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Healthcare Resource Utilization (HCRU), Quality of Life (QoL), and Employment Changes in People with Amyotrophic Lateral Sclerosis (pALS) in Italy: Results from a Real-World Survey

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OBJECTIVE

- **To outline the impact of ALS on HCRU, QoL and employment status in Italy, as reported by physicians, pALS and their care partners (cALS)**

CONCLUSIONS

- **Later-stage ALS appeared to be associated with greater HCRU and impact on pALS and cALS than earlier stages.**
- **Few pALS remained in employment, and many cALS also had to change their working arrangements.**
- **Later-stage ALS appeared to be associated with worse QoL among both pALS and cALS, with late-stage pALS reporting an EQ-5D health-state 'worse than death'.**
- **These findings highlight the potential value of early diagnosis in ALS to prevent disease progression into a more resource-intensive stage.**

Introduction

- Amyotrophic lateral sclerosis (ALS) is a rare, degenerative neuromuscular disease, leading to progressive loss of muscle function, and ultimately death.[1]
- Multi-disciplinary care is a central part of ALS treatment and has a positive effect on level of satisfaction and outcomes among pALS.[2]
- Advancing disease stage is associated with significant increases in healthcare resource utilisation (HCRU).[3]
- Additionally, the debilitating nature of the condition negatively impacts the working and living arrangements of people with ALS (pALS) and their care partners (cALS).[4]
- The extensive negative effects of ALS are well documented, though studies quantifying pALS and cALS perceived QoL are less common. The EQ-5D-5L is one of the most widely used QoL measures assessing five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.[5]
- Understanding the impact of ALS on HCRU and QoL can better inform healthcare decisions and improve the quality of care and support provided to both pALS and cALS at a local level.

Methods

- Data were drawn from the Adelphi ALS Disease Specific Programme™ (DSP), a cross-sectional survey of de-identified neurologists, pALS, and cALS. Data collection in Italy took place between July–October 2020.
- The DSP methodology has been previously published[6] and was conducted according to the relevant regulations.
- Neurologists completed questionnaires reporting the demographics of pALS, and HCRU including consultations with healthcare professionals (HCPs), ALS-related hospitalizations, use of mobility, communicative, ventilatory or feeding interventions, and overall professional caregiver requirements. A subset of these same pALS and cALS reported on employment changes and their QoL.
- Neurologists designated whether pALS were in the early-, middle-, or late-stage of ALS based on their clinical judgement. pALS Milano-Torino (MiToS)[7] stages were derived using their neurologist-reported ALSFRS-R results. MiToS assesses complete loss of independence in four key domains (bulbar, gross motor, fine motor, and respiratory function), each stage being the number of domains.
- Descriptive statistics were reported throughout.

Results

- 21 neurologists recorded data on 129 Italian pALS (50, 45 and 34 designated as early-, middle- and late-stage ALS, and 83, 13, 9, 7, and 17 as MiToS stages 0-4 respectively).
- Self-reported data were provided by 22 pALS (Neurologist judgement: 10, 9, 3; MiToS: 19, 0, 0, 1, 2) and 12 cALS (Neurologist judgement: 2, 5, 5; MiToS: 7, 0, 0, 0, 5).
- pALS characteristics are reported in **Table 1**.

HCRU

- pALS hospitalisation frequency, hospitalisation duration, and total number of HCP consultations, all in the last 12 months are summarised in **Figure 1**.
- pALS use of functional, supportive, and therapeutic aids, and professional care is summarised in **Figure 2**.
- The number of hours per week of professional caregiver support received by pALS are reported in **Table 1**.

Employment status

- pALS employment statuses at the time of the survey are detailed in **Table 1**.
- The percentage of cALS who had changed their own working arrangements are reported in **Table 1**.

Quality of life

- EQ-5D-5L utility scores were derived using Italian value sets for both pALS and cALS at the different stages (**Figures 3 & 4**).
- Late-stage pALS reported a mean utility value less than 0, equating to a health state considered 'worse than death'.

