



Laser versus needle acupuncture in management of Nocturnal enuresis in children: A randomized – controlled trial.

Inas E.M Ahmed Kamel*, Nagwa.H.Mohammed, Emad N. Zikri

Complementary Medicine Department, National Research Centre, NRC affiliation: 60014618,
P.O. 12622, Dokki, Egypt



Abstract

Nocturnal enuresis is commonly described as a multifactorial pathophysiological case scenario with a high genetic background as regards immaturity of the central nervous system controlling the detrusor muscle activity.

Objective: This study aims to evaluate the efficacy and effectiveness of laser and needle acupuncture as complementary modalities for treatment of nocturnal enuresis.

Patients and Methods:

The current research study is a prospective randomized controlled trial conducted on 90 patients aged from 7 to 14 years. The patients had been categorized into 3 groups, 30 patients in each group. Group A had been subjected to laser acupuncture therapy in conjunction with Imipramine (**tofranil**) (2.5 mg/kg/day, maximum dose 50 mg/day). Group B had been exposed to needle acupuncture in conjunction with tofranil, while group C had been subjected to **tofranil** medication only.

Results

Statistically significant positive correlations were found between the number of sessions and number of dry nights among laser and needle research groups (p values <0.001 and <0.001). There were significant negative correlations between the number of sessions and changes in number of attacks among laser and needle research groups (p values <0.001 and 0.001 consecutively).

Conclusion Patients treated by laser and needle acupuncture showed statically significant improvement higher than cases taken tofranil alone.

Key words nocturnal enuresis, acupuncture, laser, needle.

1. Introduction

Nocturnal enuresis is clinically defined as involuntary loss of urine during sleep, occurring at least twice a week in children older than 5 years of age for a minimum of 3 months. It is the most frequent urologic complaint in the pediatric age group. (1,7)

According to the Traditional Chinese Medicine theory, urine production and excretion pattern is connected with the lungs, kidneys, spleen, and urinary bladder. Nocturnal enuresis is reflected as a disorder in body fluids pattern of distribution and movement. (2,4). The Chinese Medicine theory defines the pathogenesis of nocturnal enuresis as a shortage of 'qi' (energy flow) in the kidneys, lungs and spleen. (3)

In primary enuresis, the child has never been continent during sleep, whereas in secondary enuresis the one had an onset after a period of nocturnal dryness of at least 6 months. Nocturnal enuretic attacks are clinically reflected frequent if they happen 4 or more times within one week. (4)

Nocturnal enuresis is commonly described as a multifactorial pathophysiological case scenario with a

high genetic background as regards immaturity of the central nervous system organizing the detrusor muscle activity. Constipation, urethral obstruction and ectopic ureter are examples of comorbidities that may be associated with nocturnal enuresis. (5)

The traditional Chinese medicine combines needle and laser acupuncture to manage nocturnal enuresis by stimulating acupoints that act on neuro modulation of the autonomic and central nervous system improving the bladder control and coordination of neuromuscular pathways. (6)

Acupuncture is a non-pharmacologic therapy, using fine needles inserted at specific acupuncture points. In laser acupuncture, we stimulate the acupuncture points by laser beams instead of needles. Laser has several advantages, such as being easy to apply, painless, noninvasive with no side effects. Laser acupuncture is a combination of acupuncture therapy with modern technology in the form of light therapy. When laser is applied at 35–40 mW of power, it produces the same therapeutic effects as the needles. (7)

*Corresponding author e-mail: inasmahfouz83@gmail.com; (Inas E.M Ahmed Kamel).

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Methodology

The current research study is a prospective randomized controlled trial conducted on 90 patients 7 to 14 years old with negative consanguinity. The patients were selected and treated in the outpatient clinic, pediatric hospital, Cairo University from September to December 2022. All of them have been subjected to full history taking and clinical examination to exclude abdominal hernia (e.g umbilical), scar of previous abdominal operation, ambiguous genitalia and muscle wasting. The investigations undergone were urine analysis to exclude urinary tract infections, plain X-ray on the sacral spines to exclude spina bifida or any other bone anomaly and pelvi-abdominal ultrasound to exclude urinary tract anomalies (e.g renal agenesis). Patients having diabetes mellitus, diabetes insipidus or diurnal enuresis were excluded.

The patients had been categorized into 3 groups, each group included 30 patients. Group A had been subjected to laser acupuncture therapy in conjunction with tofranil. Group B had been subjected to needle acupuncture in conjunction with tofranil, (2.5mg/kg/day) while group C had been subjected to tofranil medication only.

