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ORIGINAL CONTRIBUTION

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Office based inferior turbinate coblation treatment: a randomized controlled trial on effectiveness and tolerability of medicinal honey*

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Abstract

Background: When conservative treatment for nasal obstruction fails, surgery is often applied. Inferior Turbinate Hypertrophy (ITH) is a common cause of nasal obstruction, which can be treated by means of radiofrequency coblation. This technique can be administered under local anesthesia (office based coblation; OBC) and if expedient combined with a lateralization (out-fracture) of the inferior turbinate (IT). Ointment based on medical grade honey, is known to have wound healing characteristics.

Methodology: Single center, single blinded randomized controlled trial. Fifty-five subjects received bilateral OBC of the IT. Subjects were randomized to postoperative care with either nasal saline irrigations (NSI) or NSI combined with ointment based on honey (NSI+STB). Subjects weekly reported subjectively overall nasal burden, -crusting, -pain, loss of smell by means of VAS-scores and nasal obstruction by means of the NL-NOSE scale.

Results: No significant differences between the NSI and NSI+STB groups, though the latter showed less pain. Concerning the study group as a whole, mean nasal burden score and nasal obstruction significantly decreased from 63.4 to 16.0 and 65.3 to 22.0, respectively. Nasal crusting, -pain, and loss of smell largely resolved 3-4 weeks postoperatively and were only mild. Concomitant lateralization showed a tendency to quicker resolution of the nasal obstruction.

Conclusions: OBC is a safe, well tolerated and effective treatment for nasal obstruction caused by ITH. Concerning multiple endpoints, we found no evidence of a beneficial effect of ointment based on honey as addition to NSI in postoperative care, except a clear tendency in less crusting and pain.

Key words: coblation, nasal obstruction, honey, NOSE scale, turbinate hypertrophy

Introduction

Nasal obstruction caused by inferior turbinate hypertrophy (ITH) is frequently observed in ear-, nose- and throat (ENT) practice. Surgical treatment is often applied in case conservative treatments fails. The inferior turbinates (IT) are located bilaterally in the nose and create turbulence, humidification of air and cause about 50% of airflow resistance so hypertrophy quickly results in the feeling of obstruction[(1)]. Different approaches and techniques for treatment of ITH are available. Coblation (ablation) by radiofrequency (RFC) was found to be one of the treatment options with best longterm results and minor complications, like nasal bleedings, crusting, mild to moderate pain and nasal discharge[(2)]. With RFC, radiofrequent energy is transferred by a sharp pointed probe that is brought into the turbinate causing an immediate removal of the submucosal tissue and continued postoperative scarring/contraction. Because RFC damages the overlying mucosa as less as possible, this results in a shrinkage of the turbinate whilst preserving its function[(3)]. Additionally, the turbinates can also be lateralized or outfractured, whereby the inferior turbinate is broken towards the lateral wall of the nasal cavity, thus creating more space. Lateralization has shown to result in rhinometry improvements, that are also durable[(4)].

Table 1. inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Diagnosis of bilateral ITH for > 6 weeks.	Known immunologic or systemic disease
Capable of undergoing the coblation procedure under local anesthesia.	Currently treated with anticoagulation other than thrombocyte aggregation inhibitors.
Willing to give Informed Consent and adhere to visit schedules.	Diseases that influence blood vessel quality (e.g. diabetes mellitus, vasculitis, polyangiitis granulomatosis)
Age ≥ 18 and ≤ 70 years.	Known coagulopathy.
Proficient of the Dutch language.	Known peanuts allergy.
	Craniofacial malformations.
	The presence of nasal polyps.
	History of turbinate surgery.
	Presence of nasal polyps.
	(History of) radiotherapy.
	Abnormalities requiring other modality of therapy (e.g. obstructive polyps, tumors, infection of dental origin).
	Currently enrolled in other investigational drug trial(s) or is receiving other investigational agent(s).
	A psychiatric disorder.

Postoperative care of RFC exists of prevention and removal of crusts and debris for faster mucosal recovery. In any kind of nasal surgy, postoperative saline irrigations (NSI) have proven to help preventing the formation of synechia, the removal of crusts and debris and also stimulate the recovery of nasal mucosa which in turn appears to improve the mucociliary clearance rate[5].

