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## OBJECTIVES

- Increased life expectancy of the general population has been accompanied by increased prevalence of chronic and degenerative diseases needing long-term care. Among those, dementias impose a substantial burden on healthcare systems, especially on families and caregivers.
- To estimate the **socio-economic burden** of **Alzheimer's Disease (AD)** in data-scarce Italy, focusing on healthcare resource use, productivity loss and quality of life (QoL) of patients and caregivers.

## METHODS

- This is an observational, multicentre, cross-sectional study running across seven Italian centres for AD management from April 2023.
- The study enrolled adult participants (aged 50 years or older) who had been diagnosed with AD or Mild Cognitive Impairment (MCI) for at least 3 months and who visited participating centres during the enrollment period. Enrollment occurred sequentially, according with patients' routine six-month follow-up visits. Participation was voluntary, so only individuals providing informed consent were included.
- Participants were enrolled in relation to disease severity measured using the Mini-Mental State Examination (MMSE) Scale. The study planned to enroll 70 subjects for each MMSE class defined, for a total of 280 subjects. The findings here reported refer to 212 patients, representing 76% of the overall sample.



→ - Disease severity +

- Clinical and demographic data, including disease severity, healthcare services use, loss of productivity in the last three months and QoL for patients and caregivers were collected through questionnaire. The three-month time frame was selected in accordance with previous studies demonstrating effectiveness of such an interval for estimating costs associated with neurodegenerative diseases. Moreover, short timeframe reduces risk of recall bias. Questionnaires were completed by patients or their caregivers, with the assistance of the attending physician as needed.
- Disease severity was investigated using different instruments each focusing on distinct aspects: the "Activities of Daily Living (ADL)" and the "Instrumental Activities of Daily Living (IADL)" questionnaires and the "Neuropsychiatric Inventory Questionnaire (NPI-Q)". Recourse use was investigated using the "Resource Utilization in Dementia Lite Version" (RUD-LITE) questionnaire. QoL was investigated using the European Quality of Life Scale (EuroQoL) 5D at 5 levels (EQ-5D-5L) and a Visual Analogue Scale (VAS).
- Preliminary results on AD patients' characteristics, disease severity and QoL for patients and caregivers are reported. Categorical variables are presented as frequencies and percentages, continuous variables with mean (standard deviation) and discrete variables with median (interquartile range). Moreover, healthcare resource use and productivity loss in the last three months are reported as percentage of use and as mean number of resources per month. All findings are reported by disease severity (MMSE class) and differences were assessed using chi-square or fisher tests for categorical variables and non-parametric tests for continuous variables.

## CONCLUSIONS

- This study reported community services and caregivers' daily activity and loss of productivity as the main drivers of AD burden.
- Burden increase with the disease severity both for caregivers and patients.
- The preliminary results suggested the need of a societal point of view in defining the AD burden and assessing the value of AD interventions.

## REFERENCES

- Agenzia Italiana del Farmaco (AIFA). Nota 85- Rivastigmina, Memantina, Galantamina, Donepezil. URL: <https://www.aifa.gov.it/nota-85>. Accesso: 01/10/2024
- Chowdhary N, Barbu C, Anstey KJ, et al. Reducing the Risk of Cognitive Decline and Dementia: WHO Recommendations. *Front Neurol*. 2022 Jan 10;12:765584.
- Courbage C, Montoliu-Montes G, Wagner J. The effect of long-term care public benefits and insurance on informal care from outside the household: empirical evidence from Italy and Spain. *Eur J Health Econ*. 2020 Nov;21(8):1131-1147.
- Kobelt G, Berg J, Lindgren P, Fredrikson S, Jörsson B. Costs and quality of life of patients with multiple sclerosis in Europe. *J Neurol Neurosurg Psychiatry*. 2006 Aug;77(8):918-26. doi: 10.1136/jnnp.2006.093065.
- Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res*. 1975 Nov;12(3):189-98.
- Kaufe DI, Cummings JL, Ketchel P, et al. Validation of the NPI-Q, a brief clinical form of the Neuropsychiatric Inventory. *J Neuropsychiatry Clin Neurosci*. 2000 Spring;12(2):233-9.
- Scalzone L, Cortesi PA, Ciampichini R, Belisari A, D'Angiolella LS, Cesana G, Mantovani LG. Italian population-based values of EQ-5D health states. *Value Health*. 2013 Jul-Aug;16(5):814-22.

## RESULTS

Figure 1. Patients' characteristics.

