Natural History of Vagal Nerve Stimulation Devices and Therapy for Drug Refractory Epilepsy

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Introduction

Vagus nerve stimulation (VNS) is a treatment modality for patients with medically refractory epilepsy and who are poor surgical candidates to help control the rate and possibly severity of seizures. Although approved for patients aged 12 years and above, VNS continues to be used in younger patients and has showed therapeutic benefit. In this study the survival of both, the VNS device and therapy was examined in a large cohort of epilepsy patients.

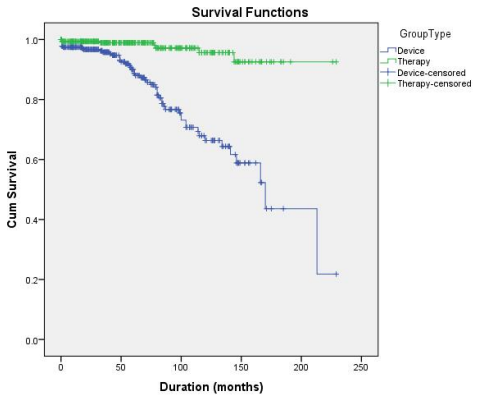
Methods

This study was approved by the Oregon Health & Science University (OHSU) Institutional Review Board and a waiver of informed consent granted. A retrospective review of electronic medical records of patients who had a VNS implantation and/or generator replacement at Oregon Health and Science University between 2005 and 2014. Failure of the device was defined as any device problems requiring surgery other than generator replacement. Devices duration was tracked through procedures, most recent appointments, and follow up calls. Failure of therapy was defined as discontinuation of therapy due to lack of efficacy even if the device was still implanted.

Results

Three hundred and sixty seven patients were implanted with a VNS system during the study period. Mean age was 23.8 years (range 2 – 65). 53% of patients were males. The median survival of the device was 170 months. Survival of therapy remained way above the 50th percentile at 10 years of follow-up. 98 and 90% of patients were still using the VNS therapy at 5 and 10 years respectively representing survival of therapy irrespective of device survival which is roughly 80% and 60% at 5 ad 10 years respectively. The most common cause of device failure was hardware and mechanical problems mainly related to the leads, including lead migration. Over 10 years (including following generator replacements), there were 66 explants due to 10 infections, 52 hardware failures, including lead breakage, migration and device malfunction, and 2 cases of revision due to hematoma/seroma at surgical site. 2 patients chose to remove their devices due to lack of therapeutic benefit. The risk of infection and mechanical/hardware failures over 10 years after implantation was 2.8% and 15% respectively. The device was reimplanted in 60 out of 64 patients (93.8%) in whom there was device failures or infection.

VNS Device versus Therapy Survival



Kaplan-Meier representation of the survival of VNS device (blue) and therapy (green)

Conclusions

VNS therapy is associated with relatively low rates of failure and long therapeutic benefit. Patients who had a device failure usually had the system revised/re-implanted. This study was not designed to measure the effectiveness of VNS in controlling refractory seizures, yet it demonstrates that about 90% of patients were still using the device at 10 years after implantation, which may be a reflection of continued therapeutic benefit.

The study was limited by its retrospective nature and the rate of patients lost to follow-up. Further studies are warranted to elucidate the pattern of therapeutic benefit of the VNS therapy over time.

References

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