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The Feasibility of Investigating Acupuncture in Patients With COVID-19 Related Olfactory Dysfunction

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Abstract

Background: Olfactory dysfunction (OD) is a common symptom in patients with coronavirus disease 2019 (COVID-19) with limited treatment options.
Objective: This pilot study aimed to investigate an acupuncture protocol in patients with COVID-19 related OD.
Methods: Thirty patients were randomized into 2 groups. The standard group was treated with budesonide nasal irrigation and olfactory training. The acupuncture group received ten sessions of acupuncture therapy in addition to the standard group treatment. Olfaction was assessed using the University of Pennsylvania Smell Identification Test, 10-point visual analog scale, and Sino-Nasal Outcome Test at baseline and after 3 months of treatment. Differences between study arms were compared using Fisher's exact and Wilcoxon rank sum tests.
Results: Eighteen of the 30 (60%) enrolled patients completed the study, including 11 (73%) in the standard and 7 (47%) in the acupuncture group. Reasons for participant drop-out included cost of travel and time constraints. There were no acupuncture complications.
Conclusions: Acupuncture as an adjunct therapy for COVID-19 related OD is well tolerated. Subsequent studies with larger sample sizes are needed to assess the effect of acupuncture on OD.

Keywords

acupuncture, COVID-19, olfaction, olfactory dysfunction, University of Pennsylvania smell identification test

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Introduction

Olfactory dysfunction (OD) is common, affecting about 20% of the general population.[1] Furthermore, patients with OD are at increased risk of death[2] and have psychosocial limitations including the inability to enjoy food and depression.[3] Common causes of OD include inflammation from an underlying sinonasal condition, infectious (post-viral), idiopathic, post-traumatic, and iatrogenic following skull base surgery.[4] While treatment of underlying sinonasal inflammation may correct OD in patients with chronic rhinosinusitis, limited treatment options exist for patients with other causes of OD.[5]

Post-viral OD (PVOD) is the second leading cause of OD after sinonasal conditions.[4] While the majority of patients with PVOD report subjective recovery after 1 year, only 30% fully recover their sense of smell.[6] When compared to the general prevalence of OD, the pooled prevalence of COVID-19 OD is higher with subjective ratings reported to be 44% and objective ratings as high as 77%.[7] In contrast to non-COVID-19 PVOD, a recent systematic review and meta-analysis showed that almost 75% of patients with COVID-19 OD recovered their sense of smell within 1 month and 95% within 6 months.[8] While the majority of patients with COVID-19 OD ultimately recover their sense of smell, expanding treatment options may hasten recovery or improve olfaction in those with persistent OD.

Olfactory training is a low-risk intervention that is recommended in the treatment of PVOD.[9] Classic olfactory training was defined by Hummel et al as twice daily exposure to a set of 4 odors, including rose, eucalyptus, lemon, and cloves.[10] Improved outcomes are seen with longer duration of olfactory training, higher odor concentrations, and shorter duration of OD prior to initiating olfactory training.[5] While there is limited data to support the use of systemic or topical steroid sprays in the setting of non-chronic rhinosinusitis OD,[11] evidence for additional treatment options is lacking.[9]

Acupuncture is a low-risk intervention that started in China approximately 3000 years ago.[12] A few studies have investigated the use of acupuncture in the treatment of PVOD with 1 randomized trial demonstrating significant improvement in University of Pennsylvania Smell Identification Test (UPSIT) scores compared to controls.[13] Acupuncture is an attractive therapeutic option because it is low risk; however, it is often not covered by insurance and may be cost prohibitive to many patients. More research is needed to understand if it can speed recovery in patients with both short and long-term OD. The objective of this pilot study was to investigate an acupuncture protocol in patients with COVID-19 related OD.

