Reversibility of Hearing Loss in Patients with Patulous Eustachian Tube Dysfunction

[redacted]

Abstract

Background: Patulous eustachian tube dysfunction (PETD) is defined as the abnormal patency of the eustachian tube causing abnormal flow of air between the nasopharynx and middle ear. Patients with PETD present with autophony, aural fulness, and fluctuating sensation of tympanic membrane (TM) movement with respiration. The etiology of PETD is not understood. Studies have found an association between PETD and radiation, weight loss, stroke, injury to CN V, as well as other factors. Treatment for PETD is limited. Studies have found improvement in patients who have undergone PE tube placement, estrogen nasal drops, eustachian tuboplasty, and eustachian tube plug placement. **Objectives:** To evaluate audiogram results in a patient with PETD.
To evaluate if audiogram results in a patient with PETD are reversible with manipulation of the TM, such as Valsalva. **Methods:** Data was obtained from a patient recently seen for hearing loss and the sensation of TM movement with respiration. Patient reported persistent hearing loss in left ear which was improved with Valsalva. Retraction of the TM was visualized on physical exam. Audiogram was obtained in office with patient in neutral position with a retracted TM and with Valsalva. **Results:** Patient was observed to have as much as a 15-decibel improvement in hearing function with Valsalva maneuver. **Conclusions:** Limited data is present regarding the reversibility of hearing loss in patients with PETD. Data obtained from patients seen in clinic may suggest that hearing loss in patients with PETD may be reversible with correction of TM retraction such as Valsalva maneuver.

Introduction

- Patulous eustachian tube dysfunction (PETD) is defined as the abnormal patency of the eustachian tube causing an abnormal flow of air between the nasopharynx and middle ear.
- Patients with PETD present with symptoms of autophony, aural fulness, and fluctuating sensation of the tympanic membrane (TM) with respiration.
- The etiology of PETD is not fully understood but studies have found an association between PETD and radiation, weight loss, stroke, injury to CN V, iatrogenic injury, dental malocclusion, and TMJ subluxation.
- Treatment for PETD is limited. Some study have found improvement in patients who have undergone PE tube placement, estrogen nasal drops, eustachian tuboplasty, or placement of a eustachian tube plug.

Objectives

- To evaluate audiogram results in a patient with PETD.
- To evaluate if audiogram results in a patient with PETD are reversible with manipulation of TM such as Valsalva.

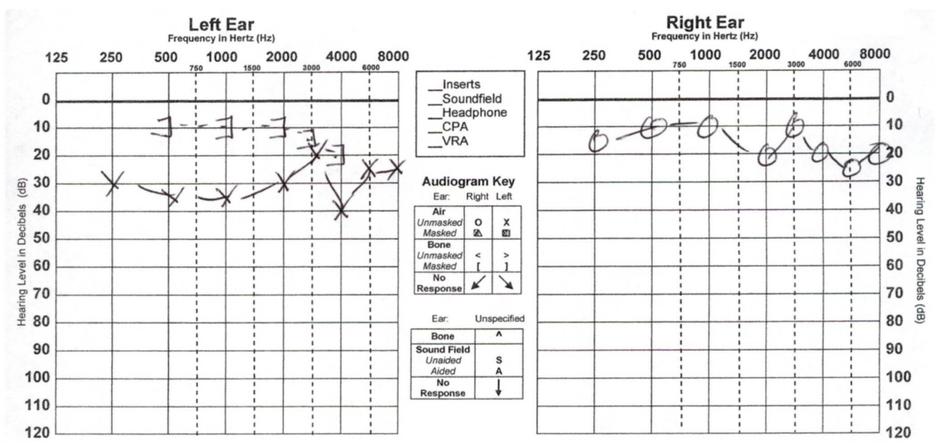
Patient Description & Methods

- Data was obtained from a patient recently seen in clinic for hearing loss and the sensation of tympanic membrane movement with respiration.
- Reported history of persistent ear infections as a child requiring >15 sets of tympanostomy tubes.
- Right sided tympanostomy tube placed in October of 2020 which was still in place.
- Reported persistent hearing loss in left ear which was improved with Valsalva.
- Retraction of left tympanic membrane visualized on physical exam.
- Audiogram was obtained in office with patient in neutral position with retracted TM and with Valsalva.

Results

- Patient had significant improvement in audiogram results in left ear with Valsalva maneuver.
- Patient was observed to have as much as a 15-decibel improvement in hearing function of left ear with Valsalva maneuver.

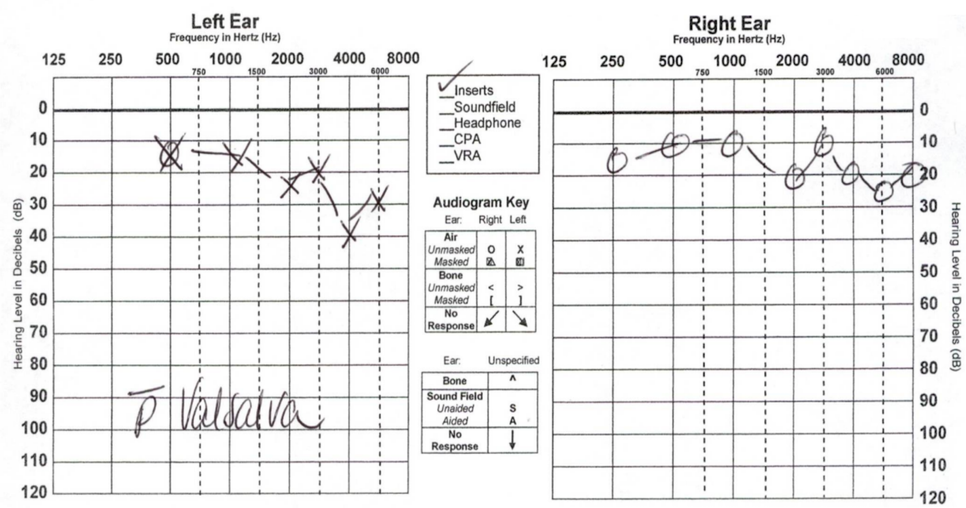
1A 1B



Figures 1a and 1b: Audiogram of left and right ear pre-Valsalva

Results Continued

2A 2B



Figures 2a and 2b: Audiogram of left and right ear post-Valsalva

Conclusions

- Limited data is present regarding the reversibility of hearing loss in patient with PETD.
- Data obtained from patients seen in clinic may suggest that hearing loss in patients with PETD may be reversible and ameliorated with correction of TM retraction such as Valsalva maneuver
- Additionally, this data suggests that this patient population may benefit from interventions such as tympanostomy tube placement which would equalize pressure between middle and external ear.

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Clinical Trial registration trends during COVID-19 for Orthopaedic Disorder Clinical Trials: A statistical forecast analysis using ARIMA

INTRODUCTION

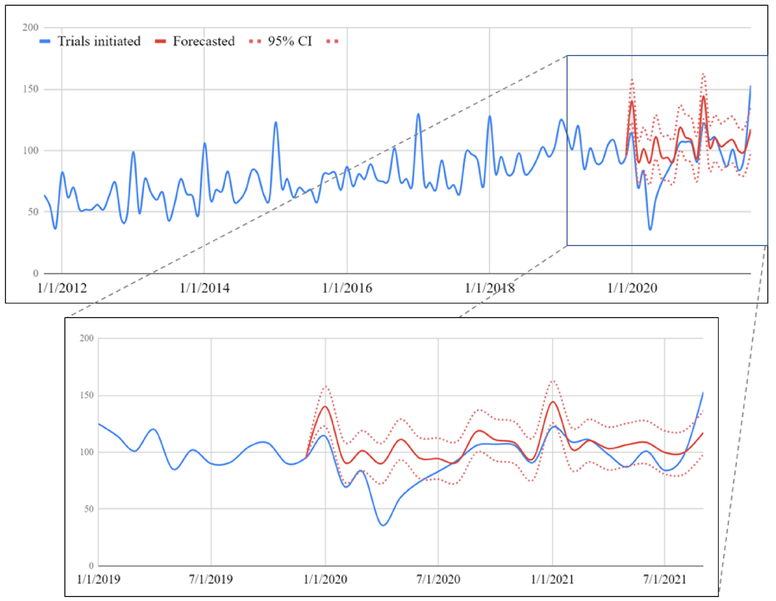
- Clinical trials are an integral part of high quality patient care in Orthopaedics due to the heavy influence that Level I evidence has on the AAOS clinical practice guidelines.
- COVID-19 pandemic has been shown to impact the conduct of clinical trials across the world.
- Our novel study looks to quantify the effect of COVID-19 on the registration and conduct of clinical trials.

METHODS

- We used clinicaltrials.gov to compile a list of clinical trials initiated between October 2011 to September 2021.
- We used the term “Orthopaedic Disorders'' to be inclusive and because clinicaltrials.gov lists “Orthopedic Disorders” as a key term for orthopaedic clinical trials.
- Using the ARIMA model in R, we estimated the number of orthopaedic disorder trials lost during the time of the pandemic.

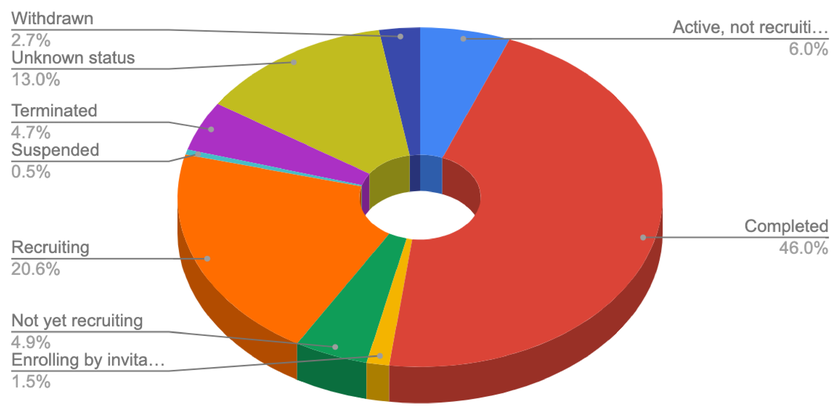
RESULTS

ARIMA Forecast Models of Orthopaedic Disorder Trials



- The number of actual registered trials showed negative deviations from the model for most of 2020
  - Except the month of August, during which there was a sharp increase in trial initiation.
- January 2020 through June 2020 had statistically significant deviations; Largest differences
  - April (-54.00; 95%CI: -71.75 - -36.24)
  - May (-51.15; 95%CI -69.01 - -33.29)

Breakdown of Trial Status



CONCLUSION

Our novel study quantifies a statistically significant decline in orthopaedic clinical trial registration during the COVID-19 pandemic compared to years prior. The decline in trial registration during the pandemic was followed by a sharp increase in trial registration, possibly reflecting a return to normal as we enter the later stages of the pandemic. While orthopaedic research was reduced during the pandemic, changes to clinical trial conduct in a post-pandemic environment may be the impetus for new and innovative research, but the long-term effects of the pandemic of orthopaedic clinical research warrant close surveillance.

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Evaluating the completeness of reporting of patient-reported outcomes in clinical trials for colostomy and ileostomy interventions

Introduction

An ostomy is a life-saving intervention that does not negatively affect life expectancy, but it requires patients to significantly alter their lifestyle. Previous studies have identified that ostomy procedures may negatively affect a patient's overall quality of life owing to radical lifestyle changes.[1] Given that quality of life is a main concern for individuals with ostomies, the need to incorporate patient perspectives within clinical trials (CTs) is essential.[2] Patient-reported outcomes (PROs) include but are not limited to, a patient's daily functionality, symptoms, emotional well-being, and treatment satisfaction.[3] Inclusion of PROs in CTs is an increasingly common practice to ensure that patient perspective and choice are assessed.[4] Given the principal role that CTs occupy in influencing clinical practice and the subjective nature of PROs, it is imperative that the methodological quality and reporting of CTs be held to the highest standard. Our primary aim was to assess patient reported outcome (PRO) adherence among colostomy- and ileostomy-related clinical trials to the International Society for Quality of Life Research (ISOQOL) reporting guidelines.

Methods

This cross-sectional analysis used MEDLINE and Embase to identify colostomy- and ileostomy-related clinical trials that included patient reported outcomes. Data were extracted in a masked, duplicate fashion. A Google form was used to record the presence of ISOQOL reporting guideline items and other publication characteristics. Concordance was assessed for all studies and was achieved if the PRO measure included items that were (1) meaningful and relevant to the hypothesized variable (face validity), from which (2) a score could be generated and (3) was appropriately reported. Next, we calculated frequencies and percentages of each ISOQOL item common to publications with PROs as primary and secondary endpoints among all publications, and we reported those additional items specific to publications with PROs as primary endpoints among those publications. We also reported the percentage of completeness of ISOQOL as a proportion of checklist items completed among all studies and as tiered rankings of completeness and quality. We used linear regression analyses to model differences in completion percentage by study characteristics. Further, we measured the association of completeness of PRO reporting before and the publication of CONSORT-PRO. To increase the reproducibility of our study, the study protocol, raw data, analysis scripts, data dictionaries, and extraction forms were deposited on Open Science Framework.

Results

Our study returned 786 articles and our final sample included 62 clinical trials after screening. Among the 62 CTs, the PRO was considered the primary outcome in 19 (19/62; 30.6%) and a secondary outcome in 18 (18/62; 29.0%). CTs most commonly evaluated multiple PROs, identified in 32 (32/62; 51.6%) of the 62 included studies. Among the 62 clinical trials, 31 (31/62; 50%) achieved two-thirds completeness of ISOQOL guidelines. Furthermore, 43 (43/62; 69.4%) clinical trials met concordance. Among the included studies, those which stated the PRO as a primary or secondary endpoint were 11.1% more complete in their reporting ($t = 2.11$, $p = 0.039$). Eleven (11/62; 17.7%) of the 62 CTs evaluated both types of ostomies, while 29 (29/62; 46.8%) evaluated colostomies only and 22 (22/62; 35.5%) evaluated ileostomies only. CTs evaluating both types of procedures had a mean completion percentage of ISOQOL guidelines of 69.1%, whereas CTs evaluating colostomies had an average of 60.1% (SD = 28.3) and CTs evaluating ileostomies had an average of 60.1% (SD = 21.3).

