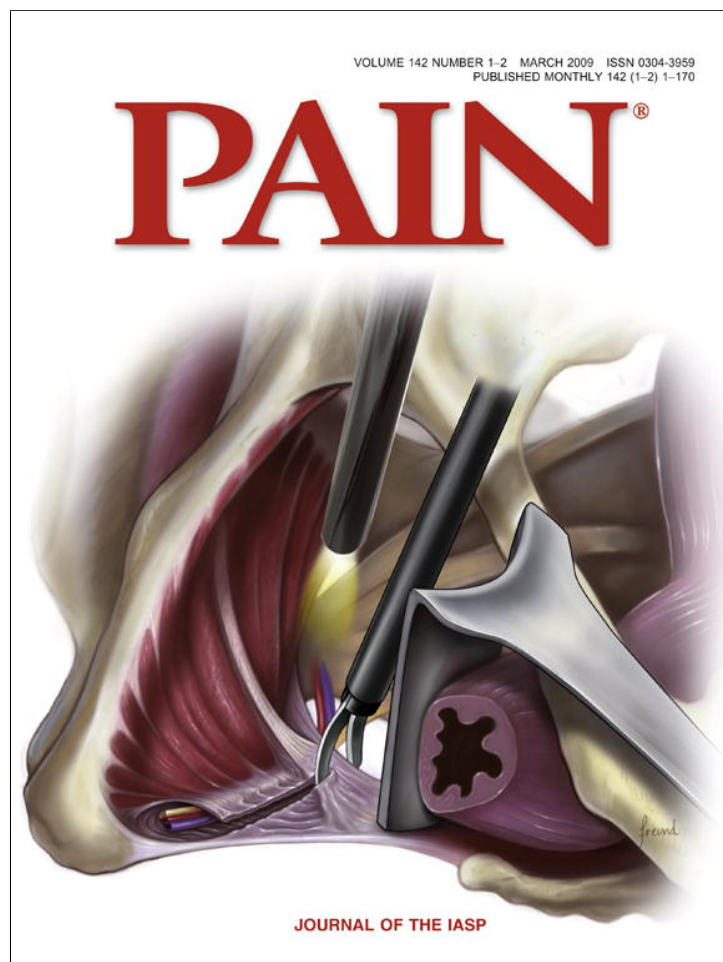


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Evaluation of diagnostic accuracy of Colour Duplex Scanning, compared to electroneuromyography, diagnostic score and surgical outcomes, in Pudendal Neuralgia by entrapment: A prospective study on 96 patients

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ABSTRACT

The objective of our study is to evaluate the detection capacity of Colour Duplex Scanning (CDS) in helping to diagnose Pudendal Neuralgia (PNa) by Pudendal Nerve Entrapment (PNE). This technique is being compared to complete Neurological Criteria (NC) based on Diagnostic Score (DS) and Electroneuromyography (ENMG) and secondly, to the results of surgery. This is a prospective study, on a consecutive series of 96 unselected patients evaluated by both CDS and NC. The CDS examinations were performed by the same operator who was unaware of the NC. The DS and the ENMG were read by a practitioner who was unaware of the CDS findings. The Peak Systolic Velocity (PSV) and the Systolic Ascension Time (AT) were the vascular criteria. Inadequate examinations were neither repeated nor removed from the analysis. Of 166 Internal Pudendal Arteries (IPAs) explored by CDS, 163 were visualised on their whole course, leading to a 98% feasibility. Of the 67 PNE identified by NC, 60 cases of Pudendal Vascular Entrapment (PVE) were detected by CDS, leading to a 89.6% sensitivity and a 67.4% specificity. Currently, there is no gold standard that can diagnose PNa by PNE with certainty. CDS is a non-invasive technique, demonstrating high diagnostic value to confirm PNE. In this study, we determined a new objective diagnostic criterion, the Pudendal Artery Ratio (PAR), which is very strong at diagnosing PNE but needs to be validated by further studies.

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1. Introduction

PNa is a pelvi-perineal neuropathic pain recorded in the territories of the three terminal branches of the pudendal nerve [4,20,23,24] and is associated with urinary, rectal or sexual dysfunction [5]. The great variability of the symptoms leads to a difficult diagnosis [6,20]. Most recently, DS (Table 1) has been providing more relevant evidence of PNa presence [5].

