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Review

Sacral neuromodulation in pediatric bladder and bowel dysfunctions: Literature review

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BACKGROUND: Sacral neuromodulation is a neurosurgical method for the correction of bladder and bowel dysfunctions of various origins that are refractory to conservative treatment.

AIM: To analyze chronic sacral neurostimulation results as a correction method for pediatric bladder and bowel dysfunction of various origins.

MATERIALS AND METHODS: The results of chronic sacral neurostimulation for treating urination and defecation disorders of various origins in children reported in the world literature were analyzed. The literature search was performed in the open electronic scientific databases eLIBRARY, PubMed, and Cochrane Library. The source selection was limited by 2002–2022.

RESULTS: Most authors report good and satisfactory results in the treatment of bladder and bowel dysfunction by sacral neurostimulation. However, the level of evidence on the effectiveness of sacral neurostimulation remains low because data were obtained from small and heterogeneous groups of patients and studies employed different criteria for inclusion and methods for analyzing the results.

CONCLUSIONS: Conducting randomized trials will allow for the assessment of the efficacy and safety of sacral neuromodulation in children with bladder and bowel dysfunctions of various origins that are refractory to standard conservative treatment.

Keywords: sacral neuromodulation; bladder dysfunction; bowel disfunction; neurogenic bladder; neurogenic bowel disfunction; children.

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Научный обзор

Сакральная нейромодуляция в лечении нарушений мочеиспускания и дефекации у детей (обзор литературы)

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Обоснование. Сакральная нейромодуляция — метод нейрохирургической коррекции нарушений мочеиспускания и дефекации различного генеза, резистентных к стандартным протоколам консервативной терапии.

Цель — проанализировать данные отечественной и зарубежной литературы, отражающие результаты применения сакральной нейромодуляции у пациентов детского возраста при нарушениях мочеиспускания и дефекации.

Материалы и методы. Проанализированы представленные в мировой литературе результаты хронической сакральной нейростимуляции в качестве способа коррекции нарушений мочеиспускания и дефекации различного генеза у детей. Поиск литературы осуществляли в открытых электронных базах научной литературы eLIBRARY, PubMed и Cochrane Library. Выборка источников в основном ограничивалась 2002–2022 гг.

Результаты. Большинство авторов сообщают о хороших и удовлетворительных результатах лечения дисфункции мочеиспускания с помощью сакральной нейростимуляции. Однако в связи с малыми гетерогенными группами пациентов, описанными в литературе, различными критериями включения в исследование и различными методиками анализа результатов уровень доказательности эффективности сакральной нейростимуляции остается низким.

Заключение. Проведение рандомизированных исследований позволит оценить эффективность и безопасность применения сакральной нейромодуляции у детей с дисфункцией мочеиспускания и дефекации.

Ключевые слова: сакральная нейромодуляция; нарушение мочеиспускания; нарушение дефекации; нейрогенный мочевой пузырь; нейрогенный кишечник; дети.

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ЭКО•ВЕКТОР

BACKGROUND

Dysfunction of the pelvic organs of varying degrees is detected in 9.3%–21.8% of school-age children [1–4]. Such disorders are characterized by a wide range of clinical manifestations, such as frequent urination, urgency, urge urinary incontinence, difficulty urinating, feeling of incomplete bladder emptying, chronic constipation, and fecal incontinence [5]. Urination and defecation impairment limits daily activities and social adaptation. Approximately 1/3 of patients with dysfunction of the pelvic organs develop depression and, in rare cases, agoraphobia [6, 7].

Some patients with urination and defecation impairment are resistant to treatment (drug therapy, physiotherapy, and behavioral therapy). Various methods of electrical stimulation can be indicated to such patients [8].

In 1963, Caldwell was the first to use anal sphincter electrical stimulation to correct urinary and fecal incontinence [9]. Subsequently, various alternative methods of invasive and noninvasive stimulation were proposed to correct urination and defecation dysfunction, namely, pelvic floor electrical stimulation using vaginal, anal, and surface electrodes, interferential therapy, magnetic field stimulation, transcutaneous tibial nerve stimulation, and sacral neuromodulation (SN) [10, 11].