Methods

Study approval was obtained by Mayo Clinic IRB #21-003531. Funding was obtained through the Department of Otolaryngology Small Grants Program 2021 (Project #93207003). Patients presenting to a tertiary rhinology clinic were recruited for participation by the study coordinator after obtaining approval by the COVID-19 Research Task Force. Patients were included if they met the following criteria: (1) at least 18 years of age; (2) PVOD greater than 4 weeks; and (3) documented positive COVID-19 PCR preceding the onset of OD. Patients were excluded if they met 1 or more of the following criteria: (1) less than 18 years of age; (2) active sinusitis; (3) untreated chronic rhinosinusitis; (4) prior diagnosis of dementia or Parkinson's disease; (5) prior head trauma or neurosurgical procedure resulting in OD; (6) inability to speak or read English; and (7) inability to understand and sign the study consent.

Phone, virtual, and in-person consents were obtained from interested patients meeting inclusion criteria. For patients seen virtually, the following screening questions were asked: (1) "Do you have purulent (colored or foul smelling) nasal or postnasal drainage?"; (2) "Do you have worsening nasal obstruction over the past 6 months?"; (3) "Do you use a steroid nasal irrigation daily to treat chronic rhinosinusitis?"; and (4) "Have you been treated with an antibiotic for a sinus infection in the past 3 months?" If the answer to any of these questions was "yes," an in-person evaluation with nasal endoscopy was conducted to determine the etiology of their OD.

Because this was a pilot study, a power/sample size calculation was not performed. Enrolled patients were randomly assigned using an Excel spreadsheet into parallel arms at the time of accrual. The study coordinator, responsible for randomization and scheduling, was unblinded. However, research staff administering outcome assessments were blinded to group allocation to minimize bias. This blinding extended to UPSIT raters and other evaluators, who remained unaware of participants' treatment groups until study completion, when data analysis began. The first arm (standard group) was treated with twice daily budesonide nasal irrigation and olfactory training. The second arm (acupuncture group) underwent weekly acupuncture therapy for a total of ten sessions with a licensed acupuncturist in addition to twice daily budesonide nasal irrigation and olfactory training. Most treatments were administered by a single licensed acupuncturist with 10 years of clinical experience, though scheduling conflicts occasionally necessitated other licensed acupuncturists in the practice (10-20 years of experience). The lead acupuncturist met with each provider to ensure protocol fidelity. Acupuncture points Du-20, Du-23, Li-20, Li-4, Lu-7, and St-36 were selected based on traditional Chinese medicine (TCM) theory and prior clinical research (Figure 1).[14-17] Li-20, previously studied for COVID-19-related OD, may stimulate the maxillary branch of the trigeminal nerve,[18] while Li-4, avoided in pregnant participants due to its labor-inducing potential, and other points target systemic and sensory regulation. A 0.20 mm × 30 mm stainless steel needle was used, with no manual stimulation to