Figure 1: Included RCTs evaluated for ISOQOL completeness

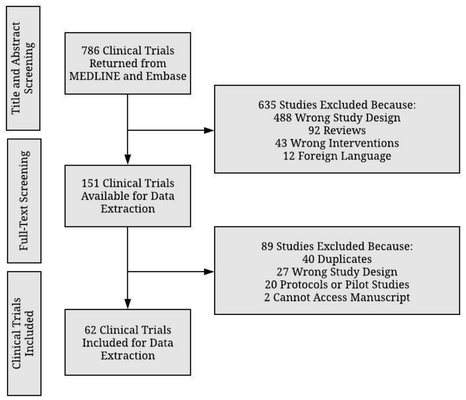
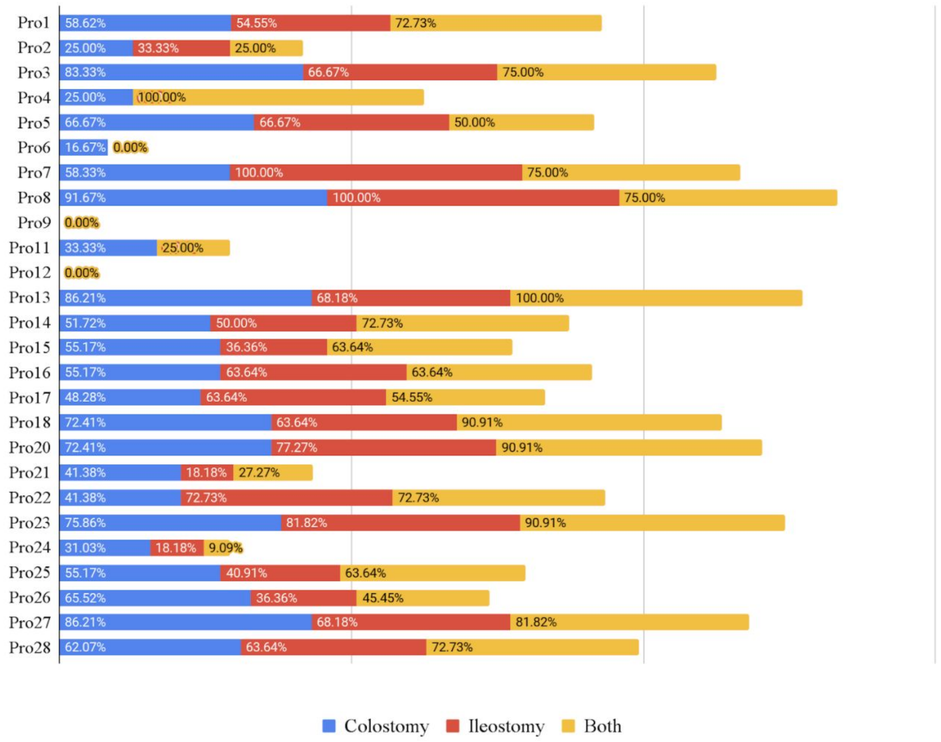


Table 1: Analysis on type of PRO measure and completeness data

	Primary	Secondary	Specified	Unspecified	total	Primary vs Secondary	Specified vs. Unspecified
	n=19	n=18	n=37	n=25	n=62	ttest	
Percent complete: M, SD	.69 .14	.77 .14	.73 .15	.45 .25	.62 .24	t = -1.70, p=.10	**t = -5.38, P<.0001**
Percent Complete Tier						Chi^2	
<.33	0	0	0	7	7	0.35 Pr = 0.56	16.96 Pr = 0.000
.33-.66	7	5	12	12	24		
>.66	12	13	25	6	31		
Robust Methodology							
No	11	14	25	24	49	1.67 Pr = 0.20	7.28 Pr = 0.007
Yes	8	4	12	1	13		
Quality (Complete + Robust)							
Low	11	14	25	24	49	3.61 Pr = 0.17	7.30 Pr = 0.026
Medium	0	1	1	0	1		
High	8	3	11	1	2		

Figure 2: Percent reporting of ISOQOL items by ostomy type



Summary

Our study found that half of colostomy and ileostomy CTs achieved two-thirds completeness of ISOQOL reporting guidelines. ISOQOL checklist items that were the least frequently reported were baseline PRO scores and whether statistical approaches for missing data and the extent of missing data were provided. Furthermore, studies that met concordance were over one-quarter more likely to have higher ISOQOL completeness than those that did not meet concordance. Interestingly, when PROs were listed as a primary endpoint, we found no association with a greater adherence to ISOQOL guidelines compared with when PROs were listed as secondary or unspecified endpoints. However, our findings demonstrate CTs on colostomy and ileostomy interventions have greater ISOQOL reporting adherence when a PRO measure is specified as a primary or secondary outcome. Such specifications may increase the quality of reporting on CTs evaluating colostomies and ileostomies. Given the increase of PRO inclusion in clinical trials, we advocate for the standardization of PRO reporting as findings from CTs may ultimately influence subsequent trials or clinical practice guidelines and the use of validated reporting guidelines such as ISOQOL

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Case Report: “Watch and Wait” or Risky Resection: The Desmoid Dilemma

Abstract

In this case, we present a 23-year-old female who presented to the emergency department (ED) complaining of acute abdominal pain. She has a history of positive genetic testing for familial adenomatous polyposis (FAP) at age 13 with subsequent endoscopy demonstrating adenomatous polyposis. Her mother had a diagnosis of stage III adenocarcinoma in the face of FAP. The patient underwent total colectomy at the age of 14 with concurrent diagnosis of a desmoid tumor. The persistence of her desmoid tumor precipitated a partial small bowel obstruction in this encounter.

Desmoid tumors are a connective tissue cancer composed of myofibroblasts, that commonly invade local structures.[1] Although generally benign, they can cause havoc as they grow around pertinent organs and vessels, creating a problematic clinical scenario.[2] Thus, desmoid tumors are also known as aggressive fibromatosis. While rare in the general population, they are frequent in patients with FAP.[1]

The scarcity of desmoid tumors has left limited guidance for therapeutic approaches. We believe a multifaceted treatment approach combining hormone, non-steroidal anti-inflammatory (NSAID), and chemotherapy, with the possibility of surgical resection, could be a superior option. A drawback to desmoid tumor treatment is the possibility of reoccurrence or surgical complications. The question at large: do we still “watch and wait” or proceed aggressively to further treatment in decreasing the risk of morbidity and mortality in this patient population?

Case Summary

Chief complaint: Acute upper mid-epigastric pain and nausea with vomiting.

History: A 23-year-old female with history of total colectomy secondary to FAP at age 14 presented to the ED complaining of acute upper mid-epigastric pain, nausea, and vomiting. Her pain was sharp and stabbing in character having worsened over the prior2 weeks. Review of systems was notable for an upper respiratory infection in the prior two weeks.

Past medical history revealed positive 3T87 DEL AG APC mutation for FAP. Maternal history was positive for FAP and stage III colorectal cancer at 24.

On admission, X-ray revealed air-fluid levels classic for SBO (Figure 1) and CT revealed a bi-lobed, centrally necrotic (Figure 2), desmoid tumor infiltrating the mesentery and surrounding the abdominal aorta (Figure 3). Given the radiographic evidence of air in the small bowel and a large fecal load on CT, a diagnosis of partial SBO was made with consideration of adynamic ileus. The patient was treated with IV fluids and oral magnesium citrate, with plan to repeat abdominal series and possible referral to general surgery.

Imaging of Infiltrative Desmoid Tumor

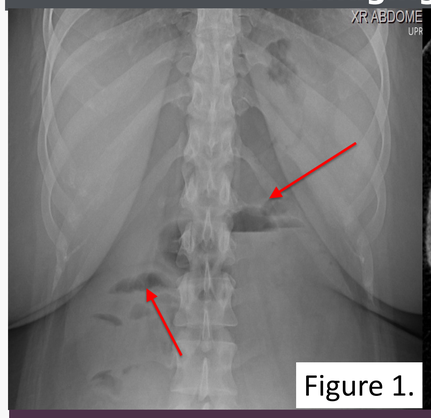

Figure 1.

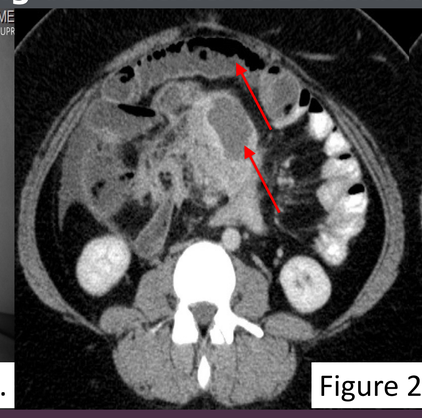

Figure 2.

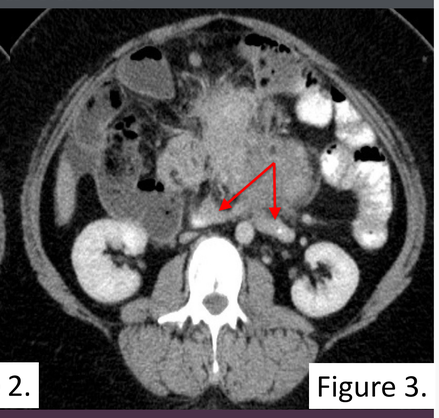

Figure 3.

Discussion

Treatment of desmoid tumors generally begins with surveillance in hopes of spontaneous regression without life altering complications. In patients with FAP and mesenteric involvement, surgery poses greater risk of recurrence and morbidity.[3,4] In this case, our patient only has her small bowel remaining, further compounding risks of surgical resection such as small bowel perforation, abscesses, and fistulas – all of which could dramatically alter the patient’s quality of life.[4] In addition, the heterogenous nature of desmoid tumors make their response to treatment unpredictable.[3]

We hypothesize that a multifactorial treatment approach may be the best approach for our patient. This includes the use of NSAIDs, hormonal therapy (tamoxifen or raloxifene), and manageable chemotherapy (anthracyclines) prior to surgery, to further decrease tumor size.[3, 5, 6]

Hormone therapy was shown to be effective in decreasing recurrence rate in 40-51% of female patients.[7, 8] When combined with NSAIDs, the response rate has been recorded over 85% [9], and chemotherapy has demonstrated a response rate of 79%.[10, 11] Attesting to said research, we believe the first possible steps in our patient’s treatment should be a multifactorial approach, possibly followed by tumor resection. Resection of tumors <7 cm (about 2.76 in) has shown a promising decrease in tumor recurrence.[12]

Ultimately, we believe more research needs to be conducted on intra-abdominal desmoid tumors, specifically in those with FAP. We hope in the future an established treatment plan can be set for such patients.

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Food security among medical students at a Midwest University

INTRODUCTION

- Food insecurity (FI) is a household condition of limited access to a nutritious food supply that has many negative effects — including poorer physical and mental health outcomes and academic performance.[1-4]
- Reported weighted food insecurity among U.S. college students was 41% compared to the 10.5% among the general population.
- We found only one study which estimated FI prevalence among medical students.[5]

OBJECTIVE

- Our aim was to estimate the prevalence of FI at an academic medical center in the midwest region and its associations with mental health and academic achievement among medical students.

METHODS

- An anonymous online survey was sent to all medical students (N=500) at a Midwestern Medical institution between March and May 2021.
- Survey items includes demographics, academic performance, mental health status, and parent/guardian educational attainment.
- The US Household Food Security Survey Module was used to estimate FI in the past 30 days.
- Responses were weighted by race/ethnicity of the known student population.

RESULTS

- We received surveys from 75 respondents (17.0% response rate). Of the respondents, 30.7% (23/75) reporated low or very low food security, which represents 26.8% of the medical student population.
- Of the 26 students who responded to *'when'* they most often worry about FI, 19 (73.1%) reported worrying during breaks in loan dispersal.
- The weighted Pearson correlation showed a statistically significant relationship between FI scores and mental health rating ($r = -0.41$, $P < .001$).

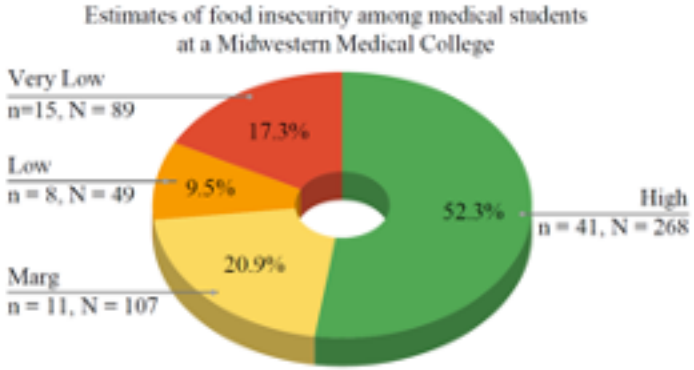

Table 1. Reported time periods of worrying about food procurement and quality

	n	N	(%)
During breaks in loan dispersals	19	142.20	80.61
Other	1	7.13	4.04
Yes- during summer months	5	23.97	13.59
Yes- during winter breaks	1	3.11	1.76

CONCLUSION

- Our study shows > 26% of medical students reported having low or very low food security among this midwestern Health Science Center.
- We found FI to be negatively correlated with mental health outcomes which may increase the stress medical students experience and lead to dropout.

SIGNIFICANCE OF FINDINGS

- The encompassing state has a shortfall of trained physicians, and FI may exacerbate known causes of medical school dropout.
- Efforts should be made to improve the rates of FI within the health sciences college, which may reduce burnout and improve mental health among medical students.

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Disruption of Pediatric Autoimmune Trials during the COVID-19 Pandemic

Background

- The prevalence of pediatric autoimmune disorders has continued to rise in the previous decade.[1]
- Clinical trials are pivotal for managing and improving the quality of life in patients with autoimmune disease; recent studies have highlighted the impact of the COVID-19 on clinical trials in other fields.[2-4]
- Recently the FDA updated their guidance on conducting clinical trials, emphasizing patient safety in light of the COVID-19 pandemic.[5]
- The disruption of Pediatric Autoimmune Clinical Trials during the COVID-19 pandemic has not been previously investigated.

Research Question

- Our objective is to quantify the amount of Pediatric autoimmune-related clinical trials disrupted due to the COVID-19 pandemic.

Methods

- ClinicalTrials.gov was searched for ongoing and discontinued trials between 01/01/2020 - 10/31/2021.
- Trials were screened for relevance to the study and the number of participants, trial location, funding source, and reason for discontinuation.
- Associations between reasons for termination, funding source, trial location, and the number of participants enrolled were evaluated.

Results

- Our search returned 415 studies, 142 of which were met criteria of being Pediatric Autoimmune trials.
- A total of 724 children were enrolled in the 21 studies that were discontinued due to the pandemic.
- Most often reason for discontinuation was recruitment (7, 33.3%) followed by 'Other' which included the drug becoming too dangerous or imaging abnormalities. (6, 28.6%). These two reasons accounted for 494 (68.3%) of the child particip

Discontinued Pediatric Autoimmune Trials during the Pandemic

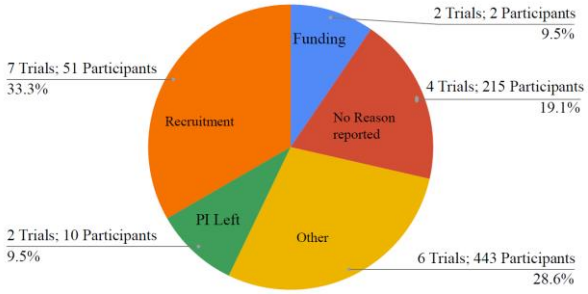

Table 1. Characteristics of discontinued Pediatric Autoimmune trials during the Pandemic

	No. of Trials	Percent	Enrollment	Percent
Location:				
US	11	52.4%	505	69.8%
Non-US	10	47.6%	219	30.2%
Funding source:				
Industry	11	52.4%	309	42.7%
Government	1	4.8%	48	6.6%
Other	9	42.9%	367	50.7%
Intervention types:				
Pharmaceutical	17	81.0%	634	87.6%
Behavioral	2	9.5%	90	12.4%
Procedure	2	9.5%	0	0.0%

Conclusion

- Our study shows 33.3% of discontinued pediatric autoimmune clinical trials were discontinued due to recruitment issues which may be explained by the COVID-19 pandemic.
- A recent study revealed individuals were unwilling to volunteer for rheumatological research studies while COVID-19 was in there community.[6]

Significance of Findings

- Our findings suggest implementing strategies to safely recruit patients for clinical trials such as minimizing direct contact, creating more remote options, and clearly defining safety protocols.

