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Research Article

Sacral Neuromodulation in Male Sexual Dysfunction – A Systematic Review

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Abstract:

Introduction: Contemporary patient care requires full consideration of sexual health as well. Sexual dysfunction has a high prevalence and significantly affects quality of life. The cost to the health care system is estimated to be high but has not yet been calculated with certainty. Therapy considers sexual appetence, sexual arousal, orgasmic experience in both genders, lubrication in women and erection in men. Sacral nerve stimulation (SNS) has been used primarily for neurogenic bladder dysfunction, idiopathic pelvic pain, nonobstructive urinary retention, and fecal incontinence. Effects have also been observed on various components of sexual function. Sexual function as a primary outcome parameter of SNS has not been studied to date.

Methods: For a systematic literature search, the Healthcare Databases Advanced Search (HDAS) platform was used, employing the Medline, EMBASE, and CINHAL search engines, and considering only publications from international peer-reviewed journals.

Results: We identified 16 studies with inclusion of a total of 662 women and 40 men in which potential effects of SNS on sexual function were noted when used in other indications. For the female sex, there was evidence for significant improvements in sexual function. The very weak data situation for the male sex so far only allows to assume similar effects. In any case, it remains unclear whether these effects are primary or secondary to SNS.

Discussion: SNS affects urinary bladder emptying, urinary bladder continence, pelvic pain, and fecal continence and defecation. The direct anatomical and physiological relationship between these organ systems and sexual function raises the question of whether there is a primary effect of SNS on sexual function. High-quality studies with sexual function as the primary endpoint should verify this.

Keywords: sexual dysfunction; arousal; orgasm; erectile dysfunction; sacral nerve modulation

Introduction

Sexual function includes physiological and psychological components [1]. In women, sexual appetence, sexual arousal, orgasmic experience, and lubrication can be distinguished; in men, libido, erection and ejaculation, and orgasmic experience are commonly defined [2,3]. Accordingly, disorders of sexual function may affect any or all aspects of sexual function. The WHO defines sexual health as the physical, emotional, mental, and social well-being related to sexuality [4]. Therefore, contemporary patient care requires full consideration of sexual health as well. In both gynecology and urology, sexual function is an integral part of diagnosis and treatment. However, sexual function should also be considered in specialties that have an anatomical and also functional relation to sexual function (colorectal surgery, oncology, radiotherapy).

Sexual function has a high impact on quality of life [5]. Data on the overall costs of treating sexual dysfunction are open [6]. Extensive data exist on the

treatment costs of erectile dysfunction, and these are estimated to be high overall [7].

Data on the incidence of sexual dysfunction show high variance for both genders due to different study designs. For example, estimated prevalences for orgasmic dysfunction in women are 16-25%, and premature ejaculation and erectile dysfunction are the most common impairments in men [8,9]. A summary in Anderson D et al provides some guidance: 52% of all men between 40 and 70 years of age report erectile dysfunction of varying degrees [2].

Tanagho et al. first described chronic sacral nerve stimulation (SNS) as a therapeutic alternative for neurogenic bladder in 1988 [10].

The therapy has been approved in Europe since 1994. As a minimally invasive therapy for urinary urge incontinence [11] of idiopathic 5 pelvic pain [12-14] and nonobstructive urinary retention, there is now a wide therapeutic spectrum for sacral nerve stimulation (SNS) in urology/urogynecology. Since the initial description of the successful treatment of fecal incontinence in 1995 by Matzel et al [15], its dissemination in coloproctology has also been taking place with high dynamics. In contrast, SNS for the indication "non-obstructive defecation disorder" [16] has shown only limited success and is now rarely used for this indication.

SNS involves permanent subsensory electrical stimulation of the S 3 or S 4 nerve roots. This is achieved by placing a percutaneously implantable electrode immediately presacral to the S 3 or S 4 spinal nerves. The effect is checked in a test phase lasting several weeks using a test electrode and an external pulse generator. The indication for full implantation is then only given if there is significant symptom relief under the test stimulation. In this case, a pacing device is then implanted ipsi- or contralaterally, below the dorsal iliac crest, and continuous pacing is started [17]. Both a lithium battery-powered implant (INTERSTIM II 3058, Medtronic, Minneapolis, MN, USA) and rechargeable systems (Axonics r-SNM System, Axonics Modulation Technologies, Inc., Irvine, CA, USA; INTERSTIM 3058 (Micro 97810), Medtronic, Minneapolis, MN, USA) are approved.

