Levels of Evidence: Clinician Perspectives on the Potential of DBS for Pediatric Patients with Treatment-Resistant OCD

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Background

- Deep brain stimulation (DBS) is currently used in pediatric patients with treatment-resistant dystonia, though no randomized control trials (RCTs) were conducted before this use and practitioners relied on evidence from use in adults.
- Accumulated research supports the safety and effectiveness of DBS for obsessive-compulsive disorder (OCD) in adults (Wu et al.2021). Given that approximately 10-20% of children with OCD have treatment-resistant presentations, it is likely that there will be interest in offering DBS for some children (POTS 2004).

Methods

- In-depth, semi-structured interviews were conducted with clinicians (n=24) with expertise in treating pediatric patients with treatment-resistant OCD.
- Interview transcripts were analyzed using thematic content analysis.

Results: Clinician Perspectives

- The World Society for Stereotactic and Functional Neurosurgery (WSSFN) has argued that at least two successful randomized controlled trials (RCTs) should be available before DBS treatment for a psychiatric disorder is considered “established.”
- Clinicians were asked: whether two successful RCTs is a necessary level of evidence to offer DBS for treatment-resistant OCD in pediatric patients.
- Nearly half of clinicians (n=11; 45%) were in favor of two successful RCTs:

  - Some clinicians (n=5; 21%) proposed alternative standards to offer DBS to pediatric patients

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<th>RCTs constitute appropriate level of evidence</th>
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<td>“Yeah, I think we should have at least that level of evidence [two RCTs].” (003)</td>
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<td>“I would like to have evidence. [...] And I would love to see at least two trials, preferably independent trials.” (023)</td>
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Evidence to Justify Efficacy of Treatment

- “We have to study it. I think we do, because otherwise we don’t know it’s effectiveness or efficacy.” (011)
- “[W]e probably should not be offering it without some solid evidence that there are reasonable benefits to expect.” (012)

- Some clinicians (n=4; 17%) identified challenges with pursuing two successful RCTs

  - Few centers with capacity
  - Not enough participants
  - Take too long

  - “It would be very difficult to get two separate randomized controlled trials. There’s so few centers that really have the capacity to do this.” (001)
  - “[T]here’s no way you’re going to get an adequate number of patients to participate in a clinical trial that will have enough power to actually be useful. If we wait for that, it’s just never going to happen.” (014)
  - “Two randomized controlled trials, that’s going to take a very long time to do.” (020)

- Some clinicians (n=5; 21%) proposed alternative standards to offer DBS to pediatric patients

  - “My inclination is to say one randomized blinded, well-conducted study should be sufficient.” (001)
  - “As long as families and caregivers and parents knew that there hadn’t been those trials, and that whatever the level of risk was, I think it would be reasonable that they could pursue it without the trials.” (022)
  - “I guess I would want to make sure that [...] there was adequate evidence of safety. [...] So I guess it would depend on the safety of it in children and adolescents [...]” (024)

Conclusion

- These preliminary results on clinician perspectives will be useful for researchers, ethicists, and policy-makers as interest in using DBS for treatment-resistant conditions in pediatric patients grows. Additional research is needed to understand other important stakeholder perspectives (e.g., prospective patients, caregivers).

References


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