a Pearson's test and considered significant if  $P < 0.05$ .

## RESULTS:

TABLE 1. Implantation rates of day 5 fresh and vitrified blastocysts.

	(n)		(n)		
	Fresh All	G1	Vitrified All	G1	G2
Early Blastocyst	25% (16)		25% (16)	50% (4)	50% (4)
Blastocyst	43.1% (51)	75% (4)	40.4% (47)	48.3% (29)	0% (3) 53.9% (26)
Expanded Blastocyst	48.1% (233)	50.9% (112)	45.5% (121)	42.9% (105)	63.3% (30) 34.7% (75)
Hatching Blastocyst	65.1% (192)	71.7% (138)	47.3% (55)	56.1% (82)	59.5% (42) 52.5% (40)
TOTAL	53.5% (492)	62.6% (254)	43.5% (239)	48.6% (220)	58.7% (75) 43.4% (145)

Grade 1 blastocysts, both fresh and frozen (62.6% and 58.7%), yielded significantly improved implantation rates compared to G2 (43.5% and 43.4%). In the fresh transfer group rates for expanded (48.1%) and hatching blastocysts (65.1%) were also significantly different. Vitrification did not impact on outcomes when comparing both embryo development and grade.

**CONCLUSION:** Whilst blastocyst development and grade on day 5 impacts implantation rates, subsequent cryopreservation by vitrification does not reduce implantation rates. Reliable vitrification methods allow single blastocyst embryo transfer to be successfully implemented for women aged  $< 38$ .

## ENDOMETRIOSIS

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**A NOVEL ORAL GnRH ANTAGONIST, ELAGOLIX, IS EFFECTIVE FOR REDUCING ENDOMETRIOSIS-ASSOCIATED PELVIC PAIN: RESULTS OF A 24-WEEK RANDOMIZED STUDY.** B. Carr, K. Chwailis, R. Jimenez, J. Burke, P. Jiang, C. O'Brien. University of Texas Southwestern Medical Center, Dallas, TX; Abbott Laboratories, Abbott Park, IL; Neurocrine Biosciences, San Diego, CA. **NCT00973973**

**OBJECTIVE:** To evaluate efficacy and safety of elagolix, a novel oral GnRH antagonist, for the treatment of endometriosis-associated pelvic pain.

**DESIGN:** A Phase 2, randomized, double-blind, placebo-controlled, parallel group study of women with surgically confirmed endometriosis, and moderate or severe dysmenorrhea and nonmenstrual pelvic pain (NMPP) at baseline, who received elagolix 150mg q.d. ( $n = 66$ ) or placebo ( $n = 66$ ) for 8 weeks followed by 16 week open-label treatment with elagolix 150mg q.d.

**MATERIALS AND METHODS:** Assessment of dysmenorrhea, NMPP, dyspareunia and endometriosis-related analgesic use was recorded daily. Changes from baseline in the monthly mean (1 month = 4 weeks) of daily pain scores (0-3 scale) and percent of days with analgesic use were summarized and analyzed by ANCOVA.

**RESULTS:** For all assessments, the average reduction from baseline to week 8 was significantly greater with elagolix compared with placebo (dysmenorrhea -1.1 vs -0.4, NMPP -0.5 vs -0.2, dyspareunia -0.6 vs -0.2, percent days with analgesic use -21.6% vs -9.2%,  $P < 0.01$  for all). Additional improvements were observed for elagolix patients during the open-label treatment period; patients who were initially randomized to placebo had comparable improvements by week 24 (dysmenorrhea -1.4 and -1.3, NMPP -0.8 and -0.5, dyspareunia -0.8 and -0.6, percent days with analgesic use -29.2% and -20.6%; elagolix and placebo, respectively). Quality of life (QoL, EHP-5) and patient's global impression of change (PGIC) were significantly improved with elagolix treatment consistent with reductions in pain. Over the 24 week study period, the most commonly occurring adverse events in patients receiving elagolix were nausea, headache, and hot flush, each of which occurred in 9.9% of patients.