One of the main issues for PNa is PNE [3]. Due to a retraction of the sacro-spinous ligament and/or of the falciform process, high pressure is created in the Pudendal Canal (PC) enclosure [1,6]. This neuralgia by PNE, also called Alcock's Canal Syndrome is a rather new concept [1] and its identification is crucial since this may lead to surgical decompression [15]. However, there is no current diagnostic gold standard to confirm the PNE [1,6].

DS (Table 1), validated by several studies [5,21], was based on a combination of criteria, leading to diagnosis of PNa. Clinical signs combined with a complete neurological evaluation (neuropathic

pain diagnostic questionnaire (DN4)) [9], spine Magnetic Resonance Imaging and psychological assessment, allowed for the elimination of other aetiologies of PNa. The ENMG of the perineum, based on concentric needle electromyography and pudendal nerve motor conduction study, shows abnormal sacral reflexes or motor nerve latencies, in cases of troncular pudendal neuropathy and can evaluate the degree of severity [5,11]. However, ENMG cannot differentiate entrapment from other causes of pudendal nerve lesion and in cases of PNE, ENMG cannot ascertain the localization of the site of compression [15]. This leads to either false positive or false negative results. So, ENMG is not sufficient to confirm this diagnosis of entrapment with certainty.

In comparison, the CDS of internal pudendal vessels, satellites of the nerve, is more likely to indicate pressure in the PC (Fig. 1) and significant changes of arterial flow at this level can be related to an entrapment.

In our study, we proposed to evaluate the capacity of CDS in diagnosis of PNa by PNE, compared to complete NC based on DS and ENMG. For a subgroup of patients for whom surgery was finally indicated, we compared the test to surgical outcomes. This non-invasive method can be applied in IPA, providing functional infor-

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Table 1

DS: two major criteria or one major and two minor criteria or four minor criteria.

Major criteria	Minor criteria
1. Pain in the territories of at least two of the three terminal branches of the pudendal nerve: rectal inferior, perineal and dorsal clitoris	1. Neuralgic type of pain (positive DN4)
2. "Sexual Arousal Syndrome"	2. Pain in the territory of only one terminal pudendal branch
3. Positive Tinel sign (Trigger zone at the ischial spine or Alcock's canal reproducing the pain)	3. Aggravating pain with sitting position/during the day; improvement in orthostatism/during the night
4. Positive block injection test (>36 h)	4. Positive trigger zone (×Tinel sign) at the ischial spine or Alcock's canal (comparing to the opposite side)
	5. Abnormal ENMG results (sacral reflexes, motor nerve latencies)

mation on the PC. Our working hypothesis was to demonstrate a new criterion, able to confirm entrapment. If the CDS exploration showed signs of PVE, then results were more likely to confirm a PNa by PNE.

2. Methods

We conducted a prospective study on a consecutive series of ambulatory patients. Only one criterion for patient inclusion was necessary: all had perineal or pelvi-perineal pain. The study population was unselected since patients did not show any pretest likelihood of PNa by PNE. We did not include patients who had previously been treated by surgery for this pathology. All the patients were examined by both CDS and NC. In our protocol study, subsequent evaluation of CDS against surgical outcomes in the subgroup of operated patients was also planned.

According to our inclusion criterion, 96 patients were enrolled between March 1, 2007 and July 31, 2007: 24 males and 72 females, ranging in age from 22 to 83 (mean age: 47.9 ± 4.9). Of this series, 8 patients had already been operated on for this indication. Of the remaining 88, NC failed to establish diagnosis for 5. In contrast, we stress that these 5 subjects were successfully explored by CDS. Thus, the comparative study was performed on 83 patients.

The findings were reported in special charts and provided by a team of medical practitioners of a large pelvic and perineal pain unit comprised of the surgeon, who established the DS, the electro-

physiologist who practised the ENMG and the anaesthetist who performed the block injection test. This team was unaware of the results of the CDS findings. During the same day, patients underwent a CDS before or after the other tests. All CDS explorations were performed by the same medical practitioner, who was also the most fully trained of the team. He was unaware of the results of NC and collected CDS results in a case-report form that he registered in his own computer.

To perform CDS examinations, patients were examined in the anterior decubitus. They were all scanned with a Nemio colour Duplex ultrasound machine (Toshiba Medical Systems Corporation, Japan), using a convex array transducer (3.75 MHz) and an endocavitary array transducer (6.0 MHz) imaging probe and pulsed Doppler.

