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APS Therapy – A new way of treating chronic backache – a pilot study

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APS Therapy - A new way of treating chronic backache - a pilot study

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Background: Transcutaneous electrical nerve stimulation (TENS) has been extensively used to control acute and chronic pain, but its effects are controversial. The development of Action Potential Simulation (APS) therapy may have introduced a different mode in the treatment of pain with electrical apparatus.

Methods: Patients with chronic backache due to osteoporosis were included in this randomized, "patient blinded", placebo-controlled study to evaluate the clinical efficacy of the APS therapy apparatus. Seventy-six patients took part in the study (43 in the APS group, 33 in the placebo group). Each patient received treatment every second day for 16 minutes with a total of 6 treatments. Visual Analogue Pain Scales (VAPS) evaluations were performed directly before each treatment which reflected the pain situation of the previous 48 hours.

Results: A statistically, highly significant result was obtained in the APS group. The improvement was reflected in the mean pre-treatment baseline VAPS value of 57,79 in the APS group that diminished to a post-treatment value after the sixth treatment of 9,7 ($p = 0,0001$). A specific difference between the two groups could not be demonstrated because the trial population in the groups was too small and the power of the study was to small.

Conclusion: APS treatment may be an effective treatment for chronic backache in the osteoporotic patient.

Key words:
Electrical Therapy; Backache from Osteoporosis.

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Introduction

Scribonius Largus, a Roman in ancient times, used a decapitated torpedo fish pressed against the patient's head or any other painful part to induce numbness and pain relief.[1] A wide variety of medical stimulating devices in the 1800's were advocated for the treatment of many kinds of diseases and also for the relief of pain. Since the 1900's little attempts have been made to separate bona fide uses of electrical stimulation for the treatment of pain from other useless means of therapy. The application of electrical stimulation for any purpose in the medical field virtually disappeared due to this reason.

The "gate-theory" of Wall and Melzack first described in 1965 provided the first potential explanation for the control of pain by the effects of electrical stimulation.[2] Since then a new interest arose in this field. The "gate theory" has always been controversial, as there are certain conditions such as hyperalgesia, which it does not fully explain. It may be that the relief of pain by electrical stimulation of a peripheral nerve, or even of the spinal cord, is due to a frequency-related conduction block which acting on primary afferent branch points where dorsal column fibres and dorsal horn collaterals diverge. It also appears from clinical reports (using spinal cord stimulation) that patients show a significant preference for a minimum pulse repetition rate of 25 pulses per second.[3]

The potential advantage of electrical stimulation as an adjunct to other pain therapies is that these treatment modalities are non-invasive and are relatively safe. Few side-effects or complications have been associated with its use.[4] However, it has been found to be of little or no value in the treatment of acute post-operative pain (e.g. post thoracotomy pain).[5]

Transcutaneous electrical nerve stimulation (TENS) was, since its discovery in the 1970's, the most commonly used electrical stimulation apparatus available. The mechanism of action of TENS is not completely understood. It is thought by some that analgesia may be produced by the modulation of nociceptive input in the dorsal horn of the spinal cord by peripheral electrical stimulation of the large sensory afferent nerves, which would comply with the "gate-theory" (as mentioned above).[1] Alternatively, electrical stimulation of certain receptor sites in the dorsal horn is thought to produce and release endogenous opioids.[6]

The development of APS Therapy in 1992 in South Africa brought another perspective of electrical treatment to the fore.*

It is claimed to have a different pulse wave when compared to TENS. The device uses an electrical current that supposedly mimics the normal physiological action potential of nerve conduction. This may be a unique concept to electro-physics. In comparison with TENS, it needs only a treatment time of 16 minutes maximum per day (suggested by the manu-

facturer), whereas TENS needs continuous treatment sessions, from 1 hour up to 18 hours per day.[7]

The APS Therapy device has been developed primarily for use in chronic pain management situations, although it may reduce swelling due to injury and may also restore mobility to stiff joints and muscles.

Technical Specifications of the APS Therapy Device	
Wave Form:	Simulated Action Potential
Wave Type:	Monophasic Square Pulse with Exponential Decay
Amplitude:	Adjustable, 0 - 24.4 mA peak into 500 ohm load
Pulse Rate:	150 Hz
Pulse Width:	800 µsec - 6.6 msec
Modulation:	Variable pulse width; automatic adjustment depending on distance between electrodes.
Burst:	Continuous
Voltage:	0 - 46 Volts (open circuit.)

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Presented here is a study on the use of APS Therapy on patients suffering from chronic osteoporosis associated with backache. This trial was developed purely to evaluate the clinical efficacy of the apparatus.

Material and Method

Approval for the study was obtained from the Combined Ethics Committee of the University of the Orange Free State and the Provincial Health Authorities. A randomized, "patient-blinded", placebo-controlled study was done on 76 patients suffering from backache with osteoporosis. The electrodes were connected to their backs and they could see the LCD display reading on the APS Therapy device. No current was delivered to the placebo group, although the LCD displayed a reading and the patients could turn the knob on the APS Therapy device to keep the reading between 1,0 mA and 1.7 mA. No indication was given to any patient as to what they could or might feel or experience during the treatment.

Due to the fact that osteoporosis is a disease of the elderly no limitations were put on age. The majority of these patients came from old-age homes which might have had an influence on the results. (see later.)

All patients had X-rays taken of their backs and had full blood counts and chemical analysis done. X-rays confirmed osteoporosis and degenerative changes in the vertebral column, but none of the blood results were out of range (e.g. full blood count, electrolyte profile, kidney and liver functions).

The protocol was designed for six visits. At visit 1, after a thorough physical examination, every patient gave a VAPS value for their backache. This value represented a combined impression of their back pain for the previous three months and was the baseline on which the whole trial was built.