SN is one of the promising methods in the treatment of urinary disorders of various origins. This is a minimally invasive technique for correcting nonobstructive incontinence and/or urinary retention, urgency, and frequent urination [11, 12]. In some countries, this method is licensed for the correction of fecal incontinence and chronic constipation in patients with ineffective conservative therapy [12].

SN was developed by American scientists Tanagho and Schmidt in 1982 [13]. Over the past 40 years, the implantation of sacral neurostimulators in adults has been performed in more than 300,000 patients [12]. Although the mechanism of action of SN is not completely clear, most authors believe that SN, apparently, affects the spinal and higher centers of regulation of defecation and urination through afferent signaling, and not through direct motor stimulation of target organs [14–16].

Currently, no randomized trials have characterized objectively the efficacy and safety of SN in the correction of urinary and defecation dysfunction in pediatric patients [17]; therefore, its use can be considered off label and only if all other treatment methods are ineffective [18–20].

The work aimed to analyze Russian and international literature data and present SN results in pediatric patients with urination and defecation disorders.

MATERIALS AND METHODS

Literature search was performed in the open electronic databases of scientific literature eLIBRARY, PubMed, and Cochrane Library using the keywords “bladder dysfunction,” “bowel dysfunction,” “neurogenic bladder dysfunction,” ‘neurogenic bowel dysfunction,” “functional constipation,” “neurogenic constipation,” “fecal incontinence,” “sacral neuromodulation,” “sacral neurostimulation,” “pediatric neuromodulation,” and “pediatric neurostimulation.” The selection of sources was mainly limited to 2002–2022.

By keywords, 87 literature sources were selected, and a final list of 57 (full text only) publications in Russian (1) and English (56) was formed. These publications contain information about SN and its results in pediatric patients with urinary and defecation disorders. Materials published before 2000 were included in the review if they contained significant historical data on SN. SN results are considered depending on the etiology (idiopathic and neurogenic). To form a sample by nosology in the analyzed papers, data on considering SN results were not sufficient.

RESULTS AND DISCUSSION

In 2001, Hoebeke et al. showed for the first time the possibility of using percutaneous SN in pediatric patients. They published SN results in 41 pediatric patients with neurogenic bladder. Six months after successful test stimulation, 28 children showed improvements, such as an increase in the cystometric capacity of the bladder, a decrease in the urination frequency, and an increase in the urinary retention period. A year later, a relapse was registered in seven pediatric patients, and the remaining 21 patients showed a significant improvement [21].

Most authors believe that neuromodulator implantation should be performed in two stages, namely, test stimulation and permanent implantation, because the test stage enables selection of stimulation parameters more accurately and avoid false-negative results [22]. According to various researchers, the duration of the test stimulation period ranges from 10 to 30 days [23, 24]. Moreover, some authors have described one-stage implantation of a stimulator in pediatric patients to reduce the number of repeated interventions and the X-ray load [25, 26].

Sacral neuromodulation in neurogenic dysfunction of urination and defecation

Guys et al. presented for the first time the results of a single, prospective, randomized (by urodynamic parameters) controlled study of the treatment outcomes of 42 pediatric patients with urinary incontinence associated with a neurogenic bladder, where group 1 received standard conservative therapy, whereas group 2 underwent SN. A year later, during follow-up examinations, nine pediatric patients with an implanted neurostimulator had improved intestinal motility, six had a feeling of a full bladder, five had no relapses of inflammatory processes

of the lower urinary tract during the entire follow-up period, and one had a decrease in urine leakage, although there was still the need for intermittent catheterization. In the control group, during the same follow-up period, no improvements during the therapy were observed. When comparing the results of urodynamic studies, no significant statistical differences were revealed, except for the functional bladder capacity, which was better in the control group, and leak point pressure, which was better in the SN group [27].

Based on data from a randomized crossover study of SN results in pediatric patients with neurogenic disorders of urination and defecation, Haddad et al. demonstrated that SN improved statistically significantly the treatment results for urinary and/or fecal incontinence compared with standard treatments [28]. However, similar to Guys et al., the researchers assessed the dynamics of the condition subjectively, according to the diary of urination and defecation. In contrast to Guys et al., Haddad et al. did not reveal any changes according to the urodynamic examination, except for a statistically significant increase in cystometric bladder capacity in the SN group compared with the conservative treatment group in both phases of the crossover study [28].