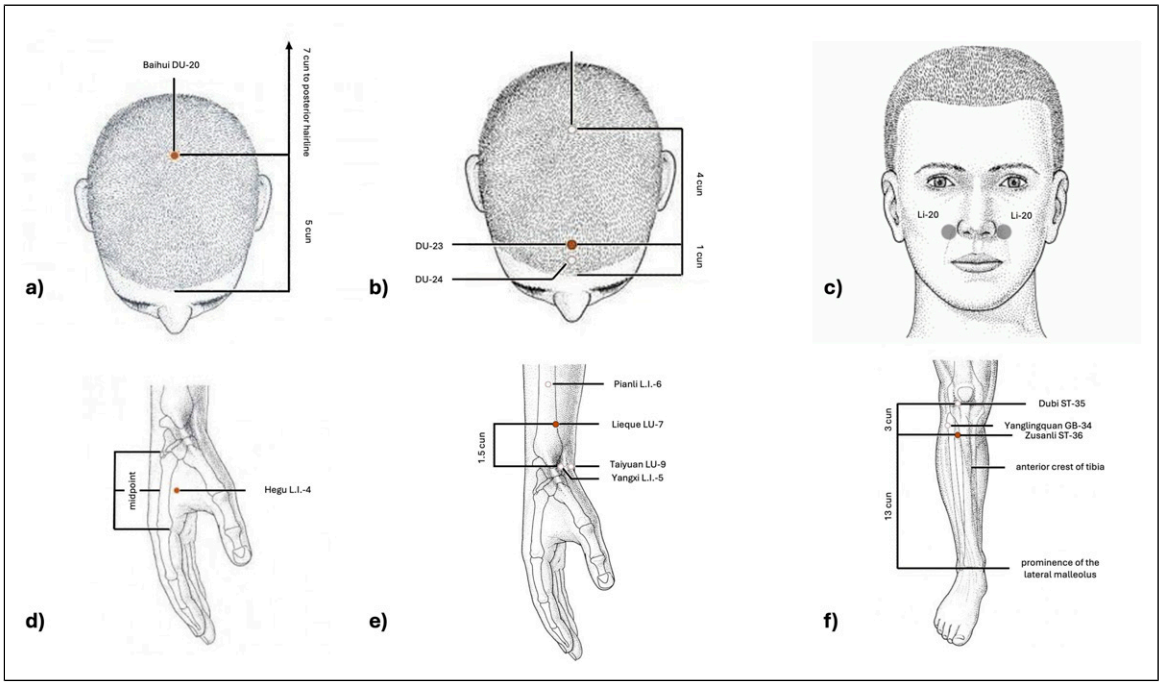

Figure 1. Acupuncture point locations for anosmia; (a) Du-20 is located at the top of the head; (b) Du-23 is located approximately 1 cm above the hairline; (c) Li-20 is located at the nasolabial groove; (d) Li-4 is located on the dorsal side of the hand between the thumb and index finger; (e) Lu-7 is located 1.5 inches above the crease of the wrist along the radius; (f) St-36 is located 3 inches below the knee on the lateral side of the tibia.

achieve de qi (a sensation of soreness, numbness, or distension). Needles were inserted to a depth of 5-10 mm, depending on the acupoint, and retained for 25 minutes per session. No moxibustion was performed in this study. Enrolled patients were allowed to opt out of the study at any point.

Clinical data collected included demographic information and duration of OD. Objective and subjective assessments of olfaction were measured at the time of enrollment and after 3 months of treatment. These included the 40-item UPSIT, a 10-point visual analog scale (VAS), and the Sino-Nasal Outcome Test (SNOT-22). Overall differences in UPSIT, VAS, and SNOT-22 scores were calculated by subtracting the post-treatment from the pre-treatment score. A clinically significant change in UPSIT score was defined as an increase in total score by at least 5 points.[19] A higher score on the VAS corresponded to a worse perceived sense of smell with 0 representing normal smell and 10 representing no smell at all. A decrease by at least 1 point in the SNOT-22 olfactory question was considered clinically significant.

Continuous features were summarized with means and standard deviations, as well as medians and interquartile ranges (IQRs). Categorical features were summarized with frequencies and percentages. Statistical analyses were performed using SAS version 9.4 (SAS Institute; Cary, NC) and R version 3.6.2 (R Foundation for Statistical Computing; Vienna, Austria). All tests were two-sided and *P*-values <0.05 were considered statistically significant.

Results

Participant demographics are summarized in Table 1. Thirty participants were enrolled between June 23rd, 2021 and April 17th, 2023 with 15 participants randomized to each group (Figure 2). Of the 30 enrolled patients, 18 (60%) completed the study. This included 7 (47%) in the acupuncture group and 11 (73%) in the standard group. Reasons for participant loss after randomization included inability to attend weekly acupuncture appointments, travel costs, and time constraints precluding follow-up. One patient in the acupuncture group experienced headache and hyperglycemia with budesonide use and withdrew from the study. No adverse effects were encountered during the acupuncture sessions.

Thirteen (72%) of the patients who completed the study were female and aged 48.8 years on average (range: 18.9 to 80.7). Twelve (67%) patients had OD duration greater than 12 months. Mean pre-treatment UPSIT, VAS, and SNOT-22 scores were 24.4, 7.6, and 30.1, respectively. No significant differences were observed in age, sex, duration of OD, and pre-treatment UPSIT, VAS, and total SNOT-22 scores between groups.

Olfactory outcomes are shown in Table 2. There was a mean UPSIT improvement of 3.2 in the standard and 2.6 in the acupuncture group, a mean VAS improvement of 1.7 in the standard and 1.9 in the acupuncture group, and a mean total SNOT-22 improvement of 3.5 in the standard and 7.1 in the acupuncture group. An UPSIT score increase by at least

Table 1. Descriptive Characteristics of the Study Groups.

