A descriptive epidemiological study of pediatric sleep medications in Japan: a health insurance claims-based analysis

EPH168

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BACKGROUNDS

- Insomnia in children can affect not only their physical and mental development but also their cognitive development, which can interfere with their school and social life.
- There are few reports on the actual treatment of pediatric insomnia in Japan.
- In Japan, melatonin is approved for the indication of "Improving sleep-onset difficulties associated with childhood neurodevelopmental disorders," but other sleep medications are used off-label in children.

OBJECTIVES

- The aim of this study was to investigate the prescribing practices of sleep medications for patients aged 0 to 17.

METHODS

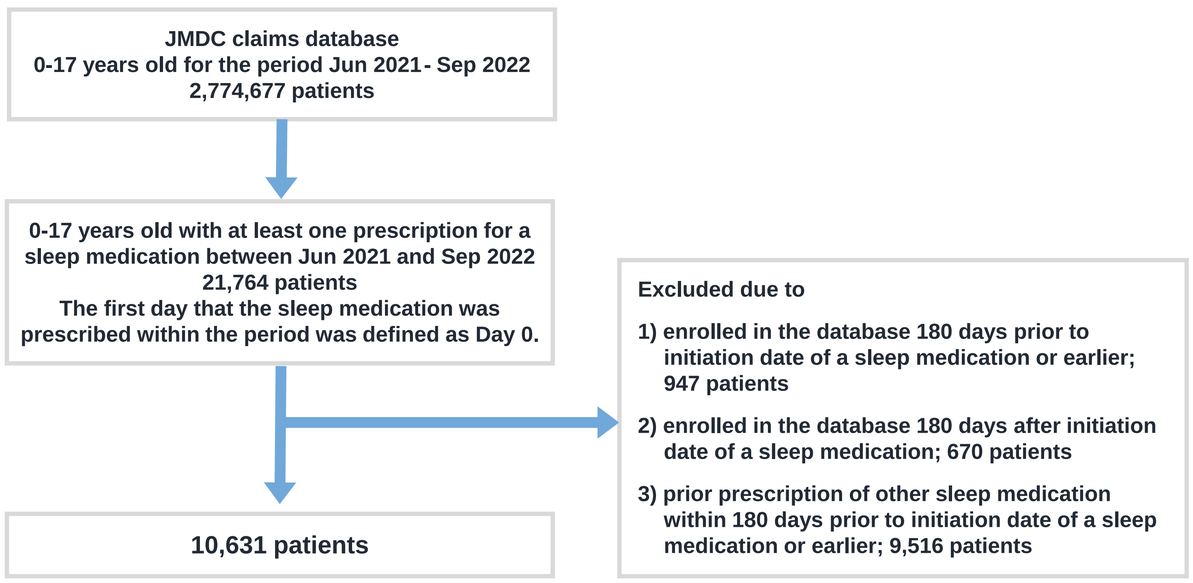
- A large-scale nationwide claims database (from June 2021 to September 2022) provided by JMDC Inc. was used.
- Patients who could be followed for 180 days from the date of their first prescription of sleep medications were included in the analysis.
- The sleep medications were classified into five categories: melatonin receptor agonists (MRA), melatonin, dual orexin receptor antagonists (DORA), Z-drugs and benzodiazepines (BZD). The type, initial dose, and duration of sleep medication prescriptions, patient comorbidities, and concomitant psychotropic medications were analyzed.

Generic name	Class
Brotizolam	BZD
Estazolam	
Flunitrazepam	
Flurazepam	
Haloxazolam	
Lormetazepam	
Nitrazepam	
Quazepam	
Rilmazafone	
Triazolam	

Generic name	Class
Melatonin	Melatonin
Ramelteon	MRA
Eszopiclone	Z-drugs
Zolpidem	
Zopiclone	
Suvorexant	DORA
Lemborexant	

RESULTS

Figure 1. Flow diagram



- Older children were prescribed more often.
- The most common comorbidities within 180 days prior to initiation of sleep medications were insomnia (32.8%), autism spectrum disorder (14.6%), and depression (11.3%) (Table 1).