Extensive studies exist on the question of the mechanism of action, but a definitive clarification is not yet available. Nerve modulation of somatic and autonomic efferents as well as afferents [18, 19], but also modulation of central areas responsible for continence function [20-22] appear to be the essential basis.

When SNS is used for the treatment of urinary and fecal continence and idiopathic pelvic pain, improvements in sexual function have also been observed from the beginning [23]. However, it has not yet been clarified whether this is a secondary effect of improvement in 6 the aforementioned conditions or direct effects on sexual function [24, 25]. Therefore, we would like to summarize the current state of research on possible effects of SNS on sexual function in this review. Since, on the one hand, anatomical and physiological similarities exist between the genders and thus findings can be derived independent of sex, and, on the other hand, internationally sex-segregated data are only available on a total of 22 men, we include studies on both genders. We discuss possible perspectives for a targeted use of SNS for the therapy of sexual dysfunction then with a focus on the male gender.

To date, sacral nerve stimulation (SNS) has been used primarily for neurogenic bladder dysfunction, idiopathic pelvic pain, non-obstructive urinary retention and fecal incontinence. Effects on various components of sexual function have also been observed. We aim to evaluate whether sexual function is a primary outcome parameter of SNS, as it has not been studied so far.

Methods

A literature search was performed using the Healthcare Databases Advanced Search (HDAS) platform. The search engines Medline, EMBASE and CINHAL were used. Only publications from international journals that use a peer-review process were considered. The terms "sex", "neuromodulation", "nerve stimulation", and "sacral" were used for the search query. Case reports were not included. The last update of the literature search was on 07/01/2023. Both genders were considered in the literature search. An ethics vote was not required.

Results

Sexual function as a primary outcome parameter of SNS has not been studied previously. However, evidence of improvements in sexual function in both genders during the use of SNS has been repeatedly published since 2005 for the indications of urinary urgency incontinence and urinary bladder voiding dysfunction [22-34], fecal incontinence [23, 34, 35], and idiopathic pelvic pain [27, 28, 36]. After few reviews could only provide a rough overview of the impact of SNS on sexual function [36, 37, 38], Khunda et al. published the first high-quality meta-analysis in 2019 [39].

Overall, there are evaluated results from all 16 studies reviewed on 706 patients (662 women and 40 men). The vast majority of data exists on urologic indications for SNS "urinary bladder voiding dysfunction (overactive bladder, chronic retention, and idiopathic pelvic pain). Only 9.1% of indications for SNS are for fecal incontinence (61 patients).

The most commonly used instrument for evaluation in the men studied was the International Index of Erectile Function (IIEF-5) [40]. In women, the validated female sexual function index (FISI) [42], in rare cases the Questionnaire for Screening for Sexual Dysfunctions, QSD; [43], the Golombok Rust Inventory of Sexual Satisfaction (GRISS) [44], the Symptom Checklist-90 (SCL-90) [45], the Maudsley Marital Questionnaire (MMQ) [46] and the McGill-Mah Orgasm Questionnaire) [47] were predominantly used. In one paper [22], the Pelvic Floor Distress Short Form (PFIQ-7), Pelvic Floor Impact Questionnaire Short Form (PFD-20), and Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire Short Form (PISQ-12) instruments were used as a supplement. Jadav et al applied the 9 electronic Personnel Assessment Questionnaire - Pelvic Floor (ePAQ-PF) [51]. Sexual satisfaction before and during SNS was the focus in each case.

Because there is explicitly no evidence for a primary effect of SNS on sexual function, all publications attempted to identify possible circumstantial evidence for a primary relationship between neuromodulation and the almost universally observed improvement in sexual function.

