



Edward Via College of Osteopathic Medicine

CAROLINAS

The Efficacy of Facial Effleurage on Acute Rhinosinusitis

Chelsea Weidman, M.S.; Matthew Cannon, D.O.; Randal Gregg, Ph.D.; Alexis Stoner, Ph.D., MPH; Christopher McCarthy, M.D.; Jerome Aya-ay, M.D.; Oshea Escamilla, D.O., Jillian Bradley, Ph.D.

The Edward Via College of Osteopathic Medicine – Carolinas Campus

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Introduction

Acute Rhinosinusitis

- Sudden onset of symptoms (<12 weeks) include anterior/posterior mucopurulent discharge PLUS nasal obstruction/pressure/pain
- RS is the 5th most common diagnosis in the U.S. for which antibiotics are prescribed
- Typically viral etiology, but can be bacterial, fungal or allergic
- Regardless of etiology, antibiotics are prescribed to 85-98% of patients in the US

Facial Effleurage



- Facial effleurage is an Osteopathic Manipulative Technique where the physician applies pressure to the tissues in an effort to remove any blockages within the lymphatic flow. Hypothetically, this will move the antigens into the draining lymph nodes allowing the activation of the immune system. This would also allow the environment to become refreshed providing new inflammatory cells into the area to fight the invading pathogenic agent.

Physical Touch Control

- Moving the patient in all the steps as the Facial effleurage, without applying any pressure
- This will hopefully capture placebo effects, without providing any beneficial effects of the lymphatic movement caused by the osteopathic technique.

Antibiotics

- - Antibiotics are the standard of treatment for patients with acute rhinosinusitis. The responsible physician for this study decided the best antibiotic treatment for the patients. The most recommended antibiotic treatment is amoxicillin ± clavulanate

Hypothesis

Our hypothesis is that the Osteopathic Manipulative Technique, Facial Effleurage, will cause significant changes in the concentration and effectiveness of the immune system resulting in significant benefits for patient symptom severity, symptom duration, and time to symptom resolution, especially compared to patients who do not receive the OMT treatment.

Methods

Overall Study Design

Day 1: Initial Visit

- Eligibility
- Randomization
- Survey and Sample Collection

Day 3
Night and
Morning
TSS

Day 5
Night and
Morning
TSS

Day 7: Follow-up Visit

- Survey and Sample Collection



Patient Eligibility

Inclusion Criteria	Exclusion Criteria
Ages 18-70	Temperature ≥ 102.5°F
Presenting with acute RS	Used topic antibiotics within last 30 days
OR Healthy (control)	Taken oral antibiotics within last 15 days
Independently read the informed consent form	Has a comorbidity, taking antibiotics or antiviral therapy
	Needs to be hospitalized
	Is currently pregnant, nursing or suspect they may be pregnant
	Bone fractures to the face or neck
	Visible nasal polyps, abscesses, incisions

Randomized into treatment groups

Healthy Patients + No Treatment

Healthy Patients + Physical Touch Control

Healthy Patients + Facial Effleurage

Rhinosinusitis + Antibiotics

Rhinosinusitis + Physical Touch Control

Rhinosinusitis + Facial Effleurage

Rhinosinusitis + Antibiotics + Physical Touch Control

Rhinosinusitis + Antibiotics + Facial Effleurage

Setting

The study is being performed at two sites of a direct-payment outpatient clinic. Both sites are in the same mid-sized, manufacturing and industrial, rural town.

Demographics

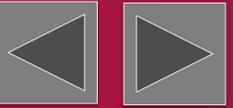
	Healthy Control n=117	Healthy Control + Physical Touch n=117	Healthy Control + Facial Effleurage n=117	Rhinosinusitis + Antibiotics n=117	Rhinosinusitis + Physical Touch n=117	Rhinosinusitis + Facial Effleurage n=117	Rhinosinusitis + Antibiotics + Physical Touch n=117	Rhinosinusitis + Antibiotics + Facial Effleurage n=117
Age (mean ± SD)	30.14	30.14	30.14	30.14	30.14	30.14	30.14	30.14
Gender								
Female	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)
Male	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)
Race								
White	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)
Black	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)
Ethnicity								
Hispanic or Latino	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)
Not Hispanic or Latino	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)
Education								
High School or less	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)
Some college	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)
College graduate	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)
Postgraduate	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)
Insurance								
Medicaid	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)
Medicare	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)
Private	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)
Other	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)
Marital Status								
Married	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)
Single	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)
Divorced	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)
Widow	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)
Employment								
Employed	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)	105(90%)
Unemployed	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)
Retired	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)
Other	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)	12(10%)

