Observed Changes in Quality of Life Measures and Cerebrospinal Fluid Flow Parameters in Migraine Subjects Receiving Chiropractic Care

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Introduction

This observational case series followed eleven migraine subjects investigating consistency and sustainability of previously observed changes in cerebrospinal and venous outflow parameters.

Using Phase Contrast MRI (PC-MRI) imaging, craniospinal flow changes were measured before-after subjects received a National Upper Cervical Chiropractic Association (NUCCA) atlas correction.

Inclusion

Subject's must be or have:

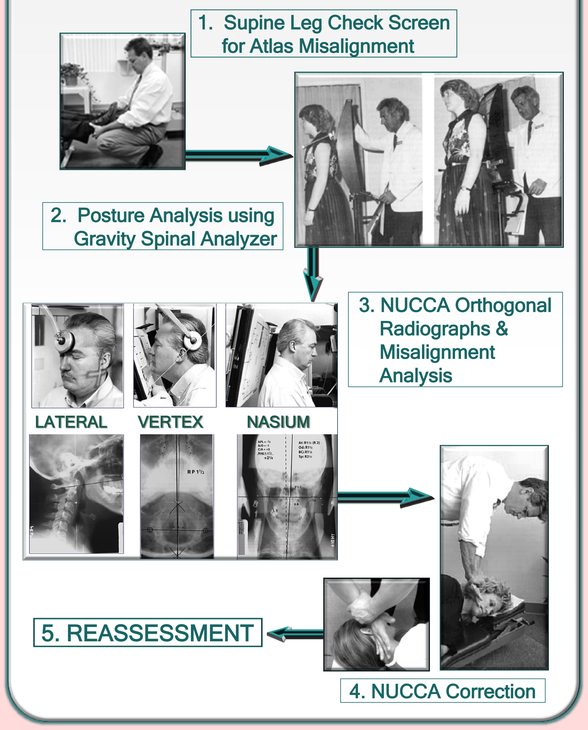
1. Male or female, 21 to 65 years of age.
2. Sign written informed consent.
3. Naïve to Upper Cervical Chiropractic care.
4. Migraine with or without aura according to the International Classification of Headache Disorders (ICHD).
5. Ten to twenty-six headache days per month over the last 4 months.
6. Be suitable candidates for therapeutic intervention as assessed by NUCCA investigator.

Exclusion

Presence of:

1. Any medical or psychiatric condition, that would interfere with study compliance.
2. More than twenty-six headache days a month.
3. Acute medication overuse.
4. Pregnancy or lactation.
5. Severe cervical spine degeneration.
6. Claustrophobia.
7. Current participation in a research study or within the past thirty days.
8. Chiropractic care outside of the study protocol is prohibited.
9. History of significant head or neck trauma (as judged by the investigator) within one year prior to study entry.

NUCCA Correction Procedure By Board Certified Doctor



Study Methods

Subject Conveyance

Subject Inclusion
- ✓ Fit inclusion criteria
- ✓ Sign consent
- ✓ Neurologist screen
- ✓ Baseline MIDAS
- ✓ 30-day HA diary
- ✓ NUCCA Screen

NUCCA Care
- ✓ NUCCA protocol followed for 8 weeks
- ✓ VAS each visit
- ✓ Check HA Diary
- ✓ Check adverse reactions 7 day after intervention

End of Study
- ✓ Neurologist exit interview
- ✓ MIDAS
- ✓ Collect HA Diary

Outcomes Collection

Baseline
- ✓ PC-MRI #1
- ✓ VAS
- ✓ HIT-6
- ✓ MSQL
- ✓ NUCCA Screen

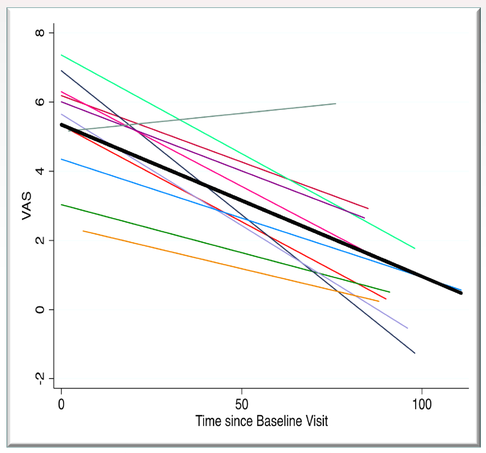
Week 4
- ✓ PC-MRI #2
- ✓ VAS
- ✓ HIT-6
- ✓ MSQL

Week 8
- ✓ PC-MRI #3
- ✓ VAS
- ✓ HIT-6
- ✓ MSQL

Results

- ✓ Eighteen **(18)** subjects screened.
- ✓ Eleven subjects studied; **8** female, **3** males.
- ✓ Average age: **41 years (range 20 - 61).**
- ✓ Ten **(10)** subjects presented migraine without aura.
- ✓ Six **(6)** subjects reported chronic migraine.
- ✓ Migraine duration range: **2 to 35 years.**
  - ✓ Mean: **23 years**.
- ✓ Subjects remained on medications. Use decreased.
- ✓ Total measured Entrance Skin Radiation Exposure of before-after correction radiographs was, **352 millirads** (3.52 millisieverts).
- ✓ Ten subjects self-reported tolerable mild neck pain occurring for more than 24 hours after intervention. Pain had little impact on daily activities.

