ORIGINAL ARTICLE

A study of the effects of home administered transcutaneous electrical nerve stimulation on quality of life, psychosocial and incontinence outcomes in children with overactive bladder syndrome

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ABSTRACT

Main problem There is uncertainty about the effect of transcutaneous electrical nerve stimulation on quality of life and psychosocial outcomes in children with lower urinary tract symptoms. We aim to describe its impact on quality of life, psychosocial outcomes and lower urinary tract symptoms in Australian children with overactive bladder while exploring the role of confounders including baseline co-morbidities and length of transcutaneous electrical nerve stimulation usage at home.

Methods Children aged four to 18 years with symptoms of overactive bladder were given a transcutaneous electrical nerve stimulation machine for use at home. Data was collected at baseline and again three months later using a modified Paediatric Incontinence Quality of life Questionnaire, Strengths and Difficulties Questionnaire and an Incontinence Questionnaire and compared using paired t-tests. Separate analysis by gender, lower urinary tract symptoms and comorbidities was conducted.

Results Thirty-one children (15 girls) aged six to 16 years enrolled. The mean change in total Quality of Life Questionnaire score from baseline to post-treatment was -0.2 (95%CI-0.5 to 0.1; p=0.1), change in total Strengths and Difficulty Questionnaire score was -0.1 (95%CI-1.5 to 1.2; p=0.8) and change in total Incontinence Questionnaire score was -1.9 (95%CI-2.9 to -1.0; p=0.0004).

Five participants who were positive for lower urinary tract symptoms at baseline became negative post treatment, whereas no participants without symptoms at baseline became positive post-treatment (p=0.025).

Conclusions Transcutaneous electrical nerve stimulation monotherapy administered at home is potentially an effective treatment option for children with overactive bladder without adversely affecting their quality of life and psychosocial wellbeing.

Keywords children, overactive bladder, quality of life, transcutaneous electrical nerve stimulation, urinary incontinence

INTRODUCTION

Daytime urinary incontinence affects approximately 20% of school-aged children.[1] Overactive bladder (OAB) is the most common cause. The International Children's Continence Society (ICCS) defines OAB as "urinary urgency, usually accompanied by frequency and nocturia, with or without urinary incontinence in the absence of urinary tract infection or other obvious

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pathology."[2] Children who have urinary incontinence are more likely to have behavioural and psychological problems than other children, which can cause potential issues in adulthood.[1]

The most prominent treatment options for OAB in children include urotherapy, anticholinergic medication and more recently Transcutaneous Electrical Nerve Stimulation (TENS).[3] Anticholinergics are known to have side effects which can potentially affect compliance,[4,5] and cognitive function in both adults[6] and children.[4] Sacral neuromodulation with implanted electrodes is a recommended third line intervention for OAB in adults[7]; no similar guidelines exist as yet in children.[8] TENS monotherapy is considered an effective and safe alternative[1,3] with no significant direct adverse effects.[3,5]

Although parasacral TENS is an easy to use, non-invasive treatment for OAB, little information is available on whether using TENS affects quality of life and psychosocial outcomes in children. Our study is part of a larger international study on TENS use which found a discrepancy in the effect TENS has on quality of life between Australian and Brazilian children.[9] There was admittedly a difference in the methodology of administering the TENS therapy between geographical locations that mirrored practice realities. The Brazilian participants administered TENS for 20 minutes, three times per week in an outpatient clinic, whereas the Australian participants were given a TENS machine and requested to wear it at home daily for 60 minutes. In our Australian study utilising locally generated prospective data, we will explore the impact of TENS use in the home on quality of life, psychosocial symptoms and lower urinary tract symptoms. Potential confounding factors, such as baseline constipation and bladder dysfunction, which may also impact on quality of life of the children will be explored.

METHODS

This study was approved by the Sydney Children's Hospital Network Human Research Ethics Committee (HREC/17/SCHN/384). Participants were recruited from outpatient urinary continence clinics at two tertiary hospitals in NSW, Australia, The Children's Hospital at Westmead (CHW) and The John Hunter Children's Hospital Newcastle (JHCH). The inclusion criteria were children with symptoms suggestive of OAB (by clinician diagnosis) requiring additional treatment after inadequate response to at least one month of urotherapy. All children aged four to 18 years who attended the clinics between March 2018 and 2020 and met the inclusion criteria were invited to participate. Patients who had previously used or were currently using anticholinergic medications for overactive bladder syndrome, or with neurological or urological causes for the urinary incontinence (for which TENS therapy is unlikely to be effective) were excluded. As children with concomitant faecal incontinence have a higher risk of psychosocial comorbidity,[10] they were also excluded from participation.

