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医学生物物理

不同功能性电刺激方案联合生物反馈治疗儿童神经源性逼尿肌尿道无收缩尿失禁的疗效

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【摘 要】**目的**:研究不同功能性电刺激(FES)方案联合生物反馈治疗儿童神经源性逼尿肌尿道无收缩(NADS)尿失禁的疗效。**方法**:纳入68例NADS尿失禁患儿,采用随机数字表法分为对照组(n=34)和观察组(n=34)。对照组在每次治疗中,均以患儿可耐受的初始阈电流强度进行FES联合生物反馈治疗;观察组则在每次治疗中期,在初始阈电流基础上增加电流强度至患儿可耐受的新的阈刺激强度,并持续至治疗结束。每次治疗时间为40 min,每周3次,疗程为12周。在治疗结束后至少6个月门诊随访疗效。分析两组治疗前后及随访6个月时的尿动力学检查(UDS)指标与尿失禁症状,对比两种方案疗效。**结果**:两组患儿治疗结束及随访6个月时,UDS指标逼尿肌漏尿点压、膀胱容量、逼尿肌最大压力、逼尿肌顺应性与尿失禁症状72 h总排尿次数、总尿失禁次数、国际尿失禁咨询委员会问卷评分均明显改善(P<0.05),且观察组均显著优于对照组(P<0.05);治疗结束及随访6个月时,观察组总有效率均显著高于对照组(P<0.05)。**结论**:FES联合生物反馈治疗儿童NADS尿失禁,疗效确切且持续稳定,治疗中期增加电流强度方案疗效更佳,临床应用价值高。

【关键词】尿失禁;功能性电刺激;生物反馈;尿动力学
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Therapeutic effect of different functional electric stimulations combined with biofeedback in children with urinary incontinence due to neuropathic acontractile detrusor and sphincter

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Abstract: Objective To evaluate the efficacy of functional electric stimulation (FES) combined with biofeedback treatment for children with urinary incontinence due to neuropathic acontractile detrusor and sphincter (NADS). **Methods** Sixty-eight children with urinary incontinence due to NADS were enrolled and randomly divided into control group and observation group, 34 children in each group. The children in control group received the initial threshold of FES and biofeedback treatment during the whole treatment. In observation group, the current was increased in the middle of treatment until it reached a new tolerable threshold of intensity, and the increased current lasted until the end of treatment. A 12-week treatment was performed for 40 minutes each time and 3 times per week. After the completion of treatment, the children were followed-up at least for 6 months. The indices of urodynamic study and incontinence symptoms of pre- and post-treatment and 6 month later were assessed in order to compare the treatment efficacy between the two groups. **Results** The evaluation performed at the completion of treatment and 6 months after the treatment showed that the children in both groups had significant improvements in the indices of urodynamic study including detrusor leak point pressure, maximal detrusor pressure, maximum bladder capacity and mean detrusor compliance, and incontinence symptoms such as 72 h total urinary volume, total voiding times total incontinence times, and the score of international continence inquiring committee's questionnaire (P<0.05). Moreover, those improvements in observation group were superior to those in control group (P<0.05). The observation group had higher overall effective rate compared to control group (P<0.05). **Conclusion** FES combined with biofeedback has a clear and stable therapeutic effect in the pediatric patients with urinary incontinence due to NADS. Moreover, increasing the current in the middle of the treatment could achieve a better clinical outcome, with a higher clinical value.

Keywords: urinary incontinence; functional electric stimulation; biofeedback; urodynamics

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前 言

儿童神经源性逼尿肌尿道无收缩(Neuropathic Acontractile Detrusor and Sphincter, NADS)尿失禁常由脊髓脊膜膨出和隐性脊柱裂引起,不仅严重影响患儿生活质量与身心健康,甚至会导致肾功能衰竭而危及生命[1-3]。随着医疗技术的高速发展,儿童NADS尿失禁的治疗有了极大的进步,但因药物治疗不良反应大,长期效果欠佳,手术治疗创伤大、术后并发症较多、复发率高等不足,临床均不易被接受,因此积极寻找一种理想治疗方法具有重要的现实意义。功能性电刺激(Functional Electric Stimulation, FES)与生物反馈疗法因其零创伤、痛苦小、安全系数高、疗效肯定等优势,正成为近年尿失禁康复治疗领域的研究热点[4-6]。本研究将分析FES联合生物反馈治疗儿童NADS尿失禁的疗效,并对比FES全程维持初始阈电流强度与中期增加电流强度两种方案的临床疗效。