	Healthy Control n=117	Healthy Control + Physical Touch n=117	Healthy Control + Facial Effleurage n=117	Rhinosinusitis + Antibiotics n=117	Rhinosinusitis + Physical Touch n=117	Rhinosinusitis + Facial Effleurage n=117	Rhinosinusitis + Antibiotics + Physical Touch n=117	Rhinosinusitis + Antibiotics + Facial Effleurage n=117
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Results

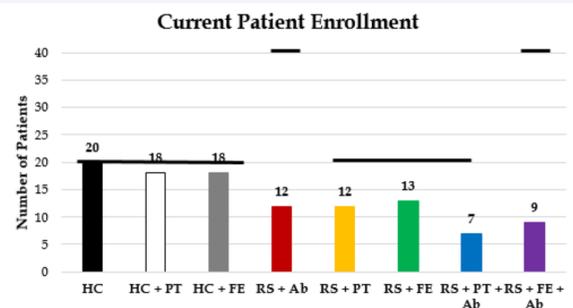


Fig. 1 Current Patient Enrollment and target numbers for patient enrollment

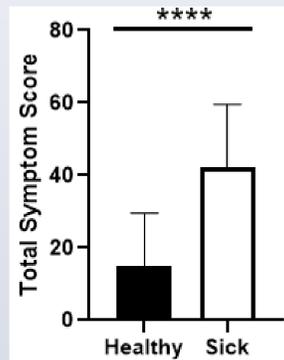
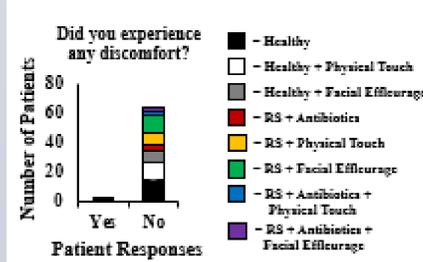


Fig. 2 The severity of symptoms as measured by the Total Symptom Score for all patients presenting with the symptoms of acute rhinosinusitis (sick) and patients without those symptoms (healthy). **** indicates a two-tailed p -value of <0.0001 . The mean for healthy patients is 15, the mean for sick patients is 42.02.

Fig. 3. Patients reported feeling any discomfort with the treatments. One patient in the healthy control group, who did not receive any treatment, and two patients in the healthy control + Facial Effleurage group reported mild, momentary discomfort.



Results Continued

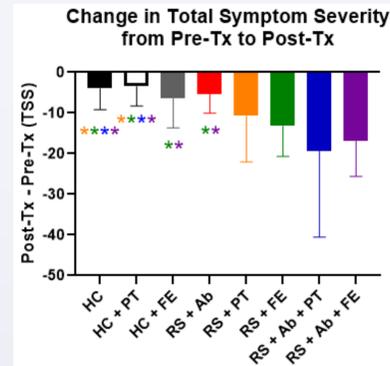
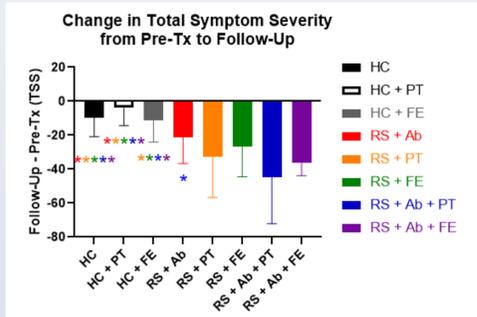


Fig. 4 The difference in the severity of symptoms (TSS) prior to treatment (Pre-Tx) and 1 hour after the initiation of treatment (Post-Tx) * indicates a two-tailed p -value of ≤ 0.05 . The color of the asterisks indicates which group was compared and found significant.



A	Treatment Group	Rate of Clinical Success	B	Treatment Group	Rate of Symptom Resolution
	RS + Antibiotics	2/7 (29%)		RS + Antibiotics	2/7 (29%)
	RS + Physical Touch	2/7 (29%)		RS + Physical Touch	4/7 (57%)
	RS + Facial Effleurage	3/12 (25%)		RS + Facial Effleurage	5/12 (42%)
	RS + Antibiotics + Physical Touch	0/2 (0%)		RS + Antibiotics + Physical Touch	2/2 (100%)
	RS + Antibiotics + Facial Effleurage	1/3 (33%)		RS + Antibiotics + Facial Effleurage	2/3 (67%)

Fig. 5 Clinical Success was considered as the patient-reported lack of rhinosinusitis symptoms. The Rate of Clinical Success was calculated as the number of patients without rhinosinusitis symptoms / total patients in treatment group, at the follow-up visit (A). Symptom Resolution occurred when the TSS at the follow-up visit was not significantly different than the average healthy control TSS (B). The percentage of patients that achieved Symptom Resolution at each time point is indicated

Fig. 3 The difference in the severity of symptoms (TSS) prior to treatment (Pre-Tx) and 1 hour after the initiation of treatment (Post-Tx) * indicates a two-tailed p -value of ≤ 0.05 . The color of the asterisks indicates which group was compared and found significant.

