Retrospective Study

Risk Factors and a Nomogram for Prediction of Refractory Pudendal Neuralgia: A Retrospective Multivariate Analysis Study

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Background: Pudendal neuralgia (PN) is one of the most common forms of genital pain. About 4% or higher of patients suffering from chronic pain.

Objectives: The aim of this study was to evaluate the risk factors for prediction of refractory PN (RPN).

Study Design: A retrospective multivariate analysis study.

Setting: This retrospective analysis included 112 patients with PN who received the pudendal nerve block treatment at the Pain Department of General Hospital of People's Liberation Army.

Methods: Univariate and multivariable logistic regression analyses were used for covariates selection. A nomogram was developed to estimate nonresponse to the pudendal nerve block.

Results: The median age of patients and duration of patients were 48.0 and 1.25 years, respectively. Among 112 patients, there were 64 good responders to the pudendal nerve block for neuropathic pain and 48 nonresponders. Multivariate analysis of 112 patients with PN demonstrated high self-rating depression scale scores (> 32) (odds ratio [OR], 95% confidence interval [CI]: 0.11, 0.01-0.77), damage to more than 2 terminal branches (OR, 95% CI: 0.22, 0.07-0.71), sensory deficit at S2-S4 on the dermatome map (OR, 95% CI: 0.22, 0.05-0.90), and duration of pain (> 4 years) (OR, 95% CI: 0.10, 0.03-0.42) were significant prognostic factors for nonresponse to the pudendal nerve block.

Limitations: There are information biases for retrospective analysis, thus making it more difficult to come up with definitive conclusions. Large-scale randomized clinical trials are warranted to evaluate the risk factors for prediction of RPN.

Conclusions: A longer duration of pain was correlated with a worse prognosis of the neurological disease. Patients with depression were prone to nonresponse to the pudendal nerve block treatment. Pain involved in more than 2 terminal branches and small fibers, affected at S2-S4 dermatome map, were considered to poor prognosis.

Key words: Nomogram, refractory pudendal neuralgia, multivariate analysis, risk factor analysis

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Pudendal neuralgia (PN) is a painful neuropathy of the pudendal nerve (1). This condition has not been widely known, and many pain physicians often fail to recognize it. The incidence of PN is estimated to be 1/100,000. Spinosa et al (2) reported in the literature that the incidence in the general population is only 1%, and the impact on women is greater than that on men. Orphanet (a European Web site that provides information on orphan drugs and rare diseases) stated PN has affected 4% of patients receiving pain counseling, and 3 out of every 7 men are affected. Most pain physicians believe that the actual

prevalence may be much higher than described in the existing literature.

The diagnosis of PN is not easy and is usually based on excluding other conditions that cause pain in the perineal area. The "Nantes Criteria" for the diagnosis of PN was published in 2006, which are now widely accepted by pain physicians in practice (3). The pudendal nerve block was usually carried out to help the diagnosis and possible treatment of PN. Multiple approaches have been reported to practice the pudendal nerve block, including transperineal, transgluteal, transrectal, and most often in women, a transvaginal approach. A cocktail of local anesthetics and steroids were injections around the pudendal nerve. Typically, patients were given a series 3 unilateral or bilateral injections. Only the first injection achieved the purpose of diagnosis, and the remaining 2 injections are used to deliver steroids to the nerves. This steroid was injected to reduce the inflammation, which usually occurred within 2 weeks. Patients who did not respond with immediate pain relief on the first practice would not be diagnosed as PN. Physical therapy was reported to be effective for patients with PN, including behavioral modifications, acupuncture, or pharmacologic management by using tricyclic antidepressant agents, gabapentin, or opioid drugs (3). Surgical nerve decompression was reserved for those patients with a suspected compressed nerve and who are resistant to conventional treatment methods (4,5). As mentioned above, the pudendal nerve block using local anesthetic agents and steroids, as a diagnostic technique, has also been reported as useful in treating persistent pain due to PN (6-8). However, Labat et al (9) documented 46 cases of therapeutic blocks of the pudendal nerve, in which 39 patients had medical benefit for 1 month or less, 6 for 3 months, and 1 for > 3 months.