The meta-analysis by Khunda et al [39] distinguishes between primary and secondary outcome parameters. For the primary outcome parameters, significant improvements in the standardized mean difference (SMD) of sexual function (-0.39; 95% CI: -0.58 to -0.19; $p = 0.0001$) and a significant reduction in sexual complaints (OR 0.22 (0.09, 0.53); $p = 0.0009$; heterogeneity $I2 = 0\%$) were found for SNS. Subgroup analysis revealed significant effects of SNS on sexual function when using only the 5 highest quality studies (SMD = -0.40 (-0.59, -0.21); $p < 0.0001$; $I2 = 0\%$), when excluding all studies with neuropathic patients (SMD = -0.34 (-0.57, -0.11); $p = 0.004$; $I2 = 49\%$), when excluding all studies with pelvic pain (SMD = -

0.42 (-0.68, -0.17); p = 0. 001, I2 = 28%), when excluding all studies with use of a modified stimulation method (SMD = -0.40 (-0.62, -0.19); p = 0.0002; I2 = 18%), when excluding all studies with industry support (SMD = -0. 49 (-0.88, -0.11); p = 0.01; I2 = 38%), and only marginally significant when using only those studies with a mean patient age < 51 years (SMD = -0.75 (-1.49, 0.00); p = 0.05; I2 = 68%). Significant improvements in sexual function were seen in all studies using SNS for urinary bladder dysfunction (SMD = -0.42 (-0.65, -0.20); p = 0.0003; I2 = 44%), but not in the two studies included by Khunda et al. using SNS for fecal incontinence (SMD = -0.16 (-0.60, 0.27); p = 0.46; I2 = 0%). A subgroup analysis 10 included only studies that used the FSFI: there was a significant improvement for sexual function during SNS (SMD = -0.44 (-0.75, -0.14); p = 0.004; I2 = 49%). For secondary outcome parameters, according to the FSFI, there was a significant trend for improvement in the "appetence" domain, significant improvement in the "desire," "arousal," "satisfaction," and "pain" domains, but not for the "lubrication" and "orgasm" domains. Components of the "electronic Pelvic Assessment Questionnaire" (ePAQ) were examined supplementally: The effects of urinary bladder symptoms, vaginal symptoms, and dyspareunia on sexual function did not change significantly after SNS (SMD = 0.38; -0.06 to 0.82; p = 0.09; I2 = 0%, (SMD = 0.05; -0.80 to 0.91; p = 0.90; I2 = 53%, SMD = 0.03; -0.41 to 0.46; p = 0.90; I2 = 0%). The meta-analysis by Khunda et al. thus confirmed the conclusions of previous research groups dealing with this topic [36, 37] with regard to female sex. All reviews on the topic [36-38] concluded that there was evidence for efficacy of SNS on sexual function when used to treat other indications. A recent original paper from Saudi Arabia found significant

improvement in sexual function in patients of both genders regardless of age and diagnosis [40]. Since it cannot be differentiated whether these are only secondary effects, high-quality studies with the primary outcome parameter sexual function are required to clarify this issue.

The original papers are summarized in Table 1.

Table 1: Overview of existing studies (modified according to (41))

Study	Study type	Number of patients w: m with complete evaluation	Age in mean (rounded without comma)	Method	Mean duration of follow-up in months	Indication for SNS	Result regarding SF	p-Value
Banakhar et al. 2021 [40]	**Prospective cohort study**	**w: m 8: 5**	**47**	**FSFI IIEF-5**	**4 (exactly dated programmed order)**	**Urinary bladder voiding dysfunction (overactive bladder and chronic retention) and idiopathic pelvic pain, impotence (1 patient m)**	**Significant improvement in FSFI score in all female patients p=0.013 and IIEF-5 in all males p=0.003 4 months after surgery**	**Desire p = 0,002 Arousal p = 0,01 Orgasm p = 0,012 Satisfaction p = 0,015**
De Oliveira et al. 2018 [23]	**before/after prospective clinical study**	**w: m 15: 9**	**41**	**FSFI IIEF-5**	**20,7 Median**	**Urinary bladder voiding dysfunction (overactive bladder and chronic retention) and idiopathic pelvic pain, fecal incontinence (1 patient).**	**Improvement in all domains of the FSFI - but not all significant. Total Score IIEF-5 improved in 4 men (p 0.06)**	**Desire p = 0,18 Arousal p = 0,11 Lubrication p = 0,04 Orgasm p = 0,13 Satisfaction p = 0,46 Pain p = 0,67**
Banakhar et al. 2014 [24]	**before/after prospective clinical study**	**23 Women**	**51**	**FSFI**	**4 Mean (queried by Khunda et al., see there).**	**Urinary bladder voiding dysfunction (overactive bladder and chronic retention and "frequency urgency syndrome")**	**Total score significantly improved P = 0,011**	**Desire p = 0,014 Arousal p = 0,067 Lubrication p = 0,625 Orgasm p = 0,035 Satisfaction p = 0,076 Pain p = 0,134**
Gill et al. 2011 [25]	**before/after prospective clinical study**	**10 women (after exclusion of sexually inactive women)**	**59**	**FSFI (+FSHQ)**	**3,2 Mean**	**Urinary bladder voiding dysfunction (overactive bladder and chronic retention)**	**Total score significantly improved P = 0,023**	**Desire p = 0,25 Arousal p = 0,047 Lubrication p = 0,313 Orgasm p = 0,688 Satisfaction p = 0,031 Pain p = 0,375**

