VIVISTIM

Vagal Nerve Stimulation for Stroke Recovery

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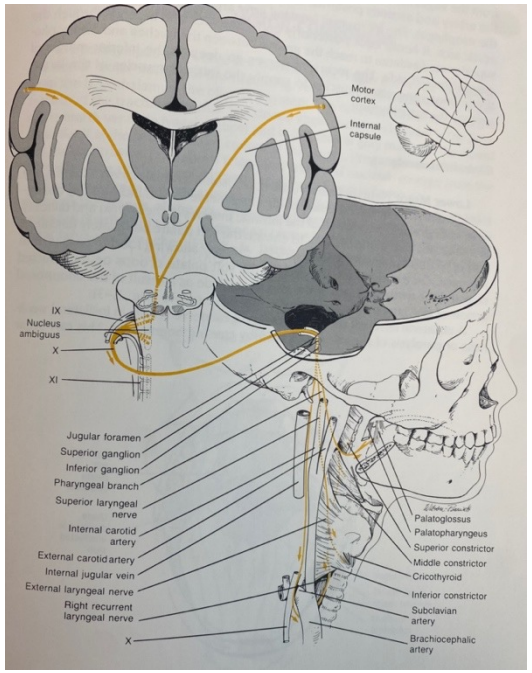
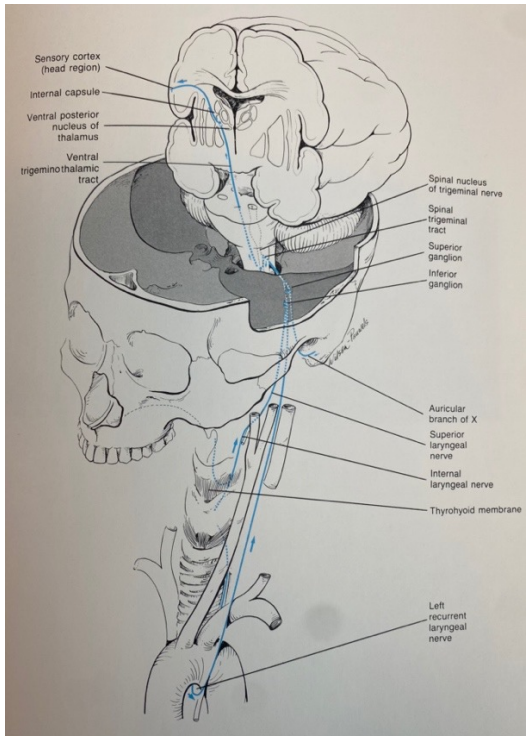
NEUROPLASTICITY

- The capacity of the nervous system to modify itself, functionally and structurally, in response to experience and injury

