Transvaginal Pudendal Nerve Blocks in Patients With Pudendal Neuralgia: Two-year Follow-up Results

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Abstract

Purpose: Pudendal neuralgia (PN) is an extremely painful neuropathy of the pudendal nerve resulting in a negative impact on a patient's quality of life. The aim of this study is to evaluate the 2-years outcomes of repetitive doses of the transvaginal pudendal nerve injections (PNI) and to compare the success of the PNI concerning anatomical levels (endopelvic and extrapelvic portion) of the pudendal nerve pathology.

Methods: This retrospective longitudinal cohort study consists of patients with PN diagnosed with the first four essential Nantes criteria. Diagnostic PNI was performed on 67 patients to fulfill the fifth criteria of Nantes. After the drop-outs, further analyses were carried out with a total of 56 patients.

Results: The efficacy of the PNIs significantly declined over time. Pudendal nerve blocks provided a significant decrease in pain scores; however, this decrease lost its strength significantly in the 24th month. The intervention was more effective in entrapments of the pudendal nerve between sacrospinous and sacrotuberous ligaments or below (Level-2) when compared to the injuries in the endopelvic part (Level-1). More than 50% pain reduction continued in five patients with pathology at Level-1 and 24 patients with pathology at Level-2.

Conclusion: Repeated PNIs could provide a significant decrease in pain scores for both short and long-term periods. However, the efficacy of the PNIs declined over two years. The success of PNIs may be affected by the anatomical level of the nerve injury; therefore, interligamentous pudendal nerve entrapment cases have more benefits than the cases of pudendal nerve entrapment in the endopelvic part. However, it is recommended to perform therapeutic nerve blocks even in patients with suspected endopelvic pudendal nerve pathology before the referral to surgery.

Introduction:

Pudendal neuralgia (PN) is an extremely painful neuropathy of the pudendal nerve. Pain is often described as a burning, sharp, and shooting sensation, while, as in many entrapment syndromes, numbness and/or paresthesia may occur on the anatomic pathways of the nerve [1]. Besides all these, PN-associated symptoms, such as hesitance, urgency, painful bowel movements, constipation, and sexual dysfunction, can accompany perineal pain, negatively impacting the patient's quality of life [2–4]. Several studies reported that most patients are diagnosed after two to 10 years of symptoms of the onset of the PN [3, 5, 6]. Difficulties encountered in the treatment of patients suffering from PN are usually a result of its delayed diagnosis.

Different etiological mechanisms may be involved in the development of the PN [7, 8]. Cumulative and recurrent mechanical microtrauma is the most common cause of PN [1]. Mechanical trauma such as compression, stretching, or irritation of the pudendal nerve may occur anywhere along the nerve pathway from the sacral roots to the end organ. It is potentially challenging to determine the exact site of pudendal nerve injury. Filler et al. [6] has categorized the pudendal nerve entrapment syndromes into four subgroups based on the anatomical location of the entrapment: Type I, is the entrapment at the exit of

the greater sciatic notch; Type II, is the entrapment at the level of the ischial spine, sacrotuberous ligament, and lesser sciatic notch entrance; Type III is the entrapment in association with internal obturator muscle spasm at the entrance of the Alcock canal; Type IV is the distal entrapment of terminal branches. After then, Pereira et al. [9] studied PN according to the segmental anatomy of the pudendal nerve. Recently, Neuropelveology has been introduced as a new discipline focused on determining the level of the lesion (below, in, or above the pelvis) [10]. Entrapment of the endopelvic part of the pudendal nerve may cause similar perineal or perianal pain with the extrapelvic pudendal nerve entrapment. Additionally, the nerve pathology in the endopelvic portion should be considered in the presence of persistent PN when accompanied by sciatica [11, 12].

Long-lasting treatment modalities have been challenging in the pain management of the PN. Repeated blockage of the pudendal nerve with local anesthetics plays an essential role in the treatment of PN [13]. Different routes of injections, and various types of image-guided pudendal nerve injection (PNI) techniques, which intend to infiltrate local anesthetic agents within proximity to the corresponding nerve, were described previously [14–19]. Recently, our pelvic pain workgroup reported that finger-guided transvaginal PNI might be an alternative approach to the ultrasound-guided technique, as a safe and effective treatment for PN management [15].

To date, most studies in the field of PN have focused on diagnosis [20, 21], and the description of the injection techniques [18, 19, 22–24]. Such reports, however, have been insufficient to assess the long-term effects of the PNI. Thus, we hypothesized that repetitive doses of transvaginal PNI have short and long-lasting effects in patients with PN. To the best of our knowledge, the present study is the first report evaluating the success rate of the repetitive doses of the transvaginal PNI in two years after the treatment was completed. The secondary aim of the present study was to compare the success of the PNI concerning suspected anatomical levels (endopelvic and extrapelvic portion) of the pudendal nerve pathology.