Although the treatment of the pudendal nerve block for PN has been widely explored (10), there are few publications to evaluate the risk factors associated with the efficacy and safety of the pudendal nerve block in PN patients. The aim of our study was to evaluate the risk factors associated with refractory PN (RPN), which was defined as nonresponse to the pudendal nerve block.

Methods

We analyzed the medical data of patients who received treatment at the Pain Department of General Hospital of People's Liberation Army (PLA) from January 1, 2017 to June 30, 2019. Inclusive criteria in the study were patients with pain located in the area served by the pudendal nerve (perineal [PeN], dorsal clitoris/penile [DCN], and/or inferior anal [IAN] nerves). Patients who did not respond with immediate pain relief on the first practice would not be diagnosed as PN. Clinical follow-up was up to 3 months after discharge. Institutional Review Board from ethics committee of PLA General Hospital approval was obtained.

Data from the medical history, age, gender, duration, intensity, pain position (both before and 3 months after a series of 3 computed tomography [CT]-guided blocks of the pudendal nerve), pain at the terminal branches, negative life events, history of surgery, trauma, carcinoma, infection, number of registered departments, and the self-rating depression scale (SDS) were collected. A Visual Analog Scale (VAS) was used to measure the intensity of the pain (11). Using a ruler, the VAS score can be determined by measuring the distance (mm) on the 10-cm line between the "painless" anchor and the patient's mark. The scores range from 0-10. The higher the score, the greater the pain intensity.

The PeN and DCN arise from the PN at the exit of the Alcock canal; whereas, the IAN starts in the pudendal canal (12). Each terminal branch supplies sensation to the following different perineal structures: the IAN to the anal canal, caudal third of the rectum, skin of the posterior vulva, and perianal region; the PeN to the inferior third of the vagina, urethra, and labia; and, finally, the DCN to the clitoris, pubis, and inguinal territory. Painful areas were located by the compression of the terminal branches at the perineum and of the IAN at the Alcock canal (Tinel sign). The second segment of the PN enters the gluteal region below the pyramidal muscle and ends between the sacrospinous and sacrotuberous ligaments (13). Consequently, the exploratory approach to the second segment is difficult, and suspicion of damage is based on clinical findings, such as radiation of pain to the lower limbs (hip to toes).

Patients whose median intensity of pain evaluated by VAS scores decreased < 30% and, in the meantime, the scores of quality of life scale, 36-Item Short-Form Health Survey (SF-36) increased < 10% 3 months after discharge from the hospital, compared with that upon admission, were considered no response to the pudendal nerve block. Patients who had no response to the pudendal nerve block were defined as RPN.

CT-guided nerve block was performed in 112 patients. Patients were placed in the supine position at first. And then the site of needle entry was identified by using a metallic marker situated on the skin. Once

the pudendal canal was identified, 1% lidocaine hydrochloride was subcutaneously injected, then a 15-cm 22-gauge fine needle was inserted into the pudendal canal. Initially, a 4% solution of 3 mL of contrast material (Omnipaque 300, GE Healthcare) was injected. Once the correct position of the contrast medium in the vagina was confirmed, 10 mL of 0.3% ropivacaine and 1 mL of 40 mg triamcinolone acetonide (Kenalog, Bristol-Myers Squibb) were injected evenly.

Statistical Analysis

Normally distributed data were represented as mean ± standard deviation (SD), and nonnormality data were represented as median and the interquartile range. Categorical data were presented as number and ratio. Logistic regression analyses were used to identify the independent factors associated with the RPN. Variables with $P < 0.1$ in the univariate analysis were then included in the multivariable model, using the iterative process of backward selection. On multivariate analysis, a P value < 0.05 was considered significant. Statistical analysis was performed using the SPSS statistical package (version 26; SPSS Inc., Chicago, IL, USA).