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Patient Centered Care Approaches through Usage of Person Centered Language for Major Depressive Disorders with Peripartum Onset

INTRODUCTION

Removing systemic barriers to mental health screening and treatment may decrease the morbidity and mortality linked to Major Depressive Disorder with Peripartum Onset (MDD-PPO).[1]

Implementing person-centered language (PCL) in medical literature guides physician education and is one of the ways through which we can reduce stigma and improve perinatal health equity.

Research Question

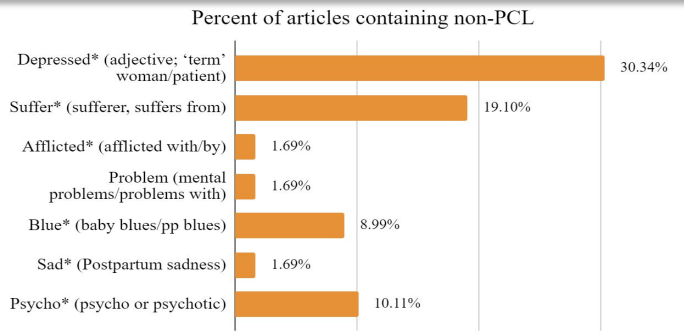
Our primary objective is to quantify adherence to PCL guidelines among the peer-reviewed articles pertaining to MDD-PPO.

METHODS

500 articles were examined for pre-specified, non-PCL terminology from a systematic search of MDD-PPO-related PubMed articles published from January 1, 2014, to March 7, 2021.

Screening and data extraction were conducted in a masked, duplicate fashion and resolved through arbitration with 100% inter-rater agreement reached.

The proportion of articles *without* deviance from American Medical Association's Manual of Style (AMAMS)[2] guidelines compared to the total number of articles included were analyzed.



RESULTS

Out of the 178 articles, 50.56% (90/178) publications were PCL adherent.

The most commonly used non-PCL words were 'depressed,' 'suffer', 'psycho/psychotic', 'blue'.

Other search terms such as 'disabled', 'Mentally ill', 'Manic', 'Anguished', 'Unstable', 'Irritable', 'Crazy', 'Sick', and 'Insane', were not found within the articles.

CLINICAL RELEVANCE

Recommended list of alternative words and phrases to use in medical literature and patient interaction	
Instead of this...	**Use that...**
Depressed	Women diagnosed with MDD-PPO; postpartum depression
Suffering	Currently diagnosed with; experiencing
Psychotic/Psycho	Women diagnosed with MDD-PPO, postpartum psychosis
Blue	Women diagnosed with MDD-PPO

PCL is especially critical for professionals encountering MDD-PPO, as previous studies demonstrated that derogatory behaviors occur most commonly in the obstetrics-gynecology setting.[3,4]

Therefore, implementing our recommendations can lead to adherence to treatments and follow-up care thereby preventing adverse events such as fetal morbidity.[5]

SIGNIFICANCE OF FINDINGS

Reports of patients experiencing judgment, disrespect, or verbal abuse while accessing patient care are common.[6]

Utilizing PCL is a first step in practicing person-centered care; which emphasizes individual preferences, needs, and values along with the importance of informed decision making, respect, privacy, confidentiality, and non-discrimination.[7,8]

PCL is also congruent with the osteopathic principles and philosophy of recognizing the body as a unit.

Therefore, PCL should be integrated into all physicians' clinical practice.

CONCLUSION

PCL is viewed more positively by patients, may lead to better patient-provider relationships, and is recommended by the AMA and APA.

Implementation of PCL requirements within journal and accountability will aid in continuing the shift toward reducing stigma and increasing advocacy for the treatment of individuals with MDD-PPO.

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Disruption of Clinical trials in Pediatric Orthopaedic Research during COVID-19

INTRODUCTION

- The number of pediatric orthopaedic cases continues to rise.
- Clinical trials for the treatment of these cases are critical to enhance the quality of life of these children.
- In response to the COVID-19 pandemic, the FDA updated guidance on conducting clinical trials to prioritize patient safety.
- The disruption of pediatric orthopaedic-related clinical trials due to the COVID-19 pandemic has not previously been evaluated.

OBJECTIVE

- Our objective is to quantify the amount of pediatric orthopaedic-related clinical trials disrupted due to the COVID-19 pandemic.

METHODS

- ClinicalTrials.gov was searched for ongoing and discontinued trials between 01/01/2020 - 10/31/2021.
- Trials were screened for relevance to the study and the number of participants, trial location, funding source, and reason for discontinuation.
- Inclusion criteria: Clinical trials that involved Orthopaedic related disorders with pediatric patients
- Associations were evaluated using Mann-Whitney U tests or ANOVA, where appropriate.

RESULTS

- Our search returned 544 trials, of which 128 were included with a total of 15,194 participants. Of the included Pediatric trials of orthopedic conditions, 9 were discontinued with a total of 497 participants. Of the 9 discontinued trials, 1 of 3 stated COVID-19 as a reason (Figure 1).
- The Mann-Whitney U test and ANOVA showed no statistically significant difference in enrollment between trials discontinued due to COVID-19 compared to other discontinued trials, nor among funding, or location (Table 1).

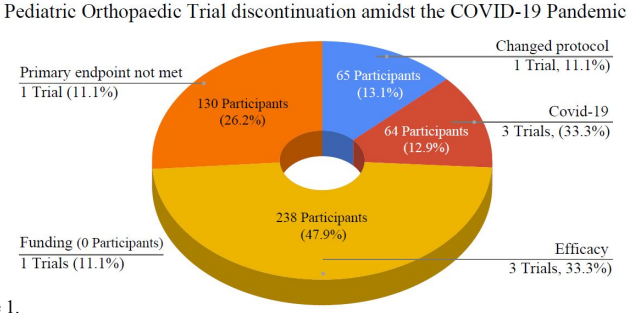

Figure 1.

Table 1. Characteristics of discontinued Pediatric Orthopedic trials during the Pandemic

	No. of Trials	Percent	Enrollment	Percent
Location:				
US	6	66.7%	476	95.8%
Non-US	3	33.3%	21	4.2%
Funding source:				
Industry	6	66.7%	412	82.9%
Government	0	0.0%	0	0.0%
Other	3	33.3%	85	17.1%

CONCLUSION

- Our study shows 33% of discontinued pediatric orthopaedic-related clinical trials cited COVID-19 as a reason for discontinuation.
- About 12% of all children were enrolled in discontinued trials.
- These findings highlight the importance of developing safety strategies to continue research during global emergencies.

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The Use of Osteopathic Manipulative Therapies for the Reduction of Prescribed Opiate Morphine Milligram Equivalents in Patients Receiving Treatment for Chronic Pain: A Retrospective Study

Background

- As of November 2020, the prevalence of chronic pain was 20.4% in the United States. Of those, most patients with chronic pain are in rural areas. Many of these patients are on long-term opiate therapy to address their pain. Presently, there is limited data on multimodal pain management approaches that include osteopathic manipulative therapies.
- With the ongoing opiate epidemic in the United States, safe reduction in Morphine Milligram Equivalents in patients using multimodal techniques is becoming a greater priority.
- Osteopathic techniques exist to safely and effectively treat patients of all ages with a variety of ailments.

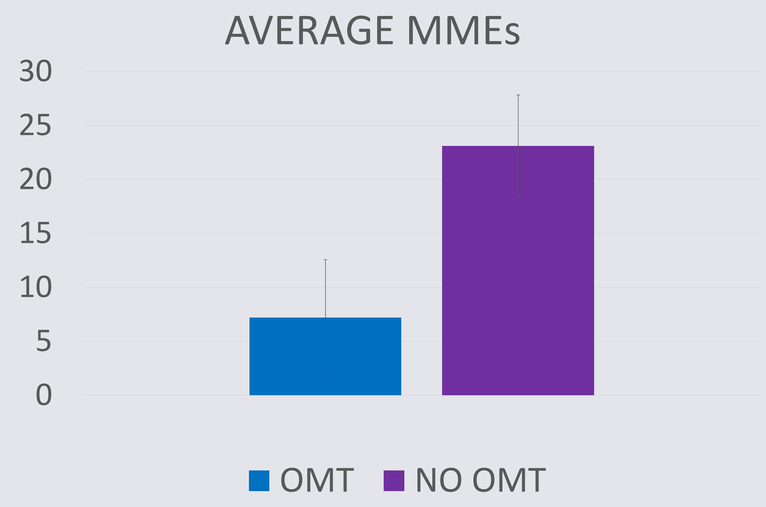
Methods

- A retrospective study of patients within a rural outpatient primary care setting who were receiving treatment for chronic pain between the dates of January 1, 2021 and July 31, 2021 were analyzed.
- 210 patients with a diagnosis of chronic pain were included in the analysis. 30 were actively
- receiving OMT; 180 were not.
- Patients who were actively receiving OMT were compared to those who were not.
- Patients “actively receiving OMT” were defined by having received at least one dedicated OMT treatment during the data period. Modalities included well-known OMT techniques only.
- The primary outcome being assessed was total average opiate MMEs prescribed per month.
- Patient age and total length of opiate therapy were documented.

Results

	OMT (n=30)	No OMT (n=180)	*P*-value
Average MMEs Prescribed	7.18 (±14.42)	23.09 (±32.24)	0.006655[a]
Average Age in years	49.47(17.05)	59.21(14.89)	0.001352[a]

[a]One Factor ANOVA



Conclusions

- Augmenting chronic pain regimens with OMT appears to lead to fewer MMEs to achieve adequate pain control.
- OMT is anecdotally safe and efficacious for treating a variety of chronic pain complaints.
- OMT could be a viable option in helping combat the opiate epidemic.
- Further prospective study involving the use of OMT in patients with chronic pain is warranted.
- IRB approval has been obtained to pursue ongoing research by offering and providing OMT to patients being managed for chronic pain.

Limitations

- While this was a retrospective analysis of patients, ongoing prospective study is recommended to show improvement in patient outcomes.
- Objective measures such as reduced MMEs do not provide a complete picture of pain management. Subjective measures such as pain perception have great importance but are hard to objectively measure.
- Accurate average length of time receiving opiates could not be obtained as the Oklahoma Bureau of Narcotics and Dangerous Drugs (OBNDD) only allows for records to be searched back to 4 years.
- It is unknown whether patients receiving OMT required fewer MMEs before or after OMT was added to their treatment regimen.
- It is unknown to what extent MME reduction was prioritized in both patient groups.
- There is limited published data on the efficacy of OMT for chronic pain.

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Pet therapy reduces blood pressure in elderly (>65 years old) females: A preliminary report

[redacted]

INTRODUCTION

The increasing prevalence of hypertension within the United States is a major concern for health care professionals. The CDC reports almost half of adults within the United States have been diagnosed with hypertension[1]. Research has shown that increased stress can lead to higher blood pressure and a higher risk for cardiovascular disease.[1] This fact is particularly concerning in the elderly population as social stressors, such as decreased social engagement and activity, can also increase their morbidity and mortality. Pet therapy has been shown to improve the social, psychological, and physical health of the elderly by helping fill this psychosocial gap.[2] Previous studies indicate that pets can decrease blood pressure results, but they tend to have small sample sizes and focus on pet ownership or long-term therapy.[3]

OBJECTIVES

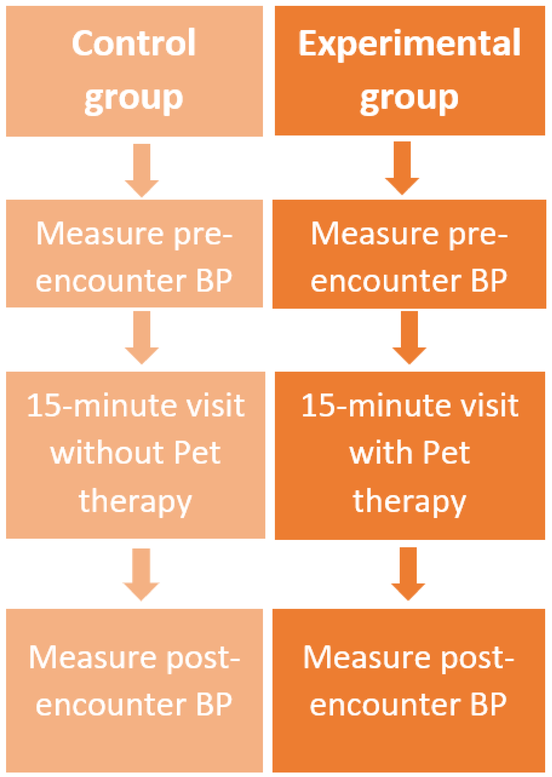
- ❑ To determine if short-term pet therapy interactions reduce blood pressure in elderly female assisted-living residents.
- ❑ To establish a protocol for elderly people who would benefit from pet therapy but cannot have a pet.

METHODS

Eight female volunteers currently living in an assisted living facility with unknown blood pressure consented to having their blood pressure taken twice. Blood pressure was measured manually before the encounter and after the encounter. All encounters consisted of a 15-minute visit with at least one of the investigators. However, the control group was not exposed to pet therapy whereas the experimental group was exposed to pet therapy.

PET THERAPY DOG- Cannoli

EXPERIMENTAL DESIGN OUTLINE



RESULTS

Preliminary Changes in Systole & Diastole Before & After an Encounter with or without Pet Therapy

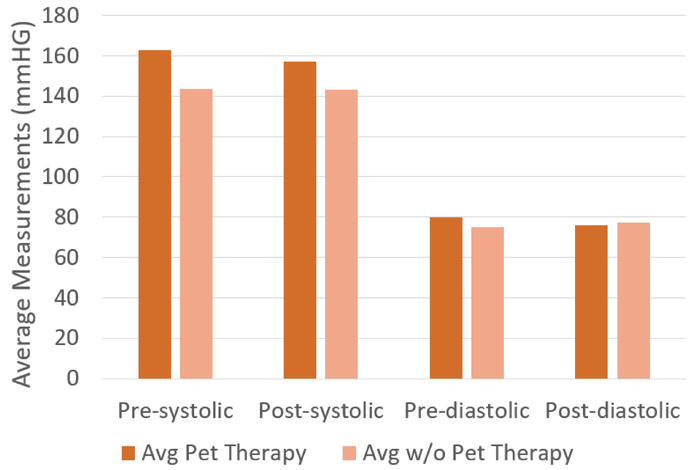


Figure 1. Average measurements in diastolic and systolic blood pressure before and after a 15-minute visit for both control and experimental groups.

Average Changes in Systole & Diastole Before & After an Encounter with or without Pet Therapy

	Pre-systolic	Post-systolic	Pre-diastolic	Post-diastolic
Avg Pet Therapy	162.6	157.0	79.8	76.0
Avg w/o Pet Therapy	143.7	143.3	75.0	77.3

Table 1. Numbers reflect the average changes in systolic and diastolic BP taken before and after a 15-minute visit for both control and experimental groups.