Figure 1. ALS-related a) hospitalisations, b) nights in hospital, c) HCP consultations, in the last 12 months

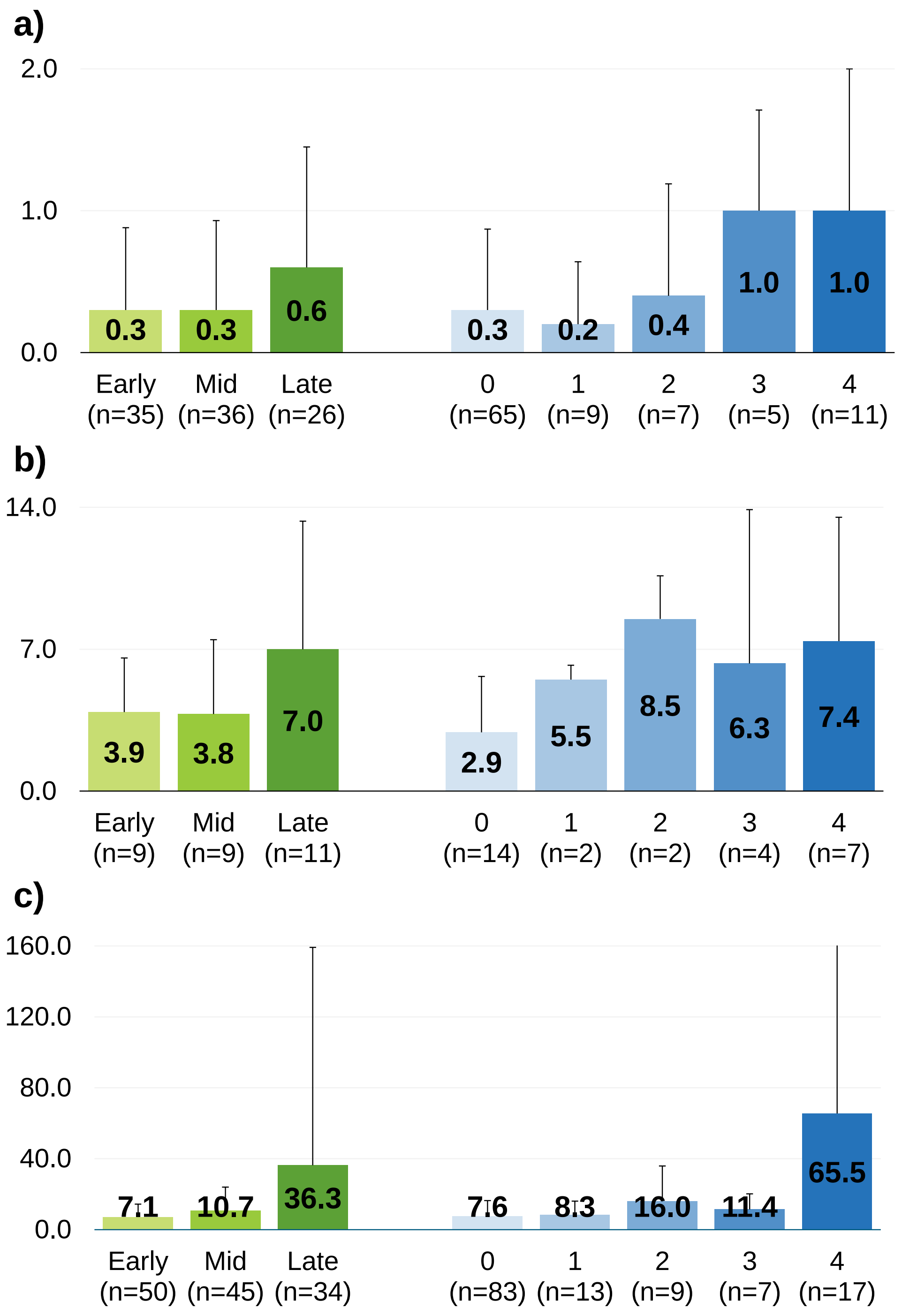
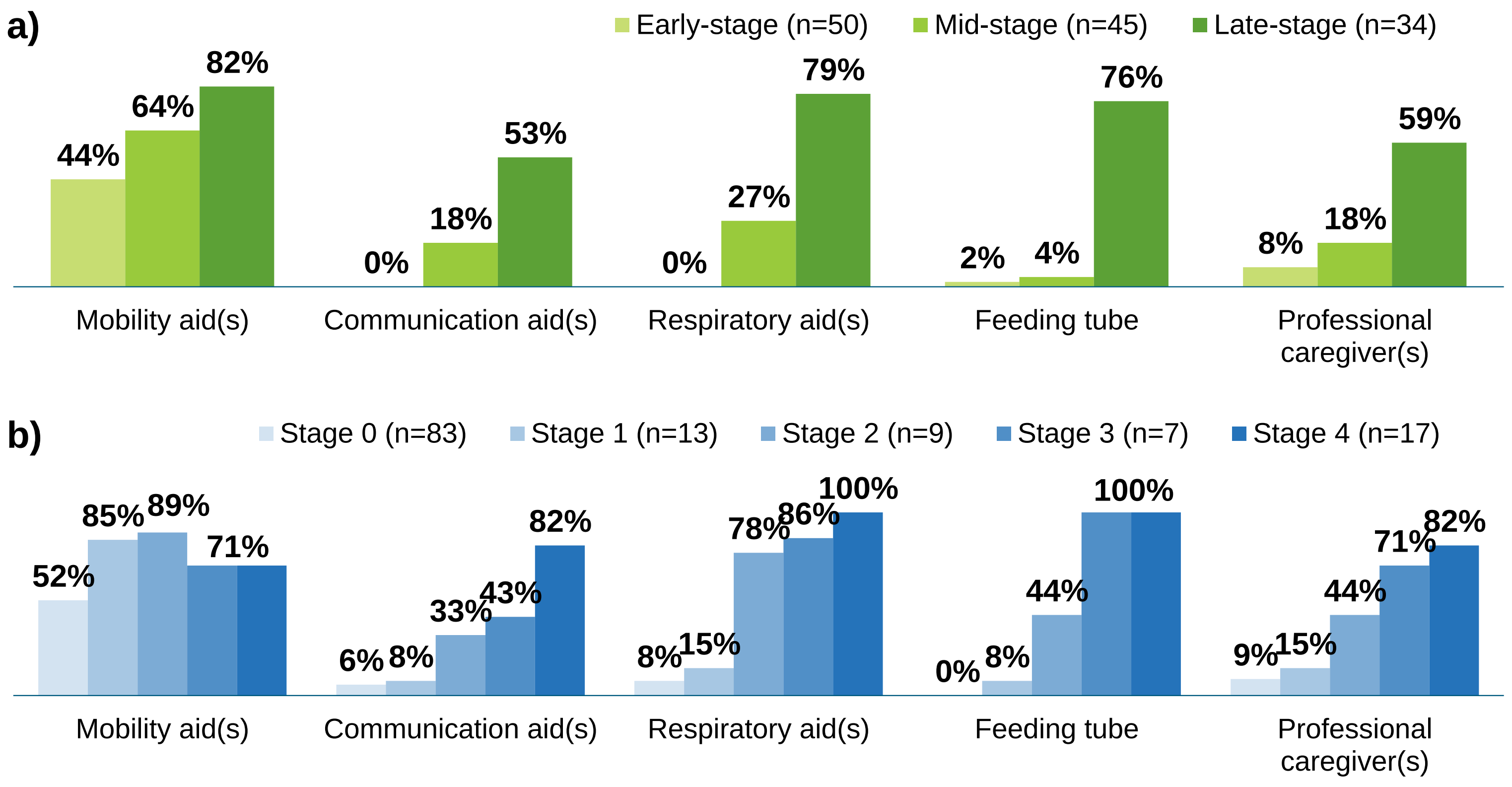