Results

A total of 112 patients with PN were included in our study. The median age was 48.0 years (from 20 years to 85 years) and the median duration of pain was 1.25 years (from 0.08 years to 20 years). Upon admission, the median intensity of pain perceived by patients and that evaluated by VAS was 7.09 ± 0.94 (mean ± SD), and 4.08 ± 1.48 (mean ± SD) 3 months after discharge. The effected terminal branches of the pudendal nerve (distribution of pain) were as follows: 35.7% at the PeN, 37.5% at the DCN, and 71.4% at the IAN, and 30% of the patients referred to pain in 2 or more territories. Usually, the second and third segments correspond to the infrapiriform canal and the pudendal canal (Alcock canal), respectively. Thirty-three percent of the patients suffered from pain in the second segment. Fifty-five percent of patients complained of isolated pain at the terminal branches and 45% of mixed pain in 2 or more territories. The PeN was the most affected terminal branch, while the DCN was more persistent. Pain was amplified as more branches were involved.

A descriptive analysis of the cohort's characteristics was shown in Table 1. Pain worsened with sitting in 22 patients (19.6%), and 34 (30.4%) awakened in the morning with minimal or no symptoms. Eighty-five patients (75.9%) had significant hyperalgesia or allodynia, and 56 of 112 (56.0%) had paraesthesia in the perineum and genital area. A hot poker-like sensation in the vagina or rectum was felt in 23 patients (20.5%). Painful intercourse and sexual dysfunction presented in 76 patients (67.9%). Straining or burning on urination was confirmed in 34 patients (30.4%), and increased urinary urge and frequency in 9 (8.0%). Of the 112 treated patients, there were 64 good responders to the pudendal nerve block, based on the results of the VAS scores and SF-36 questionnaire, and 48 nonresponders. The median length of follow-up was 7 weeks (from 6 to 10 weeks).

The results of the univariate analysis were shown in Fig. 1 and Table 2. According to the univariate analysis, 8 possible risk factors were identified, including duration of pain > 4 years, negative life events (life event scale (LES) scores > 32), sensory deficit of S2-S4, pain at the DCN, pain at 2 or more branches, number of registered departments, radiation of pain to lower limbs, and SDS. Significant differences were found in duration of pain > 4 years ($P < 0.001$), LES scores > 32 ($P = 0.001$), pain at 2 or more branches ($P = 0.004$), SDS ($P = 0.006$). SDS scores were obtained as a continuous variable in the original data but was converted to 4 categorical variables for statistical analysis (< 53 assigned 0; 53-62 assigned 1; 63-72 assigned 2; > 72 assigned 3). Radiation of pain to lower limbs ($P = 0.04$) (continuous variables of duration of pain, LES scores, and SDS were transferred as categorical variables based on clinical experiences). For the other 3 variables, different trends across groups also existed as all P values were < 0.1.

Factors with $P < 0.1$ in the univariate analysis were then included in the multivariate analysis. The result of multivariate logistic analysis for RPN was shown in Fig. 2. By using the iterative process of backward selection, nonsignificant variables ($P > 0.05$ on likelihood ratio test) were removed in a stepwise procedure. The sensory deficit of S2-S4 (odds ratio [OR], 95% confidence interval [CI]: 0.22, 0.05-0.90), SDS (OR, 95% CI: 0.11, 0.01-0.77), pain at 2 or more branches (OR, 95% CI: 0.22, 0.07-0.71) and duration of pain > 4 years (OR, 95% CI: 0.10, 0.03-0.42) were found to be significant predictors of nonresponse to the pudendal nerve block (Fig. 2). We developed a nomogram for predictors of nonresponse to the pudendal nerve block. The nomogram for estimating nonresponse to the pudendal nerve block was shown in Fig. 3.