Number of Female Participants

	# of participants
w/ Pet Therapy	5
w/o Pet Therapy	3

Table 2. Initial number and sample size of participants in study.

CONCLUSION

Initial findings from this preliminary study of the effects of short-term pet therapy are promising.

- 15-minute visit with a therapy dog: systolic blood pressure decreased by 3.44% , diastolic blood pressure decreased by 4.76% compared to controls
- Findings confirm previous studies utilizing the use of animals in reducing stress in humans
- To our knowledge, this is the first study to investigate short-term (one visit) pet therapy on blood pressure in elderly females.
- This study may have a large impact on how medical professionals can better treat elderly patients

NEXT STEPS

For this project to succeed in all its goals, there are some things we hope to implement and keep in mind for gathering future data:

- Improvements: plan to utilize a stopwatch to decrease human error
- Implement an equal amount of both male and female participants
- Gather data from Native Americans for a comparison study (currently waiting for approval)
- Provide a larger sample size database to improve accuracy of results
- Incorporate participants from various nursing homes or elderly day centers

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ACKNOWLEDGEMENTS

We would like to thank Heritage Grove for their participation in this study.

Examination of homologies between Covid-19 vaccines and common allergens: the potential for T cell-mediated responses for allergic rhinitis and asthma.

INTRODUCTION

T-cell mediated antigen cross-reactivity between viruses and allergens is a relatively new area of study in clinical immunology; a discipline that may be particularly useful regarding the COVID-19 virus and the allergic response in humans.

It has previously been demonstrated that the COVID-19 virus shares protein sequences with common allergens like grass pollens, dust mites, and molds. Thus post-infection, COVID-19 oriented T-cells may provide a mediated immune response to these allergens.

Similarly, vaccination against COVID-19 may play a role in protection against T-cell-mediated chronic inflammation in allergic disease.

OBJECTIVES

Our objective was to explore the potential overlap between the COVID-19 vaccines from Pfizer and Moderna and common allergens indexed through two known and reputable databases.

METHODS

Given the protective factor of COVID-19 vaccines against the virus and their mass distribution, our objective was to explore the potential overlap between the COVID-19 mRNA vaccines from PFizer-BioNtech and Moderna and known allergens indexed through the University of Nebraska's FARRP Allergen Protein Database (allergenonline.org) and the FASTA tool, using the BLOSUM 50 scoring matrix as previously published.5 Given the Codex Alimentarius Commission recommendation likelihood of cross-reactivity criteria, we reported allergens with 35% (or greater) similarity over segments of 80 amino acids (Criteria A) and those with short (8 or more amino acids) identical matches (Criteria B).

RESULTS

For the Pfizer vaccine, we identified 1 allergen meeting Criteria A, from pine nuts, and 6 that met Criterion B from Tufted Grass and Alternaria Alternata, the most common fungal allergen associated with asthma (Figure 1).6 For the Moderna vaccine, we found 7 allergens meeting Criteria A and 12 that met Criteria B. Allergens meeting Criteria A included Spreading Pellitory (grass), lipocalin from Guinea Pigs, ragweed, wheat endosperm, sesame, and dust mites. Allergens that met Criteria B were Kentucky Blue, Cat, and Timothy Grasses, and Penicillium Crustosum (mold; Figure 1). Both vaccines showed matching sequences (Criteria B) with perennial ryegrass (Table 1).

Figure 1. Allergens with 35% (or greater) similarity over segments of 80 amino acids (Criteria A)

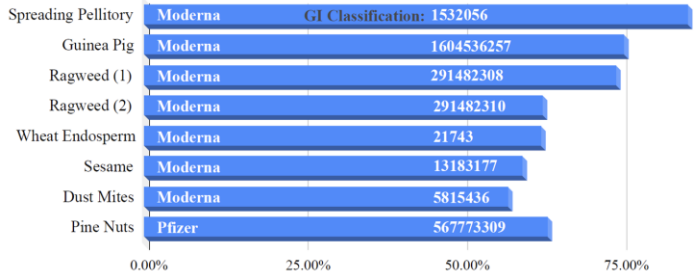

Table 1. Allergens with ≥ 8 sequential amino acids match (Criteria B)

Common Allergen Name	GI Class
Moderna	
Mold (Cheese)	371537645
Hazel	29170509
Perennial Ryegrass	4416516, 6634467
Timothy Grass	345108717
Kentucky Bluegrass (KBG 31, 60, 41, clone 7.2)	113560, 113562, 539056, 113561
Orchard Grass, Cat Grass	14423124, 18093971
Yorkshire Fog/Tufted Grass	2266625
Pfizer	
Perennial Ryegrass	4416516
Yorkshire Fog/Tufted Grass	2266625
Fungal Allergen	1850540, 1173071, 5777795
Soil-Borne Fungus	19879657

CONCLUSION

Considering the homologous overlap of known allergens and the COVID-19 vaccines, an altered T-cell mediated immune response may be observed in allergic asthma and allergic rhinitis reaction after vaccination

SIGNIFICANCE OF FINDINGS

These results suggest that vaccination with the Pfizer-BioNtech and Moderna COVID-19 vaccines may contribute to T-cell cross-reactivity with allergens that impact allergic asthma and allergic rhinitis.

Further research should assess the clinical implications of COVID-19 vaccination on the severity and symptomatology of the allergic disease, in addition to natural viral infection.

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Intradermal scar injections for the treatment of neuropathic pain post fascial gunshot wound – *Case Report*

Abstract

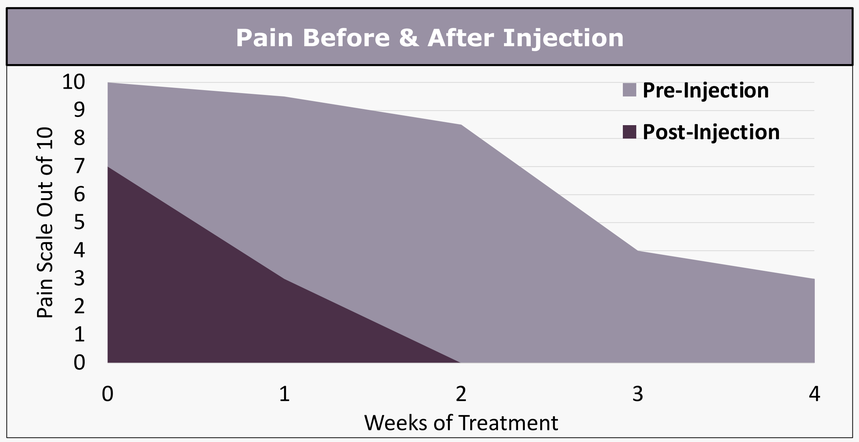
The successful use of intradermal lidocaine injections for neuropathic pain following traumatic injuries, such as a gunshot wound (GSW), has not been widely studied in literature.[1] A quick literature review demonstrates that similar surgical neurologic injury has commonly been recorded post mastectomy, hernia repair and thoracotomy.[2-4] Regardless of injury type, neuropathic pain from scars has minimal treatment options, often requiring patients to take strong pain medications. The purpose of this case study is to investigate the use of intradermal lidocaine injections as a viable option for traumatic neuropathic pain. We hypothesize that this therapeutic approach could not only help with pain, but also decrease narcotic use. In this case report, we have a 27-year-old female who presented with chronic atypical facial pain and migraines (3-4 per week) following a GSW 5.5 years prior. The patient was given intradermal lidocaine injections into her scars and frontalis muscle trigger points. Post-injection, she reported decreased pain (reported from a 10/10 to a 7/10) and noted a dramatic decrease in her narcotic use (typical use was 4-5 times per day) during the following week. After 4 weeks of treatment, the patient noted that her pain was now a 3/10, she has not had a migraine in recent weeks, and has not required narcotics. The downfall of such treatment is the possibility of a placebo effect. However, we feel this is contradictory due to our patient's decrease in narcotic use. We believe more research needs to be conducted into this therapeutic application.

Case Summary

Chief Complaint: Chronic burning facial pain and migraines

History: The patient presents with neuropathic pain and migraines following a GSW approximately 5.5 years ago. Attesting to this, she has had subsequent surgeries that led to the repair of a broken jaw, replaced left temporal mandibular joint, loss of hearing on the left side, left cheek plates, a cadaveric chin, and a right eyebrow raise. As a result to such surgeries and remaining bullet fragments, the patient accrued scars on her left forehead, left cheek, left posterior auricular area, left mandible, and right upper forehead above her hair line. The patient notes chronic pain predominantly on her right forehead scar, chronic migraines at her left temple occurring 3-4 times per week, and frontal branch fascial paralysis – all following the GSW. She has been on chronic oxycodone-acetaminophen for recurrent fascial pain, and rizatriptan and sumatriptan for her migraines.

Pertinent Labs: Patient currently has elevated liver enzymes.



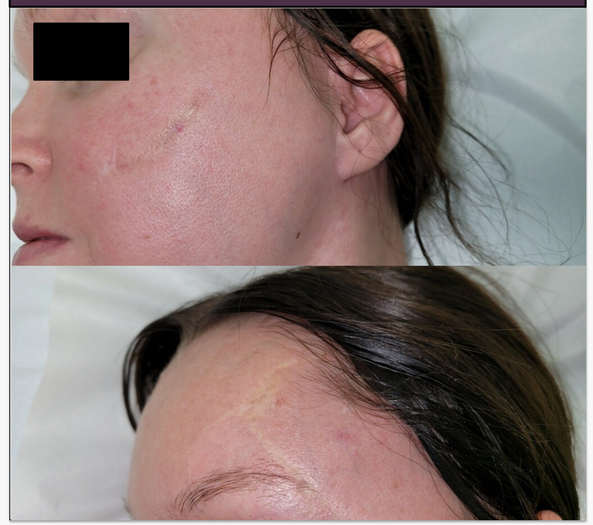
Injection Treatment Course

Week Number	CCs of lidocaine	Pain Pre-Injection*	Pain Post-Injection*
0	7	10	7
1	15	9.5	3
2	10	8.5	0
3	10	4	0
4	10	3	0

*Pain scale out of 10

Patient stopped using narcotic pain medication

Injection into Facial Scar



Discussion

It has been hypothesized that injecting local anesthetic into scar tissue and trigger points can not only improve neuropathic pain, but also help restore nerve sensation. In this case, we believe this was observed. Our patient's pain and migraines not only dramatically decreased – but her frontal nerve fascial paralysis was improved per the patient's perception. Additionally, our patient's migraines we no longer present following treatment. This is intriguing as lidocaine's half-life is approximately 2 hours. As such, one would not expect a fast-acting anesthetic to exert its effect for a prolonged period as witnesses in this case.

Due to decreased chronic pain, intradermal injections could help with the avoidance of narcotic use. Our patient chronically used oxycodone-acetaminophen 4-5 times per day. Subsequently, she had elevated liver enzymes. Oxycodone is metabolized by the livers CYP3A enzyme isoforms, while acetaminophen by the CYPE1 enzyme. Literature suggests the CYP3A isoforms may influence the metabolism of acetaminophen to a greater magnitude than previously understood.[5,6] Additionally, the possibility of abuse of oxycodone-acetaminophen puts patients at increased risk for acetaminophen induced hepatotoxicity. Ultimately, it is possible that the use of intradermal anesthetic injections could help with chronic pain and migraines due to traumatic neuropathic injury. If correct, a secondary effect would be decreased narcotic use. Attesting to our findings in this case, we believe more research needs to be conducted into this therapeutic application.

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Latinas, osteoarthritis, and a language barrier for care:

An analysis of the Behavioral Risk Factor Surveillance System.

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INTRODUCTION

- Osteoarthritis (OA) is a very prominent musculoskeletal disorder that affects approximately 303 million people worldwide.[1,6]
- Numerous studies have shown language barriers interfere with the ability of Spanish speakers to communicate their pain symptoms to non-Spanish speaking physicians.[2,3,5,7]
- The challenge that language barriers present to the Latina population in regards to the diagnosis and treatment of osteoarthritis remain largely unknown.

RESEARCH QUESTION

- Does a language barrier play a role in the diagnosis and treatment of OA in Latina women?

METHODS

- We analyzed data from the CDC's Behavioral Risk Screening and Surveillance System, combining the 2017-2020 cycles using sampling weights provided by BRFSS, adjusted for multiple cycles.
- To distinguish language groups, we assessed what version of the survey was submitted—English or Spanish.
- Next, we calculated prevalence estimates for arthritis diagnosis, limitations, and joint pain (ranged 0-10) and tested for associations between language groups and by age (40+ and 65+).

RESULTS

- Among Latinas aged 40+, the odds of being diagnosed with OA were lower for Spanish-speaking women than English speaking; however, among those 65+, there was no significant association (Table).
- Spanish speaking Latinas 65+ were more likely to report being limited by pain than the English speaking group (Table).
- Differences in pain score between Spanish and English speaking groups were statistically significant for the 40+ (t = 5.25. $p < .001$) and 65+ age ranges (t=5.27, $p <$ 0.001; Figure).

Average Arthritis Pain score (1-10) among English and Spanish Speaking Latinas

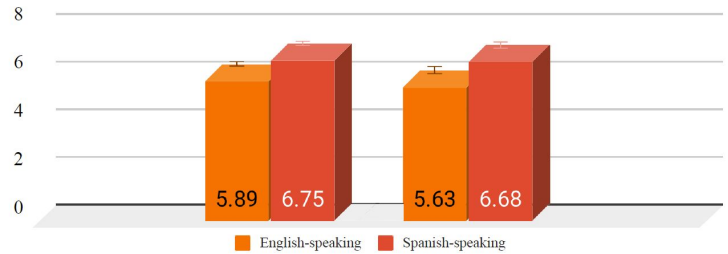

Table 1. Arthritis and symptoms among latina women 40+ years and 65+ years and over.

	Women 40+			*Women 65+*		
	English Speaking	Spanish Speaking	Odds Ratio	English Speaking	Spanish Speaking	Odds Ratio
	N, (%)	N, (%)	(95%CI)	N, (%)	N, (%)	(95%CI)
Have you been told you have arthritis?						
Yes	1646975 (18.91%)	1587645 (18.23%)	**.89 (.81-.98)**	608658 (23.6%)	770928 (29.89%)	1.11 (.95-1.30)
Limited because of symptoms						
Yes	361314 (24.37%)	390020 (26.31%)	1.08 (.89-1.30)	115223 (18.26%)	174318 (27.62%)	**1.43 (1.09-1.87)**
Arthritis affects ability to work						
Yes	314868 (21.55%)	338956 (23.2%)	1.09 (.91-1.33)	91227 (14.87%)	118501 (19.31%)	1.12 (.84-1.50)

CONCLUSION

- Our study shows that Spanish speaking Latina women who are 40+ are less likely to be diagnosed with OA.
- Spanish speaking Latinas 40+ and 65+ groups reported a higher average joint pain.
- Results from this study shed light on the fact that language barriers have a major effect on the quality of holistic healthcare that osteopathic physicians are required to provide.[4]

SIGNIFICANCE OF FINDINGS

- Language barriers pose a threat to the long term health outcomes of the Latina population.
- There is a gap in adequate treatment following the diagnosis which is represented by reports of higher intensity pain.
- Implementing translators in all medical settings can lessen the adverse outcomes that result from language barriers. [4]

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CENTERS FOR DISEASE CONTROL AND PREVENTION
2022 Winter CME Seminar

Asthma medications in schools:
A cross-sectional analysis of the Asthma Call Back Survey

1.

