

Spasticity in multiple sclerosis – a cross-sectional survey in Germany

MOVE 1 – **MO**bilitäts**VE**rbesserung
bei Spastik in Multipler Sklerose

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Background

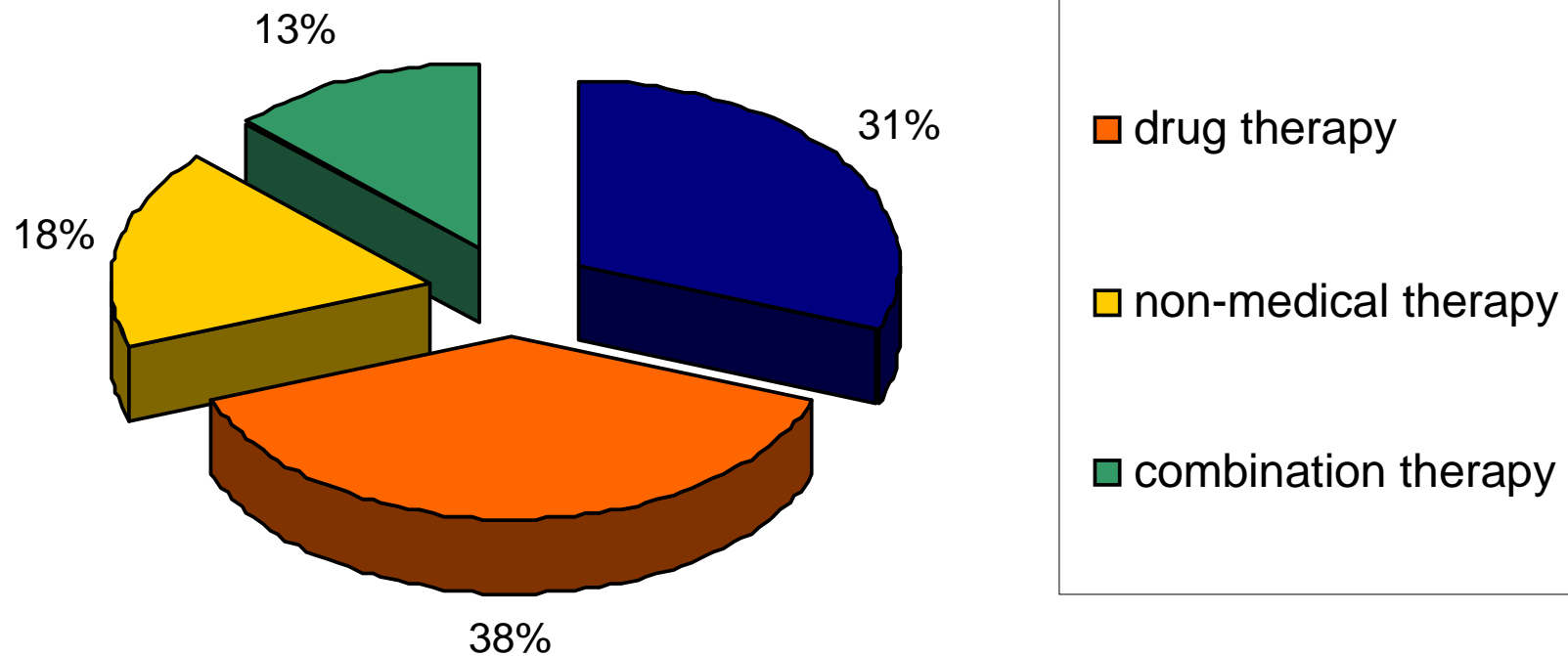
| | Without spasticity | Minimal and mild spasticity | Moderate spasticity | Severe spasticity |
|--|-----------------------|-----------------------------------|------------------------|----------------------|
| % Patients (n=20.969) | 15,7 | 50,3 | 17,2 | 16,8 |
| Degree of disability PDDS*, p≤0,0001 | 1,6 | 3,5 | 4,8 | 5,9 |
| QoL (SF-36) (n=9.244) | n=1.492 | n=4.608 | n=1.530 | n=1.614 |
| PCS** | 47,4 | 39,3 | 32,7 | 28,7 |
| MCS*** | 52,1 | 51,3 | 48,2 | 45,8 |

