had more comorbid conditions (mean 5.8 vs 2.4 without narcolepsy, $P<0.001$). Common conditions in patients with narcolepsy included respiratory diseases (57% vs 32% without narcolepsy, $P<0.001$) and mental disorders (56% vs 14% without narcolepsy, $P<0.001$). Injury/trauma occurred in nearly twice as many narcolepsy patients (30% vs 17% without narcolepsy, $P<0.001$). Compared to patients without narcolepsy, those with narcolepsy had significantly more mean annual inpatient days (0.71 vs 0.15), emergency department visits (0.51 vs 0.15), outpatient office visits (8.6 vs 2.3), EEG (0.13 vs 0.0053), and brain CT/MRIs (0.26 vs 0.02), all $P<0.001$. Total annual mean healthcare costs were $13,348 higher for narcolepsy patients ($15,797 vs $2,449, $P<0.001$). Medical services accounted for more than half ($8,185) of this cost differential.

Conclusion: In an insured population of pediatric patients, narcolepsy diagnosis was associated with significantly greater comorbidity burden and higher healthcare utilization and costs than in those without narcolepsy.

Support (If Any): Jazz Pharmaceuticals.

0813

SODIUM OXYBATE TREATMENT OF NARCOLEPSY IN PEDIATRIC PATIENTS: LONG-TERM EFFICACY AND SAFETY

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Introduction: Narcolepsy symptom onset primarily begins in childhood/adolescence. Sodium oxybate (SXB) was evaluated as a treatment for narcolepsy in pediatric patients in a placebo-controlled, randomized-withdrawal study with an open label extension. Results of long-term efficacy and safety assessments are reported.

Methods: Children and adolescents with narcolepsy with cataplexy who were on SXB treatment or were SXB-naïve were eligible. After a two-week double-blind, placebo-controlled withdrawal period (DB), participants entered an open-label safety period (OL) for a total study duration of 1 year. Baseline efficacy assessments occurred when participants were on a stable dose of SXB prior to the DB. Change in weekly number of cataplexy attacks was calculated from daily cataplexy diaries. Epworth Sleepiness Scale for Children and Adolescents (ESS-CHAD) was assessed at each visit. Safety evaluations included anxiety (Multidimensional Anxiety Scale for Children 10-item [MASC-10]), depression (Children's Depression Inventory 2nd Edition Self-Report Short Version [CDI 2:SR{S}]) and suicidality (Columbia-Suicide Severity Rating Scale [C-SSRS]) assessments, and treatment-emergent adverse events (TEAEs).

Results: As of the 10 February 2017 datacut: 106 were enrolled; 79 completed ≥6 months and 46 completed 1 year. Efficacy for cataplexy and excessive daytime sleepiness (EDS) was demonstrated after the DB, and was maintained during the OL. The median (Q1, Q3) change from baseline in weekly number of cataplexy attacks was 0.0 (-2.25, 4.17) at study end, with little change throughout. Similarly, among completers, the median (Q1, Q3) change from baseline in ESS-CHAD score was 0.0 (-3.0, 3.0) at study end. No increase of mean T-scores on MASC-10 or CDI 2 was observed. Two serious TEAEs occurred (acute psychosis and suicidal ideation) with both participants endorsing positive responses on the C-SSRS. The most common TEAEs (>10%) were nausea, vomiting, headache, and decreased weight.

Conclusion: SXB demonstrated long-term effectiveness (up to 1 year) in reducing cataplexy and EDS in pediatric patients with narcolepsy. The safety profile was consistent with adult studies and no new safety concerns were identified.

Support (If Any): Jazz Pharmaceuticals.

0814

IMPACT OF MATERNAL VOICE ON SLEEP OF NEONATES IN THE INTENSIVE CARE UNIT

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Introduction: About 10% of U.S. newborns require treatment in a neonatal intensive care unit (NICU). The NICU environment, which differs dramatically from the in utero milieu, could influence the development of newborn sleep patterns. Whether NICU environment has differential impact on sleep for preterm versus term newborns, and whether exposure to the mother's voice can modulate that impact, is unknown.

Methods: Neonates underwent 12-hour, attended polysomnography in the NICU. Their mothers were recorded reading children's books. This recording was randomized to be played continuously during either the first or second 6-hours of the polysomnogram. Sleep-wake stage distributions, entropy, and EEG power were calculated for each 6-hour block. Quantitative sleep measures were regressed on gestational age (GA), with adjustment for neurological examination (Thompson) sores. Data were compared for epochs with, versus without, the recorded maternal voice playing.

Results: For 20 neonates ≥35 weeks gestation at birth, but not 27 born preterm at 33–34 weeks, associations of quantitative sleep measures with increasing GA varied with maternal voice exposure. During the voice recording, among neonates ≥35 weeks gestation, increasing GA was associated with increased percent time awake ($R^2=0.52$, $p<0.001$), increased wakefulness bout duration ($R^2=0.39$, $p=0.003$), decreased overall sleep ($R^2=0.52$, $p<0.001$), decreased REM sleep bouts per hour ($R^2=0.35$, $p=0.004$), and increased sleep-wake entropy ($R^2=0.47$, $p=0.001$). These remained significant after adjusting for Thompson scores (adjusted model $R^2=0.25$ to 0.49, each $p<0.003$). Without the voice recording, none of these associations were significant. EEG power at 2-4Hz and 4-8Hz increased with GA in both age groups ($R^2=0.14$ to 0.47, $p=0.01$ to <0.001); this was not changed by the voice recording. For infants <35 weeks gestation, no other associations emerged between sleep measures and GA or postmenstrual age, during or without the maternal voice recording.

Conclusion: NICU patients born at ≥35 weeks gestation, but not more premature neonates, show sleep-wake patterns that appear to respond increasingly with age to enriched maternal voice exposure. Newborns may become progressively more responsive to their mothers' voice as they approach full term.

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