INTRODUCTION

- Asthma is the most common childhood chronic disease in the United States, with over 7.1 million children currently diagnosed. Moreover, one-third of those diagnosed with asthma in the US are children.[1,6]

- Quality treatment of complex conditions, such as asthma, requires appropriate patient screening and education.[1,3]

- Long-term goals of asthma management include achieving symptom control, maintaining a normal activity level, and minimizing risk of asthma-related mortality, exacerbations, persistent airflow, and side-effects of treatment.[1,3,5]

RESEARCH QUESTION

- Our objective was to analyze the amount of children with asthma permitted to carry medications in school and to assess the prevalence of children with an asthma action plan in school.

METHODS

- Using the CDC's 2017 & 2018 BRFSS Asthma Call Back Survey for children, we assessed the prevalence of children in school that are allowed to carry medication and if they had an asthma action plan.

- We included only children who were *in school* and were reported to *currently have asthma*, ranging in age from 0-17 in BRFSS defined *age groups* show in Figure 2..

- We assessed if there was a difference in allowance of asthma medication in schools or having asthma action plans based on *urbanicity* (rural vs. metro area).

Asthma medications allowed in school

Figure 1a.

Written asthma action plan in school

Figure 1b.

Age groups of children with asthma whose school did not allow children to carry their medication with them (Left) and did not have an asthma action plan.

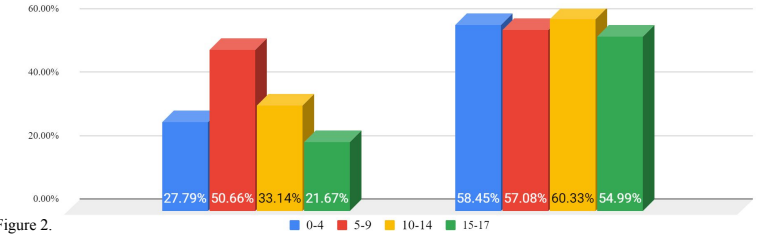

Figure 2.

SIGNIFICANCE OF FINDINGS

- Improving asthma control status positively impacts school absenteeism, academic success, and quality of life. These factors are further elevated with increased levels of asthma control, school environmental conditions, and teacher knowledge of student's condition.[9]

- Establishing relationships between schools, healthcare students, and physicians is essential for effective asthma management plan implementation, especially in the educational setting. [4,7]

- Implementing protocols for stock albuterol to be supplied in schools increases access to medication for children who are not permitted to carry it.[8]

- The Osteopathic Principles and Practices should guide an osteopathic physician's asthma management plan through the understanding that the body is a unit of mind, body, and spirit; capable of self-regulation, self-healing, and self-maintenance once that unity is restored.

Results

- Nearly 35% of students reported that they were not allowed to carry asthma medications (Figure 1a) and 58% did not have a written asthma action plan (Figure 1b).

- Reported urbanicity was not significantly associated with either medication access at school (P=.46) or having an action plan (P=.57).

- Further, nearly 51% of children ages 5 - 9 and 33% of children ages 10-14 were unable to carry medications at school (Figure 2).

CONCLUSION

- More than one-third of students were not permitted to carry asthma medications and nearly 3 out of 5 did not have a written asthma action plan.

- These findings indicate the need for both access to medication in schools in addition to written action plans to improve asthma management in school.

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Analysis of the Evidence Underpinning the American Academy of Orthopedic Surgeons Knee Osteoarthritis Clinical Practice Guidelines

INTRODUCTION

Clinical Practice Guidelines (CPGs) are important tools which support decision-making by clinicians in patient management and are be based upon a comprehensive review of available literature. Because these guidelines have wide-reaching implications in patient care, these CPGs should be critically appraised to ensure their recommendations adhere to high-quality standards of reporting. This study aimed to assess the quality and completeness for RCTs used to support two CPGs published by the American Academy of Orthopedic Surgeons (AAOS) for (1) surgical and (2) non-surgical management of osteoarthritis of the knee.

METHODS

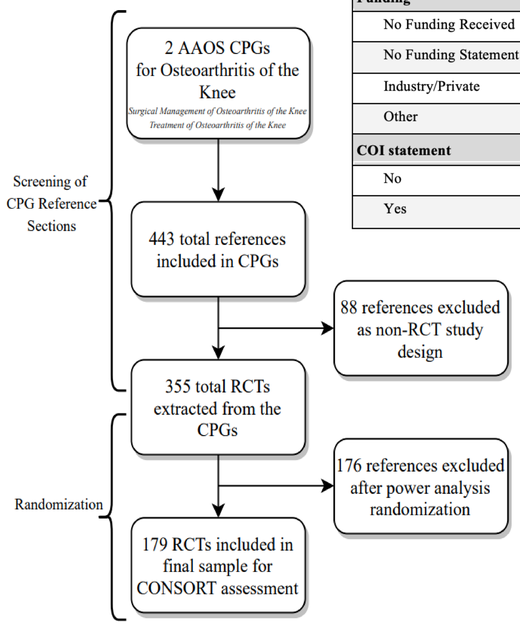
We evaluated the completeness of reporting for each item on the Consolidated Standard of Reporting Trials (CONSORT) 2010 checklist for all RCTs included in our analysis. Screening and extraction of RCTs included in our study was conducted in a double-masked fashion. We then evaluated the percent adherence of RCTs according to the CONSORT 2010 checklist criteria. We conducted a multiple regression analysis assessing CONSORT adherence against characteristics of the included studies (i.e. type of intervention, funding source, etc.).

Characteristics of the included clinical practice guidelines

Clinical Practice Guideline	Year of Publication	Geographical Region	References per Guideline	RCT's per Guideline	RCT as a Proportion of All Studies Cited by CPG
Surgical Management of Osteoarthritis of the Knee	2015	United States	220	162	73.64%
Treatment of Osteoarthritis of the Knee	2013	United States	223	193	86.55%
Date Range:	2013-2015	**Totals:**	**443**	**355**	**80.1%**

Multiple-Regression Analysis of Clinical Trial Publication Characteristics

	No. (%) of Articles (n=23)	Unadjusted model coefficient, (SE)	t-value	*P*	Consort coefficients, (SE)	Consort Standardized Coefficients	t-Value	*P*
Type of intervention								
Device	17, (9.5)	1 (Ref)	1 (Ref)	-	1 (Ref)	1 (Ref)	-	-
Drug	78, (43.6)	3.23, (4.0)	0.79	0.429	2.48, (3.59)	0.08	0.69	0.491
Surgical	34, (19.0)	-7.35, (4.53)	-1.62	0.107	-5.59, (4.01)	-0.14	-1.39	0.165
Combo/Other	50, (27.9)	4.66, (4.28)	1.09	0.278	3.02, (3.75)	0.09	0.81	0.421
Publication Year								
Before 2010	112, (62.6)	1 (Ref)	1 (Ref)	-	1 (Ref)	1 (Ref)	-	-
After 2010	67, (37.4)	5.9, (0.02)	2.46	0.015	5.61, (2.21)	0.17	2.54	0.012
Funding								
No Funding Received	13, (7.3)	1 (Ref)	1 (Ref)	-	1 (Ref)	1 (Ref)	-	-
No Funding Statement	64, (35.8)	0.67, (4.23)	0.16	0.875	-2.81, (4.11)	-0.09	-0.68	0.495
Industry/Private	44, (24.6)	15.02, (4.39)	3.42	0.001	11.78, (4.28)	0.32	2.75	0.007
Other	58, (32.4)	16.34, (4.27)	3.83	0	11.66, (4.35)	0.35	2.68	0.008
COI statement								
No	87, (48.6)	1 (Ref)	1 (Ref)	-	1 (Ref)	1 (Ref)	-	-
Yes	92, (51.40)	6.81, (2.30)	2.95	0.004	5.06, (2.12)	0.16	2.39	0.018



Summary of CONSORT Completeness Scores for AAOS Clinical Practice Guidelines

	CPG 1 (Non-Surgical)	CPG 2 (Surgical)	Total
Total Percent Complete, Mean (SD)*	**73.65, (12.49)**	**62.87, (17)**	**68.47, (15.74)**

*Total percent complete based on score/total for each RCT.

RESULTS

A representative sample of 179 RCTs were assessed for adherence to CONSORT criteria. The overall adherence was 68.5% with significant differences between those published prior to and since the development of the 2010 CONSORT guidelines (p=0.0205). We also found that RCTs receiving funding from Industry/Private sources showed more complete adherence than RCTs which reported receiving no funding (p=0.008). We found that RCTs cited in the CPGs often failed to adequately report methods for randomization and blinding according to the standards set forth by CONSORT 2010 guidelines. Finally, studies that included a Conflict-of-Interest statement had significantly higher CONSORT adherence (p=0.018).

CONCLUSION

We found suboptimal CONSORT adherence for RCTs cited in AAOS CGPs for management of osteoarthritis of the knee. Therefore, the AAOS CPGs are out of date and lack high quality reporting of evidence. It is important that the evidence used to guide clinical decision-making be of the highest quality in order to optimize patient outcomes. For clinicians to confer the greatest benefits to their patients, CPGs should provide the totality of evidence and emphasize emerging high quality RCTs to ensure up-to-date, evidence-based clinical decision making.

Evaluating Reporting of Patient Reported Outcomes in Randomized Controlled Trials Regarding Inflammatory Bowel Disease: a Methodological Study

INTRODUCTION

Patient-reported outcomes in randomized controlled trials pertaining to inflammatory bowel disease are important in identifying patients' perspective of treatment. Incompletely reported patient-reported outcomes within trials could misrepresent information for clinicians, and may contribute to treatment which lacks accommodation of patient input. Our study evaluates completeness of reporting of patient-reported outcomes and risk of bias to identify how well trialists are adhering to known resources for trials.

METHODS

We used MEDLINE, Embase, and the Cochrane Central Register of Controlled Trials to identify eligible trials from 2006-2020 with at least one patient-reported outcome measure related to inflammatory bowel disease. The trials were screened in duplicate using Rayyan. We then compared trial completion of reporting to the CONSORT-PRO adaptation, and assessed risk of bias using the Cochrane Collaboration RoB 2.0 Tool. To measure trial and reporting characteristics, we performed bivariate regression analyses.

Table 1: Bivariate Regression Analyses Between Study Characteristics and Completeness of PRO Reporting.

Characteristic	**Total 29 (100)**	**Coef. (SE)**	**t**	***P***
Year of publication, No. (%)				
< 2014	8 (27.59)	1 (Ref)	-	-
≥ 2014	21 (72.41)	15.89, (6.95)	2.29	0.03
Intervention of RCT, No. (%)				
Device	1 (3.45)	1 (Ref)	-	-
Diet	1 (3.45)	44.76, (22.18)	2.02	0.054
Drug	24 (82.76)	14.98, (16.01)	0.94	0.358
Therapy	3 (10.34)	41.19, (18.11)	2.27	0.032
Includes COI statement, No. (%)				
No statement	6 (20.69)	1 (Ref)	-	-
Reports COI	9 (31.03)	-0.86, (9.38)	-0.09	0.928
Reports No COI	14 (48.28)	9.9, (8.68)	1.14	0.265
Journal Requirement of Reporting Guidelines, No. (%)				
Not Mentioned	2 (6.9)	1 (Ref)	-	-
Recommended	14 (48.28)	1.94, (14.07)	0.14	0.891
Required	13 (44.83)	2.66, (14.14)	0.19	0.852
Mention of CONSORT or CONSORT-PRO within RCT, No. (%)				
No	29 (100)	1 (Ref)	-	-
Yes	0 (0)	-	-	-
PRO as a primary or secondary outcome, No. (%)				
Primary	7 (24.14)	1 (Ref)	-	-
Secondary	22 (75.86)	-15.55, (7.35)	-2.12	0.044
Overall ROB, No. (%)				
High	5 (17.24)	1 (Ref)	-	-
Some Concerns	16 (55.17)	-6.26, (9.09)	-0.69	0.497
Low	8 (27.59)	6.18, (10.11)	0.61	0.546
Length of PRO Follow-up				
3 months or less	21 72.41	0, (0.02)	0.04	0.968
3+ to 6 months	5 17.24	-11.29, (8.97)	-1.26	0.219
6+ months to 1 year	3 10.34	2.76, (11.12)	0.25	0.806
1 years +	0, (0)	-	-	-
Sample size				
Mean (SD)	86.34 (63.09)	0, (0.05)	-0.09	0.933

Figure 1:

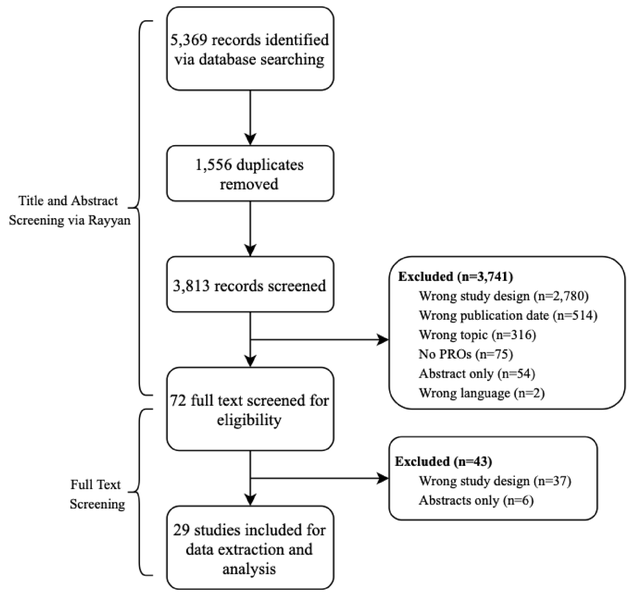


Table 2. Completion of CONSORT-PRO Checklist by Primary and Secondary Outcome Designation.