* Patient Determined Disease Steps, ** Physical Summary Score; *** Mental Summary Score

Rizzo et al, Mult Scler 2004

Background

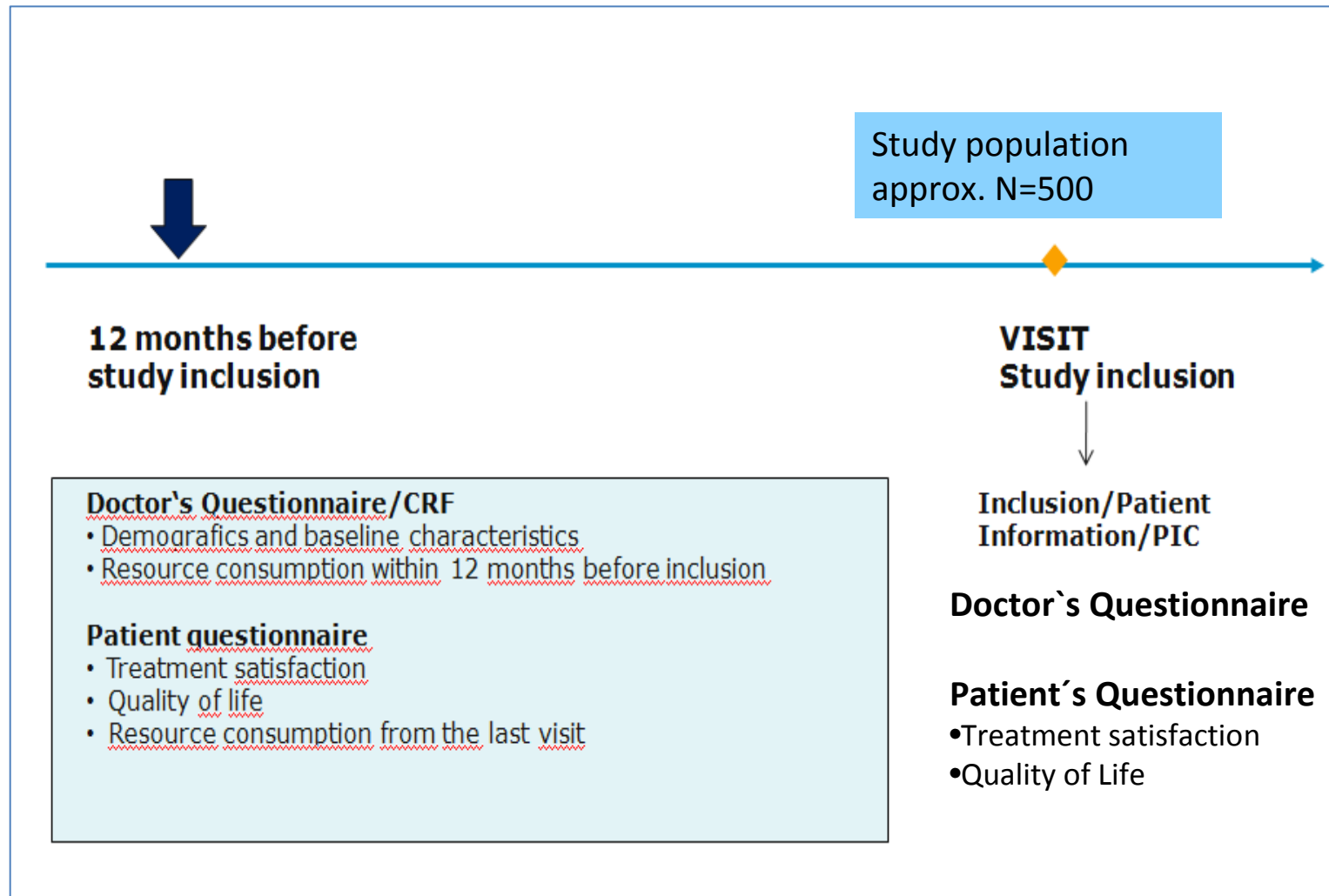
Patients with spasticity (65%)



