Effectiveness of Combined Cognitive Processing Therapy with Stellate Ganglion Block for Posttraumatic Stress Disorder: a Randomized Clinical Trial

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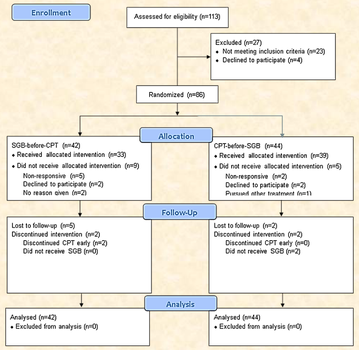
STRIVE

Introduction:

- Posttraumatic stress disorder (PTSD) is common among military personnel and veterans. Standard treatment options lack acceptable long-term success rates.
- First-line cognitive-behavioral treatments like cognitive processing therapy (CPT) are effective in treating PTSD, especially when delivered in a massed (i.e., daily) format. However, many patients, continue to struggle with PTSD symptoms after CPT.
- Stellate ganglion block (SGB) is an anesthetic injection which "resets" sympathetic arousal and physical reactivity, with 15+ years of research demonstrating reduced PTSD symptoms.
- The effectiveness of CPT combined with SGB remains understudied.

Method: Study Design and Setting



This open label randomized wait-list controlled trial was conducted by collaborators at an academic medical center located in central Ohio (CPT) and a stellate ganglion block center of excellence in Maryland (SGB). Participants were recruited across the US. Study procedures were approved by The Ohio State University Biomedical Institutional Review Board (2021H0228).

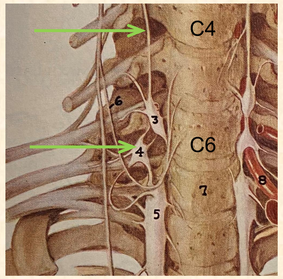
- Military personnel and veterans were recruited and consented from January 2022 to March 2024.
- Individuals meeting eligibility criteria were randomized to one of two treatment groups: (1) SGB the week before massed CPT or (2) SGB 3 months after completing massed CPT.
- All participants attended massed CPT sessions remotely via telehealth during study weeks 1 and 2.
- SGB was administered at an established stellate ganglion block center of excellence in Annapolis, MD, during week 0 or week 12, depending on their randomly assigned group.

Interventions: Cognitive Processing Therapy (CPT)

- Cognitive processing therapy (CPT) is one of three individual manualized trauma-focused psychotherapies that is strongly recommended for the treatment of PTSD by the VA/DOD Clinical Practice Guideline for the Management of PTSD and Acute Stress Disorder. Recent research has shown that CPT's effect on PTSD symptoms is accelerated when delivered in a massed (i.e., daily) format. Massed evidenced-based treatment for PTSD has higher treatment retention (13.6% dropout versus 24.8% dropout) and treatment completion.
- In this study, 60-minute CPT sessions were scheduled daily for 10 consecutive business days (i.e., "massed" CPT) and delivered remotely via telehealth. Research therapists were clinical psychologists, social workers, mental health counselors, and postdoctoral psychology trainees who had completed an approved CPT training workshop with follow-up consultation and supervision.

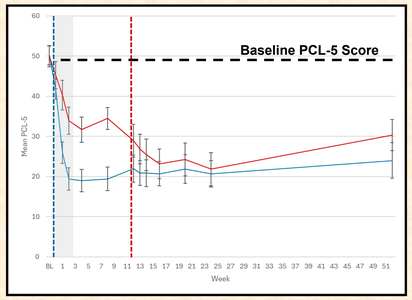
Interventions: Stellate Ganglion Block (SGB)

- Stellate Ganglion Block was performed using real-time ultrasonography. A total volume of 7-10 mL of ropivacaine 0.5% was injected around and the cervical sympathetic chain at the level of the C4 and C6 vertebrae. Participants were positioned supine with their head turned slightly to the left. Using a high frequency broadband linear transducer the cervical sympathetic chain area was scanned with color Doppler to identify potential vascular variations. A 25-gauge needle was then introduced into the ventral fascia of the longus coli at the C6 level. After negative aspiration, 7-8 mL of 0.5% ropivacaine was injected over 2 minutes. These steps were repeated at the C4 level using 1.5-2 mL of 0.5% ropivacaine.