An additional medicine used for postoperative care is medical grade honey, that has gained relative prominence over the past years within the field of wound healing. Different studies have shown that honey has a thick viscosity and low pH, both of which provide an anti-bacterial effect and since honey does not contain corticosteroids or antibiotics it is possible to use for longer period of time[6]. It also stimulates the generation of new blood vessels and growth of tissue in different types of wounds such as burns, infected wounds caused by trauma and skin ulcers[6,7]. In vitro, honey has shown to have antibacterial as well as immune system activating abilities[7]. In vivo, the ability to decrease inflammation, discomfort and otorrhea in patients with chronically discharging open mastoid cavities was proven[8]. Honey has proven to decrease pain after tonsillectomy, however showing limited results after endoscopic sinus surgery[9–11].

STB™ wounddressing is an ointment based on honey (STB), created and developed by the University of Wageningen (Wageningen, The Netherlands), that has been used in the past decade as a treatment for chronic superficial wounds and damaged mucosa within cavities (e.g. ear and nose). It is well tolerated and used in the ENT-discipline for the treatment of epistaxis or to diminish crusting of the nasal mucosa in for example nasal Granulomatosis with polyangiitis. To our knowledge no studies have been performed to address its effectiveness after minimally invase endonasal surgery or in nasal diseases. No serious side effects have been reported with the use of STB™ wounddressing, except minor burning or tinging sensations[7,12].

The purpose of this study was to evaluate the process of inferior turbinate coblation under local anesthesia as well as to evaluate the addition of STB to nasal saline irrigations during the post-procedure follow-up.

Materials and methods

Study design

The study was carried out as a single center, single blinded, randomized controlled trial on postoperative care according to the CONSORT guideline. After collection of baseline data, randomization to the intervention arm (NSI+STB) or control arm (NSI) took place in a 1:1 allocation ratio (intention-to-treat). This study was approved by the Medical Research Ethics Committee (MREC) Isala (number: NL70712.075.19). Recruitment took place from October 2019 until February 2020.

Subjects plus eligibility criteria

All subjects were diagnosed with ITH by means of anterior rhinoscopy and nasendoscopy after excluding different causes for nasal obstruction (e.g. polyposis nasi and significant septal deviations). Based on failed conservative treatment of ITH with maximum intranasal corticosteroids and antihistamines, a decision about office based coblation (OBC) was made. Subjects received information about this study and were asked to partici-

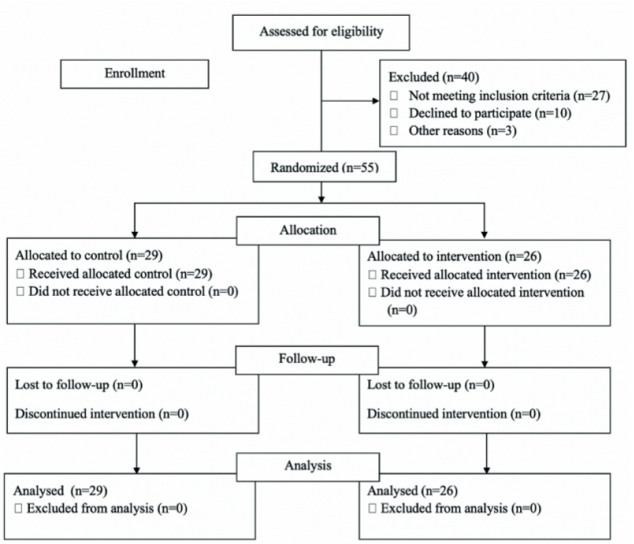

Figure 1. Consort diagram.

pate if inclusion- and exclusion criteria were met (Table 1).

Before OBC subjects were seen by the investigator where informed consent and baseline data was obtained (timeline: T0). Relevant demographic and clinical information were obtained at this stage. Atopic status was noted, and subjects were allowed to use antihistamines if allergic.

Interventions

All OBC's were carried out by the ENT-surgeons of Isala Klinieken (Zwolle, Netherlands) with an ArthroCare® Coblator II (RF80000E) System on display mode 4, meaning an output voltage of 182.5VRMS. Depending on the anatomy of the turbinate, usually 2 punctures were made (caudal and medial), and in some cases 3 punctures. The choice for lateralization was made intra-operatively depending on experience and routine of the surgeon. Postoperatively, for 6 weeks, subjects were instructed to rinse their nose 3 times daily with the aid of the provided rinsing device, and if applicable apply STB, after rinsing their nose.