Methods:

This retrospective longitudinal cohort study was conducted with self-referred patients who underwent PNIs for a therapeutic purpose and followed up for two years at the Obstetrics and Gynecology Department between November 2016 and December 2020. The study protocol was approved by the institutional ethics committee (registration number: 6.11.2020, 22/24), and written informed consent was obtained as a routine procedure before all interventions.

Patient selection:

Women admitted to the outpatient clinic with a complaint of chronic pelvic pain underwent clinical examination by combining gynecological, urological, and neurological evaluation with a multidisciplinary perspective. Patients suspected of PN, according to the first four essential Nantes criteria [21], were referred to a senior neuropelveologist (AK) and underwent a detailed neuropelveological assessment. As a part of the neuropelveological work-up, patients were evaluated to determine the level of the lesion (the

endopelvic and extrapelvic portion of the pudendal nerve) [10]. The portion of the pudendal nerve from the sacral plexus to the ischial spine level was defined as the endopelvic portion of the nerve (Level-1). The extrapelvic portion of the pudendal nerve was defined as the area from the sacrospinous ligament until the end organ (Level-2). (Figure-1) After the neuropelvic assessment, a single dose of PNI was offered for diagnostic purposes to define the patients who fulfill the fifth criteria of Nantes [21]. Then further repeated doses of the therapeutic PNIs were continued with the patients who fulfilled all the five criteria of Nantes.

Data collection:

All patients' data were retrieved from both the hospital database and the International Pelvic Pain Society assessment forms.

Description of the transvaginal pudendal nerve infiltration technique:

The patients underwent therapeutic repeated PNIs twice for three weeks apart if they responded to the initial diagnostic PNI, as with the previously reported technique for transvaginal PNI.¹⁵

After the patients were placed in the supine lithotomy position, vaginal asepsis was provided using a 10% povidone-iodine solution. The sacrospinous ligament was palpated by the index and middle fingers to guide the needle through the vagina. The needle was advanced over the same route with the other hand while still palpating the sacrospinous ligament. A needle was directed posteromedially to the ischial spine at a depth of 10 mm. Standardized doses of a mixture of local anesthetic (8 mL of 0.5% bupivacaine and 2 mL of 8 mg dexamethasone) using a 20-gauge, 12-cm needle (Uniplex; Pajunk, Gelsinger, Germany) was applied following the negative aspiration test. The function of a positive PNI was assessed 30 minutes after placing the PNI using sensory tests with both pinprick and alcohol swab tests.

Outcome measures:

Characteristics of patients and pain: The age, parity, body mass index, duration of pain, events thought to be the initiator of their pain (obstetric history, vaginal surgery), associated symptoms (dysmenorrhea, dyspareunia, pain worsened by sitting position, dysuria, dyschezia, sciatica, buttock pain, suprapubic pain).

Pain intensity scores: The pain intensity was assessed through face-to-face interviews. Pain intensity was evaluated using an 11-cm visual analog scale (VAS) (0: no pain; 10: the worst pain ever) [25]. VAS pain scores were calculated as the mean pain intensity scores at least one week before the procedure and at the 1st, 3rd, 6th, 12th, and 24th months after the therapeutic blocks were completed.

Pain improvement: Effectiveness of the PNIs' was defined as $\geq 50\%$ improvement of the initial pain, and relative improvement was defined as 30–50% improvement of the initial pain [26]. Treatment failure was defined as the return of pain to its worst condition or pain reduction less than 30% of the initial pain. Pain

improvement was evaluated at the 1st, 3rd, 6th, 12th, and 24th months after therapeutic blocks were completed.

Estimated anatomic level of the pudendal nerve insult: The endopelvic portion of the pudendal nerve insult was clinically suspected as with the following findings: (1) pain radiation in the sciatic nerve distribution, (2) induction of the triggered pain by vaginal palpation of the pudendal nerve below the sciatic spine, (3) the presence of slight sensory disturbance in the sacral dermatomes, in case of the exclusion of disc herniation and other neurologic pathologies. The extrapelvic portion of the pudendal nerve pathologies was diagnosed with the following findings: (1) no pain radiation in the sciatic nerve distribution dermatome (2) no sensory disturbance in the sacral dermatomes, (3) if the pain was limited in the area of the perineal dermatome.

