

Does osteopathic treatments improve the symptoms of headache and/or head-pressure in patients with Chronic Rhinosinusitis (CRS)?

A randomized controlled trial

Roos S¹, Steinbauer U¹, Amann P¹, Schwerla F², Resch KL³

¹COE - European College of Osteopathy, Germany

²German Academy of Osteopathy (AFO), Research Commission

³German Institute for Health Research (DIG)

Background

- CRS is one of the most widespread chronic diseases.
- Inflammations of the mucosa of the nose as well as of the paranasal sinus are among the 3 most frequent human diseases.

Present therapy of CRS

- **Drug therapy:**
Antibiotics, Corticosteroids, Antihistamines, etc.
- **Surgical therapy:**
Functional endoscopic surgery of paranasal sinus (FESS)
- **Alternative therapies:**
Herbal compounds
Acupuncture treatment
Nasal saline irrigation

Objective

Primary question

Do osteopathic treatments improve the intensity and frequency of headache and/or the head-pressure in patients with Chronic Rhinosinusitis (CRS)?

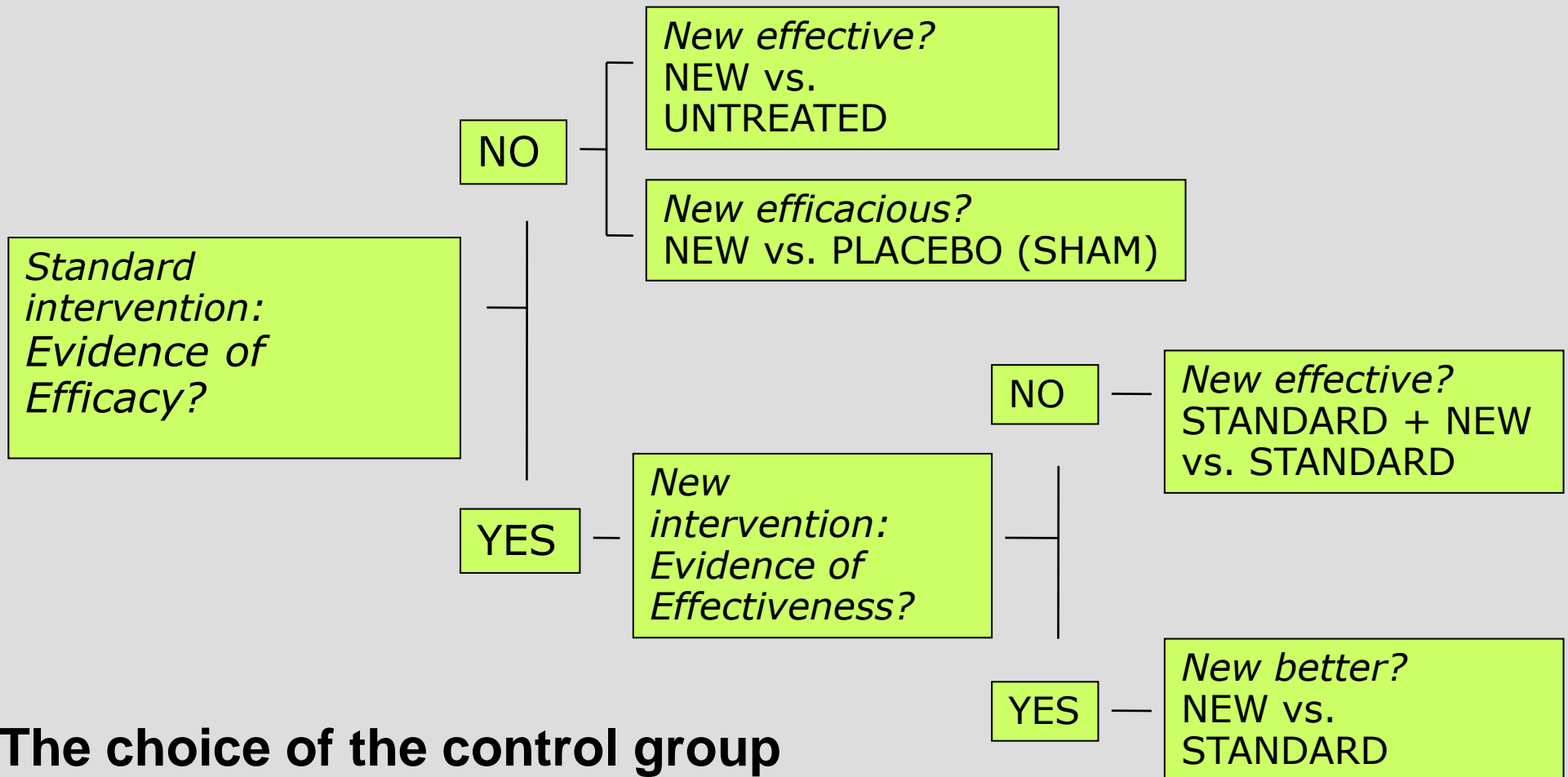
Secondary question

Do osteopathic treatments improve the symptomatic of CRS as a whole?

