Polysomnographic Findings in Pediatric Patients With Narcolepsy Type 1 and Narcolepsy Type 2: A Retrospective Review

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INTRODUCTION

- Narcolepsy is a rare, chronic sleep disorder characterized by sleep-wake cycle dysregulation and symptoms that affect patients with narcolepsy throughout the 24-hour day[1-3]
- Symptom onset typically occurs in adolescence or young adulthood; however, patients are usually diagnosed in adulthood[4-6]
  - Both narcolepsy type 1 (NT1) and type 2 (NT2) diagnoses require the presence of excessive daytime sleepiness and sleep-onset rapid eye movement (REM) period(s) (SOREMPs) on a Multiple Sleep Latency Test (MSLT) or nocturnal polysomnogram (PSG)[7]
- As there are few large PSG datasets for children and adolescents with NT1 and NT2, additional data are needed to better characterize this patient population and their sleep characteristics

OBJECTIVE

- To characterize daytime and nighttime sleep features in pediatric patients with NT1 and NT2

METHODS

DATA SOURCE AND PATIENTS

- A retrospective review of registry data from patients at 22 US hospitals between 2009 and 2017 was conducted
- Data were included from patients who:
  - Were aged ≤18 years
  - Were diagnosed with NT1 or NT2
  - Underwent a clinical evaluation and sleep testing with overnight PSG and MSLT

DATA ANALYSIS

- This study was designed for hypothesis generation and was not statistically powered for comparisons between groups
- All data were analyzed descriptively

RESULTS

PATIENT DEMOGRAPHICS AND CLINICAL CHARACTERISTICS

- In total, 471 patients in the Pulse Infoframe registry were identified for inclusion in this analysis (**Table 1**)
- Median (IQR) age at time of diagnosis was 12.0 (8.5-15.0) years
- Patient sex was evenly distributed, and most patients were white/Caucasian (48%) or Black/African American (41%) and non-Hispanic (89%)
- 70% (n=331) of patients had a diagnosis of NT1 and 30% (n=139) had a diagnosis of NT2

TABLE 1: Patient Demographics and Clinical Characteristics

Characteristic	Overall (N=471)
Age at diagnosis, median (IQR), y	12.0 (8.5-15.0)
Sex, n (%)	
Female	224 (48)
Male	247 (52)
Race, n (%)	
American Indian or Alaska Native	1 (<1)
Asian	9 (2)
Black or African American	194 (41)
Caucasian or white	227 (48)
Mixed or >1 race	12 (3)
Pacific Islander	2 (<1)
Other	18 (4)
Unknown	8 (2)
Ethnicity, n (%)	
Hispanic	24 (5)
Not Hispanic	421 (89)
Unknown	26 (6)
Narcolepsy subtype, n (%)[a]	
NT1	331 (70)
NT2	139 (30)

[a]Narcolepsy subtype was unknown for 1 patient.
IQR, interquartile range; NT1, narcolepsy type 1; NT2, narcolepsy type 2.

MSLT

Sleep Latency

- Median (IQR) sleep latency on the MSLT was 2.1 (1.0-3.9) minutes for patients with NT1 and 3.5 (1.7-5.6) minutes for patients with NT2 (**Figure 1**)

FIGURE 1: Sleep Latency on the MSLT

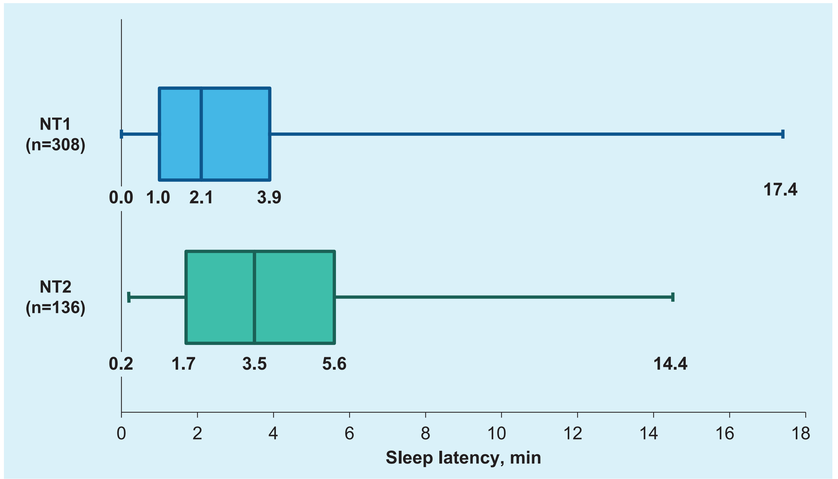


Figure displays median, IQR, and range.
IQR, interquartile range; MSLT, Multiple Sleep Latency Test; NT1, narcolepsy type 1; NT2, narcolepsy type 2.