At first, abdominal and pelvic vessels were examined by transcuteaneous exploration. Then, by the endocavitary way (vaginal in females and rectal in males), the operator visualised, on each side, the IPA which lies next to the nerve. Once the ischial spine (dark area, hypo-echoic) and the sacrospinous ligament (bright area, hyper-echoic) were correctly identified, IPA was depicted by CDS near the tip of the ischial spine [14]. The operator evaluated velocities before and after the PC, constituted by the sacro-spino-tuberal ligamentary grip and Alcock's canal. The normal and pathologic spectra of IPA are shown below (Fig. 2A and B). An examination was considered as adequate when both proximal (before the PC) and distal flows (after the PC) could be explored, and inadequate if only proximal or distal flows were studied. However, incomplete results were kept in the analysis.

For the diagnosis of IPA compression, we chose to evaluate PSV and AT, which are common velocity criteria, proposed in several studies [10,12,13,16,19]. According to the hemodynamical principles, PSV increases as an artery narrows, on the level of stenosis and falls distal to stenosis, whereas AT increases both on the level of stenosis and distal to stenosis. For PSV criteria, we proposed to evaluate the PAR, based on PSV measured before and after the PC. As there is not yet a current concept of the cut-off values, we aimed to classify the compressed IPA according to our criterion experienced by our team (Table 2). These velocity criteria permitted a complete evaluation of the hemodynamical consequences of a compression of the artery. According to our experience, a value of PAR more than or equal to 1.3 suggested a PVE. Other accessory qualitative criteria, visualised downstream from the stenosis, were used to help diagnosis such as broken flow, spread of velocities and demodulated flow [10,16,19]. Although a lengthening of AT could usually be an additional argument to diagnose a stenosis, this criterion was less relevant in our study, as described below.

To evaluate this new method, we calculated the diagnostic value of CDS by using the following parameters: sensitivity, specificity and both positive and negative predictive values. In the analysis of diagnostic criteria, the mean values of PAR and AT, in patients with PNE and in others without PNE, using unpaired Student's *t*-tests were compared.

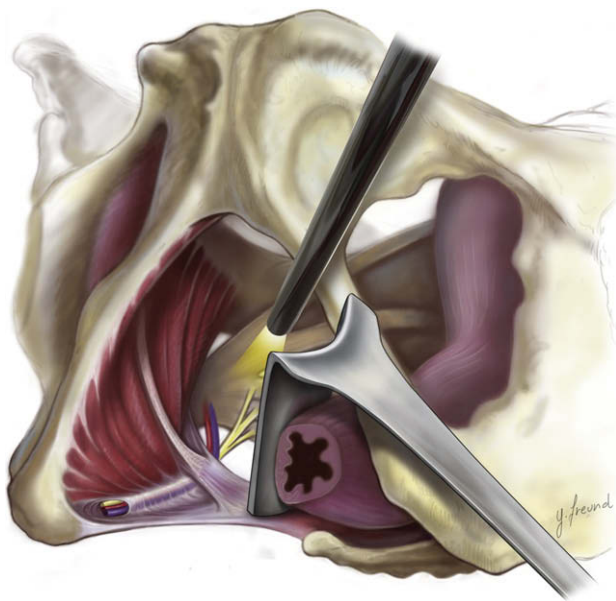


Fig. 1. Anatomy of the pudendal canal. Internal pudendal vessels satellites of the nerve, visualised in the interligamentary grip and Alcock's canal (E. Baurtrant's copyright).