Study design I

- The appropriate choice of the study design always depends on the objective being investigated
- When proving an effect of an intervention today, the **randomized controlled trial** (RCT) is the gold standard
- For the chosen objective the **effectiveness** of an osteopathic treatment should be assessed: a **pragmatic trial** (versus the **efficacy** and an **explanatory trial**)
- For an appropriate sham-treatment the **mode of action** of the index treatment has to be known

Study design II



The choice of the control group

Prof. Dr. K.L. Resch, personal communication, 2007

Study design III

- **Randomized controlled trial** with follow up four months after end of treatments
- **Two groups:**
 - Intervention group:** 5 osteopathic treatments at two week intervals
 - Control group:** “untreated” control group for 10 weeks („waiting-list-design“). Consecutively 5 osteopathic treatments

Eligibility criteria

Inclusion criteria:

- minimum age of 18 years
- diagnosed CRS by a physician
- headache/ head pressure for > 1 year
- headache or head-pressure above the level of 3 on the numeric-rating scale (NRS) from 0-10

Exclusion criteria:

- due to the profession (e.g. varnisher, chemistry)
- seasonal (hay fever, allergy to pollen)
- systemic disease (e.g. asthma)
- migraine

Outcome measures

Primary outcome measure

The intensity and frequency of headache and/or head pressure subjectively felt by the patient.

Measuring instrument: Numeric rating scale (NRS) 0-10

Secondary outcome measure

Total pathology of CRS

Measuring instrument: Sinonasal assessment questionnaire (SNAQ-11)

Osteopathic findings and intervention

- **Osteopathic findings**

cranial standardized record of findings
visceral standardized record of findings
parietal „black-box-examination“

- **Evaluation system of the dysfunctions**

0 = not affected/ full mobility

1 = slightly affected / limited mobility

2 = strongly

affected / blocked

- **Intervention** Osteopathic treatment, specific to the individual findings of the patient

Time table

OSTEOPATHIE GROUP	Time points	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	
	Scan of the NRS and/or SNAQ	○	○	○	○	○			○				○
Treatment	X	X	X	X	X								
CONTROL GROUP	Treatment	-----					X	X	X	X	X		
	Time of waiting												
	Scan of the NRS and /or SNAQ	○	○	○	○	○	○	○	○	○	○	○	○
Period in Weeks	0	2	4	6	8	10	12	14	16	18	20	>32	

○ 1. Follow-Up

○ 2. Follow-Up

Flow chart

101 patients assessed for eligibility

40 patients excluded

61 patients randomized

31 patient allocated to osteopathic treatment group

31 analyzed data

1. Follow-Up (n=31)

30 patients allocated to waiting list group

29 analyzed data
(1 drop out)

26 patients treated in the waiting list group
(3 drop outs)

1. Follow-Up (n=26)

2. Follow-Up (n=57)
51 complete data

Base-line characteristics

		Intervention group (n=31)	Control group (n=29)	p-value
		Mean \pm SD	Mean \pm SD	
age		44.8 \pm 12.8	42.1 \pm 12.5	0.420
gender	men	12	3	
	women	19	26	
Duration (years)		14.1 \pm 12.2	11.0 \pm 7.9	0.253
actual headache (NRS)		3.1 \pm 2.6	3.2 \pm 2.6	0.928
actual head-pressure (NRS)		3.7 \pm 2.5	4.2 \pm 2.3	0.817
SNAQ-11		71.1 \pm 22.4	65.2 \pm 24.9	0.551

Results

Inter-group differences (NRS-Scores)

	Longitudinal changes T1 to T5		Between- group difference, and 95 % CI	p - value
	Control group (n=29)	Osteopathic group (n=31)		
actual headache intensity	-0.2	1.5	1.7 (-0.1 to -3.2)	0.039
actual head- pressure	-0.2	1.6	1.8 (-0.3 to -3.3)	0.002
Frequency of headache	-0.4	2.6	3.0 (-1.2 to -4.8)	0.001
Frequency of head-pressure	-0.1	3.0	3.1 (-1.3 to -4.8)	0.001