1 材料与方法

1.1 研究对象

经山东大学第二医院医学伦理委员会批准,前瞻性连续收集2014年1月~2017年1月在山东大学第二医院小儿外科诊断为NADS尿失禁患儿68例,采用随机数字表法进行随机抽样将患儿分为对照组(n=34)和观察组(n=34)。收集患儿的性别、年龄及病史等临床资料,其中对照组男23例(67.65%),女11例(32.35%),平均年龄(8.62±3.51)岁;观察组男20例(58.82%),女14例(41.18%),平均年龄(9.73±4.78)岁。纳入标准:(1)年龄4~14岁;(2)经MRI和尿动力学检查(UDS)诊断为NADS尿失禁;(3)尿常规检查正常。排除标准:(1)伴严重心、脑、肝、肾器质性疾病;(2)伴泌尿系、生殖器或肛门直肠畸形;(3)伴急性泌尿系统感染;(4)既往行泌尿生殖系统手术。与患儿及其父母充分沟通,获得知情同意书。

1.2 治疗方法

FES联合生物反馈治疗每次时间为40 min,每周3次,疗程为12周,由同一操作者实施。在治疗结束后至少6个月门诊随访疗效。FES治疗:两组患儿均应用法国PHENIX低频神经肌肉刺激治疗仪进行,参数设置为频率40 Hz,脉宽250 μs。对照组予以初始阈电流强度治疗,全程20 min不增加电流强度;观察组先予以当次初始阈电流强度治疗10 min,中期适当增加电流强度(2~5 mA)后再治疗10 min,需确保最大电流强度低于患儿疼痛阈值,治疗全程可耐受且无明显不适感。生物反馈治疗:两组患儿均应用丹麦DUET Logic尿动力学仪,采用直肠测压管和肛塞电极检测盆底肌压力信号变化和电活动辅助生物反馈治疗。首先指导患儿进行正确的盆底肌收缩和松弛,构建基础收缩的直肠内压、肌电图增加值及维持收缩状态的时间,根据上述参数设计生物反馈治疗程序[7],然后嘱咐患儿在生物反馈治疗仪提示下收缩与松弛盆底肌,全程20 min。

1.3 疗效观察

1.3.1 UDS指标 依据国际儿童排尿控制协会指南,对两组患儿于治疗前后及随访6个月时进行UDS检查,使用尿流动力学分析仪(Urody-5000)测定逼尿肌漏尿点压(Detrusor Leak Point Pressure, DLPP)、膀胱容量(Maximal Bladder Capacity, MBC)、逼尿肌最大压力(Maximal Detrusor Pressure, MDP)及逼尿肌顺应性(Mean Detrusor Compliance, MDC)。

1.3.2 尿失禁症状 指导患儿父母持续记录并运用排尿日记[8],收集72 h总排尿量、总排尿次数及总尿失禁次数;指导患儿于治疗前后及随访6个月时完成国际尿失禁咨询委员会问卷(International Continence Inquiring Committee's Questionnaire, ICI-Q-SF)。

1.3.3 疗效判定标准 尿失禁治愈:自觉尿失禁症状完全消失;有效:自觉尿失禁症状明显好转,尿失禁次数减少50%以上;无效:自觉尿失禁症状无明显改善,尿失禁次数减少50%以下。有效率计算公式:有效率=(治愈患儿例数+有效患儿例数)/总患儿例数[9]。

1.4 统计学方法

应用SPSS 22.0软件进行数据统计分析。计量资料用均数±标准差表示,计数资料以百分比表示。满足正态分布的计量资料采用方差检验分析组间差异,不满足正态分布的计量资料采用秩和检验分析组间差异;计数资料间的比较采用χ^2检验。双侧P<0.05时,差异有统计学意义。

2 结 果

2.1 两组患儿临床基线资料比较

两组患儿年龄、性别、病史间比较(表1),差异均无统计学意义(P>0.05),两组具有可比性。

2.2 两组患儿治疗前后及随访6个月时UDS指标比较

本研究68例患儿均完成了至少6个月的临床随访。治疗前,两组患儿UDS指标DLPP、MBC、MDP及MDC水平比较,差异无统计学意义(P>0.05);治疗结束及随访6个月时,两组患儿UDS指标DLPP、MBC、MDP及MDC较治疗前均明显改善(P<0.05),且观察组显著优于对照组(P<0.05),见表2。

表1 两组患儿临床基线资料比较[例(%)]

Tab.1 Comparison of clinical baseline characteristics [cases(%)]