Discussion

PN is one of the most disabling forms of genital

Table 1. *Descriptive analyses of 112 patients with PN.*

Variables	All patients (n = 112)
Age (y), median, IQR	48.0 (34.3, 63.0)
Gender, women, no (%)	75 (67.5)
Hyperalgesia or allodynia, no (%)	85 (75.9)
Paraesthesia, no (%)	56 (0.50)
A hot poker-like sensation, no (%)	23 (20.5)
Burning on urination, no (%)	34 (30.4)
Increased urinary urge, no (%)	9 (8.0)
Painful intercourse or sexual dysfunction, no (%)	76 (67.9)
Pain worsened with sitting, no (%)	22 (19.6)
Awaken with minimal or no symptoms in the morning, no (%)	34 (30.4)
Duration of pain (> 4 years), no (%)	32 (28.6)
Negative life events (LES scores > 32), no (%)	50 (44.6)
Pain at the terminal branches, no (%)	
DCN	50 (44.6)
PeN	41 (36.6)
IAN	79 (70.5)
2 or more branches	44 (39.3)
Radiation of pain to lower limbs, no (%)	37 (33.0)
Perineal history, no (%)	
Trauma	22 (19.6)
Surgery	20 (17.9)
Carcinoma	15 (13.4)
Infection	33 (29.5)
History of hip surgery, no (%)	13 (11.6)
Sensory deficit of S2-S4, no (%)	22 (19.6)
Number of registered departments, median, IQR	2 (1, 3)
SDS, no (%)	
< 53	37 (33.0)
53-62	39 (34.8)
63-72	20 (17.9)
>72	16 (14.3)

Abbreviations: PN, pudendal neuralgia; IQR, interquartile range; LES. life event scale; DCN, dorsal clitoris nerve; PeN, perineal nerve; IAN, inferior anal nerve; SDS, self-rating depression scale.

pain. About 4% or might significantly higher of patients suffer from chronic pain. Many studies (30-31) have shown that the incidence of PN is higher in women than in men. Female gender is associated with an increased risk of developing this disease. The main reason short-term morbidities for the mother arising from perineal trauma may include bleeding, infection, hematoma, and acute postpartum perineal pain. In the longer term, women are at an increased risk of chronic perineal pain (32). In addition, several studies (33-34) have been done specifically on women with chronic pelvic pain. This suggests that PN or perineal pain is seen as a female-specific disease. But in our study of RPN, we did not find a difference in the number of men and women with RPN. The possible reason is that PN is often caused by childbirth and chronic pelvic inflammation in women. With the disappearance of the inducement, PN will also be cured. PN that occurs in this situation does not easily develop into RPN. PN has devastating effects on patients' quality of life. Their usual daily activities were severely restricted, especially when sitting (Table 1). This is a very common situation in current society, where many people have office jobs or journeys requires frequent and longtime sitting (14). Of the 112 treated patients, there were 64 good responders to the treatment of CT-guided block of the pudendal nerve. Our analysis demonstrated that the variables, including high SDS scores (> 32), damage to > 2 terminal branches, sensory deficit at S2-S4 on the dermatome map, and duration of pain (> 4 years) were classified as bad prognostic factors.

The patients suffering from PN for > 4 years were considered as a bad prognostic factor to the treatment of the pudendal nerve block in our multivariate study, with a 9 times lower response to the pudendal nerve block treatment compared with those suffering from PN for < 4 years. A study (15) reported that the average time from symptoms onset to diagnosis was 5.5 years. Other researchers (16.17) have reported that patients with PN symptoms for > 10 years were less likely to recover after surgery. These data indicate that long-term pain was associated with a poor prognosis.

Our study identified bad responders to the pudendal nerve block treatment associated with depression (SDS scores > 32). Chronic pain could adversely affect the prognosis and treatment of depression, and vice versa. The severity of pain significantly correlated with the degree of depression. The severity of pain before initiation of antidepressant treatment was a negative predictor of treatment response (18). At the same time, depression also had an adverse effect on the treatment of chronic pain (19). Patients with chronic pain and depression were prone to have more pain complaints, and also comorbid with increased severity and duration of pain symptoms (18). Some studies (18,19) have reported that patients with comorbid pain and depression have a poorer response to pain treatment compared with nondepressed patients.