Results

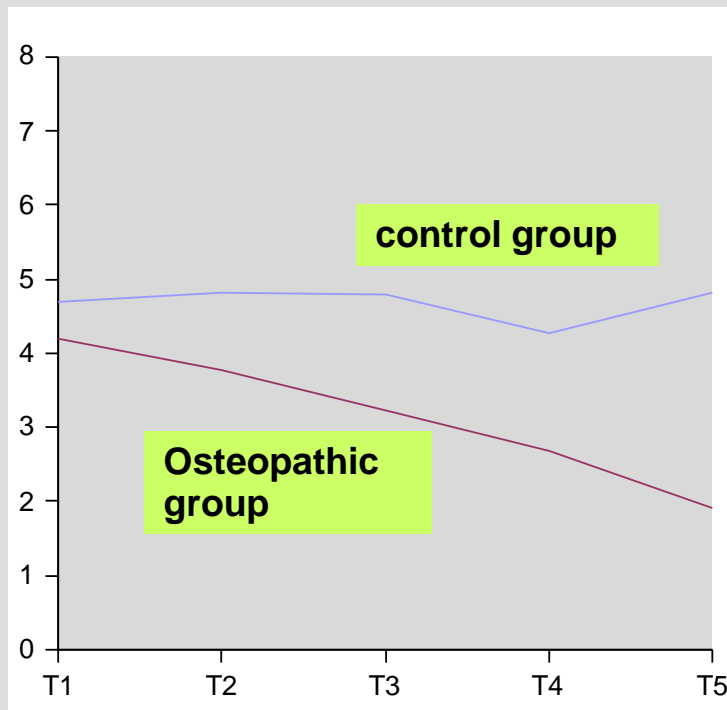
Within-group longitudinal changes (NRS-Scores)

	Begin of treatment (T1)	End of treatment (T5)	Intra-group difference, and 95% CI	p - value
Actual headache				
Osteopathic group	3.2	1.7	1.5 (0.4 to 2.6)	0.011
Control group	3.2	3.4	-0.2 (1.0 to -1.3)	0.760
Actual head pressure				
Osteopathic group	3.7	2.1	1.6 (0.6 to 2.6)	0.002
Control group	4.2	4.4	-0.2 (1.0 to -0.4)	0.682
Frequency headache				
Osteopathic group	5.6	3.0	2.6 (1.5 to 3.7)	<0.001
Control group	4.3	4.7	-0.4 (-1.9 to 1.1)	0.601
Frequency pressure				
Osteopathic group	6.2	3.2	3.0 (1.7 to 4.2)	<0.001
Control group	6.4	6.5	-0.1 (-1.3 to 1.2)	0.956

Results

Analysis of the relevant disorders Time dependent comparison within the groups

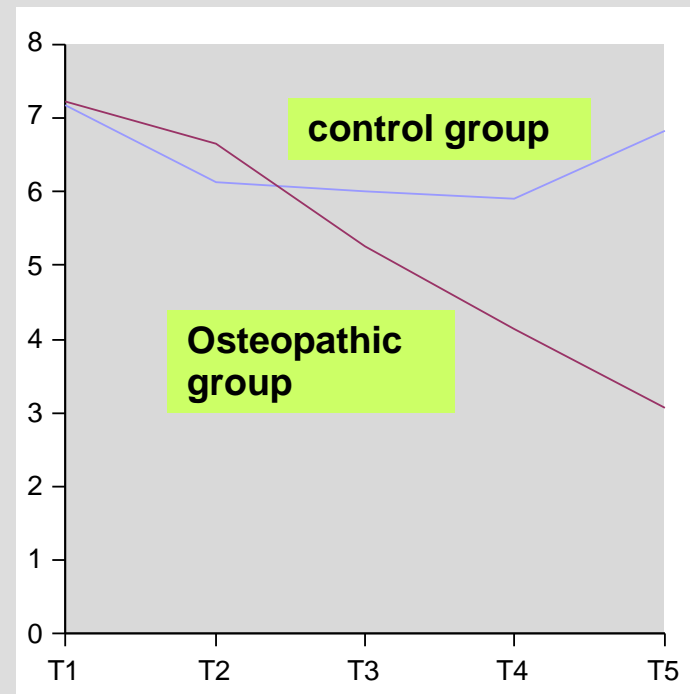
Intensity



Osteopathic group:
improvement 55%

Control group:
Worsening 2%

Frequency



Osteopathic group:
improvement 57%

Control group:
Improvement 6%

Results

Secondary parameters

SNAQ-11: Total symptomatic of CRS, within group longitudinal changes

	Begin of treatment (T1)	End of treatment (T5)	Intra-group difference, and 95% CI	p - value
Osteopathic group	71.2	34.9	36.3 (27.1 to 45.5)	<0.001
Control group	65.2	52.1	13.1 (-1.5 to 27.7)	0.076