Variables	Control group (n=34)	Observation group (n=34)	t/χ^2 value	P value
Age (years)	8.62±3.51	9.73±4.78	1.091	0.279
Male	23(67.65)	20(58.82)	0.570	0.450
History			1.620	0.655
Myelomeningocele	25(73.53)	24(70.59)		
Intraspinal cyst	1(2.94)	3(8.82)		
Diastematomyelia	6(17.65)	4(11.76)		
Occult spinal dysraphism	2(5.88)	3(8.82)		

表2 两组患儿UDS指标比较

Tab.2 Comparison of UDS indices between the two groups

Variables	Groups	Pre-treatment	Post-treatment	6 months after treatment	P_1 value	P_2 value	P_3 value
DLPP/kPa	Control	2.21±0.86	2.73±0.91	2.63±0.77	0.018	0.038	0.626
	Observation	2.13±0.95	3.32±1.21	3.18±1.19	<0.001	<0.001	0.632
	P value	0.717	0.026	0.027	-	-	-
MDP/kPa	Control	5.72±1.45	4.88±1.20	5.05±1.28	0.011	0.047	0.574
	Observation	5.39±1.96	4.16±1.05	4.45±1.12	0.002	0.018	0.275
	P value	0.433	0.011	0.044	-	-	-
MBC/mL	Control	215.69±37.50	244.62±45.20	237.48±40.30	0.005	0.024	0.494
	Observation	212.30±36.50	270.70±59.60	260.16±49.30	<0.001	<0.001	0.430
	P value	0.707	0.046	0.042	-	-	-
MDC/mL·kPa^{-1}	Control	66.21±20.65	85.23±36.65	80.51±35.57	0.010	0.047	0.592
	Observation	65.56±29.30	108.75±45.70	99.36±40.70	<0.001	<0.001	0.374
	P value	0.916	0.022	0.046	-	-	-

UDS: Urodynamic study; DLPP: Detrusor leak point pressure; MDP: Maximal detrusor pressure; MBC: Maximum bladder capacity; MDC: Mean detrusor compliance; P_1: Pre-treatment *vs* post-treatment; P_2: Pre-treatment *vs* 6 months after treatment; P_3: Post-treatment *vs* 6 months after treatment

2.3 两组患儿治疗前后及随访6个月时尿失禁症状比较

治疗前,两组患儿72 h内总排尿量、总排尿次数、总尿失禁次数及ICI-Q-SF评分比较,差异无统计学意义(P>0.05);治疗结束及随访6个月时,两组患儿72 h总排尿次数、总尿失禁次数及ICI-Q-SF均明显改善(P<0.05),且观察组显著优于对照组(P<0.05),见表3。

2.4 两组患儿治疗疗效比较

对照组在治疗结束及随访6个月时两次疗效评估的有效率比较,差异无统计学意义(P>0.05);观察组在治疗结束及随访6个月时两次疗效评估的有效率比较,差异无统计学意义(P>0.05);观察组在治疗结束及随访6个月时总有效率均显著优于对照组(P<0.05),见表4;随访期间,两组患儿均未观察到不良事件。

3 讨 论

儿童NADS尿失禁给患儿及其家庭带来大量的负面情绪、身心痛苦及经济负担,及时有效干预可最大程度改善患儿预后[1-3]。提高尿液流出道阻力是NADS尿失禁患儿治疗的关键,但当前临床上常用的治疗方法如尿道周围注射药物、外科人工尿道括约肌植入术、膀胱颈口悬吊术等并发症多、复发率高且费用高昂[10-12]。而盆底康复治疗,即FES与生物反馈疗法,具有方便、安全、无创和无不良反应等优点,现

表3 两组患儿尿失禁症状比较

Tab.3 Comparison of incontinence symptoms between the two groups

Variables	Groups	Pre-treatment	Post-treatment	6 months after treatment	P_1 value	P_2 value	P_3 value
Total urinary volume (mL)/72 h	Control	2 009.32±616.38	2 052.65±775.61	1 993.76±818.96	0.799	0.930	0.762
	Observation	2 144.77±891.72	2 030.12±671.48	2 049.65±706.86	0.551	0.628	0.907
	P value	0.469	0.898	0.764			
Total voiding times/72 h	Control	48.52±17.68	39.52±14.26	40.10±15.21	0.024	0.039	0.872
	Observation	49.80±19.65	32.93±12.45	33.19±12.59	<0.001	<0.001	0.929
	P value	0.779	0.040	0.045			
Total incontinence times/72 h	Control	31.18±8.92	24.89±6.16	26.62±7.01	0.001	0.022	0.284
	Observation	30.09±7.66	20.82±5.93	23.15±6.37	<0.001	<0.001	0.123
	P value	0.591	0.007	0.036			
ICI-Q-SF	Control	15.78±5.52	11.78±4.21	13.25±4.78	0.001	0.047	0.183
	Observation	16.09±5.58	9.96±2.96	11.03±4.11	<0.001	<0.001	0.222
	P value	0.819	0.043	0.044			