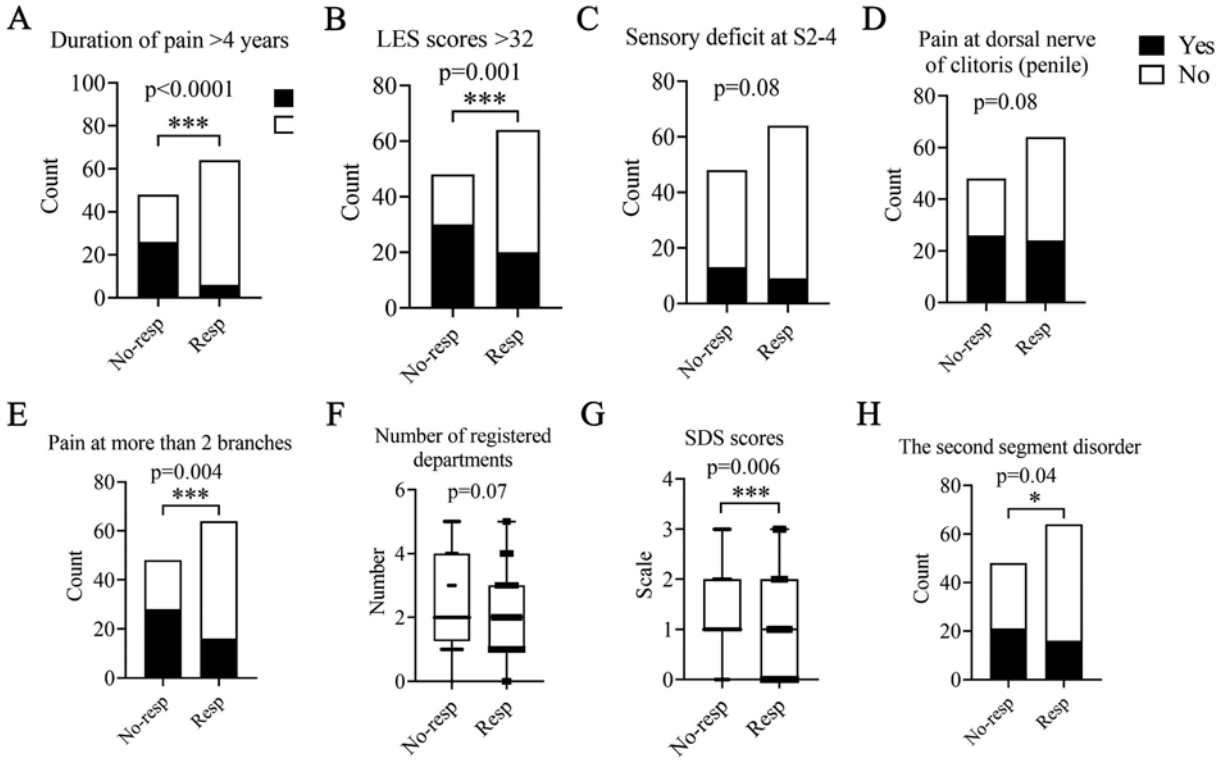

Fig. 1. *Univariate analyses in relation to the response to CT-guided block of the pudendal nerve.*
A *The number of patients suffering from PN for more than 4 years between nonresponse and good response to the pudendal nerve block.* B *The number of patients with negative life event (LES > 32) between nonresponse and good response to the pudendal nerve block.* C *The number of patients with small fibers affected at S2-S4 dermatome map between nonresponse and good response to the pudendal nerve block.* D *The number of patients with pain restricted to DCN between nonresponse and good response to the pudendal nerve block.* E *The number of patients with pain involved in more than 2 terminal branches between nonresponse and good response to the pudendal nerve block.* F *The number of registered departments between nonresponse and good response to the pudendal nerve block.* G *The number of patient with depression (SDS scores) between nonresponse and good response to the pudendal nerve block.* H *The number of patient with pain restricted to the second segment between nonresponse and good response to the pudendal nerve block.*
Abbreviations: CT, computed tomography; PN, pudendal neuralgia; LES, life event scale; DCN, dorsal clitoris nerve; SDS, self-rating depression scale.