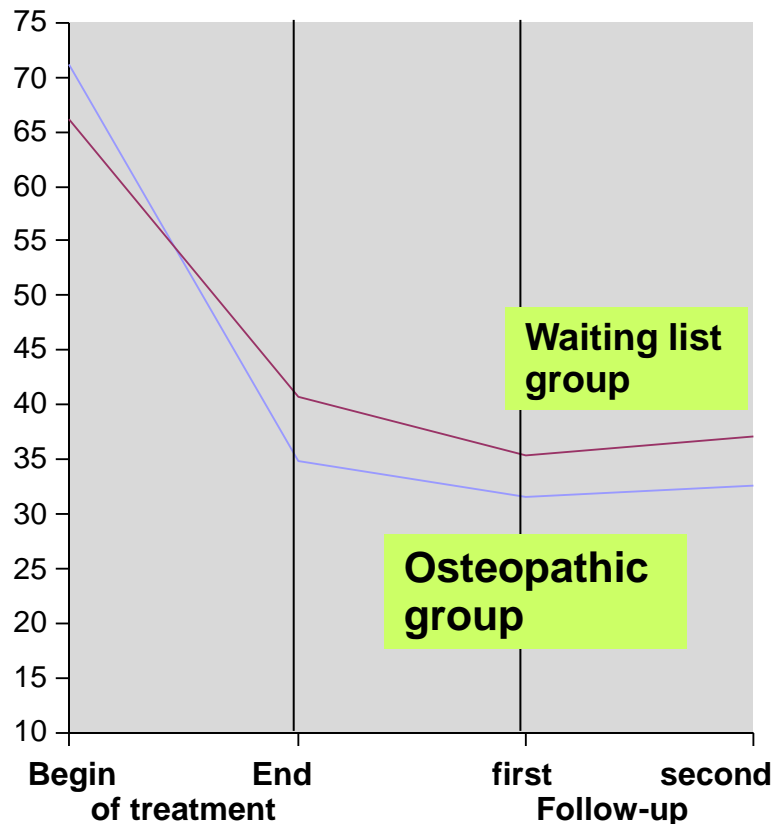
Improvement in the osteopathic group: 51%

Osteopathic dysfunctions:

- Structures of the paranasal sinuses most frequently involved (e.g. Maxilla, Os ethmoidale, Os frontale, Os sphenoidale and Os occipitale)
- Visceral and parietal findings much less

Results

Analysis of reproducibility and sustainability of the trial



SNAQ-11: Total symptomatic of CRS

	Begin	End	First Follow-up	Second Follow-up
Osteopathic group (n=27)	71.2	34.9	31.5	32.6
Treatment of the „waiting“ group	66.1	40.7	35.4	37.1

First Follow-up: 4 weeks after the last treatment of each patient
Second Follow-up: about 2.5 years from the begin of the study

Conclusion

- Five osteopathic treatments within an eight-week period seem to have caused a clinically relevant relieve of the overall symptomatology and of pain in CRS.
- The positive evidence for the effectiveness of osteopathic treatments for patients with CRS found by this study is promising.

Acknowledgement

- We thank the organizing committee for inviting us to this Conference.
- We thank the German Association of Osteopaths (VOD) for financial support.