No detailed indications for SN based on anorectal manometry data have been formulated, and pronounced changes in manometric parameters do not correlate with the unsatisfactory SN results [29]. According to various authors, fecal incontinence improved in 63%–78% of patients who received SN [28, 30, 31]. However, in constipation of neurogenic origin, the efficiency of SN was low [32].

Indications for SN based on urodynamic examination data have also not been established, since at present, no urodynamic patterns have been identified, based on which good outcomes of SN can be predicted [33, 18].

Mason et al. believe that in patients with detrusor overactivity, SN results will be better than in patients with detrusor hypocontractility; however, they do not consider detrusor hypocontractility as a contraindication [34].

Based on the analysis of SN results in 21 patients with bladder dysfunction associated with congenital malformations of the spine and spinal cord, Pellegrino et al. believed that in the case of vesicoureteral reflux, dilatation of the upper urinary tract of >10 mm, and deterioration of kidney function over time, SN is not advisable [26]. Moreover, Chen et al. considered that vesicoureteral reflux is not a contraindication for SN. Moreover, according to these authors, SN causes a decrease in detrusor hyperactivity and a decrease in vesicoureteral reflux, which was confirmed by improved urodynamic examination data in the urinary retention phase. Based on the multivariate analysis, Chen et al. concluded that in patients with complications of congenital malformations of the spine and spinal cord such as chronic urinary retention, SN outcomes were worse than those with incontinence or urge to urinate. Improvement was registered in 26.09% of patients with urinary retention, 56.25% of those with urinary incontinence, and 58.82% of those with imperative urges. According to the assessment scale of neurogenic dysfunction of defecation, some improvements in defecation function were also noted [35]. The SN results reported by Chen et al. were slightly worse than the SN results in neurogenic bladder dysfunction published previously by other authors. This is consistent with the data reported by Pellegrino et al., who believed that regardless of the initial symptoms of urination disorders in patients with congenital malformations of the spine and spinal cord, the SN results will be worse than in other pathologies, leading to a neurogenic bladder [26]. The probable cause of the low efficiency of SN in patients with spinal dysraphia is the impaired formation of spinal sacral nerves that form the lumbosacral plexus, which serves as a source of innervation of the lower urinary tract [25]. van der Jagt described various variants of disorders in spinal nerve and lumbosacral plexus formation in patients with spinal dysraphia based on magnetic resonance imaging tractography [36].

No consensus on the timing of SN use after spinal cord surgery (or spinal and spinal cord injury) has been established for the treatment of urinary and defecation disorders. According to some authors, this period should be at least 12 months [27, 37]. Sievert et al. believe that SN can be performed during spinal shock in patients with complete spinal cord rupture, proving this by analysis of the SN results in 10 patients with complete spinal cord rupture. Compared with the control group, these patients were observed to have an increase in bladder capacity and a decrease in the frequency of urinary tract infections in a follow-up examination (on average, 26.2 months after SN initiation) [38]. The validity of this approach can be indirectly confirmed by experimental data obtained by Chen et al., who stimulated *n. pudendus* in dogs 1 and 6 months after a simulated complete rupture of the spinal cord. The study revealed that early stimulation (after 1 month) causes an increase in compliance and bladder capacity, and stimulation after 6 months is no longer effective [39].

In patients with partial spinal cord damage caused by spinal cord injury, SN is used to correct detrusor overactivity, nonobstructive urinary retention, detrusor-sphincter dysynergia, and fecal incontinence [17]. According to Lombardi et al., SN is more effective in patients with spinal cord injury grades D and C according to the ASIA spinal cord injury scale [40]. According to a meta-analysis performed by Hu et al., the efficiency of SN in partial spinal cord injury was 45% (95% CI 36%–55%, $p = 0.23$, $I_2 = 31\%$) in the test phase and 75% (95% CI 64%–83%, $p = 0.46$, $I_2 = 0\%$) with outpatient follow-up period of 8.4–61.3 months [41].

Sacral neuromodulation in idiopathic dysfunction of urination and defecation

Both in adults and children with failure of conservative treatment, SN is also used for idiopathic bladder dysfunction and functional defecation disorders [12, 42].