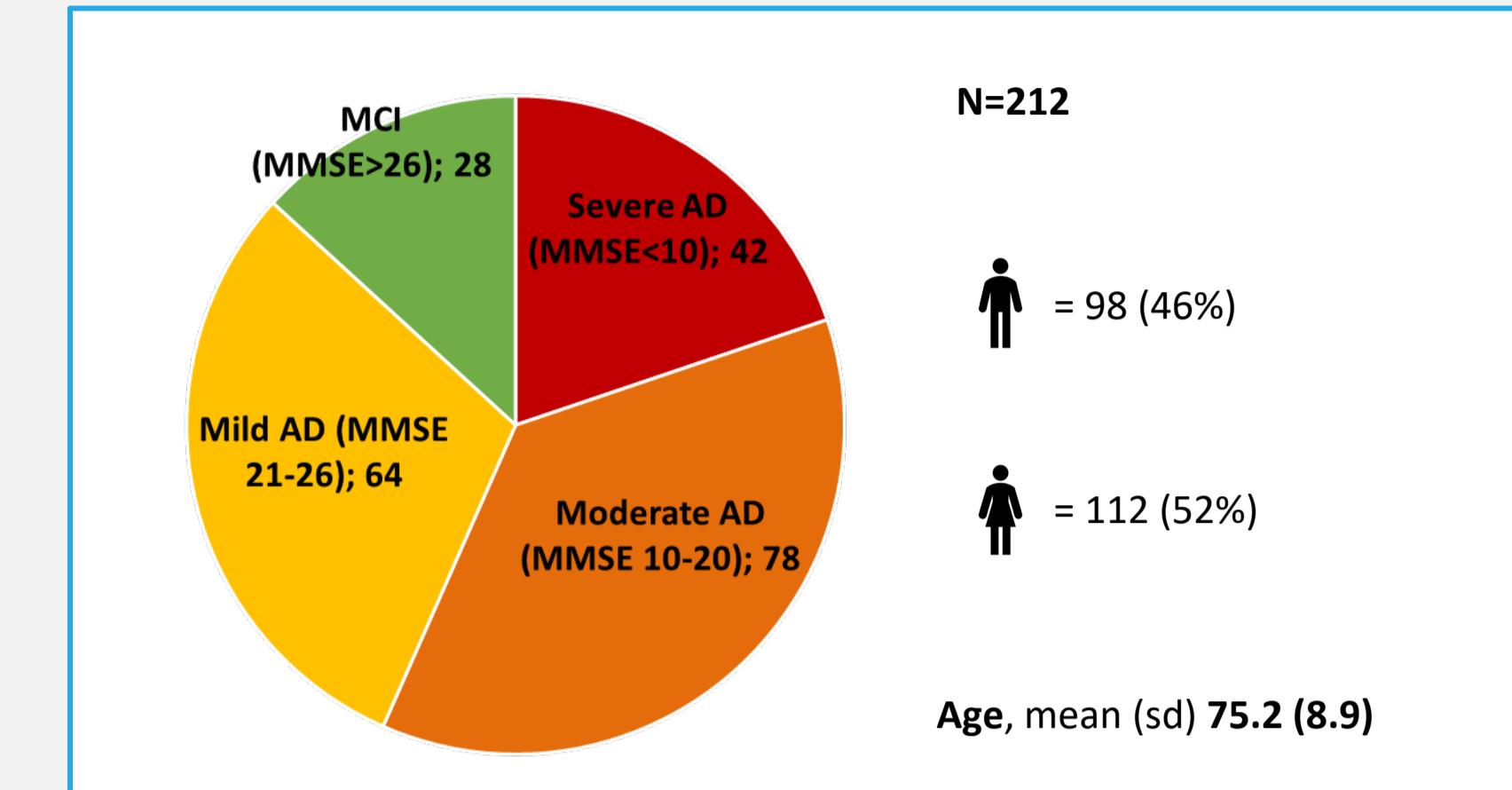


Table 1. Patients' clinical characteristics

	MCI (MMSE>26)	Mild AD (MMSE 21-26)	Moderate AD (MMSE 10-20)	Severe AD (MMSE <10)	All
Years since Diagnosis*, mean (sd)	1.3 (2.3)	1.9 (2.1)	2.8 (3.6)	3.9 (3.7)	2.6 (3.1)
NPI, median(q <sub>1</sub> -q <sub>3</sub> )					
Score*	3.0 (1.0-4.0)	2.0 (1.0-4.0)	3.0 (1.0-5.0)	5.0 (3.0-6.0)	3.0 (1.0-5.0)
Severity*	4.0 (2.0-9.0)	5.0 (2.0-7.0)	5.0 (2.0-9.5)	9.5 (6.0-13.0)	5.5 (2.0-10.0)
Stress*	5.0 (1.0-9.0)	5.0 (2.0-10.0)	4.5 (2.0-12.0)	11.0 (6.0-15.0)	6.0 (2.0-11.5)
IADL*, median(q <sub>1</sub> -q <sub>3</sub> )	7.0 (5.0-8.0)	5.0 (2.0-8.0)	3.0 (1.0-5.0)	0.0 (0.0-1.0)	3.0 (0.5-6.0)
ADL*, median(q <sub>1</sub> -q <sub>3</sub> )	12.0 (11.5-12.0)	12.0 (11.0-12.0)	11.0 (8.0-12.0)	6.0 (3.0-8.0)	11.0 (7.0-12.0)
CCI, median(q <sub>1</sub> -q <sub>3</sub> )	1.0 (1.0-2.0)	2.0 (1.0-3.0)	1.0 (1.0-2.0)	2.0 (1.0-2.0)	1.0 (1.0-2.0)
Patient housing, N pts (%)					
own home	28 (100.0)	60 (93.8)	73 (93.6)	40 (95.2)	201 (94.8)
caregiver's home	0 (0.0)	4 (6.3)	4 (5.1)	2 (4.8)	10 (4.7)
Patient living*, N pts (%)					
alone	18 (64.3)	52 (81.3)	68 (87.2)	28 (66.7)	166 (78.3)
with a family member	0 (0.0)	5 (7.8)	3 (3.8)	10 (23.8)	18 (8.5)