Outcomes

Scores of the primary outcome measure overall nasal burden and secondary outcome measures nasal crusting, nasal pain and loss of smell were measured by means of a digital visual analogue scale (VAS). Furthermore, retrospective sub-analyses concerning the effectiveness and tolerance of OBC and lateralization were performed on the primary study groups and also on the entire population as a whole. Subjective nasal obstruction was measured with the Dutch version of the nasal obstruction symptom evaluation (NL-NOSE) scale. This is a validated disease-specific questionnaire scoring from 0 to 100, with a higher score corresponding to less nasal patency[13,14]. Every week postoperatively (T1-T6), subjects received an e-mail with a link to an electronic clinical research form (eCRF) containing questions regarding the primary and secondary objectives. This eCRF was embedded in ResearchManager®. Objective measurement of nasal obstruction was measured by a PNIF (Peak Nasal Inspiratory Flow) before OBC and at after 6 weeks. The average of 3 scores within 10% of highest range was noted[15]. If data from the previous week were missing, subjects received an e-mail or phone call with a reminder to fill in their eCRF. Six weeks postoperatively a second PNIF was performed.

Sample size

Sample size was calculated for a minimal clinical important difference of 20 points (VAS 0-100) with an assumed standard deviation (SD) of 23. An unpaired T-test (alfa 5%, power 90%, enrollment ratio 1:1) resulted in 29 patients per group. Considering an attrition rate of 10% resulted in 33 patients per arm. Due to a slow inclusion rate however, we were only able to include 55 patients (reaching a power of 80%), hence the difference in size of treatment arms.

Allocation and randomization

Subjects were randomized at site to the NSI arm or NSI+STB arm using ResearchManager®. The software randomized the subject with a code (A or B) belonging to one of the treatment arms. They received a corresponding coded box containing study medication. The research team did not know which coded box contained which medication. Every endpoint was measured while the research team was blinded. Unblinding took place after receiving all data from the last subject.

Data analysis

Categorical variables were presented as frequency and percentages (%). Depending on distribution, continuous variables were presented as mean (SD) or median (interquartile range; IQR). Concerning both the interventions NSI+STB and NSI as well as the total OBC sample, estimated means with 95% confidence intervals (CI) of repeated measurements were obtained by linear mixed model analyses and plotted longitudinally. VAS-variables overall burden, crust, pain, loss of smell, and NL-NOSE scale score (all T1 to T6), were analyzed by means of linear mixed model analysis. Dependent variables were the postoperative endpoints. Fixed factors were treatment and time. Baseline values (T0) and lateralization were handled as covariate. Additionally, concerning the total OBC sample, postoperative time points were tested against baseline values, using Bonferroni-corrected p-values. Covariance structures were based on Akaike's Information Criterium. Paired comparisons concerning PNIF and overall nasal burden were performed with paired t-test or Wilcoxon signed rank test. Unpaired comparisons PNIF, overall nasal burden, crust, pain, loss of smell and NOSE-scale were performed with the independent t-test or Mann-Whitney U test. Correlati-

Table 2. Subject demographics and characteristics.

	N = 55	N = 29	N = 26
Demographics			
Gender (male)	40 (72.7%)	20 (69.0%)	20 (76.9%)
Age (years)	39.6 (±14.2)	38.1 (±13.8)	41.3 (±14.7)
Burden			
Burden period (weeks)	208 (104 – 520)	208 (104 – 520)	234 (104 – 502)
Medical history			
Previous septal correction	4 (7.3%)	3 (10.3%)	1 (3.8%)
Previous FESS	2 (3.6%)	2 (6.9%)	0 (0%)
Co-morbidity			
Allergy	5 (9.1%)	2 (6.9%)	3 (11.5%)
OSAS	15 (27.3%)	8 (27.6%)	7 (26.9%)
Septal deviation	11 (20.0%)	6 (20.4%)	5 (19.2%)
Snoring	4 (7.3%)	1 (3.4%)	3 (11.5%)
Smoking			
Smoker	11 (20.0%)	6 (20.7%)	5 (19.2%)
Stopped smoker	14 (25.5%)	7 (24.1%)	7 (26.9%)
Never smoked	30 (54.5%)	16 (55.2%)	14 (53.8%)

Data are in means (±SD), median (IQR) or frequency (%); FESS, functional endoscopic sinus surgery; OSAS, obstructive sleep apnea syndrome.

