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SHORT REPORT

Sex disparities in clinical features and burden of narcolepsy type 1

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Summary

To investigate potential sex-related differences in patients with narcolepsy type 1, we carried out an analysis of baseline data from 93 women and 89 men with narcolepsy type 1 who participated in the TElemedicine for NARcolepsy (TENAR) trial. The following data were considered: sociodemographics; diagnostic (disease history, polysomnography, orexin, human leukocyte antigen) and clinical features, including sleepiness (Epworth Sleepiness Scale), cataplexy and other narcolepsy symptoms; disease severity (Narcolepsy Severity Scale); pharmacological treatment; depressive symptoms (Beck Depression Inventory); and self-reported relevance of eight narcolepsy-related issues. We found that, compared with men, significantly more women reported automatic behaviours (55.4% versus 40%) and had higher Epworth Sleepiness Scale (median 10 versus 9) and Beck Depression Inventory scores (median 10.5 versus 5), and there was a trend for a higher Narcolepsy Severity Scale total score in women (median 19 versus 18, $p = 0.057$). More women than men were officially recognized as having a disability (38% versus 22.5%) and considered 5/8 narcolepsy-related issues investigated as a relevant problem. More severe sleepiness and a greater narcolepsy-related burden in women could mirror sex differences present in the general population, or may be related to suboptimal management of narcolepsy type 1 or to more severe depressive symptoms in women. Future studies and guidelines should address these aspects.

KEYWORDS
depression, gender, impairment, narcolepsy, sex, sleepiness

1 | INTRODUCTION

Recent studies on female mouse models of narcolepsy with cataplexy have suggested the existence of relevant sex-related differences in narcolepsy, especially concerning an earlier onset and more severe cataplexy (Coffey et al., 2021; Piilgaard et al., 2022; Sun et al., 2022). Surprisingly, potential sex-related differences in clinical presentation have been poorly studied in patients with narcolepsy type 1 (NT1).

Sparse data suggested that women with narcolepsy, compared with men, may have a longer diagnostic delay, shorter sleep latency in the Multiple Sleep Latencies Test (MSLT) and a higher Beck Depression Inventory (BDI) score (Jara et al., 2011; Luca et al., 2013; Won et al., 2014) and, in one study reporting data from newly diagnosed,

untreated patients, women reported higher occurrences of cataplexy (Won et al., 2014).

A frequent limitation of previous studies is that patients with NT1 were rarely distinguished from those with type 2 narcolepsy, and only a few studies have systematically evaluated sex differences in patients with a confirmed diagnosis of NT1 as defined with the current criteria (American Academy of Sleep Medicine, 2014). We aim to contribute to fill this gap by comparing narcolepsy-related features in female and male patients with a definite diagnosis of NT1.

2 | METHODS

The study design was cross-sectional. We carried out an analysis of baseline data from 93 women and 89 men with NT1 (mean age of 34.2 and 33.9 years, respectively) who participated in the TElemedicine for NARcolepsy (TENAR) randomized–controlled trial (Ingravallo et al., 2020). Briefly, the TENAR trial was an open, parallel, two-arm, 12-month randomized–controlled trial with the aim of demonstrating the non-inferiority, with regard to excessive daytime sleepiness (EDS) control, of multidisciplinary care via tele-visit compared with standard in-person care for patients with narcolepsy. Adolescents (≥ 14 years old) and adults diagnosed with narcolepsy (American Academy of Sleep Medicine, 2014) who attended the Narcolepsy Center of the IRCCS Istituto delle Scienze Neurologiche in Bologna, Italy, from July 2020 to October 2021, were invited to participate. Of the 223 participants deemed eligible for inclusion, 208 agreed to be included and underwent the baseline visit; 189 participants had NT1 and were considered for the present study.

The following data were analysed.