ADL=Activities of Daily Living. IADL= Instrumental Activities of Daily Living. CCI= Charlson Comorbidity Index. NPI= Neuropsychiatric Inventory Questionnaire. Pts= patients

\*p<0.05 differences among disease severity levels (MMSE classes)

Table 2. Healthcare resource use in the three months preceding enrollment.

	MCI (MMSE>26)	Mild AD (MMSE 21-26)	Moderate AD (MMSE 10-20)	Severe AD (MMSE >10)	All
Patients on AD treatment <sup>1</sup>	10 (35.7)	35 (54.7)	53 (67.9)	21 (50.0)	119 (56.1)
Patients using healthcare resources, N (%)					
Tests and exams	12 (42.9)	30 (46.9)	35 (44.9)	18 (42.9)	95 (44.8)
Aids and appliances	3 (10.7)	5 (7.8)	5 (6.4)	8 (19.0)	21 (9.9)
N resources per month, mean (sd)					
Tests and exams	0.2 (0.4)	0.1 (0.2)	0.0 (0.1)	0.2 (0.4)	0.1 (0.3)
Aids and appliances	0.0 (0.1)	0.0 (0.1)	0.1 (0.3)	0.1 (0.2)	0.1 (0.2)
Hospitalisations	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	0.1 (0.2)	0.0 (0.0)
Outpatient visits	0.4 (0.7)	1.0 (1.9)	1.1 (3.1)	1.1 (2.4)	1.0 (2.4)
Other community services					
homecare nurse	0.0 (0.1)	0.0 (0.1)	0.1 (0.5)	0.1 (0.2)	0.1 (0.3)
homecare help	2.3 (6.6)	0.0 (0.3)	0.8 (3.3)	0.0 (0.1)	0.6 (3.1)
homecare assistant*	0.0 (0.0)	2.6 (8.1)	3.5 (8.5)	8.6 (13.0)	3.9 (9.4)