Table 3. Pre- and post-OBC nasal obstruction scores.

	Pre-OBC (T0)	Post-OBC (T6)	p-value
Overall nasal burden	6.8 (5.0 – 8.0)	1.1 (4.0 – 2.1)	<0.000
NOSE scale	70 (55 – 75)	20 (10 – 35)	<0.000
PNIF-scores	131.5 (109.5 - 165.8)	152.0 (127.3 - 182.6)	0.068

Data are in median (IQR); p-value calculated with Wilcoxon signed-rank test

ons were calculated with Pearson's r. Alpha 5%, two-tailed, was used as significance level. All statistical analyses were performed using SPSS Statistics version 26.0 (IBM Corp. 2019).

Results

Descriptives

Sixty-five patients were included in this study, of which 1 patient was excluded after signing informed consent (Figure 1). Both groups were comparable regarding sex, age and nasal burden and nasal obstruction before OBC (Table 2).

NSI+STB versus NSI

The effect of STB as additional treatment on overall burden score was not statistically significant (p=0.687; Figure 2a). Neither was there a significant difference found for the effect of STB on nasal pain (p=0.441; Figure 2b), loss of smell (p=0.561; Figure 2c), nasal crusting (p=0.667; Figure 2d) and the NL-NOSE scale (p=0.529; Figure 2e). There was a tendency to less nasal crusting in the NSI+STB group, nevertheless this difference reached no statistical significance (p=0.912; Figure 2d).

Office based coblation

The NSI and the NSI+STB groups together (total), showed a significant decrease in overall nasal burden 6 weeks postoperatively (p<0.001; Figure 2a). Loss of smell also significantly improved after OBC (p<0.001; Figure 2c). Nasal obstruction as measured bij means of the NL-NOSE scale also decreased significantly from 70 to 20, i.e. from a fairly bad problem to a very mild problem (p<0.001; Figure 2e). PNIF did not increase significantly between pre- and post-OBC (p=0.068; Table 3). Furthermore, there was a weak correlation between the PNIF score and NL-NOSE scale pre-OBC (ρ=-0.315; p<.020). This correlation was not reproduceable at 6 weeks follow-up (ρ=-.072; p<0.635; Table 3).

Lateralization

Forty-one subjects (74.5%) received an additional lateralization and showed a trend to better NL-NOSE scale scores during the first 5 weeks of follow-up. After 6 weeks no significance difference towards better subjectively nasal patency was found (p=0.073; Figure 2f). Lateralization as fixed factor in the linear mixed model analysis did not influence overall burden, nasal pain, -crusting, loss of smell and the NL-NOSE scale.

Adverse events

A total of 6 adverse events (AE) were reported. In the NSI group one subject (3.4%) reported inflamed mucosa and received tre-