	Standard (N = 11)	Acupuncture (N = 7)	Total (N = 18)	*P*-value
Age				0.53[a]
N	11	7	18	
Mean (SD)	46.7 (18.21)	52.0 (22.87)	48.8 (19.67)	
Median (IQR)	48.2 (31.5, 62.8)	56.1 (33.0, 74.8)	49.4 (33.0, 63.7)	
Range	18.9, 72.7	20.4, 80.7	18.9, 80.7	
Sex, n (%)				1.00[b]
Male	3 (27%)	2 (29%)	5 (28%)	
Female	8 (73%)	5 (71%)	13 (72%)	
Race, n (%)				
White	11 (100%)	7 (100%)	18 (100%)	
Current smoker, n (%)				1.00[b]
Yes	2 (18%)	1 (14%)	3 (17%)	
No	9 (82%)	6 (86%)	15 (83%)	
Duration of olfactory loss, n (%)				1.00[b]
<12 months	4 (36%)	2 (29%)	6 (33%)	
>12 months	7 (64%)	5 (71%)	12 (67%)	
Baseline UPSIT				0.86[a]
N	11	7	18	
Mean (SD)	24.5 (7.20)	24.3 (5.85)	24.4 (6.53)	
Median (IQR)	24.0 (20.0, 31.0)	24.0 (19.0, 31.0)	24.0 (19.0, 31.0)	
Range	12.0, 36.0	19.0, 33.0	12.0, 36.0	
Baseline VAS				0.41[a]
N	11	7	18	
Mean (SD)	7.9 (1.58)	7.1 (1.77)	7.6 (1.65)	
Median (IQR)	8.0 (6.0, 9.0)	7.0 (6.0, 9.0)	8.0 (6.0, 9.0)	
Range	5.0, 10.0	5.0, 10.0	5.0, 10.0	
Baseline SNOT-22				1.00[a]
N	11	7	18	
Mean (SD)	29.9 (15.25)	30.3 (16.26)	30.1 (15.17)	
Median (IQR)	27.0 (22.0, 43.0)	27.0 (22.0, 48.0)	27.0 (22.0, 43.0)	
Range	5.0, 56.0	6.0, 54.0	5.0, 56.0	

[a]Wilcoxon rank sum *P*-value.
[b]Fisher exact *P*-value.

5 points was seen in 3 (27%) of the standard therapy patients and 3 (43%) of the acupuncture patients. Three patients in the standard (27%) and 3 patients in the acupuncture group (43%) had an improvement in their SNOT-22 olfactory score by at least 1 point.

Discussion

While this pilot study demonstrated the safety of an acupuncture protocol in the setting of COVID-19 related OD, it also revealed challenges that may be encountered in future efficacy studies. As a feasibility study, we prioritized recruitment, retention, and safety over efficacy and therefore did not include a sham acupuncture arm. Future trials should include a sham arm and detailed procedural reporting (eg, needle specifications, qi standards) to enhance rigor and reproducibility. This study had a high dropout rate, with less than half of the acupuncture group completing treatment, likely due to logistical barriers (eg, travel to a tertiary center) and unmet expectations for rapid improvement. The dropout rate could be improved in subsequent studies by involving local acupuncture clinics for out-of-state patients and providing travel reimbursement. Counseling patients about the unknown time course for olfaction improvement and encouraging completion of the treatment arm prior to randomization may increase participant retention.