Humphreys et al. presented SN outcome in 23 patients with idiopathic bladder dysfunction. Stimulants were permanently implanted in 21 patients after successfully completing the trial period. Subsequently, stimulants were removed in two patients. Of the remaining 19 patients, 3 (15.79%) achieved complete regression of urinary incontinence; 13 (68.42%), improvement; 2 (10.53%), remained unchanged; and 1 (5.26%), deterioration. Among 16 patients with enuresis, 2 (12.5%) showed complete regression of these symptoms, 9 (56.25%) had improvement, 4 (25%) had unchange condition, and 1 (6.25%) had an increase in symptoms. Improvement occurred in 60% of the patients with urinary retention [43].

Roth et al. summarized the experience of SN in 18 patients with idiopathic bladder dysfunction (after the permanent implantation phase). For 27 months on average according to the diary of urination and defecation, urinary incontinence decreased or regressed in 88% of the patients, and imperative urge to urinate was registered in 69% of cases. Urinary retention and the need for intermittent catheterization persisted in 75% of patients despite SN [44].

Significantly better results (than those of Humphreys et al.) obtained by Roth et al. could be due to the different selection criteria used, which were not described in detail by these researchers, lack of randomization for urodynamic parameters, and variability of methods for analyzing the results.

Dwyer et al. performed a retrospective analysis of SN results in 105 pediatric patients, including 35 patients who had undergone bladder or urethral surgery before SN without improvement in urological symptoms and 9 patients who received ineffective intradetrusor injection of botulinum toxin A. In the course of SN, improvement was noted in 88%, 67%, and 66% of patients with urinary incontinence, frequent and/or imperative urges, and enuresis, respectively. According to the case diary, an increase in the frequency of defecation per week in patients with constipation was recorded in 79% of cases, and constipation regressed in 40% of cases. The mean follow-up period was 2.72 years [23].

van der Wilt et al. analyzed the treatment results of 30 pediatric patients with severe functional constipation. The average frequency of defecation increased from 5.9 to 17.4 times in the first 3 weeks after the implantation of the neurostimulator, and the episodes of encopresis on the Wexner scale and the intensity of abdominal pain decreased. During follow-up, which averaged 22.1 months, improvement during SN use was noted in 42.9% of patients [45].

The efficiency of SN does not depend on the presence or absence of fecal incontinence in pediatric patients with functional constipation [46]. Unlike adults, fecal incontinence in children is most often the result of poorly controlled functional constipation caused by colon overflow, and in connection with this, no studies have focused on the correction of this pathology associated with functional constipation by SN [47].

Sulkowski et al. presented the SN results in 29 pediatric patients with urination and defecation dysfunction of various origins and demonstrated the possibility of SN use in patients with anorectal anomalies. With SN application, 46% of patients with constipation due to the appearance of independent colon peristalsis stopped using appendicocecostomy for antegrade irrigation of the colon, and regression was registered in 10 of 11 patients with urological symptoms [48].

Ramage et al. conducted a systematic review of SN results, predominantly in pediatric patients with defecation disorders, and reported improvement in constipation in 79%–85.7% of patients, regression in 40% with impaired defecation frequency, and decreased frequency of fecal incontinence episodes in 75%. However, in 280 patients, 106 (38%) had complications, in which 72% of the cases required reintervention, with a follow-up period of 12–48 months [49].

Reoperations and complications of sacral neuromodulation

According to Pellegrino et al., the reoperation rate after SN in pediatric patients approaches 100%, which is attributed to battery replacement, implant migration during growth, device removal, etc. [26] Clark believed that implant migration can be the main cause of reoperations. According to his data, an increase in the child's height by an average of >8.1 cm (4–12.5 cm) led to the migration of the implant and/or electrodes and the need for revision [50].

Mason suggested that a low body mass index is a predisposing factor of reoperation because a thin layer of subcutaneous fat does not protect the neurostimulator and electrodes from damage during physical activity and frequent falls in young children compared with adolescents [34]. However, an opposite opinion was raised. Based on an analysis of SN in 65 pediatric patients, Fuch considered that no statistically significant correlations exist between the need for reoperation and body mass index, as well as age and sex [24].