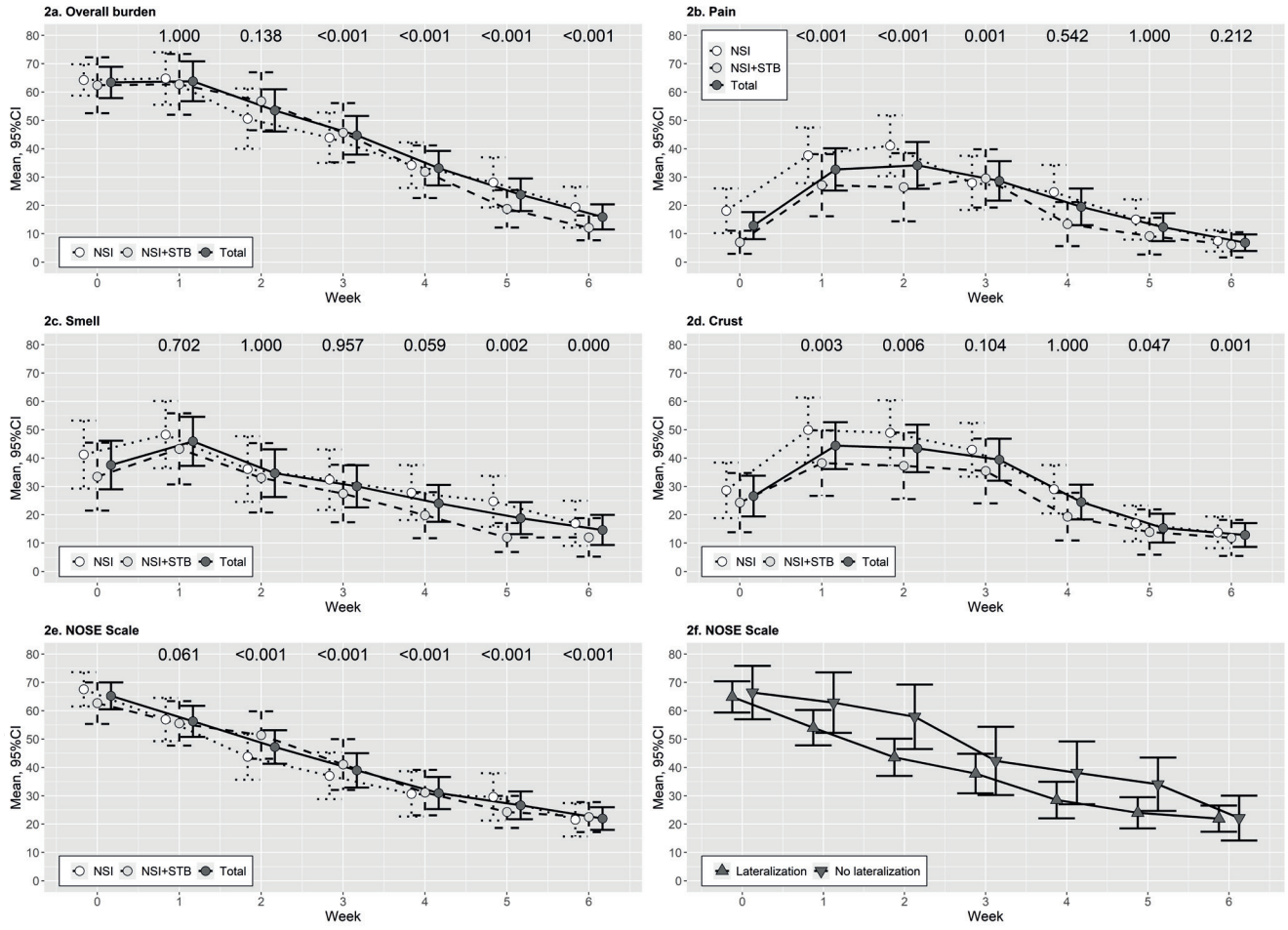

Figure 2. Figures 2a-e show VAS-scores during follow-up (0-6 weeks) for both treatment groups and total population. Figure 2f shows VAS-scores during follow-up (0-6 weeks) for lateralized versus non-lateralized subjects. Figures show means (95%CI); baseline values are displayed (week 0).

atment with antibiotics. Within the NSI+STB group two subjects were diagnosed with inflamed mucosa and two with a rise in purulent nasal secretions of which three subjects (11.5%) received antibiotics. One subject reported a headache, an adverse event not reported before. None of the adverse events could be directly related to the received study medication.

Discussion

The aims of this trial were to determine the short-term effects of office based coblation and the effects of honey-based ointment (STB) on nasal wound healing in addition to nasal saline irrigations after office based coblation of the inferior turbinates. To our knowledge, this study was the first to investigate the effects of an ointment based on honey for wound healing after office based coblation.

No clinically relevant differences could be objectified between treatment groups after 6 weeks for overall nasal burden, nasal pain, the formation of nasal crusts, loss of smell and the NL-NOSE scale. We did however find a significant interaction-effect towards less nasal pain in the STB+NSI group during the first 2 weeks (p=0.040; Figure 2b). Even though this result is minimal, it is concurrent with the studies of Chang et al., Ozlugedik et al. and Thamboo et al.[9,10,16], who reported about less pain in subjects treated with honey. In addition, Figure 2d shows that there was less crusting in the STB+NSI group during the first 3 weeks (T1-T3), when crusting may be expected to be the highest. This difference however was not statistically significant. This trend is in line with one of the purposes of STB and our hypothesis. No difference between treatment groups was seen for loss of smell (Figure 2c), which in retrospect could be expected.