- The procedure was considered successful if Horner's syndrome (i.e., ptosis, miosis, and scleral injection) was observed within 20 minutes of the first injection. 100% of SGB procedures were successful. Every SGB was performed by one of two SGB experts with over 10 years of ultrasound-guided SGB experience (JL & SM).

Results: Primary Outcome—PTSD Symptom Severity



Legend

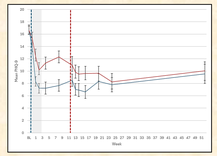
➢ **Blue Line = SGB-before-CPT**
(stellate ganglion block before massed cognitive processing therapy)

➢ **Red Line = SGB-after-CPT**
(massed cognitive processing therapy before the stellate ganglion block)

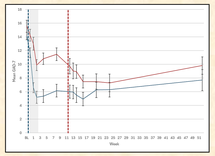
- SGB procedure *before* CPT is represented by the vertical blue dashed line
- Massed CPT is represented by the grey shaded region
- SGB procedure *after* CPT is represented by the vertical red dashed line.

- Change in PCL-5 scores significantly differed between groups over time (F(12,724)=3.0, p<.001).
- Relative to baseline, PCL-5 scores decreased in both groups (SGB-before-CPT: F(12,724)=23.4, p<.001; SGB-after-CPT: F(12,724)=21.1, p<.001), but **reductions were faster in SGB-before-CPT**.
- **PCL-5 scores were significantly lower in SGB-before-CPT at week 1** (F(1,724)=14.4, p<.001), **week 2** (F(1,724)=14.2, p<.001), **week 4** (F(1,724)=10.2, p=.001), and **week 8** (F(1,724)=15.2, p<.001).

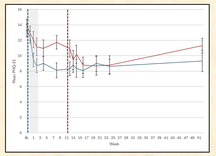
Results: Secondary Outcomes



Depression (PHQ-9)



Anxiety (GAD-7)



Somatic Symptoms (PHQ-15)

- PHQ-9, GAD-7, and PHQ-15 scores significantly differed between groups over time.
- PHQ-9 scores significantly decreased in both groups, but reductions were **faster in SGB-before-CPT**. PHQ-9 scores were significantly lower in SGB-before-CPT at week 1 (F(1,728)=9.7, p=.002), week 2 (F(1,728)=5.7, p=.018), week 4 (F(1,728)=9.3, p=.002), and week 8 (F(1,728)=11.9, p<.001).
- GAD-7 scores significantly decreased in both groups but reductions were **faster in SGB-before-CPT**. GAD-7 scores were significantly lower in SGB-before-CPT at week 1 (F(1,725)=24.3, p<.001), week 2 (F(1,725)=15.6, p<.001), week 4 (F(1,725)=19.4, p<.001), week 8 (F(1,725)=19.1, p<.001), week 12 (F(1,725)=7.1, p=.008), week 13 (F(1,725)=5.7, p<.001), week 14 (F(1,725)=5.7, p=.017), and week 16 (F(1,725)=4.5, p=.035).
- PHQ-15 scores significantly decreased in both groups, but reductions were **faster in SGB-before-CPT**. PHQ-15 scores were significantly lower in SGB-before-CPT at week 1 (F(1,726)=4.0, p=.046), week 2 (F(1,726)=4.5, p=.034), week 8 (F(1,726)=9.3, p=.002), and week 12 (F(1,726)=5.3, p=.022).

Conclusions

- **Results support SGB increasing CPT's effectiveness when received prior to CPT.**
- **Military personnel and veterans who do not benefit from an initial course of massed CPT have significant reductions in PTSD symptoms when SGB was performed after CPT.**
- **Receiving SGB before CPT appears especially useful for patients looking for faster treatment response since the combination of SGB prior to CPT is associated with larger and faster reductions in PTSD symptoms.**
- **These conclusions may be generalizable to the nonveteran population, because aside from combat, the most common trauma exposures were physical assault (76.7%) and transportation accident (69.8%).**

Calm the body. Calm the mind.
James Lynch MD

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