	Primary Outcome 7 (24.14)		**Secondary Outcome 22 (75.86)**		**Total 29 (100)**	
	Complete	***Not Complete***	***Complete***	***Not Complete***	***Complete***	***Not Complete***
CONSORT-PRO item	***n (%)***	***n (%)***	***n (%)***	***n (%)***	***n (%)***	***n (%)***
Introduction						
P1b. Abstract—PRO as primary/secondary endpoint*	7 (100)	0 (0)	10 (45.45)	12 (54.55)	17 (58.62)	12 (41.38)
2a. Rationale for including PRO endpoint (1)	4 (57.14)	3 (42.86)	7 (31.82)	15 (68.18)	11 (37.93)	18 (62.07)
P2bi. PRO hypothesis present (0.5)	0 (0)	7 (100)	2 (9.09)	20 (90.91)	2 (6.9)	27 (93.1)
P2bii. PRO domains in hypothesis (0.5)	0 (0)	7 (100)	0 (0)	22 (100)	0 (0)	29 (100)
Methods						
P6ai. Evidence of PRO instrument validity	7 (100)	0 (0)	19 (86.36)	3 (13.64)	26 (89.66)	3 (10.34)
P6aii. Statement of the person completing the questionnaire	5 (71.43)	2 (28.57)	9 (40.91)	13 (59.09)	14 (48.28)	15 (51.72)
P6aiii. Mode of administration (paper, e-PRO)	0 (0)	7 (100)	1 (4.55)	21 (95.45)	1 (3.45)	28 (96.55)
P7a. How sample size was determined (not required unless PRO is a primary endpoint)*	5 (71.43)	2 (28.57)	-	-	5 (71.43)	2 (28.57)
P12a. Statistical approach for dealing with missing data (imputation, exclusion, other)	1 (14.29)	6 (85.71)	4 (18.18)	18 (81.82)	5 (17.24)	24 (82.76)
Results						
13ai. Report no. questionnaires submitted/available for analysis at baseline	3 (42.86)	4 (57.14)	12 (54.55)	10 (45.45)	15 (51.72)	14 (48.28)
13aii. Report no. questionnaires submitted/available for analysis principle time point for analysis	2 (28.57)	5 (71.43)	8 (36.36)	14 (63.64)	10 (34.48)	19 (65.52)
15. Demographics table includes baseline PRO	6 (85.71)	1 (14.29)	20 (90.91)	2 (9.09)	26 (89.66)	3 (10.34)
16. Number of pts (denominator) included in each PRO analysis	1 (14.29)	6 (85.71)	7 (31.82)	15 (68.18)	8 (27.59)	21 (72.41)
17ai. PRO results reported for the hypothesised domains and time point specified in the hypothesis—OR—reported for each domain of the PRO questionnaire if no PRO hypothesis provided	2 (28.57)	5 (71.43)	4 (18.18)	18 (81.82)	6 (20.69)	23 (79.31)
17aii. Results include confidence interval, effect size or some other estimate of precision	7 (100)	0 (0)	18 (81.82)	4 (18.18)	25 (86.21)	4 (13.79)
18. Results of any subgroup/adjusted/exploratory analyses	5 (71.43)	2 (28.57)	6 (27.27)	16 (72.73)	11 (37.93)	18 (62.07)
Discussion						
P20. PRO study limitations	7 (100)	0 (0)	16 (72.73)	6 (27.27)	23 (79.31)	6 (20.69)
P21. Implications of PRO results for generalizability, clinical practice	4 (57.14)	3 (42.86)	8 (36.36)	14 (63.64)	12 (41.38)	17 (58.62)
22. PROs interpreted in relation to clinical outcomes	6 (85.71)	1 (14.29)	7 (31.82)	15 (68.18)	13 (44.83)	16 (55.17)

*Item P7a only applies to PROs identified as a primary outcome.

RESULTS

Among a sample of 29 trials, the mean completion percentage for CONSORT-PRO was 46.77%. We found patient-reported outcomes as a secondary outcome had significantly lower CONSORT-PRO reporting ($p<0.05$). In addition, percent completeness of reporting was significantly higher with both a 'therapy' intervention, and trials published following the development of CONSORT-PRO ($p<0.05$).

CONCLUSION

Incomplete patient-reported outcome reporting is common in trials focused on inflammatory bowel disease. This suboptimal reporting indicates the need for adherence to reporting guidelines. Trialists should use the CONSORT-PRO checklist, as endorsed by PROTEUS, to assess their studies in order to enhance reporting adherence.

Otolaryngology Journal Data-sharing Policies: Adherence to the FAIR principles

[redacted]

Introduction

Contemporary medical research is in a reproducibility crisis with over 70% of researchers reporting having an inability to reproduce results from a previous experiment and over 50% having failed to reproduce their own past experiment(1,2). A solution of interest is the FAIR principles, widely considered the standard of excellence with regards to research data sharing. Emphasizing Findability, Accessibility, Interoperability, and Reusability in data sharing policies is essential to practicing replicable science and advancing scientific understanding (3). The study aims to evaluate adherence to the FAIR principles across top active ENT journals to analyze the current state of data sharing and transparency in the field of Otolaryngology.

Methods

Data sharing policies were extracted and indexed among 111 ENT journals as ranked by Scimago based on SJR and h-index. A total of 100 ENT journals were included in our sample for analysis (Figure 1). The data extracted from each journal website included information relevant to adherence to the FAIR principles for scientific data management and stewardship. Each journal was evaluated for its adherence with respect to findability, accessibility, interoperability, and reusability of research (meta)data. Comprehensive data sharing policies were often non-localized on journal websites, requiring a holistic approach to data collection on the website. All extraction and screening was performed in a duplicate and blinded manner.

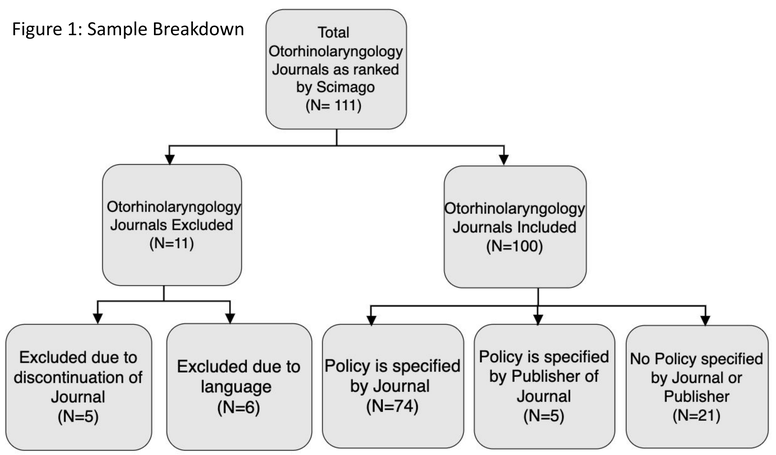
Characteristics of Otolaryngology Journals Analyzed for Data Sharing Policies

Name of Journal	*SJR*	*h-Index*	*Data Sharing Policy*
Acta Oto-Laryngologica	0.706	77	Yes, specified by Journal
Acta Otorhinolaryngologica Italica	0.765	37	No
Acta Otorrinolaringológica Española	0.312	23	Yes, specified by Journal
Advances in Oto-Rhino-Laryngology	0.501	35	No
American Journal of Otolaryngology Head and Neck Medicine and Surgery	0.614	55	Yes, specified by Journal
American Journal of Rhinology and Allergy	0.763	74	Yes, specified by Journal
American Journal of Speech-Language Pathology	0.786	67	Yes, specified by Journal
Annals of Otology, Rhinology and Laryngology	0.659	87	Yes, specified by Journal
Aphasiology	0.897	65	Yes, specified by Journal
Archives of Craniofacial Surgery	0.192	1	Yes, specified by Journal
Archives of Oral Biology	0.689	84	Yes, specified by Journal
Audiology and Neuro-Otology	1.132	75	Yes, specified by Journal
Audiology and Neurotology Extra	1.471	4	Yes, specified by Journal
Audiology and Speech Research	0.213	1	No
Audiology Research	0.113	2	Yes, specified by Journal
Auris Nasus Larynx	0.732	44	Yes, specified by Journal
B-ENT	0.17	31	Yes, specified by Journal
Brazilian Journal of Otorhinolaryngology	0.528	30	Yes, specified by Journal
British Journal of Oral and Maxillofacial Surgery	0.529	70	Yes, specified by Journal
Cleft Palate-Craniofacial Journal	0.735	74	Yes, specified by Journal
Clinical and Experimental Otorhinolaryngology	0.749	24	Yes, specified by Journal
Clinical Otolaryngology	1.016	65	Yes, specified by Journal
Clinical Rhinology	0.103	5	Yes, specified by Journal
Cochlear Implants International	0.746	30	Yes, specified by Journal
CoDAS	0.365	20	Yes, specified by Journal
Cranio - Journal of Craniomandibular Practice	0.314	43	Yes, specified by Journal
Current Opinion in Otolaryngology and Head and Neck Surgery	0.702	60	No
Dentomaxillofacial Radiology	0.768	69	Yes, specified by publisher
Dysphagia	0.932	78	Yes, specified by Journal
Ear and Hearing	1.644	103	Yes, specified by Journal
Ear, Nose and Throat Journal	0.252	45	Yes, specified by Journal
Egyptian Journal of Ear, Nose, Throat and Allied Sciences	0.138	7	Yes, specified by Journal
Equilibrium Research	0.215	11	No
European Annals of Otorhinolaryngology, Head and Neck Diseases	0.536	26	Yes, specified by Journal
European Archives of Oto-Rhino-Laryngology	0.871	67	Yes, specified by Journal
Head and Face Medicine	0.65	34	Yes, specified by publisher
Head and Neck	1.16	120	Yes, specified by publisher
Head and Neck Pathology	0.743	46	Yes, specified by Journal
Hearing, Balance and Communication	0.152	9	Yes, specified by Journal
Indian Journal of Otolaryngology and Head and Neck Surgery	0.322	19	Yes, specified by Journal
Indian Journal of Otology	0.189	8	Yes, specified by Journal
International Archives of Otorhinolaryngology	0.545	14	Yes, specified by Journal
International Forum of Allergy and Rhinology	1.284	39	Yes, specified by publisher
International Journal of Oral and Maxillofacial Surgery	1.02	96	Yes, specified by Journal
International Journal of Pediatric Otorhinolaryngology	0.668	73	Yes, specified by Journal
International Journal of Speech-Language Pathology	0.612	39	Yes, specified by Journal
International Tinnitus Journal	0.315	28	Yes, specified by Journal
Iranian Journal of Otorhinolaryngology	0.293	11	No
JAMA Otolaryngology - Head and Neck Surgery	1.431	121	Yes, specified by Journal
Japanese Journal of Head and Neck Cancer	0.101	3	No
JARO - Journal of the Association for Research in Otolaryngology	1.08	69	Yes, specified by Journal
Journal of audiology and otology	0.492	11	Yes, specified by Journal
Journal of Cranio-Maxillo-Facial Surgery	0.942	73	Yes, specified by Journal
Journal of Craniofacial Surgery	0.444	70	No
Journal of Indian Academy of Oral Medicine and Radiology	0.125	0	Yes, specified by Journal
Journal of International Advanced Otology	0.53	11	No
Journal of Laryngology and Otology	0.687	60	Yes, specified by Journal
Journal of Maxillofacial and Oral Surgery	0.35	18	Yes, specified by Journal
Journal of Oral and Maxillofacial Pathology	0.322	20	No
Journal of Oral and Maxillofacial Surgery	0.735	116	Yes, specified by Journal
Journal of Oral and Maxillofacial Surgery, Medicine, and Pathology	0.166	9	Yes, specified by Journal
Journal of Oral Biology and Craniofacial Research	0.444	14	Yes, specified by Journal
Journal of Oral Pathology and Medicine	0.809	80	Yes, specified by Journal
Journal of Otolaryngology - Head and Neck Surgery	1.03	44	Yes, specified by Journal
Journal of Otolaryngology of Japan	0.105	13	No
Journal of Otology	0.414	7	Yes, specified by Journal
Journal of Stomatology, Oral and Maxillofacial Surgery	0.292	17	Yes, specified by Journal
Journal of Vestibular Research: Equilibrium and Orientation	0.947	52	No
Journal of Voice	0.797	83	Yes, specified by Journal
Laryngoscope	1.229	142	Yes, specified by Journal
Laryngoscope investigative otolaryngology	1.034	8	Yes, specified by Journal
Medicina Oral, Patología Oral y Cirugía Bucal	0.621	51	No
Minerva Stomatologica	0.374	26	Yes, specified by Journal
Noise and Health	0.427	45	No
Operations Research for Health Care	0.934	20	Yes, specified by Journal
Operative Techniques in Otolaryngology - Head and Neck Surgery	0.165	19	Yes, specified by Journal
Opuholi Golovy i Sei	0.14	0	No
Oral and Maxillofacial Surgery	0.517	26	Yes, specified by Journal
Oral and Maxillofacial Surgery Cases	0.163	3	Yes, specified by Journal
Oral and Maxillofacial Surgery Clinics of North America	0.513	33	Yes, specified by Journal
Oral Diseases	0.777	83	Yes, specified by Journal
Oral Science International	0.236	12	Yes, specified by Journal
ORL	0.375	42	Yes, specified by Journal
Orthodontics and Craniofacial Research	0.562	53	Yes, specified by Journal
Otolaryngologia Polska	0.217	14	No
Otolaryngologic Clinics of North America	0.656	65	Yes, specified by Journal
Otolaryngology - Head and Neck Surgery	1.18	116	Yes, specified by Journal
Otolaryngology Case Reports	0.112	1	Yes, specified by Journal
Otology and Neurotology	1.169	99	Yes, specified by Journal
Otorhinolaryngologist	0.1	4	No
Otorhinolaryngology Clinics	0.1	4	Yes, specified by Journal
Otorinolaringologia	0.365	7	Yes, specified by Journal
Practica Otologica	0.1	6	No
Practica Otologica, Supplement	0.1	3	No
Revue de Laryngologie Otologie Rhinologie	0.113	24	No
Rhinology	1.329	53	Yes, specified by publisher
Sleep and Breathing	0.709	61	Yes, specified by Journal
Speech, Language and Hearing	0.304	7	Yes, specified by Journal
Trends in hearing	1.191	47	Yes, specified by Journal
Vestnik Oto-Rino-Laringologii	0.205	6	No

Results

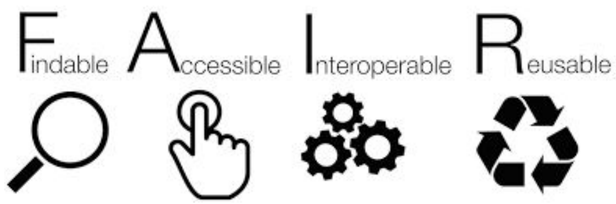
A total of 79/100 (79%) ENT journals specified a data-sharing policy provided by the publisher or the journal itself. Twenty-one (21%) ENT journals did not provide a data-sharing policy (Table 1). A total of 72/79 (91%) ENT journal data sharing policies specified that data should be assigned globally unique and persistent identifiers. There were 65/79 (82%) ENT journal data-sharing policies that mentioned data should be described with rich metadata. A total of 58/79 (73%) journal policies explained that clinical trial data must be shared. Seventy-two (91%) ENT journal data sharing policies confirmed the protection of confidentiality in patients. There were 74/79 (96%) ENT journal policies that mentioned data is registered or indexed in a searchable resource. Fifty-three (67%) ENT journal policies expressed that data should be retrievable by their identifier using a standardized communication protocol. With regards to methods of sharing data, 64/79 (81%) ENT journal policies recommended uploading to an online repository. Fifty-one (65%) policies specified the upload of data to a clinical trial registry. There were 5/79 (6%) policies that explicitly specified data is available upon request to the corresponding author. All 79/79 (100%) journal policies recommended data sharing. Lastly, 56/79 (71%) ENT journal policies outlined that data are richly described with a plurality of accurate and relevant attributes.

Figure 1: Sample Breakdown



Conclusion

Our sample may not be completely representative due to feasibility, as policies are influenced by a variety of sources and our study was limited to information provided on journal websites. While all 79 ENT journal policies recommended data-sharing, there were still clear insufficiencies and limitations evident in the sharing of ENT research (meta)data. Otolaryngology is reliant on high caliber clinical research to guide patient care and direct medical decision making. The proper, widespread sharing of research data and methods is imperative to the quality, reproducibility, and progress of the field. These gaps in data-sharing demonstrate the need for ENT journal editors to consider strictly following the FAIR principles.