The Laser device used was diode (semiconductor laser) with low power (cold laser). The machine used (Acculaser point continued waves with 100 milliwatts) power and 3000 HZ frequency. It has two probes, one shower that was not used in this study, the other one has tunable wavelength ranging from 650 to 860 nm. In this study, we used the wave length of 860 nm and the power of 100 milliwatts for 20 seconds over the following acupoints: DU20 (BaiHui), BL23 (ShenShu), BL28 (PangGuangShu), SiShenCong (3cm from the point BaiHui), RN6 (QiHai), GB20 (FengChi) and Du16 (FengFu) giving a power density of 3 Joules/Cm². The sessions were performed 3 times weekly and the mean number of sessions was 23.1±1.1.

Needle acupuncture: We used fine sterile disposable acupuncture needles (0.25x25mm) to stimulate the same acupuncture points used in laser acupuncture twice weekly. The mean number of sessions was 23.3±1.2. The sites of needle acupuncture on the skin had been sterilized by alcohol swabs before its application. The needles were entered till its ¼ th of their length.

There was an ethical approval taken from the parents before the study according to the Ethical Committee role of the National Research Centre of Egypt.

Sample size justification

A pilot sample size included 15 children was performed. It was found that the Mean±SD of reductions of wet nights were 3.6±1.1, 3.8±0.8 and 2.2±0.8 in laser, needle and control groups

respectively. Assuming the power= 0.80 and $\alpha=0.05$, and by using PASS 11th release (Hintze, 2011) the minimal sample size for a clinical trial to detect a significant statistical difference was 27 in each group. We included 30 cases in each group for possible attrition. (18)

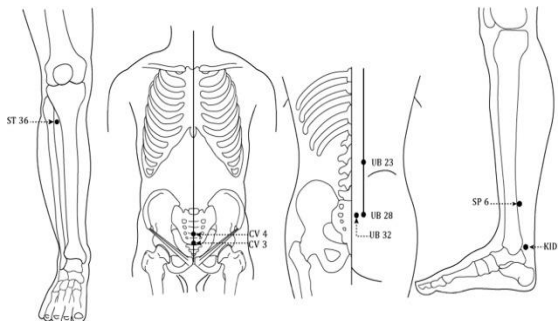


Figure (1) : the acupuncture points anatomically

Statistical methods

The collected data were coded, tabulated, and statistically analyzed using IBM SPSS statistics (Statistical Package for Social Sciences) software version 28.0, (IBM Corp., Chicago, USA, 2021). Quantitative data were tested for normality using Shapiro-Wilk test, described as mean±SD (standard deviation), and then compared using independent t-test (two independent groups) and ANOVA test (three independent groups) as well as paired t-test (paired data). Qualitative data was described as numbers and percentages and compared using Chi square test and Fisher's Exact test according to expected numbers in cells (independent groups) as well as marginal homogeneity test (paired ordinal data). Bonferoni test was used for post HOC comparisons. P-values <0.050 were considered significant, otherwise they were considered non-significant.

Result

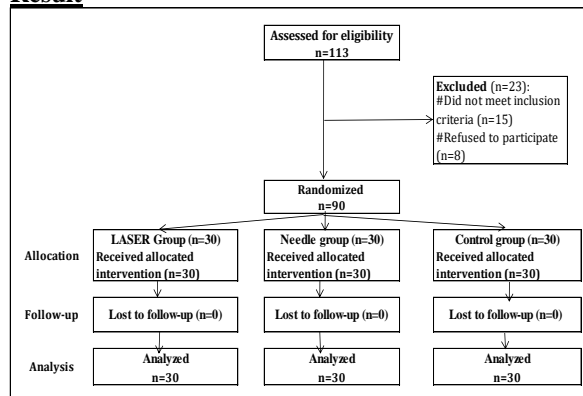


Figure (2): Consort flow chart of the studied cases

Figure 1 reveals and displays that in the clinical research study, we had recruited 113 cases. However, 23 of them were excluded as 15 cases didn't meet the inclusion criteria and 8 had refused participation in the research.

Table (1): Demographic characteristics of the cases

Variables		LASER Group (Total=30)	Needle Group (Total=30)	Control Group (Total=30)	p-value
Age (years)		8.7±1.7	8.8±1.4	8.5±1.7	^0.730
Gender	Male	19 (63.3%)	17 (56.7%)	18 (60.0%)	#0.870
	Female	11 (36.7%)	13 (43.3%)	12 (40.0%)	
Weight percentile		71.9±10.1	72.0±7.9	72.7±11.7	^0.947
Height percentile		73.1±8.7	75.3±9.4	74.8±8.1	^0.579
Sessions number		23.1±1.1	23.3±1.2	NA	∩0.648
Compliance to treatment		25 (83.3%)	25 (83.3%)	24 (80.0%)	#0.927

NA: Not Applicable. #Chi square test. ^ANOVA test. ∩Independent t-test.