Therefore, antidepressant therapy is particularly important for chronic PN. A low-dose regimen of amitriptyline is the best choice in neuropathic patients for the initial treatment of local symptoms of pain, also it has been used as first-line treatment of PN. A study (20) confirmed the effectiveness of antidepressants for neuropathic pain as one patient being treated with a tricyclic antidepressant obtained at least 50% pain relief. Dividing patients into 2 groups (responders or nonresponders) according to the Patient Global Impression of Improvement questionnaire is a common resource used by many researchers to assess their response to treatment.

The small fibers provide pain and temperature information through the C-fibers (8,21-22). The PN carries 50% of the sensory fibers (10). Information on pain and temperature is transmitted through the C-fibers (21), they are involved in the pathogenesis of small-fiber sensory neuropathy at the perineum. Exploration of the superficial perineal sensitivity provides information about the status of the terminal branches. The sensory analysis includes cotton swab testing to establish an S2-S4 dermatome map and palpation of the vestibule. The absence of signs and symptoms during the physical examination confirms the integrity of the C-fibers. C-fiber damage can be considered an early indicator of peripheral neuropathy (23). In our study, the overall sensory deficit at S2-S4 was 19.6% (Table 1). Our results suggest that sensory deficit at S2-S4 was significantly associated with RPN. A quantitative somatosensory

Table 2. *Univariate analyses in relation to the response to the pudendal nerve block.*

Variable	OR (95% CI)	*P* value
Age (> 65 vs ≤ 65 years)	0.62 (0.23-1.68)	0.35
Gender (women vs men)	0.62 (0.27-1.40)	0.25
Duration of pain (> 4 vs ≤ 4 years)	0.09 (0.03-0.24)***	< 0.001
Negative life events (LES scores > 32 vs ≤ 32)	0.27 (0.12-0.60)***	0.001
Pain at DCN (yes vs no)	0.51 (0.24-1.09)	0.08
Pain at PeN (yes vs no)	0.58 (0.27-1.27)	0.18
Pain at IAN (yes vs no)	0.82 (0.36-1.87)	0.63
Pain at 2 or more branches (yes vs no)	0.24 (0.11-0.53)***	< 0.001
Radiation of pain to lower limbs (yes vs no)	0.43 (0.19-0.96)*	0.04
History of trauma (yes vs no)	1.40 (0.53-3.67)	0.49
History of surgery (yes vs no)	0.90 (0.34-2.38)	0.83
History of carcinoma (yes vs no)	1.60 (0.51-5.10)	0.43
History of infection (yes vs no)	1.03 (0.45-2.33)	0.95
History of hip surgery (yes vs no)	1.23 (0.38-4.02)	0.73
Number of registered departments		
1 vs 0	0.08 (0.01-1.29)	0.08
2 vs 0	0.13 (0.02-0.69)	0.17
3 vs 0	0.25 (0.05-1.34)	0.11
4 vs 0	0.08 (0.01-0.52)**	0.01
5 vs 0	0.25 (0.04-1.70)	0.16
Sensory deficit of S2-S4 (yes vs no)	0.44 (0.17-1.14)	0.09
SDS		
53-62 vs < 53	0.11 (0.03-0.46)***	0.002
63-72 vs <53	0.49 (0.13-1.86)	0.30
> 72 vs < 53	0.49 (0.11-2.18)	0.35

Abbreviations: OR, odds ratio; CI, confidence interval; LES, life event scale; DCN, dorsal clitoris nerve; PeN, perineal nerve; IAN, inferior anal nerve; SDS, self-rating depression scale.
*$P < 0.05$, **$P < 0.01$, ***$P < 0.001$