Parnell et al. 2015 [22]	**before/after prospective clinical study**	**33 Women**	**67**	**FSFI (+ PFIQ-7, PFD-20, PISQ-12)**	**1,5**	**Urinary bladder voiding dysfunction (overactive bladder and chronic retention)**	**Improvement of sexual function in sexually active women**	**PISQ-12: Sexualfunktion verbessert p = 0,034 PFDI-20 verbessert p = 0,05 PFIQ-7 verbessert p = 0,05**
Van Voskuilen et al.2012 [34]	**before/after prospective clinical study**	**8 Women**	**54**	**QSD (+SCL-90)**	**Routine Follow-up ?**	**Urinary bladder voiding dysfunction (overactive bladder and chronic retention, urgency-frequency syndrome) and fecal incontinence (1 patient)**	**Weak improvement overall**	**Improved orgasm rating but not significant**
Lombardi et al.2008 [33]	**before/after prospective clinical study**	**31 Women**	**38**	**FISFI**	**3**	**"Lower urinary tract symptoms" (LUTS).**	**Over all significant improvement in sexual function**	**Total Score bei neurogenics p = 0,018 Total Score bei idiopathics p = 0,024 Female sexual distress scale FSDS toal score neurogenics p = 0,02 FSDS total score idiopathics p = 0,032**
Lombardi et al. 2008 [64]	**before/after prospective clinical study**	**22 Men**	**43**	**IIEF-5**	**3**	**„Lower urinary tract symptoms "(LUTS**	**„Remarkable and long-lasting improvement of erectile function in 30 % of patients"**	**Median IIEF-5 score of group A (Neurogenics) shifted from 14.6 (range 11–18) to 18 (range 12–23) (P < 0.02). Five of group A (35.7%) (non-obstructive retention) median score of 14.6 presurgery vs. 22.2 postSNM, with an average increase of 52% (range 27.8–100%). The median IIEF-5 score for group B (Idiopathics) varied from 15.5 to 18. Two of them (25%) reached a median score of 22.5 (range 22–23) compared to 15.5 (range 15–16) presurgery, with a median difference of 45.2% (range 43.6–46.7%).**