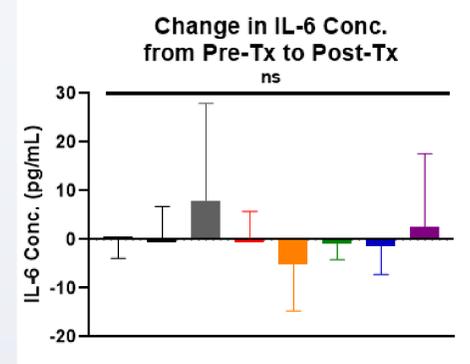


Fig. 6 Blood was drawn from patients prior to treatment and 1 hour after treatment began. IL-6 levels were determined via ELISA. The post-treatment numbers were subtracted from the pre-treatment numbers to determine the change between the treatments (Post-Tx).

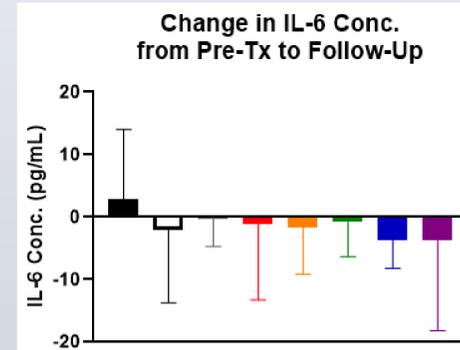


Fig. 7 Blood was drawn from patients prior to treatment and 7 days after treatment. IL-6 levels were determined via ELISA. The follow-up numbers were subtracted from the pre-treatment numbers to determine the change after 7 days (F/U).

Results Continued

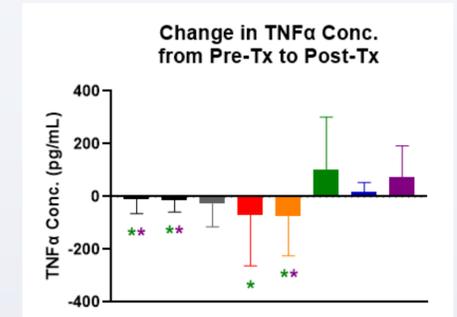


Fig. 8 Blood was drawn from patients prior to treatment and 1 hour after treatment began. TNF α levels were determined via ELISA. The post-treatment numbers were subtracted from the pre-treatment numbers to determine the change between the treatments (Post-Tx).

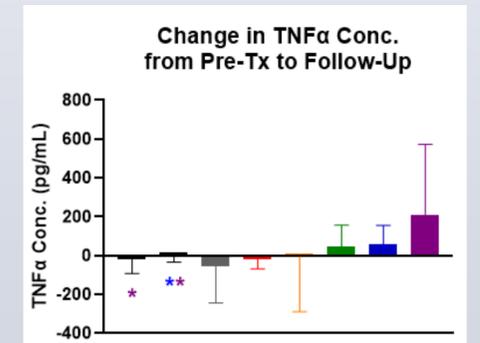


Fig. 9 Blood was drawn from patients prior to treatment and 7 days after treatment. TNF α levels were determined via ELISA. The follow-up numbers were subtracted from the pre-treatment numbers to determine the change after 7 days (F/U).

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Conclusions

- This project is still ongoing and collecting data. We have enrolled about half of the participants needed. (Fig. 1)
- We are able to reliably measure significantly worse symptoms in patients with acute rhinosinusitis symptoms with the Total Symptom Score survey (Fig. 2)
- We are not causing any significant patient discomfort with the facial effleurage technique, or with the newly derived physical touch technique (Fig. 3)
- We have demonstrated a significant change in the levels of serum cytokines and antibody isotypes in patients with acute rhinosinusitis, suggesting that the inflammatory environment is being refreshed by the lymphatic technique. (Fig. 8 and other data not shown here)
- We have measured significant changes in white blood cell numbers after Facial Effleurage, changes in serum complement levels, and differences in mucosal cytokine levels (data not shown here)

The Facial Effleurage OMM technique significantly improves the severity of symptoms experienced by patients with acute rhinosinusitis 1 hour after treatment (Fig. 4) and that effect is long-lasting until at least the follow-up visit 7 days after treatment (Fig.5) compared to healthy controls, and to patients who only receive antibiotics.

- This improvement in symptoms is most likely driven by a significant movement in inflammatory cells, cytokines, antibodies, and effector molecules.

Acknowledgements

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