Statistical analyzes:

The Statistical Package for the Social Sciences (SPSS), version 20.0 (2011, IBM Corp., Armonk, NY, USA), was used for statistical analysis. Results were presented as medians and interquartile ranges (IQR) for numerical data and frequencies and percentages for categorical variables. The compatibility of numerical variables to normal distribution was evaluated using the Kolmogorov-Smirnov test.

The Friedman test was performed to determine whether there was a difference between the VAS scores measured over time. The Wilcoxon Signed Ranks test was used to compare VAS scores before and after interventions, while the Fisher's exact test was used for comparing categorical variables. A p -value of <0.05 was considered sufficient for statistical significance.

The sample size calculation was based on the primary outcome VAS scores. Taking an effect size of 0.35, a error of 0.05, the correlation among repeated measures as 0.5, the numbers of measurements as 5, and the number of groups as 3, 51 participants are required to achieve a power of 80% for conducting between factors repeated measures ANOVA. By considering the possible losses during the follow-up period, the study was carried out with 59 patients [27].

Results:

A total of 879 women were admitted to the clinic with a complaint of chronic pelvic pain and underwent a multidisciplinary clinical examination. Accordingly, 79 patients were suspected of PN with regards to the first four essential Nantes criteria. Of those offered diagnostic PNIs to fulfill the fifth criteria of Nantes, 67 accepted the intervention and underwent unilateral local anesthetic diagnostic PNI. Six patients did not respond to the diagnostic block, and then the remaining 61 patients, who responded to the diagnostic block, were offered repeated doses of therapeutic PNIs. Two of the 61 patients refused further therapeutic injections, one patient got pregnant, and two patients were lost to follow-up during the two-year follow-up period. After excluding these patients from the study, further analyses were carried out with a total of 56 patients. (Figure-2)

The median (IQR) age of participants was 37 (31 – 42) years, and the median (IQR) body mass index was 25.6 (23.0 – 28.3) kg/m². The median (IQR) pain duration was 30 (12 – 66) months. Most of the participants had no history of previous vaginal surgery (n=56), and in 40 patients, there was no pain-inducing factor (Table-1). The effectiveness of the PNI significantly declined over time (Table-2). Pudendal blocks provided a significant decrease in VAS scores; however, this decrease lost its strength significantly at the 24th month (Figure-3, Table-3). The intervention was more effective in entrapments of the pudendal nerve between sacrospinous and sacrotuberous ligaments or below (Level-2) when compared to the injuries in the endopelvic part (Level-1) (Table-4).

Discussion:

The main finding of this study was that the finger-guided transvaginal repeated PNIs provided a significant decrease in VAS scores for both short and long-term periods (two-year follow-up). However, this decrease in VAS scores lost its strength significantly in the 24th month. Another important finding was that the therapeutic PNI was more effective, especially in cases of clinically suspected entrapments of the pudendal nerve between sacrospinous and sacrotuberous ligaments or below (Level-2) when compared with the entrapments in the endopelvic part of the pudendal nerve (Level-1).

PNI is commonly used as a therapeutic procedure in patients with refractory PN when the first-line conservative treatment is failed [6, 15, 19, 28]. According to our study, more than 50% pain reduction was observed in at least half of the patients at each time point. Furthermore, our results showed more than 30% improvement in pain intensity in 91.5% of patients at the 1st month, 82.1% at the 3rd month, 76.8% at the 6th month, 73.2% at the 12th month, and 66.1% at the 24th month. More than 30% pain reduction means a notable improvement for patients who have been suffering from PN for a long time. From our point of view, a series of two PNIs at three-week intervals seems to be highly successful, and significant pain relief or even cure is possible.

In the literature, there are considerable discussions ongoing among researchers concerning the long-term benefits of the PNI. Results from other studies evaluating the effectiveness of pudendal block therapy over time are quite variable, ranging from 6.8 to 89% at 12-month follow-up visits [17, 26, 29]. Fanucci et al. [29] reported the clinical efficacy of CT-guided repeated PNI in 92% of patients at 12 months. On the contrary, Mamlouk et al. [17] reported that long-term pain relief was observed in only 2 of the 31 patients (6.6%). They observed that 14 patients' symptoms were improved temporarily after the PNI and benefited from surgical nerve release [17]. Another randomized trial reported that a single dose of PNI was effective for more than 30% in only 14.3% of patients at three months and suggested that anesthetic blockade was necessary to refer patients to surgery [30]. Similarly, in a recent systematic review, Tricard et al. [26] advocated that the PNI provides short-term benefits; at the same time, nerve decompression surgery, irreversible thermal approaches, sacral nerve, and spinal cord neuromodulation have been suggested to achieve medium as well as long-lasting pain relief. In our opinion, surgery should not be the first option to treat PN because of its invasiveness, and it might leave fibrosis behind, which is another reason for chronic pelvic pain. According to our experiences, pudendal nerve release should be considered a last

option of the treatment when minimally invasive therapeutic options (repetitive dose PNI, neuromodulation, and radiofrequency treatment) are exhausted.