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Evaluation of Industry Relationships Among Authors of Systematic Reviews and Meta-analyses Regarding Ménières Disease.

Background

Systematic reviews (SR) and meta-analyses (MA) are frequently used in the formation of clinical practice guidelines and ultimately treatment recommendations. As such, undisclosed industry ties in SRs and MAs introduce bias into the foundation of treatment guidelines potentially leading to poor recommendations. The purpose of this study was to quantify the presence of conflicts of interest (COI) in SRs and MAs of Ménières disease treatment and identify any related secondary characteristics of these articles.

Methods

A cross-sectional approach was used on May 28, 2020, to search the MEDLINE and Embase databases from their inception. To meet inclusion criteria, a study must be a SR or MA pertaining to a head-to-head treatment comparison for Ménières disease. Studies must be reported in English and published between September 1, 2016 and June 2, 2020. Data extraction was conducted in a masked, duplicate fashion and included: favorability of study results/discussion, presence of author on the Open Payments Database, Pro Publicas Dollars for Profs, Google Patent, and the United States Patent and Trademark Office (USPTO) and the accuracy of COI disclosure in the included study. A risk of bias assessment was subsequently performed on the included studies according to the Cochrane Collaboration risk of bias assessment criteria.

Table 1. Systematic review characteristics

Characteristic	Form Response	N (%)
Journal (n= 13)	Otology & neurotology : official publ..	4 (30.77)
	Medwave	2 (15.38)
	Otolaryngology - Head and Neck Surger..	2 (15.38)
	Acta Oto-Laryngologica	1 (7.69)
	Auris Nasus Larynx	1 (7.69)
	Cochrane Database of Systematic Reviews	1 (7.69)
	European Archives of Oto-Rhino-Laryng..	1 (7.69)
	The journal of international advanced..	1 (7.69)
Accuracy of author COI disclosure statement (n=62)	No COI found	49 (79.03)
	All COI completely disclosed in systematic review	1 (1.61)
	Incomplete COI disclosure (found to have disclosed and undisclosed)	1 (1.61)
	All COIs were undisclosed	11 (17.75)
Total Number of Authors (n=49)	No COI found	42 (85.71)
	All COIs were undisclosed	5 (10.2)
	Incomplete COI disclosure (found to have disclosed and undisclosed)	1 (2.04)
	All COI completely disclosed in systematic review	1 (2.04)
Intervention Type (n= 13)	Drug	6 (46.15)
	Device	2 (15.38)
	Multiple	2 (15.38)
	Other	2 (15.38)
	Surgical Technique/Intervention	1 (7.69)
Affiliation of First Author (n=13)	Public Academic Institution	9 (69.23)
	Government	2 (15.38)
	Private Academic Institution	1 (7.69)
	Private/Industry	1 (7.69)
	Non-Profit	0 (0.00)
Affiliation of Last Author (n=13)	Public Academic Institution	8 (61.54)
	Government	5 (38.46)
	Private Academic Institution	0 (0.00)
	Non-Profit	0 (0.00)
	Private/Industry	0 (0.00)
Source of Funding (n=13)	No Funding Received	5 (38.46)
	No Statement Present	4 (30.77)
	Public	2 (15.38)
	Multiple	2 (15.38)
	Private/Industry	0 (0.00)
	Non-Profit	0 (0.00)
	Hospital	0 (0.00)
	University	0 (0.00)
Conflict of Interest Statement (n=13)	All authors report no COI	11 (84.62)
	One or more authors report a COI	1 (7.69)
	No COI statement present	1 (7.69)
Self-citation of primary studies (n= 13)	Yes, included one or more self-cited primary studies	1 (7.69)
	No, did not include self-cited primary studies	0 (0.00)

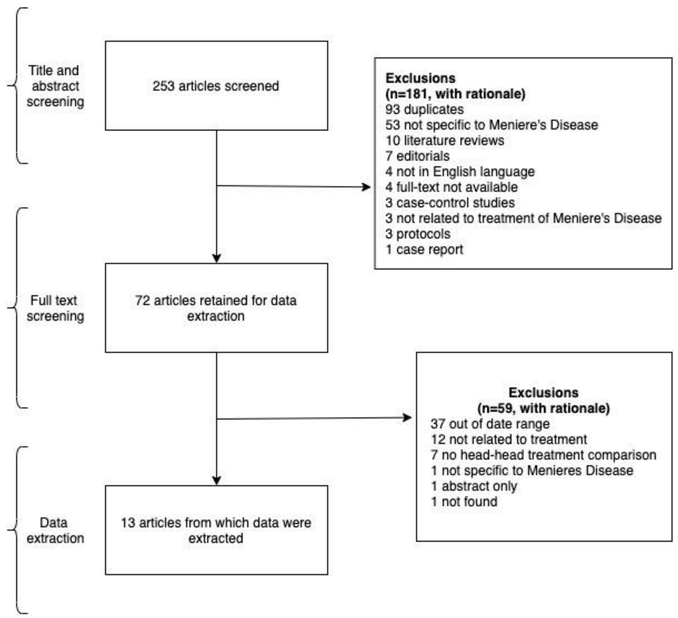


Figure 1: Flow diagram detailing the study selection process

Results

A total of 13 systematic reviews conducted by 49 authors met the inclusion criteria. Analysis of these studies and authors indicated that COIs are present in authors of SRs about Meniere's Disease; with 38.5% of reviews containing a conflict of interest and 17.75% of authors having an undisclosed COI.

Table 2. Frequency of favorability of results and conclusions by conflicts of interest disclosure

Review Outcomes		FCOI among Systematic Reviews	
		No COI (n= 8)	COI (n= 5)
Favorability of Results			
	Results Favor Treatment Group	3 (37.5)	1 (20)
	Results are Mixed/Inconclusive	3 (37.5)	2 (40)
	Results Favor Placebo/Control Group	2 (25)	2 (40)
Favorability of Discussion/Conclusions			
	Discussion Favors Treatment Group	4 (50)	1 (20)
	Discussion is Mixed/Inconclusive	3 (37.5)	1 (20)
	Discussion Favors Placebo/Control Group	1 (12.5)	3 (60)
Risk of Bias			
	High risk of bias	3 (37.5)	1 (20)
	Low risk of bias	5 (62.5)	4 (80)

Table 3. Funding source in relation to favorability of results, discussion, and conclusions

Review Outcomes		Funding Sponsor				
		Industry (n= 2)	Non-industry (n= 2)	No Funding Received (n= 5)	No Statement Listed (n= 4)	Fisher's exact
Favorability of Results						0.339
	Results Favor Treatment Group	1	0	3	0	
	Results are Mixed/Inconclusive	0	1	2	2	
	Results Favor Placebo/Control Group	1	1	0	2	
Favorability of Discussion/Conclusions						1
	Discussion Favors Treatment Group	1	0	2	2	
	Discussion is Mixed/Inconclusive	0	1	2	1	
	Discussion Favors Placebo/Control Group	1	1	1	1	
Risk of Bias						0.301
	High Risk of Bias	1	1	0	2	
	Low Risk of Bias	1	1	5	2	

Summary

Approximately 1 in 5 authors of SRs regarding Ménières disease contained an undisclosed COI. Overall authors of SRs pertaining to Ménières disease appear to be properly disclosing COI at higher rates than other fields of medicine; however, further room for improvement has been noted. We recommend standardization of COI reporting across medical journals as well as improved disclosure methods in relation to international research in an effort to ensure a fully transparent and trustworthy product.

Morphine Withdrawal-Induced Immunosuppression Modulates DNA Methylation in IEC18 cells

INTRODUCTION

Morphine cessation is known to cause immunosuppression in chronic opioid users. Individuals are more susceptible to pathogenic infections during withdrawal, due to the depletion of circulating lymphocytes, macrophages, and cytokines (Campbell et al., 2013). Morphine withdrawal can also alter the degree of methylation in DNA. Methylation of DNA is a heritable phenomena that does not change the sequence of the genome but can cause genes to be transcriptionally suppressed or enhanced. These changes in gene expression makes individuals more predisposed to acquiring a variety of pathologies (Heinbockel et al., 2018). A known transcriptional enhancer of hypermethylated DNA segments is MeCP2. MeCP2 is a protein that binds methylated-CpG regions of DNA, resulting in downstream upregulation of immune determinant genes (Horvath et al., 2018). An increase in MeCP2, indicates an upregulated immune response due to its association with activating signaling pathways such as NF-KB (Percorelli et al., 2020). Additionally, DNA methylation landscape is also altered in inflammatory bowel diseases, especially in ulcerative colitis (Karatzas et al., 2014). This study was undertaken to evaluate morphine withdrawal-induced DNA methylation modulations in rat intraepithelial cells-18 (IEC18).

METHODS

IEC18 Cell Preparation

- A 6 well plate was used to induce morphine withdrawal and placebo withdrawal.

RNA and DNA Extraction and Preparation

- Total RNA was extracted from each well.
- RNA was converted to cDNA.
- Total DNA was extracted from each well.
- Bisulfate Conversion was preformed on extracted DNA to convert nonmethylated Cs to Us.

cDNA and Methylation-specific PCR (DNA) Analysis

- PCR and gel electrophoresis was conducted, the following primers were used:
- cDNA – MeCP2e1, GLS, MOR, β-Actin
- MSP (DNA) - GLS, MeCP2, MOR

METHODS

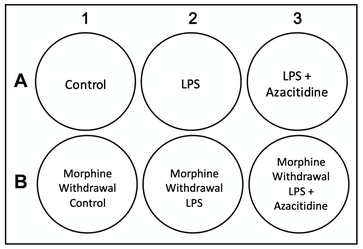
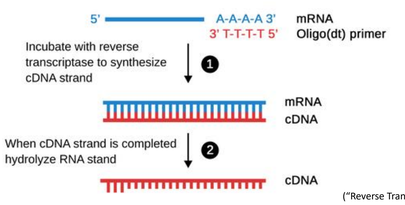
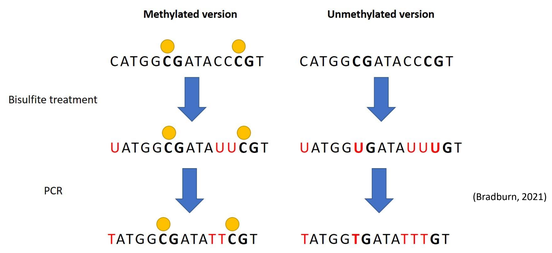


Figure 1. **Treatment protocol of IEC18 cells in 6 well plate.** Row A cells were treated with placebo withdrawal. Row B cells were treated with morphine withdrawal. Morphine (MS) treatment (3d) was followed rigorous washing to simulate morphine withdrawal. Column 1 was a control. Column 2 was exposed to LPS to stimulate an inflammation. Column 3 was exposed to LPS in addition to Azacitidine (Aza), a drug that can be used to suppress DNA methylation.



("Reverse Transcriptase PCR")

Figure 2. **RNA to cDNA conversion.** RNA from IEC18 cells were isolated and converted to cDNA with reverse transcriptase. This was done to create a more stabilized product, cDNA to be used for PCR.



(Bradburn, 2021)

Figure 3. **Bisulfate conversion of methylated and unmethylated CpG in DNA.** Methylated (M) and unmethylated (U) regions (CpG dinucleotides) of DNA can be identified by bisulfate conversion. After bisulfite conversion, non-methylated cytosines gets converted to Us which after PCR gets converted to Ts while methylated Cytosines do not change.

RESULTS

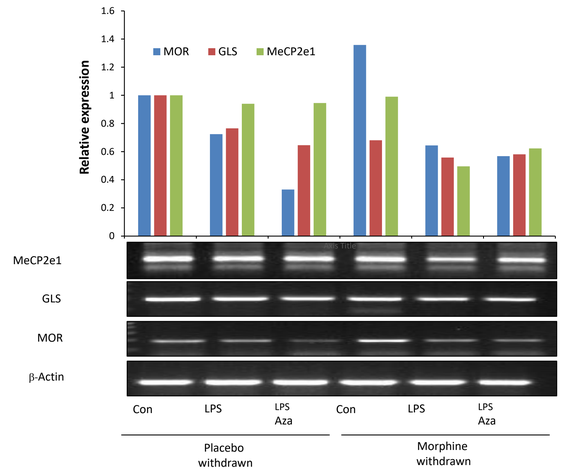


Figure 4. **Relative Expression of MeCP2e1, GLS, and MOR genes in placebo and morphine withdrawn cells.** Morphine withdrawal reduced LPS-induced expression of MeCP2 and GLS message levels but had no effect of MOR message levels.

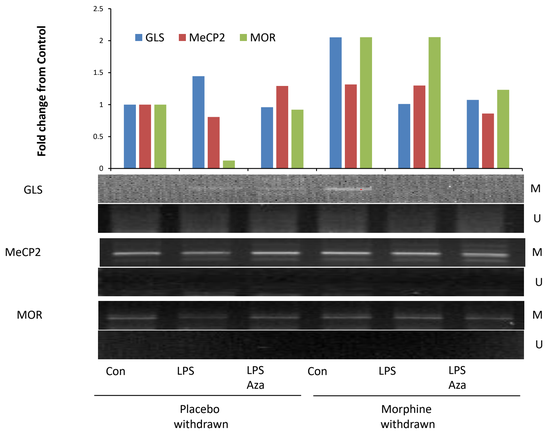


Figure 5. **DNA methylation analysis based on methylation-specific PCR.** Morphine-withdrawal-induced immunosuppression resulted in hypermethylation of MeCP2 and MOR promoters but not in GLS promoter. Morphine withdrawal itself hypermethylated GLS promoter.

CONCLUSION

Morphine withdrawal-induced immunosuppression altered the methylation of *GLS*, *OPRM1* and *MeCP2* genes which needs to be repeated few more times to geta statistically significant results.

Morphine withdrawal immunosuppression in relations with DNA methylation is still an under researched area in epigenetics. In this ongoing projects future intentions, we plan to further discover the molecular effects morphine withdrawal has on DNA methylation and how this affects downstream transcripts.

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Breastfeeding and Native American Women's Interest in Specific Food Tastes

INTRODUCTION

- A 2019 study compared interest in food categories in English and Spanish speaking postpartum mothers in Tulsa, OK. This study further investigated whether interest was possibly influenced by the decision to breastfeed.
- Food preferences during pregnancy has been investigated, however there is minimal research in postpartum, particularly breastfeeding, mothers.
- This has not been studied in the Native American population; thus, the purpose of this study is to determine if breastfeeding alters Native American women's interest in eating foods of different taste categories.

METHODS

- Women were asked if they were interested in completing a survey in the waiting room when checking in for their 6-week postpartum checkup at WW Hastings Indian Hospital in Tahlequah, OK (a Native American serving health facility owned by the Cherokee Nation of OK).
- The women were instructed to complete the survey at their own pace. Surveys contained no identifying information or protected health information.
- The survey first asked women to indicate whether they were breastfeeding, the number of infants born, and whether this was their first baby.
- Next, women were asked to rate their level of hunger on a Likert scale that ranged from 1 (not hungry at all) to 9 (very hungry), with 5 indicating "don't care."
- Women were then asked to rate their interest in eating specific foods from 6 different taste categories (salty, sweet, meaty, bitter, sour, and hot). This included foods such such as chips, ice cream, grapefruit, tuna, steak, etc.
- Additionally, women were asked to indicate which taste category was most likely the reason they rated their interest in certain foods as a "9" on the Likert scale.
- Finally, women were asked to indicate if they had eaten the foods they rated as 7-9 in the last 2-3 days. They were asked to identify these foods and why they had or had not eaten them in this time frame.