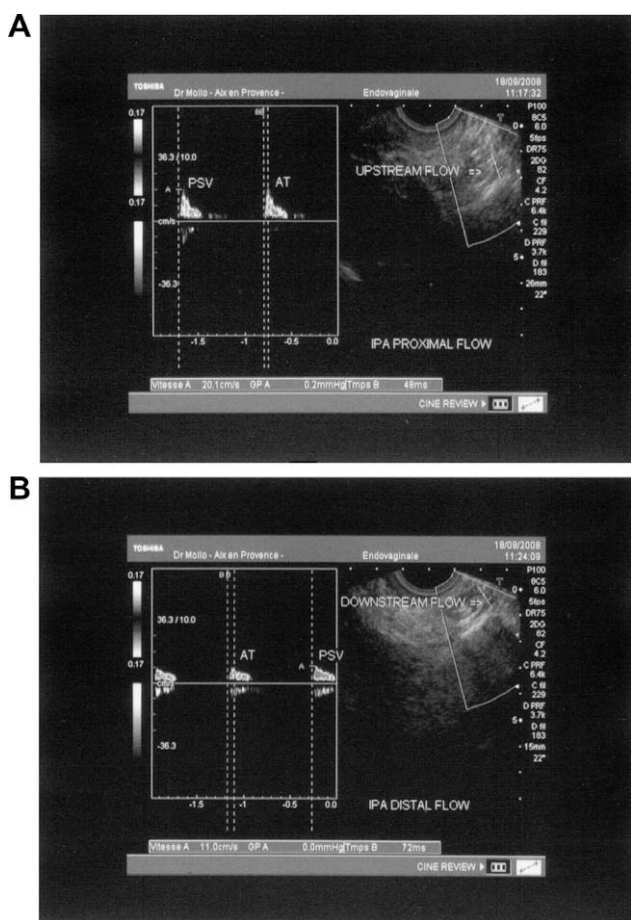


Fig. 2. (A) Proximal flow of IPA. In this figure, vascular criteria measured on proximal flow are: PSV = 20.1 cm/s and AT = 48 ms. This example illustrates a normal spectrum. (B) Distal flow of IPA. In this figure, vascular criteria measured on distal flow are: PSV = 11 cm/s and AT = 72 ms. Values of PSV, issuing from (A) and (B), allow us to calculate the PAR which is equal to 2.18. This example illustrates a pathologic spectrum with a PAR \geq 1.3.

Table 2
Vascular criterion in compressed IPA by PVE.

	Normal flow	PVE
PAR measured before and after the PC	<1.3	\geq 1.3
Flux morphology evaluated after the PC	Normal	Broken

Table 3
Breakdown of the study population according to whether perineal pain is related to PNa by PNE.

Pathology	N	%
PNa by PNE		
One pathology	46	55.4
Two concomitant pathologies	2	2.4
Perineal pain not related to PNa by PNE		
One pathology	32	38.6
Two or more concomitant pathologies	3	3.6
Total	83	100

N = number of patients.

3. Results

In our series of 83 patients (Table 3), 48 (57.8%) had a PNa by PNE, of which 2 (2.4%) were associated to another concomitant

Table 4
Aetiologies of perineal pain unrelated to PNa by PNE (differential diagnosis).

Pathology	N	%
Myofascial syndromes	12	30.0
Vestibulitis	9	22.5
Endometriosis and adenomyosis	3	7.5
Pudendal radiculopathy	7	17.5
Prothetic material complication	1	2.5
Urologic pain	2	5.0
Rectocele and enterocele	2	5.0
Post-trauma neuropathy	3	7.5
Ilio-inguinal neuralgia	1	2.5
Total	40	100

N = number of differential diagnosed pathologies.

pathology. PNE was bilateral in 19 (39.6%) and unilateral in 29 (60.4%), left sided in 20 (41.7%) and right sided in 9 (18.7%). For 35 patients (42.2%), perineal pain was not related to PNE, but to one or several other aetiologies (Table 4). These findings on the study population were provided by NC.

Of the 166 pudendal nerves (issuing from the 83 patients) explored by NC, 67 were related to PNE and 99 were unrelated to PNE.

Of the 166 IPA explored by CDS, all could be identified, but only 163 were adequately visualised on their whole course and three arteries were inadequately analyzed. All patients were examined only once, even if the examination was inadequate or difficult to perform, and all vascular examinations were kept in the analysis. We obtained a 98% feasibility for an adequate examination by CDS. For these three arteries, the operator concluded in one case, to a “not conclusive exploration” on the account of bad conditions of examination, and in the two other cases to an “occlusion”. CDS findings showed 92 PVE (including the two results of “occlusion”, where only proximal flows were recorded) and 73 normal arteries. We found that CDS had an overall 89.6% sensitivity, a 67.4% specificity, a 65% positive predictive value and a 90.4% negative predictive value. These results took into account the inadequate vascular examinations, which were kept in our analysis.