Another non-negligible result emerged from this study: despite the significant decrease of VAS pain scores at each time point when compared with the pre-block VAS scores, the effectiveness of the pudendal nerve block significantly declined over time. As expected, the failure rate gradually increased over time (8.5, 17.9, 23.2, 26.8, and 33.9% at one month, three months, six months, one year, and two years, respectively). Accordingly, we thought that the fluctuation of the success rate of the pudendal block therapy might be related to the fact that pain sensation is a subjective phenomenon, resulting in a shift in the patients' pain perceptions among success, relative improvement, and failure over time.

Good knowledge of the endopelvic and extrapelvic course of the pudendal nerve anatomy and adequate surgical experiences is essential to treat PN. While recently published studies focused on the laparoscopic surgical treatment of pudendal pain caused by endopelvic nerve pathologies, on the contrary, our study suggested that PNI might be beneficial in some of the patients who were suspected of having endopelvic pudendal nerve pathology [31, 32]. In the present study, we reported that PNI was more effective when the pathology was between sacrospinous and sacrotuberous ligaments or below compared with the endopelvic pelvic part. Although the success rate of PNI regarding anatomical level in both groups decreased over time, more than 50% pain reduction continued in five patients with pathology at Level-1 and in 24 patients with pathology at Level-2. We should also emphasize that those five patients treated without the need for surgery should not be underestimated. As we reported previously, patients might benefit from surgical decompression of the nerve when there is no adequate response to both conservative therapy and block treatment in patients with persistent PN accompanied by sciatica [12, 33–35]. Laparoscopic exploration of the pelvic nerves allows the clinician to confirm suspected diagnoses, such as deep infiltrating endometriosis, fibrosis of the retroperitoneal space, and entrapment of the pudendal nerve by atypical pudendal vessels or piriformis muscle [11, 36]. However, it is inappropriate to refer all patients to surgery with suspected endopelvic pathology of the pudendal nerve. In our clinical practice, we prefer to perform therapeutic PNIs before deciding a surgery, in case a positive response to a diagnostic block, whether endopelvic or extrapelvic pudendal nerve pathologies are suspected. Patients with endopelvic pathology, who were successfully treated by PNIs, might have double entrapment involving both the endopelvic portion and the distal part of the pudendal nerve. Another explanation for the improvement of VAS scores in patients with pudendal nerve entrapment in the endopelvic part was the choice of injection technique (between sacrospinous and sacrotuberous ligaments). Single site injection between the interligamentous plane seems acceptable, as the sacrospinous ligament level is the most common site of entrapment, and a large volume of injections fills the interligamentous space by spreading the agents to the caudal and cranial.

The main weakness of this study was the absence of a control group, and another limitation was the subjectivity of pain scores and that it could not be standardized. Hence, while the primary outcome of this study was the pain intensity, individual differences were a challenging clinical problem. Thus, we can recommend researchers use the quality-of-life assessment to monitor the improvement of the clinical

condition in their further studies to verify our results with control subjects. In addition, it is not possible to determine the exact anatomical level of pudendal nerve insult without surgery. However, based on our experience, physical examination findings can guide clinicians in classifying whether the pudendal nerve injury is endopelvic or extrapelvic. Furthermore, we think that giving patients clear information about the PNI treatment's expected effectiveness might increase the patients' dependence on treatment and follow-up period.

The strengths of our study were the well-established standardization of the patients and long-term post-block follow-up by a senior experienced neuropelvicologist. According to these data, the therapeutic pudendal nerve block option should be performed even in patients with suspected endopelvic pudendal nerve pathology before the referral to surgery.

In conclusion, our results suggested that repeated PNIs could provide a significant decrease in VAS scores for both short and long-term periods. However, the efficacy of the pudendal nerve blocks declined over two years. Additionally, the effectiveness of PNIs could also be affected by the anatomical level of the nerve injury. The pudendal nerve entrapment cases between sacrospinous and sacrotuberous ligaments or below benefited more than the cases of pudendal nerve entrapment in the endopelvic part. Therapeutic pudendal nerve injection is recommended even in patients with suspected endopelvic pudendal nerve pathology before the referral to surgery.

