An Analysis of Adherence to CONSORT Harms-Reporting in Hypoglossal Nerve Stimulator Clinical Trials

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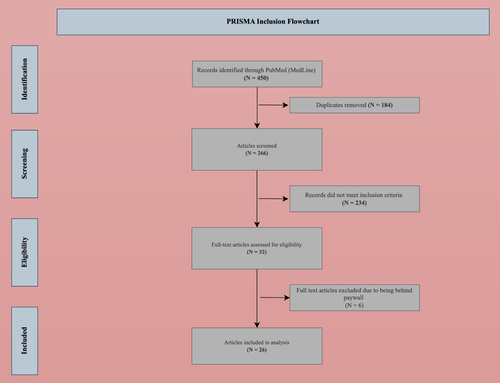
Introduction

Sleep apnea is one of the most common illnesses in the world, affecting an estimated 1 billion people throughout the world.[1] While continuous positive airway pressure (CPAP) therapy remains the gold standard for treating obstructive sleep apnea (OSA), poor patient compliance has spurred the development of alternative therapies.[2] Hypoglossal nerve stimulation (HGNS), also known as upper airway stimulation, has become a notable alternative for patients who cannot tolerate CPAP therapy as it does not require any external devices like a face mask or machine. a 2021 position statement acknowledged HGNS as a safe second-line treatment for people with moderate sleep apnea and who are intolerant to CPAP therapy.[3] This study aims to add to further evaluate the adherence to the Consolidated Standards for Reporting Trials (CONSORT) harms checklist for randomized and non-randomized trials involving hypoglossal nerve stimulation.

Methods

Twenty-six articles were included in this study. Participants in these studies were over the age of 18 and were diagnosed with obstructive sleep apnea. These patients had poor continuous positive airway pressure (CPAP) compliance and were treated with an implantable hypoglossal nerve stimulator.



Results

Of the 26 articles that were included in this study, 8 were RCTs and 18 were non-randomized trials. Only one article (1/26; 4%) referenced CONSORT within the manuscript. On average, each article met 4/10 of the CONSORT guidelines.

Study Design	***# of articles***	***Percentage***
Randomized-Control Trial	8/26	31%
Non-Randomized Control Trial	18/26	69%
Funding source		
Industry	18/26	69%
No funding	3/26	12%
Private	3/26	12%
Public	1/26	4%
Combination including industry	1/26	4%
Sample Size Range	9-227 (Median: 36.5)	

Item	**Percentage**	**# of articles**
Mentioned CONSORT guidelines at all	4%	1/26
Harms was primary vs secondary vs neither outcome		
Primary	27%	7/26
Secondary	8%	2/26
Neither	65%	17/26
# of articles that adhered to >50%	31%	8/26
# of articles that adhered to 25-50%	23%	6/26
# of articles that adhered to <25%	46%	12/26
Checklist Item #		
Item 1	46%	12/26
Item 2	42%	11/26
Item 3	15%	4/26
Item 4	15%	4/26
Item 5	27%	7/26
Item 6	19%	5/26
Item 7	50%	13/26
Item 8	42%	11/26
Item 9	42%	11/26
Item 10	50%	13/26
Item 11	27%	7/26
Item 12	23%	6/26

Conclusion

There remains a need for improved adherence to CONSORT-Harms reporting guidelines amongst HGNS RCTs and NRSIs. Our study reveals that adherence to the CONSORT-Harms checklist is generally low with no study adhering to all CONSORT items. This identifies an opportunity for improvement in how adverse events are reported in both randomized and non-randomized trials involving HGNS. Enhanced adherence will foster increased transparency of the risks and benefits associated with HGNS, thereby increasing patient safety and providing more comprehensive information for patient education. Researchers and clinicians should continue to encourage adherence to CONSORT-Harms guidelines.

Future Directions

While hypoglossal nerve stimulation is accepted as a generally safe procedure, there are significant adverse events that patients and physicians should be aware of. In order to increase awareness of guidelines surrounding adverse event reporting and patient safety, adherence to the CONSORT-Harms checklist should be improved upon in future clinical trials involving hypoglossal nerve stimulation.

Acknowledgements

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Literature Cited

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