RESULTS

- There were no striking differences in eating foods in particular taste categories, except for sweet and hot foods (Figure 1)
- In the hot group, there was less interest in eating jalapeno peppers in both groups (Figure 2)
- In the sweet group, there was a greater interest in eating bananas in non-breastfeeding women (Figure 3)
- Breastfeeding women indicated increased hunger ratings over non-breastfeeding women (Table 1)

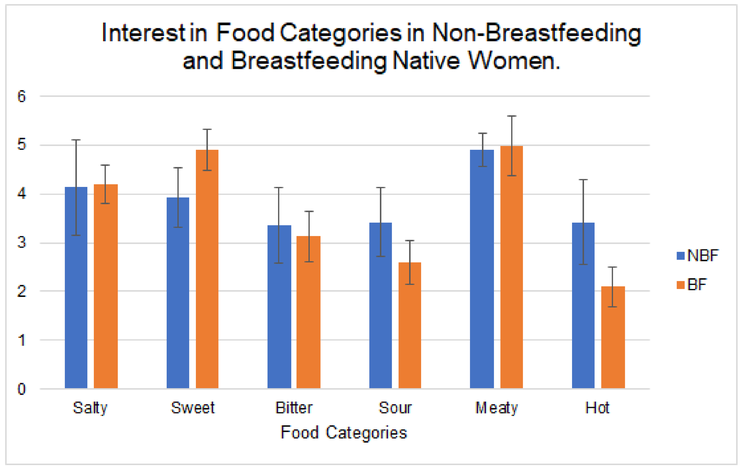

Figure 1. Averages of food category interest in non-breastfeeding and breastfeeding women.

Table 1. Total number of Native American women surveyed in the Non-breastfeeding and Breastfeeding categories along with their responses to the question "How hungry are you right now?" on a scale of 1 ("not hungry at all") to 9 ("very hungry"), with 5 representing "don't care".

	Non-Breastfeeding	Breastfeeding
Total Surveyed	6	10
Hunger rating	2.83 ± 0.75	4.75 ± 0.88

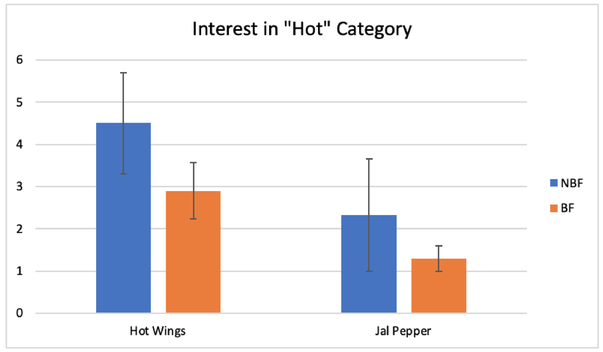

Figure 2. Averages of "Hot"" food category interest in non-breastfeeding and breastfeeding women.

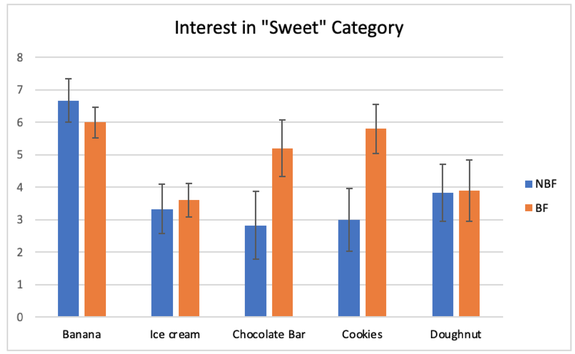

Figure 3. Averages of "Sweet" food category interest in non-breastfeeding and breastfeeding women.

CONCLUSION

- Our study showed that while breastfeeding women indicated increased hunger ratings over non-breastfeeding women, **there were no remarkable differences in the preferences for foods within the various taste categories between the breastfeeding and non-breastfeeding women, with the exception of the sweet and hot groups.**
- Non-breastfeeding women reported a greater interest in eating bananas (in the sweet category) while both groups reported less interest in eating jalapeno peppers (in the hot category).
- These findings provide the initial steps in better understanding the influence of breastfeeding on interest in eating certain foods from various taste categories in women from the Native American population.
- Thus, these findings represent how breastfeeding may affect food preferences in Native American women and furthermore, their food choices.
- This is important because maternal food choices may have implications in the health of the mother as well as her offspring. This includes health issues such as postpartum weight loss in the mother and childhood obesity in the offspring since maternal food preferences may influence family meal choices.
- Future studies including additional surveys will provide enough data to perform statistical analysis to determine validity and significance of findings.

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Person-Centered Language & HIV-Research:
A Cross-Sectional Examination of Stigmatizing Terminology in Medical Literature

INTRODUCTION

- Despite numerous initiatives and guidelines, stigmatizing language has been shown to be prevalent in some areas of medical research and among medical professionals.
- Poor awareness of person-centered language and the importance of its use leads to persistent use by medical professionals, which contributes to stigma and its impact on quality healthcare.
- However, evidence of adherence to person-centered language in HIV literature is lacking.

OBJECTIVES

- We sought to quantify the use of person-centered language in research journals that publish high volumes of HIV-related manuscripts.

METHODS

- In this cross-sectional study, we searched PubMed for HIV-related articles published between 1/1/2017 and 3/7/2021. After journal reduction and article randomization, title and abstract screening was conducted among 500 studies in a masked, duplicate fashion.
- Studies that were included were systematically searched for prespecified, stigmatizing terms, partial terms, and phrases.
- Prevalence rates of non-person-centered terminology were totaled, and the total number of articles adherent to person-centered language guidelines were reported.
- Fisher Exact tests were used to determine associations between PCL adherence and article funding source, type of article and research, among others.

RESULTS

- Among 239 studies included, 21.34% (51) of HIV-related publications in this cross-sectional analysis were found to be PCL adherent.
- Stigmatizing labels such as “HIV- or AIDS- infected-” and “HIV- or AIDS-” person or patient were used most frequently, with the former appearing in 57.32% of articles and the latter appearing in 30.54% of articles.

Figure 1. PRISMA Flow diagram for systematic search, screening, and outcomes.

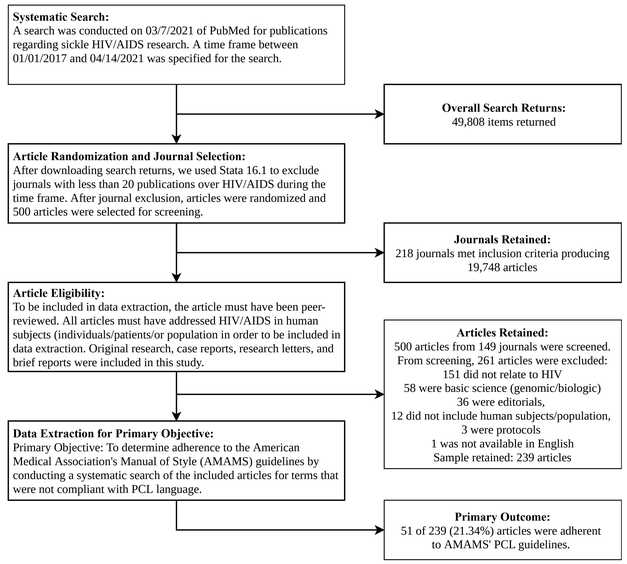
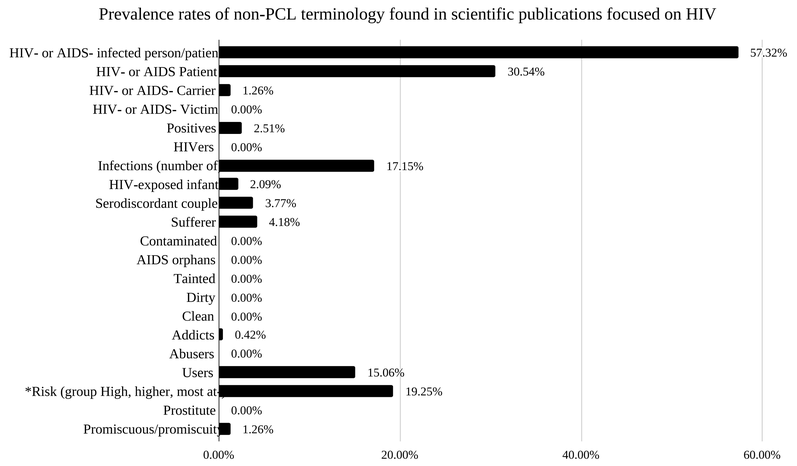


Figure 2. Prevalence of stigmatizing terminology and non-person-centered language found within published, HIV-related studies.



CONCLUSION

- Despite numerous guidelines and requirements for the use of person-centered language in research, our findings suggest that an alarming number of HIV-related articles are not following these guidelines.
- This is concerning because this labeling likely contributes to the persistence of stigma in HIV-centered care.
- The intentional use of person-centered language in medical research has the potential to minimize the use of stigmatizing language amongst medical professionals, in medical education, in medical records, and patient encounters, and thus reduce stigma.

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This optional section is where you would acknowledge Mentors, Sponsors, Grants

The Influence of the COVID-19 Pandemic on Anesthesiology Clinical Trials

Introduction

- The COVID-19 pandemic has significantly altered clinical trial conduct due to public safety measures, supply chain shortages, and resource reallocation.
- Clinical practice of surgical and perioperative specialties were especially impacted due to the reduction in elective procedures.
- Although clinical practice has been altered, the extent of disruption to Anesthesiology clinical trials is currently unknown,

Objective

- The primary objective was to evaluate the extent of clinical trial disruption in the field of anesthesiology secondary to the COVID-19 pandemic.

Methods

- We generated a systematic search on October 2, 2021 using ClinicalTrials.gov to identify clinical trials related to the practice of anesthesiology. To receive all trials potentially affected by the COVID-19 pandemic, our date range was January 1, 2020 through October 1, 2021. Investigators screened for relevant studies and extracted listed reasons for trial discontinuation. The search string is featured in the box below.

ClinicalTrials.gov:

Anesthesia OR Anesthesiology OR Anesthesiologist OR General Anesthesia OR Standard Induction of General Anesthesia OR Mask Ventilation OR Laryngeal Mask Airway OR Monitored Anesthesia Care OR Endotracheal Intubation OR Awake Fiberoptic Intubation OR Left-Sided Double Lumen Tube OR Wire Crichothyroidotomy OR Spinal Anesthesia OR Lumbar Epidural OR Regional Anesthesia OR Peripheral Nerve Block | Recruiting, Active, not recruiting, Enrolling by invitation, Suspended, Terminated, Withdrawn Studies | Interventional Studies | Phase Early Phase 1, 1, 2, 3, 4 | Last update posted from 01/01/2020 to 10/01/2021

Box 1. Search strategy to obtain clinical trials.

Results

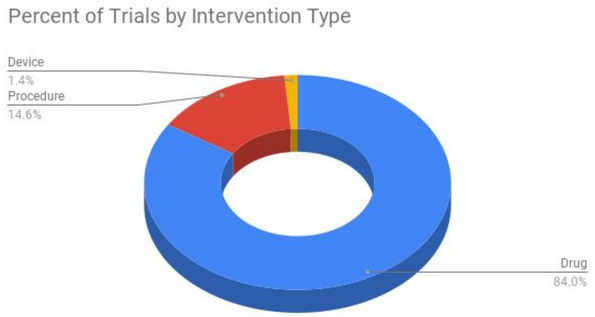

Table 1. Associations of reasons for discontinuation by trial characteristics: IQR= interquartile range, Pr= two-tailed p-value, DF= degrees of freedom

Characteristic	Does not explicitly state COVID-19 related (*n=122*)	Explicitly states COVID-19 related (*n=24*)	Total	P-value
Status				X^2 (DF=2)
Suspended	9 (6.2%)	10 (6.9%)	19 (13.0%)	chi2(2) = 20.9224 Pr = 0.000
Terminated	67 (46.0%)	9 (6.2%)	76 (52.1%)	
Withdrawn	46 (31.5%)	5 (3.4%)	51 (34.9%)	
Intervention				X^2 (DF=3)
Device	3 (2.1%)	0 (0%)	3 (2.1%)	chi2(3) = 0.9718 Pr = 0.808
Drug	102 (69.9%)	20 (13.7%)	122 (83.6%)	
Procedure	16 (11.0%)	4 (2.7%)	20 (13.7%)	
Other	1 (0.7%)	0 (0%)	1 (0.7%)	
Study Design				X^2 (DF=1)
Not Randomized	15 (10.3%)	1 (0.7%)	16 (11.0%)	chi2(1) = 1.2677 Pr = 0.260
Randomized	107 (73.3%)	23 (15.8%)	130 (89.0%)	
Study Design				X^2 (DF=1)
Masked	85 (58.2%)	18 (12.3%)	103 (70.6%)	chi2(1) = 0.2740 Pr = 0.601
Unmasked	37 (25.3%)	6 (4.1%)	43 (29.5%)	
Funding				X^2 (DF=2)
Industry	14 (9.6%)	2 (1.4%)	16 (11.0%)	chi2(2) = 0.8049 Pr = 0.669
Other	106 (72.6%)	21 (14.4%)	127 (87.0%)	
Government	2 (1.4%)	1 (0.7%)	3 (2.1%)	
Location				X^2 (DF=1)
Not U.S.	48 (33.0%)	6 (4.1%)	54 (37.0%)	chi2(1) = 1.7705 Pr = 0.183
U.S.	74 (50.7%)	18 (12.3%)	92 (63.0%)	
Enrollment				**Mann-Whitney U**
Med, IQR	5 (0-35)	32.5 (19.5-85.5)	7 (0-50)	**-2.914, P = .0036**
Range	0-407	0-400	0-407	
Total	4284	1532	5816	

Interpretation

A total of 823 clinical trials met inclusion criteria, and 146 clinical trials were discontinued within the designated date range. Twenty-four (16.4%) of the 146 clinical trials were halted explicitly due to the COVID-19 pandemic. A significant association existed between trial enrollment numbers and the likelihood of discontinuation due to COVID-19, as larger trials were more likely to be disrupted (z= -2.914, P=.0036).

Conclusions

- The COVID-19 pandemic has been a major cause of anesthesiology-related clinical trial discontinuation. With the uncertain course of the COVID-19 pandemic, we recommend that future trials examine alternative methods for trial protocols to help minimize social interaction and prevent premature trial disruption.
- It is critical to consider further efforts in maintaining trial conduction with the purpose of improving anesthetic care. The value of collective data collection and dissemination to researchers and anesthesia providers has been evident throughout the COVID-19 pandemic. Overall, anesthesia-related research must continue even during difficult times, and the unforeseen end to the COVID-19 pandemic should spark an initiative to incorporate innovative methods for data retrieval and trial conduct within the breadth of anesthesiology.

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