Pauls et al. 2007 [30]	**before/after prospective clinical study**	**7 Women**	**50**	**FISFI**	**5,7**	**Urinary incontinence and urgency frequency**	**Sexual frequency increased p 0,047 FSFI total score significant verbessert p = 0,002**	**Desire p = 0,004 Arousal unverändert Lubrication p = 0,005 Orgasm p = 0,043 Satisfaction 0,007 Pain p = 0,015**
Yih et al. 2013 [28]	**before/after prospective clinical study**	**167 Women**	**54**	**FISFI (+ ICSI-PI GRA)**	**6**	**Urinary bladder voiding dysfunction (overactive bladder and chronic retention), painful bladder syndrome/interstitial cystitis, pelvic pain**	**FSFI total score significantly improved p = 0.0044**	**Patients with FSFI < 26 improved significantly in total score p = 0,0001 Desire p = 0,047 Orgasmus p = 0,0051 Satisfaction p = 0,0001 Pain p = 0,011 Patients with FSFI >26 in the total score slight but significant deterioration**
Signorello et al. 2011 [29]	**before/after prospective clinical study**	**12 Women**	**62**	**FISFI**	**36,3**	**Urinary bladder voiding dysfunction (overactive bladder and chronic retention)**	**Significant improvement of FSFI total score p = 0.012**	**Desire p = 0,019 Arousal p = 0,031 Lubrication p = 0,01 Orgasm p = 0,052 Satisfaction p = 0,040 Pain p = 0,198**
Zabihi et al. 2008 [27]	**before/after prospective clinical study**	**36 Women**	**50**	**FISFI**	**6**	**Urinary bladder voiding dysfunction (overactive bladder and chronic retention) and idiopathic pelvic pain.**	**Total FSFI score improved p = 0.05**	**Desire p = 0,35 Arousal p = 0,03 Lubrication p = 0,03 Orgasm p = 0,04 Satisfaction p = 0,06 Pain p = 0,11**
Siegel et al. 2016 [31]	**before/after prospective clinical study**	**189 Women**	**57**	**OABqol**	**36**	**Urinary incontinence (overactive bladder) and "urgency frequency".**	**In women, significantly better sexual function after SNS than after drug therapy p < 0.05**	**-**
Ferhi et al. 2008 [26]	**before/after prospective clinical study**	**w: m 37: 4**	**53**	**Telephone interview with own questionnaire**		**Urinary bladder voiding dysfunction (overactive bladder and chronic retention)**	**41.5% of patients reported improved sexual function**	**-**
Ingber et al. 2009 [50]	**before/after prospective clinical study**	**27 Women**	**50**	**FISFI**	**6**	**Urinary incontinence (overactive bladder) and urgency frequency Pelvic pain (painful bladder syndrome)**	**FSFI total score improved but not significant p = 0.220**	**Overall, no significant improvement in SF by SNS in heterogeneous population.**

Jadav et al. 2013 [51]	**before/after prospective clinical study**	**43 Women**	**57**	**e-PAQ**	**6,8**	**Fecal incontinence**	**53.3% of patients reported improved sexual function**	**Significant improvement in vaginal and bowel-related sexual health p = 0.005**
Jarrett et al. 2005 [35]	**Retrospecti ve clinical study**	**16 Women**	**56 (median)**	**Sex Life Questionn aire**	**Routine follow-up**	**Fecal incontinence**	**Median % improvement in sex life: 40**	**-**

e PAQ electronic Personal Assessment Questionnaire, *FSDS* female sexual distress scale, *FSFI* The Female Sexual Function Index, *PFDI-20* Pelvic Floor Distress Inventory short form 2, *PFIQ 7* Pelvic Floor Impact Questionnaire—short form 7, *PISQ* Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire, *QSD* Questionnaire for Screening for Sexual Dysfunctions, *SNS* Sakralnervenstimulation, *MW* Mittelwert, *ICSI-PI GRA* Interstitial Cystitis Symptom-Problem Indices with patients rating overall change in sexual functioning on scaled global response assessments, *IIEF* International Index of Erectile Function, *OAB-qol* International Consultation on Incontinence Modular Questionnaire.

Discussion

SNS has been firmly established for the treatment of urinary bladder dysfunction, idiopathic pelvic pain, and fecal incontinence. Clinical prospective studies on this since 2005 also investigated possible effects on sexual function. Improvements in sexual function during the use of SNS were predominantly found. In contrast, no results are yet available on the primary use of SNS for the improvement of sexual function. In addition, the existing studies have significant limitations: the number of patients included is small overall, and this is especially true for the male gender. Individual sections of the questionnaires remained open, as some studies included sexually inactive women. Other methodological shortcomings were the lack of baseline values for blood hormone concentrations [33], a lack of concordance between two applied measurement tools [30], an insufficient discussion of the clinical relevance of changes in survey results in most studies, only reporting of score results in follow-up without baseline values, missing data of age and type of voiding disorder [25, 29]. Interpretation of the FSFI used in most studies is not standardized [52].

Further considerations of efficacy in both genders are initially based on neurophysiological similarities in sexual function in both genders. In both men and women, high co-incidences with sexual dysfunction are observed for urinary incontinence and fecal incontinence or defecation disorders [8, 54-56]. Because these underlying conditions are treatment indications for SNS, when sexual function improves, it is difficult to differentiate whether the improvement is a primary effect of SNS or secondary to relief/cure of the underlying condition. Observations exist of significant correlations between improvements in urinary bladder function and sexual function [29]. However, other studies have not confirmed this correlation [24, 30].