Declarations:

Author contribution:

G Basol: Protocol development, Data collection and management, Manuscript writing

A Kale: Protocol development, Data collection and management, Manuscript editing

H Gurbuz: Protocol development, Manuscript writing and editing, Data analysis

EC Gundogdu: Data collection

KN Baydilli: Data analysis

T Usta: Protocol development, Data collection

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The authors have no relevant financial or non-financial interests to disclose.

Conflict of interest:

The authors declare that they have no conflict of interest.

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Tables:

Table 1: Characteristics of patients and pain according to diagnostic pudendal block response.

		n	%
Type of delivery	Vaginal delivery	31	51.7
	Cesarean Section	20	33.3
	Vaginal delivery and C-section	9	15.0
Climacterium	Absent	52	85.2
	Present	9	14.8
Assisted vaginal delivery	None	46	75.4
	Vacuum forceps	5	8.2
	Episiotomy	10	16.4
History of vaginal surgery	None	56	91.8
	Transobturator taping	4	6.6
	Transvaginal taping	1	1.6
Pain inducing factors	Absent	40	65.6
	Vaginal delivery	12	19.7
	Vaginal operation	3	4.9
	Trauma	3	4.9
	Cesarean section	3	4.9
Estimated anatomical level	Level 1: Intrapelvic pelvic portion	16	26.2
	Level 2: Entrapment between sacrospinous and sacrotuberous ligaments and below	45	73.8
Location of pain	Right side	28	45.9
	Left side	33	54.1
Dyspareunia	Absent	4	6.6
	Present	57	93.4
Suprapubic pain	Absent	17	27.9
	Present	44	72.1
Buttock pain	Absent	14	23.0
	Present	47	77.0
Dysuria	Absent	28	45.9
	Present	33	54.1

Sciatica	Absent	48	78.7
	Present	13	21.3
Dyschesia	Absent	42	68.9
	Present	19	31.1

Table 2: Comparison of the pudendal block success over time.

Decrease in VAS	Failure	Relatively improved	Success	χ^2	p
	%	%	%		
1 st month	8.5	28.8	62.7	18.162	0.001*
3 rd months	17.9	12.5	69.6		
6 th months	23.2	21.4	55.4		
12 th months	26.8	14.3	58.9		
24 th months	33.9	14.3	51.8		

χ^2 : Friedman test value; * p<0.05. VAS: visual analog scale.

Failure: Less than 30% decrease; **Relatively improved:** 30% -50% decrease; **Improved:** more than 50% decrease.

Table 3: Comparison of response to pudendal block over time regarding VAS scores.

VAS		Median	25 th Percentile	75 th Percentile	Z	p
Pre-block (median=9)	1 st month	3	0	5	6.691	<0.001*
	3 rd month	2	0	5	6.288	<0.001*
	6 th month	2	0	5	6.226	<0.001*
	12 th month	2	0	6	6.043	<0.001*
	24 th month	3	0	6	5.915	<0.001*

Z=Wilcoxon Signed Ranks test value; p<0.05. VAS: visual analog scale.

Table 4: Comparison of the success of the pudendal block over time concerning anatomical levels.

		Estimated anatomical level					
		Level 1		Level 2		χ^2	p
Decrease in VAS scores		n	%	n	%		
1 st month	Failure	2	13.3	3	6.8	11.310	0.002*
	Relatively improved	9	60.0	8	18.2		
	Improved	4	26.7	33	75.0		
3 rd month	Failure	6	40.0	4	9.8	6.654	0.029*
	Relatively improved	2	13.3	5	12.2		
	Improved	7	46.7	32	78.0		
6 th month	Failure	6	40.0	7	17.1	4.572	0.094
	Relatively improved	4	26.7	8	19.5		
	Improved	5	33.3	26	63.4		
12 th month	Failure	8	53.3	7	17.1	7.205	0.021*
	Relatively improved	2	13.3	6	14.6		
	Improved	5	33.3	28	68.3		
24 th month	Failure	9	60.0	10	24.4	5.569	0.057
	Relatively improved	1	6.7	7	17.1		
	Improved	5	33.3	24	58.5		

χ^2 : Fisher's Exact test value; p<0.05.

Level 1: Endopelvic portion of the pudendal nerve; **Level 2:** Extrapelvic portion of the pudendal nerve.

Failure: Less than 30% decrease; **Relatively improved:** 30% -50% decrease; **Improved:** more than 50 % decrease.

Figures

Figure 1

Anatomical illustration showing endopelvic and extrapelvic parts of the pudendal nerve.

Figure 2

Flow chart of the study.

Figure 3

Change in VAS scores over time after pudendal block.