All participants were provided with a TENS machine from the same manufacturer, written instructions and a demonstration of its use by the physiotherapist during the clinic visit. Parents were asked to place two self-adhesive electrodes (50mm x 90mm) over the parasacral area (S2-3) for 60 minutes each day for three months. Families were advised to choose a time convenient for the child while at home, for instance in the afternoon after school. The TENS machine was preset at a 10 Hz frequency, with a120µsec pulse width, in normal mode.[11] In our clinic population our experience has been that many children, particularly younger children and those with sensory processing challenges, are better able to tolerate TENS at a lower pulse width. The intensity of the machine and the length of time worn daily was controlled by participant preference, although participants were instructed to adjust the intensity as high as possible, to reach a sensation within their limits of comfort. A diary was provided for families to record when the child wore the TENS, for how long, the intensity of the setting used and details of their lower urinary tract symptoms at the time. The trial coordinator contacted participants every four weeks to monitor progress and offer support. Participants reported their daily use of the device with options of not worn, worn for zero–30 minutes, 30–60 minutes and >60 minutes. The calculation of TENS use for each day were assumed to be zero, 30, 60 and 120 minutes, respectively. Total minutes of TENS use for the study were summed for all days reported and used to calculate average minutes per day that the device was used for each participant. We collected data on all participants of the study irrespective of whether they used the TENS or not, or how they used it.

We also collected data using three validated questionnaires at baseline and again at the end of the three month treatment period to explore changes. The questionnaires we used were a modified Paediatric Incontinence Quality of Life Questionnaire (PinQ),[12] the Strengths and Difficulties Questionnaire (SDQ),[13,14] and a lower urinary tract symptom questionnaire called the International Consultation on Incontinence Questionnaire: Paediatric Lower Urinary Tract Symptoms (ICIQ-CLUTS).[15]

The PinQ is a bladder specific quality of life questionnaire for children, with 28 questions covering seven categories. We used a modified version of the PinQ to give equal weighting to the categories as some categories had more questions than others. A higher score indicated a lower quality of life with score range of 1.75–7.[12]

The SDQ assesses psychological symptoms based on 25 questions about strengths and difficulties experienced by the child in everyday life. The scales assessed by the questionnaire are Emotional, Conduct, Hyperactivity, Peers and Prosocial, comprising of five questions each. The Total Difficulties score is a sum of four of the scales (all except Prosocial). The resultant scores range from 0–40: with 0–13 being normal; 14–16 borderline; and 17–40 being abnormal. The questionnaire has two versions depending on the age of the child: 4–10 years and 11–17 years.[13,14]

ICIQ-CLUTS is a parental questionnaire assessing the child's lower urinary tract symptoms. It comprises of 10 questions with score options ranging from 0–3 per question which are about enuresis, overactive bladder, voiding postponement and faecal retention. A total of 13 or more indicates clinically significant lower urinary tract symptoms. Participants were categorised as being ICIQ positive or negative based on whether or not their total ICIQ-CLUTS score was 13 or more.[15]

Data was collected at baseline from the clinic visit letters on symptoms of constipation, post void residual bladder volume (PVR) and maximum voided volume (MVV). Constipation was classified as either normal or abnormal based on the ROME IV* criteria.[16] Information about the PVR was obtained from either the bladder ultrasound conducted at the time of the patient's appointment or from the report of an ultrasound conducted prior to the first appointment. It was classified as either normal or abnormal using the ICCS age specific measurements. A PVR greater than 20mls from children aged 4–6 years and greater than 10mls from children aged 7–12 years are considered abnormal.[2]

The MVV was classified as normal or abnormal based on whether it fell into the ICCS defined normal expected maximum voided volume range. The expected MVV is calculated using a formula based on age: (age +1) x30 (up to age 12). The normal expected MVV range is 65–150% of this.[2]

A sample size of 30 children enabled us to have 80% power at 5% one-sided significance to detect a within-patient improvement of 0.5 standard deviations in continuous outcomes from baseline to three months using a one-sample t-test. Patient demographic and clinical characteristics were described using standard statistical methods and questionnaire data were described according to the relevant scoring manual. Missing data were noted and reported in the descriptive analysis.