Figure 2. Utilisation of functional, supportive, and therapeutic aids, and professional care by a) neurologist judgement and b) MiToS stages



Mobility aids included walking aids (e.g. canes, frames), manual/motorised wheelchairs, and vehicles (e.g. wheelchair accessible car).

Figure 3. pALS EQ-5D utility values

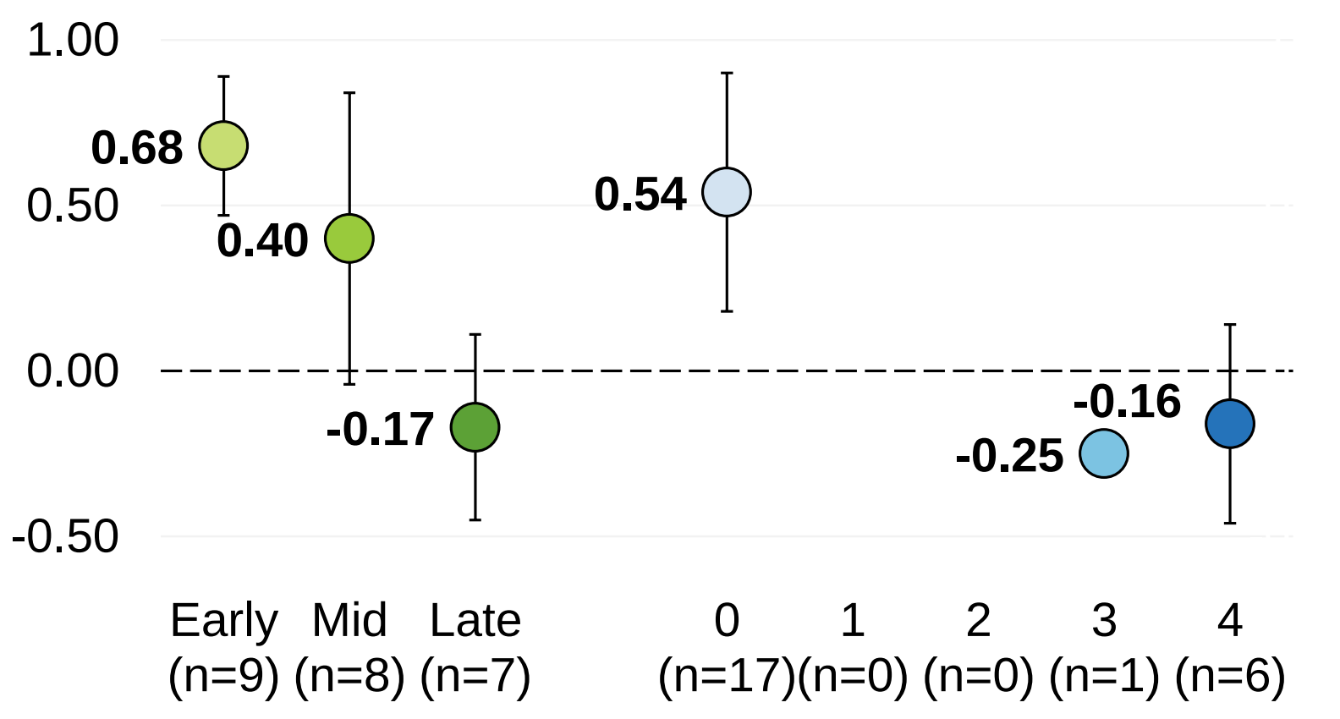


Figure 4. cALS EQ-5D utility values

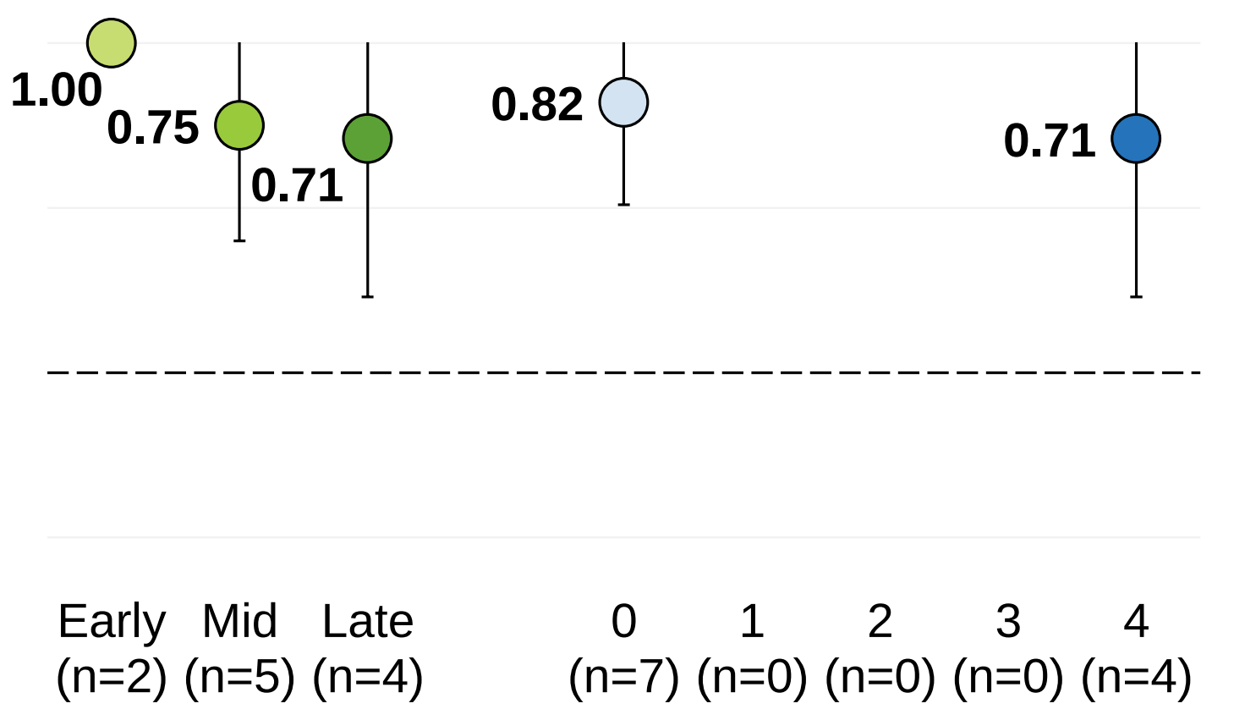


Table 1. pALS sample characteristics by disease stage

	All patients (n=129)	Neurologist Judgment			Milano-Torino (MiToS)				
		Early stage (n=50)	Middle stage (n=45)	Late stage (n=34)	Stage 0 (n=83)	Stage 1 (n=13)	Stage 2 (n=9)	Stage 3 (n=7)	Stage 4 (n=17)
Age (years), mean (SD)	62.2 (11.8)	59.4 (12.6)	63.3 (9.1)	65.0 (13.2)	61.4 (11.6)	64.3 (8.7)	70.4 (11.7)	63.1 (8.2)	59.9 (15.1)
Sex (% male)	57%	52%	53%	68%	58%	23%	56%	57%	76%
BMI, mean (SD)	23.8 (2.8)	24.3 (2.3)	23.9 (2.5)	22.8 (3.6)	24.1 (2.2)	23.3 (4.0)	22.4 (2.5)	23.3 (2.5)	23.5 (4.4)
Time since diagnosis (months), mean (SD)	27.3 (36.1)	17.3 (23.6)	23.2 (29.4)	48.2 (29.9)	21.4 (27.9)	16.8 (13.5)	21.9 (11.9)	24.8 (10.6)	67.4 (64.0)
Employment status									
Working full time	10%	22%	4%	0%	16%	0%	0%	0%	0%
Working part time	12%	14%	18%	0%	16%	15%	0%	0%	0%