An association of urinary tract disorders with impaired sexual arousal and pain during sexual intercourse [57] as well as between fecal incontinence and reduced sexual appetence, lubrication disorders, impaired orgasmic experience, pain and discomfort during sexual intercourse [55] could be clearly demonstrated. For example, 60% of 350 women with urinary incontinence surveyed reported urine leakage during intercourse and described it as significantly affecting sexual life [56]. A review of 21 studies demonstrated improvements in sexual function after surgical therapy for stress incontinence [55]. Positive effects of drug therapy for urinary urge incontinence on sexual function were shown in another review [58].

Patel et al [59] found lower correlations between impairments in sexual function in patients with rectal/sphincter dysfunction compared to those observed in urinary bladder dysfunction. In contrast, Imhof et al [54] presented a clear correlation also to fecal incontinence. Only two studies with a total of 59 participants receiving SNS for fecal incontinence examined the impact on sexual function. Jadav et al. demonstrated significant improvement in vaginal and bowel-related sexual health [51]. However, the study group used an online questionnaire (ePAO) without sufficient validation for sexual function. Jarret et al. also found evidence for improvements in sexual function in patients with SNS for fecal incontinence therapy [35]. However, due to methodological flaws, the results were also not included in the meta-analysis by Khunda et al. Despite small patient numbers and low-quality data on this issue, possible limitations in improving sexual function in patients with SNS for fecal incontinence can be discussed: As long as a patient has to fear a possible loss of stool, it is conceivable that this concern alone significantly limits sexual experience. Thus, improvements in sexual function may be achieved by SNS only if SNS can completely eliminate fecal incontinence. However, this is the case in only a few patients [35].

Overall, more studies exist with evidence for improvements in sexual function when SNS is used for urinary bladder dysfunction than when used for coloproctologic indications (Table 1).

Considering all the results to date, confounding should be discussed: Improvements in sexual function during SNS for other indications could arise as secondary effects.

Considerations of the mode of action in improving sexual function can so far only be speculative, since the mechanism of action of SNS for improving the indication of urinary bladder function, stool retention, defecation function, and pelvic pain, which has been used so far, has not been fully elucidated. However, an effect of neuromodulation in the pelvis on the complex processes of sexual function is suggested. Sympathetic nerve fibers from the hypogastric plexus inhibit urinary bladder contraction and excite urethral and urinary bladder base smooth muscle. The sympathetic nervous system controls pelvic contraction during orgasm [60]. Parasympathetic nerves reach the pelvic plexus and urinary bladder wall via the pelvic nerves. These cause urinary bladder contraction [61]. In both genders, parasympathetic nerves are involved in smooth muscle relaxation. The vasodilation thus caused causes lubrication as well as swelling of the vagina and clitoris [60, 62] and erection in males [59, 61]. The pudendal nerve contains sensory and motor fibers of the pelvic floor [57]. Afferents from all pelvic organs as well as the clitoris, perineum, penis, and lower rectum reach the central nervous system via S2-4 [60, 62, 63]. These neural pathways are stimulated by the SNS. The afferent and efferent innervation of female sexual response could be addressed by neuromodulation in S2-4 [62-63].

Due to limited data and partly insufficient study quality, no selection can be made for the indication of SNS for individual components of sexual dysfunction (loss of libido, premature ejaculation, erectile dysfunction, anorgasmia, lubrication disorders, vaginismus, etc.).

Data on the improvement of erections in men are very limited. To date, there are very few studies that have collected this in small cohorts [64]. It is not possible to make a statement about potential causal relationships based on the existing literature. Further studies with significantly higher case numbers are needed here.

Conclusion for practice

Sexual function is an essential component of overall health.

Sacral nerve stimulation can be used very effectively in the treatment of urinary bladder dysfunction, fecal incontinence, and idiopathic pelvic pain.

There is preliminary evidence of a possible improvement in erection in men as well, but the data are still very limited.

It is unclear whether this is a primary or secondary effect.

We are planning a study to investigate primary effects of sacral nerve stimulation on sexual function in both genders.

Compliance with ethical guidelines

Conflict of interest

The authors declare no conflict of interest.

This paper does not include studies on humans or animals.

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