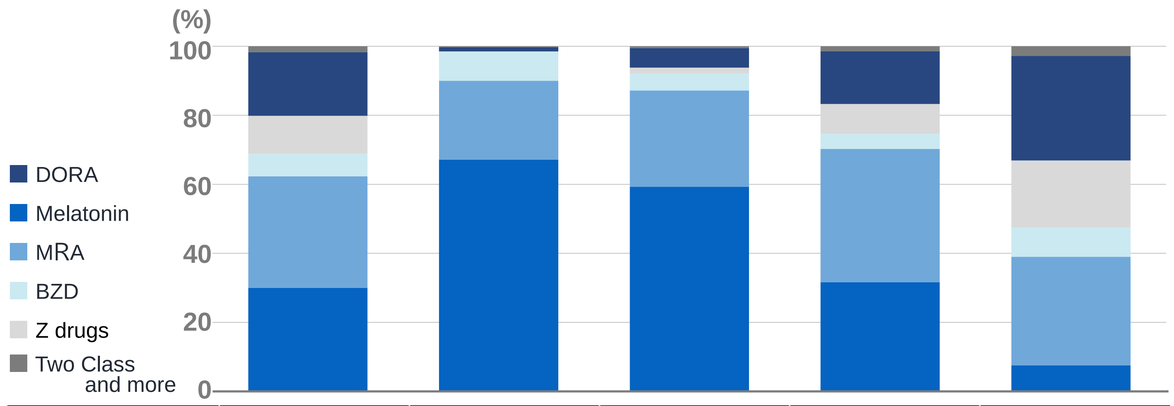
Table 1. Baseline and clinical characteristics

	Overall		0-6 years		7-11 years		12-14 years		15-17 years	
	n=10,631		n=977		n=1,899		n=3,401		n=4,354	
Sex, girl	5,840	(54.9)	355	(36.3)	787	(41.4)	2,061	(60.6)	2,637	(60.6)
Age (years old), mean and SD	13.34	3.85	4.48	1.6	9.84	1.41	13.71	0.81	16.56	0.86
Comorbidities in Days [-180, -1]										
Insomnia	3,490	(32.8)	185	(18.9)	477	(25.1)	1,103	(32.4)	1,725	(39.6)
Autism spectrum disorder	1,557	(14.6)	278	(28.5)	505	(26.6)	485	(14.3)	289	(6.6)
Depression	1,196	(11.3)	2	(0.2)	50	(2.6)	370	(10.9)	774	(17.8)
Asthma	1,007	(9.5)	208	(21.3)	282	(14.8)	285	(8.4)	232	(5.3)
Attention deficit hyperactivity disorder	951	(8.9)	75	(7.7)	404	(21.3)	261	(7.7)	211	(4.8)
Anxiety disorder	951	(8.9)	19	(1.9)	116	(6.1)	296	(8.7)	520	(11.9)
Schizophrenia [a]	597	(5.6)	21	(2.1)	84	(4.4)	183	(5.4)	309	(7.1)
Psychotropic prescribed in Days [-180, -1]										
Antipsychotic drugs	2,480	(23.3)	155	(15.9)	551	(29.0)	782	(23.0)	992	(22.8)
Anxiolytics	1,914	(18.0)	111	(11.4)	144	(7.6)	504	(14.8)	1,155	(26.5)
Antidepressants	1,485	(14.0)	2	(0.2)	94	(4.9)	461	(13.6)	928	(21.3)
Attention deficit hyperactivity disorder drugs	1,241	(11.7)	53	(5.4)	597	(31.4)	360	(10.6)	231	(5.3)
Antiepileptics	791	(7.4)	143	(14.6)	155	(8.2)	191	(5.6)	302	(6.9)

Data are presented as number (percentage) of patients unless otherwise indicated.

- Melatonin was more common in 0-11 years, MRA in 12-14 years, MRA and DORA in 15-17 years (Figure 2).