ICI-Q-SF: Score of international continence inquiring committee's questionnaire; P_1: Pre-treatment *vs* post-treatment; P_2: Pre-treatment *vs* 6 months after treatment; P_3: Post-treatment *vs* 6 months after treatment

表4 两组患儿治疗疗效比较[例(%)]

Tab.4 Comparison of therapeutic outcome between the two groups [cases(%)]

Groups	Outcome	Post-treatment	6 months after treatment	χ^2 value	*P* value
Control				0.381	0.827
	Cure	3(8.82)	2(5.88)		
	Effective	19(55.88)	18(52.94)		
	Invalid	12(35.29)	14(41.18)		
Observation				0.419	0.811
	Cure	8(23.53)	6(17.65)		
	Effective	22(64.71)	23(67.65)		
	Invalid	4(11.76)	5(14.71)		
χ^2 value		6.492	6.873		
P value		0.039	0.032		

已被广泛用于多种类型尿失禁如妇女产后压力性尿失禁[13]、老年人尿失禁[14]、脑卒中后尿失禁[6]的治疗中，并获得良好疗效。然而FES与生物反馈疗法在儿童NADS尿失禁治疗中的应用目前国内外鲜有报道，疗效尚未完全明确，临床上值得深入研究。

本研究将FES联合生物反馈用于68例儿童NADS尿失禁的治疗，并在治疗结束后至少6个月随访疗效，结果显示与治疗前相比，治疗结束及随访6个月时患儿的UDS指标DLPP、MBC、MDP、MDC与尿失禁症状72 h总排尿次数、总尿失禁次数、ICI-Q-SF均得到显著改善，疗效确切。本研究还发现治疗结束及随访6个月时，患儿两次疗效评估的有效率比较结果无显著性差异，表明FES联合生物反馈治疗儿童NADS尿失禁的近期疗效持续稳定。NADS尿失禁患儿多存在支配控尿组织的神经损害，盆底肌肉群瘫痪松弛，FES以一定强度向盆底肌肉群发放低脉冲电流，刺激盆底肌肉和神经，既可引导盆底肌收缩，模拟正常的自主运动，使其恢复因神经受损而丧失的功能[15]；又能快速激活阴部

神经纤维的传导，进而直接作用于包括尿道外括约肌在内的盆底横纹肌群，改善肌肉间的协调能力；还能加强腹下抑制性神经纤维的作用，抑制从膀胱传出的上行性神经通路，从而抑制膀胱兴奋性[16]。Radziszewski[17]将FES用于治疗脊髓损伤并发NADS尿失禁患者证实，FES可明显改善患者UDS指标，疗效显著，并随访发现在FES治疗结束两年后疗效仍然保存稳定，有力支持了本研究结果。生物反馈则通过将盆底肌肉群电信号活动转换为声音或视觉信号变化，指导患儿根据这些反馈自主进行正确有效的盆底肌群锻炼，逐渐提高控尿能力[18]。游泳等[9]研究显示，30例NADS尿失禁患儿接受为期12周的生物反馈盆底肌锻炼，治愈率为27%，有效率为67%，疗效明显，与本研究结果提示相符。

本研究中在治疗中期增加电流强度至新的阈刺激强度进行FES的观察组，与全程始终以初始阈电流强度进行FES的对照组相比，UDS指标与尿失禁症状均进一步改善，总有效率更高，疗效更佳。贾俊华等[19]研究亦发现，对尿失禁患者治疗中期增加电流强度进行FES，可显著提高疗效。可能原因为FES中期增加电流强度，可诱导更多的阴部神经传入纤维产生动作电位，使盆底肌群得到更充分的锻炼，从而改善其舒缩协调功能，达到提高控尿能力的目的。

综上所述，FES联合生物反馈疗法可显著改善NADS尿失禁患儿UDS指标与尿失禁症状，疗效确切且持续稳定，治疗中期增加电流强度方案疗效更佳，为NADS尿失禁患儿提供了一种新的无创、方便、安全可靠的治疗手段，临床应用价值高。

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