

were not significantly different between treatment groups (66.79, 65.19 and 68.0 for placebo, elagolix 150mg QD and elagolix 200mg BID; respectively). Least square (LS) mean change from baseline at month 3 was significantly higher (i.e. better) for each elagolix dose compared to placebo (5.09, 9.65 and 12.3 for placebo, elagolix 150mg QD and elagolix 200mg BID respectively; each  $p < 0.01$ ). Similar results were observed at month 6 (each  $p < 0.05$ ). Mean index scores were similar at baseline (0.73, 0.72 and 0.75 for placebo, elagolix 150mg QD and elagolix 200mg BID; respectively). LS mean changes from baseline were higher (i.e. better) for each elagolix dose compared to placebo at month 3 (0.06, 0.09 and 0.1 for placebo, elagolix 150mg QD and elagolix 200mg BID respectively; each  $p < 0.01$ ). Similarly, each elagolix dose had higher LS mean changes at month 6 ( $p < 0.05$  for elagolix 200mg BID only). **CONCLUSIONS:** Both doses of elagolix significantly improved health-related quality of life measured by EQ-5D-5L among endometriosis patients

#### PIH26

##### SIMULTANEOUS DEVELOPMENT OF PATIENT-REPORTED OUTCOME MEASURES FOR MASSETER MUSCLE HYPERTROPHY IN AN ASIA POPULATION

Crawford B<sup>1</sup>, Goodman GJ<sup>2</sup>, Kono T<sup>3</sup>, Kim ST<sup>4</sup>, Garcia J<sup>5</sup>

<sup>1</sup>Syneos Health, Tokyo, Japan, <sup>2</sup>Monash University, Clayton, Australia, <sup>3</sup>Tokai University, Tokyo, Japan, <sup>4</sup>Yonsei University, Seoul, Korea, Republic of (South), <sup>5</sup>Allergan plc, Irvine, CA, USA

**OBJECTIVES:** To develop Lower Facial Shape Questionnaire (LFSQ) patient-reported outcome (PRO) measures for masseter muscle hypertrophy (MMH) specific to Asian patients using a simultaneous development approach. The LFSQ assesses symptoms, impacts, and satisfaction associated with MMH and follows guidelines for good research practices established by the US Food and Drug Administration (FDA). **METHODS:** Participants  $\geq 18$  years old with physician-assessed MMH were recruited from Australia, China, Japan, and South Korea. A conceptual framework was developed using literature reviews and participant interviews (concept elicitation [CE]). Concept criteria included frequency and level of bothersomeness, saturation, and clinical relevance. Draft PRO measures were validated for content with cognitive interviews (CIs). All interviews were conducted in local languages. **RESULTS:** The CE population included 59 participants (mean age 38 years [SD=10], 92% female). The most commonly reported symptoms included prominence of the jaw (64%), square shape (58%), and teeth clenching (56%). Other frequently (>30%) reported concepts included asymmetry, teeth grinding, large facial appearance, and jaw pain. Approximately 50% of patients reported psychosocial impacts such as feeling less attractive, self-conscious, and less confident. Saturation was reached for 94% of concepts. Satisfaction items were subsequently based on relevant symptom and impact concepts. Based on CE, the draft LFSQ consisted of 7 items each for symptoms and impacts, and 9 satisfaction items. The CIs included 20 participants (mean age 34 [SD=11.7], 80% female), most of whom indicated that they would not add additional items and who correctly interpreted the instructions; therefore, revisions were minor. **CONCLUSIONS:** The CE and CI results from this study support the content validity of the LFSQ in assessing the symptoms, impacts, and satisfaction of MMH in Asia patients. The psychometric properties of the LFSQ need to be further evaluated to support validity.

#### PIH27

##### THE FATHERS' FEELING OF BEING PREPARED AND THE EXPERIENCE OF DELIVERY

Karácsony I<sup>1</sup>, Kovács Á<sup>1</sup>, Szabó L<sup>2</sup>, Boncz I<sup>2</sup>, Pakai A<sup>3</sup>, Brantmüller É<sup>4</sup>, Ferenczy M<sup>1</sup>, Oláh A<sup>2</sup>

<sup>1</sup>University of Pécs, Szombathely, Hungary, <sup>2</sup>University of Pécs, Pécs, Hungary, <sup>3</sup>University of Pécs, Zalaegerszeg, Hungary, <sup>4</sup>University of Pécs, Kaposvár, Hungary