**CONCLUSION:** Elagolix treatment was well tolerated and resulted in consistent, sustained reduction in dysmenorrhea and NMPP and improve-

ments in QoL and PGIC in women with moderate to severe endometriosis-associated pelvic pain.

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**PLASMA ADIPOKINES AND ENDOMETRIOSIS RISK: PROSPECTIVE DATA FROM THE NURSES' HEALTH STUDY II (NHS2) COHORT.** D. K. Shah, K. F. Berry, S. A. Missmer. Division of Reproductive Endocrinology and Infertility, Department of Obstetrics, Gynecology, and Reproductive Biology, Brigham and Women's Hospital and Harvard Medical School, Boston, MA; Channing Laboratory, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA; Department of Epidemiology, Harvard School of Public Health, Boston, MA.

**OBJECTIVE:** Case-control studies have demonstrated altered levels of the inflammatory adipokines leptin and adiponectin in plasma and peritoneal fluid of women with endometriosis. It remains unclear whether inflammation results in endometriosis, or whether the presence of endometriosis creates an inflammatory state, or both. We hypothesized that higher leptin levels and lower adiponectin levels would be predictive of subsequent development of endometriosis.

**DESIGN:** Prospective, nested case-control study.

**MATERIALS AND METHODS:** Blood samples were collected from 29,611 women within the prospective NHS2 cohort. Questionnaires were completed at the time of blood collection and biennially thereafter. Leptin and adiponectin were assayed by quantitative sandwich enzyme immunoassays. 350 cases of laparoscopically confirmed endometriosis were risk-set matched 2:1 with 693 controls based on age, race, and infertility status. Relative risks (RR) and 95% confidence intervals (CI) were calculated using conditional logistic regression models adjusting for matching factors.

**RESULTS:** The median time from blood draw to diagnosis of endometriosis was 31 months (interquartile range 13-53 months). Unadjusted analyses suggested increased diagnosis of endometriosis among women in the highest quartile of plasma leptin and the lowest quartile of plasma adiponectin. However, comparing the highest to lowest quartiles after adjusting for body mass index (BMI), there was no significant association between endometriosis and leptin (RR 1.2, 95% CI 0.7-2.0), adiponectin (RR 0.8, 95% CI 0.4-1.3), or the adiponectin:leptin ratio (RR 0.8, 95% CI 0.4-1.3). The data were unchanged when stratified by BMI.

**CONCLUSION:** Plasma leptin and adiponectin did not predict endometriosis when collected prior to disease diagnosis. The altered levels of these adipokines in women with endometriosis may be a result of the disease process rather than an etiologic factor.

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**HYPOTHALAMIC-PITUITARY-ADRENAL RESPONSES ARE ALTERED IN WOMEN WITH DISTURBED SLEEP DUE TO CHRONIC PELVIC PAIN ASSOCIATED WITH ENDOMETRIOSIS.** J. A. L. Gemmill, N. Sinaii, I. Khachikyan, B. Stegmann, G. Chrousos, P. Stratton, J. Segars. Program in Reproductive and Adult Endocrinology, NICHD/NIH, Bethesda, MD; Biostatistics and Clinical Epidemiology Service, CC/NIDR, Bethesda, MD; Department of Obstetrics and Gynecology, University of Iowa, Iowa City, IA.

**OBJECTIVE:** To evaluate whether clinical symptoms accompanying chronic pain were associated with an altered hypothalamic-pituitary-adrenal (HPA) response in women with chronic pelvic pain (CPP) associated with endometriosis (endo).

**DESIGN:** Cohort study.

**MATERIALS AND METHODS:** Healthy volunteers (HV) and women with CPP, aged 18-50, were studied. Women with CPP had symptoms suggesting endo and underwent surgery for diagnosis and treatment. Women completed Duke Health Profile, Endometriosis Quality of Life, and Pelvic Pain questionnaires. Corticotropin-releasing hormone (CRH) was administered in the follicular phase, and adrenocorticotrophic (ACTH) and cortisol (Cort) levels were measured at baseline and at 15, 30, 45 and 60 minutes. ACTH and Cort area under the curve (AUC) were calculated. The association between fatigue, disturbed sleep patterns, body pain, more severe non-