Aims of the study

- To determine the type, characteristics and burden of spasticity in MS patients
 - To describe the health care situation of patients with MS-associated spasticity
 - To describe quality of life and satisfaction with treatment, and
 - To evaluate the cost of MS-induced spasticity from different perspectives, health insurance, society and patient.
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MOVE 1 – Study Design



Patient population

Inclusion Criteria

- Diagnosed with any disease sub-type of MS with spasticity of at least 12 months duration
- Male or female, aged 18 years or above
- Willing and able to give written informed consent for participation in the study
- Personal contact at visit 1 and information regarding the past 12 months is available

Exclusion Criteria

- Spasticity due to other reasons
- Patients with relevant cognitive impairment or unable to understand the language of the questionnaire

Methods

Physician's questionnaire

- Characteristics of MS and spasticity
 - Disease course
 - EDSS
 - 10 m walking test
 - Degree and type of spasticity
 - Modified Ashworth Scale
 - Barthel Index
- Resource use
- Sick leave
- Satisfaction with drug treatment for spasticity

Physician's questionnaire (global)

- Global impression of spasticity
- Satisfaction with treatment options

Patient's questionnaire

- Demographic data
- Employment
- Spasticity
 - Numeric Rating Scale (NRS): spasticity and sleep
 - Impairment in daily living
 - Localization of spasticity
- Resource use
- Sick leave
- Quality of life
 - EQ-5D
 - MSQoL-54
- Fatigue (WEIMuS)
- Satisfaction with current medical treatment

Demographic data

of centres 42
of patients 414

148 men (35.7%)

266 women (64.3%)

age 48.6 +/- 9.6 years (mean +/- sd)

median 48 (range 25-80)

Disease characteristics

| Course of MS (n = 414) | n | % |
|------------------------|-----|------|
| Not determined | 1 | 0.3 |
| Primary progressive | 44 | 10.6 |
| Secondary progressive | 184 | 44.4 |
| Relapsing-remitting | 185 | 44.7 |

| | n | mean (SD) | median (range) |
|-------------------------------------|-----|------------|-------------------|
| # of relapses in the last 12 months | 122 | 1.5 (0.7) | 1.0 (1–4) |
| Time since diagnosis (years) | 413 | 13.9 (8.3) | 13.0 (0–53) |
| Time since spasticity (years) | 405 | 8.2 (5.9) | 7.0 (0–36) |

Spasticity (physician's view)

| Type (n=414) | n | % |
|--------------------------|-----|------|
| permanent | 284 | 68.6 |
| paroxysmal | 107 | 25.8 |
| permanent and paroxysmal | 23 | 5.6 |