- Patients' characteristics at diagnosis, including age at onset, age at diagnosis, diagnostic delay, disease duration, MSLT results (mean sleep latency, number of sleep-onset rapid eye movement periods [SOREMPs]), cerebrospinal fluid hypocretin 1/orexin A level (CSF-hcrt1), human leukocytes antigen (HLA) status.
- Sociodemographic features at study enrollment (baseline), including education, relationship/marital status, occupational status, official recognition of disability.
- Clinical features at baseline, including sleepiness (Epworth Sleepiness Scale, ESS), frequency and duration of cataplexy attacks, occurrence of other narcolepsy symptoms (hypnagogic hallucinations, sleep paralysis, disrupted nocturnal sleep, automatic behaviours), disease severity (Narcolepsy Severity Scale, NSS), pharmacological treatment for narcolepsy, depressive symptoms (BDI), and body mass index (BMI).
- Whether (yes/no) eight narcolepsy-related issues (sleepiness, sleep attacks, cataplexy, concentration difficulties, memory problems, maintaining work pace, achieving goals, relationships with others) were considered a relevant problem by the patients. These issues were selected by the research team based on the literature, and from a questionnaire on the impact of narcolepsy in the school environment that was developed in collaboration with patients, who suggested including some of these issues (unpublished data).

In the descriptive analysis, data were presented as median and interquartile range (IQR) for continuous variables, and with absolute (*n*) and relative (%) frequency for categorical variables. Differences between female and male patients regarding sociodemographic, diagnostic and clinical features were evaluated with Mann–Whitney test or Chi-square test. A p-value < 0.05 was considered significant. Statistical analyses were performed using Stata SE 14.2.

3 | RESULTS

Table 1 shows patients' characteristics at time of diagnosis; these were comparable between the two sexes.

With regard to baseline features, reported in Table 2, women more often had an official recognition of disability status compared with men (38% versus 22.5%), were significantly more likely to report automatic behaviours (55.4% versus 40%) and had higher ESS scores (median 10 versus 9). Regarding the NSS, there was a trend for a higher total score in women (median 19 versus 18, $p = 0.057$), who had higher NSS sub-scores for sleepiness and "disturbed nighttime sleep". Women also had higher BDI scores (median 10.5 versus 5) and 37.1% of women versus 15.9% of men had clinically significant depressive symptoms (i.e. BDI > 13), with 15.7% of women showing mild depression, 20% moderate depression and 1.4% severe depression, versus 9.5%, 4.8% and 1.6% of men, respectively ($p = 0.028$).

Finally, women had a significantly lower BMI (24 versus 26.8) than men, and more frequently considered all narcolepsy-related issues investigated as relevant problems, excluding cataplexy, memory problems, and problems with others (Figure 1).

No other significant differences were found.

4 | DISCUSSION

This study aimed to investigate potential sex-related differences in a well-characterized cohort of 182 patients with NT1. We did not find differences either in disease history and laboratory findings at diagnosis, or in frequency and duration of cataplexy attacks and prescribed pharmacological treatment for narcolepsy. On the other hand, compared with men, women were more likely to report automatic behaviours, greater sleepiness and disrupted nocturnal sleep; they were more often officially recognized as having a disability, and more often considered several EDS-related problems relevant. Women also reported more depressive symptoms, a finding not related to a potential confounder role of BMI (lower than that of men).

Concerning disease history and laboratory findings at diagnosis, in the TENAR population we did not find the delayed diagnosis and higher sleep propensity with more SOREMPs in the MSLT in women that were reported by Won et al. in a population of 109 younger patients affected by narcolepsy with and without cataplexy (Won et al., 2014). Nor did female and male patients with NT1 significantly differ regarding diagnostic delay in the large population from the European Narcolepsy Network—EU-NN, with the female sex providing only a minimal

TABLE 1 Patients' characteristics at diagnosis.