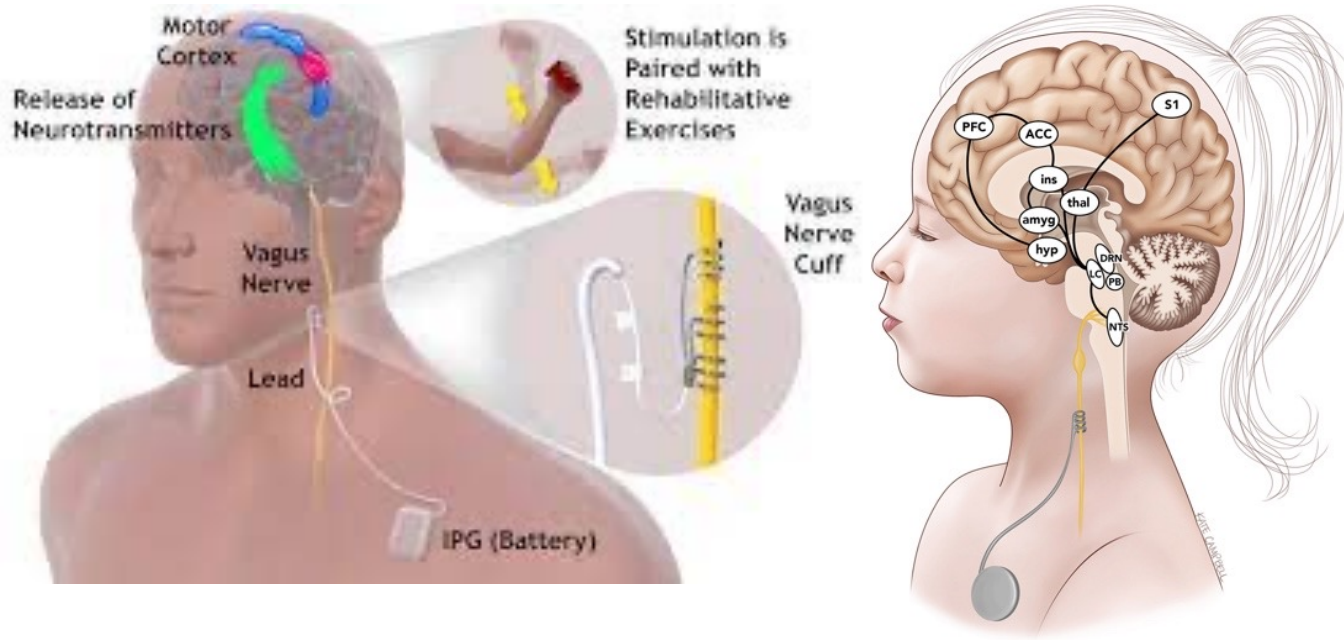
VAGUS NERVE

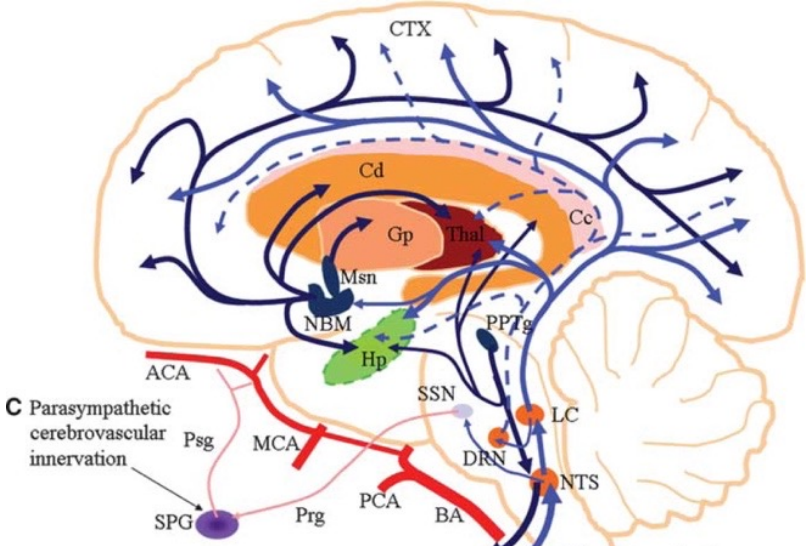
- A nerve that arises from the base of the brain (medulla)





VAGAL NERVE STIMULATION





ELIGIBLE PATIENTS

- Unilateral cortical ischemic stroke > 9 months and < 10 years before time of implantation
- Age >22 years and <80 years
- Fugl-Meyer Assessment of the upper extremity ≥20 and ≤50
- Ability to communicate, understand, follow two step commands
- Right or left side upper extremity weakness
- Ability to flex and extend the wrist, abduct and extend the thumb and at least two other fingers

- Exclusion:
  - History of hemorrhagic stroke
  - Ongoing dysphagia or aspiration
  - Medications that may interfere with VNS
  - Prior vagus nerve injury such as during carotid endarterectomy
  - Depression (Beck Score >29)
  - High surgical risk
  - Current use of a stimulation device (pacemaker, neurostimulator)
  - Psychological instability, substance abuse
  - Pregnancy
  - Recent Botox injections to extremity
  - Severe spasticity (Ashworth ≥3)
  - Significant sensory loss

POST SURGICAL REHABILITATION

- Rehabilitation therapy usually begins two weeks after surgery. The rehabilitation protocol involves:

- 6 weeks
- 3 sessions per week
- Each session is 90 minutes long

- Once the 6-week sessions are completed, patients continue with a daily 30-minute, home based, self-directed therapy program. The VNS is activated at home by the patient using a handheld magnet.

RESULTS

- In 2018, Kimberley *et al*. published results from a blinded and randomized trial investigating the benefits of VPS after chronic stroke in human subjects who experienced **injury 4 months to 5 years prior to study initiation** (Kimberley TJ, *et al*. Vagus nerve stimulation paired with upper limb rehabilitation after chronic stroke. Stroke. 2018; 49:2789-2792). **Ninety days following treatment** investigators found that **VNS treated patients had 88% meaningful improvement in upper extremity function** while **rehabilitation patients alone demonstrated 33% meaningful recovery.** Proof of concept showed that VPS during rehabilitation sessions was beneficial when compared to rehabilitation alone.

- In 2021, Dawson *et al*. published a 19 center, 108 patient randomized and blinded VNS-Rehabilitation post stroke study (Dawson J, et al. Vagus nerve stimulation paired with rehabilitation for upper limb motor function after ischaemic stroke (VNS-REHAB): A randomized, blinded, pivotal device trial. 2021 Apr 24;397(10284):1545-1553). **Ninety days following treatments** the authors noted **meaningful improvement in 47% of the VNS-Rehab group** as compared to **24% in the Rehab group that had not received VNS**.
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