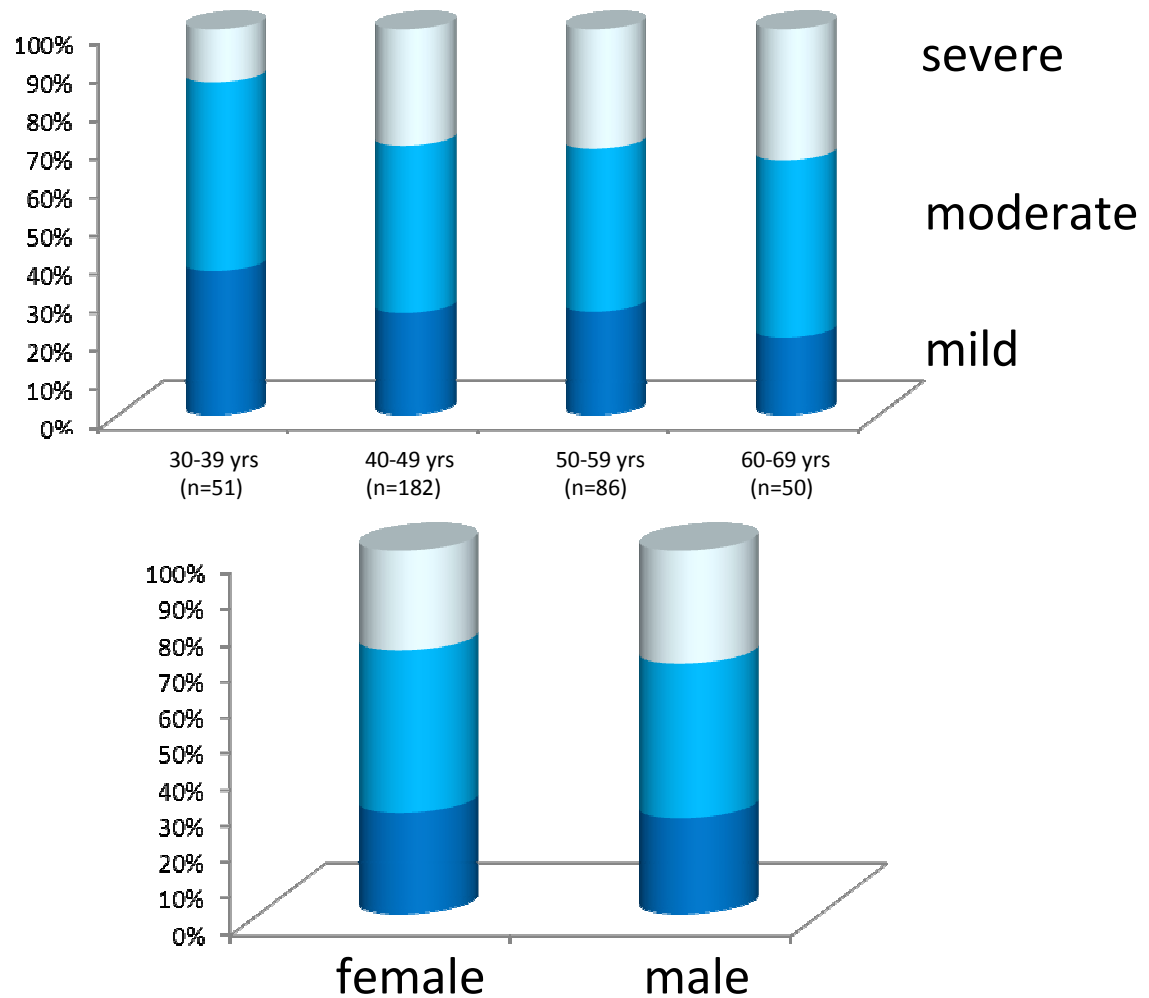
| Severity (n=414) | n | % |
|------------------|-----|------|
| mild | 113 | 27.3 |
| moderate | 182 | 44.0 |
| severe | 119 | 28.7 |

Severity of spasticity

mild:
113 (27.3%)

moderate:
182 (44.0%)

severe:
119 (28.7%)