Previous literature suggests a possible benefit of acupuncture as a treatment for OD; however, more rigorous studies are needed. A study by Vent at al assessed olfaction using the Sniffin' Sticks Test in 30 patients with more than 6 months of PVOD treated with either ten sessions of acupuncture or oral vitamin B complex. Defining treatment success as an increase in threshold, discrimination, and identification (TDI) scores of 6 points or more, 53% of patients undergoing acupuncture improved their olfactory scores compared to 13% of those treated with oral vitamin B.[20]

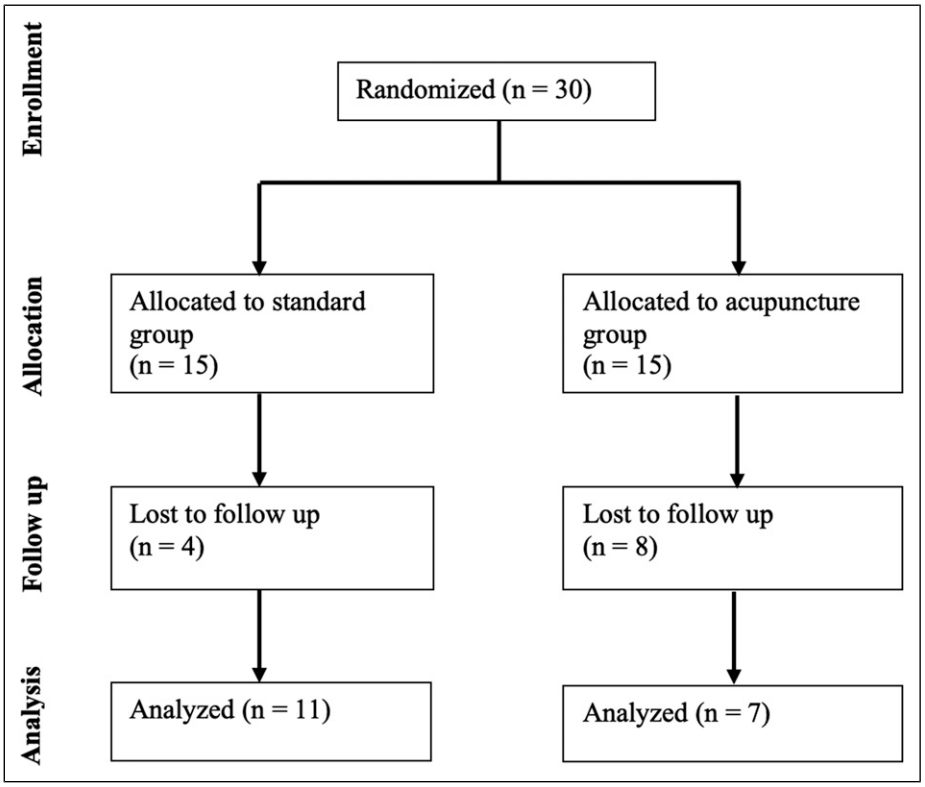

Figure 2. CONSORT diagram showing the flow of participants through each stage of a randomized trial.

Table 2. Olfactory Outcomes of the Study Groups.

	Standard (N = 11)	Acupuncture (N = 7)	Total (N = 18)	*P*-value
UPSIT improvement				0.78[a]
N	11	7	18	
Mean (SD)	3.2 (5.56)	2.6 (6.48)	2.9 (5.75)	
Median (IQR)	2.0 (1.0, 7.0)	0.0 (−2.0, 9.0)	2.0 (0.0, 8.0)	
Range	−7.0, 15.0	−7.0, 10.0	−7.0, 15.0	
UPSIT improvement > = 5, n (%)				0.63[b]
No	8 (73%)	4 (57%)	12 (67%)	
Yes	3 (27%)	3 (43%)	6 (33%)	
VAS improvement				1.00[a]
N	11	7	18	
Mean (SD)	1.7 (2.23)	1.9 (2.34)	1.8 (2.20)	
Median (IQR)	1.5 (−0.5, 4.0)	2.0 (−1.0, 4.0)	1.8 (−0.5, 4.0)	
Range	−1.0, 5.0	−1.0, 5.0	−1.0, 5.0	
SNOT-22 improvement				0.89[a]
N	11	7	18	
Mean (SD)	3.5 (16.05)	7.1 (10.53)	4.9 (13.93)	
Median (IQR)	4.0 (0.0, 16.0)	5.0 (−1.0, 11.0)	4.5 (0.0, 11.0)	
Range	−28.0, 31.0	−3.0, 28.0	−28.0, 31.0	
SNOT-22 olfactory improvement, n (%)				0.63[b]
No	8 (73%)	4 (57%)	12 (67%)	
Yes	3 (27%)	3 (43%)	6 (33%)	

[a]Wilcoxon rank sum *P*-value.
[b]Fisher Exact *P*-value.