The outcomes of change in PinQ, SDQ and ICIQ-CLUTS from baseline to three months were calculated and explored using one sample t- tests. The paired binary outcome of ICIQ positive at baseline/post-treatment was compared using McNemar's test and a 95% confidence interval for the difference was calculated using a generalised estimating equation model. Associations between potential comorbidities of constipation, post-void residual and maximum voided volume and baseline PinQ score and outcomes were explored using two-sample t-tests. Changes in PinQ, SDQ and ICIQ-CLUTS total scores from baseline to three months were compared between males and females and changes in PinQ and SDQ scores from baseline to three months were compared between participants with and without ICIQ positive symptoms at baseline, using two-sample t-tests.

RESULTS

Thirty-one children participated in the study, 26 from CHW and five from JHCH. Fifteen were girls and the age ranged from 6–16 years. At baseline 28 had urgency, 12 had frequency, 14 had daytime urinary incontinence and eight were classified as ICIQ positive based on parental questionnaire responses in the ICQI-CLUTS. Fifteen were classified as constipated, eleven had an abnormal post-void residual and 18 had a smaller than expected maximum voided volume (Table 1).

At baseline the mean PinQ score was 3.3 for those with constipation and 3.5 for those without constipation (difference=-0.2; 95%CI -0.8 to 0.3; p=0.3). Similarly, the mean PinQ score for those with abnormal post void residual volume was 3.2, and for normal post void residual was 3.5 (difference=-0.3; 95%CI -0.8 to 0.3; p=0.4). The mean PinQ score for those who had abnormal maximum voided volume was 3.6 and for those who were normal was 3.0 (difference=0.6; 95%CI 0.1 to 1.1; p=0.03) (Table 1).

Subgroup analysis by gender at baseline showed no evidence of differences in total PinQ, SDQ and ICIQ-CLUTS scores between the females and males. At baseline, the mean total PinQ score was 3.5 (range 2.3 to 4.6) for females and 3.3 (range 2.5 to 4.1) for males. The mean total SDQ score was 17.1 (range 11.0 to 21.0) for females and 15.3 (range 6.0 to 22.0) for males. The mean total ICIQ-CLUTS score was 11.1 (range 3.0 to 21.0) for females and 8.4 (range 3.0 to 13.0) for males.

Subgroup analysis by ICIQ status showed no difference in baseline PinQ and SDQ total scores between those who did and did not have significant ICIQ positive symptoms. The mean total PinQ score for those who were ICIQ positive was 3.8 (range 2.9 to 4.6) and for those who were negative was 3.2 (range 2.3 to 4.2). The mean total SDQ score for those who were ICIQ positive was 0.0 (range -7.0 to 10.0) and -0.2 (range -4.0 to 5.0) for those who were negative.

Based on parental ICIQ-CLUTS responses, post treatment there was a total of 27 who had urgency, eight who had frequency and 13 had daytime urinary incontinence (Table 2). Of the eight who were ICIQ positive at baseline, five became negative post treatment (p=0.025). All 21 participants who were ICIQ negative at baseline remained negative post treatment (Table 3).

Of the 31 participants, four never used the TENS machine and one was lost to follow-up. For the possible total 90 days the TENS could have been worn, on average it was not worn for 24.6% of days, worn for <30 minutes 11.6% of days, for 30-60 minutes for 54.9% of days and >60 minutes for 8.9% of days.

There was no correlation between the mean length of time participants wore the TENS per day and changes in the PinQ, SDQ or ICIQ-CLUTS scores. The Pearson correlation coefficient (p value) was -0.08 (p=0.75) for change in mean PinQ score, 0.09 (p= 0.67) for change in mean SDQ score and 0.02 (p=0.93) for change in mean ICIQ-CLUTS score (Table 3).