Localization of spasticity

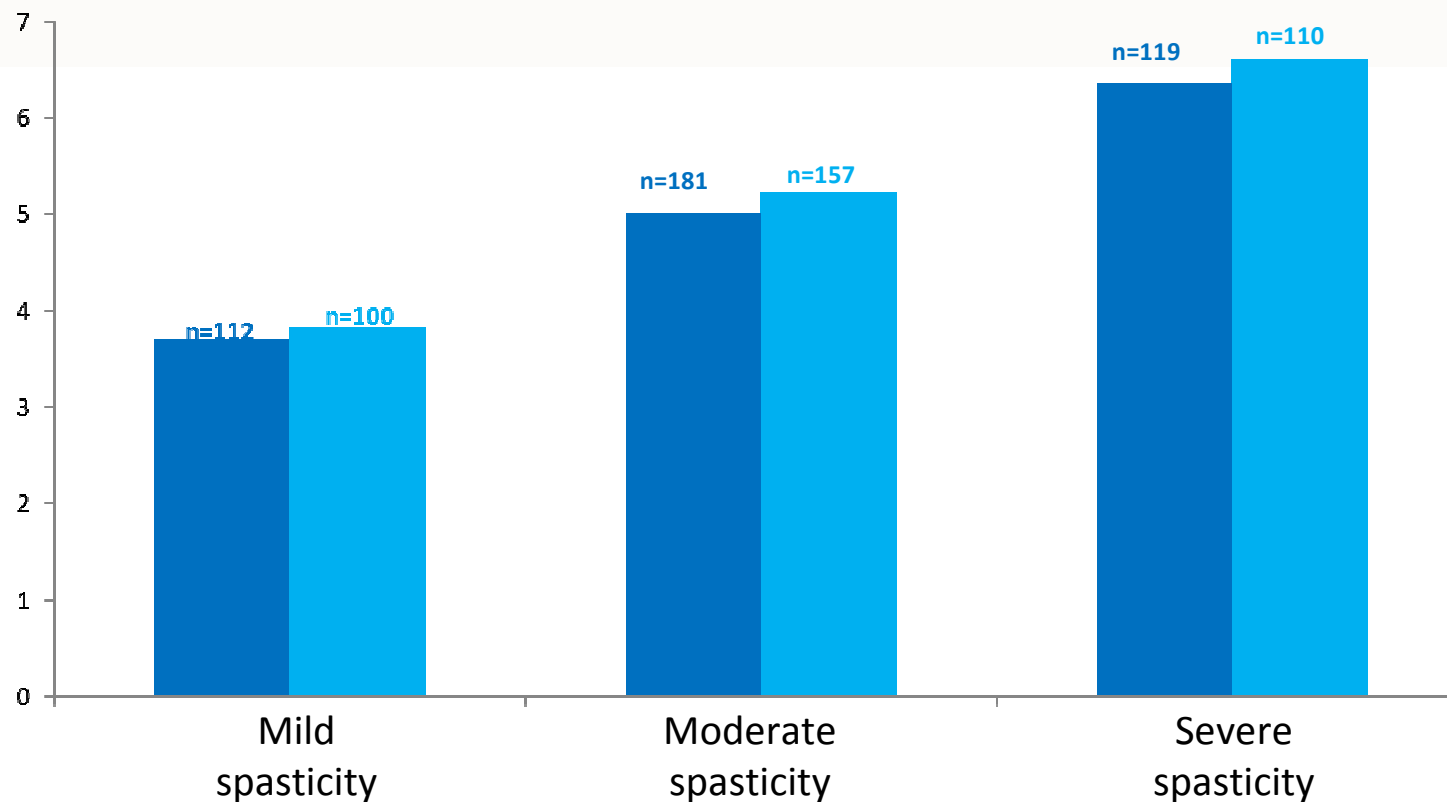
| Physician's questionnaire (n=414) | n | % |
|-----------------------------------|-----|------|
| monospasticity | 17 | 4.1 |
| hemispasticity | 32 | 7.7 |
| paraspasticity | 233 | 56.3 |
| tetraspasticity | 130 | 31.4 |
| other | 4 | 1.0 |

| Patient's questionnaire (n=397) | n | % |
|---------------------------------|-----|------|
| leg | 213 | 53.7 |
| leg and arm | 79 | 19.9 |
| other | 2 | 0.5 |
| leg and other | 57 | 14.4 |
| leg and arm and other | 46 | 11.6 |