The initial application was 16 minutes between 1.0 mA and 1.7 mA; after which they waited for 3 minutes and received another 16-minute treatment. A VAPS was given directly after the second session and a further evaluation 30 minutes later.

The second and consecutive treatments were applied every second day with a VAPS given before and after each treatment. The "before" reading reflected the pain scale of the previous 48 hours (after the previous APS Therapy). These were the figures that were taken into account for the statistical analysis.

Follow-up phone calls to some of the patients were done three and six months after the initial treatment. Mobility was also taken into account by asking them simple questions like: "Do you feel better than before? Do you feel more

TABLE I Demographic data			
Gender:	Female:	51	67.1%
	Male:	25	32.9%
Distribution:	APS Therapy:	43	56.58%
	Placebo:	33	43,42%

TABLE III	VAPS Baseline values	
Mean Values	Baseline values	Std. Deviations
APS group	57.79	20.54
Placebo	63.33	23.61

	General trend		VAPS	
Mean Values	Before second Visit	Std Dev.	After last Visit	Std. Dev.
APS group	48.67	25.05	9.67	14.46
Placebo	54.35	25.57	28.37	23.79

TABLE II	Statistical Analysis							
MEAN VALUES	Age	Std Dev.	Mass	Std Dev.	Systolic BP	Std Dev.	Diastolic BP	Std Dev.
APS group	62.84	14.19	76.72	18.24	140.67	16.33	82.79	9.55
Placebo group	66.15	14.60	77.67	15.70	142.55	25.52	87.15	14.67

TABLE IV Paired T-test to examine the difference in pre- and post-treatment

APS Group

Variable	Mean	Std. Dev	T	P-value	95% CI
Visit 1	6.52	15.89	1.880	0.0746	(-0.72 : 13.8)
Visit 2	27.05	18.26	6.623	0.0001	(18.5 : 35.6)
Visit 3	26.10	20.43	5.712	0.0001	(16.5 : 35.7)
Visit 4	22.95	26.87	3.822	0.0011	(10.4 : 35.5)
Visit 5	20.10	20.13	4.465	0.0003	(10.7 : 29.5)
Visit 6	9.67	17.77	3.358	0.0001	(5.03 : 21.7)

Placebo group

Variable	Mean	Std. Dev	T	P-value	95% CI
Visit 1	5.75	19.55	1.018	0.3304	(-6.68 : 18.2)
Visit 2	10.81	13.67	2.624	0.0254	(1.64 : 20.0)
Visit 3	17.45	12.20	4.744	0.0008	(9.25: 25.6)
Visit 4	12.18	23.76	1.700	0.1199	(-3.76 : 28.2)
Visit 5	13.90	14.63	3.152	0.0103	(4.08 : 23.7)
Visit 6	28.37	22.86	1.688	0.1223	(-3.72 : 27.0)

mobile or loose?" Two patients were totally pain-free after three months and one after six months.

Statistical methods

Per treatment group changes from baseline to each time point, were calculated. These changes are summarized by means, and the two groups are compared by 95% confidence intervals (CI) for the mean difference in change APS group - placebo. A positive mean difference APS - placebo indicates that the improvement in the APS group was higher than in the placebo group. For each group, 95% confidence intervals were also calculated for the mean change to determine whether there was a significant change in the group.

Results and Discussion

From the results it can be seen that for both groups, APS and placebo, there were statistically significant improvements from baseline to all subsequent time points, except for APS-group, visit 1 (p = 0.0746) and in placebo-group, visits 1, 4 and 6 (p-values of 0.3304, 0.1199 and 0. 1223, respectively).

The 95% confidence intervals indicate that there were clinically significant improvements on many of the time points in APS-group (cases where lower limit of 95% CI is 10 or higher), but also in the placebo-group, but less often.

The 95% CI comparing the changes between the two groups indicates that there is a tendency for APS to improve more than placebo (the confidence interval goes from a slightly negative value to a large positive value) especially following the first visit and after the third visit. Only one negative value was found in the APS-group but three were found in the placebo-group.

Conclusion

1. The "mean" values obviously show that in the APS Therapy Group there is a marked difference between values at Baseline 57.79; Visit 2 (Before) and Visit 6 (After) (e.g. mean of 48.69 down to a mean of 9.7). With the placebo group the difference from baseline 63.33; visit 2 (Before) 57.52 down to Visit 6 (After) 28.37.
2. The paired T-test to examine the difference between "Before" and "After" treatment showed a marked positive result in the APS Therapy group. Except for the value "baseline to before 2nd treatment" with a p-value of 0,4139, all the others were statistically significant - (p-value 0,0001 nine times; one 0,0055 and one 0.0043).
   Of the six visits in the placebo group four out of the six were statistically not significant. The p-value of the others also displayed higher overall values.
3. The reason why so many of the placebo group had good relief on placebo treatment cannot be explained, but probably is due to the fact that the majority of these patients came from old age homes. When admitted to the Pain Control Unit they received more attention than they were used to and this factor may have played a major role in the results obtained from the placebo group.
4. Clinically the effect of treatment was very successful. Out of 43 APS Therapy group patients, 7 ended with a "O" VAPS score and 16 with a score of 5 and less (i.e. 23 out of 43 with a score of 5 or less). All the others decreased their VAPS score by more than 40. All were extremely happy with the treatment and six months later 6 patients still had good relief (the one with no pain at all is included in this group).
5. The trial population was too small to come to a definite conclusion of the "between groups" situation.

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** Because no literature exists on any medical trials done with APS before, references will be taken from the booklet issued by the manufacturer, Tech Pulse® Pty.) Ltd.*