Health-related quality of life in stage one hypertensive subjects after a chiropractic correction

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ABSTRACT

Introduction

This study measured changes in SF-36 v. 2® scores in subjects with decreased blood pressure resulting from a National Upper Cervical Chiropractic (NUCCA) correction of an Atlas misalignment. Health-related quality of life (HRQL) measures usually show a decrease due to pharmacologic side effects. A primary reason for non-adherence to hypertension pharmacologic treatment regimens is related to medication side effects with subsequent measureable decreases HRQL. It was the intent to determine if such a decrease in HRQL occurred in the Chiropractic intervention. The SF-36 affords valid baseline hypertension specific data allowing HRQL evaluation of blood pressure reduction methodology.

Methods

SF-36 v. 2® data collected from subjects diagnosed with stage one hypertension were studied in response to correction of Atlas (C 1 vertebrae) misalignment. Article limitations prevented inclusion of these results in the primary publication reporting blood pressure changes. Randomized subjects receiving actual (n=25) or 'placebo' (n=24) Atlas corrections, provided weekly data over eight visits. Using pen and paper format, subject written responses were recorded using double entry verification into a field protected Access database. Analysis by SF Health Outcomes™ Scoring Software featured missing data estimation and data quality evaluation capability presented noteworthy results.

Results

t-test analysis in SAS revealed a modest increase of HRQL in the treated group. Pre-8 week Post SF-36 PHC for the treated group demonstrate increase from 46.00 to 49.60 ($p \leq 0.006$). The placebo pre-post SF-36 PHC change showed slight increase, 49.61 to 50.62 ($p \leq 0.32$). SF-36 MHC increased for treated showed increase, 47.77 to 52.22 ($p \leq 0.01$) and placebo, 48.44 to 52.55 ($p \leq 0.14$).

Conclusion

An improvement in scores of subjects responding to the NUCCA correction responder compared to non responders was observed. Lack of expected statistical results decrease the significance of observed changes. Larger population sample sizes may eliminate this limitation. Further study may reveal that the NUCCA correction may decrease blood pressure and increase HRQL, a valued endpoint in addressing hypertension.

Baseline Descriptive Characteristics

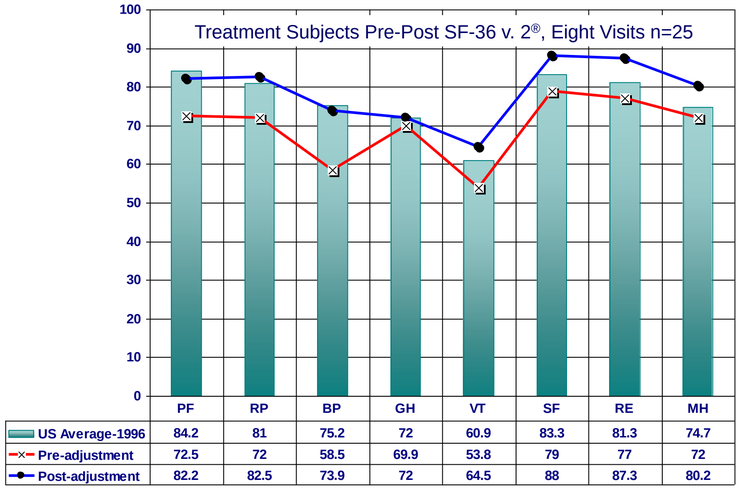
Variable	All	Control	Treatment
	Mean ± SD	Mean ± SD	Mean ± SD
N	50	25	25
Age (years)	52.7±9.6	51.8 ± 10.9	53.6±8.3
Demographic/Ethnicity	%	%	%
Men	70	80	60
Race			
Caucasian	96	100	92
African American	0	0	0
Multi-Racial	2	0	4
Hispanic	2	0	4

METHODS

- Study Design-Randomized, double-blind, with a placebo control. Subjects and BP assessor (RN) were blinded.
- The trial was conducted in accordance with the Good Clinical Practice/ International Conference on Harmonization guidelines, with mandatory signed informed consent by the Institutional Review Board.

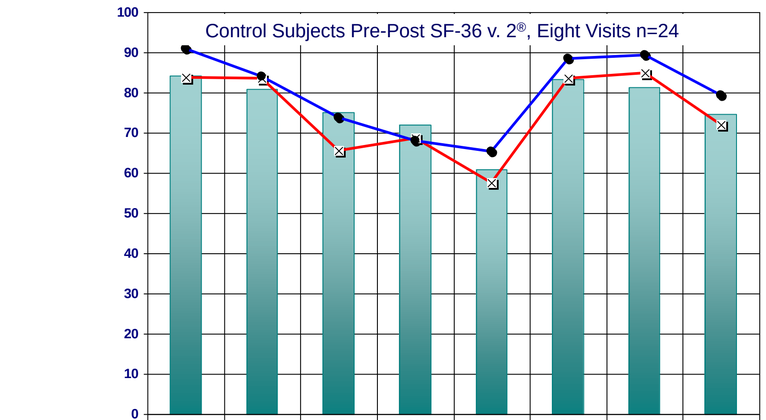
Exclusion criteria:

- No physical evidence of Atlas misalignment on preliminary screening
- Stage-2 or higher hypertension
- Prescribed regimens of more than two (2) antihypertensive medications
- Incapacity/ unwillingness to suspend antihypertensive regimens for screening/study duration
- Second- or third-degree heart block without pacemaker
- Concomitant refractory angina pectoris
- Recent (<12 months) stroke, MI, or cardiovascular surgery
- BMI >39
- Active drug/alcohol addiction (or abstinent <1 year)
- Psychiatric diagnosis
- History of cervical fractures or cervical surgeries
- History of prior Atlas alignment by National Upper-Cervical Chiropractic Association (NUCCA) protocols
- Unwillingness to forego other chiropractic/osteopathic services for study duration;



	PF	RP	BP	GH	VT	SF	RE	MH
US Average-1996	84.2	81	75.2	72	60.9	83.3	81.3	74.7
Pre-adjustment	72.5	72	58.5	69.9	53.8	79	77	72
Post-adjustment	82.2	82.5	73.9	72	64.5	88	87.3	80.2

The SF-36 v. 2® is a multi-purpose, short-form health survey with 36 questions. It yields an 8-scale profile of functional health and well-being scores including physical (PCS) and mental health (MCS) summary measures. Quality of life is often reduced in hypertension patients. (**PF** – physical functioning, **RP** – Role Physical, **BP** – Bodily Pain, **GH** – General Health, **VT** – Vitality, **SF** – Social functioning, **RE** – Role Emotional, **MH** – Mental Health).



	PF	RP	BP	GH	VT	SF	RE	MH
US Average-1996	84.2	81	75.2	72	60.9	83.3	81.3	74.7
Pre-placebo	83.7	83.5	65.5	68.6	57.6	83.5	85	72
Post-Placebo	91	84	73.8	68.1	65.3	88.5	89.3	79.4

Quality of life measures-SF-36 v. 2®

SF-36 v. 2® data were analyzed using SF Health Outcomes™ Scoring Software (QualityMetric, Inc., Lincoln, R.I.) using the weekly recall period with missing data analysis. SF-36 measures were then analyzed both using t-tests and Mann-Whitney tests with corresponding plots. More of the changes are statistically significant for the treatment group than for the control group. For the sake of consistency, it is probably easier for the reader to follow if we use t-test p-values throughout. The conclusions for t-tests and Mann-Whitney tests are very similar. All change is very modest.

SF-36 Category Scales by Group

SF-36 Category	Visit	Control Mean (SD) or p	Treatment Mean (SD) or p	p (diff)
Physical Functioning	Baseline	50.45 (7.72)	50.12 (8.09)	0.08
	8 Weeks	53.36 (4.58)	49.82 (10.27)	0.13
	p (diff)	0.04	0.008	0.66
Role Physical	Baseline	50.32 (7.12)	45.93 (8.12)	0.048
	8 Weeks	50.36 (7.89)	49.94 (6.39)	0.84
	p (diff)	0.87	0.003	0.09
Bodily Pain	Baseline	46.52 (6.86)	43.61 (10.45)	0.25
	8 Weeks	49.81 (7.45)	50.02 (7.03)	0.92
	p (diff)	0.88	0.009	0.047
General Health	Baseline	48.96 (8.32)	49.58 (9.36)	0.81
	8 Weeks	48.48 (10.17)	50.57 (9.44)	0.46
	p (diff)	0.87	0.17	0.40
Vitality	Baseline	49.7 (8.7)	47.76 (11.40)	0.51
	8 Weeks	53.1 (9.5)	52.91 (11.39)	0.96
	p (diff)	0.09	0.03	0.64
Social Functioning	Baseline	49.3 (8.3)	47.37 (9.53)	0.45
	8 Weeks	51.2 (8.9)	51.24 (7.02)	1.00
	p (diff)	0.32	0.03	0.56
Role Emotional	Baseline	48.9 (8.7)	45.23 (11.32)	0.21
	8 Weeks	50.8 (7.9)	49.93 (8.68)	0.72
	p (diff)	0.31	0.003	0.34
Mental Health	Baseline	47.9 (9.8)	47.92 (12.05)	1.00
	8 Weeks	51.9 (8.9)	52.46 (9.91)	0.83
	p (diff)	0.02	0.008	0.91

Physical (PCS) and Mental Health (MCS) Summary Measures

SF-36 Summary	Visit	Control Mean (SD) or p	Treatment Mean (SD) or p	p (diff)
Physical Summary (PCS)	Baseline	49.61 (6.45)	46.00 (9.61)	0.13
	8 Weeks	50.62 (6.76)	49.60 (8.08)	0.63
	p (diff)	0.32	0.006	0.18
Mental Summary (MCS)	Baseline	48.44 (9.71)	47.77 (12.50)	0.83
	8 Weeks	52.55 (10.05)	52.22 (9.47)	0.81
	p (diff)	0.14	0.01	0.71

VAS Summary

(Value ± Standard Error)

100 mm line

	Treatment Pre	Treatment Post	Control Pre	Control Post
Measured VAS	21.2 ± 0.2 mm	19.0 ± 3.5 mm	21.9 ± 5.1 mm	21.0 ± 2.6 mm

There is very modest improvement for the treatment group as measured by the Visual Analog Scale, but no significant change for the control group.

Adjustment Discernment

'Discernment Inquiry' completed at end of study:

What's your impression about your group assignment?

☐ *My impression is that my procedure was authentic.*

☐ *My impression is that my procedure was "placebo."*

Comments: _____

N	Subject Discernment
12	Adjusted reported, thought 'adjusted'
13	Adjusted reported, thought 'placebo'
6	Placebo reported, thought 'adjusted'
10	Placebo reported, thought 'placebo'
8	Placebo reported, no idea

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