Results - VAS Scale



Each colored line shows the individual linear fit for each of the 11 subjects; a black line shows overall average linear fit.

Phase Contrast MRI

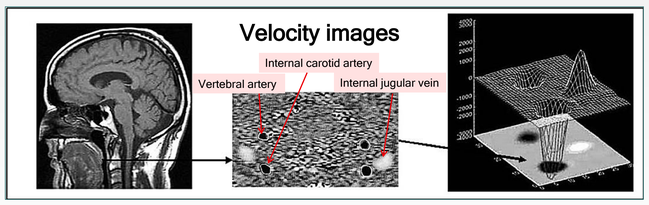


Fig. 1 Fig. 2 Fig. 3

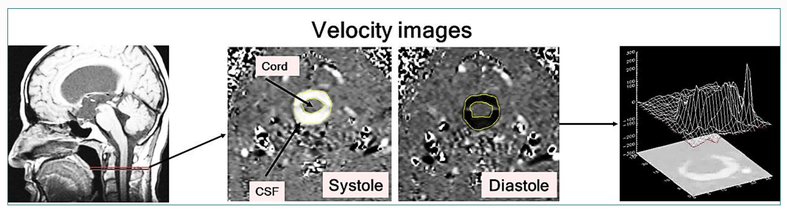
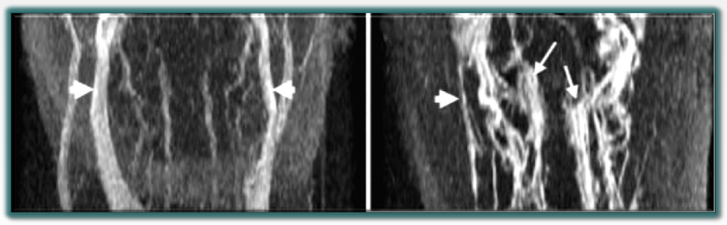


Fig 1: **Shows a 'scout' lateral MRI image. Note the transverse line. The velocity encoded image obtained from this region is Fig 2.**

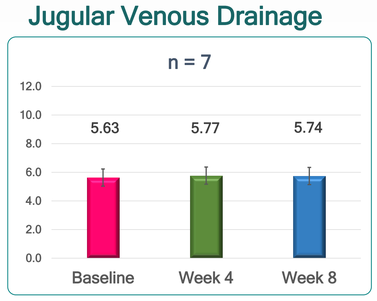
Fig 2: **Shows a cardiac gated Phase Contrast Velocity Encoded Image of the area noted in Fig 1.**

Fig 3: **Demonstrates the proprietary translation of MRI data; Intracranial Compliance Index (ICCI) is determined using this data.**

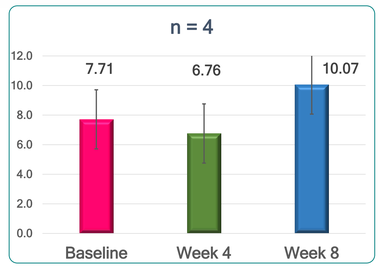
Results - Intracranial Compliance Index



Jugular Venous Drainage



Secondary Venous Drainage



Results - HRQoL Measures

	Baseline Mean (SD)	4 week Mean (SD)	8 week Mean (SD)	Difference Baseline to 4 wks. Mean (95% CI) p-value	Difference Baseline to 8 wks. Mean (95% CI) p-value
Headache Diary					
Headache days per month	14.5 (5.7)	11.4 (5.2)	8.7 (4.3)	3.1 (0.19, 6.0) p = 0.039	5.7 (2.0, 9.4) p = 0.006
Headache Intensity	2.8 (0.96)	2.6 (0.89)	2.1 (1.18)	0.17 (-0.53, 0.86) p = 0.604	0.69 (-0.32, 1.71) p = 0.158
Health Related Quality of Life					
HIT - 6	64.2 (3.8)	55.3 (7.7)	53.8 (6.8)	8.9 (4.9, 13.0) p < 0.001	10.4 (6.9, 13.8) p = 0.001
MSQL - R	38.4 (17.4)	69.1 (22.7)	73.5 (28.0)	30.7 (22.4, 38.9) p < 0.001	35.1 (23.5, 46.6) p < 0.001
MSQL - E	53.3 (23.5)	82.4 (16.9)	81.2 (29.2)	29.1 (15.9, 42.3) p < 0.001	27.9(12.9, 43.1) p = 0.002
MSQL - P	54.1 (18.1)	83.2 (16.9)	86.8 (16.9)	29.1 (16.8,41.4) p < 0.001	32.7 (21.3, 44.5) p < 0.001

	Baseline Mean (SD)	12 week Mean (SD)	Difference Mean (95% CI) Baseline to 12 wks. p-value
MIDAS	46.7 (27.7)	14.6 (23.8)	32.1 (13.2, 51.0) p = 0.004

Conclusions

- ✓ Consistency of magnitude & direction of improvement across HRQoL measures indicates improvement in headache health.
- ✓ One pilot study limitation is the absence of a control group.
- ✓ Many pharmaceutical studies have showed substantial placebo effect.
- ✓ Results indicate a randomized controlled trial is warranted .
- ✓ Sample size estimates can be determined for future study.
- ✓ Literature reports a secondary venous outflow pattern exists for many migraine patients.
- ✓ Significance of increase in compliance of subjects with secondary drainage remains unknown.

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