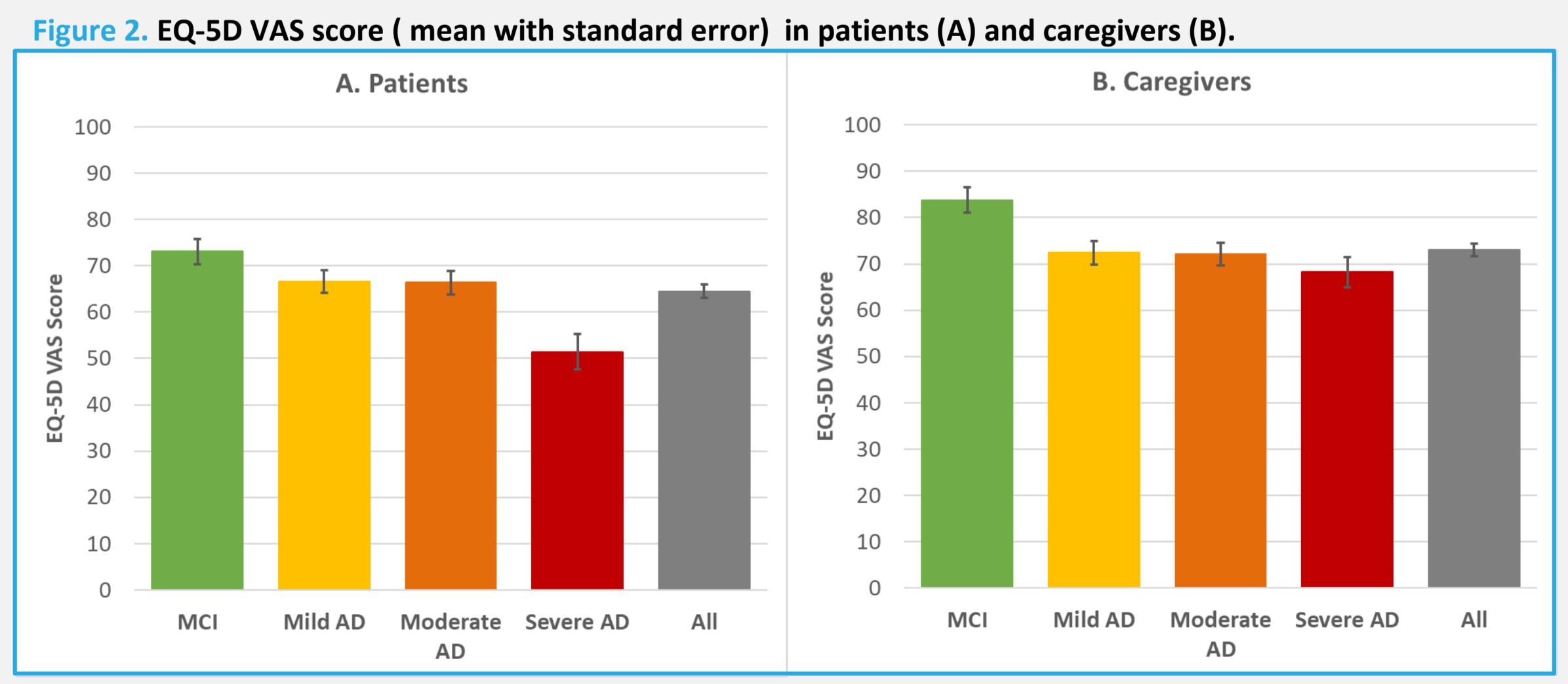
<sup>1</sup> AD treatment includes donepezil, memantine, rivastigmine. \*p<0.05 differences among disease severity levels (MMSE classes)

Table 3. Caregiver's time spent on patient care in the last 30 days.

	MCI (MMSE>26)	Mild AD (MMSE 21-26)	Moderate AD (MMSE 10-20)	Severe AD (MMSE >10)	All
Sleep					
Time(hours per day), mean (sd)	6.6 (1.7)	6.4 (1.7)	6.5 (1.4)	6.4 (1.6)	6.5 (1.6)
Patients daily activities					
Time(hours per day)*, mean (sd)	0.6 (0.9)	1.2 (2.6)	2.3 (3.5)	3.2 (2.7)	1.9 (2.9)
Days per month*, mean (sd)	6.1 (11.5)	10.1 (13.3)	14.5 (13.7)	20.2 (12.7)	13.2 (13.8)
Patients other activities					
Time(hours per day)*, mean (sd)	1.4 (1.4)	2.3 (2.2)	3.5 (3.3)	3.6 (2.2)	2.9 (2.7)
Days per month*, mean (sd)	12.4 (13.2)	18.3 (13.0)	20.5 (11.6)	21.5 (10.9)	19.0 (12.4)
Patients supervision					
Time(hours per day)*, mean (sd)	0.8 (0.9)	1.9 (3.7)	3.8 (5.8)	4.1 (4.6)	6.4 (1.7)
Days per month, mean (sd)	11.6 (14.1)	13.8 (14.3)	16.2 (13.7)	19.2 (12.5)	15.5 (13.8)

\*p<0.05 differences among disease severity levels (MMSE classes)

Figure 2. EQ-5D VAS score ( mean with standard error) in patients (A) and caregivers (B).



## CONTACT INFORMATION

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