The mean change in total Modified PinQ score from baseline to post-treatment was -0.2 (95%CI -0.5 to 0.1; p=0.1), change in total SDQ score was -0.1 (95%CI -1.5

Table 1. Baseline characteristics and questionnaires

Characteristics			**n (%) N=31**		
Referring Centre:					
	CHW		26 (84)		
	JHCH		5 (16)		
Gender:					
	Girls		15 (48)		
Age:					
Range 6–16 years	Mean		9		
Overactive Bladder Symptoms:					
	Urgency		28 (90)		
	Frequency		12 (39)		
	Wetting		14 (45)		
ICIQ positive	Yes		8 (26)		
	No		21 (68)		
	Unknown		2 (6)		
Constipation†				**Mean PinQ**	**P value**
	Yes		15 (48)	3.53	0.3
	No		15 (48)	3.26	
	Unknown		1 (4)		
PVR†					
	Normal		19 (61)	3.48	0.4
	Abnormal		11 (35)	3.23	
	Unknown		1 (4)		
MVV†					
	Normal		11 (35)	3.05	0.03
	Abnormal		18 (58)	3.62	
	Unknown		2 (7)		
Questionnaires:					
Modified PinQ‡					
Range 2.3 - 4.6	Mean		3.4		
SDQ§					
Range 6.0 - 22.0	Mean		16.2		
CLUTS¶					
Range 3.0 – 21.0	Mean		9.7		

†Normal PVR, MVV, according to ICCS criteria; Constipation, according to ROME IV criteria
‡PinQ: Higher score equates to lower quality of life
§SDQ: Higher score equates to lower mental wellbeing
¶CLUTS: Higher score equates to positive Lower Urinary Tract Symptoms

to 1.2; p=0.8) and change in total ICIQ-CLUTS score was -1.9 (95%CI -2.9 to -1.0; p=0.0004) for the whole cohort. This demonstrated an improvement in lower urinary tract symptoms statistically, but no evidence of change in PinQ or SDQ scores with treatment (Tables 1,2,3).

Comparing baseline to post treatment, subgroup analysis by gender showed no difference in mean change in PinQ scores, -0.2 for females and -0.3 for males (difference=-0.1; 95%CI -0.5 to 0.7; p=0.8); the mean change in SDQ scores was 0.0 for females and -0.3 for males (difference=0.3; 95%CI -2.5 to 3.1; p=0.8) and mean change in ICIQ- CLUTS scores was -1.6 and -2.1 for females and males respectively (difference=0.5; 95%CI -1.5 to 2.4; p=0.6) (Table 4).

Again, subgroup analysis by ICIQ status showed no difference in mean change in PinQ scores from baseline to post treatment for those with positive and negative ICIQ symptoms. It was -0.3 for those positive for ICIQ symptoms and -0.2 for those who were negative (difference=0.1; 95%CI- 0.7 to 0.8; p=0.8); the mean change in SDQ scores was 0.0 and -0.2 for those positive and negative for ICIQ symptoms respectively (difference=-0.2; 95%CI -3.3 to 2.9; p=0.9) (Table 4).

Table 2. Post treatment results

Characteristics			n (%) N=30
OAB symptoms:			
	Urgency		27 (90)
	Frequency		8 (27)
	Wetting		13 (43)
Questionnaires:			
Modified PinQ‡	Mean (SD)		3.1 (0.7)
SDQ§	Mean (SD)		16 (4.7)
CLUTS¶	Mean (SD)		7.8 (3.9)

1 patient was lost to follow-up
‡PinQ: Higher score equates to lower quality of life (range 1.75–7)
§SDQ: Higher score equates to lower mental wellbeing (range: normal 0–13, borderline 14–16, abnormal 17–40)
¶CLUTS: Higher score equates to positive Lower Urinary Tract Symptoms (abnormal is >=13)

Table 3. Change from Baseline to Post Treatment

Characteristics		n (%) N=29	95% CI	p VALUE
Questionnaires†:				
Modified PinQ‡	Mean	-0.23	-0.5 to +0.1	0.1
SDQ§	Mean	-0.1	-1.5 to +1.2	0.8
CLUTS¶	Mean	-1.9	-2.9 to -1.0	0.0004
ICIQ positive:	Baseline	8 (26%)		
	Post treatment	3 (10%)	-31 to -3.5	0.025
Correlation between wearing TENS (mins/day) and questionnaire change				
Modified PinQ‡	Coefficient	-0.08		0.8
SDQ§	Coefficient	0.1		0.7
CLUTS¶	Coefficient	0.02	0.93	

† not everybody responded to all questions in PinQ
‡ PinQ: Higher score equates to lower quality of life (range 1.75–7)
§SDQ: Higher score equates to lower mental wellbeing (range: normal 0–13, borderline 14–16, abnormal 17–40)
¶CLUTS: Higher score equates to positive Lower Urinary Tract Symptoms (abnormal is >=13)