**OBJECTIVES:** The father's presence is more and more common during the delivery of the baby, moreover it can be considered as a general practice. Our goal was to get to know how the men, who participated in the survey, prepared for the events in the delivery room and what kind of circumstances and factors this affected. **METHODS:** We have chosen 97 men for our quantitative and descriptive research with convenience sampling. We carried out the data collection with a self-made survey in Szombathely and the surrounding villages in 2016. Descriptive statistics with frequency range, Chi2-test ( $p < 0.05$ ) was performed with Microsoft Excel. **RESULTS:** 95 men, the majority of the fathers being present in the delivery room were glad to be part of the events and 92 persons would do that for the next time too. In the majority of the cases, i.e. 88 cases the father's presence in the delivery room resulted from a mutual decision, but we have not found any connection between this fact and the intensity of preparation ( $p > 0.05$ ). The fathers' age and the level of preparation were not interrelated either. The feeling of providing assistance was not different in the stages of labor ( $p > 0.05$ ), and delivery ( $p > 0.05$ ), in case of the fathers who were advised by health professionals and in case of the fathers who were not informed previously. The results show a significant connection between the men, who felt that they were not prepared for the delivery and those who were not calm and felt lost or who were nervous and would have rather left the delivery room ( $p < 0.05$ ). **CONCLUSIONS:** It can be concluded that it is important to inform and advise the fathers before the childbirth since the feeling of being prepared and their previous knowledge affect their experience of the birth positively and it reduces the negative feelings.

#### PIH28

##### DAY-TO-DAY FLUCTUATIONS IN OLDER ADULTS' COGNITIVE FUNCTIONING: MOVING BEYOND SINGLE TIME POINT ASSESSMENTS

Allaire JG<sup>1</sup>, Zhang S<sup>1</sup>, Gamaldo AA<sup>2</sup>

<sup>1</sup>North Carolina State University, Raleigh, NC, USA, <sup>2</sup>Penn State University, University Park, PA, USA

**OBJECTIVES:** Utilizing a daily assessment design, the current study sought to examine the extent to which older adults' cognitive functioning exhibits short-term fluctuation. **METHODS:** The study consisted of 206 community-dwelling older adults with an average age of 73 years (range 60 – 94; SD = 7.00). The sample was comprised of 57% females and was 30% African American. After completing a baseline battery of tests, participants completed a computerized cognitive

battery on eight different occasions within a 2-week period. This battery included measures of processing speed, memory, inductive reasoning, and executive functioning. **RESULTS:** Multilevel modeling results indicated that the amount of variability within participants over 8 occasions was significant and comparable to the variability between participants. Older age, depressive symptomatology, and high stress levels were significantly associated with increased daily variability in cognitive test performance. In contrast, more years of education and better self-rated health was significantly associated with less daily variability in cognitive test performance. **CONCLUSIONS:** The findings from this study suggest that older adults' cognitive functioning from day-to-day is highly variable and that this inconsistency may be associated with a number of psychosocial and health factors. Consequently, assessments of cognition on a single occasion or occasion separated by weeks or months may not be an adequate approach for assessing older adults cognitive functioning.

#### PIH29

##### BENEFITS OF ADENOTONSILLECTOMY IN CHILDREN WITH MILD OBSTRUCTIVE SLEEP APNEA SYNDROME

Buchanan PM<sup>1</sup>, Paruthi S<sup>2</sup>, Mitchell R<sup>3</sup>

<sup>1</sup>Saint Louis University Center for Health Outcomes Research (SLUCOR), Saint Louis, MO, USA,

<sup>2</sup>Saint Louis University, Saint Louis, MO, USA, <sup>3</sup>University of Texas Southwestern Medical Center, Dallas, TX, USA