Table (2): Number of dry nights per week among the study cases

Time	LASER Group (Total=30)	Needle Group (Total=30)	Control Group (Total=30)	^p-value
Before treatment	1.9±1.1	1.9±1.1	1.8±0.8	0.840
After treatment	5.4±1.0a	5.3±1.3a	4.3±1.4b	0.001*
Change	3.5±1.1a	3.4±0.9a	2.5±1.0b	<0.001*
\$p-value	<0.001*	<0.001*	<0.001*	

Change= After – Before. ∩Paired t-test. ^ANOVA test. Homogenous groups had the same symbol “a,b” based on post hoc Bonferroni test. *Significant.

Table (3): Number of nocturnal enuresis attacks per week between the research study groups.

Time	LASER Group (Total=30)	Needle Group (Total=30)	Control Group (Total=30)	^p-value
Before treatment	5.8±1.2	5.6±1.1	5.8±1.1	0.734
After treatment	2.2±1.1a	2.4±1.2a	3.4±1.6b	<0.001*
Change	-3.6±1.4a	-3.2±1.2a	-2.4±1.4b	0.002*
p-value	<0.001*	<0.001*	<0.001*	

Change= After – Before. ∩Paired t-test. ^ANOVA test. Homogenous groups had the same symbol “a,b” based on post hoc Bonferroni test. *Significant.

Table (1) reveals and displays the demographic data and number of sessions in conjunction to compliance in each group, there was no significant statistical difference between the study groups regarding age, gender, weight, and height as well as sessions number.

Table (2) showed that: there is no significant statistical difference between the study groups concerning number of dry nights before treatment. Number of dry nights after treatment significantly increased in all groups. This increase showed no statistical significant difference between laser and needle acupuncture group. However, the increase of the dry nights in control group (on Tofranil) was less than laser and needle groups .

Table (3) reveals that there was no significant statistical difference between the research study groups concerning number of attacks before treatment protocol used. Number of attacks after treatment was significantly highest among control group with no significant difference between LASER and Needle groups. the decrease in the number of attacks as shown in the table was statistically significant (p value = 0.002) moreover in the difference across groups was

shown in the table were laser and needle groups had label A while control group had label B based on post hoc Bonferroni test ,and hence control significantly had least decrease with no significant difference between laser and needle groups.

Table (4) reveals and displays the correlation of compliance to research groups in which there was statistically significant increased number of dry nights particularly in compliant groups of cases p values =0.001,<.001,0.003 ,among laser, needle and control groups consecutively .In addition the table shows that there was a statistically significant reduction in the number of attacks p values=0.003,0.005,<0.001 among laser ,needle and control research groups consecutively.

Table (5) showed that: There were significant positive correlations between number of sessions and number of dry nights among laser and needle research groups (p values <0.001,<0.001). There were significant negative correlations between number of sessions and changes in number of attacks among laser and needle research groups (p values <0.001, 0.001consecutively.

Table (4): Comparison according to compliance to treatment regarding changes in number of dry nights, number of attacks among the research groups cases

Group	Changes	Compliant	Non-compliant	^p-value
LASER group	Number of dry nights	3.8±1.0	2.0±0.0	0.001*
	Number of attacks	-3.9±1.3	-2.0±0.7	0.003*
Needle group	Number of dry nights	3.6±0.8	2.2±0.4	<0.001*
	Number of attacks	-3.4±1.2	-2.0±0.7	0.005*
Control group	Number of dry nights	2.8±0.8	1.5±0.8	0.003*
	Number of attacks	-2.8±1.2	-0.7±0.5	<0.001*

^Independent t-test. *Significant.

Table (5): Correlations between number of sessions and changes in number of dry nights, number of attacks.

Changes	LASER Group(Total=30)		Needle Group(Total=30)	
	r	p-value	r	p-value
Number of dry nights	0.682	<0.001*	0.696*	<0.001*
Number of attacks	-0.665	<0.001*	-0.566	0.001*

Pearson correlation test. *Significant.