DISCUSSION

Our study, which is the first study of its kind in Australia, potentially confirms the efficacy of home TENS therapy for OAB in children with no adverse change in quality of life and psychosocial health. This is part of an international study, partnering with Brazil and Germany[9] and is one of the first to look at the impact of

Table 4. Mean change by Gender and LUTS

Characteristics	Mean Difference	95% CI	p VALUE
By gender:			
Questionnaires:			
Modified PinQ‡ (N=21)	0.1	-0.5 to +0.7	0.8
SDQ§ (N=29)	0.3	-2.5 to +3.1	0.8
CLUTS¶ (N=29)	0.5	-1.5 to +2.4	0.6
By ICIQ Status:			
Questionnaires:			
Modified PinQ‡ (N=21)	0.1	-0. to +0.8	0.8
SDQ§ (N=29)	-0.2	-3.3 to +2.9	0.9

‡PinQ: Higher score equates to lower quality of life (range 1.75–7)
§SDQ: Higher score equates to lower mental wellbeing (range: normal 0-13, borderline 14–16, abnormal 17–40)
¶CLUTS: Higher score equates to positive Lower Urinary Tract Symptoms (abnormal is >=13)

TENS on quality of life and psychosocial outcomes in children. Santos et al[9] found a significant improvement in the quality of life in the Brazilian cohort but not from the Australian or German cohort. The increased interaction the Brazilian children had with clinical staff or the reduced burden of wearing the TENS may have enhanced the quality of life of the Brazilian participants.

Our study also examined whether adherence to wearing TENS was associated with improved treatment outcome and quality of life. Previous studies found treatment adherence to be a problem for children due to the length of time and frequency required to wear TENS[17] but Cui et al[18] found using the TENS did not cause pain or distress. Although we found no evidence of correlation between length of TENS use and the change in total PinQ, SDQ and ICIQ-CLUTS scores in our participants, the increased length of time of TENS was worn by the Australian cohorts compared to the Brazilian cohort, could have been more burdensome than wearing it for 20 minutes in clinic three times per week.

Our study did demonstrate that TENS monotherapy improved lower urinary tract symptoms. Although our overall numbers were small, five out of a total of eight (62.5%) of our participants with ICIQ positive symptoms at baseline showed resolution of symptoms at the end of the study period. This result is consistent with previous studies[3] demonstrating the effectiveness of TENS for treating overactive bladder. Some studies suggest that wearing TENS for a longer period of time improves lower urinary tract symptoms[19] but we were unable to demonstrate that in our study. The discordances between our study findings and some of the hitherto published studies are interesting. Sacral

neuromodulation is believed to work through both central and peripheral nervous systems either by decreasing the afferent overload to the central nervous system (CNS) or recalibrating the threshold for void initiation in the control centres in the CNS.[20] These multimodulatory level neuroplasticity changes are complex and are often influenced by multiple neuronal and environmental factors.

The lack of gender differences found in our study was noteworthy. Although earlier population studies demonstrated that the prevalence and severity of daytime urinary incontinence was higher in girls,[21,22] in our study there were similar numbers of girls and boys enrolled. In previous studies the impact on quality of life for daytime urinary incontinence was worse for girls,[2] however the PinQ scores in our study were similar between the genders. We may not have been able to detect any gender differences because our study participants were from tertiary pediatric centers who may have had more severe symptoms than the general population.

The small sample size and broad age range are limitations in our study and possibly influenced our ability to demonstrate a clearer relationship between TENS use at home and quality of life in children with overactive bladder syndrome. However, being a pragmatic study, we reported on the data collected from all the participants irrespective of TENS usage, to represent what actually happens when TENS are prescribed to reflect generalisability. Our study reports on the all-round efficacy of TENS therapy at home and highlights the need for more research on the optimum conditions for TENS therapy administration.

CONCLUSIONS

The use of TENS at home for treating overactive bladder syndrome in children appears to be safe and effective, with no adverse effect on quality of life or psychosocial outcomes identified after three months of use. With the growing concern about adverse effects of medications used for treating overactive bladder, TENS delivered at home should potentially be considered as a first line of treatment for children with this condition notwithstanding the limited improvement in some metrics.

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DISCLOSURE

The authors declare no conflict of interest.

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This study has been approved by the Sydney Children's Hospital Network Human Research Ethics Committee (HREC/17/SCHN/384).

Informed consent was obtained from all participating families.

Registry is the Australian New Zealand Clinical Trials Registry (ANZCTR) and the Registration number is: ACTRN12617000938303

Animal study N/A

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