Thank you for your attention



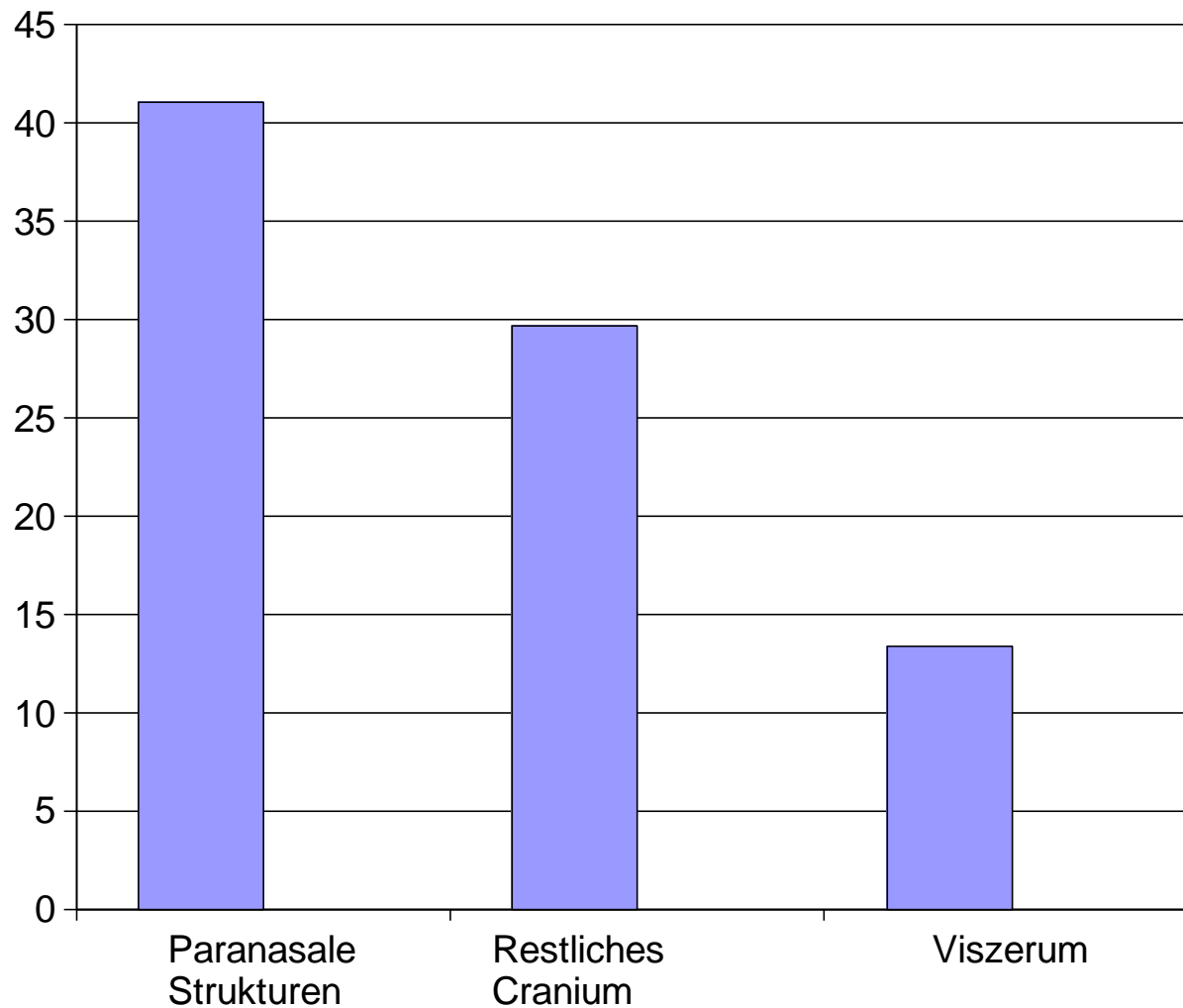
Email: f.schwerla@german-afo.de

References:

- Benninger MS, Ferguson BJ, Hadley JA, Hamilos DL, Jacobs M, Kennedy DW, Lanza DC, Marple BF, Osguthorpe JD, Stankiewicz JA, Anon J, Denny J, Emanuel I, Levine H. Adult chronic rhino-sinusitis: definitions, diagnosis, epidemiology, and pathophysiology. *Otolaryngol Head Neck Surg.* 2003 Sep;129(3 Suppl):S1-32.
- Cherry WB, Li JT. Chronic rhinosinusitis in adults. *Am J Med.* 2008 Mar;121(3):185-9.
- Harvey R, Hannan SA, Badia L, Scadding G. Nasal saline irrigations for the symptoms of chronic rhino-sinusitis. *Cochrane Database of Systematic Reviews* 2007, Issue 3
- Kalish LH, Arendts G, Sacks R, Craig JC. Topical steroids in chronic rhino-sinusitis without polyps: a systematic review and meta-analysis. *Otolaryngol Head Neck Surg.* 2009 Dec;141(6): 674-83.
- Khalil H, Nunez DA. Functional endoscopic sinus surgery for chronic rhino-sinusitis. *Cochrane Database of Systematic Reviews* 2006, Issue 3, updated 2008
- Lund VJ. Maximal medical therapy for chronic rhino-sinusitis. *Otolaryngol Clin North Am.* 2005 Dec; 38 (6):1301-10,

Ergebnisse

Quantitative Analyse der osteopathischen Dysfunktionen Mittelwerte



Summe der Bewertungen (0/1/2) der gefundenen Dysfunktionen (n=57, Mittelwerte, Skala= 0 bis 114)