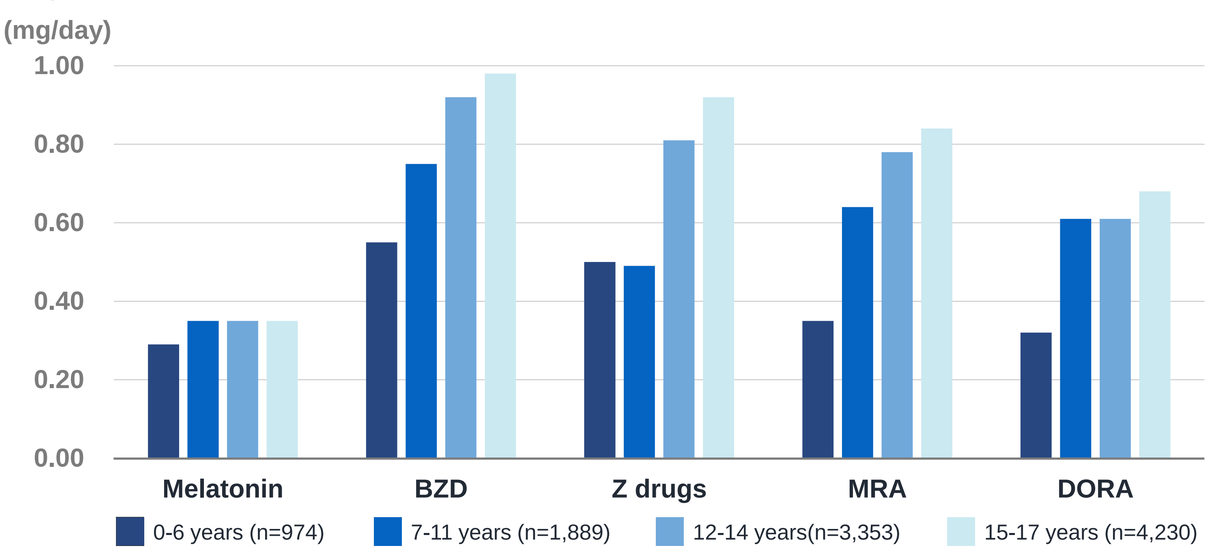
Figure 2. Initial sleep medication



Main drugs	Overall n=10,631		0-6 years n=977		7-11 years n=1,899		12-14 years n=3,401		15-17 years n=4,354	
	n	%	n	%	n	%	n	%	n	%
Ramelteon	3,439	32.3	223	22.8	529	27.9	1,314	38.6	1,373	31.5
Melatonin	3,182	29.9	656	67.1	1,126	59.3	1,074	31.6	326	7.5
Lemborexant	1,471	13.8	4	0.4	77	4.1	393	11.6	997	22.9
Zolpidem	663	6.2	1	0.1	26	1.4	182	5.4	454	10.4
Suvorexant	490	4.6	8	0.8	32	1.7	129	3.8	321	7.4
Eszopiclone	441	4.1	0	0.0	6	0.3	95	2.8	340	7.8
Brotizolam	311	2.9	3	0.3	15	0.8	84	2.5	209	4.8
Nitrazepam	158	1.5	54	5.5	48	2.5	19	0.6	37	0.8

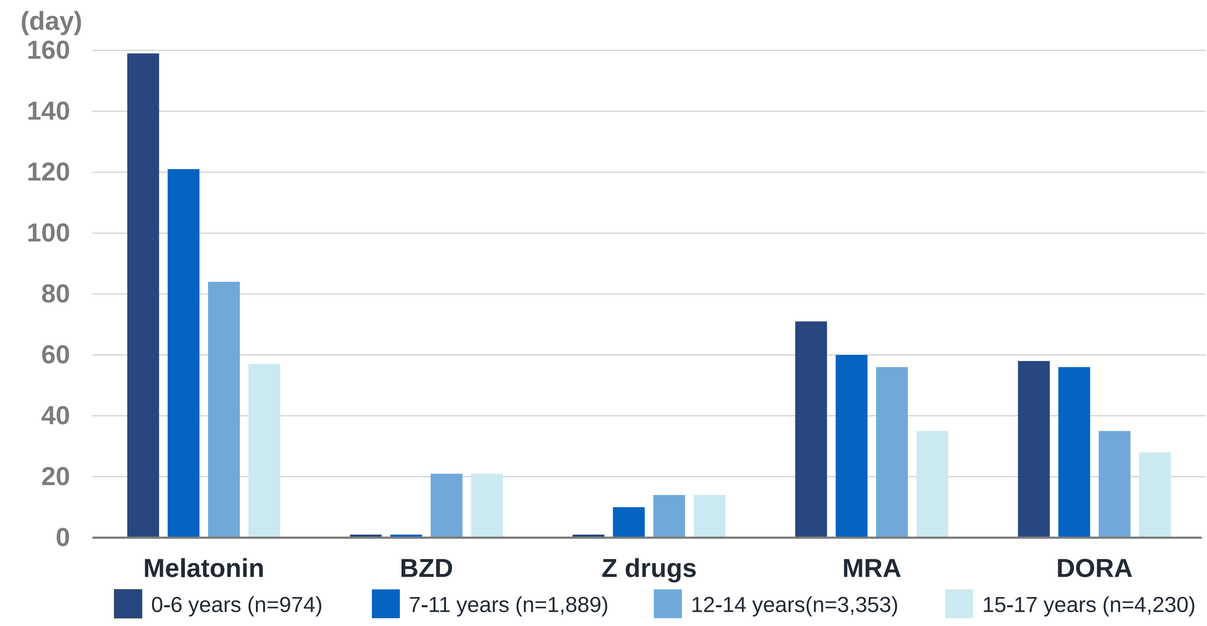
- A trend toward higher initial doses was observed as patient age increased (Figure 3).

Figure 3. Initial dose (Flunitrazepam-equivalent dose)



- For melatonin, MRA, and DORA, the median duration of prescription was higher for younger age groups (Figure 4).

Figure 4. Prescription period, median



CONCLUSION

- This study is the first to describe the use of sleep medications in pediatric patients in Japan.
- Our findings indicate that MRA and melatonin are most frequently used in children, followed by DORA.
- Melatonin was used for the longest period among the categories. Approximately 90% of children prescribed sleep medications had neuropsychiatric comorbidities.