Of the 67 nerves (48 patients) with identified PNE by NC, only 34 nerves (23 patients) could be operated on at that time, as the

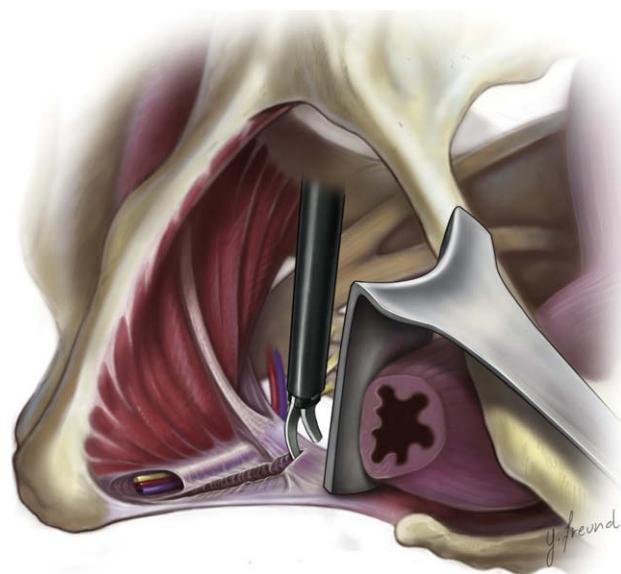


Fig. 3. Pudendal decompression with TIR procedure. Decompression of the interligamentary grip and the Alcock's canal, by the Trans-Ischio-Rectal (TIR) procedure (E. Baurtrant's copyright).

first stage of treatment was not sufficient for improvement or recovery. A surgical decompression by Trans-Ischio-Rectal (TIR) procedure was performed (Fig. 3), giving perfect access to the sacrospinous ligament and the falciform process of Alcock's canal [5,6]. In this subgroup, the surgeon could establish diagnosis with certainty and evaluate the severity of entrapment through an Intra-Operative Score (IOS) [5,6], numbered from 0 to 4 at the PC, with a PNE confirmed by a score ≥ 2 . Of the 34 nerves treated by surgery, IOS confirmed PNE for 31, while it rejected it for three. Of the 34 IPA, CDS found 29 PVE and five normal arteries. We stress that on the three nerves wrongly operated on because of false positive NC results, CDS found two normal arteries. As a result, we obtained a 90.3% sensitivity and a 67% specificity. Although these results arose from a smaller number of cases, they were superposed on the previous results described above.

In our series of 83 subjects, patients with PNE showed a significant increase of PAR (1.85 ± 0.78 versus 0.98 ± 0.38 ; $p < 0.001$), compared to patients suffering from perineal pain unrelated to PNE. Similarly, AT significantly fluctuated between the two groups (67.53 ± 6.67 ms versus 59.36 ± 4.7 ms; $p < 0.01$).

In the 23 operated patients, we still observed a significant increase of PAR (1.96 ± 0.22 versus 1.13 ± 0.74 ; $p < 0.05$), while AT did not significantly fluctuate (67.43 ± 5.03 ms versus 48 ± 23.54 ms; p not significant), because of a lack of statistical power.

4. Discussion

Alcock's Canal Syndrome is a rather new concept with an unknown incidence [1]. A recent increase in the understanding of the pathology allows for improved diagnosis [20]. However, there is no current gold standard that leads to the confirmation of PNa by PNE with certainty [1,6].

Our working hypothesis was to determine a new vascular criterion able to confirm entrapment. To the best of our knowledge, this is the first evaluation of the detection capacity of CDS in helping and supporting diagnosis. For this hypothesis, we took as physiopathological model the Thoracic Outlet Syndrome, which is also a neurovascular entrapment syndrome producing complex and intricate disorders. The exploration of the vascular component by CDS can contribute some diagnostic elements, such as anatomic injuries or hemodynamical data [18,25]. Similarly, significant changes in vascular flow, related to entrapment, can be observed in both Thoracic Outlet Syndrome and the PC.

In our study, we evaluated significant changes of arterial flow in the PC and compared them to the results of the NC. We suggested using the ratio of the PSV before and after the PC, as velocity criterion. According to criterion established by our team and regarding to the results of our analysis, we suggest that a cut-off value of PAR more than or equal to 1.3 indicated a PVE. We also measured the AT. In some difficult cases, additional qualitative criteria may help the diagnosis of stenosis.

Our prospective trial was performed on a consecutive series of 96 unselected patients, all examined by both CDS and NC. Results of this original study showed a 98% feasibility for an adequate examination by CDS. Performance of this new test for diagnosis of PNa due to PNE seemed to be very strong with an overall 89.6% sensitivity, a 67.4% specificity, a 65% positive predictive value and a 90.4% negative predictive value. These results took into account the inadequate vascular examinations, which were kept in our analysis. Patients with a PNE demonstrated with NC showed a significant increase of PAR, compared to the patients without a PNE. Similarly, AT significantly fluctuated between the two groups.