**OBJECTIVES:** The early treatment of mild obstructive sleep apnea syndrome (OSAS) with adenotonsillectomy (T&A) is controversial. The objectives were to compare changes in validated quality of life (QOL) and symptom measurements among a subset of children with OSAS who were randomized to one of 2 arms, adenotonsillectomy (T&A) or watchful waiting with supportive care (WWSC). **METHODS:** Data from the Childhood Adenotonsillectomy Trial, a multicenter, randomized controlled study of adenotonsillectomy for OSAS were used to evaluate changes in quality of life and symptom improvement. Children aged 5 to <10 years with OSAS were randomized to undergo T&A or WWSC. Mild OSAS was defined to be an apnea-hypopnea index (AHI) < 5. Children underwent polysomnography, and parents completed the Peds QOL inventory, Pediatric Sleep Questionnaire (PSQ), the 18-item OSA QOL and the modified Epworth Sleepiness Scale (ESS) at baseline and at 7 months. Changes in the QOL and symptom surveys were assessed in each arm (paired t-tests) and compared between arms (independent samples t-tests). **RESULTS:** There were 241 children with mild OSAS, half of which (n = 120) received a T&A. There was no difference in treatment group in gender, ethnicity, race, BMI (normal, overweight, obese), tonsil size (0-50% vs 51-100%), and age. T&A patients had a decrease in AHI ( $p < 0.0001$ ), modified ESS ( $p < 0.0001$ ), total OSA QOL ( $p < 0.0001$ ) and total PSQ ( $p < 0.0001$ ). The WWSC patients also saw a change in modified ESS ( $p = 0.02$ ), total OSA QOL ( $p = 0.006$ ) and total PSQ ( $p = 0.04$ ). The changes in the WWSC were not as large as the changes in the T&A group ( $p < 0.001$  for all). **CONCLUSIONS:** In children with mild OSA (AHI < 5), adenotonsillectomy, compared to watchful waiting, resulted in improved quality of life and parent reported symptoms.

#### PIH30

##### FINANCIAL BURDEN OVER TIME IN OLDER ADULTS WITH CANCER, HEART DISEASE, OR DIABETES

Jones SM, Chennupati S, Nguyen T, Fedorenko CR

Fred Hutchinson Cancer Research Center, Seattle, WA, USA

**OBJECTIVES:** The diagnosis of cancer and other diseases can lead to an increase in financial burden. Financial burden negatively affects quality of life and survival and can decrease medication adherence and persistence. Whether financial burden remains stable over time for people with chronic disease is understudied. This study examined the occurrence of patient-reported financial burden in older adults with cancer, heart disease, or diabetes. **METHODS:** Public data use files from the National Health and Aging Trends Study (NHATS) were analyzed. NHATS surveys older adults (65+) yearly and currently has six surveys fielded between 2011 and 2016. We limited the NHATS sample to participants that reported a diagnosis of cancer (n=845), heart disease (n=459), or diabetes (n=554). We also ran analyses on participants that reported only cancer (n=211), heart disease (n=83) or diabetes (n=154) but no other serious chronic conditions. Financial burden was determined by whether participants reported one of the following on each survey: Paying the minimum on credit cards; paying medical bills over time; receive financial help from others; receive food stamps; other help with food; and help with utilities bills. We tested change over time using time series analysis. **RESULTS:** Proportion of people with cancer reporting financial difficulty at each survey ranged between 18% and 24% (11%-20% in those with cancer only). In heart disease, the proportion ranged from 23% to 34% (21%-26% in those with heart disease only). For diabetes, proportion reporting financial difficulty at each survey ranged between 28% and 34% (15% to 27% in those with diabetes only). Financial difficulty prevalence did not change over time (all  $p > 0.15$ ). **CONCLUSIONS:** Financial difficulties did not decrease over time. Disease management for these conditions may need to include screening for financial burden and referral to other services such as financial counseling and copy assistance.

#### PIH31

##### IMPACT OF ELAGOLIX ON QUALITY OF LIFE MEASURED BY SF-12 IN WOMEN WITH HEAVY MENSTRUAL BLEEDING ASSOCIATED WITH UTERINE FIBROIDS: EVIDENCE FROM A PHASE 2B RANDOMIZED TRIAL

Soliman AM<sup>1</sup>, Wang A<sup>1</sup>, Owens CD<sup>1</sup>, Diamond M<sup>2</sup>

<sup>1</sup>AbbVie, North Chicago, IL, USA, <sup>2</sup>Department of Obstetrics and Gynecology, Augusta, GA, USA

**OBJECTIVES:** Evaluate the impact of elagolix, an oral gonadotropin-releasing hormone antagonist, on health-related quality of life (HRQOL) measured by SF-12 in women with uterine fibroid (UF)-related heavy menstrual bleeding (HMB). **METHODS:** Premenopausal women aged 18 to 51 years with HMB (> 80 mL blood loss per menstrual cycle) associated with UF were enrolled in a Phase 2b, randomized, placebo-controlled trial with 6-month treatment of elagolix. Trial