Table (6): Improvement one month after medical treatment and discontinuation of medication between the study cases

Improvement	LASER Group (Total=30)	Needle Group (Total=30)	Control Group (Total=30)	p-value
Continued	22 (73.3%)a	21 (70.0%)a	11 (36.7%)b	#0.006*
Discontinued	8 (26.7%)	9 (30.0%)	19 (63.3%)	

#Chi square test. Homogenous groups had the same symbol "a,b" based on post hoc Bonferroni test. *Significant.

Table (6) showed that: improvement one month after medical treatment and discontinuation was statistically significant among laser and needle research groups being least frequent in control group with no significant difference between LASER and Needle groups

Discussion

Nocturnal enuresis is a clinically distressing disease that affects many children worldwide. Extreme research efforts, all over the globe, have been performed to uncover the most efficient and effective management protocol. In the current study, we had implemented needle and laser acupuncture to stimulate neuronal pathways helping symptoms improvement. (8)

Our research results clearly revealed that needle and laser acupuncture decrease the number of nocturnal enuresis attacks and increase the number of dry nights in a statistical significant way helping the quality of sleep.

In the current research, our results have shown statistically significant reduction of wet nights and number of attacks among the laser group in comparison to patients receiving tofranil. We recommend usage of laser acupuncture in children, since it is pain free, non-invasive intervention

compared to a meta-analysis of two very-low-grade clinical studies done showed statistically significant efficacy of laser acupuncture compared to sham laser acupuncture in decreasing the number of wet nights in children having nocturnal enuresis as shown by (9). Many clinical research trials proved that laser and needle acupuncture exerted their effects through stimulating the release of various chemical substances, such as histamine, bradykinin, and adenosine triphosphate, causing depolarization of acupuncture points. This electrophysiological bioactivity is conducted via afferent fibers to the cerebrum that consecutively activates the hypothalamus and limbic system. This stimulation can regulate the micturition center in the forebrain. (10)

A prior research study, similar to the current study in methodology, had recruited 20 patients, 14 males and 6 females. All cases had been managed with acupuncture for nocturnal enuresis for a duration of 35-40 minutes on both sides. Research groups had revealed in their results that cases managed with acupuncture had statistically significant reduction levels of bedwetting and better sleep. Average number of treatments was 6 acupuncture sessions. Acupuncture was performed on the acupuncture points: DU20 (BaiHui), BL23 (ShenShu), BL28

(PangGuangShu), SiShenCong (3cm from the point BaiHui), RN6 (QiHai), GB20 (FengChi) and Du16 (FengFu).(11)

Preceding studies investigating acupuncture usage showed that it causes increased nocturnal bladder capacity and hypothesizes an antidiuretic action. Recent research evidence revealed that laser irradiation, with either red or infrared light on acupoints located mainly in the lower abdomen and lumbar areas, can raise nocturnal bladder volume, reduce the number of wet nights and enhance the recovery rate in enuresis. A general system of channels and organs operate within the body. Triggering specific acupoints, activating those channels, corrects disharmony and dysregulation of organ systems. These facts clarify and support the current research findings that showed marked improvement in symptom profile in cases managed with needle or laser acupuncture regarding relief of dysregulation of urinary system and reduction of wet nights.(12)

Furthermore, in harmony with the current research study findings, the therapeutic impact of acupuncture and cold laser was achieved through improving function of the detrusor muscle and bladder sphincter activity by acting on spinal micturition centers and parasympathetic innervation of the pelvis. (13, 14)

In addition, it was concluded by previous research efforts that acupuncture suppresses spinal and supraspinal reflexes and raising β -endorphin levels in serum and the central nervous system that inhibit bladder contractions. Those findings further justify our results in the current study. (15)

Also, laser acupuncture improves nocturnal enuresis by increasing the secretion of enkephalin leading to improvement of the inhibitory control of the micturition centre in the pons of the brain stem.(16)

From the results achieved in our study, we conclude that laser and needle acupuncture are effective in controlling the symptoms of nocturnal enuresis in children. Interestingly, it has been revealed in the current research that cases that have been using stimulation of acupoints in both types in the study have markedly improved after one month of follow-up.

We recommend including more number of patients in further studies. Laser can be tried with different wavelengths and higher power because the world association of laser therapy (WALT) (17) mentioned that low power laser is totally safe whatever the power and energy used as long as we exclude the cases contraindicated to laser such as: cancer patients or those having cardiac diseases. Also, more sessions of laser or needle therapy may be performed with long follow-up periods. We may add laboratory parameters such as enkephalin, β -endorphin to evaluate their correlations with the clinical symptoms and signs.

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