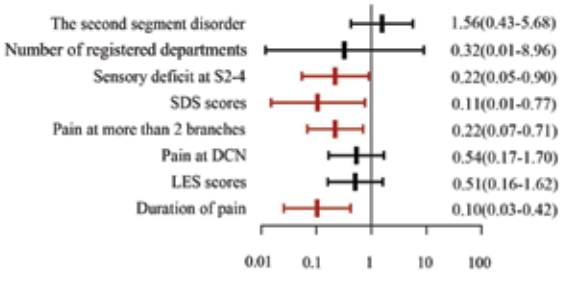

Fig. 2. *The result of multivariate logistic analysis for non-response to the treatment of CT-guided block of the pudendal nerve.*
Abbreviations: CT, computed tomography.

thermotest could be used to confirm small fiber neuropathy of the PN.

We would rather inject a compound composed of contrast material, anesthetics, and steroids directly into the middle of the pudendal canal, similar to Filippiadis et al's study (24), rather than inject at the ischial spine (25-28). We used one injection site instead of 2 different injection sites (25,27) because the injections typically filled the pudendal canal and extended cranially into the space between the sacrospinous and sacrotuberous ligaments. This single-site procedure may result in a relatively short process time (most processes < 20 minutes).

Like in the treatment of other neuropathic pain, the initial treatment of PN should always be conservative, including oral medications and physical therapy. If there is no improvement in the level of pain, patients are then offered CT-guided injections of the nerve. Surgical decompression may be an option when patients do not have sufficient pain relief by other methods (11). Pudendal neuropathy has been described as a tunnel syndrome; it is treated in a manner somewhat analogous to treatments for the carpal tunnel syndrome, namely: nerve protection, medications, and pudendal nerve perineural injections (PNPI) given as a series of 3 at 4-week intervals. If conservative treatments fail decompression of the pudendal nerve(s). Pulsed radiofrequency has been used as an alternative to PNPI. Sacral neuromodulation or spinal cord neuromodulation is considered treatments of last resort when all treatments, including nerve decompression, have failed to provide adequate pain control (29,30). Other methods (31-34) for PN have also been reported recently. However, each treatment method has its own limitations, and there is a lack of large sample clinical studies to observe its efficacy. The treatment of PN remains difficult. Therefore, it is clinically significant for us to study and quantify the risk factors for RPN. On the one hand, it suggests that neurophysical examination and neuroimaging should be emphasized in the early stage of the disease, and pay attention to the psychological treatment of patients, so as to prevent the occurrence of RPN. On the other hand, it also provides an idea for pain doctors to choose treatment methods; namely, when there are risk factors for the occurrence of RPN in patients, the pudendal nerve block, which may not be

effective, should be carefully selected. While decompression of the pudendal nerve(s), sacral neuromodulation and spinal cord neuromodulation should be considered more.

Conclusions

A longer duration of pain is correlated with a worse prognosis of the neurological disease. Patients with depression are prone to nonresponse to the pudendal nerve block treatment. PN involved in more than 2 terminal branches and small fibers affected at S2-S4 dermatome map are classified as bad prognostic factors.

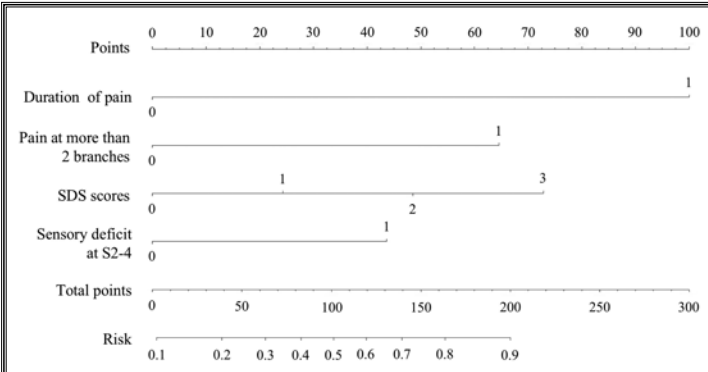

Fig. 3. *A new nomogram for estimating nonresponse to CT-guided block of the pudendal nerve.*
Abbreviations: CT, computed tomography.

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