Number of SOREMPs

- The median (IQR) number of SOREMPs recorded during a 5-minute nap was 4.0 (3.0-4.0) for both patients with NT1 and NT2 (**Figure 2**)

FIGURE 2: Number of SOREMPs on the MSLT

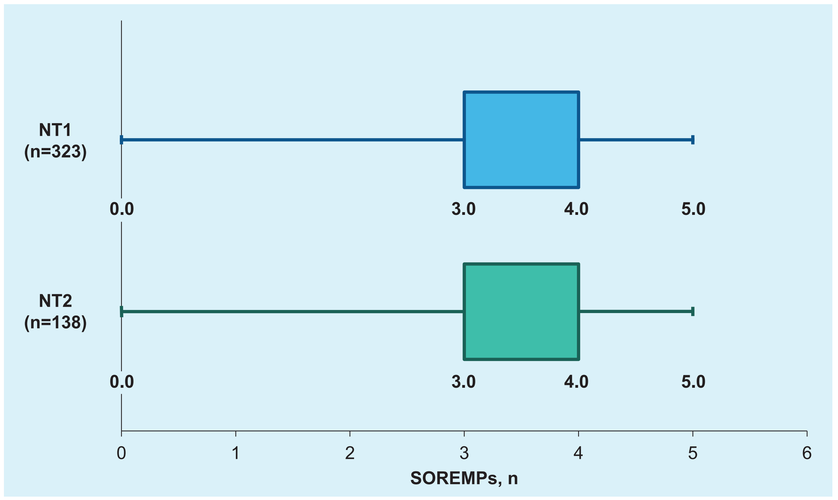


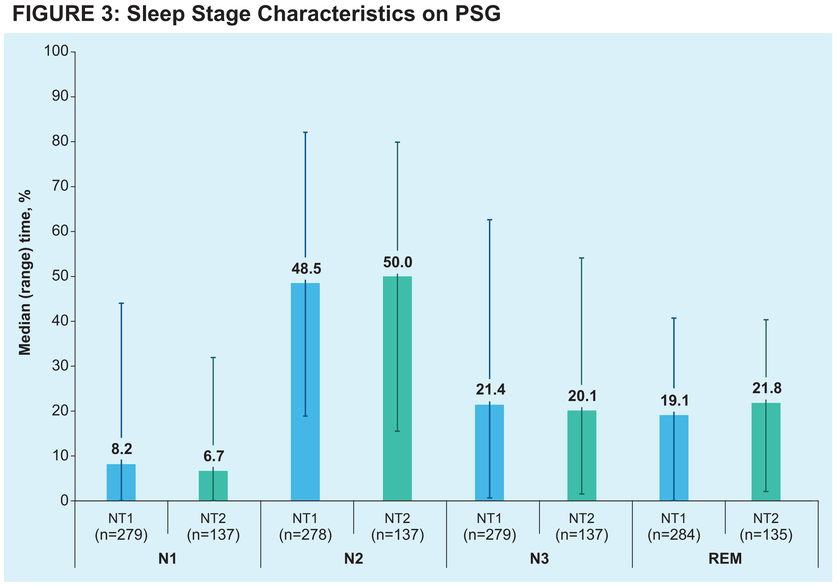
Figure displays median, IQR, and range. Both median and Q3 were 4.0 for patients with NT1 and NT2.
MSLT, Multiple Sleep Latency Test; NT1, narcolepsy type 1; NT2, narcolepsy type 2; SOREMP, sleep-onset rapid eye movement period.

PSG

N1, N2, N3, and REM Sleep

- Patients with NT1 and NT2 had generally similar median (range) percentage of time spent in sleep stages N1, N2, and N3, as well as median (range) REM percentage (**Figure 3**)

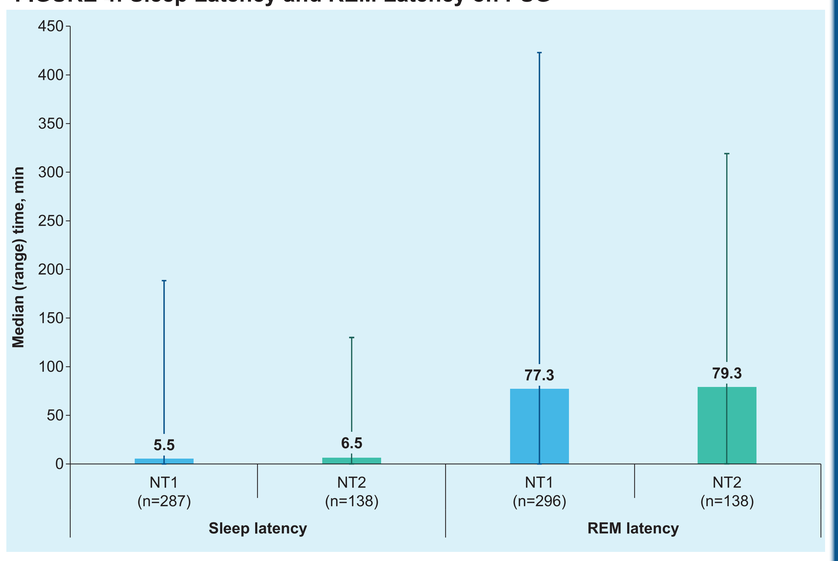
FIGURE 3: Sleep Stage Characteristics on PSG



NT1, narcolepsy type 1; NT2, narcolepsy type 2; PSG, polysomnogram; REM, rapid eye movement.