	Women ($n = 93$) *n* (%) or median (IQR)	Men ($n = 89$) *n* (%) or median (IQR)	*p*
Age at onset (years)	14 (10–24.5)	15 (10–22)	0.990
Age at diagnosis (years)	21 (13.5–38.5)	21 (13–33)	0.582
Diagnostic delay (years)	4 (1.5–11)	4 (1–10)	0.678
Disease duration (years)	12 (7–21.5)	11 (8–24)	0.575
MSLT—mean sleep latency (min)	2.2 (1.3–4.1)	2.4 (1.5–4.1)	0.456
MSLT—number of SOREMPs	5 (4–5)	4 (3–5)	0.295
CSF orexin (pg ml^{-1})	11.1 (0–38.9)	19.6 (0–56.2)	0.353
HLA-DQB1×06:02 positive*	75 (97.4)	68 (94.4)	0.359

Note: Data on HLA typing were available for 77 women and 72 men only.
Abbreviations: CSF, cerebrospinal fluid; IQR, interquartile range; MSLT, Multiple Sleep Latency Test; SOREMPs, sleep-onset rapid eye movement periods.

contribution in predictive multivariable models (Zhang et al., 2022). Our findings also suggest that previous reporting on sex-related differences in cataplexy occurrence, frequency and impact in mouse models (seldomly in untreated patients with narcolepsy) should be translated with caution to the clinical population, and call for further observations.

On the other hand, in our cohort, women reported more EDS, disrupted nocturnal sleep and EDS-related problems than men, despite the lack of differences in the pharmacological treatment for narcolepsy.

We may hypothesize that several conditions concur in enhancing EDS in women with NT1. EDS is common in women, with a significantly higher ESS score for female subjects until the 4th decade of life, and is associated with a combination of lifestyle, health (including hormonal and circadian rhythm factors) and sociodemographic factors (including education, disability and psychological distress; Baker et al., 2009; Boyes et al., 2017). Moreover, some studies suggest that women may be more sensitive to sleepy feelings or are more willing than men to report perceived daytime sleepiness (Kim & Young, 2005).

The burden of EDS in women with NT1 could also be exacerbated by social or family conditions. For instance, in Italy, as in many other European countries, women still bear a greater load in family life (household roles, raising children, family caregiving), and therefore they may have less opportunity to rest or follow sleep hygiene recommendations. It may also be possible that, because most of the women included were of child-bearing age, they may tend to take less medication than prescribed (Barker et al., 2020).

Finally, the greater degree of depressive symptoms reported by women may worsen quality of sleep and perception of sleepiness and of EDS-related problems. While the reciprocal relationship between EDS and depressive symptoms is well known (Konjarski et al., 2018), longitudinal studies are needed to test this latter hypothesis. Recent findings concerning patients with narcolepsy and idiopathic hypersomnia showed that in women, depression, anxiety, fatigue and sleep inertia prevail, suggesting the need to dedicate more attention to pathophysiological mechanisms and associations of these factors, particularly in women (Nevsimalova et al., 2022).

On the other hand, we did not ask patients whether they were recognized as having a disability for narcolepsy only. Future studies should also include information regarding disability history, and other information needed to better understand the relationship between narcolepsy and disability (e.g. employment status before the diagnosis, effect of medication, and coping in terms of acceptance of the disease and the medication), as well as recent motherhood/fatherhood, breastfeeding period, responsibilities in care of children or as a caregiver, and any personal or work support received.

Regarding study limitations, it should be considered that the population analysed was mainly composed of young adults with a long-standing history of NT1, routinely attending follow-up visits at the Outpatients Clinic for Narcolepsy. Almost all patients were prescribed one or more medications registered for narcolepsy, Italian narcolepsy patients receive free access to all approved specific medications, which are provided for free by the National Health Service, and are educated to schedule naps and to follow sleep hygiene with the aim of reaching good EDS control. Therefore, data cannot be generalized to all patients with NT1. Moreover, some evidence of differential item functioning (i.e. different psychometric properties of an item in different groups of respondents) with regard to sex for at least one ESS item (e.g. "sitting inactive in a public meeting") and different sex-based effects of age on ESS scores have been reported (Ulander et al., 2021), and we used a non-validated question to investigate the relevance of the eight narcolepsy-related issues. Finally, other factors, including medications, may have an influence on the results. However, the consistent findings we found in several different measures of subjective sleepiness and EDS-related problems strongly support our results beyond possible semantic/psychometric inconsistencies. Moreover, the lack of differences concerning cataplexy and other NT1-associated symptoms such as hallucinations and sleep paralyses made the hypothesis of a reporting bias on the part of women, with an overestimation of symptoms and burden, unlikely. Even if the results of the scales and questionnaires might have been influenced by the ceiling effect and habituation after filling them out for a few years, as there were no sex differences in disease duration and treatment the ceiling effect and habituation cannot explain the differences found between the two sexes.