Of the 48 patients (67 nerves) for whom diagnostic evaluation by NC identified PNE, 23 patients (34 nerves) were operated on.

For many of the authors [1,2,20] and for our team [4,5,7], 30–50% of patients saw improvement or recovery within the first stage of treatment with physical therapy and block injections [4,6]. In case of failure, surgical decompression was an option [5,7,8,17,21,22] leading to an 86% improvement rate with the TIR procedure [5,6].

Subsequently, in our subgroup of operated patients, the diagnosis of PNE was established with certainty thanks to IOS evaluation and led to a 90.3% sensitivity and a 67% specificity. Although these results arose from a smaller number of cases, they were superposed on the previous cases as described above. We specified that of the three nerves wrongly operated on because of false positive NC results, two were found negative by CDS examination. In the 23 operated patients, we still observed a significant increase of PAR. The AT did not significantly fluctuate because of a lack of statistical power. In addition, this lack of statistical power led to a high dispersion of individual values and it was not possible to calculate a correlation score between IOS and PAR.

We underline that the present study had the advantage of being performed in a context close to the common clinical practice. The tests were conducted in a busy CDS Department of a large Pelvic and perineal pain unit, without duplicate examination of the same patient. Moreover, our purpose was to allow for the largest possible detection of the PNa by PNE, among unselected patients. Lastly, we kept in the evaluation all the findings of the vascular examinations, even if they were inadequate.

Following common clinical procedures, we obtained a good sensitivity. The positive results were due to the fact that our operator was well trained. This pointed out that the results were strongly operator-dependant. As for specificity, our results appeared less relevant. Of the 32 false positive findings, 9 may be explained by the fact that in cases of vestibulitis, contraction of muscles could reproduce the conditions of entrapment syndrome. The same phenomenon could explain the 12 other cases, where the patients suffered from myofascial syndromes (piriformis syndrome or other musculo-skeletal syndromes). Finally, the remaining 11 cases were due to other causes, such as urologic pathology.

In addition, our study confirmed the known limits of the CDS technique. Firstly, good technical conditions were crucial. This test remains dependant on the quality of the machine, the patient's condition for undergoing ultrasonographic examination and the time factor. Secondly, even if CDS was able to detect a PVE, it failed to determine specifically the cause of compression.

Our results led to the following practical decisions: as we reached a 89.6% sensitivity and a 90.4% negative predictive value, we concluded that a normal CDS flow very probably excluded a PNE. We obtained a lower specificity and positive predictive value (67.4% and 65%, respectively) which means that vascular compression indicated PNE in two thirds of cases. This lack of specificity underlines the practical limits of this examination, when the result is positive.

Using the context of a common clinical practice, we obtained positive results of the CDS technique performance, mainly for sensitivity and negative predictive value. These results will certainly meet the clinician's expectations in helping to diagnose PNa by PNE. A normal CDS flow very probably excludes a PNE. In our study, we were able to determine a new objective CDS criterion, the PAR, with a cut-off value of 1.3. However, our results have to be confirmed by further studies and our next objective will be to validate the PAR in a larger series of operated patients. Also, even if this technique appears to be very promising as an initial means of diagnosis, it needs to be improved in order to define additional ultrasonographic criteria, which could lead to a better specificity. Another interesting line of study could reside in the comparison of the couple ENMG and CDS, with the couple DS and surgical outcomes.

Contributors

M. Mollo was responsible for the trial design, trial management for CDS examinations, statistical analysis, data interpretation, and manuscript writing.

E. Baurtant was responsible for patients' recruitment, trial management for the team of medical practitioners who reported NC, TIR surgical nerve decompression procedures and took part in data interpretation and manuscript writing.

A.K. Rossi-Seignert was in charge the ENMG testing.

S. Collet and R. Boyer took part in pain management and block injection tests and were in charge anaesthesia for the pudendal surgeries.

D. Thiers-Baurtant took part in patients' recruitment and was a member of the team of medical practitioners who reported NC.

All contributors have seen and approved the final version of the manuscript.

Conflict of interest statement

All contributors declare that they have no conflict of interest.

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