- Median (range) sleep latency and REM latency time were generally similar between patients with NT1 and NT2 (**Figure 4**)

FIGURE 4: Sleep Latency and REM Latency on PSG

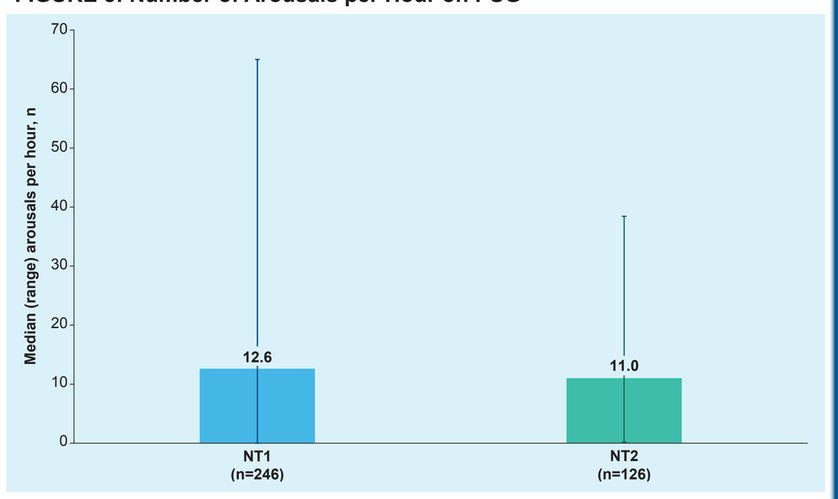


NT1, narcolepsy type 1; NT2, narcolepsy type 2; PSG, polysomnogram; REM, rapid eye movement.

Arousals per Hour

- The median (range) number of arousals per hour was 12.6 (0.0-65.0) for patients with NT1 and 11.0 (0.1-38.4) for patients with NT2 (**Figure 5**)

FIGURE 5: Number of Arousals per Hour on PSG



NT1, narcolepsy type 1; NT2, narcolepsy type 2; PSG, polysomnogram.

- Patients with NT1 and NT2 experienced median (range) 59.7 (0.4-3935.3) and 49.6 (3.4-208.2) minutes of wake after sleep onset, respectively

STUDY LIMITATIONS

- The registry data are from 2009-2017 and do not reflect current treatment practices
- The overall range across metrics was wide for both groups of patients

CONCLUSIONS

- Polysomnographic findings, including sleep-onset latency, SOREMPs, and arousal data from this cohort of pediatric patients were numerically similar across pediatric patients diagnosed with NT1 and NT2
- Future research may focus on additional sleep parameters (eg, microarchitecture) to identify features differentiating NT1 and NT2 in pediatric patients

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DISCLOSURES

SI is affiliated with a hospital that has received funding for research from Avadel Pharmaceuticals and has received research grant funding from Centessa Pharmaceuticals, Harmony Biosciences, Jazz Pharmaceuticals, and the National Institutes of Health.

KM has received grant support from Harmony Biosciences and Jazz Pharmaceuticals and has served as a consultant for Avadel Pharmaceuticals, Alkermes, Inc., Harmony Biosciences, Jazz Pharmaceuticals, Synchronicity Pharma, Takeda Pharmaceutical Co., and Taysha Gene Therapies. She is on the Data and Safety Monitoring Board for Idorsia Pharmaceuticals.

AMM has served as an investigator, consultant, speaker, and/or on advisory boards for Alkermes, Inc., Apnimed, Avadel Pharmaceuticals, Axsome Therapeutics, Eisai, Harmony Biosciences, Jazz Pharmaceuticals, Lilly, Noble Pharmaceuticals, Novartis, and Takeda Pharmaceutical Co.; has received grant funding from Coverys Community Healthcare Foundation, Geisinger Health Plan, Harmony Biosciences, Jazz Pharmaceuticals, the National Institutes of Health, ResMed Foundation, and UCB Pharmaceuticals; is the Chief Executive Officer of DAMM Good Sleep, LLC; and serves as an advisor for FloraWorks, Neura Health, and OpenEvidence.

RB has served as a consultant, speaker, and/or on advisory boards for Avadel Pharmaceuticals, Harmony Biosciences, and Jazz Pharmaceuticals.

JO has served as a consultant to AGB Pharma (Sweden) and on an Independent Safety Monitoring Board for Idorsia Pharmaceuticals.

LEO has served on advisory boards for Avadel Pharmaceuticals, Harmony Biosciences, and Jazz Pharmaceuticals.

GF and **NS** have no competing interests to disclose.

JH and **FHG-S** are employees of Pulse Infoframe.

JG was an employee of Avadel Pharmaceuticals and is a consultant to Alkermes, Inc.

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