In conclusion, this report highlights possible sex disparities in clinical features and NT1-related burden. Awareness of these differences on the part of clinicians and researchers is important, as is the need for more consideration regarding EDS and depressive symptoms in women with NT1, also in light of their work and non-work responsibilities.

TABLE 2 Patients' sociodemographic and clinical features at baseline.

	Women ($n = 93$) *n* (%) or median (IQR)	Men ($n = 89$) *n* (%) or median (IQR)	*p*
Age (years)	29 (20–46)	30 (21–45)	0.925
Education			
Elementary/middle school	33 (35.5)	28 (31.5)	0.630
High school	46 (49.5)	43 (48.3)	
Higher education	14 (15.0)	18 (20.2)	
Had a partner	42 (45.2)	34 (38.2)	0.341
Had children	31 (33)	24 (27)	0.350
Number of children	2 (1–2)	2 (2–2)	0.152
Occupational status			
Worker	38 (40.9)	47 (52.8)	0.376
Student	32 (34.4)	26 (29.2)	
Homemaker	2 (2.2)	0 (0)	
Retired	7 (7.5)	6 (6.7)	
Unemployed	14 (15.0)	10 (11.3)	
Part-time work schedule[a]	14 (36.8)	9 (19.2)	0.068
Officially recognized as disabled person	35 (38.0)	20 (22.5)	0.023
Epworth Sleepiness Scale score	10 (8–14)	9 (6–12)	0.043
Cataplexy frequency			
< 1 per year	15 (17.2)	17 (20.7)	0.345
1 per year–1 per month	18 (20.7)	19 (23.2)	
1 per month–1 per week	18 (20.7)	18 (21.9)	
1 per week–1 per day	27 (31)	26 (31.7)	
>1 per day	9 (10.3)	2 (2.4)	
Cataplexy duration			
< 10 s	77 (89.5)	74 (92.5)	0.370
10 s–2 min	9 (10.5)	5 (6.3)	
2–10 min	0 (0)	1 (1.3)	
Other narcolepsy symptoms			
Hypnagogic hallucinations	54 (58.1)	47 (52.8)	0.476
Sleep paralysis	47 (50.5)	46 (51.7)	0.877
Disrupted nocturnal sleep	32 (34.4)	22 (24.7)	0.153
Automatic behaviours	53 (55.4)	36 (40.0)	0.044
Narcolepsy Severity Scale (total score)	19 (13–31.5)	18 (13–24)	0.057
Sleepiness	11 (8–15)	10 (7–14)	0.050
Cataplexy	6 (2–8)	5 (2–7)	0.391
Hallucinations	1 (0–5)	0 (0–3)	0.159
Sleep paralysis	0 (1.5–4)	0 (0–3)	0.354
Disturbed nighttime sleep	1 (1–2)	0 (0–1)	0.007
Beck Depression Inventory score	10.5 (5–17)	5 (2–10)	< 0.001
BMI	24 (21–29.7)	26.8 (23.8–31.1)	0.004
Treatment for narcolepsy			
Modafinil	34 (42.5)	42 (51.2)	0.266
Sodium oxybate	60 (75.0)	61 (74.4)	0.929
Pitolisant	11 (13.8)	13 (15.9)	0.706
Venlafaxine	28 (35.0)	20 (24.4)	0.139
No pharmacological treatment	13 (14)	7 (7.9)	0.187

TABLE 2 (Continued)

	Women ($n = 93$) *n* (%) or median (IQR)	Men ($n = 89$) *n* (%) or median (IQR)	*p*
Number of drugs for narcolepsy			
0	13 (14)	7 (7.9)	0.473
1	36 (38.7)	36 (40.4)	
2	35 (37.6)	39 (43.8)	
3	9 (9.7)	6 (6.7)	
4	0 (0)	1 (1.1)	

Abbreviations: BMI, body mass index; IQR, interquartile range.
[a]The rate was calculated considering only working patients.