EDSS and spasticity

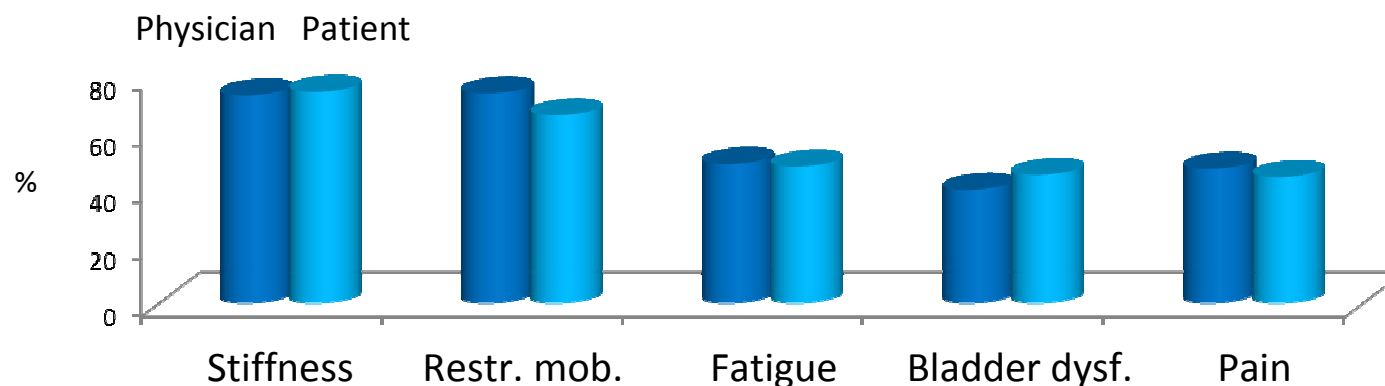
EDSS at inclusion (n=412) **5.25** (mean, SD=1.7), median=5.5 (range 1-9)

EDSS -12 months (n=367) **5.05** (mean, SD=1.8), median=5.0 (range 0-9)



Symptoms of spasticity

| | Physician (n=411) | | Patient (n=397) | |
|---------------------|-------------------|------|-----------------|------|
| | n | % | n | % |
| Muscle stiffness | 303 | 73.2 | 308 | 74.4 |
| Restricted mobility | 306 | 73.9 | 274 | 66.2 |
| Fatigue | 203 | 49.0 | 199 | 48.1 |
| Bladder dysfunction | 165 | 39.9 | 187 | 45.2 |
| Pain | 196 | 47.3 | 184 | 44.4 |
| Other | 9 | 2.2 | 18 | 4.3 |

