Late Complications of Intrathecal Baclofen (ITB) Pump Management

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Introduction: Intrathecal baclofen (ITB) therapy has been instrumental in improving management of spasticity in diagnoses such as spinal cord injury (SCI), brain injury, cerebral palsy, stroke, multiple sclerosis and other neurologic conditions. Given the history of patient satisfaction with ITB (Campbell, Krach), we explored factors associated with discontinuation of the above treatment among subjects previously managed successfully with ITB.

Objectives: 1). To examine complications of the ITB system and their frequency among SCI and non-SCI subjects
2) To explore whether complications with the pump led to discontinuation of the ITB system
3) To classify complications as medical (infection in pump system analyzed apart from illness unrelated to pump); technical (pump or catheter malfunction):,or social/financial (transportation, adequate caregiver, funding for pump maintenance).

Design: Retrospective Chart Review

Participants/Methods: Subjects were drawn from the spasticity clinic within an academic rehabilitation medicine department of a tertiary care hospital. Although 67 subjects met criteria for study inclusion, only 45 had complete records for all parameters of interest. All ethnicities and both genders were included. Independent variables included diagnosis causing spasticity, eventual daily bacofen dose (mcg/day), age, years of pump usage, and living situation (nursing home vs. community). Of the 22 subjects eliminated after preliminary review, 15 lived in a nursing home and had been refilled periodically by an agency representative arranged by that location. The other 7 were excluded due to early management at a different hospital or clinic.

Results: There were 17 subjects with SCI (37.8%), 11 traumatic or anoxic brain injury (24.4%), 11 cerebral palsy, and 6 with other etiologies of spasticity including stroke, multiple sclerosis, and hereditary spastic paraparesis. Those with dual diagnosis were assigned to the category of SCI. We identified 28 total complications among 22 subjects. Four subjects experienced more than one complication of the same or different etiologic category (technical, medical, or social) and one subject had three complications. Table 1 illustrates comparisons between groups

Significance differences between groups were not seen among age, years with pump, gender, ethnicity, or daily baclofen dose. Although overall adverse events in SCI patients did not differ significantly from other diagnostic groups, infections isolated as a type of complication did demonstrate a larger effect. The number of infections among patients in nursing homes was significantly higher (p= 0.046) than those living in the community.

Discussion: Overall a high number of complications existed in the sample studied, with nearly half of the subjects affected. Krach and colleagues had examined satisfaction in cerebral palsy patients after 1 year or more of ITB and found that 22 of 100 subjects had experienced 32 total complications related to surgery or hardware. Their study did not adopt a broader definition of complications that encompassed infections and other medical issues. Campbell's study had used a similarly broad definition of adverse events and identified 153 instances with 27 of those device-related. Similar to both studies, a high rate of satisfaction and desire to retain the pump was noted in our study. This was particularly true in SCI patients. Despite adverse events, only 2 SCI subjects abandoned ITB treatment at the end of the study (12%), relative to almost 36% of subjects with other diagnoses. Infections were seen among subjects with multiple diagnoses but the majority had risk factors for pump seeding including tracheostomy, indwelling Foley, or history of chronic UTI's. The majority of infections did not occur in the immediate postoperative setting. In one patient with history of chronic UTI's who was at increased risk, infection in the postoperative setting arose even with 2 weeks of preoperative prophylactic antibiotics. Unlike the study by Fjelstad et al., we observed no increased risk of infection among subjects with a PEG tube.

Of our sample 46.7% resided in a nursing home. At the end of the study period, 1/3 of subjects in a nursing home discontinued ITB treatment, relative to only 1/5 living in the community. In addition, 2 subjects declined continuation of treatment exclusively for nonmedical reasons. Reasons for voluntary discontinuation of the pump included loss of funding or underfunding for pump maintenance and/or medication; living remotely with inability to reliably travel to clinic; unsafe supervision at home creating safety concerns for care of the ITB device.

Conclusion: Late complications of infection are observed in subjects with ITB living in a nursing home. A larger study will be needed to confirm the increased risk of infection in the SCI population.

Table 1

Subsets in our Sample of N=45	N	% of Total
SCI	17	37.8
SCI Non	28	62.2
Nursing home	21	46.7
Community	24	53.3
Rates ≤ 400 mcg/day	18	40.0
Rates >400 mcg/day	27	60.0
Pump retained @end of study	33	73.3
Pump explanted	12	26.7
If complications, pump retained	10	22.2
If complications, pump not retained	10	22.2
Without complications, retained	23	51.1
Without complications, not retained	2	8.8

References:

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