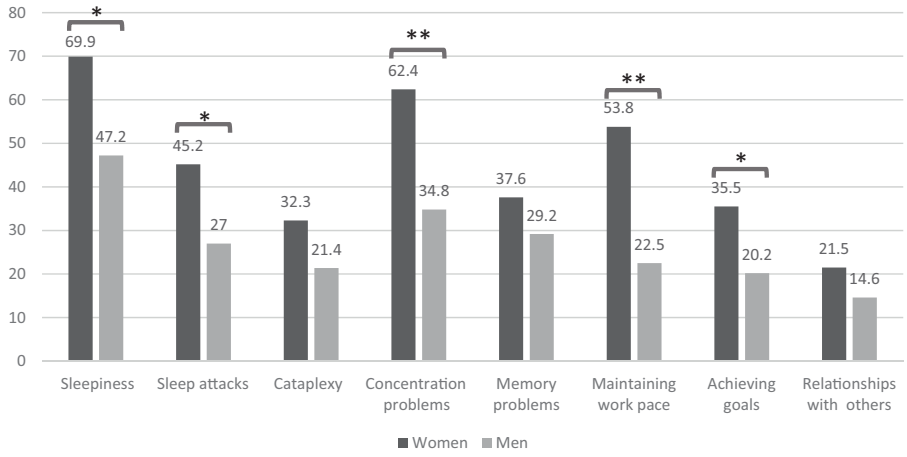

FIGURE 1 Percentage of participants who considered the narcolepsy-related issues investigated a relevant problem: comparisons between female and male patients (*$p < 0.05$; **$p < 0.001$).

Due to the study limitations, and its cross-sectional design, these results should be considered as preliminary. Ad hoc designed studies are needed to investigate sex- and gender-related differences in patients with narcolepsy, and their effect on objective and subjective sleep measures. These aspects should be addressed by, and included in, future clinical practice guidelines.

Finally, only a minority of patients had a partner and at most a third of them had children, without significant differences between women and men, but the median young age of the sample may prevent possible sex-related differences from being apparent. However, the question of how narcolepsy affects personal life, including childbearing, needs more investigation, possibly by adopting a mixed method study including quantitative and qualitative data. This is even more important in the years to come, as new drugs for narcolepsy have been or will be approved.

CLINICAL TRIAL REGISTRATION STATEMENT

The TENAR trial (number 121/2018/SPER/AUSLBO) is registered on ClinicalTrials.gov (Identifier: NCT04316286).

PATIENT CONSENT STATEMENT

Written informed consent was obtained from all participants.

AUTHOR CONTRIBUTIONS

Francesca Ingravallo: Conceptualization; funding acquisition; investigation; writing – original draft; methodology; supervision; resources; project administration. **Chiara Bassi:** Investigation; writing – original draft; visualization; validation; data curation; methodology. **Corrado Zenesini:** Conceptualization; writing – original draft; validation; methodology; software; formal analysis; data curation. **Luca Vignatelli:** Conceptualization; investigation; funding acquisition; methodology; validation; writing – review and editing; project administration; resources. **Uberto Pagotto:** Conceptualization; funding acquisition; methodology; writing – review and editing; project administration; supervision; resources. **Fabio Pizza:** Conceptualization; investigation; funding acquisition; methodology; writing – review and editing; project administration; supervision; resources. **Giuseppe Plazzi:** Conceptualization; funding acquisition; methodology; writing – review and editing; project administration; supervision; resources.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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