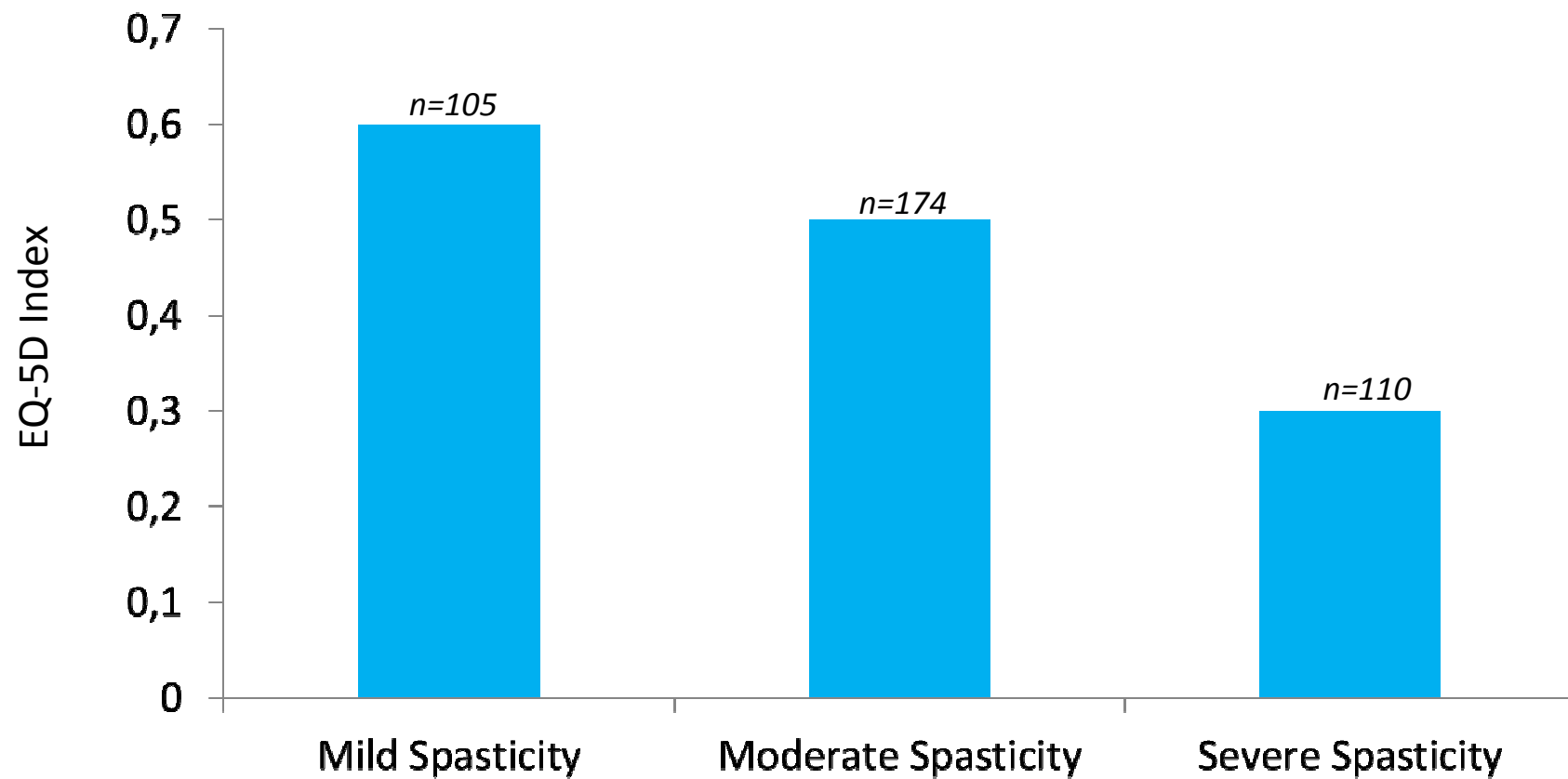


Spasticity – patient's view

| | mild | | moderate | | severe | | total | |
|-----------------------------------|-------------------------------------|--------------------|-------------------------------------|---------------------|-------------------------------------|---------------------|----------------------------|---------------------|
| | Mean (SD) | Median (range) | Mean (SD) | Median (range) | Mean (SD) | Median (range) | Mean (SD) | Median (range) |
| NRS spasticity (n=390) | 3.2 (2.1) n=99 | 3 (0-9) | 4.5 (2.2) n=174 | 5 (0-10) | 6.2 (2.4) n=117 | 7 (0-10) | 4.7 (2.5) | 5 (0-10) |
| NRS sleep (n=384) | 2.1 (2.2) n=105 | 2 (0-8) | 3.0 (2.6) n=172 | 3 (0-9) | 4.3 (3.0) n=107 | 4 (0-10) | 3.1 (2.7) | 3 (0-10) |
| # of spasms per day (n=224) | 3.0 (2.7) n=66 | 2 (0-14) | 9.4 (53.5) n=101 | 3 (0-540) | 10.1 (24.3) n=57 | 4 (0-180) | 7.7 (38.0) | 3 (0-540) |