Dai et al randomized 50 patients with more than 1 month of PVOD to undergo either ten sessions of acupuncture or observation without any treatment over a 3 month period.[13] Defining treatment success as an UPSIT score increase of at least 4 points, 44% of patients receiving acupuncture improved their olfactory scores compared to 16% of those undergoing observation. More recently, Drews et al randomized 60 patients with PVOD of any duration to receive 12 sessions of verum or sham acupuncture.[21] A clinically significant improvement in olfaction defined as TDI score increase greater than 5.5 points was seen in 20% of the verum group compared to 10% of the sham group, although this did not reach statistical significance. Strictly defining the minimal clinically important difference in UPSIT and TDI scores would help estimate the effect size in subsequent randomized controlled trials investigating acupuncture as a treatment for PVOD.

In contrast to the above studies, our study looked specifically at patients with COVID-19 related OD. As previously mentioned, over 95% of patients recover their sense of smell 6 months after developing COVID-19.[8] In contrast, PVOD of any cause has a slower spontaneous recovery rate with about 60% of patients recovering their sense of smell within 6 months.[22] Viruses are known to invade the olfactory neuroepithelium and can cause damage to central processing pathways such as the olfactory bulb.[23] COVID-19 is unique in that it spares the olfactory neuroepithelium and instead affects the supporting sustentacular and basal cells.[24,25] This difference in pathophysiology may suggest a shorter window of treatment for COVID-19 OD compared to PVOD, after which treatment resistance ensues. In our study, only 2 patients had an OD duration of less than 6 months with the majority (67%) having an OD duration of over 1 year. A subsequent efficacy study comparing a cohort of patients with less than 6 months of COVID-19 OD with a similar cohort of patients with greater than 6 months of OD may better elucidate a time window for treatment.

The choice of acupoints was informed by TCM and prior studies, but their specific mechanisms in COVID-19 OD remain speculative. Acupuncture at Li-20 may enhance sensory input via the trigeminal nerve, which interacts with olfactory bulb processing, while Du-20 and Du-23 could promote neuroplasticity or cerebral perfusion relevant to olfactory recovery.[15,18] However, these pathways are not fully mapped for COVID-19 OD, unlike broader PVOD contexts where acupuncture has shown promise.[13,20] Future studies should incorporate neuroimaging or biomarkers to explore how these acupoints influence olfactory pathways in this population.

Conclusions

This pilot study established the feasibility and safety of an acupuncture protocol in patients with COVID-19 related OD. Subsequent efficacy studies can enhance participant retention through increased funding, collaboration with local acupuncture clinics, and better alignment of patient expectations. Employing validated olfactory tests (eg, UPSIT, Sniffin' Sticks) and defining minimal clinically important differences will enable precise sample size and power calculations. Including a sham acupuncture arm, a no-intervention control, and an acupuncture-only group will help isolate acupuncture's specific effects from placebo responses, addressing a key limitation of this study. Additionally, mechanistic studies incorporating neuroimaging or molecular markers are needed to clarify how acupoints like Li-20 and Du-20 influence olfactory recovery in COVID-19 OD, given its distinct pathophysiology. Such studies would likely require a multiyear enrollment period across multiple institutions.

Authors' Note

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Author Contributions

Michael F. Armstrong: design, conduct, analysis, presentation Thomas J. O'Byrne: design, analysis Jason J. Calva: design, conduct Molly J. Mallory: conduct Sara E. Bublitz: conduct Alexander Do: conduct Carlos D. Pinheiro Neto: conduct Garret W. Choby: conduct; Erin K. O'Brien: conduct Brent A. Bauer: design, conduct Janalee K. Stokken: design, conduct, analysis, presentation

Declaration of Conflicting Interests

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Ethical Statement

Ethical Approval

Ethical approval for this study was obtained from Mayo Clinic Institutional Review Board #21-003531 and all subjects signed written consent.

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