Boswell et al. analyzed the long-term SN results in pediatric patients; of 187 patients, 154 reoperations were

performed in the period from 2002 to 2019. In this group, 83 revision interventions were performed, and 89%, 8% and 2% of these were caused by device malfunction, pain, and infection, respectively [51].

According to Rensing, who presented the SN results in 61 pediatric patients, 19.7% required reoperation during the follow-up period, which averaged 2.3 years [25].

Other authors also reported a frequency of reoperations lower than those of Boswell et al. and Ramage et al., which is probably due to the shorter follow-up period. Hadad et al. reported that 18% of 33 patients required reoperation within 15 months of follow-up [28]. Mason et al. reported a 23% reoperation rate in 30 patients over 15 months of follow-up [34], and according to Fuchs, of their 63 patients, 25% of cases received reinterventions within 1.9 years [24].

None of the above studies mentioned battery replacement, as patients probably did not use the device long enough to deplete the battery, which lasts 5–7 years depending on the stimulation program [52, 53]. This is indirectly confirmed by Groen et al., based on a 15-year follow-up period (median 11 years) of 18 pediatric patients, where 8 underwent revision for infection or lead failure, 2 had battery replacement, and 4 had device removal because of a malfunction [31]. Thus, reintervention was performed in 78% of cases, which coincided with the results presented by Boswell et al. [51] and Ramage et al. [49], that is, the frequency of reinterventions increases depending on the follow-up duration.

Quality of life in patients after sacral neuromodulation

Stephany analyzed SN results in 14 pediatric patients with urinary dysfunction and indicated a significant improvement in the quality of life based on the Pediatric Quality of Life scale, especially the psychosocial aspect, even if in 24% of patients who received SN, those with impaired pelvic organs required repeated interventions [54].

Lu et al. noted the high satisfaction of the patients' parents with SN results, assessed using the Glasgow Children Benefit Inventory questionnaire, including the parents of those pediatric patients who underwent repeated surgeries. A statistically significant improvement in quality of life scores on the GSS PedsQL (a scale of quality of life in pediatric patients with gastrointestinal symptoms) and the Fecal Incontinence Quality of Life Scale was found, while the latter correlated with a decrease in the incidence of fecal incontinence [46].

Removal of the neurostimulator

Some authors believe that the neurostimulator can be removed after the disappearance of clinical manifestations because SN can lead to a "cure of overactive bladder" in patients with an initially severe and refractory course [25, 43, 55]. Rensing et al. removed 11 stimulants during the 5-year postoperative period, 3 of them because of complications and 8 stimulants were removed after regression of symptoms. By regression, the authors meant the absence of urological symptoms when the stimulator was deactivated for 6 months [25]. Unfortunately, the results of the urodynamic studies before the removal of the stimulator were not included in this article.

Further research will indicate whether the improvements seen in pediatric patients are truly the result of neuronal remodeling induced by SN exposure [25, 43, 55] or whether the regression of urologic abnormalities is the result of the natural disease course, especially in cases of idiopathic hyperactive bladder [51].

CONCLUSION

Despite the successes achieved in the conservative and surgical treatment of patients with urination and defecation impairment of various origins, some patients are still resistant to treatment, which leads to an ever-increasing interest in SN. Although most authors report good and satisfactory results in the treatment of pelvic organ dysfunction using this method, the level of evidence for the efficiency of SN is low because of small and heterogeneous groups of patients described in the literature, lack of standard methods for selecting patients for SN and data analysis, and high reoperation rates. The emergence of new models of stimulators with rechargeable batteries [56] and improvement of the electrode implantation technique [57] in the future would reduce the frequency of reoperations in pediatric patients after SN.

Randomized trials are required to evaluate the efficiency and safety of SN in pediatric patients with urination dysfunction of various etiologies and resistant to standard conservative treatment protocols.

ADDITIONAL INFORMATION

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Author contributions. *A.M. Khodorovskaya* wrote the text of the article and searched and analyzed the literature sources. *A.V. Zvozil* performed the search and analysis of literature sources. *V.A. Novikov* created the study design and edited the article text. *V.V. Umnov, D.V. Umnov*, and *D.S. Zharkov* searched and analyzed the literature sources and performed stage editing. *S.V. Vissarionov* performed the final editing.

All authors made a significant contribution to the research and preparation of the article, as well as read and approved the final version before its publication.

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