Quality of life

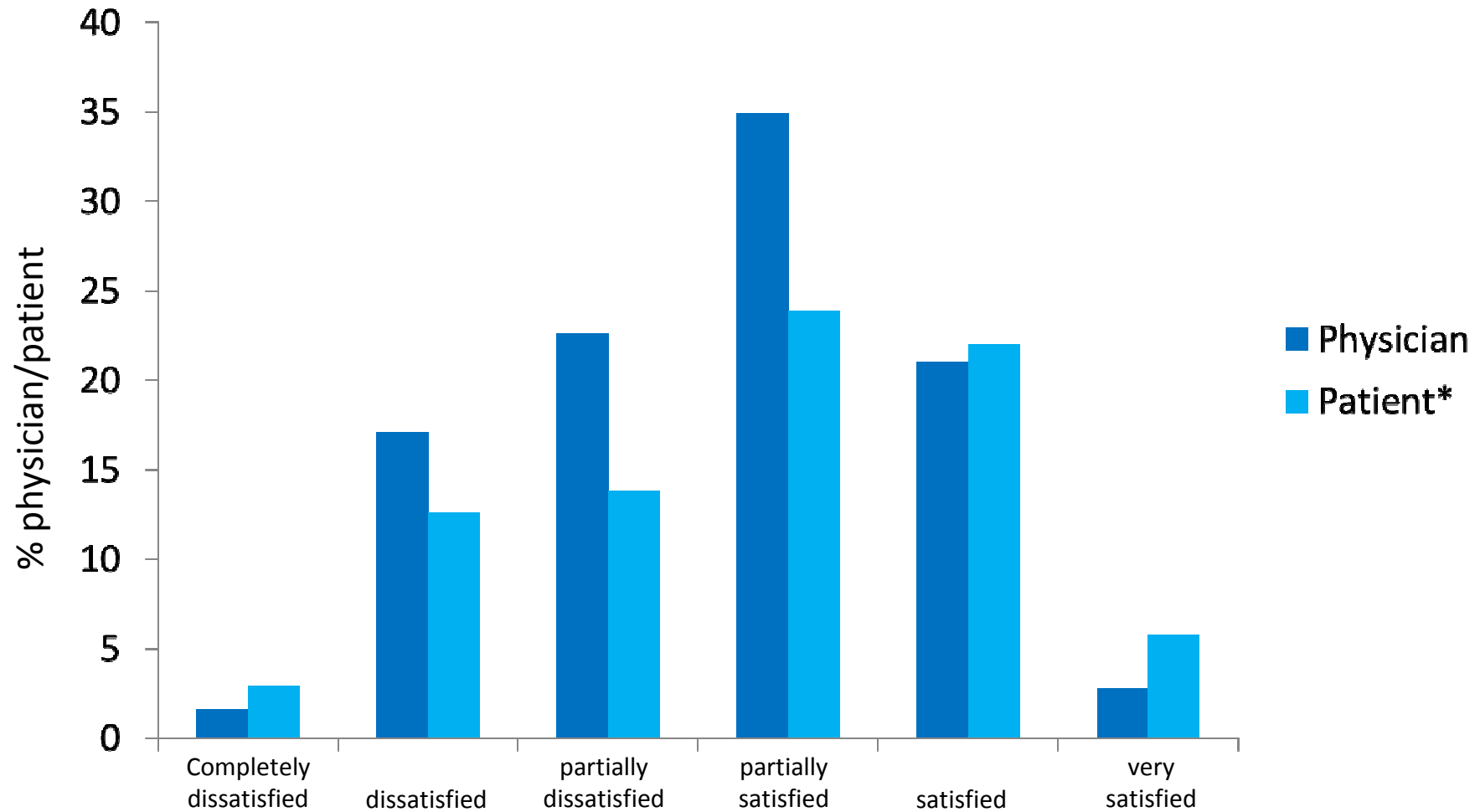
EQ-5D depending on severity



Drug treatment for MS induced spasticity

| | mild (n=38) | | moderate (n=99) | | severe (n=91) | | total (n=414) | |
|------------------------|----------------|------|--------------------|------|------------------|------|------------------|------|
| | n | % | n | % | n | % | n | % |
| with drug treatment | 42 | 37.2 | 112 | 61.5 | 98 | 82.4 | 252 | 60.9 |
| without drug treatment | 69 | 61.1 | 66 | 36.3 | 19 | 16.0 | 154 | 37.2 |

Satisfaction with effectiveness of current antispastic drug treatment



*19.1% of patients did not rate satisfaction with effectiveness of medication

Conclusions

- In this study, the majority of MS patients suffered from either moderate or severe spasticity, mainly affecting legs
 - Spasticity has an impact on activities of daily living
 - The most disturbing symptoms of spasticity were muscle stiffness and restricted mobility, but pain, fatigue and bladder dysfunction were also present
 - Disability worsened and QoL decreased with increasing spasticity
 - The majority of patients (60,9%) were treated with antispastic drugs
 - Patients and physicians were not satisfied with the effectiveness of antispastic drug treatments that were available during the study period (2011)
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