On long term sick leave	12%	2%	16%	21%	7%	8%	11%	14%	35%
Homemaker	10%	14%	9%	6%	12%	15%	0%	14%	0%
Student	2%	0%	0%	6%	0%	0%	0%	0%	12%
Retired	52%	41%	53%	65%	45%	62%	89%	71%	47%
Unemployed	3%	6%	0%	3%	4%	0%	0%	0%	6%
Hours of professional care per week, mean (SD)	*n=20*	*n=3*	*n=5*	*n=12*	*n=5*	*n=2*	*n=1*	*n=1*	*n=11*
	43.3 (48.0)	10.0 (2.0)	15.6 (8.3)	63.2 (53.6)	14.8 (6.9)	12.0 (11.3)	10.0 (-)	10.0 (-)	68.0 (53.4)
cALS had changed working arrangements (% yes)	*n=12*	*n=2*	*n=5*	*n=5*	*n=7*	*n=0*	*n=0*	*n=0*	*n=5*
	42%	0%	40%	60%	29%	-	-	-	60%

Strengths

- Physician, pALS and cALS perspectives were all sought.
- Two staging systems were considered, and reasonably good concordance was observed between them.
- The real-world study design enables capture of data for pALS and cALS in general, independent of any therapeutic intervention or management strategy.

Limitations

- The DSP is not based on a truly random sample of physicians and pALS/cALS. While minimal inclusion criteria governed the selection of the participating physicians, participation is influenced by the willingness to complete the survey.
- The DSP is a cross-sectional study, data were captured at time of survey and not followed over time.

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