Possible reasons that overall nasal burden did not differ significantly might be that the outcome measure was defined too vague, however it was chosen to be this non-specified so that every subject would be able to relate to it. Furthermore, the more clearly defined secondary outcome measures however also did not differ significantly, which might imply that overall nasal burden is too multifactorial. For this reason, treatment with additional STB might not be associated strong enough with the outcome measures, however no other related covariates were discovered. A longer follow-up would probably not

have been contributional, since the biggest difference between groups was expected to be in the first weeks because of the physiological process of wound healing. Nasal crusting and loss or gain of smell as outcomes for studies regarding honey have not been investigated before[12], opposed to NSI which has previous shown to be effective against nasal crusting[17–19].

For both groups combined, OBC shows to be effective treatment in decreasing nasal burden between T0 and T6, as well as objective (PNIF) and subjective nasal patency (NL-NOSE scale) as shown by respectively Figure 2a, Figure 2e and Table 3. These results confirm the previous investigated positive effects of OBC[3,20,21]. Also, due to its minimal invasive character we provide evidence for OBC to be possible under local anesthesia.

This study was not able to improve subjective nasal patency (NL-NOSE scale) at 6 weeks, bearing in mind that this this study was not powered for lateralization. Moss et al. (2015) did show significant improvements after 1 to 6 months post-operative and non-significant trends towards less nasal symptoms after 2-6 years post lateralization[4], so longer follow-up for our study would have been interesting. None of the subjects reported that the lateralization was painful, although some reported that the sound of breaking the turbinate was disturbing.

Between T0 en T6 objective nasal patency, measured with PNIF did not differ significantly. There was a weak correlation between PNIF and NL-NOSE-scale at T0, which could not be reproduced at T6. These results are somewhat in line with the results of Rujanavej et al., who reported a low correlation between the nasal blockage sensation and PNIF[22]. We would however recommend to use rhinomanometry as well as PNIF since these two tests test different aspects of nasal airflow and combined give a more accurate measurement of nasal patency[23].

One of the limitations of this trial was that it was carried out as a single-blinded trial meaning that patients knew whether they used STB ointment. In the future a double-blinded placebo-controlled trial would be recommended. Multiple nasal endoscopies during follow-up could give better insight in the healing process however, due to the short follow-up, was this not feasible. Also, a power of 80% was reached but it had to be downsized from 90% due to a shortage of time. This resulted in a skewness of randomization with the NSI group and the NSI+STB group containing 29 and 26 subjects, respectively.

Taking notice of these limitations, this study does form a base for future studies and confirms the effectiveness of OBC. Although there was no clear clinical effect of STB on nasal wound healing after OBC, with no evidence for side effects, STB is safe to use and could be applied as an addition to NSI during the first weeks after a nasal procedure to reduce pain. Furthermore, this study supports the existing evidence that lateralization of the nasal turbinates is a safe and useful addition to coblation treatment, although further research is advised.

Conclusion

Treatment with ointment based on honey (STB™ wounddressing) as addition to NSI does not significantly improve overall nasal burden and the NL-NOSE scale after OBC. STB did show a clear trend towards less nasal crusting during the first weeks post-OBC. Also, there was a significant interaction-effect of treatment with STB on pain. Furthermore, this study strengthens the evidence that OBC is a well-tolerated and effective treatment in patients with inferior turbinate hypertrophy. Lateralization might be an effective addition to OBC for increasing nasal patency short after OBC, that can be performed under local anesthetics with no side effects.

Clinical trial

Trial was registered at Netherlands Trial Register. NTR ID: NL8061; Date registered: 2019-10-02; NL70712.075.19.

Authorship contribution

TWA: designed the study, collected data, performed statistical analyses, and wrote the manuscript; MAE: performed statistical analysis, and reviewed/edited the manuscript; ABR: designed the study and reviewed/edited the manuscript.

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Ethics approval and consent to participate

Ethical approval for this study was provided by the Medical Ethical Research Committee Isala (number: NL70712.075.19). Informed consent was obtained for every subject that participated in this study.

Consent for publication

Not applicable.

Availability of data and materials

On request, all data and study protocol can be made available.

Conflict of interest

There is no conflict of interest to be reported for this study.

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