Cleveland Clinic Neurological Institute

Ambulatory and Non-Ambulatory Patients

Assessing the Efficacy of Intrathecal Baclofen Therapy in Austin C. Griffin, BA¹, Justin Abbatemarco, MD², Jennifer Hartman, MPAS, PA-C³, Noble Jones, BS, MS⁴, Keith McKee, MD⁵, Andre Machado, M.D., Ph.D.⁶, Nagel Sean, MD⁷ and Francois Bethoux, MD⁵

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Background

- Spasticity is a common symptom of multiple sclerosis (MS) that causes stiffness and spasms, impaired ambulation, and pronounced issues with activities of daily living.
- Intrathecal Baclofen (ITB) therapy is a treatment option for severe spasticity refractory to oral medications. There is a dearth of long-term studies assessing ITB efficacy in both ambulatory and non-ambulatory MS patients.

Objective

This case series evaluated the outcomes of MS patients with medically intractable spasticity treated with ITB over five years to determine efficacy outcomes and assess differences between ambulatory and non-ambulatory patients.

Methods

- Patients were identified from an IRB-approved clinical registry. Clinical encounter data was extracted from the registry and electronic medical records.
- All MS patients who had undergone implantation of an ITB pump between 2001 and 2014 and had follow-up data for at least 3 years and up to 5 years were included.
- The following outcome measures were collected: pain Numeric Rating Scale (NRS), Modified Ashworth Scale (MAS), and Timed 25 Foot Walk (T25FW).

Table 1. Patient Clinical Characteristics

Characteristic Patients, N* Age (47.1 ± 9.8 Years)* Sex, Female **Disease Duration (Years)* Disease Course**

Baseline MAS (0-32)‡ Baseline Pain (0-10)‡ **Baseline T25W (Seconds)***

Baseline Assistive Device

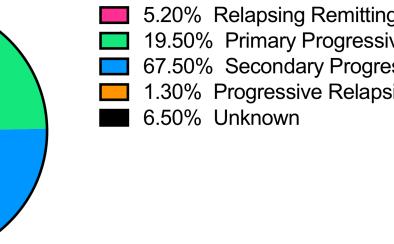
Mean ± SD for numerical variables, frequency (%) for categorical variables t Median and interguartile range

Figure 1. MS Disease Course Distribution 5.20% Relapsing Remitting **19.50%** Primary Progressive 67.50% Secondary Progressive 1.30% Progressive Relapsing 6.50% Unknown

Figure 1. Pie chart of MS disease course distribution

Results

Ambulatory	Non-Ambulatory
40	37
46.5 ± 8.7	47.7 ± 10.9
19 (47.5%)	29 (78.4%)
14.9 ± 9.5	18.1 ± 7.1
10% Relapsing 85% Progressive 5% Unknown	0% Relapsing 91.9% Progressive 8.1 % Unknown
14.5 (10.8-20.25)	24 (16.5-26)
4 (0-7)	5 (0-7.75)
25.4 ± 23.7	N/A
20% None 27.5% Unilateral 47.5% Bilateral 5% Unknown	N/A



Results Figure 2. MAS Score Comparisons MAS Scores in Ambulatory vs. Non-Ambulatory Patients All Patients

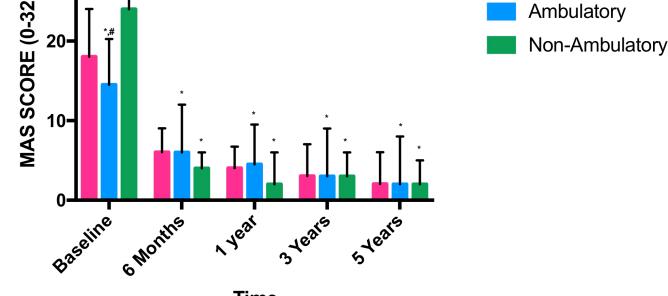


Figure 2. Measurement of modified ashworth scores in ambulatory and non-ambulatory patients (*P < 0.05 versus baseline, † P < 0.05 versus ambulatory, #P < 0.05 versus non-ambulatory).

Figure 3. Pain Score Comparisons

Pain Scores in Ambulatory vs. Non-Ambulatory Patients

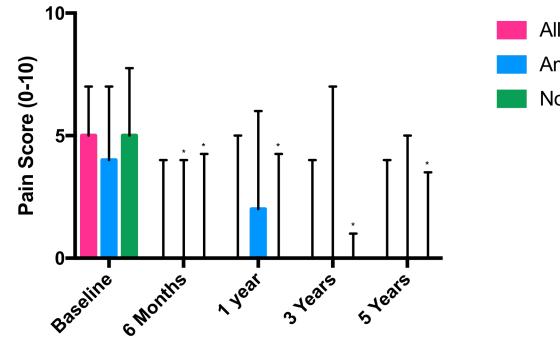


Figure 3. Measurement of pain scores in ambulatory and non-ambulatory patients (*P < 0.05 versus baseline, † P <0.05 versus ambulatory, #P < 0.05 versus non-ambulatory).

All Patients Ambulatory Non-Ambulatory

Summary

- MAS score improvement was observed at all follow-up times was observed in the entire sample and in both groups.
- In ambulatory patients, the median MAS score was 14.5 (10.8-20.25) at baseline and 2 (0-8) after 5 years on ITB therapy (Figure 2).
- In non-ambulatory patients, the median MAS was 24 (16.5-26) at baseline and 2 (0-5) after 5 years of ITB therapy (Figure 2).
- Pain scores improved between baseline and all follow-up visits in the non-ambulatory group (Figure 3).

Conclusion & Discussion

- ITB therapy provides long-term reductions in spasticity (as measured by MAS) regardless of baseline ambulatory status.
- 2. Pain reduction appears more consistent in non-ambulatory patients.
- 3. Further Study is needed to clarify effects of ITB on other relevant parameters including strength and quality of life.

References

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