

Safety and Tolerability of Research Lumbar Punctures in Patients with Parkinson's Disease



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Abstract

Objective: To establish the frequency of adverse experiences related to research lumbar punctures among patients with Parkinson's disease (PD).

Background: Cerebrospinal fluid (CSF) analysis plays an increasingly important role in biomarker research for PD. No data have been published on the safety of research lumbar puncture (LP) in patients with PD or PD with Dementia (PDD). Motor symptoms of PD and dyskinesia resulting from PD treatment could complicate collection of CSF.

Methods: We reviewed data on patients with confirmed diagnosis of PD/PDD. We examined incidence of adverse events associated with research LP. All patients underwent bedside LP using a 24-gauge atraumatic Sprotte needle or had LP under fluoroscopic guidance. Unified Parkinson's Disease Rating Scale (UPDRS) noted patient's severity of resting tremor, rigidity and dyskinesia.

Results: Among PD/PDD patients (n=40), 6 experienced AE (15%), all were 'mild' or 'mild-moderate' in severity; all resolved the same day as LP. Site pain/shooting pain during procedure reported as the most frequent event (10%). One case of headache (2.5%) and one case of nausea/lightheadedness (2.5%) were reported. There was no correlation between AEs and tremor, rigidity or dyskinesia. There were also no serious adverse events.

Conclusions: Research LPs can be done safely in patients with PD/PDD with low incidence of AEs, including post-LP headache. Severity of movement disorder does not increase the patient's risk. Based upon patient self-reports, research LPs seem to be well tolerated in this patient population.

Background

PD biomarkers, especially from CSF are playing an increasing role in PD research and identifying causes of and treatments for PD. No data are published on LP safety in the PD population. PD motor symptoms and treatment-associated dyskinesia could complicate CSF collection and lead to increased incidence of AEs. In addition, the LP experience in geriatric populations is reported to be associated with stigma. Safety and qualitative analyses are warranted for conducting research LPs in this population. Stigma existence and severity could effect willingness to undergo research LP.

Objectives

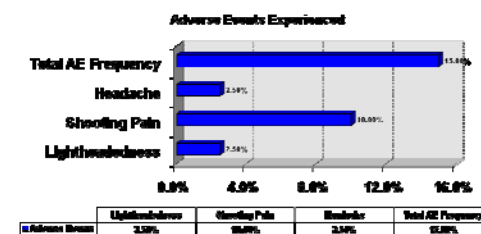
1. To assess the safety of research lumbar puncture in patients with Parkinson's disease by examining the frequency of adverse events and correlation to movement disorders.
2. To assess patient motivation and gather retrospective qualitative information on LP experiences.

Methods

- We examined incidence of adverse events associated with research LP. All patients underwent bedside LP using a 24-gauge atraumatic Sprotte needle or had LP under fluoroscopy.
- Unified Parkinson's Disease Rating Scale (UPDRS) noted patient's severity of resting tremor, rigidity and dyskinesia.
- A survey tool was developed through a pilot study on a small subset of patients. Patients were surveyed in person or over the telephone using this tool. Data on the perceived quality of the experience were collected. Patients were also asked about previous LPs and what they consider to be their primary and secondary motivation.

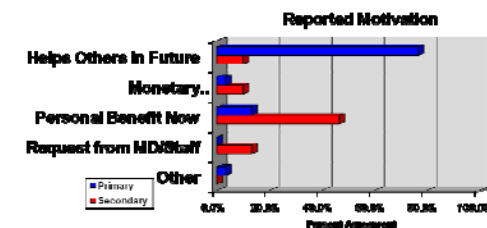
Results

Quantitative: Among the 40 PD/PDD patients, 6 experienced AE (15%), all were 'mild' or 'mild-moderate' in severity and all resolved the same day as the LP, requiring not further intervention. Site or shooting pain during procedure reported as most frequent (10%). One case of headache (2.5%) was mild, atypical, spontaneously resolved by positioning supine and did not require an epidural blood patch. One case of nausea/lightheadedness (2.5%) was reported. There is no correlation between AEs and tremor, rigidity or dyskinesia; one AE participant had moderate dyskinesia, one AE participant had tremor and rigidity rated '2' on the UPDRS. Other AE participants rated normal in tremor and rigidity, absent dyskinesia.



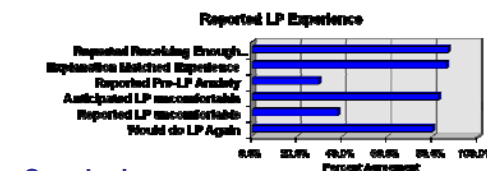
Previously published results of AE frequency in an Alzheimer's disease (AD) and normal controls cohort reported similar retrieval techniques and similar in frequency of AEs in the AD/MCI population: 4 AEs in 67 patients, 1.1% reported frequency of post-LP headache. (Peskind et. al. Alzheimer Dis Assoc Disord 2005)

Qualitative: Patients reported results on primary and secondary motivation: *Altruism* primary (76.7%), secondary (10%), *Monetary Compensation* primary (3.3%) secondary (10.0%), *Personal Benefit* primary (13.3%) secondary (46.7%), *MD Request* primary (0%) secondary (13.3%), and *Other* primary (3.3%) secondary (0%).



Patient reported results from the LP experience:

- 86.9% felt they were given enough information to make an informed decision. 86.2% felt the information given *matched* the experience.
- 29.7% reported pre-LP anxiety (rated on a scale of 1-5, 1 no anxiety, 5 severe anxiety); 1.48 total mean for anxiety severity.
- 82.7 reported anticipating the LP to be uncomfortable, 38% reported the LP as being uncomfortable.
- 80% indicate if asked, they would do the LP again.



Conclusions

Research LPs can be done safely in patients with PD/PDD with low incidence of AEs, including post-LP headache. Severity of movement disorder does not increase the patient's risk. Based upon patient self-reports, research LPs seem to be well tolerated in this patient population with minor affect from the reported stigma. Further study is needed to assess influence on participation due to potential selection bias.

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